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Review Article

Compliance of Published Randomized Controlled Trials on the Effect of Physical Activity on Primary Dysmenorrhea with the Consortium's Integrated Report on Clinical Trials Statement: A Critical Appraisal of the Literature

Abstract

Background: Randomized Controlled Trials (RCTs) are reliable methods for the evaluation of treatment effectiveness, which should be rigorous and must report with clarity. This study aimed to assess the compliance of published RCTs about the effect of physical activity on primary dysmenorrhea with the CONSORT 2017 statement. **Materials and Methods:** In this study, the review of literature was carried out based on Consolidated Standards Of Reporting Trials (CONSORT). All the clinical trials focused on the effect of the physical activity on primary dysmenorrhea indexed in Web of Science, Pubmed, Scopus, Google Scholar, Science Direct, Embase, Magiran and Scientific Information Database (SID) were searched using keywords of dysmenorrhea, randomized clinical trial, physical activity and exercise from 2000 to 2019. Out of 1423 articles, 30 RCTs were critically appraised using CONSORT 2017 checklist. The reporting quality score of articles was identified between zero and 43. **Results:** The compliance rate with the CONSORT checklist was 55.58%. The mean (SD) score of the reporting quality was 23.37 (-5.15) with a minimum of 16 and a maximum of 37. The maximum weakness was in reporting the sample size and full trial protocol 23.33% and 6.67% respectively. Regarding new items of the consort 2017, if the blinding was not possible, the description of any attempts to limit bias was not described in 70% of articles. **Conclusions:** Reporting sample size, trial protocol, method of blinding, and control of bias are issues that require more attention in reporting of RCT studies. We recommend that the authors use the CONSORT 2017 statement for conducting and reporting the clinical trials.

Keywords: *Exersice, dysmenorrhea, randomized controlled trial, review*

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Access this article online

Website: www.ijnmrjournal.net

DOI: 10.4103/ijnmr.IJNMR_223_19

Quick Response Code:

Introduction

Randomized Controlled Trials (RCTs) are increasingly being used, and are considered as the highest level of evidence in medical sciences. The design of RCTs, due to their strong robustness in producing data is associated with less bias and it is obvious that it produces the most valuable data. So they are the most reliable ways of assessing the effectiveness of treatments in the field of medical sciences.[1] Evidence Based Medicine (EBM) is based on the results of RCTs because the results of this type of study is objective, scientific, and methodical.[2] The quality assessment of articles plays an important role in the establishment of EBM and improves the quality of services in the field of health through applying the results of these research in the clinical settings. EBM also improves the cost-effectiveness of services by eliminating unnecessary medical expenses.[3] Consequently, there is a major effort to improve the reporting quality of the clinical trials.[4,5] Consolidated Standards of Reporting Trials (CONSORT) developed by the CONSORT Group to decrease the problems resulted from inadequate reporting of randomized controlled trials. It is part of the larger Enhancing the Quality and Transparency Of health Research (EQUATOR) Network, which is an international initiative aimed at enhancing the transparency and accuracy of reporting in health research to increase the merit and reliability of medical research literature.[6] The CONSORT 2010 toolkit

How to cite this article: Manouchehri E, Alirezaei S, Latifnejad Roudsari R. Compliance of published randomized controlled trials on the effect of physical activity on primary dysmenorrhea with the consortium's integrated report on clinical trials statement: A critical appraisal of the literature. Iran J Nurs Midwifery Res 2020;25:445-54.

Submitted: 14-Jan-2020. **Revised:** 03-Aug-2020. **Accepted:** 01-Sep-2020. **Published:** 07-Nov-2020.

