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Critical Appraisal of the Published Randomized Controlled Trials That Examined the Effect of Counseling-Educational Interventions On Exclusive Breastfeeding

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ABSTRACT

Background & aim: Due to the significance of randomized controlled trials (RCTs) in evidence-based care, it is essential to evaluate the quality of reporting of published RCTs in order to apply the results of trials in the field of breastfeeding counseling and training.

Methods: In this critical review, the related articles were identified via searching in the English databases including Scopus, PubMed, Cochrane Library, and Google Scholar as well as Persian databases of SID, Magiran and IranDoc, using the relevant keywords. All the articles published from 2010 until 2021 were retrieved. Data collection tools included demographic questionnaire and CONSORT checklist. The quality of clinical trials was evaluated by two assessors using CONSORT 2010. The scoring range was 0-44.

Results: A total of 17 articles were critically appraised. The overall compliance rate of the articles with the items in the CONSORT checklist was 49.2%. The greatest weakness in reporting was observed in the title and abstract (1.00± 0.35). The mean total score of quality of reporting was 18.35±3.33, with the minimum and maximum scores of 12 and 25, respectively.

Conclusion: The appraised articles had an average quality. It is necessary that RCTs be conducted and reported in accordance with standard principles and be thoroughly reviewed critically with relevant checklists including CONSORT. Training of researchers can help to improve the quality of clinical trial reporting.

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Introduction

Providing evidence-based health services requires sufficient knowledge to improve medical science and health; randomized trial studies provide valuable information (1).

Numerous Randomized Clinical trials (RCTs) are considered to be the 'gold standard' of evidence-based clinical practice. RCTs have validity for determining the efficacy of new interventions (2). RCTs are often the preferred trial design to evaluate the effectiveness and complications of therapeutic interventions (3). However, various biases may emerge during the designing, implementation, and reporting the stages of these studies (4, 5). In addition, evidence offers that the quality of the published RCTs in medical journals is suboptimal (6, 7). On the other hand, the acceptable reporting quality of RCTs is essential to decision-making of journal reviewers, expert advice and clinical application, and unbiased meta-analysis as an interpretation of evidence. Therefore, to progress the clarity and transparency of RCT reports and recognize the importance of such clarity in reporting of these studies, an international group of epidemiologists, statisticians, and editors developed the Integrated Standards Checklist for Consolidated Standards of Reporting Trials (CONSORT) for

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RCT reporting in 1996 (8), which was revised in 2010 and 2017. The purpose of CONSORT is to provide a guide for authors to improve the reporting of their trials. CONSORT checklist is a summary of all the essentials that must be reported in an RCT (9, 10).

Evidence shows that despite compiling a consort checklist, adherence to trials guidelines was not sufficient, and even the surveys reported poor adherence to a consort designed for non-pharmacological treatments (11). Chen et al. (2010) which evaluated the quality of abstracts in randomized controlled clinical trial in Chinese medical journals concluded that the quality of abstracts in randomized controlled trial trials needed to be improved (12). The results of the study by Tabatabai et al. (2018) showed that although the reporting quality of clinical trials related to herbal remedies has improved over time in the Middle East, it remains less than desirable (13). The study by Schulz et al. (1994) also indicated that clinical trials in the field of gynecology and obstetrics do not have a good reporting quality (14).

Breastfeeding is a key priority in public health all over the world. Breastfeeding is undoubtedly the excellent route of supplying favorable nutrition for infants. Breast milk is a convened biological fluid and the optimal nutrition for neonates, which provide the most beneficial nutritional balance in terms of quality and quantity (15-17).

According to the literature, the decreased rate and early discontinuation of breastfeeding could adversely affect maternal, neonatal, social health, thereby impose additional costs on healthcare systems. According to the World Health Organization (WHO), United Nations Children's Fund (UNICEF), and the American Academy of Pediatrics, exclusive breastfeeding is recommended as the most favorable manner of feeding for newborns during the first six months of life, and it should be continued until two years old (18-20). Despite that various health organizations have emphasized on the exclusive breastfeeding until six months for neonates, the rate of exclusive breastfeeding is unfavorable in many countries; for instance, the rate of exclusive breastfeeding in Iran has been estimated as 25%. The declining rate of breastfeeding is currently considered to be a main public health concern (21-25).

