



Menopausal Symptoms Management Decision Aid Trails: A Systematic Review and Meta-analysis

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Abstract

Objectives: The present study systematically reviewed the literature on the effects of menopausal symptom management aids on knowledge, decision conflict, and satisfaction about menopause-related symptom management.

Methods: All clinical trial and quasi-experimental studies published in English-language from 1990 to 2021 were searched in CINAHL, PROQUEST, Web of Sciences, Google Scholar, PubMed, and Scopus databases. In addition, we used the Ovid search interface for MEDLINE, Embase, CENTRAL, and Cochrane Library. The effect of interventions on continuous outcomes, including knowledge, decisional conflict, and decisional satisfaction, with a standardized mean difference (SMD), was reported in the present study. The included studies were assessed for statistical heterogeneity by using the I^2 test and examining the P value.

Results: The results indicated the limited effect of the decision aid-based intervention on the decisional conflict, satisfaction with the decision, and knowledge. However, it is worth mentioning that the findings indicated high heterogeneity among the studies reviewed in the present study.

Conclusions: In the previous studies, the decision aid booklets used mostly provided limited and incomplete information on the available strategies to alleviate the symptoms perceived in menopause, so design and conduct a study with a strong, robust methodology and a comprehensive decision aid tool to alleviate the symptoms of menopause and study of its impact on postmenopausal women's decision making is necessary.

Keywords: Menopause, Decision aid, Clinical decision support systems, Knowledge

Introduction

Menopause women sometimes experience symptoms during menopause (1,2) and are mostly forced to look for a strategy to alleviate them (3). Although hormone therapy was the primary treatment method, it is contraindicated for some women and is no longer acceptable to many menopausal women (4,5).

Studies indicated that 50%–80% of middle-aged women seek non-pharmacological and non-hormonal strategies to relieve menopausal symptoms (6,7). Further, the decision about treatment options can be difficult and challenging due to the variations in costs, unknown side effects, and women's lack of knowledge on the valid scientific evidence about their use, for example, the standard dose (8-10). Most women state that they do not have enough knowledge to decide on the use of non-hormonal methods to manage menopausal symptoms (11,12). O'Connor and colleagues in Ottawa developed a decision support framework (13). The aim was to aid patients in making informed decisions based on their satisfaction and values. The decision aids are designed to support patients' participation in decision-making in clinical scenarios (14,15).

There is a lack of scientific evidence about shared

decision-making and using decision aid to choose a way for menopausal symptoms management. Further, a meta-analysis study was not done on the findings of the early studies. The present study systematically reviewed the literature on the effects of menopausal symptom management aids on knowledge, decision conflict, and satisfaction about menopause-related symptom management.

Materials and Methods

Data Source and Search Strategies

In this systematic review, all clinical trial and quasi-experimental studies about the effect of a decision aid on knowledge, decisional conflict, and decisional satisfaction in choosing the menopausal symptoms management method published in English until 2021 were searched from CINAHL, PROQUEST, Web of Sciences, Google Scholar, PubMed, and Scopus databases and we used the Ovid search interface for MEDLINE, Embase, CENTRAL and Cochrane Library.

The effect of interventions on continuous outcomes, including knowledge, decisional conflict, and decisional satisfaction, with a standardized mean difference



Key Messages

- ▶ Decision aids may affect the decisional conflict, satisfaction with the decision, and knowledge about choosing a way to the management of menopause-related symptoms.
- ▶ There is not enough evidence to support or refute that decision aids can improve women's satisfaction and decrease conflict with the decision.
- ▶ Improving women's knowledge and satisfaction about choosing an appropriate way to manage their menopausal symptoms is important as quality markers of care during this period of life.
- ▶ Further randomized controlled trials are needed to study the effect of decision aids on women's satisfaction and conflict of decision.

(SMD), was reported in the present study. In addition, the references of relevant articles were reviewed to find other related articles. The article search strategy was in accordance with the Medical Subject Headings (MeSH) thesaurus.

Inclusion and Exclusion Criteria

The PICO criterion, including participants (menopause women) AND intervention (Decision aid OR Shared decision-making OR Decision support technique) AND comparison group (Control group) AND outcome (Decision conflict OR Decision Satisfaction OR Knowledge), was followed in this study (see Supplementary file 1). The participants in all of these studies were menopausal women, and providing a decision aid booklet with or without counseling was considered as an intervention.

