Complementary Therapies in Medicine 38 (2018) 61–66

Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevier.com/locate/ctim

Quality of reporting of randomized controlled trials of herbal medicines conducted in metabolic disorders in Middle East countries: A systematic review

Ozra Tabatabaei-Malazy[a,b,h], Zhaleh Shadman[a,b,h], Hanieh-Sadat Ejtahed[c,h], Rasha Atlasi[d,e,h,i], Mohammad Abdollahi[b,f,g,h,j], Bagher Larijani[b,*,h]

[a] Diabetes Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran
[b] Endocrinology and Metabolism Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran
[c] Obesity and Eating Habits Research Center, Endocrinology and Metabolism Molecular − Cellular Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran
[d] Evidence based Practice Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences, Tehran, Iran
[e] Department of Medical Library & Information Science, School of Allied Medical Sciences, Tehran University of Medical Sciences, Tehran, Iran
[f] Toxicology and Diseases Group, Pharmaceutical Sciences Research Center, Tehran University of Medical Sciences, Tehran, Iran
[g] Department of Toxicology and Pharmacology, Faculty of Pharmacy, and Pharmaceutical Sciences Research Center, Tehran University of Medical Sciences, Tehran, Iran

ARTICLE INFO

Keywords:
Randomized controlled trial
Herbal medicine
Metabolic disorders
CONSORT statement
Systematic review

ABSTRACT

Introduction: Based on WHO recommendation for considering herbal medicine as an inexpensive appropriate method to treat metabolic disorders, conducting randomized controlled trials (RCTs) is increasing worldwide. Since poor quality RCTs can lead to wrong conclusion, we assessed the quality of reporting of herbal medicines' RCTs conducted in Middle East in a systematic review study.

Materials & methods: All herbal medicines' RCTs in metabolic disorders (diabetes mellitus, metabolic syndrome, hyperlipidemia, obesity and osteoporosis) conducted in Middle East countries and published before January 2017 were included. To obtain all related studies PubMed, Scopus, Web of Science, Cochran library, and Embase web databases were searched. Exclusion criteria were animal studies, non-herbal medicines' RCTs, RCTs conducted in Type 1 diabetes, in children or pregnant women. We used Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist for reporting study selection processes as well as Consolidated Standards of Reporting Trials (CONSORT) statement for assessment of quality of reporting.

Results: Out of 5319 identified studies, 215 RCTs were included. The proportion of published RCTs in the topic increased significantly over the time ($P < 0.001$). The total mean ± SD score for 37 items of CONSORT checklist was 21.15 ± 4.27. Most of RCTs (60%) were not reported randomization in the title. Some important items were incompletely reported including trial registration (42.3%), sample size estimation (38.1%), randomization method (35.3%), generation of allocation (27.9%), and concealment of allocation (13.5%).

Conclusions: Our findings indicate that the quality of reporting of herbal medicines' RCTs in metabolic disorders has improved over time in Middle East, but remains suboptimal.

1. Introduction

By increasing prevalence of metabolic disorders, especially type 2 diabetes mellitus (T2DM), obesity, dyslipidemia, osteoporosis and metabolic syndrome (MetS), it seems to be required to discover more new drugs for treating and management of these disorders.[1] Since synthetic drugs may cause uncomfortable adverse effects, have less accessibility in some countries, and also have high costs, considering alternative medicines for management of the metabolic disorders may be of great importance. Currently, an increasing interest has been shown among people of developed and developing countries to use herbal medicines as medications of metabolic disorders and also by the scientists to

* Corresponding author.
E-mail addresses: tabatabaeiml@sina.tums.ac.ir (O. Tabatabaei-Malazy), zhaleh_shadman@yahoo.com (Z. Shadman), haniejtahed@yahoo.com (H.-S. Ejtahed), rashaatlasi@gmail.com (R. Atlasi), Mohammad.Abdollahi@UToronto.Ca, Mohammad@TUMS.Ac.Ir (M. Abdollahi), emrc@tums.ac.ir (B. Larijani).
[h] Endocrinology & Metabolism Research Institute, No.10, Next to Dr. Shariati Hospital, jalal al Ahmad Hwy., North Kargar Ave., Tehran, Postal Code:1411713137, Iran.
[i] Enghelab Ave, Ghods Ave, Farredanesh Alley, No #17,Tehran, Iran.
[j] Division of Toxicology, Department of Toxicology & Pharmacology, Faculty of Pharmacy, and Pharmaceutical Sciences Research Center, Tehran University of Medical Sciences, Tehran 1417614411, Iran.

https://doi.org/10.1016/j.ctim.2018.04.004
Received 28 September 2017; Received in revised form 11 January 2018
Available online 11 April 2018

