

# The Effectiveness of Midwife-Led Interventions to Address Post-Partum Post-Traumatic Stress Disorder: Critical Appraisal of Clinical Trials

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## ABSTRACT

**Background & Objective:** Clinical trials are studies that can provide the most reliable evidence to investigate the impact of various interventions in health research. Due to the importance of these studies in producing valid scientific evidence, this study was conducted to critically evaluate the published clinical trials regarding the effectiveness of midwife-led interventions on preventing post-traumatic stress disorder after childbirth.

**Materials & Methods:** In this critical appraisal, we searched for published randomized clinical trials articles related to midwife-led interventions in preventing post-traumatic stress disorders in reputable databases using the keywords "traumatic childbirth", "post-traumatic stress disorder", "intervention", "counseling", "midwife", "clinical trial" and their equivalent in Persian, without time limit. Out of 18581 retrieved articles, 12 articles were evaluated using CONSORT-2018. This checklist consisted of 26 sections and 42 items. Each item was scored based on the reported in the article under review. The tool scores ranged from zero to 42. Data were analyzed using SPSS 21.

**Results:** The overall compliance of the quality of the reviewed articles with the checklist criteria was estimated at 60.1%. The mean overall quality was 25.1±3.6 and therefore the articles were of moderate quality. The title and abstract sections, background, goals, and interpretation of the results were of high quality, whereas the discussion section and other information were of low quality. Half of the articles did not report the type of randomization, method of generating allocation sequence and allocation concealment.

**Conclusion:** In order to use the results of clinical trials in evidence-based care related to the effectiveness of midwifery-led interventions on reducing post-traumatic stress disorder, improving the quality of articles is essential, and using a standard checklist should be on the agenda of authors and reviewers of journals.

**Keywords:** CONSORT, Critical appraisal, Post-traumatic stress disorder, Traumatic childbirth,



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## Introduction

Science is the continuous and systematic accumulation of information that leads to the knowledge about facts, and discovering laws governing phenomena. Science aims to describe, explain, predict phenomena and finally control them, and knowledge management includes three stages of knowledge production, dissemination, and exploitation, and until the produced knowledge is not published, evaluated, and criticized, it cannot be relied on or have it exploited scientifically, instrumentally or strategically (1). To achieve this, it is important to pay attention to the quality of conducted researches as well as their quantitative growth, because

low-quality research is a major obstacle to effective access to existing knowledge (2).

Therefore, translation and knowledge exchange is a long-term goal for researchers to be effective in developing the existing body of knowledge (3). Therefore, the only way to improve the standards of clinical care and design a comprehensive and beneficial medical science program is to improve the conducted research, which is not possible except by looking critically at previous articles and pondering their quality (4).

One of the valuable studies in the field of knowledge translation in medical sciences is clinical trial studies

that examine the effectiveness of three themes of knowledge translation, information exchange, and strategies, and adherence to evidence-based sciences, and play an important role in health policy and planning (5). But looking at the multiplicity of these studies in a large number of journals, we conclude that these articles are not accurate enough in design, writing, and implementation and therefore will cause errors. If the design and methodology of the clinical trial are inappropriate and the results are unrealistically magnified, the productivity of the results will lead to treatment failure and medical errors (5, 6). Therefore, along with the Consolidated Standards of Reporting Trials (CONSORT) statement, increasing the quality of studies that lead to research validation requires clarification of the results and compilation of a complete report of the available findings, which facilitates interpretation of the results and saves service providers from confusion in clinical decisions (7, 8).

One of the most important areas in reproductive health and obstetrics is childbirth where the need for evidence-based care is indispensable. Birth of a baby is an important and sensitive event in mothers' lives and ensuring the physical and mental health in mothers and babies is one of the most important goals of service providers (9), so that maternal health is considered as an indicator of development in all countries (10). Childbirth is a natural and physiological event but if a person perceives it as stressful and does not have coping techniques to deal with the stressor, she will face post-traumatic stress (11-13). Childbirth becomes a negative memory and a complex incident leading to psychological disorders (14). Postpartum trauma is an anxiety disorder which is accompanied by symptoms such as recalling of the incident, sleep problems, panic attacks, unwanted thoughts, and avoidance symptoms (15, 16), and may lead to problems such as depression, drugs and alcohol abuse, breastfeeding, communication, and attachment issues with the baby, avoiding sex, requesting unnecessary cesarean section, avoiding medical care such as cervical cancer screening and future Pap smears (17). Its prevalence is reported 4% in the general population and 18.5% in high-risk pregnancies in the postpartum stage in a systematic review and meta-analysis study conducted by Yildiz *et al.* in 2017 reviewing 59 studies (18). The prevalence of traumatic childbirth in Iran is 48.3% (19) and the rate of post-traumatic stress disorder is up to 39% (20). Therefore, prevention and treatment are crucial. Pilot studies that have dealt with post-traumatic stress prevention methods and interventions have reported different results that need to be investigated in terms of accuracy so that they can be used in maternal care (24-21).