Data Extraction

The collected articles were carefully studied, and two authors separately reviewed the title and abstract of all

searched studies in terms of the inclusion criteria. If there was not enough information in the abstract and title of the studies, the authors reviewed the full text of the articles. Among 3986 articles obtained from searching for various references mentioned, articles with duplicate titles were separated. Further, articles were reviewed based on the title and abstract, as 72 relevant articles were finally identified after a thorough review of the titles, and their full text was reviewed. Eventually, 19 relevant articles were included in the present review study (Figure 1).

Conflict or disagreement was resolved by consensus and consultation with a third review author of the research team. The study-related data, such as time, author, methodology, type of intervention, participants' characteristics, number of randomized participants, and number of dropped participants, were extracted. Table 1 indicates a summary of the data and details of the relevant articles.

Assessment of Risk of Bias in Included Studies

The two authors separately assessed the risk of bias

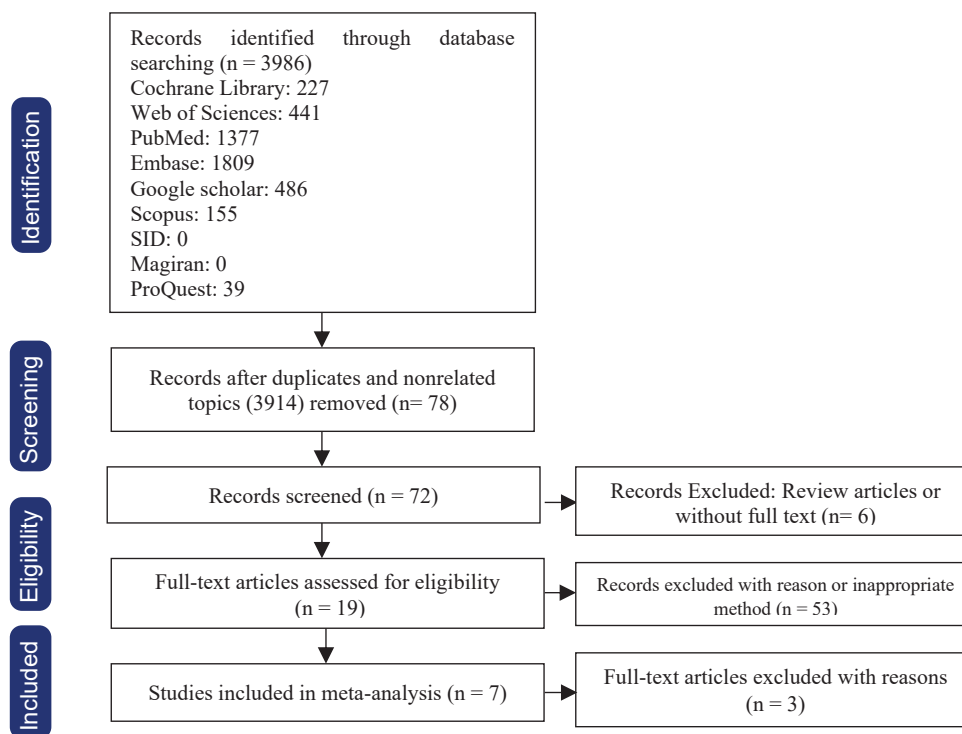


Figure 1. The Study Flowchart to Identify Relevant Literature for the Review.

Table 1. Characteristics of the Trials and Participants in this Systematic Review and Meta-analysis