Given the importance of breastfeeding and its impact on the growth and development of infants, the promotion of breastfeeding has recently gained special attention worldwide with increasing human knowledge and growing body of research. Today, several approaches are available for the promotion of breastfeeding; one of the most effective approaches is to provide counseling-supportive services and breastfeeding training (26, 27). It has been suggested that family-centered training and support (especially prenatal support) could promote exclusive breastfeeding (28). In the study by Gholami Tabar et al. (2011), they reported that providing prenatal training, support system, and counseling before and after childbirth could enhance breast milk consumption in the infants (29). Similarly, other studies have indicated that properly training of pregnant women encourages breastfeeding and prolongs exclusive breastfeeding (30, 31).

Numerous RCTs have demonstrated the effectiveness of breastfeeding counseling and training in promotion and improvement of exclusive breastfeeding. Since the use of evidence-based care is critical in clinical interventions and breastfeeding care, and given the importance of RCT papers in evidence-based care, it is essential to appraise the quality of published studies in order to apply the results of RCTs in breastfeeding counseling and training. The present study was performed aimed to critically appraise the reporting randomized controlled trials which examined the effect of counseling-educational interventions on exclusive breastfeeding.

Materials and Methods

This critical review study was performed in 2021 to evaluate the quality of the RCT reports in Iran, and evaluate the effect of counseling-educational interventions on exclusive breastfeeding, which have been published in reputable databases.

Related articles were identified via searching in the English databases including Scopus, PubMed, Cochrane and Google Scholar as well as Persian databases of SID, Magiran, IranDoc, using the keywords in title and abstract such as

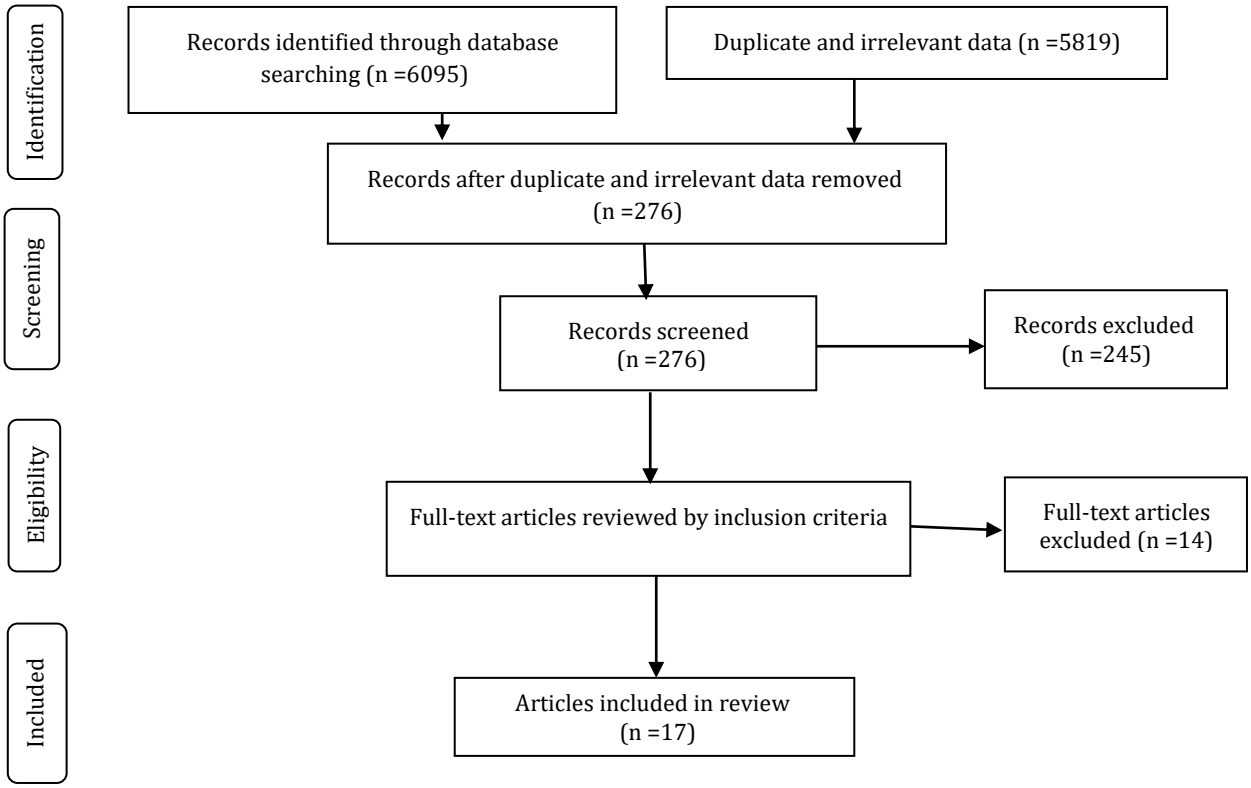
(Breastfeeding OR Breast Feeding OR Lactation OR Human Milk) AND (Counseling OR education OR Training Programs) AND (Exclusive Breast Feeding OR Exclusive Breastfeeding OR breastfeeding exclusivity OR Breastfeeding Status) AND (Randomized Controlled Trials OR Randomized Clinical Trials OR clinical trial OR RCT) and their Persian equivalents with Boolean OR and AND operators. All the published articles were retrieved until the outset of the search phase. The search and selection processes of the trials were shown using the PRISMA flowchart (Figure 1).