To achieve this goal, the CONSORT standard checklist is used to correctly report clinical studies. This checklist consists of 26 items in which the following topics are included: how to write the title, summary, introduction, materials and methods, results, discussion;

how to record the study, how to access the study protocol, and the source of funding. The CONSORT statement also includes a flow diagram that looks at how participants have been accessed during the study (25).

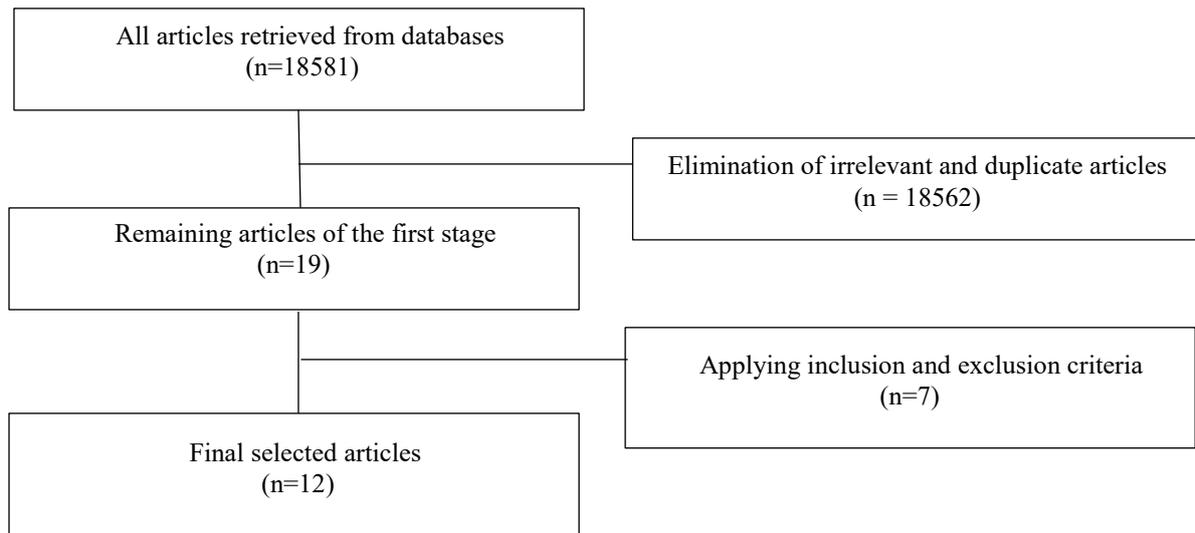
Clinical trials on the effectiveness of midwife-led interventions to follow-up of post-traumatic stress disorders after childbirth have not been critically evaluated so far. Hence due to the importance of maternal mental health and in order to guide healthcare providers to prevent post-traumatic stress disorders after childbirth, the present study was conducted to critically analyze related published articles using the CONSORT assessment tool.

## Materials and Methods

This descriptive critical appraisal of the literature was performed to appraise the quality of published clinical trials on the effect of midwife-led interventions on reducing post-traumatic stress disorder after delivery. To achieve this goal, articles in this regard were searched in reputable databases including Web of Science, PubMed, Scopus, Google Scholar, SID, PsycINFO, Embase, and Clinical Key using the keywords "traumatic delivery", "post-traumatic stress disorder", "Intervention", "counseling", "midwife", and "clinical trial" without a time limit until September 2019. Our inclusion criteria were: dependent variable of post-traumatic stress disorder, post-traumatic stress after childbirth, the midwife-led intervention, and intervention to prevent or treat post-traumatic stress disorder, also the type of study should have been an experimental and human clinical trial. Exclusion criteria included studies other than clinical trials, review studies, letters to the editor, articles presented at the conferences, Also, studies focused on other variables such as depression and anxiety, and studies in which intervention by someone other than midwives such as psychologists and nurses.

The total number of articles retrieved from databases were: ISI=39, PubMed=137, Google Scholar=17900, SID=5, Scopus=38, PsycINFO=25, Embase=256, and Clinical Key=181, which were a total of 18581 articles. Duplicate and overlapping articles in the database were removed at the first stage, so eventually, 19 articles remained and by considering the inclusion and exclusion criteria, 12 articles were critically appraised. The article search flowchart is shown in [Figure 1](#). The articles were evaluated by three Reproductive Health Ph.D. students under the supervision of Professor in Reproductive Health.