Author/Country	Type of Study	Interventions	Sample Size (Age)	Outcomes	Conclusion
Rothert/ Michigan (33)	RCT	Three groups- (Brochure, written information, and lecture)	248 (40-60)	DC, satisfaction wh decision	Positive effect
O'Conner et al/ Canada (13)	Before and After study	Supportive audiotape and DA booklet	94 (50-60)	DC/Knowledge	Positive effect
O'Conner et al/ Canada (20)	RCT	DA booklet for intervention group pamphlet for the control group	Intervention group = 81 Control group = 84 (50-69)	DC/Knowledge	Positive effect
O'Conner et al/ Canada (14)	RCT	DA with the images for the intervention group Usual DA without images for the control group	Intervention group = 101 Control group = 100 (50-69)	Knowledge	No significant changes in the short term
Rostom et al/ Canada (32)	RCT	Computer-based DA intervention for the intervention group and booklet with audio for control	Intervention group = 25 Control group = 26 (40-70)	Knowledge and satisfaction	Positive effect
Cranney et al/ Canada (21)	Before and after study	DA intervention based on the Ottawa criteria	18 (45-85)	DC/Knowledge	Positive effect
Murray et al/ London (30)	RCT	Intervention group: DA including a booklet with counseling Control group: Normal clinical care	Intervention group = 103 Control group = 102 (Mean age = 51)	DC Anxiety Menopausal symptoms	The positive effect of an intervention for DC
Bastian et al/ Canada (23)	Before and after study	DA and telephone follow-up one and nine months after the intervention	289 (45-54)	Decisional confidence/ decisional satisfaction	The optimal use of DA affected the decisional confidence. However, some women seemed to need telephone counseling
Colleen et al/ USA(22)	RCT	The study had active and delayed arms. • Active arm provides decision aid at two weeks of initial surveys • Delay arm and DA provision at the end of the study	581 Active arm = 289 Delay arm = 292 (45-54)	Decisional satisfaction/CD Confidence in decision	Positive effect on the decisional confidence and satisfaction
Legare et al/ Canada (28)	RCT	• Intervention group: DA • Control group: pamphlet	Intervention group = 97 Control group= 87 (Mean age = 55.3)	DC Knowledge	DA had a greater impact on the decision-conflict
Fortin et al/ Canada (29)	RCT	• Computer-based DA for the intervention group • Another intervention group of one-on-one consultation • Control group: normal care	DA intervention group = 44 Intervention group of one-on-one consultation = 49 Control group = 50 (48-52)	Change in behavior/ risk perception	Recommended that adding DA in clinical management is not necessary for one-on-one counseling and reduces costs
Michelle et al/ Canada (26)	RCT	Intervention = pharmacist consultation Control = DA	Pharmacist consultation = 49 DA = 56 (48-52)	DS/DC	Pharmacist consultation or decision aid had the same influence the DC and DS
Saver et al/ USA (34)	RCT1 RCT2	• Brochures and web-based decision support intervention • Usual care and web-based DA intervention	Intervention group 1 = 204 Control group 1 = 205 (40-75) Intervention group 2 = 25 Control group 2 = 24 (40-75)	DC/DS/ Knowledge	Web-based decision support was had a positive effect on the knowledge and DS. Also, the unclear effect of DA was reported
Shapira et al/ USA (35)	RCT	• - Intervention group: computer-based DA • - Control group: menopausal physiology training pamphlet	Intervention group = 89 Control group = 88 (45-74)	DC/DS/ Knowledge	A significant difference was reported in the knowledge, decisional satisfaction, and decision conflict in the DA group
Becker et al/ USA (24)	RCT	Intervention group: Ottawa decision support Control: standard training booklet	Intervention group = 86 Control group = 90 (40-65)	DC/DS/ Knowledge	Further studies are recommended among populations of different countries with different characteristics in terms of education
Nananda et al/ Canada (25)	RCT	• Emailing DA for the intervention group 1 • DA along with the trainer for the intervention group 2 • Educational pamphlet control group	Intervention group 1 = 45 Intervention group 2 = 50 Control group = 50 (45-65)	DC/DS/ Knowledge	The decision aid emailed without a trainer had a greater impact on the knowledge, DC, and DS
Legare et al/ Canada (27)	RCT	DA for the intervention group and brochure for the control group	Intervention group = 44 Control group = 41 (45-64)	DC/Knowledge	Further investigation was needed in this regard
Menard et al/ Canada (36)	Pre -Post study	Intervention group: 13-page decision aid with evidence-based content with the introduction of references (sites, books, and scientific articles)	24 (50-64)	DC/Knowledge	DC help to improve knowledge and reduce decisional conflict

RCT: Randomized clinical trial, DA: Decision aid, DS: Decision satisfaction, DC: Decision conflict.

based on the Cochrane booklet for all included studies in terms of the criteria of selection bias, performance bias, assessment bias, and reporting bias. The bias risk of each item for clinical trial studies was classified as “low risk,” “high risk,” and “unclear.” Then, the judgments of the two authors were compared and matched, and in case of any conflict, the third person was consulted, and the result was determined.

Data Analysis

The statistical analysis was done using STATA16 (StataCorp, College Station, Texas, USA). The SMD and 95% confidence interval were estimated as the effect size for the desired outcomes, including decisional conflict, decisional satisfaction, and knowledge. The random-effect model was used to evaluate the heterogeneity of the studies. The included studies were assessed for statistical heterogeneity by using the I^2 test and examining the P value. A P value less than 0.05 and I^2 more than 75% indicate considerable heterogeneity (16,17).

