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REVIEW

In Cochrane reviews, risk of bias assessments for allocation concealment were frequently not in line with Cochrane's Handbook guidance

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Abstract

Objectives: The aim of the article was to analyze whether the risk of bias (RoB) judgments for allocation concealment in Cochrane systematic reviews (CSRs) were in line with recommendations from the Cochrane Handbook.

Study Design and Setting: From CSR, we extracted data about judgments and supporting comments about allocation concealment for each included randomized controlled trial (RCT). We compared whether judgments for supporting comments were in line with Cochrane Handbook recommendations.

Results: We analyzed judgments and comments of 721 CSRs in which 10,280 RCTs were included. By following the Cochrane Handbook guidance, we found that judgments for allocation concealment were discrepant for 2,928 trials (29%). Most discrepancies were made for trials where RoB was judged as low (2,693 trials; 92%). Cochrane authors used 66 categories of comments describing envelopes as a method of allocation concealment. In 66 envelope-related categories, describing RoB assessments from 1,529 (15%) of the analyzed RCTs, most of the judgments were low RoB, although only one of those categories is associated with low RoB according to the Cochrane Handbook. Twenty categories of supporting comments, including 642 trials, were related to randomization, not allocation concealment.

Conclusion: One-third of RoB judgments about allocation concealment in Cochrane reviews were discrepant from the Cochrane Handbook recommendations. © 2018 Elsevier Inc. All rights reserved.

Keywords: Bias; Risk of bias; Systematic reviews; Cochrane; Allocation concealment; Quality; Standards

1. Introduction

A bias is a systematic error or deviation from the truth that can lead to underestimation or overestimation of a true effect of the studied intervention in randomized controlled trials (RCTs). It is impossible to know for sure how exactly methodological flaws in study design will affect study results; and therefore, it is customary to assess the risk of bias (RoB) in trials. Cochrane's RoB tool is nowadays considered a standard measure of such risk in RCTs [1].

Cochrane's RoB tool was published in 2008 and updated in 2011. It includes judgments and comments for seven domains of bias, including assessment of randomization sequence and allocation concealment as two domains of selection bias, blinding of participants and personnel as performance bias, blinding of outcome assessors as detection bias, incomplete outcome data as attrition bias, selective reporting as reporting bias and an additional domain of other bias, for any other type of bias that may be found in an RCT [2]. For each of the seven domains, a judgment should be made whether the RoB is high, unclear, or low, and accompanying comment should explain the judgment [2].

In RCTs, random assignment of participants involves two separate steps, including, first, generation of unbiased randomization schedule and second, using the randomized schedule for assigning participants to comparison groups without foreknowledge of upcoming allocations [3]. This second step is also called allocation concealment, which was first used in 1994 [4]. Allocation concealment is therefore a method used to prevent selection bias by concealing the allocation sequence

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What is new?

Key findings

- Almost a third of judgments of risk of bias related to allocation concealment were erroneous, based on the supporting comments the Cochrane authors and by comparing those comments and judgments with the Cochrane Handbook.

What this adds to what was known?

- Judgments of risk of bias in included trials are important components of a systematic review, and risk of bias assessments impact review conclusions.
- If judgments are erroneous, than the conclusions of a review may be misleading.

What is the implication and what should change now?

- Interventions for improving judgments of allocation concealment in Cochrane reviews are warranted.

(e.g., computer-generated random numbers) from those assigning participants to intervention [5].

Assessing RoB is a standard part of a production of Cochrane systematic reviews (CSRs), and the results of that assessment will influence analyses of data and conclusions of a review. Odgaard-Jensen et al. concluded that trials with inadequate or unclear allocation concealment can yield larger estimates of effect compared with trials with adequate allocation concealment [6]. However, if the assessments of certain risks of bias are not in line with recommendations for assessment of bias, this can negatively affect conclusions about the body of evidence produced by CSRs.

The Cochrane Handbook describes three methods that should be judged as low RoB for allocation concealment: central allocation (including telephone, Web-based and pharmacy-controlled randomization), sequentially numbered drug containers of identical appearance, and sequentially numbered, opaque, sealed envelopes [2]. The Handbook explicitly indicates that the situation where "*assignment envelopes were used without appropriate safeguards* (e.g., *if envelopes were unsealed or non-opaque or not sequentially numbered*)" should be judged as unclear RoB. After reading a number of Cochrane reviews, a reader can observe differences in judgments for the same comments and the same comments given different judgments that are not necessarily in line with guidance available to Cochrane authors. Therefore, the aim of this study was to analyze whether judgments of RoB (high, low, or unclear risk) for allocation concealment in CSRs are in line with guidance provided by the Cochrane Handbook for Systematic Reviews of Interventions.

2. Methods

This was a methodological study about assessments of RoB in published CSRs.

2.1. Inclusion and exclusion criteria

We considered for inclusion 955 CSRs of the interventions published from July 2015 to June 2016 in Cochrane Database of Systematic Reviews. We excluded diagnostic, empty, and withdrawn reviews, overviews of systematic reviews, as well as reviews that included only nonrandomized studies. If the CSRs included both RCTs and nonrandomized studies, they were included, but data for allocation concealment were analyzed only for randomized trials.