The data extracted from the studies included in this study were presented in Table 1.

The inclusion criteria were all the RCTs published in Iran which examined the effect of counseling-educational interventions on exclusive breastfeeding. The exclusion criteria were letters to editor, conferences papers, and dissertations. All the articles were assessed by two independent reviewers, and the extracted data were recorded in the relevant forms. It is notable that in case of difference between the reviewers, the subject was re-examined with consensus in the presence of one observer.

Data collection forms included demographic information (journal name, year of publication, language, number of authors, specialty, and first author's degree and academic rank) and CONSORT checklist 2010.

Figure 1. The PRISMA flowchart of the study's selection process



The CONSORT checklist is a commonly used important assessment tool in clinical trial articles, which consists of 25 items and six main sections of clinical trial studies (Title and Abstract, Introduction, Methods, Results, Discussion and other information), each one consists of various subsets (9). In the scoring of checklist, each item is assigned one point if it is mentioned in the checklist and zero point if it is not.

The total scores assigned to the reported items are considered as the total quality score of the article, the minimum and maximum scores for each article is determined as 0 and 37, respectively.

Data were analyzed by SPSS (version 16) using descriptive statistics (Mean ± SD and Number (Percent)).

Results

In the initial search, 6095 articles were obtained. After removal of duplicate and irrelevant articles, 31 full-text articles were retrieved to assess eligibility and ultimately, 17 articles were criticized. The mean total score of quality was 18.35±3.33, with the minimum and maximum scores of 12 and 25, respectively. None of the published randomized clinical trials which examined the effect of counseling-educational interventions on exclusive breastfeeding reported all the sub-items listed in the CONSORT checklist.

According to the information presented in Table 1, among 17 published clinical trials, only one study (5.9%) was listed under the heading of 'randomized trial', while in 16 articles (94.1%), the item was not observed relied on the CONSORT checklist. However, 16 articles mentioned the use of randomization method. In the Method section, the sample size calculation was not reported in 12 articles (70.6%), the method of random allocation sequences was not reported in 11 articles (64.7%), and the type of randomization was not reported in 14 articles (82.4%). In the Results section, 9 studies (52.9%) provided no data on the number of lost samples and those excluded after randomization in each group. Table 2 showed the scores of each article divided by the six sections of the CONSORT tool. Table 3 showed the frequency distribution of the reported cases of the CONSORT items in the published clinical trials about the impact of counseling-training interventions on exclusive breastfeeding, as well as the mean, minimum, and maximum scores of the six sections CONSORT checklist (Title and abstract, Introduction, Methods, Results, Discussion, Other information).