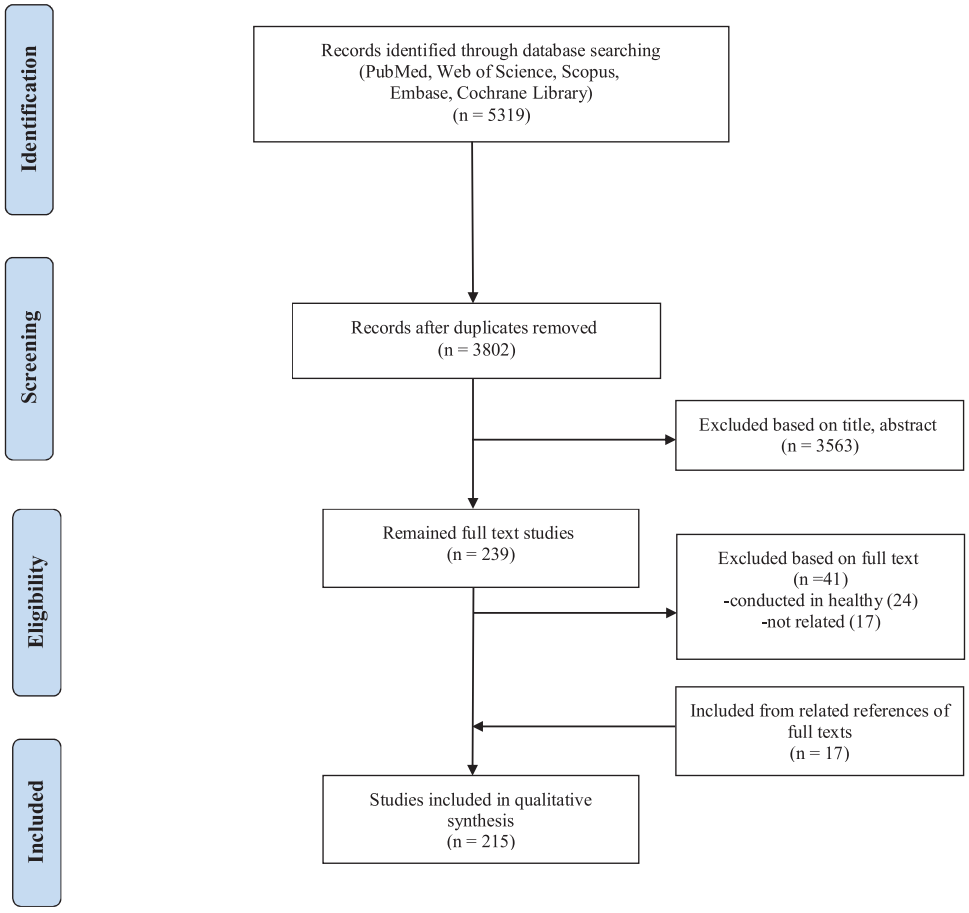

Fig. 1. Flow diagram of the study selection process according to PRISMA checklist.

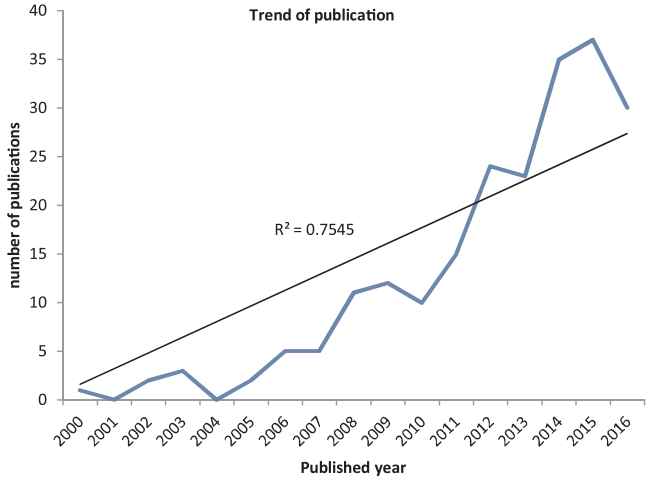

Fig. 2. Trend of publications of RCTs in herbal medicines in Middle East countries over the time.

conduct and publish studies in this field.[2–9] The history of drugs' development indicates that herbal medicines play a key role in the discovery of synthetic drugs. In other words, despite explosive developments in synthetic drugs, herbal medicines are still the main source for discovery of new drugs.[10–15] However, the scientific evaluations in efficacy of medicinal plants are limited.

Clinical trials are often used to assess the safety, efficacy or effectiveness of medical interventions. The "gold standard" of a clinical trial is when participants are randomly allocated into groups that introduced randomized clinical trials (RCTs).[16,17] On the other hand, systematic review and meta-analysis of the RCTs is defined as the first level or the strongest level of evidence according to evidence-based medicine (EBM) ranking system.[18] Because meta-analysis of RCTs with poor quality of reporting would be resulted in wrong conclusions and harmful treatments, the quality of methodological reporting in RCTs is important.[19] In this regard, the Consolidation Standards of Reporting Trials (CONSORT) Statement was set a standard checklist for regular assessment of reporting of how to design, analysis, and interpretation to reduce problems following inadequate reporting of RCTs. In different systematic review studies, an improvement of reporting of RCTs after using CONSORT statement has been shown.[20–22] Although the number of RCTs of herbal medicines is increasing worldwide, most of systematic review studies have assessed the quality of reporting of RCTs conducted with non-herbal medications.[23] Remained the systematic review studies in this field have assessed reporting of RCTs of Traditional Chinese Medicine (TCM) in China and Korea.[24–26] However, a lack is observed in systematic assessment of the quality of reporting herbal medicines' RCTs conducted in Middle East region. We aimed to assess systematically this topic in RCTs published by scientists affiliated to Middle East region countries.

