Methodological reporting quality of randomized controlled trials in three leading sports medicine journals over 10 years

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Research

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Abstract

Background

Randomized controlled trials (RCTs) are the gold standard scientific testing for medical interventions. However, low-quality RCTs may provide misleading evidence. This research elucidated the methodological reporting quality of randomized controlled trials (RCTs) in three sports medicine journals over 10 years following the CONSORT statement.

Methods and Findings

In this study, we evaluated the methodological reporting quality of RCTs in three major sports medicine journals, including Journal of Science and Medicine in Sport, British Journal of Sports Medicine and Clinical Journal of Sports Medicine from 2008 to 2017. The methodological reporting quality, including the allocation sequence generation, allocation concealment, blinding, type of analysis, handling of dropouts were revealed. Number of patients, funding source, type of intervention and country were retrieved. The methodological reporting quality was descriptively reported. A total of 475 trials were involved and 166 (34.9%) trials reported adequate allocation generation, 124 (26.1%) trials reported adequate allocation concealment, 262(55.2%) trials reported adequate blinding, 122 (25.7%) trials reported type of analysis and 100 (21.1%) trials reported handling of dropouts.

Conclusions

This study shows that the methodological reporting quality of RCTs in the three major sports medicine journals were unsatisfactory and it can be further improved.

Introduction

Randomized controlled trials (RCTs) in which people are allocated randomly (only by chance) to receive certain clinical interventions are the gold standard of scientific testing for new medical interventions. The evidence quality of clinical studies was stratified based on one report by the US Preventive Services Task Force[1], which said the level I evidence should be obtained from at least one properly designed RCT. The properly designed RCTs are the basis of high level evidence in the evidence based medicine (EBM).

Thus, low-quality RCTs are very misleading. Studies have demonstrated that odds ratios were exaggerated by 41% for inadequately concealed trials and by 30% for unclearly concealed trials and trials that were not double-blinded also yielded larger estimates of effects with odds ratios being exaggerated by 17%[2]. An increased estimate of benefit was associated with those without adequate methods[3]. If studies of low methodological quality are incorporated into the meta-analyses, the benefit of intervention

is significantly altered[3]. Therefore, the best research evidence should be clinically relevant and it is extremely important to improve the quality of the RCTs.

CONSORT, which stands for Consolidated Standards of Reporting Trials, offers a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting and aiding their critical appraisal and interpretation. At present the CONSORT Statement is endorsed by prominent general medical journals, many specialty medical journals and leading editorial organizations[4].

Sports medicine, also known as sports and exercise medicine, is a branch of medicine that deals with physical fitness and the treatment and prevention of injuries related to sports and exercise. Recent years has witnessed a rapid development of sports medicine and many RCTs have been carried out to elaborate on some controversial issues in this area. Although assessment of the reported methodology of RCTs in various research fields including surgery[1], gastroenterology[5], endocrinology[6], urology[7] and spine surgery[8] has been studied previously, evaluation of the methodological reporting quality of RCTs in sports medicine has not been reported before. The quality of RCTs in sports medicine remains to be established. The quality of reporting of randomized trials in the Journal of Bone and Joint Surgery was reported by Bhandari, M. et al, whose conclusion was the reporting of RCT was variable, and generally low qualitative[9], and the methodological quality of research published in the American Journal of Sports Medicine[10]. However, the methodological reporting quality of RCTs in sports medicine has not been reported before, and the quality of RCTs in sports medicine remains to be established. According to Yoon et al[11], the CONSORT criteria might further increase the quality of reporting of sports injury conference abstracts in the future. To address this issue, we systematically assessed the methodological reporting quality of RCTs published in three major sport medicine journals, namely *American Journal of Sports Medicine*, *British Journal of Sports Medicine*, *Journal of Science and Medicine in Sport* over 10 years from 2008 to 2017.

Methods

The current study included all RCTs published as full-text articles in the three most high-cited journal, the American journal of sports medicine (IF=7.074 in 2017), British journal of sports medicine (IF=7.867 in 2017), Journal of Science and Medicine in Sport (IF=3.929 in 2017) in recent 10 years from 2008 to 2017. We selected these three journals because they are the leading sports medicine journals focusing on sports medicine and their methodological reporting quality of RCTs has never been systematically studied.