Discussion

This study was performed aimed to critical appraise the reporting randomized controlled trials which examined the effect of counseling-educational interventions on exclusive breastfeeding based on the CONSORT checklist 2010. The overall compliance rate of the articles with the items in the CONSORT checklist was 49.2%. According to the findings, no studies were found based on international checklists to review the RCT reports on breastfeeding. Therefore, the researchers compared the results of the present study with the past findings regarding the critique of the clinical trials in midwifery. The appraised articles in the study by Sharifi et al (2021) had an average quality and the overall quality compliance rate with the CONSORT checklist which was estimated about 50% (49). Considering that Sharifi's study used the 2010 Consort, which has more details than the previous versions, the report presented on the desired quality of the articles can be promising. In the study conducted by Irani et al. (2017), the RCTs which examined the effects of massage on the severity of labor pain were assessed, and the compliance rate of the reviewed studies was estimated as 54% (50). In the studies performed by Sarayloo et al. (2018) and Bahri et al (2016), which reviewed the articles published on menopause, poor quality of the RCT reports has been reported (51, 52). Moreover, Talachi et al. (2012) confirmed the poor quality of RCT reports (53), Goenka et al. (2019) reported the overall compliance of the RCT articles in Indian medical journals is 54%, which was extremely poor (54).

In the assessment of the RCTs published in 2013 in JAMA and BMJ journals, Susvirkar et al (2018) reported a wide range for the percentage of the total score (PTS) of the articles (59.4-97.1%), showing the poor compliance rate of the articles (55). Based on the aforementioned studies, it could be concluded that the quality of the clinical trial reports based on CONSORT checklist is not favorable, which could be due t

Table 1. Frequency distribution of reported CONSOR items in the Published Clinical Trials on the effect Counseling-educational interventions on exclusive breastfeeding

Section/Topic	Item No	Checklist item	Reported	Not reported
Title and abstract				
	1a	Identification as a randomised trial in the title	1 (5.9)	16 (94.1)
	1b	Structured summary of trial design, methods, results, and conclusions	16 (94.1)	1 (5.9)
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	17 (100)	0 (0)
	2b	Specific objectives or hypotheses	15 (88.2)	2 (11.8)
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	12 (70.6)	5 (29.4)
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	0 (0)	17 (100)
Participants	4a	Eligibility criteria for participants	17 (100)	0 (0)
	4b	Settings and locations where the data were collected	17 (100)	0 (0)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	11 (64.7)	6 (35.3)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	15 (88.2)	2 (11.8)
	6b	Any changes to trial outcomes after the trial commenced, with reasons	0 (0)	17 (100)
Sample size	7a	How sample size was determined	5 (29.4)	12 (70.6)
	7b	When applicable, explanation of any interim analyses and stopping guidelines	0 (0)	17 (100)
Randomisation				
Sequence generation	8a	Method used to generate the random allocation sequence	6 (35.3)	11(64.7)
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	3 (17.6)	14 (82.4)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	0 (0)	17 (100)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2 (11.8)	15 (88.2)
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	3 (17.6)	14 (82.4)
	11b	If relevant, description of the similarity of interventions	8 (47.1)	9 (52.9)
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	17 (100)	0 (0)
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	3 (17.6)	14 (82.4)
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	10 (58.8)	7 (41.2)
	13b	For each group, losses and exclusions after randomisation, together with reasons	8 (47.1)	9 (52.9)
Recruitment	14a	Dates defining the periods of recruitment and follow-up	17 (100)	0 (0)

Section/Topic	Item No	Checklist item	Reported	Not reported
	14b	Why the trial ended or was stopped	0 (0)	17 (100)
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13 (76.5)	4 (23.5)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	16 (94.1)	1 (5.9)
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	16 (94.1)	1 (5.9)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	0 (0)	17 (100)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	3 (17.6)	14 (82.4)
Harms	19	All-important harms or unintended effects in each group	0 (0)	17 (100)
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	4 (23.5)	13(76.5)
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	14 (82.4)	3 (17.6)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	17 (100)	0 (0)
Other information				
Registration	23	Registration number and name of trial registry	8 (47.1)	9 (52.9)
Protocol	24	Where the full trial protocol can be accessed, if available	7 (41.2)	10 (58.8)
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	11 (64.7)	6 (35.3)

the inadequate knowledge of researchers regarding the methodology of clinical trials and their negligence to comply with CONSORT checklist in article writing. However, since the authors had access to the latest version of the Consort tool at the time of their study, they had to use it to report their findings. In addition, lack of emphasis of journal guidelines on the need to use the CONSORT items in writing reports may be the other cause of poor quality of RCT reports.

