Retracted randomised controlled trials were cited and not corrected in systematic reviews and clinical practice guidelines

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ORIGINAL ARTICLE

Retracted randomized controlled trials were cited and not corrected in systematic reviews and clinical practice guidelines

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Abstract

Background and Objectives: To investigate whether and when the correction is done in Systematic Reviews (SRs) and Clinical Practice Guidelines (CPGs) when included Randomized Controlled Trials (RCTs) have been retracted.

Methods: In this meta-epidemiological study, we included SRs and CPGs citing the retracted RCTs from the Retraction Watch Database. We investigated how often the retracted RCTs were cited in SRs and CPGs. We also investigated whether and when such SRs and CPGs corrected themselves.

Results: We identified 587 articles (525 SRs and 62 CPGs) citing retracted RCTs. Among the 587 articles, 252 (43%) were published after retraction, and 335 (57%) were published before retraction. Among 127 articles published citing already retracted RCTs in their evidence synthesis without caution, none corrected themselves after publication. Of 335 articles published before retraction, 239 included RCTs that were later retracted in their evidence synthesis. Among them, only 5% of SRs (9/196) and 5% of CPGs (2/43) corrected or retracted their results.

Protocol and Registration: We developed and registered the protocol before conducting this study (https://osf.io/cjbdf/).

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Competing interests: TAF reports grants and personal fees from Mitsubishi-Tanabe, personal fees from SONY, grants and personal fees from Shionogi, outside the submitted work; In addition, TAF has a patent 2020-548,587 concerning smartphone CBT apps pending and intellectual properties for Kokoro-app licensed to Mitsubishi-Tanabe. The other authors have no conflict of interest.

Ethical approval: Not required.

Data sharing: Dataset available from the corresponding author upon the request.

Transparency statement: The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Dissemination to participants and related patient and public communities: We plan to present our findings at a national scientific meeting. We also plan to use social media outlets to disseminate findings.

Conflict of interest: Yuki Kataoka: none known. Masahiro Banno: none known. Yasushi Tsujimoto: none known. Takashi Ariie: none known. Shunsuke Taito: none known. Tomoharu Suzuki: none known. Shiho Oide: none known. Toshi A. Furukawa: grants and personal fees from Mitsubishi-Tanabe, personal fees from SONY, grants and personal fees from Shionogi, outside the submitted work; In addition, TAF has a patent 2020-548,587 concerning smartphone CBT apps pending, and intellectual properties for Kokoro-app licensed to Mitsubishi-Tanabe.

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Conclusion: Many SRs and CPGs included already or later retracted RCTs without caution. Most of them were never corrected. The scientific community, including publishers and researchers, should make systematic and concerted efforts to remove the impact of retracted RCTs.

Keywords: Systematic review; Clinical practice guideline; Retraction; Correction; Retraction watch database; Meta-epidemiological study

1. Introduction

Systematic Reviews (SR) and Clinical Practice Guidelines (CPG) aggregating randomized controlled trials (RCT) are vital sources of information for clinical decision making [1]. There are guidelines on how to report SRs [2] and to create CPGs [3] in a rigorous scientific manner. One important point to remember is that all these methodologies assume that the data used in their evidence synthesis is valid [4].

In recent years, much attention has been paid to the retraction of papers due to scientific misconduct [5,6]. Notable recent examples include RCTs of ivermectin [7,8] and a cohort study of hydroxychloroquine, both for COVID-19 [9]. In addition, there are high profile retractions, some researchers retracted dozens of articles due to misconduct [10,11]. An increasing number of studies have investigated the fate of such retracted studies: some studies have evaluated the impact of retracted articles on social media [12] or reported on the ongoing citations of retracted articles in some specialties such as radiation oncology, dentistry, or COVID-19 [6,13–15]. The Cochrane Database of Systematic Reviews has developed a new policy to address potentially problematic studies including retraction [16]. The policy provides practical guidance for the management of retracted articles for Cochrane Review authors.

However, to the best of the current authors' knowledge, no studies have comprehensively examined how retracted RCTs are acknowledged in the evidence synthesis in SRs and CPGs. In this study, we, therefore, investigated whether and when the correction is done in SRs and CPGs when they included retracted RCTs.