The methods we used were similar to those described previously[8]. In short, trials were considered to be RCTs if the words “random”, “randomly”, “randomization”, “randomized” were used in the text to describe the allocation method. Nevertheless, trials published as abstracts, quasi-randomized trials, trials with animals, trials with cadavers, subgroups analysis of RCTs, trials being part of some large RCTs, observational studies nested within RCTs and trials without the outcomes of randomized patients were excluded from the study.

The relevant trials were searched and identified by the two co-first authors, who hand-searched all the issues of the three journals published from 2008 to 2017. For PubMed search the strategy recommended by Robinson and Dickersin was adopted[12] to include all potentially eligible trials. Geographical, publishing, clinical and epidemiological characteristics of RCTs were extracted. Methodological reporting quality was critically appraised by the following items selected from the CONSORT 2010 checklist[13]:

1. Primary outcome: adequate if the primary outcome stated explicitly.
2. Sample size calculation: adequate if presented.
3. Presence of baseline: adequate if basic information of patients in each study was described (at least 2 characteristics).
4. Generation of allocation sequence: adequate if the method was defined and was considered random beyond any doubt (e.g., computer-generated sequence, random table, coin toss or shuffle cards). “Yes” (e.g., random number table, computer random number generator), “unclear” (insufficient information to permit judgment of “yes” or “no”), or “no” (the description involves some systematic, nonrandom approach).
5. Allocation concealment: adequate if an proper method to avoid knowing or expecting the allocation sequence in advance was confirmed to have been used (e.g., central/pharmacy randomization, envelopes or independent person). “Adequate” (e.g., central allocation or sequentially numbered, opaque, sealed envelopes), “unclear” (insufficient information to permit judgment of “yes” or “no”), or “no” (e.g., open table of random numbers, alternation or rotation, date of birth).
6. Blinding: adequate if stating the use of any type of blinding of participants, outcome reviewers, researchers, or caregivers. “Yes” (e.g., no blinding, but the review authors judge that the outcome and the outcome measurement are not likely to be influenced by lack of blinding; blinding of participants and key study personnel ensured and unlikelihood that the blinding could have been broken; either participants or some key study personnel were not blinded, but the outcome assessment was blinded, and the non-blinding of others is unlikely to introduce bias), “unclear” (insufficient information to permit judgment of “yes” or “no”), “no” (e.g., no blinding or incomplete blinding, and the outcome or outcome measurement is likely to be influenced by the lack of blinding; blinding of key study participants and personnel attempted, but likelihood that the blinding could have been broken; either participants or some key study personnel were not blinded, and the non-blinding of others is likely to introduce bias).
7. Double-blinding: adequate if stating that the study was double-blinded.
8. Type of analysis: Intention-to-treat (ITT) if randomized patients with available data were accounted clearly as having been analyzed in their assignment group. Per-protocol analysis if only data of patients who have finished the routine were reported.
9. Handling of dropouts: adequate if less than 20% of trial participants were lost to follow-up, and reasons for all losses to follow-up were stated.

The agreement of the two authors was rated by calculation of kappa value. Any disagreement was resolved by discussion between the two reviewers or seeking for senior reviewer's help if necessary. The primary aim of this study was to describe the current quality of the methodology. As previously reported[14], "Low risk of bias" trials were defined as being conformed to 4 criteria[8]: adequate generation of allocation, adequate concealment of allocation, ITT analysis and adequate handling of dropouts.

Descriptive statistics (mean, standard deviation, median) were used. A one way ANOVA followed by SNK test was used for strata comparisons. All statistical analyses were performed with Statistical Program for Social Sciences (SPSS) version 11.0 for Windows (SPSS Inc., Chicago, IL, USA).

Results

Kappa values for the interobserver agreement between the two reviewers were 0.92 for the allocation concealment, 0.90 for the double blinding, and 0.90 for the sample size calculation. All these values indicated almost perfect or substantial agreement.