2. Materials & methods

2.1. Search strategy

All relevant available randomized controlled trials (RCTs) conducted to assess effectiveness of herbal medicines in subjects suffered from obesity, T2DM, osteoporosis, hyperlipidemia, or MetS and published before January 2017 were included. To obtain all related studies PubMed, Scopus, Web of Sciences, Cochran library, and Embase web

Table 1
Trend of publications of RCTs in herbal medicines for metabolic disorders in Middle East countries over the time.

Disease	2000 n(%)	2001 n(%)	2002 n(%)	2003 n(%)	2004 n(%)	2005 n(%)	2006 n(%)	2007 n(%)	2008 n(%)	2009 n(%)	2010 n(%)	2011 n(%)	2012 n(%)	2013 n(%)	2014 n(%)	2015 n(%)	2016 n(%)	Total n(%)	Total score (mean ± SD)
Type 2 diabetes mellitus	0 (0.0)	0 (0.0)	1 (0.8)	1 (0.8)	0 (0.0)	2 (1.6)	4 (3.1)	1 (0.8)	7 (5.5)	9 (7.0)	4 (3.1)	8 (6.3)	16 (12.5)	17 (13.3)	20 (15.6)	21 (16.4)	17 (13.3)	128 (100.0)	10–31 (21.26 ± 4.23)
Dyslipidemia	1 (2.8)	0 (0.0)	1 (2.8)	2 (5.6)	0 (0.0)	0 (0.0)	1 (2.8)	1 (2.8)	3 (8.3)	1 (2.8)	4 (11.1)	3 (8.3)	2 (5.6)	3 (8.3)	5 (13.9)	3 (8.3)	6 (16.7)	36 (100.0)	12–29 (20.0 ± 3.98)
Metabolic Syndrome	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (15.0)	0 (0.0)	1 (5.0)	2 (10.0)	1 (5.0)	3 (15.0)	0 (0.0)	3 (15.0)	2 (10.0)	5 (25.0)	20 (100.0)	13–25 (21.30 ± 3.36)
Obesity	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.3)	2 (12.5)	2 (12.5)	3 (18.8)	8 (50.0)	0 (0.0)	16 (100.0)	18–30 (24.69 ± 4.48)
Osteoporosis	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (6.7)	1 (6.7)	0 (0.0)	2 (13.3)	1 (6.7)	1 (6.7)	4 (26.7)	3 (20.0)	2 (13.3)	15 (100.0)	13–27 (19.0 ± 4.23)
Total	1 (0.5)	0 (0.0)	2 (0.9)	3 (1.4)	0 (0.0)	2 (0.9)	5 (2.3)	5 (2.3)	11 (5.1)	12 (5.6)	10 (4.7)	15 (7.0)	24 (11.2)	23 (10.7)	35 (16.3)	37 (17.2)	30 (14.0)	215 (100.0)	10–31 (21.15 ± 4.27)

databases were systematically searched. The used search terms were "herbal medicine", "plant", "metabolic syndrome", "obesity", "obese", "overweight", "body mass index", "dyslipidemia", "hyperlipidemia", "osteoporosis", "osteopenia", "diabetes mellitus", "type 2 diabetes", "non-insulin dependent" and their Medical Subject Headings (MeSH) or Embase subject heading (Emtree) terms limited in human. In addition, the studies should be affiliated to Middle East Countries including Bahrain, Cyprus, Egypt, Iraq, Iran, Israel, Jordan, Kuwait, Lebanon, Oman, Palestine, Qatar, Saudi Arabia, Syria, Turkey, United Arab Emirates, and Yemen.[27]

Whenever the data was inaccessible or incomplete, we sent at least 3 emails to corresponding authors. The title and then the abstract of the papers were looked through to exclude the duplicated articles by two researchers independently; moreover, hand searching was performed in reference lists of included studies for full-text retrieval. In case of contrast, included and excluded studies were assessed by a third researcher. Within multiple publications from the same study, only the largest study was included. English language was considered as language restriction.

2.2. Study selection

All RCTs that met the following criteria were included: 1) conducted in above-mentioned metabolic disorders; 2) using herbal medicine at least in one of interventional groups; 3) using different groups to compare the effect of studied medicinal plants to each other; 4) comparing the effect of one or more studied herbal medicines to synthetic drugs. Studies which followed the above criteria, but conducted in the healthy population, children, pregnant women, patients with type 1 DM or other metabolic disorders than above-mentioned were excluded. Other exclusion criteria were animal studies, *in vitro* studies, RCTs with Traditional Chinese Medicine, narrative reviews, systematic reviews, letters to the editor and thesis.

