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REVIEW ARTICLE

A methodological quality review of citations of randomized controlled trials of diabetes type2 in leading clinical practice guidelines and systematic reviews

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Abstract

Objective Evaluate methodological quality of type 2 diabetes RCTs conducted in Iran and cited in clinical practice guidelines and systematic reviews and meta-analyses.

Methods We conducted a descriptive methodological quality review, analyzing 286 Randomized Controlled Trials (RCTs) on diabetes mellitus published in Iran from July 2004 to 2021. We searched six databases systematically and evaluated eligible articles using the CONSORT 2010 checklist for abstracts. Two investigators assessed the data using a 17-item checklist derived from CONSORT. Additionally, we examined the citations of each RCT in 260 clinical practice guidelines, with a specific focus on the adequate reporting of outcomes.

Results Out of 6667 articles, 286 analyzed. Poor reporting and failure to meet criteria observed. Only 3.8% cited in guidelines. Reporting rates: primary outcomes (41.9%), randomization (61.8%), trial recruitment (12.6%), blinding (50.8%). 27.9% cited in systematic reviews, 50.34% in systematic reviews and meta-analyses, 26.57% in meta-analyses. 67.8% of papers cited in systematic reviews. Adherence highest for participants, objective, randomization, intervention, outcome; lowest for recruitment, trial design, funding source, harms, and reporting primary outcomes.

Conclusions Poor methodological reporting and adherence to CONSORT checklist in evaluated RCTs, especially in methodological sections. Improvements needed for reliable and applicable results in guidelines, reviews, and meta-analyses. Inadequate outcome reporting challenges researchers, clinicians, and policymakers, impacting evidence-based decision-making. Urgent improvements in RCT registration necessary.

Keywords Randomized controlled trials · Diabetes · Reporting · Clinical practice guideline

Background

According to the world health organization (WHO) estimates, diabetes is one of the major health burdens in the world, affecting approximately 422 million adults. It is estimated that between 2000 and 2030, the world population will be increased by 37%, and in line with this, the number of individuals with diabetes will be increased by 114% a way that a 69% increment will occur in the adult population with diabetes in developing countries [1]. Diabetes mellitus is a chronic metabolic disease that has reached pandemic proportions worldwide and represents a significant public health burden [2].

In 2016, the prevalence of diabetes among individuals aged 18 and above in Iran was estimated to be 10.3%. This prevalence was found to be 9.6% in men and 11.1% in women. Among the countries in the Eastern Mediterranean Regional Office (EMRO) region,, Iran has the third-highest prevalence of type 2 diabetes. Furthermore, within Iran, type 2 diabetes accounts for more than 90% of diabetics [3]. Considering these factors, it is anticipated that the Middle East region will face a substantial rise in the burden of diabetes in the coming decades [4–7].

Since randomized controlled trials are generally considered a gold standard for evaluating therapeutic interventions and evidence-based medicine; therefore, proper design and

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accurate reporting are of considerable importance [8–10]. The quality of an RCT could influence the clinical decision in practice [11]. Poor quality of key methodological features in RCTs can affect the estimates of the efficacy of interventions and lead to harmful treatments [11, 12]. Well-designed, well-performed, and well-reported RCTs provide the most unbiased data to reduce uncertainty about the implications of a finding of interest and improve the reliability of the results [9]. To prevent ambiguous reports in RCTs, the International Committee of Medical Journal Editors (ICMJE) recommends the use of reporting guidelines to improve the quality of health study reports [13, 14]. Practice guidelines have begun to attract the attention of medical research investors and health policymakers as indicators of potential social impact [15]. When a study is presented in medical guidelines, it could serve as impactful evidence in health care and improve clinical effectiveness by implementing evidence-based care in daily practice [16, 17]. The CONSORT[1] statement is used worldwide as a reporting guideline that is focused on RCTs [9]. The statement was initially developed in 1996 [18] and was updated in 2010 to incorporate new elements [13, 19]. However, there is a need to perceive the impact of research on the healthcare system. Such an analysis will provide a situation for funding agencies to identify effective research with high efficiency in health care policy and increase public perception of diabetes research and the scientific process. It also can lead to the development of more operative strategies in research and increase the likelihood of successful research outcomes [20, 21]. In turn, physicians and other medical practitioners are expected to keep up-to-date with relevant guidelines for their scientific judgment to improve patient-reported outcomes in daily practice [15, 22, 23]. In order to adequately report the results of randomized controlled trials, it is necessary to provide comprehensive information about the design, implementation, and writing the results of the study. Consequently, if an RCT is methodologically well-designed, there should be a critical look at the methods of studies given their quality. In addition to acknowledging the study conducted by Gohari et al. in Iran, which reported the poor quality of RCTs in diabetes, particularly in terms of randomization and blinding of participants [24], our research introduces a new approach. Building upon this previous study, we aimed to improve adherence to the Consort checklist and assess the inclusion of these studies in medical guidelines, systematic reviews, and meta-analyses. What sets our research apart is the comprehensive evaluation of 260 guidelines specifically focused on diabetes. This extensive analysis allowed us to not only assess the methodological quality of RCTs conducted in Iran but also examine their utilization in various medical guidelines, systematic reviews, and meta-analysis studies. This novel approach provides a valuable contribution to the existing literature on diabetes research and guideline development in Iran.

Materials and methods

This study was conducted in Iran and designed in two phases.

Phase 1 focused on evaluating the quality of reports on randomized controlled trials (RCTs) published in the context of type 2 diabetes in Iran. The emphasis was on assessing the choice of outcomes in these trials.
Phase 2 aimed to track the articles cited in medical guidelines, systematic reviews, and meta-analysis studies related to type 2 diabetes in Iran. The objective was to identify RCTs conducted in Iran that were referenced in these influential publications within the field.Overall, this two-phase approach allowed us to comprehensively assess the quality of reports on RCTs in type 2 diabetes, with a specific focus on the choice of outcome measures.

Additionally, it enabled us to track the utilization of RCTs conducted in Iran in influential medical guidelines, systematic reviews, and meta-analysis studies. The included medical guidelines, systematic reviews, and meta-analysis studies were thoroughly reviewed to extract information on the cited RCTs conducted in Iran. Any discrepancies in data extraction were resolved through consensus among the investigators.