Main characteristics of the included trials are summarized in Table 1. A total of 580 studies were retrieved from the three journals. Of these 580 studies, 105 were excluded because they had a nonrandomized design, letters or reviews, subgroup analyses, a pooled analysis of RCTs or cost-effective studies alongside RCTs (Fig. 1). Finally, 475 trials were suitable for the analysis including 200 from the American Journal of Sports Medicine (n = 200), 148 from the British Journal of Sports Medicine (n = 148) and 127 from Journal of Science and Medicine in Sport (n = 127). As for results of the 475 trials, 332 (69.9%) reported statistically significant results and 143(30.1%) showed no difference between study group and control group. Geographically, Europe contributed 44.0%, North America (USA and Canada) contributed 15.2%, Asia and Oceania contributed 35.8% and Africa and South America contributed 5.1% (Table 1). For funding, 326 (68.6%) trials reported funding resource and 149 did not report. An ascending trend was found with regard to the number of published RCTs from 2008 to 2017 (Fig. 2).

Among the 475 trials, only 13 trials adequately reported all items. Baseline data were adequately presented in 333 (70.1%) trials. The generation of the allocation sequence was adequate in 166 (34.9%) trials including 114 with computer, 19 with random table and 33 with other methods and unclear in the remaining 309 trials. The allocation concealment was adequate in 124 (26.1%) trials and unclear in 351 trials. Adequate blinding was reported in 262 (55.2%) including 138 (29.1%) single blinding and 124 (26.1%) double blinding trials and no blinding in 213 trials. For type of analysis report, 122 (25.6%) used intention to treat analysis and 27 (5.7%) used per protocol analysis and 347 (73.1%) did not report type of analysis. Only 100 (21.1%) reported handling of dropouts (Table 2).

We intentionally selected 2010 as a time point because the CONSORT statement was significantly revised in this year. According to different strata, it is found generally that methodological reporting quality has not been significantly improved between 2008–2010 and 2011–2017. The reporting methodological quality between three journals are different. The American Journal of Sports Medicine shows better

reporting methodological quality, statistically significant results($p < 0.001$), allocation sequence generation ($p < 0.001$), baseline($p = 0.024$), allocation concealment ($p < 0.001$), type of analysis($p < 0.001$)and handling of dropout($p = 0.005$) compared with the other two journals. Generally, the quality of multi-center trials is superior to single-center trials. But there is no statistical difference for the items. For funding, trials with industrial funding showed better adequate allocation sequence generation ($p = 0.028$), adequate allocation concealment ($p < 0.001$), adequate type of analysis ($p = 0.011$) and adequate handling of dropout($p = 0.002$). For different interventions, significant difference was detected. For numbers of patients, trials with more than 100 patients showed better results in adequate baseline, adequate blinding, adequate type of analysis and adequate handling of dropout. The quality of the reported methodology is summarized in Table 3.

Discussion

In the current study, we described the current methodological reporting quality in three major sports medicine journals. It is noted that 29.9% of all RCTs did not present adequate baseline data, 65.1% did not report adequate generation of the allocation sequence,73.9% did not report adequate allocation concealment, 44.8% did not report adequate blinding way, 73.1% did not perform adequate analysis and 78.9% did not report adequate handling of dropouts. These findings suggest that more efforts should be taken to improve the methodological reporting quality of RCTs in major sports medicine journals. And this is in accord with the conclusion by Brophy et al[10].

Although the history of clinical trials dates back to 600 B.C. [15], the clinical study of pulmonary tuberculosis by Austin Bradford Hill is recognized as the beginning of modern randomized controlled trials which ushered in a new era[16]. Currently the Cochrane Library has already collected over 150, 000 RCTs which have become the solid basis of the evidenced based medicine (EBM). Therefore, the quality of evidence is extremely important[17].

The quality of RCTs is largely dependent on the study design and methodology conducted. Although the quality of design and methodology is not necessarily correlated with methodological reporting quality[18], under most circumstances, we can only depend on the information contained in the written paper. There is a possibility that a trial with a biased design, if well reported, could be considered of high quality, whereas a well-designed trial with poor reporting quality could be neglected. Nevertheless, some studies proposed that the reporting quality of RCTs could be used as a means to evaluate the methodological quality[19]. Therefore, it's clearly a poorly reported RCT could be very misleading. Thus, to improve the reporting quality has gradually become a common consensus worldwide. To improve the standards of written reports of RCTs, in 1996, the "CONSORT" (Consolidated Standards of Reporting Trials) was published[20] and revised in 2001[21] and 2010[13].The CONSORT statement of 2010 comprises a 25-item checklist and a flow diagram. The checklist describes how the trial is designed, analyzed and interpreted. Based on the 2010 version, we carried out this study. We selectively chose "sample size calculation,

allocation concealment, blinding, type of analysis, handling of dropouts" to evaluate the reporting methodological quality, for these are the most important factors influencing the RCTs quality.