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and CONSORT 2017 tool, published in the Journal of the American Medical Association (JAMA)[7,8] contains a checklist and a flowchart that authors can use to report RCTs. Many of the prestigious medical journals and international review teams use this tool to facilitate quality assessment and interpretation of RCTs.[9]

Non-Pharmacologic Treatments (NPTs) such as surgery, rehabilitation, education, and psychotherapy are a range of interventions that have specific methodology complications, such as the complexity of the intervention process, the impact of the care providers, the care centers' expertise, and blinding problems.[10] For this reason, the CONSORT Group designed a separate version for the NPT studies, which was first published in 2008.[11] Changes made to the CONSORT 2017 for NPT studies include changes in the tool for better understanding for its users, and it has 3 new items. The 2017 version of CONSORT for NPT studies help authors, reviewers, and researchers to clarify the reports and evaluate the quality of articles.[12]

Dysmenorrhea is one of the problems that cause women to use some NPTs.[13] Primary Dysmenorrhea (PD) is known to occur in the absence of pathologic causes, but in the secondary dysmenorrhea, pains follow the pathology of pelvic organs.[14] In a systematic review, the incidence of dysmenorrhea was 17–80%.[15] The most commonly used drugs to treat PD are nonsteroidal anti-inflammatory drugs. However, 10–25% of women do not respond to these drugs or the side effects of these drugs are not tolerable to them or they are not generally in agreement with drug use. Millions of women with PD are seeking alternative therapies, complementary treatments, and natural treatments, and there are many effective therapies that can relieve dysmenorrhea, which include the use of essential fatty acids, vitamins, acupuncture, herbal remedies, aromatherapy, reflexology, acupressure, massage therapy, and physical activities.[16] Exercise (physical activity) reduces dysmenorrhea by improving the blood flow to the pelvic organs and stimulating the release of beta-endorphins, a non-specific pain reliever.[17] Also, most exercise interventions in dysmenorrhea have little side effects and are preferred to pharmacologic and herbal therapies.[18] Different types of exercise have been investigated in several studies, but clinical trials have not been critically evaluated on the effects of exercise on PD. Also, no study has met the full CONSORT guideline for NPT RCTs for assessing the reporting quality of studies on this issue. Inadequate and poor quality reporting of clinical trials is a problem that interferes with researchers ability to assess, appraise, replicate, and synthesize study findings and influences physicians, clinicians, health professionals and policy-makers' decision-making. Assessing the reporting quality of published clinical trials is an essential way to identify items that need improvement in future articles. Considering the importance of RCTs in therapeutic interventions, the present study was conducted to review the literature to identify the compliance of published RCTs regarding the effect of physical activity on PD with the CONSORT statement extension 2017.

Materials and Methods

In this study, the review of the literature was carried out based on Consolidated Standards Of Reporting Trials (CONSORT). CONSORT Statement is an evidence-based, minimum set of recommendations and standard way for authors to report randomized clinical trial findings, transparently. In addition to reporting, it aids their critical appraisal and interpretation. The literature search for RCTs related to the effect of physical activity on PD was conducted for published documents from 1st January 2000 until 30th December 2019. Journals were indexed in the databases of Web of Science (12), Pubmed (30), Scopus (136), Google Scholar (1030), ScienceDirect (9), Embase (172) and also Magiran (32) and Scientific Information Database (SID) (2). The articles were searched by English and Persian keywords of "randomized controlled trial", "clinical trial", " treatment of dysmenorrhea ", "pain of period", "exercise", "yoga", "physical activity", or combining these words in the title and abstract. The included articles were clinical trials focused on all physical activities for PD treatment in non-athletic women. They were also in Persian and English languages, where original research and their full text was available. Studies including meta-analysis, case-control, observational, cross-sectional, cohort, and case studies were excluded. There were 1423 studies, which had the inclusion criteria and were collected using the EndNote software in a separate library file. Of these, 208 duplicate articles were eliminated. The articles were evaluated in terms of their titles and abstracts through which 1118 articles were eliminated. Of the remaining 97 articles, 67 articles were excluded in the full text screening due to not being relevant. Finally, 30 articles related to the topic of the study were included in the process of critical appraisal. The process of selecting articles is shown in Figure 1. To be assured of the retrieval of all related articles, the search for articles in databases was repeated by the co-author.