2. Methods

2.1. Protocol and registration

This meta-epidemiological study was conducted and reported in accordance with a guideline for reporting meta-epidemiological methodology research [17] (Table S1). The protocol of the

2.2. Search and selection for retracted RCTs

We searched the Retraction Watch Database (RWD) for retracted RCTs on 27th July 2021 using the term "random*" in the title although limiting the article type to "clinical study." [18]. RWDpresent study has been published in OSF [19]. contains more than 28,000 entries of retracted articles dating back to 1,756 [18]. The database contains titles of articles but not abstracts. Two independent reviewers (YK, and MB) then identified RCTs from the full-text articles retrieved based on the search results. An RCT is defined as "a work that reports on a clinical trial that involves at least one test treatment and one control treatment, concurrent enrollment and follow-up of the test- and control-treated groups, and in which the treatments to be administered are selected by a random process" [20]. We did not include quasi-randomized controlled trials. Disagreements were resolved through discussion.

2.3. Search and identification of SRs and CPGs citing retracted RCTs

We searched each retracted RCT in the Web of Science (WOS) on 18th Oct 2021 [21] to identify references which cited the retracted RCTs. The articles not indexed in the WOS were excluded. We placed no restrictions on the date or language.

We included all SRs and CPGs citing the identified retracted RCT articles published before November 2021. The SR was defined as "a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies" [3]. We included any SR, with or without meta-analysis. The definition of the CPG was "statements that include recommendations intended to optimize patient care. They are informed by systematic reviews of evidence and an assessment of the benefits and harms of alternative care options" [3]. If updated SR was found, we only included the first publication. If there were concurrent publications of CPGs, we only included one publication.

From the searched titles and abstracts, different pairs of two of seven review authors (YK, MB, YT, TA, ST, TS, and SO) independently selected SRs and CPGs. Disagreements were resolved through discussion. We then retrieved the full text articles and different pairs of two of seven review authors (YK, MB, YT, TA, ST, TS, and SO) independently identified SRs and CPGs. We resolved any disagreement through discussion or, if required, we consulted a third reviewer. We excluded articles published in journals without websites because the judgment of correction of SR or CPG in such journals was difficult, in other words, print-only journals were excluded for lack of access to all volumes.

What is new?

Key findings

- We identified 587 articles (525 SRs and 62 CPGs) citing retracted RCTs.
- A considerable number of SRs and CPGs cited already retracted RCTs and none corrected themselves later.
- Only a small minority of SRs (5%, 9/196) and CPGs (5%, 2/43) which cited RCTs that were later retracted corrected, or retracted their findings.

What this adds to what was known?

- There are anecdotal reports of publications citing retracted RCTs and point to the problem of their continued citation after retraction.
- However, there are no studies that comprehensively examined the fate of retracted RCTs on SRs and CPGs in their evidence synthesis.

What is the implication and what should change now?

- The results indicate that publishers and researchers should make efforts to remove the impact of retracted RCT.

2.4. Primary outcome

We calculated the proportion of correction among SRs and CPGs, respectively. For SRs, the denominator was the number of SR articles which used the retracted article in the results section for evidence synthesis. We excluded from the denominator the SRs which cited an RCT that was later retracted but did not use to obtain the results. The numerator was the number of SR articles which corrected or retracted the results irrespective of the reasons. For CPGs, the denominator was CPGs which cited retracted RCT in the explanation of recommendations. The numerator was the number of CPGs which corrected the explanation of recommendation considering the retracted RCT. We presented the outcome separately for articles published before and after retraction.

2.5. Data extraction

We extracted the following data from the search results of the WOS of the included articles: the number of authors, country of the authors, publication date, and the number of citations as of 21st Apr 2022 [22]. We used the Selenium package version 3.141.0 and the ChromeDriver version 96.0.4664.45 under Python 3.7 to extract these data. Different pairs of two of seven review authors (YK, MB, YT, TA, ST, TS, and SO) independently evaluated where the retracted articles were cited in the full text of SRs or CPGs.

In addition, one of seven review authors (YK, MB, YT, TA, ST, TS, and SO) inspected the online article pages in the journal of the included SRs and CPGs to determine whether their texts were corrected and if corrected, when they were corrected [23]. Then another reviewer confirmed the results of the inspection. We resolved the disagreements through discussion. We conducted the inspections between the fourth and the 13th of May 2022.