Studies have demonstrated that endorsement of the CONSORT statement is associated with improved RCTs reporting methodological quality[22–24]. In recent years, the number of studies reporting methodological quality of RCTs based on the CONSORT statement has been increasing dramatically[25].

As we searched and reviewed, trials in many fields[5, 8, 14, 26, 27] showed inconsistence and non-adherence to the CONSORT statement, including anesthesiology[26], spine surgery[8], gastroenterology[5], surgery[14] and four high-impact medical journals[27]. Therefore, it is safe to conclude that the CONSORT statement has not been widely recognized although it has been introduced for almost twenty years. The CONSORT statement was significantly revised in 2010. According to different strata, it is found generally that methodological reporting quality has not been significantly improved between 2008–2010 and 201–2017. However in this study only allocation sequence generation and handling of dropout is improved after 2010 and the difference is statistically significant ($p < 0.01$), which indicated that the improvement of the reporting quality of RCTs in sports medicine still needs more attention.

The methodological reporting quality of RCTs in sports medicine has not been previously published. We hypothesized that the CONSORT statement was not well endorsed in this area. Randomization is the key of RCTs procedure which assigns all participants to each study group by equal chance. An appropriate sequence generation method directly determines the randomization. In this study, we employed similar criteria previously reported[8]. A study considered with adequate sequence generation should clearly and properly address the sequence generation methods, such as random number table or a computer random number software. Sequence generation based on systematic methods such as the date of admission or with only simple statement like "we randomly assigned" was regarded as inadequate. In this study, we found that less than half (34.9%) reported adequate generation of allocation sequence.

Adequate sequence generation alone is not sufficient to prevent bias. If the sequence is open to investigators, health care providers and participants who will be aware of the upcoming assignment, selection bias is likely to generate[28]. Thus, allocation concealment is considered to be an important part of randomization[29] and authors who report randomized trials should provide enough details on how allocation concealment was implemented so that the reader is able to determine the likelihood of success. In this study, we found that only 26.1% trials reported adequate allocation concealment and envelope was the major means.

Blinding is an important means to reduce bias. However, in the treatment of sports-related diseases, it is difficult or impossible to compare surgical or rehabilitation interventions with a double-blinded method. Nevertheless, the 2011 Cochrane Handbook defines adequate blinding. First, the outcome and the outcome measurement are not likely to be influenced by lack of blinding. Second, either the participants or some key study personnel are not blinded, but the outcome assessment is blinded. Although it is not easy to conduct a double-blind surgical trial, it is basically possible to find a blinded outcome assessor. In

this study, 262 (55.2%) trials reported adequate blinding including 138 with single blinding and 124 with double blinding.

An intention-to-treat (ITT) analysis of the results is based on the initial treatment assignment and not on the treatment eventually received. In contrast, a per-protocol analysis only focuses on patients who complete the entire clinical trial following the protocol. It could overestimate the practical value of an intervention. In this study, only 122 (25.7%) trials reported employing ITT analysis and 27 (5.7%) reported per-protocol analysis, which was far away from the standard of the CONSORT statement.

Missing data caused by patients dropping out of the study before completion is a major problem in the analysis of clinical trials. It can result in reduced sample size, biased treatment comparison and influence the overall statistical power of the study[30]. A review of 71 randomized controlled trials in four top medical journals showed dropout rates of 20% or more in 18% of trials[31]. Therefore, it is important to report an adequate handling of dropouts since it could notify readers' unsatisfactory reasons for dropouts including adverse events, lack of efficacy, lost to follow-up, death and so on. In this study, only 100 (21.1%) reported handling of dropouts.