The CONSORT 2017 extension was used for the quality assessment of selected articles. This tool consists of 6 sections and 43 items. The scores of the articles were classified into four categories: poor (<10.50), average (10.50-21), good (22-31.50), and excellent (31.50-43). The articles were assessed by two researchers, independently. A random sample of 10 articles was crosschecked to ensure about the accuracy and inter-rater concordance. In the cases of inconsistency, the supervisor's opinion was used. The data were analyzed using the Statistical Package for Social Science (SPSS, IBM, USA), version 19A.

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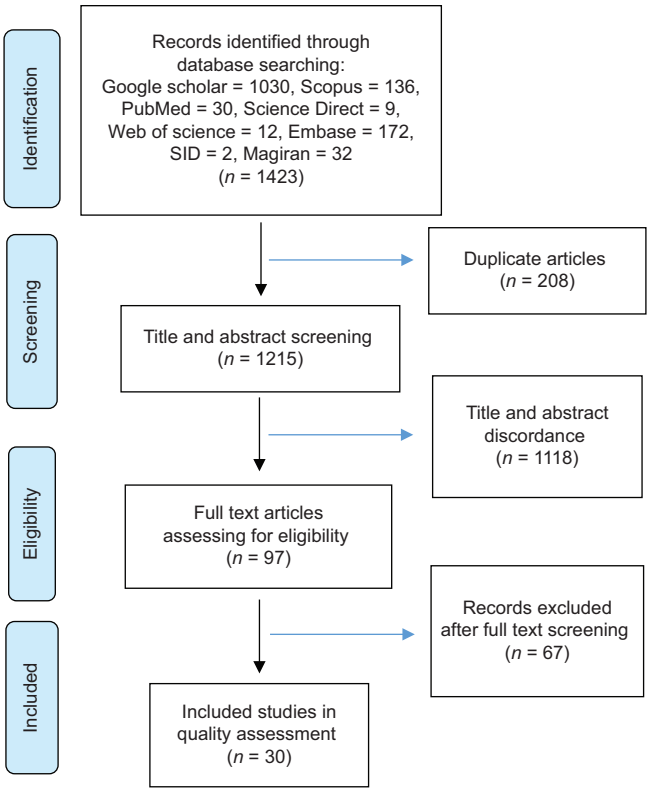

Figure 1: Flowchart Process for selecting articles

Ethical considerations

Intellectual property rights were considered for all the authors. All articles were reviewed in the initial screening. They were not included in the study if they did not comply with the inclusion criteria.

Results

In this study, 30 articles were assessed for quality assessment, regarding the effect of physical activity on the PD. Articles were published between 2006 and 2017. Most articles 6 (20%) were published in 2016 and the least articles were published in 2006, 2010, and 2011 (3.33%). Most studies were conducted in Iran [15 (50%)], followed by India [7 (23.33%)] and Egypt, New Zealand, and South Korea [1 (3.33%)] [Table 1]. The language of 23 (76.67%) articles were English. The authors of 10 (33.33%) articles were midwives, 2 (6.67%) articles were yoga specialists, 4 (13.33%) articles were physiotherapists and 2 (6.67%) articles were rehabilitation specialists. Also, in 3 (10%) articles, the study was conducted by gynecologists, in 4 (13.33%) articles by physical education and sport science specialists, in 2 (6.67%) articles by sport physicians and in 1 (3.33%) article by a nurse. Only in 13.33% of the articles statisticians were contributed. The mean length of articles' review process was 4 months, varied from 1 to 8 months. The overall compliance rate of the selected articles with CONSORT 2017 was 55.58%. The highest score attributed to the articles was 83.70% and the lowest score was 37.20% [Table 2].