2.6. Statistical analysis

We used descriptive statistics to summarize. For survival analysis, we used the publication and retraction date of RCTs from RWD. We estimated the time to correction using the Kaplan-Meier method. We used R ver. 4.1.2 (R Foundation for Statistical Computing, Vienna, Austria).

2.7. Ethical consideration

We used publicly available data only, and ethical considerations for participants were unnecessary.

2.8. Patient and public involvement

Patients and members of the public were not involved in the research because it was designed to investigate the current methodological practice in the SR and CPG.

2.9. Differences between the protocol and the review

We did not conduct univariate and multivariable analyses, because of the small number of corrected SRs or CPGs.

3. Results

3.1. Search results

Figure 1 shows the study flow chart. From 28,960 records indexed in the RWD, we identified potentially eligible 189 RCT records. Excluding three protocols, three systematic reviews, one nonrandomized study, and 30 records not indexed in the WOS, we finally included 152 retracted RCT articles (Table S2). The reasons of retraction of RCTs are shown in Table S3. By citation search of the 152 retracted RCT articles in the WOS, we found 6,951 records citing these retracted RCTs. By title and abstract screening, we selected 718 articles for full text examination. After full text screening, we finally included 525 SRs and 62 CPGs (Table S4).

3.2. Primary outcomes

Of the 525 SRs and 62 CPGs, 252 (43%) articles cited RCTs already retracted before their publication (Table 1), and 335 (57%) articles cited RCTs which were later