Except for the above items which could affect the process to draw a right conclusion, funding source is another item. The result of the item "funding source" indicated that trials with industrial funding showed better quality in adequate allocation concealment ($p < 0.001$), adequate type of analysis ($p = 0.011$) and adequate handling of dropout($p = 0.002$). It suggested that we should focus on which kind institutions funded a trial, rather than whether there was a funding institution when we evaluate quality of a RCT.

The current study had several limitations. First, the methodological reporting quality could differ from the actual methodological quality. As we focused on the methodological methods of the trials, information not find in the published manuscript was deemed as deletion, which resulted that there is a possibility that a well-designed and well-conducted trial is considered with high risk of bias if the methodological methods were not reported adequately. Second, we only extracted major item instead of all items from the CONSORT 2010 statements. Third, although the three sports medicine journals with the highest impact factors were included, many sports medicine related RCTs are published in other journals. To some extent, this study reflects the methodological reporting quality of RCTs in sports medicine studies.

Abbreviations

RCT: randomized controlled trial, CONSORT = Consolidated Standards of Reporting Trials, EBM = evidence-based medicine.

Declarations

Conflict of interest

No competing interest declared.

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References

1. *Guide to clinical preventive services, continued. Report of the US Preventive Services Task Force*. J Am Osteopath Assoc, 1991. 91(5): p. 491–9.
2. Schulz KF, et al. Empirical evidence of bias. Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. Jama. 1995;273(5):408–12.
3. Moher D, et al. Does quality of reports of randomised trials affect estimates of intervention efficacy reported in meta-analyses? Lancet. 1998;352(9128):609–13.
4. El-Bahy AA, et al. Antiapoptotic effect of DDB against hepatic ischemia-reperfusion injury. J Toxicol Sci. 2011;36(2):145–54.
5. Bai Y, et al. Methodological reporting of randomized clinical trials in major gastroenterology and hepatology journals in 2006. Hepatology. 2009;49(6):2108–12.
6. Zhai X, et al. Methodological Reporting Quality of Randomized Controlled Trials in 3 Leading Diabetes Journals From 2011 to 2013 Following CONSORT Statement: A System Review. Med (Baltim). 2015;94(27):e1083.
7. Narayan VM, et al. Improved Reporting of Randomized Controlled Trials in the Urologic Literature. Eur Urol. 2016;70(6):1044–9.
8. Chen X, et al. Methodological reporting quality of randomized controlled trials in three spine journals from 2010 to 2012. Eur Spine J. 2014;23(8):1606–11.
9. Bhandari M, et al. The quality of reporting of randomized trials in the Journal of Bone and Joint Surgery from 1988 through 2000. J Bone Joint Surg Am. 2002;84(3):388–96.
10. Brophy RH, Kluck D, Marx RG. Update on the Methodological Quality of Research Published in The American Journal of Sports Medicine: Comparing 2011–2013 to 10 and 20 Years Prior. Am J Sports Med. 2016;44(5):1343–8.
11. Yoon U, Knobloch K. Quality of reporting in sports injury prevention abstracts according to the CONSORT and STROBE criteria: an analysis of the World Congress of Sports Injury Prevention in 2005 and 2008. Br J Sports Med. 2012;46(3):202–6.
12. Robinson KA, Dickersin K. Development of a highly sensitive search strategy for the retrieval of reports of controlled trials using PubMed. Int J Epidemiol. 2002;31(1):150–3.
13. Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Bmj. 2010;340:c332.