2.3. Data extraction

All 37 items of CONSORT 2010 statement were separately checked for each study. Each reported and non-reported item was considered as yes (or scored 1) and no (or scored 0), respectively. Thus the total score for reporting items was expected from 0 to 37. Other extracted data were included year of publication, studied metabolic disorder, country, and sum of scores. All of the extracted data were presented in an excel sheet.

2.4. Data synthesis and analysis

This study is reported according to Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) along with CONSORT 2010 checklists.[28] The PRISMA checklists are shown in supplementary figures. Descriptive statistics were expressed as mean ± standard deviation (SD). All analytic tests including descriptive, chi square, and correlation were performed by StatsDirect.

3. Results

The number of initial search results and included studies in accordance to PRISMA checklist are shown in Fig. 1. Two hundred five RCTs were selected as our final research database. The trend of annual publications in RCTs with HMed over the time is depicted in Fig. 2. The most productive year was 2015 with 37 published RCTs (17. 2%). No published RCTs was found in the field within 2001 and 2004 in Middle East countries. There was a strong positive correlation between year of publications and number of published RCTs ($r = 0.95$, $P < 0.001$).

The trend of annual publications in RCTs over the time is presented in Table 1 for each one of the five metabolic disorders. The most RCTs were conducted in type 2 diabetic patients (59.5% of published RCTs).

Table 2
Percentages of reported items according to CONSORT 2010 checklist for included RCTs in five metabolic disorders in Middle East countries.

Item	Diabetes' RCTs N (%)	Dyslipidemia' RCTs N (%)	Metabolic Syndrome' RCTs N (%)	Obesity' RCTS N (%)	Osteoporosis' RCTs N (%)	Total RCTs N (%)
Identification of randomization in title	52(40.6)	13(36.1)	8(40.0)	11(68.8)	2(13.3)	86(40.0)
Sample size Calculation	56(43.8)	13(36.1)	2(10.0)	9(56.3)	2(13.3)	82(38.1)
Randomization methods	40(31.3)	8(22.2)	8(40.0)	13(81.3)	7(46.7)	76 (35.3)
Generation of allocation	44(34.4)	3(8.3)	3(15.0)	8(50.0)	2(13.3)	60(27.9)
Concealment of allocation	21(16.4)	4(11.1)	0(0.0)	3(18.8)	1(6.7)	29 (13.5)
Blinding	88(68.8)	21(58.3)	10(50.0)	14(87.5)	10(66.7)	143 (66.5)
Reporting adverse effects	78(60.9)	18(50.0)	13(65.0)	12(75.0)	7(46.7)	128(59.5)
Registration of trial	58(45.3)	10(27.8)	6(30.0)	14(87.5)	3(20.0)	91(42.3)

The most number of publications for diabetes was happened in year 2015 (21 RCTs). This event for dyslipidemia, MetS, obesity and osteoporosis was shown in different years 2016/6, 2016/5, 2015/8, and 2014/4 RCTs, respectively.

Quality of reporting of some of CONSORT-2010 items for HMed RCTs conducted in 5 metabolic disorders in Middle East countries have been presented in Table 2. The total mean ± SD score for 37 items of CONSORT was 21.15 ± 4.27. In most of RCTs (60%), randomization was not reported in the title. Some important items were incompletely reported including sample size estimation (38.1%), randomization method (35.3%), generation of allocation (27.9%), concealment of allocation (13.5%), and trial registration (42.3%) (Table 3).

4. Discussion

Our study showed a significant rising in examination of herbal medicine RCTs in adults with metabolic disorders over the time. Although, the quality of reporting of these studies has improved over the time, it is still suboptimal in Middle East countries.

Rapid growth in aging and urbanization of population has resulted in increasing the prevalence of metabolic disorders as a main component of non-communicable diseases (NCDs) worldwide.[29] Although, more attention has been paid on research in metabolic disorders in recent years,[30–35] their good care and management has remained as a challenge. Due to low adverse effect and reasonable cost of herbal medicines, their safety and efficacy have been assessed in many interventional studies for drug discovery and development.[7,36] The high prevalence of diabetes and its cost have resulted in introducing as the most important health problem.[37] Therefore, research in different field of diabetes and its complications from basic to clinical sciences has been paid more attention by scientists and researchers.[38–41] Regarding concerns high tendency of people to consume herbal medicines both in developed and in developing countries as well as WHO announcement on lack of evidence-based knowledge on safety and efficacy of herbal medicines,[42] RCTs in this field have been more conducted worldwide.[8,36,43,44] It was shown in Gagnier et al. study [36] a rising in herbal medicine' RCTs from one trial in 1970s to 94 trials in 2000s that is in line with our results; from one trial in 2000–215 trials in 2016.