Consort 2018 checklist was used to check the quality of the articles. This tool is the latest edition of the Consortium Checklist used in clinical trial studies with social and counseling (non-pharmacological) context (26).



**Figure 1.** Flowchart of article search

This checklist contains 26 items to evaluate six main sections of clinical trial studies. These six sections include title and abstract, introduction, materials and methods, results, discussion, and other information. The title and the abstract section include one item in two parts A and B with a minimum and maximum score of zero to two, the introduction includes an item in two parts A and B with a minimum and maximum score of zero to two, materials and methods include 19 items in two parts A and B with minimum and maximum score zero to 19, results in the section includes 10 items considering divisions A and B with minimum and maximum score zero to 10, discussion section includes 3 items with minimum and maximum score zero up to three and other information section includes 6 items considering divisions A and B with a minimum and maximum score of 0 to 6 points.

Each article gets a score of one if it provides the item requested in the checklist, and a score of zero if it does not mention it, which brings the sum of the total scores between zero (lowest score) and 42 (highest score) (26). Ethical issues such as non-plagiarism, removing duplicate articles, and refusal to make data were considered. Data were analyzed using SPSS 21 (SPSS Inc., Chicago, IL., USA) through descriptive statistics (frequency and percentage, mean, and standard deviation).

## Results

In our study, 12 articles on the effectiveness of midwife-led interventions on the prevention of postpartum post-traumatic stress disorder were critically analyzed. The scores obtained in all items of the CONSORT\_2018 checklist are shown by category (questions and articles, title and abstract, introduction, materials and methods, results, discussion, and other information) in [Tables 1](#) and [2](#). All the studies that have

been performed on this subject were during the last twenty years, which if are divided into two equal parts, 7 cases were published between the years 1998-2007 and 5 cases between the years 2011-2017. The language of the articles was English in 11 cases and Persian in 1.

In this checklist, a score of one means reporting the checklist items, and a score of zero means not mentioning the item by the authors of the article. The total score is between zero and 42. In this study, overall, 303 (60.1%) items received score one and 201 (39.8%) items received score zero. In other words, the overall compliance of the quality of the reviewed articles with the checklist criteria was estimated at 60.1%.

The average obtained, based on the checklist was  $25.1 \pm 3.6$ . None of the authors fully complied with all the items in the checklist, and the range of obtained scores were 20-32. In general, in each section of the checklist, the items reported in the title and abstract section were 79.1%, introduction 95.8%, materials and methods 68.4%, results 67.5%, discussion 47.2%, and other information 9.7%. This indicates that the highest quality in the articles of this field is related to the introduction and the lowest quality to the other information section.

Taking a closer look at the various sections reported in the articles based on the CONSORT checklist, as shown in [Table 1](#), indicates that different parts that have been reported in the articles are as follows: the title and abstract sections 79.1%, background and objectives 95.8%, trial design 50%, interventions 94.4%, outcomes 50%, sample size determination 62.5%, randomization 50%, concealment 41.7%, blindness 91.6%, statistical methods 41.6%, disease detection 58%, risks 8.3%, limitations 41.7%, trial registration 16.7%, financing 16.7%, generalizability 0%, and interpretation 100%, and finally stakeholder participation in 16.7%.

**Table 1.** Quality of published clinical trial reports on the effect of midwife-led interventions on prevention of post-traumatic stress disorder after delivery using the CONSORT tool

Title	Number	Checklist items 2018	reported	Not reported
<b>Title and Abstract</b>	1-A	Identification as a randomized trial in the title	7(58.3)	5 (41.7)
	1-B	Structured summary of trial design, methods, results, and conclusions	12(100)	0(0)
<b>Background and Objectives</b>	2-A	Scientific background and explanation of rationale	12(100)	0(0)
	2-B	Specific objectives or hypotheses	11(91.7)	1(8.3)
<b>Trial design</b>	3-A	Description of trial design (such as parallel, factorial), including allocation ratio	12(100)	0(0)
	3-B	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	0(0)	12(100)
<b>participants</b>	4-A	Eligibility criteria for participants	12(100)	0(0)
	4-B	Settings and locations where the data were collected		
<b>Interventions</b>	5-A	The amount of interventions, performed exactly as planned by the participants and the researcher	12(100)	0(0)
	5-B	Is more information available about the intervention in question	11(91.7)	1(8.3)
	5-C	If feasible, how intervention providers were selected for each group	11(91.7)	1(8.3)
<b>consequences</b>	6-A	Completely defined pre-specified outcomes, including how and when they were assessed	12(100)	0(0)
	6-B	Any changes to trial outcomes after the trial commenced, with reasons	0(0)	12(100)
<b>Sample size</b>	7-A	How the sample size is specified	6(50)	6(50)
	7-B	If applicable, explain any intermediate analysis and cessation instructions	9(75)	3(25)
<b>Randomization</b>	8-A	The method used to generate a random allocation sequence	6(50)	6(50)
	8-B	Type of randomization; details of any restriction (such as blocking and block size	6(50)	6(50)
<b>concealment</b>	9	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence until interventions were assigned	5 (41.7)	7(58.3)
<b>implementation</b>	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10(83.3)	2(16.7)