By conducting the study in Iran, we were able to specifically assess the quality of reports on RCTs and their impact on medical guidelines, systematic reviews, and meta-analyses within the Iranian context.

Information Sources

To achieve this, we performed a systematic search of six databases, including ISI Web of Science, Scopus, PubMed, Science Direct, The Cochrane Library, and ProQuest, between July 2004 and July 2021. The search strategy involved exploring relevant phrases and keywords in medical subject headings, such as Mesh terms in the PubMed database, EMTREE thesaurus in the EMBASE database, and ProQuest Thesaurus.

The following phrases and keywords were utilized to search for relevant articles in the title, abstract, and full-text: Diabetes Mellitus Type 2, Adult-Onset,NIDDM, MODY, T2DM,T2D, Randomized Controlled Trials, RCT, RANDOM*, interventional study. Additionally,

[1] Consolidated Standards of Reporting Trials (CONSORT).

we included the keyword "Iran" in our search strategy to specifically identify RCTs conducted in Iran.

For example, the search strategy may include the following combination of keywords: "Diabetes Mellitus Type 2" AND "RCT" AND "Iran". This would ensure that the search results are limited to RCTs conducted in Iran within the context of type 2 diabetes.

The provided example search strategy was used in the PubMed database. It focused on finding studies related to Type 2 Diabetes Mellitus (T2DM) and randomized controlled trials (RCTs) conducted in Iran. The search terms included various combinations of keywords and medical subject headings (MeSH) to capture relevant articles.

((("Diabetes Mellitus, Type 2"[Mesh] OR (Diabet*[tiab] AND (type2[tiab] OR "type 2"[tiab] OR "Type II"[tiab] OR "Type 2 Diabetes"[tiab] OR Adult-Onset[tiab] OR Maturity-Onset[tiab] OR Non-Insulin-Dependent[tiab] OR " Noninsulin Dependent"[tiab] OR Slow-Onset[tiab] OR Stable[tiab] OR Ketosis-Resistant[tiab])) OR NIDDM[tiab] OR MODY[tiab] OR T2DM[tiab] OR T2D[tiab]))
AND
((("Randomized Controlled Trials as Topic"[Mesh] OR "Controlled Clinical Trial" [Publication Type] OR "Controlled Clinical Trials as Topic"[Mesh] OR "Randomized Controlled Trial" [Publication Type] OR "Controlled Clinical Trial"[TIAB] OR RCT[TIAB] OR placebo [tiab] OR "Clinical Trials as Topic"[Mesh] OR "experimental study"[tiab] OR "quasi-experimental study"[tiab] OR "Quasi Experimental Studies"[TIAB] OR (Studies[TIAB] AND Quasi-Experimental[TIAB]) OR "Non-Randomized Controlled Trials as Topic"[Mesh] OR (Clinical Trial*[TIAB] AND Non-Randomized[TIAB]) OR Non-Randomized Clinical Trial[TIAB] OR Nonrandomized Controlled Trials as Topic [TIAB] OR "interventional study"[TIAB] OR "Double-Blind Method"[Mesh] OR "double blind procedure"[TIAB] OR "Single-Blind Method"[Mesh] OR "single blind procedure"[tiab] OR "triple blind"[tiab] OR crossover[TIAB] OR cross over[TIAB] OR "crossover procedure"[TIAB] OR assign[TIAB] OR match[TIAB] OR matched[TIAB] OR allocation[TIAB] OR allocated[TIAB] OR "prospective study"[tiab] OR placebo [tiab] OR "Placebo Effect"[Mesh] OR drug therapy [sh] OR cluster[tiab] OR effects[tiab] OR (clinical trials[TIAB] AND randomized[TIAB]) OR randomised[tiab] OR randomly[tiab] OR RCT[TIAB] OR RANDOM*[TIAB] OR TRIAL [TIAB] OR experiment*[tiab] OR quasi-experiment*[tiab] OR intervention*[tiab] OR groups[tiab])) AND (Iran[ad] OR Iran[tiab])

All potentially eligible articles identified through the search were collected for further analysis. The inclusion criteria were defined to select RCTs conducted in Iran and focusing on type 2 diabetes.

By adding "Iran" as a keyword in our search strategy, we aimed to specifically identify RCTs conducted in Iran within the context of type 2 diabetes. This allowed us to focus our analysis on the quality of reports on RCTs conducted within the Iranian population, providing valuable insights into the research landscape and the choice of outcome measures in this specific setting.Once the articles were collected, the CONSORT for Abstract checklist items were applied to assess the reporting quality of the identified RCTs. The CONSORT for Abstract checklist provides a set of criteria to evaluate the completeness and transparency of reporting in the abstracts of RCT [25].

Eligibility criteria

The eligibility criteria for the selection of studies in Phase 1 of this study were as follows:

Inclusion criteria:

1. Randomized Controlled Trials (RCTs) conducted in Iran.
2. Focus on Type 2 diabetes.
3. Published between 2004 and 2021.

Exclusion criteria:

1. Non-RCTs.
2. Trials specifically on Gestational Diabetes Mellitus.
3. Animal studies.
4. Educational interventions on patients with diabetes.
5. In-vitro studies.
6. Case reports.
7. Reviews, systematic reviews, and meta-analyses.
8. Cohort studies.
9. Editorials, letters, comments, brief communication, and protocols.

10. Other studies with different designs, such as non-randomized controlled trials, before/after studies, pre/post-trial, quasi-experimental, and observational studies.
11. Duplicated publications.

By applying these eligibility criteria, we included a total of 286 RCTs conducted on Type 2 diabetes in Iran between 2004 and 2021. This selection ensured that we focused specifically on RCTs conducted in Iran and relevant to Type 2 diabetes, while excluding other study designs and non-relevant publications.

Quality assessment

To summarize the search protocol, we utilized the PRISMA (Preferred Reporting for Systematic Reviews and Meta-Analyses) flow diagram, as shown in Fig. 1 [26].

