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

Leyla Mortazavi Ghehi1, Mohammad Asghari Jafarabadi2, Sevil Hakimi1, Roghaiyeh Nourizadeh1, Esmat Mehrabi1,2*, Mehdi Ebrahimpour1

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 I² 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...
(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

<table>
<thead>
<tr>
<th>Author/Country</th>
<th>Type of Study</th>
<th>Interventions</th>
<th>Sample Size (Age)</th>
<th>Outcomes</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rothert/ Michigan (33)</td>
<td>RCT</td>
<td>Three groups - Brochure, written information, and lecture</td>
<td>248 (40-60)</td>
<td>DC, satisfaction with decision</td>
<td>Positive effect</td>
</tr>
<tr>
<td>O’Connor et al/ Canada (13)</td>
<td>Before and After study</td>
<td>Supportive audiotape and DA booklet</td>
<td>94 (50-60)</td>
<td>DC/Knowledge</td>
<td>Positive effect</td>
</tr>
<tr>
<td>O’Connor et al/ Canada (20)</td>
<td>RCT</td>
<td>DA booklet for intervention group pamphlet for the control group</td>
<td>Intervention group = 81 (50-69)</td>
<td>DC/Knowledge</td>
<td>Positive effect</td>
</tr>
<tr>
<td>O’Connor et al/ Canada (14)</td>
<td>RCT</td>
<td>DA with the images for the intervention group</td>
<td>Usual DA without images for the control group</td>
<td>Intervention group = 101 (50-69)</td>
<td>Knowledge</td>
</tr>
<tr>
<td>Rostom et al/ Canada (32)</td>
<td>RCT</td>
<td>Computer-based DA intervention for the intervention group and booklet with audio for control</td>
<td>Intervention group = 25 (40-70)</td>
<td>Knowledge and satisfaction</td>
<td>Positive effect</td>
</tr>
<tr>
<td>Canny et al/ Canada (21)</td>
<td>Before and after study</td>
<td>DA intervention based on the Ottawa criteria</td>
<td>18 (45-85)</td>
<td>DC/Knowledge</td>
<td>Positive effect</td>
</tr>
<tr>
<td>Murray et al/ London (30)</td>
<td>RCT</td>
<td>Intervention group: DA including a booklet with counseling</td>
<td>Intervention group = 103 (Mean age = 51)</td>
<td>DC Anxiety Menopausal symptoms</td>
<td>The positive effect of intervention for DC</td>
</tr>
<tr>
<td>Bastian et al/ Canada (23)</td>
<td>Before and after study</td>
<td>DA and telephone follow-up one and nine months after the intervention</td>
<td>289 (45-54)</td>
<td>Decisional confidence/delusional satisfaction</td>
<td>The optimal use of DA affected the decisional confidence. However, some women seemed to need telephone counseling</td>
</tr>
<tr>
<td>Colleen et al/ USA(22)</td>
<td>RCT</td>
<td>The study had active and delayed arms:</td>
<td>581</td>
<td>Decisional confidence/decisional satisfaction</td>
<td>Positive effect on the decisional confidence and satisfaction</td>
</tr>
<tr>
<td>Legare et al/ Canada (28)</td>
<td>RCT</td>
<td>Intervention group: DA</td>
<td>Intervention group = 97 (Mean age = 55.3)</td>
<td>DC Knowledge</td>
<td>DA had a greater impact on the decision-conflict</td>
</tr>
<tr>
<td>Fortin et al/ Canada (29)</td>
<td>RCT</td>
<td>Computer-based DA for the intervention group</td>
<td>DA intervention group = 44 (40-75)</td>
<td>Change in behavior/ risk perception</td>
<td>Recommended that adding DA in clinical management is not necessary for one-on-one counseling and reduces costs</td>
</tr>
<tr>
<td>Michelle et al/ Canada (26)</td>
<td>RCT</td>
<td>Intervention = pharmacist consultation</td>
<td>Pharmacist consultation = 49 (48-52)</td>
<td>DS/DC</td>
<td>Pharmacist consultation or decision aid had the same influence the DC and DS</td>
</tr>
<tr>
<td>Save et al/ USA (34)</td>
<td>RCT1</td>
<td>Brochures and web-based decision support intervention</td>
<td>Intervention group 1 = 204 (40-75)</td>
<td>DC/DS’ Knowledge</td>
<td>Web-based decision support was had a positive effect on the knowledge and DS. Also, the unclear effect of DA was reported</td>
</tr>
<tr>
<td>Shapiro et al/ USA (35)</td>
<td>RCT</td>
<td>Intervention group: computer-based DA</td>
<td>Intervention group = 89 (45-74)</td>
<td>DC/DS’ Knowledge</td>
<td>A significant difference was reported in the knowledge, decisional satisfaction, and decision conflict in the DA group</td>
</tr>
<tr>
<td>Becker et al/ USA (24)</td>
<td>RCT</td>
<td>Intervention group: Ottawa decision support Control: standard training booklet</td>
<td>Intervention group = 86 (40-65)</td>
<td>DC/DS’ Knowledge</td>
<td>Further studies are recommended among populations of different countries with different characteristics in terms of education</td>
</tr>
<tr>
<td>Nananda et al/ Canada (25)</td>
<td>RCT</td>
<td>Emailing DA for the intervention group 1</td>
<td>Intervention group 1 = 45 (45-65)</td>
<td>DC/DS’ Knowledge</td>
<td>The decision aid emailed without a trainer had a greater impact on the knowledge, DC, and DS</td>
</tr>
<tr>
<td>Legare et al/ Canada (27)</td>
<td>RCT</td>
<td>DA for the intervention group and brochure for the control group</td>
<td>Intervention group = 44 (45-64)</td>
<td>DC/Knowledge</td>
<td>Further investigation was needed in this regard</td>
</tr>
<tr>
<td>Menard et al/ Canada (31)</td>
<td>Pre-Post study</td>
<td>Intervention group: 13-page decision aid with evidence-based content with the introduction of references (sites, books, and scientific articles)</td>
<td>24 (50-64)</td>
<td>DC/Knowledge</td>
<td>DC help to improve knowledge and reduce decisional conflict</td>
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</table>

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 I² test and examining the P value. A P value less than 0.05 and I² 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 ± 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; I² = 99.09%) and mean difference: 2.96 (95% CI: -3.82 to 6.95; I² = 77.67%)]. 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; I² = 88.95%)].

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).
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).
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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<th>Author (Ref)</th>
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Supplementary files
Supplementary file 1 contains search strategies in various Databases.

References


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