Since RCTs have known as the gold standard for providing evidence according to the EBM ranking system,[18] they have a key role in decision making for health policy makers and clinicians. A thorough assessment of a trial is vital for presenting the critical information required for quality and reliability of published research, its inadequate quality of reporting is associated with bias in interpretation of the results. Therefore, inadequate quality of reporting can exaggerate or underestimate the effect of intervention on care and management of disorders.[19] Wood et al. concluded that RCTs with inadequate allocation concealment have exposed to risk of bias.[19] Other items that will be considered to decrease the risk of bias are blinding and adequate sample size calculation.[23] Page et al.,[45] in their systematic review of meta-epidemiological studies suggested that particular caution are required for interpreting the results of trials with inadequate reporting in sequence generation, allocation concealment and blinding. Therefore, many efforts have been made to assess the quality of RCTs reporting. Methodological reporting of RCTs on diabetes which published in three major diabetes journals including *Diabetes Care*, *Diabetes* and *Diabetologia* between 2011 and 2013 years was evaluated by CONSORT checklist.[46] Within 305 enrolled RCTs, most of them (256 trials) was conducted in United States and Europe. Quality of reporting was found for generation of allocation (35.4%) and concealment of allocation (28.5%). In addition, intention-to-treat analysis was used in 23.8% of the RCTs. Finally, it was found that quality of reporting of RCTs in three major journals of diabetes remained suboptimal. In another study, the quality of reporting RCTs of Traditional Chinese Medicine (TCM) was assessed in thirteen TCM journals.[46] They found a significant increase in proportion of published RCTs over the studied period from 18.6% in 1999–35.9% in 2004. They found incompletely reporting for some of important components of CONSORT checklist such as sample size calculation (1.1%), randomization sequence (7.9%), allocation concealment (0.3%), and implementation of the random allocation sequence (0%) in studied RCTs. Finally, they concluded that the quality of reporting of TCM RCTs has improved over the time but the quality of reporting is poor. Although in our results were reported sample size calculation (38.1%), generation of allocation (27.9%), and concealment of allocation (13.5%), quality of our results were reported suboptimal similar to those were found in above studies.

Methodological quality of RCTs that assessed with the CONSORT checklist in surgery was shown an improvement in volume and quality of the RCTs, and a rising in low risk of bias in trials over the time.[47] The highest increase in publication was in Africa/South America, and the second or third rank was in Asia/Oceania or in Europe, whereas the highest and the lowest proportion of low risk of bias were from Europe, and Asia/Oceania, respectively. Although in our study the quality of RCTs reporting from different regions was not compared, the methodological reporting from Middle East countries was not satisfied totally.

Despite relative improvement of quality of RCTs reporting by CONSORT statement, the quality is not still optimal. Considering these needs, some efforts such as endorsement of reporting guidelines by journals (traditional and non-traditional medicine journals) have occurred. Some systematic reviews have shown the impact of journal endorsement of CONSORT on completeness of RCTs reporting.[22,26,48] In spite of the considerable advances occurred while completing RCTs reporting subsequent to the CONSORT endorsement by various journals, the quality of RCTs reporting still calls for further improvement. Among other efforts have been made to enhance the quality of reports of interventions in herbal medicine prepared a substantial number of CONSORT Statement extensions. In this regard, a team of scholars and editors focused on traditional Chinese medicine (TCM) has recently developed the extended version of the CONSORT 2010 Statement for Chinese herbal medicine (CHM) Formulas, referred to as CONSORT-CHM Formulas 2017, wherein the idea of TCM is introduced and the properties of CHM formula are incorporated.[49] For the purposes of a

Table 3
Percentages of reported items according to CONSORT 2010 checklist for included RCTs in the field in Middle East countries over the time.

Item	2000 n(%)	2001 n(%)	2002 n(%)	2003 n(%)	2004 n(%)	2005 n(%)	2006 n(%)	2007 n(%)	2008 n(%)	2009 n(%)
Identification of randomization in title	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (40.0)	2 (40.0)	4 (36.4)	1 (8.3)
Sample size calculation	0 (0.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (8.3)
Randomization methods	1 (100.0)	0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	3 (25.0)
Generation of allocation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (20.0)	0 (0.0)	4 (36.4)	0 (0.0)
Concealment of allocation	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Blinding	1 (100.0)	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	2 (100.0)	4 (80.0)	2 (40.0)	6 (54.5)	5 (41.7)
Reporting adverse effects	1 (100.0)	0 (0.0)	1 (50.0)	2 (66.7)	0 (0.0)	2 (100.0)	4 (80.0)	5 (100.0)	7 (63.6)	6 (50.0)
Registration of trial	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (9.1)	0 (0.0)