The quality of reporting of randomized controlled trials (RCTs) was evaluated using a 17-item modified CONSORT for Abstract checklist. Each included abstract was assessed for the presence or absence of items recommended by the CONSORT for abstracts extension [7]. The ratings of 'adequate' and 'no description' were used to indicate the level of detail provided by the authors for each item. Ratings ranged from zero to 1, with zero representing no description and 1 representing adequate description.

Two reviewers, who were well-trained and experienced in evidence synthesis, independently screened the titles and abstracts based on the CONSORT 2010 checklist. They identified all potentially eligible articles and obtained the full texts of these articles. Any disagreements between the reviewers were resolved through discussion to reach a consensus. In cases where there was insufficient information in the title and abstract to determine eligibility, the full texts of the articles were downloaded and reviewed. Any discrepancies in article selection were resolved by consulting a third author for a final decision. Once the final selection was made, data extraction was performed on all full-text articles. Descriptive statistics were calculated for each reporting item and each RCT.

Phase2

In Phase 2 of the study, the focus was on determining the utilization of the identified RCTs in medical guidelines, systematic reviews, and meta-analyses. This phase involved assessing the inclusion of these RCTs in clinical diabetes guidelines and evaluating the number of citations in systematic reviews and meta-analyses. To begin, a total of 260 English full-text clinical diabetes guidelines were extracted. Each of these guidelines was reviewed to assess whether any of the identified RCTs were cited within them. The aim was to determine the extent to which these RCTs were considered and referenced in the development of clinical guidelines.

Furthermore, the study also evaluated the number of citations of the identified RCTs in systematic reviews and meta-analyses. This analysis aimed to assess the extent to which these RCTs were incorporated into higher-level evidence syntheses and analyses.

To conduct this evaluation, relevant keywords were used in the search strategy, including "medical guideline," "clinical guideline," "clinical practice guideline," "practice guideline," "clinical protocol," and "diabetes guideline." These keywords were used to identify clinical diabetes guidelines, systematic reviews, and meta-analyses that may have cited the identified RCTs.The study focused on diabetes clinical guideline information obtained from various databases, including PubMed, Clinical Key, WHO, Trip Databases, International Guidelines Library, National Guideline Clearinghouse, UK National Clinical Guideline Centre, UK National Institute for Health Care Excellence, Scottish Intercollegiate Guidelines Network, British Columbia Guidelines, Canadian Medical Association Guidelines, Australian National Health and Medical Research Council: Clinical Practice Guidelines, New Zealand Guidelines Group, ACP Clinical Practice Guidelines, GAIN Guidelines, IDF CLINICAL PRACTICE GUIDELINES, ADA Clinical Practice Recommendations, American Association of Clinical Endocrinologists Medical Guidelines, Canadian Diabetes Association Clinical Practice Guidelines, Joslin Clinical Guidelines, ISPAD Clinical Practice Consensus Guidelines, and Google Search Engine.

The search strategy aimed to identify clinical guidelines related to diabetes from these databases. A total of 260 clinical guidelines were extracted from these databases.

The bibliographic details from the references of these guidelines were carefully examined, including the full text of each article. The titles, bibliographic information, and references of the 260 "appraised" guidelines were coded for further analysis.

Additionally, bibliographic information from systematic review and meta-analysis studies was also extracted. The references of these systematic reviews and meta-analyses were scanned, and all 286 papers were searched to obtain the authors' addresses and other bibliographic information.

The analyses were based on the published papers or bibliographic details, including examining their citations in clinical guidelines, systematic reviews, and meta-analysis studies.

By conducting these comprehensive searches and analyses, the study aimed to determine the extent to which the identified RCTs were cited and utilized in clinical guidelines, systematic reviews, and meta-analyses related to diabetes.

Results

Phase1

In Phase 1 of the study, the focus was on assessing the quality of reports on randomized controlled trials (RCTs) published on type 2 diabetes. A total of 286 articles were retrieved from the six databases that were searched, as mentioned earlier. (Fig. 1).

According to Fig. 1, the search strategy conducted between 2004 and 2021 resulted in a total of 6,667 articles being downloaded from the six databases mentioned earlier. After screening the titles and abstracts of these articles, 6,350 articles were excluded, leaving 317 articles for further evaluation. (Fig. 1). Out of the 317 articles, 286 articles met the eligibility criteria and were assessed for the bibliometric assessment. These 286 articles were considered for further analysis in Phase 1 of the study, which focused on the quality of reports on randomized controlled trials published on type 2 diabetes. The exclusion of articles during the screening process and the final selection of eligible articles for assessment provide insights into the rigorous process undertaken to ensure the relevance and quality of the articles included in the study. These results serve as a basis for the subsequent analysis and evaluation of the identified articles in the study.

Table 1 shows the characteristics of all 286 randomized controlled trials (RCTs) conducted on type 2 diabetes, based on the CONSORT 2010 items. The interventional procedures of these RCTs, as per the CONSORT 2010 items, are also outlined in the Table 1. The mean score of the 286 RCTs, according to the modified CONSORT for Abstract checklist, was 9.98 out of 17, with a range of 6 to 17 and a standard deviation of 2.904. This score indicates the level of adherence to the CONSORT 2010 guidelines in reporting the RCTs.