14. Ahmed Ali U, et al. Trends in worldwide volume and methodological quality of surgical randomized controlled trials. Ann Surg. 2013;258(2):199–207.
15. Zhang PL, et al. Protective effect of dl-3n-butylphthalide preconditioning on focal cerebral ischaemia-reperfusion injury in rats. Acta Neuropsychiatr. 2013;25(1):12–7.
16. Hill AB. The clinical trial. N Engl J Med. 1952;247(4):113–9.
17. Moher D, et al. Opportunities and challenges for improving the quality of reporting clinical research: CONSORT and beyond. Cmaj. 2004;171(4):349–50.
18. Mhaskar R, et al. Published methodological quality of randomized controlled trials does not reflect the actual quality assessed in protocols. J Clin Epidemiol. 2012;65(6):602–9.
19. Huwiler-Muntener K, et al. Quality of reporting of randomized trials as a measure of methodologic quality. Jama. 2002;287(21):2801–4.
20. Begg C, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. Jama. 1996;276(8):637–9.
21. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet. 2001;357(9263):1191–4.
22. Alvarez F, et al. CONSORT adoption and quality of reporting of randomized controlled trials: a systematic analysis in two dermatology journals. Br J Dermatol. 2009;161(5):1159–65.
23. Cui Q, et al. Does the CONSORT checklist for abstracts improve the quality of reports of randomized controlled trials on clinical pathways? J Eval Clin Pract. 2014;20(6):827–33.
24. Strech D, et al. Quality of reporting of randomized controlled trials of pharmacologic treatment of bipolar disorders: a systematic review. J Clin Psychiatry. 2011;72(9):1214–21.
25. Turner L, et al. Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals. Cochrane Database Syst Rev. 2012;11:Mr000030.
26. Can OS, et al. Has the quality of abstracts for randomised controlled trials improved since the release of Consolidated Standards of Reporting Trial guideline for abstract reporting? A survey of four high-profile anaesthesia journals. Eur J Anaesthesiol. 2011;28(7):485–92.
27. Ghimire S, et al. Assessment of adherence to the CONSORT statement for quality of reports on randomized controlled trial abstracts from four high-impact general medical journals. Trials. 2012;13:77.
28. Viera AJ, Bangdiwala SI. Eliminating bias in randomized controlled trials: importance of allocation concealment and masking. Fam Med. 2007;39(2):132–7.
29. Schulz KF, Grimes DA. Allocation concealment in randomised trials: defending against deciphering. Lancet. 2002;359(9306):614–8.
30. Auleley GR, et al. The methods for handling missing data in clinical trials influence sample size requirements. J Clin Epidemiol. 2004;57(5):447–53.

31. Wood AM, White IR, Thompson SG. Are missing outcome data adequately handled? A review of published randomized controlled trials in major medical journals. Clin Trials. 2004;1(4):368–76.

Tables

Table1 Principal characteristics of the included trials

	No. of trials (%)
Year	
2008-2010	112(23.6)
2011-2017	363(76.4)
No. of authors	
1-3	65(13.7)
4-6	278(58.5)
>6	132(27.8)
Journal	
American journal of sports medicine	200(42.1)
British journal of sports medicine	148(31.2)
Journal of Science and Medicine in Sport	127(26.7)
Center	
Single	435(91.6)
Multi	40(8.4)
Country	
U.S./Canada	72(15.2)
Europe	209(44.0)
Asia/Oceania	170(35.8)
Africa/South America	24(5.1)
Other	0(0)
Funding	
Industry	76(16.0)
Public	230(48.4)
None	37(7.8)
Not specific	149(31.4)

Not specific	149(31.4)
Type of intervention	
Medical	98(20.6)
Surgical	106(22.3)
Rehabilitation	162(34.1)
Others	109(22.9)
No. of patients	
≤100	349(73.5)
> 100	126(26.5)

Table 2 Methodological analysis of the 475 RCTs

	No. of trials (%)
Baseline present	333(70.1)
Generation of allocation	166(34.9)
Computer	114(24.0)
Random table	19(4.0)
Other	33(6.9)
Concealment of allocation	124(26.1)
Central/pharmacy	15(3.2)
Envelope	91(19.2)
Other	18(3.8)
Blinding	262(55.2)
Single blinding	138(29.1)
Double blinding	124(26.1)
Type of analysis	
Intention to treat	122(25.7)
Per protocol	27(5.7)
Not stated	347(73.1)
Handling of dropouts	100(21.1)
Result	
Statistically significant	332(69.9)
No difference	143(30.1)

Table 3 Methodological reporting quality of RCTs in three major sports medicine journals from 2008 to 2017 according to different strata