Title	Number	Checklist items 2018	reported	Not reported
<b>Blindness</b>	11-A	Who was aware of intervention assignment after allocation (for example, participants, providers, those assessing outcomes), and how any masking was done	12(100)	0(0)
	11-B	If relevant, description of the similarity of interventions	11(91.7)	1(8.3)
<b>statistical method</b>	12-A	How missing data were handled, with details of any imputation method	2(16.7)	10(83.3)
	12-B	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and process evaluations	8(66.7)	4(33.3)
<b>The flow of participants</b>	13-A	For each group, the numbers randomly assigned, receiving the intended intervention, and analyzed for the outcomes	11(91.7)	1(8.3)
	13-B	For each group, losses and exclusions after randomization, together with reasons	11(91.7)	1(8.3)
<b>Patient selection</b>	14-A	Dates defining the periods of recruitment and follow-up	12(100)	0(0)
	14-B	Why the trial is over or stopped	2(16.7)	10(83.3)
<b>Basic Information</b>	15	A table that shows the demographic information and clinical characteristics of each group	12(100)	0(0)
<b>People analyzed</b>	16	In each group, the number of participants (denominator of the deduction) who entered each analysis and whether the analysis was based on the main assigned groups	12(100)	0(0)
<b>Consequences and estimates</b>	17-A	For each outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	12(100)	0(0)
	17-B	For binary outcomes, it is recommended to provide both absolute and relative effect sizes	0(0)	12(100)
<b>Sub-analyses</b>	18	Results of any other analyses performed, including subgroup analyses, adjusted analyses, and process evaluations, distinguishing pre-specified from exploratory	8(66.7)	4(33.3)
<b>Risks/hazards</b>	19	All-important harms or unintended effects in each group (for specific guidance see CONSORT for Harms)	1(8.3)	11(91.7)
<b>Limitations</b>	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	5 (41.7)	7(58.3)
<b>Generalizability</b>	21	Generalizability (external validity, applicability) of the trial findings	0(0)	12(100)
<b>Interpretation</b>	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12(100)	0(0)
<b>registration</b>	23	Registration number and name of the test registration place	2(16.7)	10(83.3)
<b>protocol</b>	24	Where the full trial protocol can be accessed, if available	2(16.7)	10(83.3)
<b>Financing</b>	25	Sources of funding and other support; role of funders	2(16.7)	10(83.3)

Title	Number	Checklist items 2018	reported	Not reported
Stakeholder participation	26-A	Any involvement of the intervention developer in the design, conduct, analysis, or reporting of the trial	0(0)	12(100)
	26-B	Other stakeholder involvement in trial design, conduct, or analyses	0(0)	12(100)
	26-C	Incentives offered as part of the trial	0(0)	12(100)

**Table 2.** Scores obtained from each article based on the CONSORT-2018 checklist

Reference number	Author's Name	print year	Title and Abstract	Introduction	method	Result	discussion	Other information	Total score						
(21)	Abdollahpour	2016	2	2	13	7	1	2	27						
(24)	Taghizadeh	2007	1	2	13	7	1	0	24						
(35)	Meades	2011	1	2	11	5	2	0	21						
(22)	Gamble	2005	2	2	17	8	2	0	31						
(36)	Gozde Gokco	2016	2	2	12	6	2	1	25						
(37)	Kershaw	2005	2	2	11	6	1	0	22						
(38)	Navidian	2017	1	2	13	6	1	1	24						
(39)	Ryding	1998	1	2	10	6	1	0	20						
(40)	Selkrik	2006	1	1	15	7	2	1	27						
(41)	Nieminen	2016	2	2	16	8	2	2	32						
(42)	Ryding	2004	2	2	13	8	1	0	26						
(43)	Priest	2003	2	2	12	7	1	0	24						
Total questions		24	24	228	120	36	72	504							
(1) reported	(0) Not reported	1	0	1	0	1	0	1	0						
quantity		19	5	23	1	156	72	81	39	17	19	7	65	303	201
percentage		79.1	20.8	95.8	4.1	68.4	31.5	67.5	32.5	47.2	52.7	9.7	90.3	60.1	39.8