In terms of reporting, the term "randomized control trial" was identified in approximately 53.9% of the articles, while

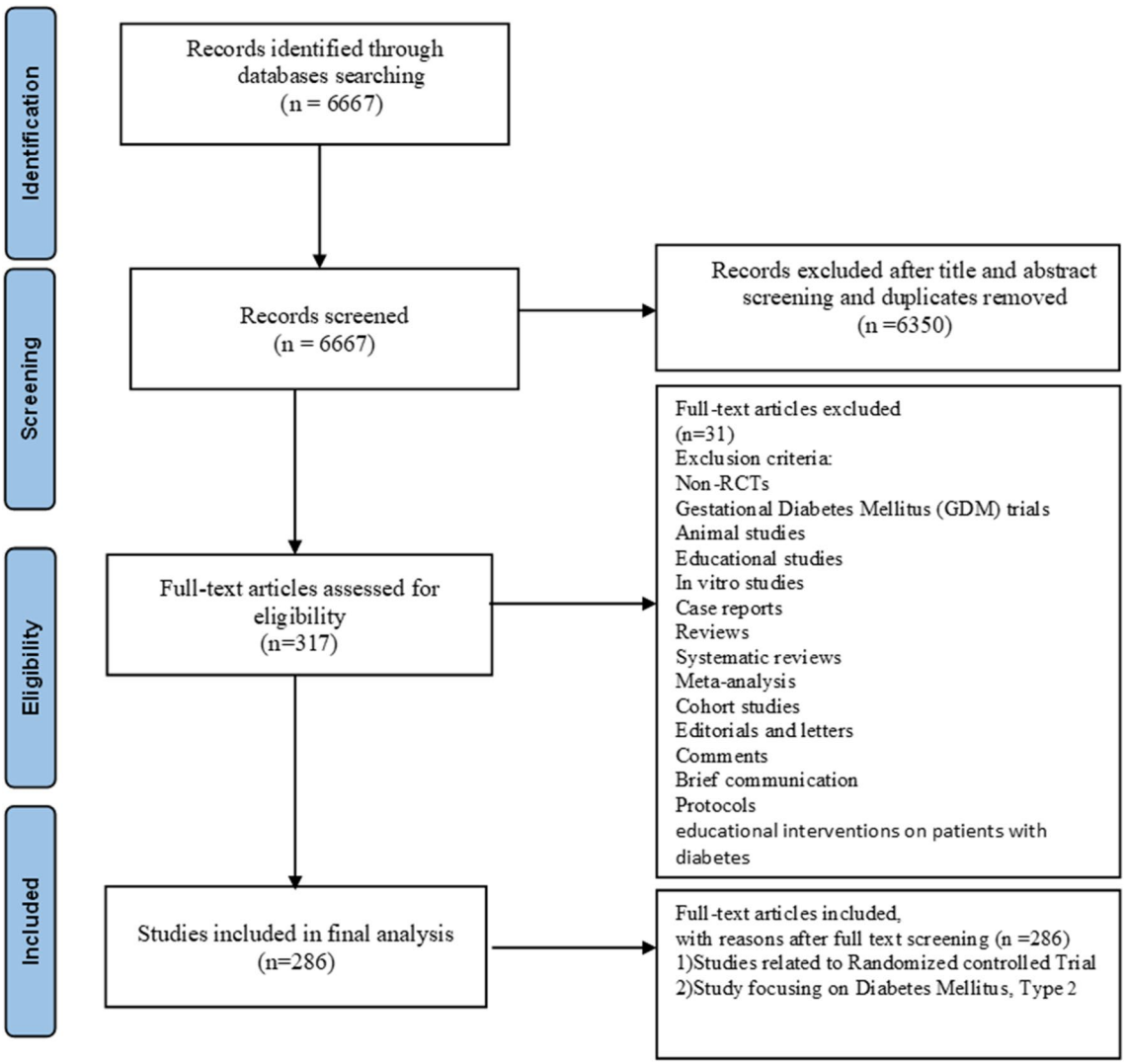

Fig. 1 PRISMA flowchart

Table 1 Adherence of RCTs to individual items of the CONSORT Checklist Abstract

Items	Descriptors	Adherence number of articles
Titles	Identification of the study as randomized	171(53.9)
Trial design	Description of the trial design (e.g., parallel, pragmatic, exploratory, cluster, non-inferiority)	115(36.3)
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	277(87.4)
Interventions	Interventions intended for each group	285(89.9)
Objective	Specific objective or hypothesis	278(87.7)
Outcome	Clearly defined primary outcome for this report	120(41.9)
Randomization	How participants were allocated to interventions	196(61.8)
Blinding (masking)	Whether participants, caregivers, and those evaluating the results were blind to group assignments	161(50.8)
Results		
Numbers randomized	Number of participants randomized to each group	172(54.3)
Recruitment	Trial status	40(12.6)
Numbers analyzed	The number of participants analyzed in each group	127(40.1)
Outcome	For the primary outcome, a result for each group and the estimated effect size and precision	211(66.6)
Harms	Important adverse events or side effects	59(18.6)
Conclusions	The general interpretation of the results	285(89.9)
Trial registration	Registration number and the name of trial registration	113(35.6)
Funding	Source of funding	73(23.0)

the description of the trial design was found in 36.3% of the articles. The trial objectives were presented in 87.7% of the published papers of the clinical trials.

Regarding the methodological procedures, the description of participants and interventions was expressed in 87.4% and 89.9% of the articles, respectively. The study specifically focused on the adequacy of reporting the selection of the primary outcome in each study. Among the assessed items in the CONSORT checklist, the poorest-reported ones were related to blinding (50.8%), primary outcomes (41.9%), the number of participants analyzed in each group (40.1%), trial design (36.3%), trial registration (35.6%), important adverse events or side effects (18.6%), and recruitment (12.6%). However, despite some reporting attempts, the description of these items in the CONSORT statement was insufficient, indicating a failure to adequately report all the items in the CONSORT checklist.

These findings highlight the areas where improvements are needed in reporting RCTs on type 2 diabetes, particularly in terms of blinding, primary outcomes, participant analysis, trial design, trial registration, adverse events or side effects, and recruitment. A more comprehensive and accurate reporting of these items in adherence to the CONSORT guidelines is essential for enhancing the quality and transparency of research in this field. (Table 1).

Phase2

In Phase 2 of the study, the aim was to determine the usage of the identified randomized controlled trials (RCTs) on type 2 diabetes in various clinical practice guidelines, systematic reviews, and meta-analysis studies. The researchers likely conducted a comprehensive search to identify relevant clinical practice guidelines, systematic reviews, and meta-analyses that incorporated the RCTs included in Phase 1. The search process may have involved searching databases, reference lists, and contacting experts in the field. The identified clinical practice guidelines, systematic reviews, and meta-analyses were then analyzed to assess the extent to which the RCTs on type 2 diabetes were utilized in these studies. This analysis could involve examining the inclusion and citation of the RCTs, as well as evaluating the impact of the RCTs on the recommendations or conclusions of the guidelines, reviews, and meta-analyses.