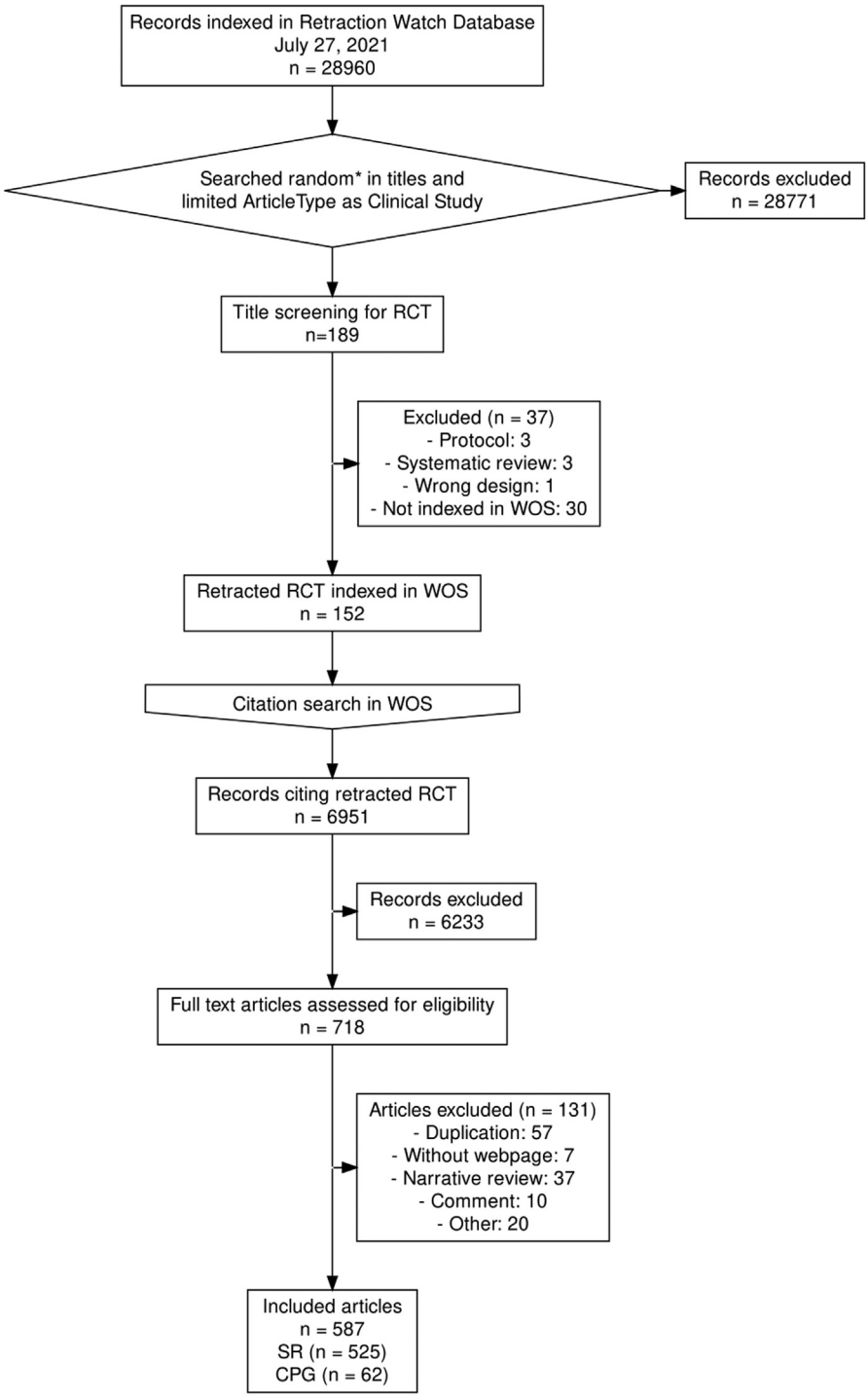

Fig. 1. Study flow chart. *Abbreviations*: WOS, Web of Science; RCT, randomized controlled trials; SR, systematic reviews; CPG, clinical practice guidelines.

retracted (Table 2). Among 252 SR and CPG articles which cited already retracted RCTs, 135 (54%) articles cited retracted RCTs in the evidence synthesis.

Among 335 SR and CPG articles, in which cited RCTs were later retracted, 239 (71%) articles cited retracted RCTs in the evidence synthesis.

Of the 135 articles citing already retracted RCTs in their evidence synthesis, 127 articles (94%) cited the retracted RCT without caution. The median days from retraction of the included RCT to the publication of the citing SR or CPG was 883 days (interquartile range [IQR]: 336, 1,714), hence apparently sufficient time to notice the

Table 1. Characteristics of SR and CPG articles which cited already retracted RCTs

Characteristic	Overall, $N = 252$[a]	Cited in the background, $N = 21$[a]	Cited in the methods, $N = 1$[a]	Cited in the evidence synthesis, $N = 135$[a]	Cited in the results but excluded, $N = 66$[a]	Cited in the discussion, $N = 29$[a]
Correction						
Mentioned as retracted	58 (23%)	3 (14%)	0 (0%)	8 (5.9%)	41 (62%)	6 (21%)
Excluded due to exclusion criteria	25 (10%)	0 (0%)	0 (0%)	0 (0%)	25 (38%)	0 (0%)
No correction	169 (67%)	18 (86%)	1 (100%)	127 (94%)	0 (0%)	23 (79%)
Type						
CPG	17 (6.7%)	1 (4.8%)	0 (0%)	11 (8.1%)	4 (6.1%)	1 (3.4%)
SR	235 (93%)	20 (95%)	1 (100%)	124 (92%)	62 (94%)	28 (97%)
Number of authors	5 (3, 7)	6 (4, 7)	13	5 (3, 7)	5.5 (4, 7)	5 (3, 7)
Citation	12 (3, 32)	12 (2, 18)	33	9 (2, 27)	18 (7, 37)	11 (4, 44)
Time from retraction to publication (days)	878 (341, 1,676)	822 (346, 1,838)	2,799	883 (336, 1,714)	958 (388, 1,679)	796 (249, 1,206)

Abbreviations: CPG, clinical practice guideline; RCT, randomised controlled trials.
[a] *n* (%); Median (interquartile range).

retraction. None of these SRs and CPGs subsequently corrected themselves after their publication up to mid-May 2022.

A total of 239 articles cited RCTs in their evidence synthesis, which was later retracted. Among them, two SRs were retracted before the RCT retraction. One was due to the plagiarism; another was due to concerns about the author's credibility (many publications by the author had been withdrawn because of fabrication). Including these two SRs, results were corrected in 5% of SRs (9/196) and 5% of CPGs (2/43). Excluding these two SRs, Figure 2 shows the time from the retraction to correction of these 237 pre-retraction-published articles. Among nine corrected SRs and CPGs, the median days from retraction to correction was 264.5 (interquartile range: 76, 1617.5).