The results of the critical appraisal of RCTs showed that in the title and abstract section, 20 articles (66.67%) did not mention the phrase of "Randomized clinical trial". In introduction section, 11 articles (36.67%) did not report the specific assumptions and aims. In the method section, only 9 (30%) studies explained how the care providers joined the program (5d), while 17 (56.67%) article provided explanations for joining the participants (5e). Also only 2 (6.67%) studies mentioned the sample size. Additionally, only 2 (6.67%) studies clearly outlined the inclusion criteria. The lack of reporting precise randomization process was not reported about blinding the random allocation method [9 (30%) articles], identification the individuals who did randomized allocation sequences of [10 (33.33%) articles)] as well as description of the method of blinding [5 (16.67%) articles]. Also 9 (30%) studies that had no possibility of blindness, explained the methods of bias reduction. Regarding statistical analysis, 16 studies (53.33%) defined statistical methods to compare the primary and secondary outcomes of the groups, and 12 (40%) explained the methods used in additional analyzes such as subgroup and modified analyzes.

In the section of results, only 8 (26.67%) studies explained the missing or excluded subjects in each group and 3 (10%) studies reported unintended effects. 11 (36.67%) studies did not list the number of participants entered in the analysis in each group. Only 19 (63.33%) studies reported the results of primary and secondary outcomes in each group (17a), and 26 (86.67%) studies reported both absolute and relative effect sizes (17b). 11 (36.67%) articles did not report the results of any sub-analysis such as subgroup analysis or modified analysis due to initial exploratory analysis. Only 3 (10%) studies reported unintended effects.

About discussion section, 15 (50%) articles mentioned the study limitations about the bias sources. Also 19 (63.33%) studies outlined the generalizability of their study findings, and 24 (80%) articles with a balance of benefits and harms and consideration of other relevant evidence interpreted consistently with the results. Finally, about the section of "other information" of CONSORT tool, 24 (80%) articles did not indicate the registration number and setting of the clinical trials. 93.33% of studies did not present instruction or protocol on the type of intervention, and 9 (30%) studies did not mention funding sources [Table 3]. Table 3 shows the reporting of methodological details.

Since CONSORT 2017 tool was used for critical appraisal of articles in this study, some items were added to the 2010 version included: how to standardize the intervention and how caregivers and participants' adherance to the protocole was assessed. In this regard, 76.67%, 30%, and 56.67% of the studies reported these issues, respectively. Regarding the

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Table 1: Characteristics of included RCTs*