The findings from Phase 2 provide valuable insights into the utilization and impact of the identified RCTs in clinical practice guidelines, systematic reviews, and meta-analyses and One citation in systematic review related to type 2 diabetes (Table 2). This information helps to assess the translation of research evidence into clinical practice and the influence of the RCTs on the development of evidence-based recommendations.

Table 2 displays the frequency of citations for each paper in diabetes guidelines, systematic reviews, and meta-analyses and One citation in systematic review related to type 2 diabetes. out of the total 286 articles identified in the study. It indicates that out of the 286 articles, 11 articles (3.8%) were cited in a total of 260 clinical practice guidelines.

This finding suggests that these 11 articles have been widely recognized and utilized as references in the development of

Table 2 Utilization and Impact of Identified RCTs in Type 2 Diabetes Research

		RCT ($n=286$)
	Guidelines	
Yes, *n* (%)	11 (3.84%)	11 (3.84%)
No, *n* (%)	275(96.15%)	275(96.15%)
	Systematic review and Meta-analysis studies	
Yes, *n* (%)	144 (50.34%)	144 (50.34%)
No, *n* (%)	142(49.65%)	142(49.65%)
	Systematic review	
Yes, *n* (%)	80(27.97%)	80(27.97%)
No, *n* (%)	206(72.02%)	206(72.02%)
	Meta-analysis	
Yes, (*n* (%)	76(26.57%)	76(26.57%)
No, *n* (%)	210(73.42%)	210(73.42%)

diabetes guidelines. The fact that they are cited in a significant number of clinical practice guidelines indicates their importance and influence in shaping clinical recommendations and best practices for managing type 2 diabetes.

The inclusion of these articles in numerous clinical practice guidelines indicates their relevance and impact on guiding healthcare professionals in the management of type 2 diabetes. These articles likely provide valuable evidence and insights that have been considered crucial in formulating evidence-based recommendations.

The information presented in Table 2 emphasizes the significant role that these 11 articles play in informing clinical practice and highlights their widespread recognition and utilization in diabetes guidelines.

Section 2 demonstrates the frequency of citations for each paper in systematic review and meta-analysis studies, out of the total 286 articles identified in the study. It indicates that out of the 286 articles, 144 articles (50.3%) have been cited in systematic review and meta-analysis studies.

This finding suggests that a significant proportion of the identified articles have been recognized and utilized as references in the conduct of systematic reviews and meta-analyses. The high frequency of citations indicates the importance and contribution of these articles in synthesizing and analyzing the available evidence on type 2 diabetes.

The inclusion of these articles in systematic reviews and meta-analyses indicates their relevance and significance in contributing to the overall body of knowledge on type 2 diabetes. These articles have likely provided valuable data, findings, and insights that have been considered essential in conducting comprehensive and evidence-based analyses.

The information presented in Table 3 highlights the substantial utilization of the identified articles in systematic review and meta-analysis studies. It underscores their impact on synthesizing and summarizing the evidence base for type 2 diabetes, and their contribution to informing research, clinical decision-making, and policy development in this field.

Section 3 displays the number of articles cited in systematic review studies, out of the total 286 articles identified in the study. According to the table, 80 articles (27.9%) were cited in systematic review studies from the pool of RCTs registered for diabetes studies.

This finding suggests that a significant proportion of the identified articles have been recognized and utilized as references in the conduct of systematic reviews specifically focused on diabetes. The fact that 27.9% of the articles were

Table 3 The list of articles cited in clinical practice guideline

Authors	Guidelines	Journal	year	IF/H- Index	Journal Index databases
Azadbakht et al. [27]	ADA, AOA AANE, ICSI	Diabetes Care	2011	19.112/380	PubMed/WOS/Scopus
Azadbakht et al. [28]	ADA	Diabetes Care	2008	19.112/380	PubMed/WOS/Scopus
Malekshahi et al. [29]	ADA	Singapore medical journal	2012	2.053/64	PubMed/WOS/Scopus
Nikooyeh et al. [30]	ADA	American Journal of Clinical Nutrition	2011	7.045 /351	PubMed/WOS/Scopus
Fallah Huseini et al. [31]	CDA	Phytotherapy Research	2006	5.882/140	PubMed/WOS/Scopus
Fallah Huseini et al. [32]	CDA	Phytotherapy Research	2009	5.882/140	PubMed/WOS/Scopus
Rahbar et al. [33]	CDA	European Journal of Clinical Nutrition	2005	4.196/165	PubMed/WOS/Scopus
Ahmadieh et al. [34]	COO	Ophthalmology	2009	12.079/256	PubMed/WOS/Scopus
Modarres et al. [35]	COO	European Journal of Ophthalmology	2009	2.597/55	PubMed/WOS/Scopus
Mir Shahi et al. [36]	COO	European Journal of Ophthalmology	2008	2.597/55	PubMed/WOS/Scopus
Akbari et al. [37]	NHMRC	Journal of Rehabilitation Research and Development	2007	1.821/108	PubMed/WOS/Scopus

American Diabetes Association (ADA); American Optometric Association (AOA); Application-Aware Network Enterprise (AANE); Institute for clinical systems improvement (ICSI); Canadian Diabetes Association (CDA); Canadian Ophthalmological Society evidence-based clinical practice guidelines for the management of diabetic retinopathy (COO); National Health and Medical Research Council (NHMRC)

cited in systematic review studies indicates their importance and contribution to the synthesis of evidence in this field.

Section 4 presents the frequency of citations for each paper in meta-analysis studies, out of the total 286 articles identified in the study. It indicates that out of the 286 articles, 76 articles (26.5%) have been cited in meta-analysis studies.

This finding suggests that a significant proportion of the identified articles have been recognized and utilized as references in the conduct of meta-analyses. The fact that 26.5% of the articles were cited in meta-analysis studies indicates their importance and contribution to the synthesis of evidence in this field.