In addition, Egger and Begg's test was used to examine the publication bias (18,19). The effect size, including SMD and 95% confidence interval (CI), was estimated for all three outcomes.

Results

The 19 interventional studies with 2920 samples (menopause women) were included in this meta-analysis. These studies were mainly conducted in Canada, the United States, and the United Kingdom. Among the

articles reviewed, a report was relevant to the article published in the proceeding of an international congress. One of the studies was a pre-post pilot study, and the rest of the articles were a clinical trial. The follow-up period after the intervention varied from two weeks to 12 months. Although all studies were analyzed for bias, several studies were excluded from the meta-analysis due to not report of mean \pm standard deviation (SD) for the outcomes and the impossibility of access via email.

Risk of Bias Assessment

Nine studies were evaluated as good and the rest as poor in terms of quality. The risk of bias assessment was unclear based on the methodological quality assessment among the 19 studies included in the review study.

A meta-analysis of seven studies indicated a significant increase in women's decisional satisfaction and knowledge in the DA-receiving groups [Mean difference: 3.20 (95% CI: -0.55 to 6.95; $I^2 = 99.09\%$) and mean difference: 2.96 (95% CI: -3.82 to 6.95; $I^2 = 77.67\%$)], respectively. Further, the results of the meta-analysis demonstrated a decrease in the decisional conflict in the groups receiving decision aid; however, this decrease was not significant [Mean difference: -0.23 (95% CI: -0.42 to -0.03; $I^2 = 88.95\%$)] (Figures 2-4).

Although visual inspection of the funnel plot suggested a slightly asymmetrical distribution for the studies included in the meta-analysis (Figures 5-7), the results of the Egger and Begg's test did not indicate the evidence of publication bias ($P > 0.05$).

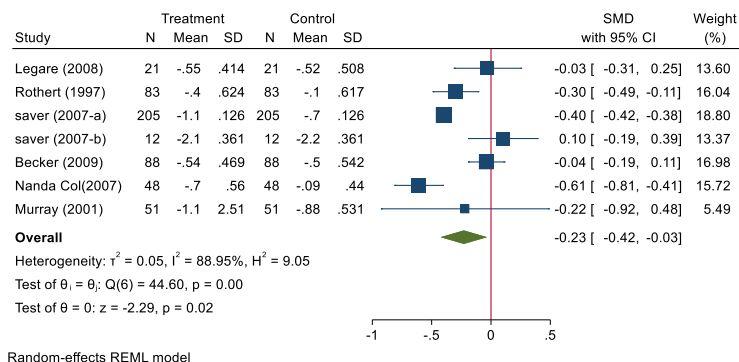


Figure 2. Forest Plot of Individual Standardized Mean Difference of Decision Conflict for Intervention Versus the Control Group.

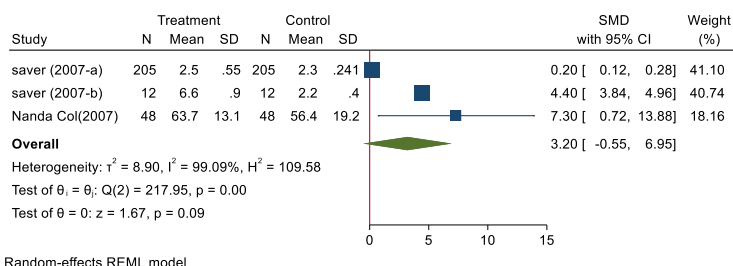


Figure 3. Forest Plot of Individual Standardized Mean Difference of Decision Satisfaction for Intervention versus the Control Group.

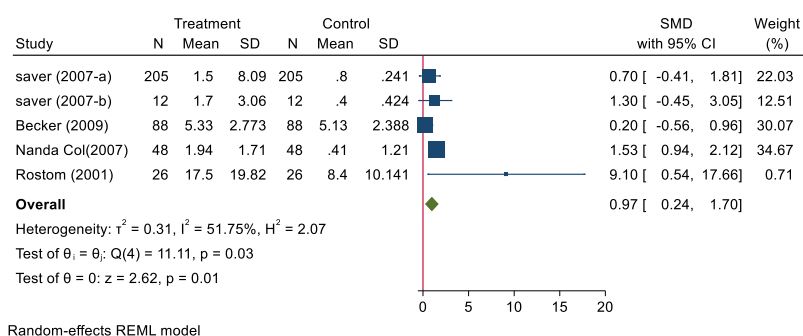


Figure 4. Forest Plot of Individual Standardized Mean Difference of Women's Knowledge for Intervention versus the Control Group.