Author/year/country	Participants	Intervention group size	Control group size	Type of intervention	Control group	Score	Article quality
Kannan *et al*. (2015) Newzealand[19]	70 students	35	35	Walk for 28 weeks	Routine dysmenorrhea treatment	37	Excellent
Yang *et al*. (2016) South Korea[20]	40 students	20	20	Yoga for 12 weeks	No intervention	36	Excellent
Azima *et al*. (2015) Iran[21]	68 students	34	34	8 weeks Isometric exercise	No exercise	31	Good
Azima *et al*. (2015) Iran[22]	120 students	40	40	Isometric exercise for 8 weeks/consecutive cycles of effleurage massage with lavender oil	No intervention	29	Good
Yonglitthipagon *et al*. (2017) Thailand[23]	34 students	17	17	Yoga for 12 weeks	No intervention	29	Good
Vaziri *et al*. (2014) Iran[24]	98 students	49	49	Aerobic exercise for 8 weeks	No intervention	27	Good
Shirvani *et al*. (2017) Iran[25]	122 Students	61	61	Stretching exercise for 8 weeks	No exercise	27	Good
Saleh *et al*. (2016) Egypt[26]	150 patients	100	50	Stretching exercise for 8 weeks	Strengthening Exercise for 8 weeks	26	Good
Rakhshaee *et al*. (2011) Iran[27]	92 students	50	42	Yoga for 12 weeks	No intervention	26	Good
Chaudhuri *et al*. (2013) India[28]	128 students	53	75	Exercise for 8 weeks	No intervention	25	Good
Reihani *et al*. (2013) Iran[29]	90 students	45	45	Walking for 12 weeks	No intervention	25	Good
Shahrjerdi *et al*. (2010) Iran[30]	179 students	124	55	Stretching exercise for 8 weeks	No intervention	25	Good
Paithankar *et al*. (2016) India[31]	50 students	25	25	Pilates for 12 weeks	Stretching exercise for 12 weeks	24	Good
Rezvani *et al*. (2013) Iran[32]	40 students	20	20	Water sport for 12 weeks	No intervention	24	Good
Motahari-Tabari *et al*. (2017) Iran[33]	122 Students	61	61	Stretching exercise for 8 weeks	Use of antispasmodic drug	24	Good
Abbaspour *et al*. (2006) Iran[34]	142 school children	97	45	8 weeks exercise	No exercise	23	Good
Ortiz *et al*. (2015) Mexico[35]	192 students	96	96	Physical therapy program for 4 weeks	No exercise	23	Good
Shah *et al*. (2016) India[36]	40 students	20	20	Stretching exercise for 8 weeks	No intervention	23	Good
Salehi *et al*. (2012) Iran[37]	40 students	20	20	Pilates for 8 weeks	No intervention	21	Good
Siahpour *et al*. (2013) Iran[38]	60 students	40	20	Aerobic exercise for 8 weeks	No intervention	21	Good
Heidarianpour *et al*. (2016) Iran[39]	20 Student	10	10	Aerobic exercise for 8 weeks	No intervention	21	Good
Nasri *et al*. (2016) Iran[40]	45 Students	30	15	Aerobic exercise for 8 weeks	No exercise	20	Moderate
Gamit *et al*. (2014) India[41]	30 students	15	15	Stretching exercise for 4 weeks	No exercise	19	Moderate
Kanwal *et al*. (2017) Pakistan[42]	66 students	33	33	Stretching exercise for 4 weeks	Treatment with TENS	19	Moderate
Mahvash *et al*. (2012) Iran[43]	50 students	25	25	exercise for 8 weeks	No exercise	19	Moderate
Shavandi *et al*. (2010) Iran[13]	30 students	15	15	Isometric exercise for 8 weeks	No intervention	19	Moderate
Gupta *et al*. (2013) India[44]	64 Students	32	32	Exercise for 8 weeks	No exercise	19	Moderate
Nag *et al*. (2013) India[45]	113 students	60	53	Yoga for 12 weeks	No intervention	17	Moderate
Thoke *et al*. (2015) India[46]	120 students	60	60	Yoga for 24 weeks	No intervention	17	Moderate
Dauneria *et al*. (2014) India[47]	56 girls	24	32	Yoga for 4 weeks	Using an anti-spasm drug	16	Moderate

*Randomized Controlled Trials

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Table 2: The mean (SD) and the minimum and maximum scores for each of the 6 examined sections

Domain	Minimum-maximum Tool score	Minimum-maximum Earned score	Mean (SD)	Compliance rate (%)
Title and abstract	0-2	0-2	1.20 (0.48)	60
Background and objective	0-2	1-2	1.63 (0.49)	81.50
Method	0-22	7-21	12.53 (2.96)	57
Results	0-11	2-9	5.93 (1.74)	54
Discussion	0-3	0-3	1.83 (1.11)	61
Other information	0-3	0-3	0.60) 0.81)	20
Total	0-43	16-37	23.73 (5.15)	55.58

item of the delay between randomization and intervention, it was not mentioned in 36.67% of articles.

Discussion

This critical appraisal of peer-reviewed literature provided a picture of the compliance of RCTs published about the effect of physical activity on PD with the CONSORT 2017 statement for NPTs. This appraisal showed that the reporting quality of RCTs has many problems, especially in those items relevant to the internal validity of trials such as randomization, allocation concealment mechanism, blinding, sample size, the flow of participants in the trial, and during the follow-up.