In contrast, Table 3 reveals that only a small percentage (3.8%) of the total articles published in the field were cited in diabetes guidelines. This suggests a potential gap between the research being conducted and the incorporation of that research into clinical practice guidelines. It emphasizes the need for researchers to prioritize the quality of their studies from the very beginning, including study design, implementation, and writing of RCTs.

Improving the quality of RCTs is crucial and requires careful attention to various aspects. Firstly, researchers should ensure that their study question and design are appropriate and relevant to the field. Secondly, they should strive to minimize systematic errors and biases in their study design and implementation. Lastly, using appropriate analysis techniques and reporting the findings accurately and comprehensively are essential aspects of conducting high-quality RCTs. These aspects should be considered when planning, conducting, and reporting RCTs. By doing so, researchers can increase the likelihood of their studies being cited in systematic reviews, meta-analyses, and influential guidelines.

Improving the quality of RCTs not only enhances their chances of being cited in systematic reviews and guidelines but also contributes to the overall body of knowledge and evidence-based practices in the field of diabetes management.

Discussion

In our study, we conducted a comprehensive analysis of 286 full-text publications on randomized controlled trials (RCTs) in type 2 diabetes. Our approach differed from a previous study [24], in two key aspects: the larger sample size and the examination of citation status in clinical practice guidelines, systematic reviews, and meta-analyses.

The findings of our study revealed poor adherence to the CONSORT guideline and low rates of trial registration in trial registries. We observed that some RCTs did not mention the CONSORT guidelines in their full text, leading to overall poor reporting quality. Additionally, we found that the implementation of reporting guidelines was inadequate, with noncompliance observed in all items and particularly in crucial aspects such as reporting primary outcomes in both abstracts and full-text publications of RCTs.

In comparison to Mathieu et al.'s study on registered and published primary outcomes in randomized controlled trials (RCTs) and specifically examines the comparison between registered and published primary outcomes, while our study assesses the broader implementation of reporting guidelines in RCTs in the field of type 2 diabetes research. They analyzed reports of RCTs in cardiology, rheumatology, and gastroenterology, while our study specifically focuses on RCTs in type 2 diabetes; our study looked at the overall adherence to reporting guidelines, including various reporting elements beyond primary outcomes. Despite these differences, both studies contribute to the understanding of the importance of transparent and comprehensive reporting in RCTs. Mathieu et al.'s findings highlight the need for improved registration and reporting practices, while our study emphasizes the need for better adherence to reporting guidelines to enhance the overall quality and reliability of RCTs in the field of type 2 diabetes research. [38].

In Yordanov study, assesses the waste of research by identifying trials with at least one domain at high risk of bias and proposing adjustments to reduce bias [39]. Our study examines the adherence to reporting guidelines and the reporting quality of RCTs, including the reporting of primary outcomes and also conducts a methodological review and simulation study, whereas our study analyzes full-text publications and evaluates the citation status of RCTs in clinical practice guidelines and systematic review and meta-analysis studies.

Despite these differences, both studies contribute to the understanding of challenges and areas for improvement in clinical trials. The BMJ study highlights the waste associated with inadequate methods and suggests the feasibility of simple and inexpensive adjustments to reduce bias. Our study emphasizes the importance of adherence to reporting guidelines to enhance transparency and reliability in reporting RCTs. Together, these studies provide insights into different aspects of research quality and offer potential avenues for improvement in clinical trial methodology and reporting practices.

The findings indicate that there is room for improvement in the quality of reported RCTs in the field of diabetes in Iran. Only 41.9% of the RCTs included in the study reported their primary outcome, suggesting a lack of adherence to reporting guidelines and potentially leading to incomplete interpretation of study findings.

Additionally, there were low percentages of articles that presented information on harms (18.6%), performed

randomizations (61.8%), carried out recruitment (12.6%), and reported the blinding process (50.8%). These omissions in reporting key methodological procedures can undermine the credibility and reliability of the research findings.

Furthermore, a small proportion of articles (3.8%) provided information on the frequency of citations in clinical diabetes guidelines, indicating limited recognition and impact of these studies in guiding clinical practice. The low percentages of articles cited in systematic review analyses (27.9%) and the majority of citations belonging to systematic review and meta-analysis studies (50.3%) also highlight the need for more comprehensive and impactful research in the field.

Overall, these findings underscore the importance of improving the quality of reported RCTs in diabetes research in Iran. It is crucial to enhance adherence to reporting guidelines, including the accurate reporting of primary outcomes, harms, randomization, recruitment, and blinding processes.

By improving the quality of reported RCTs, the level of evidence in evidence-based medicine can be strengthened, giving more credibility to research findings and reducing reliance on expert opinion. This will contribute to more informed decision-making in clinical practice in the field of diabetes. In contrast to evidence-based medicine, expert opinion is considered a lower level of evidence. While expert opinions may provide valuable insights and recommendations, they are based on individual expertise and subjective judgment, which can be influenced by personal biases or limited evidence.

Therefore, to ensure the highest level of credibility and reliability, evidence-based medicine relies on RCTs and systematic reviews as they minimize bias, provide rigorous methodologies, and offer the most robust evidence for making informed decisions in clinical practice [40, 41]. A poorly reported randomized controlled trial (RCT) can have a negative impact, particularly when physicians and researchers rely on its findings for daily practice or designing future RCTs. In such cases, the low power of a poorly reported study can lead to misleading or inconclusive results.

To address this issue, it is important for research to answer several key questions. Firstly, it should clearly state what research questions have been addressed and why they are important. This helps to provide context and rationale for the study.

Secondly, the methods used in the study need to be thoroughly described. This includes details about the study design, participant selection, interventions or treatments, outcome measures, and statistical analysis. Transparent reporting of methods allows other researchers to evaluate the study's quality and potential biases.

Thirdly, the uncertainty of effects should be clearly communicated. This involves reporting the results accurately, including measures of effect size, confidence intervals, and p-values. It is important to acknowledge any limitations or sources of uncertainty in the findings.

Lastly, the implications and meaning of the study's findings should be discussed. This includes interpreting the results in the context of existing evidence, identifying any implications for clinical practice, and highlighting areas requiring further research.