Discussion

The meta-analysis results in the present study indicated the limited effect of the decision aid intervention on the decisional conflict, decisional satisfaction, and knowledge. However, it is worth mentioning that the meta-analysis findings indicated high heterogeneity among the studies reviewed in the present study. Since not all studies compared the effect of decision aid with routine training in the control group, the heterogeneity in the early studies makes it difficult to achieve a definite result.

In reviewing the studies, the decision aid used was only to decide hormonal replacement and its advantages and disadvantages. Further, the decision aid in the studies was about the herbal products influencing the menopausal symptoms. This type of decision aid was compiled based on scientific evidence and expert opinion (11,13,20-35).

It should be noted that the content of the decision aid booklet could be very influential in the decision-making process of menopausal women. In addition, the conducted studies were criticized, as the content of the booklets did not meet the Ottawa standards and International Patient Decision aid Standards, and sometimes these booklets were researcher-made. As a result, this inconsistency could provide even incorrect or incomplete information

to women. On the other hand, the content of the booklets in the early studies was only about hormone therapy in menopause and its side effects and benefits or about the advantages or disadvantages of natural and herbal products affecting the menopausal symptoms (20,21) (Table 2).

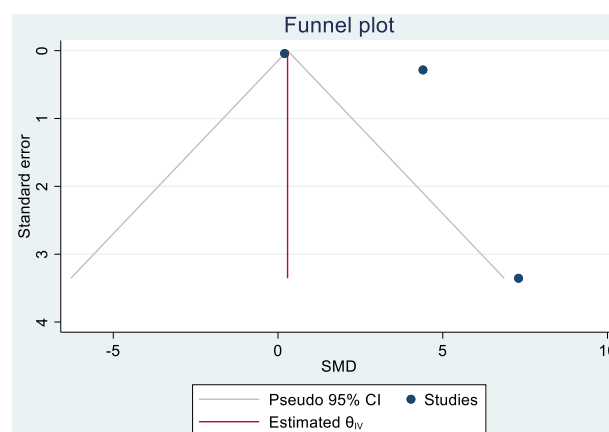


Figure 6. Funnel Plot of Standardized Mean Difference versus the Standard Error for Intervention and Control Groups and After Including the Missing Studies by "Trim and Fill" Method in Decision Satisfaction Outcome

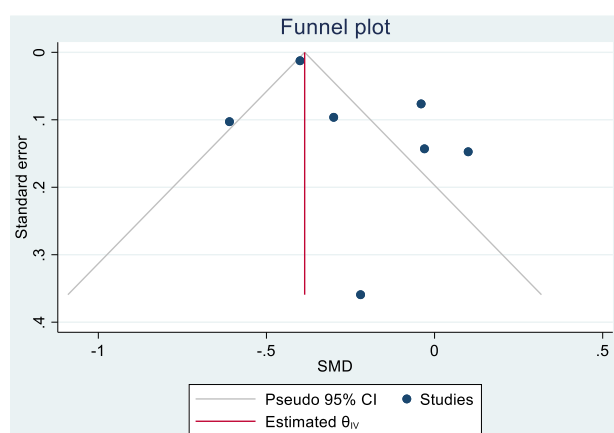


Figure 5. Funnel Plot of Standardized Mean Difference versus the Standard Error for Intervention and Control Groups After Including the Missing Studies by "Trim and Fill" Method in Decision Conflict Outcome.

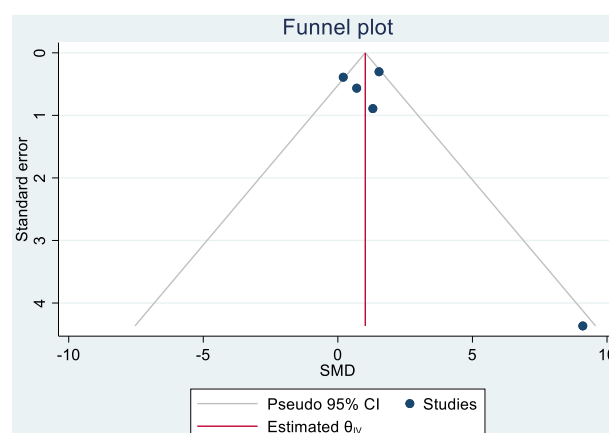


Figure 7. Funnel Plot of Standardized Mean Difference versus the Standard Error for Intervention and Control Groups and After Including the Missing Studies by "Trim and Fill" Method in 'Women's Knowledge Outcome.