In our study, the overall quality of articles was categorized as medium to good quality. It was similar to the overall quality in a study that reviewed 47 clinical trials on the effect of complementary medicine on menopausal symptoms.[48] Whereas, it was higher than the overall quality of 20 clinical trials reported in relation to the efficacy of massage therapy on labor pain intensity in the study of Irani *et al*. (2017), which classified as medium to low-level quality.[49] The probable reason for this difference could be the type of articles included in the two studies. The study of Irani *et al*. (2017) was on the articles published in Persian journals, whereas the articles in this study were indexed in both English and Persian databases that possibly have different qualities. This result has been reported in other studies as well.[50,51] This is possibly due to not enough attention of included journals to clinical trial reporting.

In our study, the overall compliance rate of articles with CONSORT 2017 statement was 55.58%. A systematic review conducted on 55 RCTs published in plastic surgery concluded that, on average, RCTs comply with just half of the CONSORT items[52] that is in line with some other studies.[53-55] But in the study of Salesi *et al*.,[56] only one-third of the articles achieved the maximum possible score on the scale, in which the evaluated clinical trials were all published in the Journal of Military Medicine of Baqiyatallah University, Iran; while in our study the various journals with different languages were included. Therefore, it seems that the trials published in general journals with general scope have higher report quality. The lack of compliance could be due to unawareness of the authors, lack of training on the distinctions of doing a clinical trial, and careless reviewing by the reviewers of these articles. In study by Geonka *et al*. (2019), the compliance rate per a sections of the CONSORT tool was reported higher than the present study[53]; but the poorest and the strongest sections were consistent with the present study. The possible reason for the higher quality in the aforementioned study is appraising the RCTs published only in 2017 in Indian medical journals, and it seems that overal compliance with the CONSORT tool has increased over time.[51,57,58] Regarding our findings, most of the RCTs did not mention the phrase of "randomized trial in the title" (1a). This finding is in contrast with some studies[51,55] and is in line with another study.[59] The present study showed that adherence to the item of reporting objectives and hypotheses in the introduction were consistent with some other studies.[55,60]

In order to design a clinical trial study, for demonstrating the power of the test and its generalizability and also to compare it with other clinical trials, a very important issue is to estimate the appropriate sample size. In our study, only about one-fifth of articles mentioned the method of sample size caculation. Many studies have also reported the same methodological flaws.[49,51,53-55,58,60,61] But in a study by Ghojazadeh *et al*.[62] on 114 RCTs, more than three-fifth of articles mentioned the sample size calculation method. Because the critical quality assessment is being done on the top ranked English-language journals. Similar to other studies, a few articles in the present study reported the changes to methods after the trial begins, which may be due to making no important changes to methods after the trial started.[55,61,63] According to the present study, most of the articles did not use a statistician in the process of their research, and the low proficiency of clinicians in statistics and methodology is a reason for the poor quality of clinical trials. If the randomization was done correctly and appropriately, the apparent and hidden biases could be reduced.[64]

As determined by CONSORT 2017, the major limitation was in reporting of methodology. Our results showed that about half of the articles used a suitable method for random allocation of a sample, while in the study of Moosavi *et al*.[65] one-third of the articles used a suitable method for this purpose. Other studies reported

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Table 3: Quality of published clinical trial reports on the effect of physical activity on the severity of dysmenorrhea using the CONSORT* 2017 tool