**Table 3.** Mean and standard deviation of scores obtained from different parts of the CONSORT checklist

Area	Minimum and maximum tool score	Minimum and maximum score obtained	Score (average± standard deviation)
Title and Abstract	0-2	1-2	1.5±0.52
Introduction	0-2	1-2	1.9±0.28
method	0-19	10-17	13±2

Area	Minimum and maximum tool score	Minimum and maximum score obtained	Score (average± standard deviation)
Result	0-10	5-8	6.7±0.96
Discussion	0-3	1-2	1.4±0.51
Other information	0-6	0-2	0.5±0.79
Total score	0-42	20-32	25.1±3.6

## Discussion

This study aimed to critically evaluate the published clinical trials related to the effect of midwife-led interventions on the prevention of post-traumatic stress disorder, based on the CONSORT-2018 checklist. So far, no study has ever critically reviewed clinical trials on Post-traumatic stress disorder. This fact made it difficult for us to compare the results of the present study with other ones, which is considered as a limitation. Because the concept of "childbirth trauma" has been emerged very recently, it has been a twenty years gap between the first clinical trial and the one after, and the limited number of articles complicates the matter.

Based on our database search, the clinical trials conducted to reduce post-traumatic stress were only 19, which were finally reduced to 12 due to our inclusion criteria to focus on midwife-led studies. These articles were retrieved based on an extensive search conducted in reputable databases, nevertheless, the number of the related articles was low and the duration of publication on this topic was short.

In a study by Melnyk *et al.*, it was reported that critical evaluation of clinical trial studies is an essential skill for obtaining evidence-based documentation to quickly help service providers about the reliability of the practice (27). Considering the fact that mean overall quality of reviewed articles was 25.1±3.6, out of the minimum and maximum score of 20-37, it is of average quality. The compliance rate of the reviewed articles with the checklist criteria was 60.1%. In the present study, the CONSORT 2018 checklist was used, which has minor changes compared to the 2010 version; including question 26, which has three items and is related to stakeholder participation. According to the latest article published in the list of studies included in the present study, in 2017, this item was not included in the new checklist and therefore has not been reviewed. Therefore, by removing the last question of the checklist, the compliance rate of articles increased from 60.1% to 64.8%. A closer look at the present article reveals that the most frequent issues in most of the studies are not reporting the type of randomization, sample size determination, method of generating allocation consequence and mechanism of allocation concealment, concealment, handling of missing data, generalizability, clinical trial registration, absolute and relative effect size, and the way of access to the complete protocol. But sections such as the abstract, statement of purpose and

background, blinding, the flow of participants and description of interventions were reported completely in almost all the articles.

In the present study, the statement of introduction and research background in 95.8% of cases was well defined. Also, the desired intervention was well mentioned in 94.4% of the articles. However, significant changes in implementation method after starting the trial was not mentioned in any of the studies. This issue was mentioned zero in an Iranian study by Moradi *et al.* (29) and 4.2% in a study by Sarayloo *et al.* (30) which is compatible with the present study.

In the present study, type of randomization and allocation concealment were mentioned in half of the articles and the method of creating the allocation sequence and the randomization type were not explained, which was consistent with the article by Moradi *et al.* This is important because the existence of selection bias in clinical trial studies is a detrimental factor in accuracy of results, which can only be avoided by using randomization and correct concealment (31). Since in the present study, the midwife played the leading role in the implementation of interventions, all articles had mentioned it well. Also, in terms of blindness, since the interventions were done by counseling, blindness was almost impossible. The articles received 91.6% of the score from this section, which was in line with a study by Taghipour *et al.* (32) on evaluating trials in the Journal of Dentistry. In the study by Moradi *et al.* (28), which targets all clinical trials, this rate was 20.8%, and 15% in a study by Irani *et al.* (29), and the reason for its inconsistency is probably the type of intervention performed. Also, in a study by Ayatollahi *et al.*, the weakness of clinical trials was in line with the present study in determining the sample size and the method of randomization and blinding (33). In the present study, only 41.7% of the cases mentioned the limitations of the study and none of the articles mentioned generalizability. However, the expression of limitations is very important because they are factors that hinder information collection and obtaining desired results.

Only 16.7% of the articles had a trial registration number which is consistent with a study by Jokar *et al.* (34), in which only 20% of the articles were registered. This is important because research centers, due to the availability of searchable clinical trial data, are able to

make the necessary decisions in support of new clinical trials, and be aware of similar published studies or ongoing efforts.