Item	2010 n(%)	2011 n(%)	2012 n(%)	2013 n(%)	2014 n(%)	2015 n(%)	2016 n(%)	Total n(%)
Identification of randomization in title	0 (0.0)	5 (33.3)	10 (41.7)	8 (34.8)	17 (48.6)	22 (59.5)	14 (46.7)	86 (40.0)
Sample size calculation	2 (20.0)	3 (20.0)	10 (41.7)	14 (60.9)	13 (37.1)	23 (62.2)	15 (50.0)	82 (38.1)
Randomization methods	1 (10.0)	4 (26.7)	8 (33.3)	9 (39.1)	16 (45.7)	21 (56.8)	12 (40.0)	76 (35.3)
Generation of allocation	0 (0.0)	2 (13.3)	13 (54.2)	9 (39.1)	11 (31.4)	15 (40.5)	5 (16.7)	60 (27.9)
Concealment of allocation	1 (10.0)	1 (6.7)	3 (12.5)	3 (13.0)	8 (22.9)	8 (21.6)	5 (16.7)	29 (13.5)
Blinding	7 (70.0)	8 (53.3)	16 (66.7)	14 (60.9)	28 (80.0)	27 (73.0)	21 (70.0)	143 (66.5)
Reporting adverse effects	4 (40.0)	5 (33.3)	16 (66.7)	15 (65.2)	22 (62.9)	23 (62.2)	15 (50.0)	128 (59.5)
Registration of trial	2 (20.0)	3 (20.0)	10 (41.7)	10 (43.5)	19 (54.3)	28 (57.7)	18 (60.0)	91 (42.3)

more rapid indexing and data retrieving, a new checklist is added in the CONSORT-CHM Formulas 2017 to enhance the reporting quality of RCTs of CHM formulas.

Our study had several strengths. First, only trials which conducted randomized and published between 2000 and 2016 were included. We assessed the quality of reporting RCTs with CONSORT statement that first published in 1996 and then updated in 2001 and 2010. Thus, all included herbal medicine trials in our study have been covered by the CONSORT 2010. Second, to evaluate the quality of reporting RCTs was focused on major items instead of all items of CONSORT. Third, this study was the first systematic review that critically assessed the quality of reporting of herbal medicine RCTs conducted in metabolic disorders in Middle East countries. In addition, the present study had some limitations. First, quality of herbal medicine RCTs was not assessed by CONSORT checklist when reporting RCTs of herbal medicines. The reason was raising the drop out the included RCTs in the present study when assessed by CONSORT in herbal interventions that focused on characteristics of herbal extract or components.

5. Conclusion

Our findings indicate that the quality of reporting of herbal medicine RCTs in metabolic disorders has improved over time in Middle East, but remains suboptimal. Despite relative improvement in completeness of herbal and non-herbal RCTs reporting after endorsement of CONSORT by journals, their quality of reporting is suboptimal. It seems other efforts such as education of researchers in focusing on methodological items of CONSORT should be considered to improve the quality of reporting.

Conflict of interests

All authors declare that there is no conflict of interests.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at https://doi.org/10.1016/j.ctim.2018.04.004.

References

1. Mishra BB, Tiwari VK. Natural products: an evolving role in future drug discovery. *Eur J Med Chem.* 2011;46:4769–4807. http://dx.doi.org/10.1016/j.ejmech.2011.07.057.
2. Kelly JP, Kaufman DW, Kelley K, Rosenberg L, Anderson TE, Mitchell AA. Recent trends in use of herbal and other natural products. *Arc Intern Med.* 2005;165:281–286.
3. Hasani-Ranjbar S, Nayebi N, Larijani B, Abdollahi M. A systematic review of the efficacy and safety of herbal medicines used in the treatment of obesity. *World J Gastroenterol.* 2009;15:3073–3085.
4. Hasani-Ranjbar S, Jouyandeh Z, Abdollahi M. A systematic review of antiobesity medicinal plants- an update. *J Diabetes Metab Disord.* 2013;12:28. http://dx.doi.org/10.1186/2251-6581-12-28.
5. Hasani-Ranjbar S, Nayebi N, Moradi L, Mehri A, Larijani B, Abdollahi M. The efficacy and safety of herbal medicines used in the treatment of hyperlipidemia; a systematic review. *Cur Pharm Des.* 2010;16:2935–2947.
6. Salari P, Rezaei A, Larijani B, Abdollahi M. A systematic review of the impact of n-3 fatty acids in bone health and osteoporosis. *Med Sci Monit.* 2008;14:RA37–44.
7. Tabatabaei-Malazy O, Larijani B, Abdollahi M. Targeting metabolic disorders by natural products. *J Diabetes Metab Disord.* 2015;14:57. http://dx.doi.org/10.1186/s40200-015-0184-8.
8. Tabatabaei-Malazy O, Atlasi R, Larijani B, Abdollahi M. Trends in publication on evidence-based antioxidative herbal medicines in management of diabetic nephropathy. *J Diabetes Metab Disord.* 2016;15:1. http://dx.doi.org/10.1186/s40200-016-0221-2.
9. Hasani-Ranjbar S, Zahedi HS, Abdollahi M, Larijani B. Trends in publication of