Section/Topic item	Checklist Item No.	CONSORT item	Reported No. (%)	Not reported No. (%)
Title and abstract	1a	Identification as a randomized trial in the title	8 (26.67%)	22 (73.33%)
	1b	Structured summary of trial design, methods, results, and conclusions	28 (93.33%)	2 (6.67%)
Introduction:				
Background and objectives	2a	Background	30 (100%)	0 (0%)
	2b	Objectives	19 (63.33%)	11 (36.67%)
Methods:				
Trial design	3a	Description of trial design	30 (100%)	0 (0%)
	3b	Important changes to methods after trial commencement	4 (13.33%)	26 (86.67%)
Participants	4a	Eligibility criteria	28 (93.33%)	2 (6.67%)
	4b	Settings and locations	30 (100%)	0 (0%)
Intervention (s)	5a	The interventions for each group	30 (100%)	0 (0%)
	5b	Different interventions components	20 (66.67%)	10 (33.33%)
	5c	How the interventions were standardized	23 (76.67%)	7 (23.33%)
	5d	How adherence of care providers to the protocol was assessed	9 (30%)	21 (70%)
	5e	How adherence of participants to interventions was assessed	17 (56.67%)	13 (43.33%)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures	22 (73.33%)	8 (26.67%)
	6b	Any changes to trial outcomes after the trial commenced	14 (46.67%)	16 (53.33%)
Sample size	7a	How sample size was determined	7 (23.33%)	23 (76.67%)
	7b	Interim analyses and stopping guidelines	2 (6.67%)	28 (93.33%)
Randomization:				
Sequence generation	8a	Random allocation sequence	16 (53.33%)	14 (46.67%)
	8b	Type of randomization	14 (46.67%)	16 (53.33%)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence, describing any steps taken to conceal the sequence	9 (30%)	21 (70%)
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10 (33.33%)	20 (66.67%)
Blinding	11a	If done, who was blinded after assignment to interventions	5 (16.67%)	25 (83.33%)
	11b	Description of the similarity of interventions	21 (70%)	9 (30%)
	11c	If blinding was not possible, description of any attempts to limit bias	9 (30%)	21 (70%)
Statistical methods	12a	Statistical methods used to compare groups	16 (53.33%)	14 (46.67%)
	12b	Additional analyses	12 (40%)	18 (60%)
Results:				
Participant flow	13a	The numbers of participants who were randomly assigned, received intended treatment, and were analyzed	27 (90%)	3 (10%)
	13b	Losses and exclusions	8 (26.67%)	22 (73.33%)
	13c	For each group, the delay between randomization and the initiation of the intervention	11 (36.67%)	19 (63.33%)
Recruitment	14a	Defining the periods of recruitment and follow-up	26 (86.67%)	4 (13.33%)
	14b	Why the trial ended or was stopped	21 (70%)	9 (30%)
Baseline data	15	A table for baseline demographic and clinical characteristics	14 (46.67%)	16 (53.33%)
Numbers analyzed	16	Number of participants	19 (63.33%)	11 (36.67%)
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)	26 (86.67%)	4 (13.33%)
	17b	Effect sizes for binary outcomes	10 (33.33%)	20 (66.67%)
Ancillary analyses	18	Results of any other analyses performed	11 (36.67%)	19 (63.33%)
Harms	19	All important harms or unintended effects	3 (10%)	27 (90%)
Discussion:				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15 (50%)	15 (50%)
Generalizability	21	Generalizability (external validity, applicability)	19 (63.33%)	11 (36.67%)

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Table 3: Contd...

Section/Topic item	Checklist Item No.	CONSORT item	Reported No. (%)	Not reported No. (%)
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	24 (80%)	6 (20%)
Other information				
Registration	23	Registration number	6 (20%)	24 (80%)
Protocol	24	Full trial protocol access	2 (6.67%)	28 (93.33%)
Funding	25	Sources of funding	9 (30%)	21 (70%)

*Consolidated Standards of Reporting Trials

a lower score for this item.[58-60] It is due to the quality or scope of the journals in the mentioned studies.[55,60] In the present study, only one-third of the articles reported allocation concealment. A systematic review of the quality of RCTs on Iranian traditional medicine, revealed that about two-thirds of articles were deficient in reporting random sequence generation and allocation concealment mechanism.[51] Also, in a study that assessed the quality of RCTs published in the New England Journal of Medicine, the British Medical Journal (BMJ), JAMA, and Lancet, about half of the studies were conducted with uncertain concealment of allocation.[66] Although in the mentioned studies, the quality evaluation was done on reliable journals, the allocation concealment report was still low. Gohari *et al*. (2016) and Bahmani *et al*. (2019) described the adherence to allocation concealment as poor.[55,58,59] The RCT results will be biased with these methodological flaws . In the trials in which the allocation sequence has been inadequately or indefinitely concealed, larger estimates of treatment effects would be reported by mistake.[67]

Only about one-third of the articles did blinding. The reason might be the type of intervention, which was some kind of physical activities, and this could justify the impossibility of the blindness in appraised studies, but most of them did not mention the methods of reducing bias, which is similar to the findings of some other studies[49,58,65] Bahmani *et al*., similarly, reported only one-third adherence to blinding items.[55,59,63] These flaws reduce the validity of the findings reported by articles.