4. Discussion

4.1. Summary of findings

This study presents the most comprehensive and up-to-date investigation of the impact of retracted RCTs in the clinically most sensitive literature on SRs and CPGs. We found 127 SRs and CPGs which cited already retracted

Table 2. Characteristics of SR and CPG articles whose cited RCTs were later retracted

Characteristic	Overall, $N = 335$[a]	Cited in the background, $N = 31$[a]	Cited in the methods, $N = 1$[a]	Cited in the evidence synthesis, $N = 239$[a]	Cited in the results but excluded, $N = 35$[a]	Cited in the discussion, $N = 29$[a]
Correction						
Corrected	11 (3%)	0 (0%)	0 (0%)	11 (5%)[b]	0 (0%)	0 (0%)
Mentioned as retracted	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Excluded due to the concern about the study group	10 (3%)	0 (0%)	0 (0%)	0 (0%)	9 (26%)	1 (3.4%)
Excluded due to exclusion criteria	26 (8%)	0 (0%)	0 (0%)	0 (0%)	26 (74%)	0 (0%)
No correction	288 (89%)	31 (100%)	1 (100%)	228 (95%)	0 (0%)	28 (97%)
Type						
CPG	45 (13%)	0 (0%)	0 (0%)	43 (18%)	2 (5.7%)	0 (0%)
SR	290 (87%)	31 (100%)	1 (100%)	196 (82%)	33 (94%)	29 (100%)
Number of authors	5 (3, 8)	4 (3, 6)	3	5 (3, 8.5)	6 (4, 8)	6 (4, 7)
Citation	32 (13, 72)	32 (10, 68)	81	31 (13, 68)	46 (16, 146)	30 (13, 64)

Abbreviations: CPG, clinical practice guideline; SR, systematic review.
[a] *n* (%); Median (interquartile range).
[b] Two SRs were retracted before the RCT retraction. One was due to the plagiarism; another was due to concerns for the author.

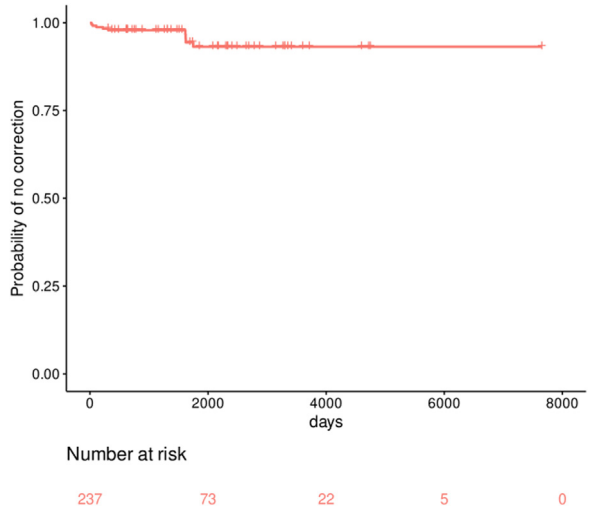

Fig. 2. Time from retraction to correction among articles published before retraction.

RCT without caution, and none of them corrected themselves during a median observation period of more than 2 years. Of 239 SRs and CPGs which included RCTs that were later retracted in their evidence syntheses, less than one in 20 corrected themselves.

4.2. Comparison with other studies

Much attention has been paid recently to the fate and impact of retracted research. Steen evaluated the harmful impact of retracted articles from 2001 to 2010 and found that a large number of patients in trials were treated based on the (mis)information based on retracted articles [24]. Several studies investigated the number of citations after retraction due to scientific misconducts [13,14,25]. Our results indicate that about a half of SRs and CPGs citing already retracted RCTs made inappropriate citations. Avenell et al. investigated the impact of the one osteoporosis research group in doubt. They found that the findings of a third of SRs and CPGs were likely to change if RCTs with concerns were excluded [26]. Hamilton investigated the continued citation of retracted radiation oncology articles. He found several SRs and CPGs cited retracted articles without caution [15]. Our results indicate that most inappropriate citations in SRs and CPGs were not corrected regardless of the timing of retractions. Self-correction in the scientific community has not improved despite repeated warnings.

4.3. Potential implications

To avoid disseminating inappropriate information, both researchers and publishers should be more careful of the possibility of retracted articles.