According to the current research, the lowest compliance rate in the published RCT reports regarding the effect of counseling-training interventions on exclusive breastfeeding belonged to the sections of Methodology (39.4%) and Results (48.82%). In the Methodology section, the compliance rate was zero in sub-items 3b, 6b, 7b, and 9. In fact, none of the assessed articles provided reports on the possible changes in the methodology and subsequent trial outcomes after the intervention. In the study by Wandalkar et al. (2019), they claimed that the difference between registered clinical trials and the final published articles in journals has a high effects coefficient, which necessitates the implementation of the CONSORT guidelines and presenting the reports on all the changes in the implementation or outcomes for all the authors and editors after starting trial (58). Furthermore, Susvirkar et al (2019) reported the compliance rate of the mentioned sub-items to be 2.1% (55). Zero compliance could be justified by two reasons; first, there are no differences between the reviewed articles in terms of methodology and trial outcomes after the initiation of the trial, second, lack of compliance could be due to the non-commitment of the authors to reporting changes.

In the Method and Randomization sections, the reporting rate of sub-items 8a and 8b was 35.3% and 17.6%, respectively, which was considered to be low. In addition, none of the assessed articles described sub-item nine, and their compliance rate was determined to be zero. Failure to apply the randomization

principle or inaccurate description of the randomization report could definitely lead to bias and method distortion in RCT studies. In the study by Irani et al (2017), none of the reviewed articles referred to the subjects of randomization method and random allocation method (50). In the research performed by Samaan et al (2013), the reporting rate of randomization methods was estimated as 5-9% (59), while it was reported to be 23% in the study by Goenka et al (2019) (54). In addition, in the study by Sarayloo et al (2019), the randomization rate with its details was reported to be approximately 46.55% (52). Gupta et al (2022) in a critical review of trial studies that published in Indian journals demonstrated that some items in method statement were underreported including allocation concealment method and analysis of the data based on the Intention-to-treat (ITT) (11).

Table 2. Scores earned per study for each of the six sections of CONSORT checklist

Authors (year)	Title and abstract	Introduction	Methods	Results	Discussion	Other information	Total score/ percent
Shariat et al (2018)	1	2	8	4	2	3	20 (54%)
Amiri et al (2017)	2	2	5	6	2	2	19 (51%)
Kohan& Heidari (2017)	1	2	7	4	2	1	17(45/ 9%)
Heidari et al (2016)	1	2	5	3	2	2	15(40/ 5%)
Parsa et al (2016)	1	1	6	5	2	3	18(48/ 6%)
Moudi et al (2016)	1	2	9	7	3	3	25(67/ 6%)
Kohan et al (2016)	1	2	9	5	3	2	22(67/ 6%)
Masoumi et al (2015)	1	2	10	5	2	3	23(62/ 16%)
Akaberian et al (2015)	1	2	7	7	1	1	19(51%)
Abdeyazdan et al (2015)	1	2	8	7	1	0	19(51%)
Mohammadi Zeidi et al (2015)	1	2	7	5	2	0	17(45/ 9%)
Sakkaky & Khairkhah (2013)	1	2	5	5	2	1	16(43/ 24%)
Keramat et al (2013)	1	2	6	4	2	1	16(43/ 24%)
Raisi Dehkordi et al (2012)	1	1	9	5	2	3	21(56/ 75%)
Golamitabar tabari et al (2011)	2	2	6	4	2	1	17(45/ 9%)
Tork Zahrani et al (2011)	1	1	7	5	2	0	16(43/ 24%)
Shrifirad et al (2011)	1	1	5	3	2	0	12(32/ 43%)

According to the aforementioned studies, it could be inferred that many RCT authors are overlooking the importance of randomization, implementation, and accurate reporting of the

research process, and even over time the accuracy of randomization reporting remains dissatisfactory due to the availability of tools such as CONSORT.