	Statistically significant	Adequate baseline	Adequate allocation sequence	Adequate allocation	Adequate blinding	Adequate type of	Adequate handling

	results n(%)	n (%)	generation n(%)	concealment n(%)	n(%)	analysis n(%)	of dropout n(%)
Year							
2008-2010(n=112)	73(65.2)	78(69.6)	26(23.2)	38(33.9)	57(50.9)	33(29.5)	10(8.9)
2011-2017(n=363)	259(71.3)	255(70.2)	140(38.6)	86(23.7)	205(56.5)	95(26.2)	90(24.8)
p value	0.213	0.903	0.003*	0.031*	0.299	0.492	<0.001*
Journal							
American journal of sports medicine (n=200)	122(61.0)	130(65.0)	103(51.5)	88(44.0)	120(60.0)	61(30.5)	51(25.5)
British journal of sports medicine (n=148)	109(73.6)	116(78.4)	35(23.6)	27(18.2)	80(54.1)	51(34.5)	35(23.6)
Journal of Science and Medicine in Sport(n=127)	101(79.5)	87(68.5)	28(22.0)	9(7.1)	62(48.8)	16(12.6)	14(11.0)
p value	0.001*	0.024*	<0.001*	<0.001*	0.133	<0.001*	0.005*
Setting							
single-center(n=435)	302(69.4)	300(69.0)	148(34.0)	115(26.4)	236(54.3)	113(26.0)	93(21.4)
multi-center(n=40)	30(75.0)	33(82.5)	18(45.0)	9(22.5)	26(65.0)	15(37.5)	7(17.5)
p value	0.462	0.074	0.164	0.587	0.191	0.116	1.000
Country							
U.S./Canada(n=72)	45(62.5)	57(79.2)	31(43.1)	20(27.8)	46(63.9)	22(30.6)	14(19.4)
Europe(n=209)	149(71.3)	157(75.1)	59(28.2)	67(32.1)	108(51.7)	67(32.1)	55(26.3)
Asia/Oceania(n=170)	119(70.0)	104(61.2)	72(42.4)	32(18.8)	95(55.9)	38(22.4)	30(17.6)
Africa/South America(n=24)	19(79.2)	15(62.5)	4(16.7)	5(20.8)	13(54.2)	1(4.2)	1(4.2)
p value	0.385	0.006*	0.003*	0.030*	0.349	0.010*	0.031*
Funding							
Industry (n=76)	50(65.8)	49(64.5)	31(40.8)	22(28.9)	52(68.4)	20(26.3)	24(31.6)
Public(n=230)	162(70.4)	172(74.8)	79(34.3)	48(20.9)	124(53.9)	72(31.3)	55(23.9)
None(n=37))	30(81.1)	22(59.5)	5(13.5)	3(8.1)	19(51.4)	2(5.4)	2(5.4)
Not specific(n=149)	102(68.5)	100(67.1)	56(37.6)	55(36.9)	77(51.7)	38(25.5)	23(15.4)
p value	0.393	0.107	0.028*	<0.001*	0.090	0.011*	0.002*
Type of intervention							
Medical(n=98)	63(64.3)	69(70.4)	29(29.6)	29(29.6)	82(83.7)	22(22.4)	23(23.5)
Surgical(n=106)	64(60.4)	63(59.4)	60(56.6)	54(50.9)	59(55.7)	25(23.6)	20(18.9)
Rehabilitation(n=162)	120(74.1)	123(75.9)	53(32.7)	34(21.0)	78(48.1)	59(36.4)	35(21.6)
Others(n=109)	85(78.0)	78(71.6)	24(22.0)	7(6.4)	43(39.4)	22(20.2)	22(20.2)
p value	0.013*	0.037*	<0.001*	<0.001*	<0.001*	0.009*	0.867
No. of patients							
≤100(n=349)	244(69.9)	231(66.2)	122(35.0)	90(25.8)	203(58..2)	70(20.1)	61(17.5)
> 100(n=126)	88(69.8)	102(81.0)	44(34.9)	34(27.0)	59(46.8)	58(46.0)	39(31.0)
p value	0.988	0.002*	0.994	0.793	0.028*	<0.001*	0.001*