evidence-based Traditional Iranian medicine in endocrinology and metabolic disorders. *J Diabetes Metab Disord.* 2013;12:49. http://dx.doi.org/10.1186/2251-6581-12-49.
10. Hasani-Ranjbar S, Larijani B. Medicinal plants as potential new target drugs in endocrine disorders-review article. *Iran J Public Health.* 2014;43:24–34.
11. Hasani-Ranjbar S, Larijani B, Abdollahi M. A systematic review of the potential herbal sources of future drugs effective in oxidant-related diseases. *Inflamm Allergy Drug Targets.* 2009;8:2–10.
12. Tabatabaei-Malazy O, Larijani B, Abdollahi M. A novel management of diabetes by means of strong antioxidants' combination. *J Med Hypotheses Ideas.* 2013;7:25–30.
13. Hosseini A, Abdollahi M. It is time to formulate an antioxidant mixture for management of diabetes and its complications: notice for pharmaceutical industries. *Int J Pharmacol.* 2012;8:60–61.
14. Rahimi R, Ghiasi S, Azimi H, Fakhari S, Abdollahi M. A review of the herbal phosphodiesterase inhibitors: future perspective of new drugs. *Cytokine.* 2010;49:123–129.
15. Newman DJ, Cragg GM. Natural products as sources of new drugs over the 30 years from 1981 to 2010. *J Nat Prod.* 2012;75:311–335.
16. Chalmers TC, Smith Jr H, Blackburn B, et al. A method for assessing the quality of a randomized control trial. *Control Clin Trials.* 1981;2:31–49.
17. Odgaard-Jensen J, Vist GE, Timmer A, et al. Randomization to protect against selection bias in healthcatre trials. *Cochrane Database Syst Rev.* 2011. ;4http://dx.doi.org/10.1002/14651858.MR000012.pub3 [MR000012].
18. Howick J, Chalmers I, Glasziou P, et al. Oxford Centre for Evidence-Based Medicine; Explanation of the 2011 Oxford Centre for Evidence-Based Medicine (OCEBM) Levels of Evidence (Background Document) Available in: www.cebm.net/index.aspx?o=5653, Accessed 2014.
19. Wood L, Egger M, Gluud LL, et al. Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. *BMJ.* 2008;336:601–605.
20. Plint AC, Moher D, Morrison A, et al. Does the CONSORT checklist improve the quality of reports of randomised controlled trials? A systematic review. *Med J Aust.* 2006;185:263–267.
21. Cui Q, Tian J, Song X, Yang K. Does the CONSORT checklist for abstracts improve the quality of reports of randomized controlled trials on clinical pathways? *J Eval Clin Pract.* 2014;20:827–833. http://dx.doi.org/10.1111/jep.12200.
22. Turner L, Shamseer L, Altman DG, et al. Consolidation standards of reporting trials (CONSORT) and the completeness of reporting of randomized controlled trials (RCTs) published in medical journals. *Cochrane Database Syst Rev.* 2012:11. http://dx.doi.org/10.1002/14651858.MR000030.pub2 [MR000030].
23. Zhai X, Wang Y, Mu Q, et al. Methodological Reporting Quality of Randomized Controlled Trials in 3 Leading Diabetes Journals From 2011–2013 Following CONSORT Statement: A System Review. *Medicine (Baltimore).* 2015;94(27):e1083. http://dx.doi.org/10.1097/MD.0000000000001083.
24. Nojomi M, Ramezani M, Ghafari-Anvar A. Quality of reports on randomized controlled trials published in Iranian journals: application of the new version of consolidated standards of reporting trials (CONSORT). *Arch Iran Med.* 2013;16:20–22 [013161/AIM.007].
25. He J, Du L, Liu G, et al. Quality assessment of reporting of randomization, allocation concealment, and blinding in traditional Chinese medicine RCTs: a review of 3159 RCTs identified from 260 systematic reviews. *Trials.* 2011;12:122. http://dx.doi.org/10.1186/1745-6215-12-122.
26. Choi J, Jun JH, Kang BK, Kim KH, Lee MS. Endorsement of improving the quality of reports on randomized controlled trials of traditional medicine journals in Korea: a systematic review. *Trials.* 2014;15:429. http://dx.doi.org/10.1186/1745-6215-15-429.
27. List of Middle East Countries by Population. Available in: http://www.en.wikipedia.org/wiki/List_of_Middle_East_countries_by_population, Accessed 23 Agu 2017.
28. Simera I, Moher D, Hoey J, Schulz KF, Altman DG. A catalogue of reporting guidelines for health research. *Eur J Clin Invest.* 2010;40:35–53.
29. GBD 2015 Disease and Injury Incidence and Prevalence Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 310 diseases and injuries, 1990–2015: a systematic analysis for the Global Burden of Disease Study 2015. *Lancet.* 2016;388(10053):1545–1602. http://dx.doi.org/10.1016/S0140-6736(16)31678-6.