Table 3. mean score and minimum and maximum scores for each of the 6 sections CONSORT checklist

section	minimum and maximum scores	minimum and maximum scores for studies	mean score
Title and abstract	0-2	0-2	1.00± 0.35
Introduction	0-2	1-2	1.88±0.33
Methods	0-17	5-10	7.00±1.62
Results	0-10	3-7	4.88±1.16
Discussion	0-3	1-3	2.05±0.42
Other information	0-3	0-3	1.52±1.17
Total	0-37	12-25	18.35±3.33

Randomization is a highly precise technique in RCT studies, and it is not sufficient to only refer to the word 'randomization' in the Method section; therefore, authors must also refer to the details of the randomization process (51). The other sub-items of the Method section (7a, 10, 11, and 12b) also had poor compliance. Among the 17 sub-items of the Method section in the current research, only six cases (35.3%) had higher compliance rates than 60%.

In the Results section, the report on sub-items 14b and 17b was determined to be zero, and none of the authors referred to these sub-items in their articles. Therefore, it could be inferred that none of the researchers faced with the potential problem of the untimely completion or termination of the study. In RCT studies, it is essential to provide an abstract of the statistical results in each study group and describe the difference between the groups, which is familiar as the effect size. As mentioned earlier, none of the studies provided data on the relative and absolute effect sizes. Susvirkar et al. (2019) has also stated that the effect size report is only 19% (55). Failure to report the relative and absolute effect sizes may be due to the inability to use the statisticians' views. Therefore, it is recommended that clinical science experts apply the views of statisticians and methodology of experts to design and conduct RCT studies.

In the present study, none of the assessed articles referred to the 'all important harms' or 'unintended effects' in each of the study groups in the Conclusion section, and the reporting rate was determined to be zero. This may be due to the nature of interventions in the areas of counseling and training (as opposed to the interventions such as procedures or drugs' prescription), as well as the fact that the researchers of the evaluated studies have not considered the potential risks of counseling and training interventions. The second reason is that the participants were exposed to any risks after the intervention.

Susvirkar et al., (2019) reported the harms of approximately 70% in their study (55). In the research by Joukar et al., (2015), adverse and important events of the intervention was only 6.8% (57). In addition to the recognition of the benefits of interventions, the articles' readers need to be aware of its possible risks. As such, the authors must accurately refer to the potential risks during the study, as well as the number of the participants that have been excluded due to complications (56). Moreover, describing the risks of interventions prevents the misinterpretation and misleading of the readers of the study's findings (57).

In the discussion section of the present study, only the 'limitations' sub-item had a low reporting rate (23.5%), which is considered to be poor compared to the study by Susvirkar et al., (2019) which reporting rate was 97.9% (55). Some journals designate specific structures for authors in the discussion section, and 'limitations of the study' is a component of such structures; this component must be mentioned by authors, along with methods to be used for the reduction of risks or their compensation.

The reporting rate of the 'trial registry' sub-item in the current research was estimated as 47.1%. In the study by Bahri et al. (51), the reporting rate of the 'trial registry' sub-item has been determined to be zero, while it has been reported to be 46.8% in the research by

Sarayloo et al. (52) and 93.8% in the study by Susvirkar et al. (55). The International Committee of Medical Journal Editors in 2004 announced that the registration of trials before recruitment is essential for their publication. Nevertheless, the reporting rate of RCT studies remains low (56).

Critical evaluation is influenced by the individual's point of view who in this regard tried to overcome it by using a checklist as well as reviewing the scoring of articles and using a third researcher in scoring.

Conclusion

The quality of reporting RCTs regarding counseling-training interventions for breastfeeding is not favorable in Iran. Considering that clinical trials could be the optimal source for evidence-based practice, there is an urgent need for more commitment of researchers, authors, journal editors, and reviewers of health sciences journals to RCT studies. In addition, it is recommended that researchers comply with the use of various tools and CONSORT for training, implementation, and evaluation in RCT studies. Therefore, it is suggested that valid tools be designed and developed for research assessments by researchers, new statements and guidelines be accurately and thoroughly applied by authors, and instrument-based articles be reviewed properly and accurately by journal editors and reviewers.

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Conflicts of interest

Authors declared no conflicts of interest.

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