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



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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, Cochrane 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 \pm 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

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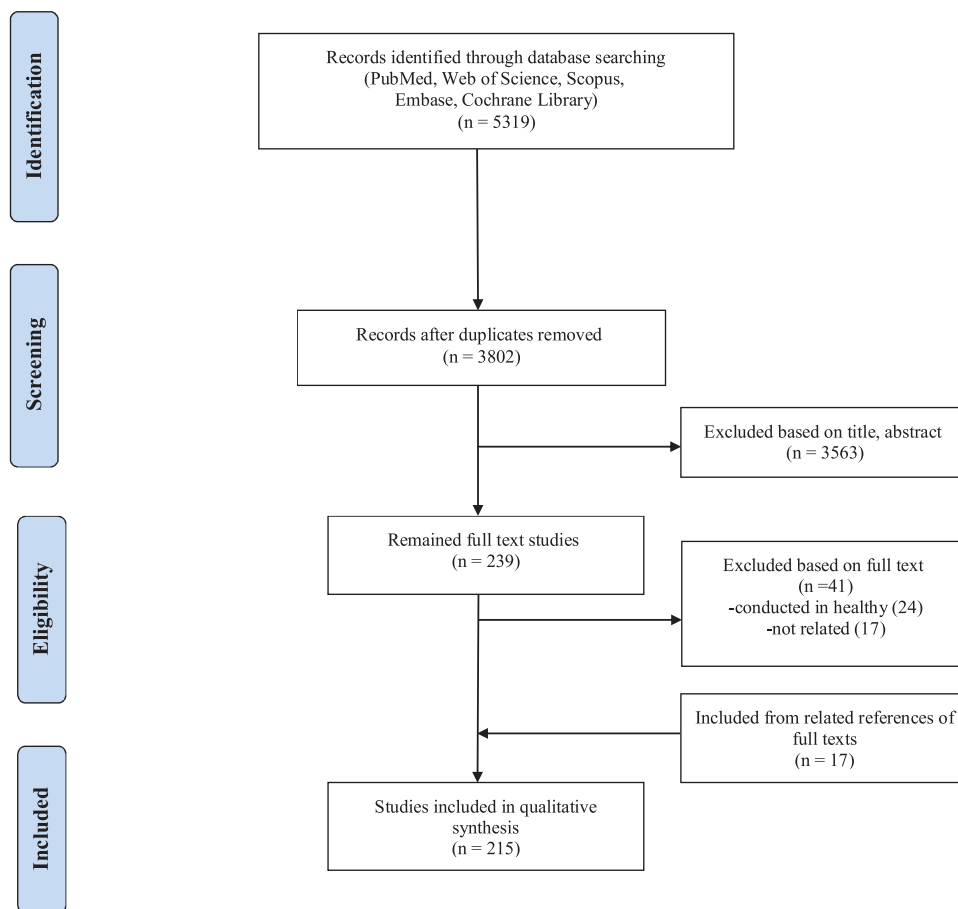


Fig. 1. Flow diagram of the study selection process according to PRISMA checklist.

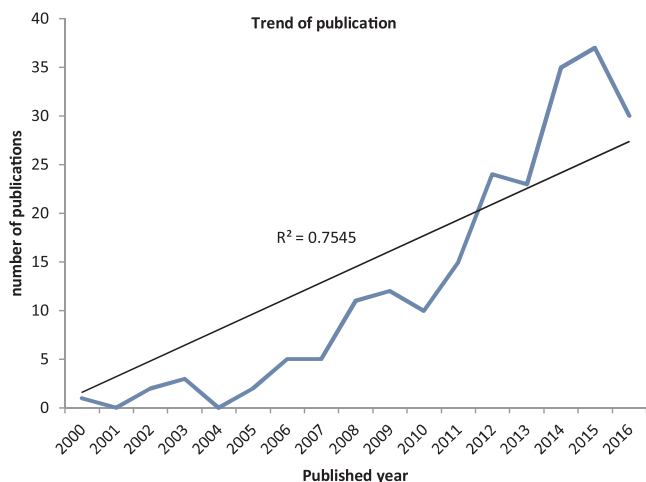


Fig. 2. Trend of publications of RCTs in herbal medicines in Middle East countries over the time.

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

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