By addressing these questions and ensuring comprehensive reporting, researchers can help minimize the negative impact of poorly reported RCTs. It allows for a better understanding of the study's limitations, facilitates critical evaluation by other researchers, and promotes the use of reliable evidence in clinical decision-making and future research design [42].

In 2012, a comprehensive systematic review was conducted, encompassing 50 studies and analyzing 16,000 randomized trials. The purpose of this review was to assess the quality and completeness of reporting in these trials, specifically focusing on adherence to the CONSORT checklist, which provides guidelines for transparent and comprehensive reporting of RCTs. The findings of this systematic review revealed that there were improvements in the completeness of reporting, as indicated by increased adherence to CONSORT checklist items. However, despite these improvements, significant deficiencies in reporting still persisted.

This study highlight the ongoing need for researchers to prioritize and enhance the reporting quality of RCTs. Transparent and comprehensive reporting is crucial for ensuring the credibility, reproducibility, and applicability of study findings. By addressing reporting deficiencies, researchers can contribute to the advancement of evidence-based medicine and facilitate informed decision-making in healthcare [43].

Although the CONSORT statement provides valuable guidelines for transparent and comprehensive reporting, its implementation and adherence by researchers can vary. Some researchers may not fully understand or prioritize the importance of adhering to the CONSORT guidelines, leading to incomplete or inadequate reporting.

Moreover, the reporting quality of RCTs is just one aspect of assessing their methodological quality. Other important considerations include the study design, sample size, randomization process, blinding, and statistical analysis. Even if the reporting is comprehensive, the methodological quality of the study may still be flawed, limiting the usefulness of the findings.

To address these challenges and ensure the usefulness of RCT reporting, ongoing efforts are needed to educate researchers on the importance of adhering to the CONSORT guidelines. Journals and reviewers also play a crucial role in enforcing reporting standards and encouraging comprehensive reporting. Additionally, researchers should strive to

improve the methodological quality of their studies beyond just reporting, ensuring robust study designs and rigorous analysis.

By addressing these issues, the scientific community can work towards enhancing the usefulness and reliability of RCT reporting, ultimately contributing to evidence-based medicine and informed decision-making in healthcare [18, 44, 45]. According to a 2016 update from a systematic review of 185 randomized trials in diabetes research conducted in Iran, it was found that the quality of reporting in these trials was not optimal and was also incomplete. However, there is a positive trend of improvement over time [24].

To the best of our knowledge, this study represents the first analysis of published randomized controlled trials (RCTs) in type 2 diabetes in Iran, specifically focusing on their adherence to the CONSORT guideline and their citation in medical guidelines, meta-analyses, and systematic reviews. The findings highlight the need for improvement in the quality of RCTs conducted in type 2 diabetes, particularly in terms of methods and reporting of primary outcomes. The adherence to CONSORT guidelines appears to be insufficient. Although there has been an overall improvement in the reporting of RCTs over time, certain methodological aspects, such as randomization, blinding, reporting of outcomes, random number generation, and adverse effects, were poorly reported.

The findings of the present study indicate that only a small number of studies were cited in clinical practice guidelines. This suggests that physicians and researchers may face challenges in accessing and utilizing research that is deemed useful for clinical decision-making. To effectively apply and respond to research, accurate and appropriate descriptions of the study's purpose, methods, populations, and interventions are crucial for designing and conducting further research.

Unfortunately, it appears that many authors are unaware of how to achieve these goals and where to find reliable results. This highlights the importance of specific reporting guidelines, such as CONSORT, STARD, PRISMA, STROBE, or other guidelines developed in various scientific fields. These guidelines can serve as valuable resources for researchers, providing them with a framework to ensure the validity and reliability of their research findings [46].

In summary, the utilization of specific reporting guidelines, such as CONSORT, STARD, PRISMA, STROBE, or other relevant guidelines, can greatly assist researchers in finding valid and reliable medical information. These guidelines not only aid in the accurate reporting of research findings but also improve the accessibility and usability of research for physicians and other researchers in clinical practice and future studies.

Despite the availability and promotion of reporting guidelines, many authors continue to neglect their implementation in their research reports. This lack of adherence can result in incomplete or inaccurate reporting of research methods, results, and other essential details [22, 43, 47–49].

Addressing the issue of poor adherence to reporting guidelines requires a multifaceted approach. Researchers, authors, and institutions must be educated and informed about the significance of adhering to these guidelines and the potential impact on research quality and reliability. Journals and publishers also have a crucial role to play by actively encouraging and enforcing the use of reporting guidelines during the submission and publication process.

In conclusion, research funders and institutions have a vital role to play in ensuring good reporting practices for RCTs. By providing training opportunities and incorporating reporting guidelines into their evaluation processes, they can empower researchers to produce high-quality reports and contribute to the advancement of scientific knowledge in a transparent and rigorous manner.

Limitations and benefits

The study acknowledges several limitations that affected the findings. Firstly, the exclusion of unpublished RCTs, particularly those with negative results, may have introduced a publication bias into the study. This means that the results may not fully represent the entire body of RCTs conducted on the topic.

Secondly, the study was limited to Iran and focused specifically on RCTs related to type 2 diabetes. This geographical and topic restriction may limit the generalizability of the findings to other regions or medical conditions.

In the next phase of the project, a worldwide systematic literature review will be conducted to address these limitations. This broader review will encompass various interventions and trial designs related to diabetes, providing a more comprehensive understanding of the challenges and approaches to Patient-Reported Outcome Measures (PROMs). Additionally, the project aims to develop a list of core outcomes specific to the diabetes field.

Despite these limitations, the study's results still offer valuable insights for researchers. They provide a perspective on how to design and implement high-quality RCTs, while also highlighting the importance of avoiding reporting bias in the publication of research studies.

It is important for future research to address the limitations mentioned, such as including unpublished studies and expanding the scope beyond a single country and medical condition. This will contribute to a more comprehensive understanding of RCTs and improve the validity and generalizability of research findings.

In addition to these limitations, it is important to highlight the benefits of the study. The findings offer valuable

insights for researchers in designing and implementing high-quality RCTs. The study emphasizes the importance of avoiding reporting bias in the publication of research studies, which contributes to the overall integrity and credibility of the scientific literature.