*$p < 0.05$

Figures

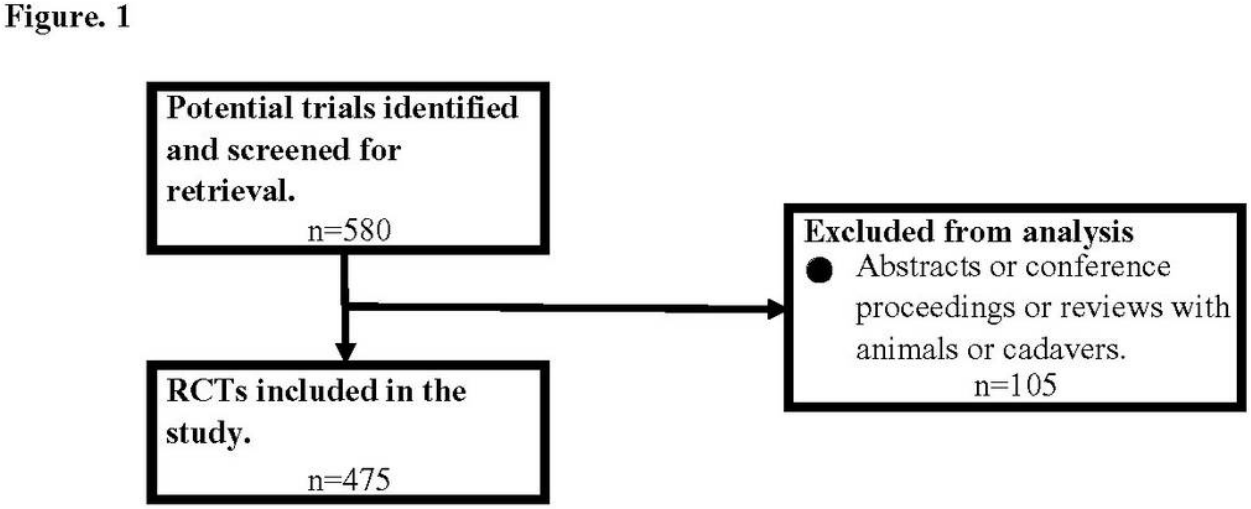

Figure 1

Flow diagram of RCTs included

Figure. 2

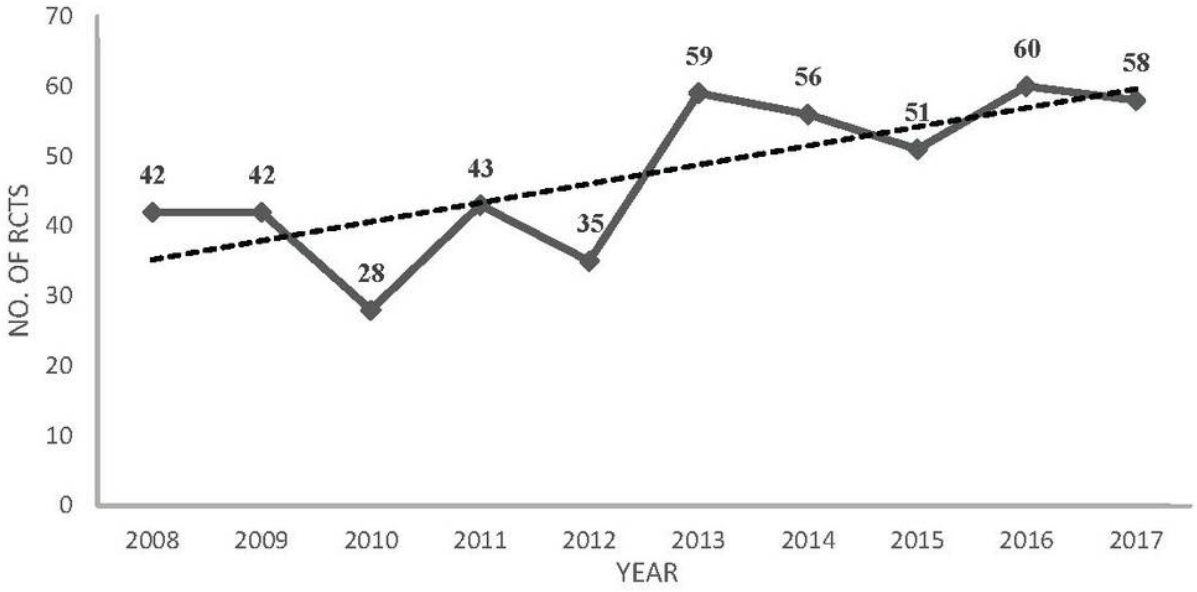

Figure 2

The trend of the number of articles during the past ten years