In the present study, in all the articles, the interpretation of the results had been done well which is consistent with the study by Irani *et al.* (29) and Sarayloo *et al.* (30). One of the limitations of this study was the limited number of studies that have designed interventions to reduce post-traumatic stress after delivery. This is important considering that in half of the deliveries, traumatic delivery leads to the post-traumatic stress disorder (19). The strength of this study is that the search and critical appraisal of articles were done by reproductive health experts who are fully oriented about the details of this issue.

## Conclusion

Since evidence-based care derived from clinical trials promotes the ability and skill to use reproducible, non-biased knowledge, it plays an important role in improving the quality of services provided to women. The results of this study showed that the quality of the clinical trial reports on the effectiveness of midwife-led interventions in the prevention of post-traumatic stress disorder after childbirth is moderate.

Therefore, it is emphasized that authors and reviewers use the CONSORT tool so that the results of relevant research can be generalized to clinical settings, help to make findings more practical, eliminate shortcomings and improve the quality of articles. Using continuous training and spreading the concept of "traumatic delivery" to midwives is recommended so that the results of these studies in maternity wards can be evidently used in practice.

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## Conflict of Interest

Authors declared no conflict of interests.

## References

1. Reynolds S. Evidence-based practice: a critical appraisal. John Wiley & Sons; 2008.
2. Altman DG. Poor-quality medical research: what can journals do? *Jama*. 2002;287(21):2765-7. [DOI:10.1001/jama.287.21.2765] [PMID]
3. Armstrong R, Waters E, Roberts H, Oliver S, Popay J. The role and theoretical evolution of knowledge translation and exchange in public health. *J Public Health*. 2006;28(4):384-9. [DOI:10.1093/pubmed/fdl072] [PMID]
4. Zeng X, Zhang Y, Kwong JS, Zhang C, Li S, Sun F, et al. The methodological quality assessment tools for preclinical and clinical studies, systematic review and meta-analysis, and clinical practice guideline: a systematic review. *Evid Based Med*. 2015;8(1):2-10. [DOI:10.1111/jebm.12141] [PMID]
5. Dobbins M, Hanna SE, Ciliska D, Manske S, Cameron R, Mercer SL, et al. A randomized controlled trial evaluating the impact of knowledge translation and exchange strategies. *Implement Sci*. 2009;4(1):61. [DOI:10.1186/1748-5908-4-61] [PMID] [PMCID]
6. He J, Du L, Liu G, Fu J, He X, Yu J, 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(1):122. [DOI:10.1186/1745-6215-12-122] [PMID] [PMCID]
7. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel group randomized trials. *BMC Med Res Methodol*. 2001;1(1):2. [DOI:10.1186/1471-2288-1-2] [PMID] [PMCID]
8. Pandis N, Chung B, Scherer RW, Elbourne D, Altman DG. CONSORT 2010 statement: extension checklist for reporting within person randomised trials. *Bmj*. 2017;357:j2835. [DOI:10.1136/bmj.j2835] [PMID] [PMCID]
9. Mannava P, Durrant K, Fisher J, Chersich M, Luchters S. Attitudes and behaviours of maternal health care providers in interactions with clients: a systematic review. *Glob Health*. 2015;11(1):36. [DOI:10.1186/s12992-015-0117-9] [PMID] [PMCID]
10. Thomas TN, Gausman J, Lattof SR, Wegner MN, Kearns AD, Langer A. Improved maternal health since the ICPD: 20 years of progress. *Contraception*. 2014;90(6):S32-S8. [DOI:10.1016/j.contraception.2014.06.026] [PMID]
11. Ballard C, Stanley A, Brockington I. Post-traumatic stress disorder (PTSD) after childbirth. *Br J Psychiatry*. 1995;166(4):525-8. [DOI:10.1192/bjp.166.4.525] [PMID]
12. Boorman RJ, Devilly GJ, Gamble J, Creedy DK, Fenwick J. Childbirth and criteria for traumatic events. *Midwifery*. 2014;30(2):255-61. [DOI:10.1016/j.midw.2013.03.001] [PMID]
13. Wijma K, Söderquist J, Wijma B. Posttraumatic stress disorder after childbirth: a cross sectional study. *J Anxiety Disord*. 1997;11(6):587-97. [DOI:10.1016/S0887-6185(97)00041-8]