To decrease the number of SRs and CPGs citing already retracted RCTs, researchers should specifically check that included studies have not been retracted. Although a previous interrupted time-series analysis has shown that retraction does reduce the number of citations of RCTs [27], the present results indicate that inappropriate citations still prevail. Furthermore, retraction information can be delayed in reaching PubMed for up to several years [28], if any information is sent at all. In some cases, it is hard to identify retraction information even on journal web pages [29]. Researchers should check carefully not only the searched abstracts and retrieved full text files but also the journal web pages [30]. Simultaneously, publishers should make the notice of retraction more clearly discoverable on their web pages. They should also send the notice of retraction to databases indexing abstracts such as PubMed as soon as possible following the International Committee of Medical Journal Editors (ICMJE) recommendation [23]. Needless to say, publishers should not publish problematic studies [31].

To improve the timely correction of SRs and CPGs published before retraction, journal editors should send the notice of retraction to publishers citing the retracted article. The retraction guideline of the Committee on Publication Ethics (COPE) and ICMJE recommends journal editors ensure retraction information to appear on all online searches for the retracted publication [23,32]. However, the scope of recommendations does not include other journals citing retracted articles. To send timely information, a semi-automated alert system connecting journals is needed. If there will be such a system, journal editors will be able to send the notice of retraction to other journals easily.

4.4. Limitations

There are several limitations in our study. First, we searched retracted RCTs in clinical medicine through title searches. If there are studies that did not declare themselves to be randomized trials in their titles, the actual number of SRs and CPGs inappropriately citing retracted RCTs may be greater than the present results. For example, we did not include RCTs by J Boldt, an anesthesiologist in the scandal involving 88 paper retractions [5]. Further study is needed to evaluate the influence of retracted RCTs in a more comprehensive manner. Second, we used the WOS to find citing SRs and CPGs. There is a possibility that we underestimated the impact among those not indexed in the WOS. Third, we did not investigate whether the conclusions and recommendations of SRs and CPGs will change when the retraction RCTs are excluded. Retraction is a concept with a certain range from minor to major [33]. A preliminary analysis including various types of study designs showed that meta-analysis including retracted studies due to issues with data tends to overestimate the effect size [34]. For example, one SR based its conclusions on the efficacy of an intervention on a meta-analysis of seven RCTs [35]. However, five of the seven RCTs were later retracted and when we exclude the five

RCTs, the results were no longer statistically significant. Or, the Clinical practice guidelines of the European Association for Endoscopic Surgery on bariatric surgery stated that the ''one-anastomosis gastric bypass was associated with marginally reduced odds for in-hospital morbidity and late complications'' when compared to the Roux-en-Y gastric bypass [36]. This statement is based on two RCTs, one of which was later retracted, and the remaining RCT did not demonstrate any superiority of the one-anastomosis gastric bypass [37]. Continuing to cite and to include RCTs which have been retracted for making false claims, without providing a clear and compelling explanation, is in itself tantamount to scientific misconduct. Fourth, in the data extraction process, articles were reviewed by different pairs of two out of the seven review authors. This may have led to some discrepancies in terms of criteria used by these different pairs, but has also reduced the possibility that the single pair of two reviewers would perpetuate their idiosyncratic criteria throughout the data extraction process.

5. Conclusions

Many SRs and CPGs cited and included RCTs that had been retracted before their own publication and never corrected themselves since then. A great majority of SRs and CPGs that included RCTs which were later retracted did not correct themselves and continued to be available even after one or more of their included RCTs were retracted. The whole scientific and medical community including publishers and researchers should make efforts to remove the impact of retracted RCTs.

CRediT authorship contribution statement

Yuki Kataoka: Formal analysis, Conceptualization, Methodology, Funding acquisition, Resources, Writing – original draft. **Masahiro Banno:** Conceptualization, Methodology, Funding acquisition, Resources, Writing – review & editing. **Yasushi Tsujimoto:** Conceptualization, Methodology, Funding acquisition, Resources, Writing – review & editing. **Takashi Ariie:** Funding acquisition, Resources, Writing – review & editing. **Shunsuke Taito:** Funding acquisition, Resources, Writing – review & editing. **Tomoharu Suzuki:** Funding acquisition, Resources, Writing – review & editing. **Shiho Oide:** Funding acquisition, Resources, Writing – review & editing. **Toshi A. Furukawa:** Conceptualization, Methodology, Resources, Writing – review & editing.

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Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclinepi.2022.06.015.

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