Regarding the report of effect sizes for binary outcomes (17b), the RCTs are so poor in the present and other studies.[51,55,60] According to nojomi *et al*. (2013), only 8.4% of articles reported this section.[60] But in the present study the review showed that it has been reported in one-third of studies. One possible explanation is that Nojomi *et al*. only searched one database (Iranmedex) with one search term for two years (2008-2010) and only included articles published in Iranian journals in the study.

As the findings of other studies, our results revealed that half of the included RCTs did not describe their limitations.[51,60] In a study about quality assessment of Iranian articles, about one-fifth of articles reported limitations, sufficiently.[60] The limitations must be stated for assessing the applicability of trials in real conditions and having a better interpretation of the results.

Similar to other studies,[49,53,54,68] only one-fifth of the RCTs had a trial registration number. In one study, it was reported in only one-tenth of RCTs.[60] The clinical trial registration number reduces the error of similar articles[69] and is critical to increasing public transparency and public confidence in the process.[54] In our study, RCTs were poor in terms of reporting of significant harms, and source of funding, which is in line with findings reported by Borrelli *et al*.,[54] Nojomi *et al*.[60] and Karpouzis *et al*.[63] But in a study aimed to explore the quality of reporting RCTs of the cardiovascular therapeutic medical devices, the compliance with registration, protocol and funding section was high (≥90%).[61] The cause of this inconsistency is that the mentioned study included articles published in five leading the general journals with high impact factor.

Poor reporting of the RCTs makes its difficult for readers to assess the validity of the trials and to correctly use research evidence to guide their clinical decision makings. Clear and transparent reporting improves the quality of evidence and applicability of findings. So, we suggest CONSORT adoption by journals for improving the reporting quality of RCTs. In this critical review, the authors assessed the quality of studies using the standard CONSORT 2017 tool to facilitate decision making about treatment effectiveness. Nevertheless, further studies are required to assess more recent articles in other fields to investigate barriers of compliance with the CONSORT statement. On the other hand, sometimes the word limitation of journals may compromise the reporting quality of the articles. We recommend that journals modify the word count requirements, or provide online sources to allow authors to show the important omitted components.

One of the limitations of this study was that we only assessed the RCTs published in English and Persian journals from 2000 to 2019, so the results cannot fully represent the reporting quality of all NPT RCTs in the under study topic. Second, some CONSORT items are much more important, but because of the lack of evidence for weighing items, we also considered equal weight for all items. Using a new version of the CONSORT tool was

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one of the strengths of this study. Also, compliance with the CONSORT criteria about the effect of physical activity on PD has not previously been assessed. Additionally, reporting quality assessment was done by two reviewers and a sample of articles was cross-checked between them. A high level of agreement ensures the consistency and reliability of the results.

Conclusion

In summary, the reporting quality of NPT RCTs is suboptimal and reporting of RCTs still requires improvement. Especially in methodology items, bias reduction techniques and providing explanations to increase the quality of articles and their applicability in the clinical settings. So we suggest that all medical journals should recommend CONSORT statement in their "Instruction/Guide for authors" for improving the reporting quality of RCTs. Also, authors are recommended to design and report the results of their non-pharmacologic treatment clinical trials using the standard CONSORT 2017 extension to assist clinicians for decision making on treatment effectiveness.

Acknowledgements

The authors would like to extend their gratitude to the librarians who helped them to access information resources in Mashhad University of Medical Sciences, Mashhad, Iran.

Financial support and sponsorship

Nil.

Conflicting interest

Nothing to declare.

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