14. Allen S. A qualitative analysis of the process, mediating variables and impact of traumatic childbirth. *J Reprod Infant Psychol.* 1998;16(2-3):107-31. [[DOI:10.1080/02646839808404563](https://doi.org/10.1080/02646839808404563)]
15. Association AP. *PsycINFO: American Psychological Association*; 2000.
16. Horowitz M, Wilner N, Alvarez W. Impact of Event Scale: a measure of subjective stress. *Psychosom Med.* 1979;41(3):209-18. [[DOI:10.1097/00006842-197905000-00004](https://doi.org/10.1097/00006842-197905000-00004)] [PMID]
17. www.birthtraumaassociation.org.uk. Post Natal post-Traumatic Stress Disorder.
18. Yildiz PD, Ayers S, Phillips L. The prevalence of posttraumatic stress disorder in pregnancy and after birth: a systematic review and meta-analysis. *J Affect Disord.* 2017;208:634-45. [[DOI:10.1016/j.jad.2016.10.009](https://doi.org/10.1016/j.jad.2016.10.009)] [PMID]
19. Abdollahpour S, Mousavi SA, Motaghi Z, Keramat A, Khosravi A. Prevalence and risk factors for developing traumatic childbirth in Iran. *Am J Public Health.* 2017;25(3):275-80. [[DOI:10.1007/s10389-016-0783-y](https://doi.org/10.1007/s10389-016-0783-y)]
20. Vizeh M, Kazemnejaz A, Afrasiabi S, Rouyhi M, Hassan M, Habibzadeh S. Prevalence of post-traumatic stress disorder after childbirth and its precipitating factors. *Bimonthly Journal of Hormozgan University of Medical Sciences.* 2012;16(4):309-16.
21. Abdollahpour S, Khosravi A, Bolbolhaghghi N. The effect of the magical hour on post-traumatic stress disorder (PTSD) in traumatic childbirth: a clinical trial. *J Reprod Infant Psychol.* 2016;34(4):403-12. [[DOI:10.1080/02646838.2016.1185773](https://doi.org/10.1080/02646838.2016.1185773)]
22. Gamble J, Creedy D, Moyle W, Webster J, McAllister M, Dickson P. Effectiveness of a counseling intervention after a traumatic childbirth: a randomized controlled trial. *Birth.* 2005;32(1):11-9. [[DOI:10.1111/j.0730-7659.2005.00340.x](https://doi.org/10.1111/j.0730-7659.2005.00340.x)] [PMID]
23. Ryding EL, Wijma K, Wijma B. Postpartum counselling after an emergency cesarean. *Clin Psychol Psychother.* 1998;5(4):231-7. [https://doi.org/10.1002/\(SICI\)1099-0879\(199812\)5:4<231::AID-CPPI172>3.0.CO;2-9](https://doi.org/10.1002/(SICI)1099-0879(199812)5:4<231::AID-CPPI172>3.0.CO;2-9) [[DOI:10.1002/\(SICI\)1099-0879\(199812\)5:43.0.CO;2-9](https://doi.org/10.1002/(SICI)1099-0879(199812)5:43.0.CO;2-9)]
24. Taghizadeh Z JM, Arbabi M, Faghizadeh S. The effect of counseling on post-traumatic stress disorder after a traumatic childbirth. *Hayat.* 2007;13(4):23-31.
25. Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P. CONSORT statement for randomized trials of nonpharmacologic treatments: a 2017 update and a CONSORT extension for nonpharmacologic trial abstracts. *Ann Intern Med.* 2017;167(1):40-7. [[DOI:10.7326/M17-0046](https://doi.org/10.7326/M17-0046)] [PMID]
26. Montgomery P, Grant S, Mayo-Wilson E, Macdonald G, Michie S, Hopewell S, et al. Reporting randomised trials of social and psychological interventions: the CONSORT-SPI 2018 Extension. *Trials.* 2018;19(1):407. [[DOI:10.1186/s13063-018-2733-1](https://doi.org/10.1186/s13063-018-2733-1)] [PMID] [PMCID]
27. Melnyk BM, Fineout-Overholt E. Rapid critical appraisal of randomized controlled trials (RCTs): an essential skill for evidence-based practice (EBP). *Pediatr Nurs.* 2005;31(1):50.
28. Moradi MT A-SM, Mobasheri M. Evaluating the quality of materials and methods for writings of final proposal in clinical trial studies in Shahrekord University of Medical Sciences based on consort checklist. *J Clin Nurs Midwifery.* 2013;2(4):1-7.
29. Irani M, Maleki N, Latifnejad Roudsari R. Assessing the Quality of randomized controlled trials published in relation to the Efficacy of Massage Therapy on Labor Pain Intensity Using CONSORT criteria. *Iran J Obstet, Gynecol Infertil.* 2017;20(supplement):56-67.