To address the limitations mentioned, the next phase of the project will involve conducting a worldwide systematic literature review. This broader review will include various interventions and trial designs related to diabetes, providing a more comprehensive understanding of the challenges and approaches to Patient-Reported Outcome Measures (PROMs). Furthermore, the project aims to develop a list of core outcomes specific to the diabetes field, which will enhance the consistency and comparability of future research studies.

By addressing these limitations and expanding the scope of the research, future studies can contribute to a more comprehensive understanding of RCTs and improve the validity and generalizability of research findings.

Conclusion

In conclusion, the study's analysis of 286 reports of RCTs conducted on type 2 diabetes in Iran revealed poor quality and adherence to the CONSORT checklist, particularly concerning methodological issues. It was also found that only a small number of articles were cited in guidelines and systematic reviews, indicating a low impact of the studies. The findings emphasize the need for authors, funding agencies, peer reviewers, and journal editors to play an active role in improving the quality of RCTs in diabetes. Collaborative efforts are necessary to integrate CONSORT guidelines into the publication process of RCTs, ensuring that studies are conducted and reported in a rigorous and transparent manner.

The study also highlights the importance of the evolution of CONSORT extensions, such as the InsPECT extensions, which have been developed by members of the EQUATOR Network to enhance the reporting and methodology of research in the field [50].

Additionally, it is worth mentioning the contribution of studies conducted in Iran to the field of diabetes research. Iran has been actively involved in diabetes research, with numerous randomized controlled trials (RCTs) registered and published in this area. While the specific number of RCTs conducted in Iran was not provided in the tables, it is important to acknowledge the potential impact of Iranian studies on the overall body of evidence.

Iran, like many other countries, faces unique challenges in managing diabetes due to factors such as cultural, socioeconomic, and healthcare system variations. Therefore, research conducted in Iran can provide valuable insights into diabetes management strategies tailored to the specific needs of the Iranian population. These studies may address important research gaps and contribute to the development of evidence-based guidelines and recommendations for diabetes care in Iran and potentially other similar contexts.

Future research efforts should continue to focus on improving the quality of RCTs conducted in Iran, ensuring rigorous study design, appropriate methodology, and transparent reporting. By doing so, Iranian studies can further enhance their impact and increase the likelihood of being cited in systematic reviews, meta-analyses, and guidelines, ultimately leading to improved diabetes management outcomes in Iran and beyond.

Overall, the study's findings call for increased attention to the quality of RCTs in diabetes research and the implementation of reporting guidelines to improve transparency, reliability, and the impact of these studies. It guides how to completely report any type of outcome in randomized controlled trial reports and facilitates systematic reviews and meta-analyses protocols. to standardize outcome reporting in primary studies [50]. The CONSORT guidelines provide a framework for researchers to report outcomes in randomized controlled trial (RCT) reports comprehensively.

By following these guidelines, researchers can ensure that all relevant information related to the outcomes of their study is included in their reports. The CONSORT guidelines help to standardize outcome reporting in primary studies, which is essential for various reasons. Firstly, it promotes transparency and allows readers to assess the validity and reliability of the study's findings. Secondly, it facilitates the replication of studies and the comparison of results across different trials. Thirdly, standardized outcome reporting improves the quality of evidence available for systematic reviews and meta-analyses, enabling researchers to draw more accurate conclusions and make informed decisions based on a larger body of evidence.

By providing a structured framework for outcome reporting, CONSORT guidelines assist researchers in ensuring that all relevant outcomes, including both primary and secondary outcomes, are reported consistently and comprehensively. This, in turn, enhances the overall quality and reliability of RCT reports and contributes to the advancement of scientific knowledge in a standardized and transparent manner. Future study reports should be optimized to avoid reporting bias and improve transparency and reproducibility. Absolutely, optimizing study reports to avoid reporting bias and enhance transparency and reproducibility is crucial for the advancement of scientific knowledge.

Here are some key steps that can be taken to achieve these objectives:

- Pre-registration: Researchers should consider pre-registering their study protocols and analysis plans to ensure

transparency and reduce the risk of selective outcome reporting. This involves publicly registering the study design, methods, and intended analyses before data collection.

- Comprehensive reporting: Authors should adhere to reporting guidelines, such as the CONSORT guidelines for RCTs, to ensure that all relevant information is included in the study report. This includes reporting details about the study design, participant characteristics, interventions, outcomes, statistical analyses, and any potential limitations.
- Open data and materials: Making research data and materials openly available can enhance transparency and reproducibility. Researchers should consider sharing their data, code, and other research materials through repositories or platforms that allow for open access.
- Sharing negative or null results: To combat publication bias, journals and researchers should actively encourage the publication of negative or null results, as they are equally valuable in contributing to the scientific knowledge base.
- Replication and reproducibility: Researchers should strive to conduct replication studies to validate and confirm findings from previous studies. Additionally, providing detailed information about study procedures, protocols, and materials used can facilitate the reproducibility of research findings.
- Peer review and peer feedback: Journals should ensure rigorous peer review processes that include the evaluation of study design, methodology, and reporting quality. Peer feedback and constructive criticism can help improve the transparency and quality of study reports.

By implementing these strategies, future study reports can minimize reporting bias, enhance transparency, and improve the reproducibility of research findings. This will contribute to the overall credibility and reliability of scientific research.

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Author contributions **A.A** designed the analysis, Performed the analysis and wrote the paper, risk of bias assessment, assessing data in medical guidelines. **M.R.M** revising it critically for important intellectual content. **A.A.K** contributed data or analysis tools. **H.R.B** designed the analysis and final approval of the version. **SS**. contributed data **Y.M.** Collected the data. **M.H.** reviewing critically for important intellectual content. **S.D** risk of bias assessment **F.H**. assessing data in medical guidelines. **M.R** assessing data in systematic review and Meta analysis. **SS.** risk of bias assessment **A.S** final approval of the version. **L.N.A** analysis and interpretation.

Declarations

Conflict of interest The authors declare that they have no conflict of interests that are relevant to the content of this article.

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