Table 2. Quality of Bias Assessment of the Included Studies According to the Cochrane Guidelines

Author (Ref)	Random Sequence Generation	Allocation Concealment	Blinding of Participants and Personnel	Blinding of Outcomes Assessment	Incomplete Outcomes Data	Selective Reporting	Overall Quality
Legare et al (27)	Low risk	High risk	Unclear	Low risk	Low risk	Low risk	High risk
Menard et al (36)	Unclear	Unclear	High risk	High risk	Low risk	Low risk	Low risk
'O'Connor (20)	High risk	High risk	Low risk	High risk	High risk	Low risk	High risk
Rothert et al (33)	Unclear	Unclear	Unclear	Low risk	Low risk	Low risk	Low risk
Saver et al (RCT1) (34)	High risk	High risk	High risk	High risk	Low risk	High risk	Low risk
Saver et al (RCT2) (34)	High risk	High risk	High risk	Low risk	Low risk	Unclear	Unclear
Becker et al (24)	Unclear	Low risk	Unclear	Low risk	Low risk	Unclear	Low risk
Schapiro et al (35)	Low risk	Unclear	Low risk	Unclear	Low risk	Unclear	Low risk
Nananda et al (25)	High risk	High risk	Unclear	Low risk	Low risk	Unclear	Low risk
Colleen et al (22)	High risk	High risk	High risk	Low risk	High risk	Low risk	High risk
Michelle et al (26)	Unclear	Unclear	Unclear	Low risk	Low risk	Low risk	Low risk
Cranney et al (21)	High risk	High risk	High risk	High risk	Low risk	High risk	High risk
Oconner et al (14)	High risk	High risk	High risk	Low risk	Low risk	Unclear	Low risk
Rostom et al (32)	Unclear	Low risk	Unclear	High risk	Low risk	Low risk	Low risk
Murray et al (30)	Low risk	Unclear	High risk	Unclear	Low risk	Unclear	Unclear
Legare et al (28)	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk
Fortin et al (29)	Low risk	High risk	High risk	High risk	High risk	Low risk	High risk
Bastian et al (23)	Low risk	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk

The results of a review of studies conducted in this field indicate that some important details were neglected in the decision aid booklets of the early studies, including the hormone therapy information based on the standard decision aid of the Ottawa site, the information about herbal medicine, and natural products, especially by mentioning the common and popular herbal products in each geographical area to alleviate the menopausal symptoms, and other various strategies, such as cognitive and behavioral interventions and the lifestyle change.

On the other hand, considering the inclusion criteria in studies was one of the most critical issues, which can predict the impact of the decision aid among menopausal women. Since the decision to manage menopausal symptoms is complicated, sometimes even women who have already chosen treatment may think and feel that it is better to change or even stop treatment and do nothing. Therefore, they face a conflict in their decision. Thus, even women who have previously used a method to manage their menopausal symptoms should not be excluded from the study. Further, the tendency to use DA presented to participants seems to be one of the most important predictors of the impact of the decision aid, which can have a significant effect on decision making.

Limitations

One of the limitations of this study was the lack of standard and comprehensive Decision aid used in the previous studies. Another limitation of this study was the high risk of bias in performed studies. Especially due to the methods of studies, blinding of participants and

researchers was not possible. Therefore, for this reason, performance bias was raised in included studies.

Conclusions

Finally, this review indicated that the decision aid to the available strategies to alleviate menopausal symptoms had not been investigated in recent years. Based on the quality assessment of studies and their valuable reported results, the weaknesses of the previous studies were mentioned in this meta-analysis. Accordingly, the new studies should be designed and reviewed with a robust methodology and a comprehensive decision aid booklet.

Authors' Contribution

EM, RN and SH designed the study and conducted the research. EM and ME did the literature search and, together with LMGH, selected the studies. EM, RN checked the quality of the studies. LMGH and MAJ performed the calculations and ME confirmed them. EM, ME, and RN interpreted the data. LMGH wrote the first draft of the paper. All the authors read the draft and provided critical feedback. All authors approved the final draft.

Conflict of Interests

The authors declare that they have no competing interests.

Ethical Issues

This study proposal was approved by the Ethics Committee of the Tabriz University of Medical Sciences, Tabriz, Iran. (Code: IR.TBZMED.REC.1399.244).

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Supplementary files

Supplementary file 1 contains search strategies in various Databases.

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