30. Sarayloo K, Latifnejad Roudsari R. Critical Evaluation of the Published Clinical Trials Regarding the Effect of Complementary Medicine on Menopausal Symptoms. *Iran J Obstet, Gynecol Infertil.* 2018;21(4):87-98.
31. Mohammady M JL. Randomization in randomized clinical trials: From theory to practice. *Hayat, Journal of School of Nursing and Midwifery, Tehran University of Medical Sciences.* 2016;22(2):102-14(Persian)
32. Taghipour A, Shakeri MT, Yousefi R, Barzanouni S. Assessment of Randomized Controlled Clinical Trials articles in the Journal of Dental School, Mashhad University of Medical Sciences: Published 2003-2015. *J Mashhad Dent Sch.* 2017;41(1):11-20.
33. Ayat-Elahi SMT JP, GHaem H. An evaluation of the quality of published clinical trials in Iranian medical journals during 2001-2004. *J Babol Univ Med Sci* 2005;7(4):64-70.
34. Joukar F HA, Asgharnejhad M, Soltanipour S, Jalali MM, Moradi M. Evaluation of clinical trial abstracts of scientific journal using the CONSORT checklist. *J Guilan Univ Med Sci.* 2015;24(95):40-51.
35. Meades R, Pond C, Ayers S, Warren F. Postnatal debriefing: have we thrown the baby out with the bath water? *Behavior Research and Therapy.* 2011;49(5):367-72. [[DOI:10.1016/j.brat.2011.03.002](https://doi.org/10.1016/j.brat.2011.03.002)] [PMID]
36. İsbir GG, İnci F, Önal H, Yıldız PD. The effects of antenatal education on fear of childbirth, maternal self-efficacy and post-traumatic stress disorder (PTSD) symptoms following childbirth: an experimental study. *Appl Nurs Res.* 2016;32:227-32. [[DOI:10.1016/j.apnr.2016.07.013](https://doi.org/10.1016/j.apnr.2016.07.013)] [PMID]
37. Kershaw K, Jolly J, Bhabra K, Ford J. Randomised controlled trial of community debriefing following operative delivery. *BJOG: An Int J Gynaecol Obstet.* 2005;112(11):1504-9. [[DOI:10.1111/j.1471-0528.2005.00723.x](https://doi.org/10.1111/j.1471-0528.2005.00723.x)] [PMID]
38. Navidian A, Saravani Z, Shakiba M. Impact of Psychological Grief Counseling on the Severity of Post-Traumatic Stress Symptoms in Mothers after Stillbirths. *Issues in mental health nursing.* 2017;38(8):650-4. [[DOI:10.1080/01612840.2017.1315623](https://doi.org/10.1080/01612840.2017.1315623)] [PMID]
39. Ryding EL, Wijma K, Wijma B. Postpartum counselling after an emergency cesarean. *Clinical Psychology & Psychotherapy: Int J Soc Res Methodol.* 1998;5(4):231-7. [https://doi.org/10.1002/\(SICI\)1099-0879\(199812\)5:4<231::AID-CPPI172>3.0.CO;2-9](https://doi.org/10.1002/(SICI)1099-0879(199812)5:4<231::AID-CPPI172>3.0.CO;2-9) [[DOI:10.1002/\(SICI\)1099-0879\(199812\)5:43.0.CO;2-9](https://doi.org/10.1002/(SICI)1099-0879(199812)5:43.0.CO;2-9)]
40. Selkirk R, McLaren S, Ollerenshaw A, McLachlan AJ, Moten J. The longitudinal effects of midwife-led postnatal debriefing on the psychological health of

- mothers. *J Reprod Infant Psychol.* 2006;24(02):133-47. [DOI:10.1080/02646830600643916]
41. Nieminen K, Berg I, Frankenstein K, Viita L, Larsson K, Persson U, et al. Internet-provided cognitive behaviour therapy of posttraumatic stress symptoms following childbirth-a randomized controlled trial. *Cogn Behav Ther.* 2016;45(4):287-306. [DOI:10.1080/16506073.2016.1169626] [PMID]
42. Ryding EL, Wirén E, Johansson G, Ceder B, Dahlström AM. Group counseling for mothers after emergency cesarean section: a randomized controlled trial of intervention. *Birth.* 2004;31(4):247-53. [DOI:10.1111/j.0730-7659.2004.00316.x] [PMID]
43. Priest SR, Henderson J, Evans SF, Hagan R. Stress debriefing after childbirth: a randomised controlled trial. *Med J Aust.* 2003;178(11):542-5. [DOI:10.5694/j.1326-5377.2003.tb05355.x] [PMID]

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