30. Larijani B, Majdzadeh R, Delavari A, et al. Iran's health innovation and science development planby 2025. *Iran J Public Health.* 2009;38(Suppl. 1):13–16.
31. Djalalinia S, Peykari N, Qorbani M, Moghaddam SS, Larijani B, Farzadfar F. Obesity researches over the past 24 years: a scientometrics study in Middle East countries. *Int J Prev Med.* 2015;6:38. http://dx.doi.org/10.4103/2008-7802.156835.
32. Massarrat S, Kolahdoozan S. Critical assessment of progress of medical sciences in Iran and Turkey: the way developing countries with limited resources should make effective contributions to the production of science. *Arch Iran Med.* 2011;14(6):370–377 [011146/AIM.003].
33. Biglu MH, Ghavami M, Biglu S. Authorship, institutional and citation metrics for publications on postmenopausal osteoporosis. *Osteoporos Int.* 2014;25(4):1337–1343. http://dx.doi.org/10.1007/s00198-013-2603-3.
34. Brüggmann D, Mäule LS, Klingelhöfer D, et al. World-wide architecture of osteoporosis research: density-equalizing mapping studies and gender analysis. *Climacteric.* 2016;19(5):463–470. http://dx.doi.org/10.1080/13697137.2016.1200548.
35. Kumar KV, Aravinda K. Trends in endocrinology related research articles in a medical journal from India. *Indian J Endocrinol Metab.* 2012;16(6):931–934. http://dx.doi.org/10.4103/2230-8210.102993.
36. Gagnier JJ, DeMelo J, Boon H, Rochon P, Bombardier C. Quality of reporting of randomized controlled trials of herbal medicine interventions. *Am J Med.* 2006;119(9) [800. e1-11].
37. NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in diabetes since 1980: a pooled analysis of 751 population-based studies with 4.4 million participants. *Lancet.* 2016;387(10027):1513–1530. http://dx.doi.org/10.1016/S0140-6736(16)00618-8.
38. Peykari N, Djalalinia S, Kasaeian A, et al. Diabetes research in Middle East countries; a scientometrics study from 1990 to 2012. *J Res Med Sci.* 2015;20(3):253–262.
39. Nasli-Esfahani E, Farzadfar F, Kouhnavard M, et al. Iran diabetes research roadmap (IDRR) study: a preliminary study on diabetes research in the world and Iran. *J Diabetes Metab Disord.* 2017;16:9. http://dx.doi.org/10.1186/s40200-017-0291-9.
40. Ramin S, Gharebaghi R, Heidary F. Scientometric analysis and mapping of scientific articles on diabetic retinopathy. *Med Hypothesis Discov Innov Ophthalmol.* 2015;4(3):81–100.
41. Mirfeizi M, Mehdizadeh Tourzani Z, Mirfeizi SZ, Asghari Jafarabadi M, Rezvani HR, Afzali M. Controlling type 2 diabetes mellitus with herbal medicines: a triple-blind randomized clinical trial of efficacy and safety. *J Diabetes.* 2016;8(5):647–656. http://dx.doi.org/10.1111/1753-0407.12342.
42. Heshmati J, Namazi N, Memarzadeh MR, Taghizadeh M, Kolahdooz F. Nigella sativa oil affects glucose metabolism and lipid concentrations in patients with type 2 diabetes: a randomized, double-blind, placebo-controlled trial. *Food Res Int.* 2015;70:87–93.
43. Tabatabaei-Malazy O, Ramezani A, Atlasi R, Larijani B, Abdollahi M. Scientometric study of academic publications on antioxidative herbal medicines in type 2 diabetes mellitus. *J Diabetes Metab Disord.* 2016;15:48. http://dx.doi.org/10.1186/s40200-016-0273-3.
44. Farzanegi P, Akbari A, Azarbayjani MA. Effect of portulaca oleracea seeds on the levels of matrix metalloproteinase 2, 9 and tissue inhibitor matrix metalloproteinase 1 in patients with type 2 diabetes. *Modares J Med Sci.* 2013;16:65–73.
45. Page MJ, Higgins JP, Clayton G, Sterne JA, Hróbjartsson A, Savović J. Empirical evidence of study design biases in randomized trials: systematic review of meta-Epidemiological studies. *PLoS One.* 2016;11(7):e0159267. http://dx.doi.org/10.1371/journal.pone.0159267.
46. Wang G, Mao B, Xiong ZY, et al. The quality of reporting of randomized controlled trials of traditional Chinese medicine: a survey of 13 randomly selected journals from mainland China. *Clin Ther.* 2007;29(7):1456–1467.
47. Ahmed Ali U, van der Sluis PC, Issa Y, et al. Trends in worldwide volume and methodological quality of surgical randomized controlled trials. *Ann Surg.* 2013;258(2):199–207. http://dx.doi.org/10.1097/SLA.0b013e31829c7795.
48. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. *Syst Rev.* 2012;1:60. http://dx.doi.org/10.1186/2046-4053-1-60.
49. Cheng CW, Wu TX, Shang HC, et al. CONSORT Extension for Chinese Herbal Medicine Formulas 2017: recommendations, explanation, and elaboration (Traditional Chinese Version). *Ann Intern Med.* 2017;167(2):w7–w20 10.7326/IstranslateForm M17-2977 1.