2.2. Screening

Two authors independently screened all titles/abstracts of CSRs, and all discrepancies in opinion were resolved by the third author.

2.3. Data abstraction

We developed a table for data abstraction, which was piloted using 10 CSRs. Two authors were involved in piloting of the data abstraction table, and calibration exercise was conducted to ensure that data will be abstracted in a uniform manner. After the piloting and calibration exercise, one author extracted data, and the second author verified 10% of all extractions. For each review, we extracted data about a Cochrane review group that published it, the number of RCTs included, judgments and comments about allocation concealment for each included RCT, and whether RCT authors were contacted to get information about this RoB domain.

2.4. Data analysis

We categorized each comment that explained judgment and performed descriptive statistics to describe the results. We then compared each supporting comment with categories of allocation concealment methodology provided by the Cochrane Handbook. Using the Cochrane Handbook, we determined which judgments were in line with the Cochrane Handbook, that is, whether there were any discrepancies in judgment compared with recommendations. Only one author (L.P.), a methodologist experienced in conducting CSRs, assessed whether judgments for explanatory comments were in line with the Cochrane Handbook. We used frequencies and percentages to present the data; data were calculated using Microsoft Excel (Microsoft, Inc., Redmond, WA, USA).

3. Results

3.1. Accuracy of RoB assessments for allocation concealment in the whole sample

We analyzed judgments and comments of 721 CSRs in which 10,280 clinical trials were included (range: 1−105). By following the Cochrane Handbook guidance, we found that judgments for allocation concealment were in line with the Cochrane Handbook for 7,324 trials (71%) and discrepant for 2,928 trials (29%). For the remaining 28 trials, we could not make any conclusion from the RoB table belonging to those trials because either there was no allocation concealment domain in the RoB tool ($N = 17$) or the authors referred reader to check RoB table of another trial ($N = 6$) or there was no RoB table for the analyzed trial in a Cochrane review ($N = 5$).

3.2. Categories of allocation concealment methods used by Cochrane reviewers

We categorized supporting comments for RoB associated with allocation concealment in 295 categories, of which 109 (37%) appeared more than once, and 57 categories (19%) occurred more than five times. Twenty most frequent categories are shown in Table 1, whereas all categories we used are shown in Supplementary Table 1. The most common category of explanatory comment for judging RoB related to allocation concealment was *Not described/unclear*, used by Cochrane authors for 5,947 trials (58%).

3.3. Types of discrepant judgments for allocation concealment

Among the 2,928 trials with discrepant judgments, most discrepancies were found in trials where RoB for allocation concealment was judged as low. There were 2,693 trials (92%), which were judged as low RoB; among them, 13 were supposed to be judged with high RoB, and the rest as unclear RoB for allocation concealment. There were 128 trials (4.4%) that were judged as having high RoB; all of them should have been judged as unclear RoB for allocation concealment. All the 107 trials (3.7%) judged discrepantly as unclear RoB for allocation concealment should have been judged with high RoB because of open allocation. Flowchart shown in Fig. 1 summarizes this assessment.

When we compared comments supporting judgments for RoB related to allocation concealment with Cochrane Handbook, in 1,267 trials (43%), a comment did not describe allocation concealment method at all. Cochrane authors judged these RCTs as low or high RoB, instead of unclear. In 1,045 trials (36%), Cochrane authors provided comments regarding using envelopes as a method of allocation concealment, but the explanation missed one or more components of the correct envelope method described in the Cochrane Handbook: sequentially numbered opaque sealed envelopes (SNOSE). Therefore, all those trials describing envelope methods that did not include a full SNOSE description should have been judged as unclear for RoB related to allocation concealment. Examples of such categories are *sealed envelopes* and *opaque sealed envelopes*, which Cochrane authors predominantly judged as low RoB for allocation concealment.

There were 338 trials (12%) where a comment provided insufficient information to properly judge whether allocation concealment method was in line with the Cochrane Handbook. In nine trials, field for comment regarding this RoB domain was completely blank—there was no explanation of the judgment at all. There were 27 trials where Cochrane authors wrote comments such as adequate, inadequate, concealed, yes, no—without any further justification regarding allocation concealment method. The remaining 242 trials had various types of discrepancies, which should have been different compared with the one Cochrane authors made. For example, Cochrane authors wrote "*allocation concealment was not reported*" and then judged this domain as high RoB, whereas lack of information should lead to the judgment of unclear RoB.

3.4. Comments for allocation concealment describing using envelopes

The most commonly used categories of explanatory comments described using envelopes as a method of allocation concealment; there were 66 envelopes-related categories, describing RoB assessments from 1,529 (15%) of the analyzed RCTs. Cochrane authors used various terminology when describing these envelope-related methods (Table 2). Only one of those 66 categories should have been rated as low RoB for allocation concealment, the one describing SNOSE, in line with the recommendations from the Cochrane Handbook. However, among 268 RCTs that used this category, 266 rated it as low RoB, and two rated it as unclear RoB (Table 2).

All the other 65 envelopes-related categories, found in 1,261 RCTs, should have been rated either as unclear or high RoB. However, as many as 1,008 RCTs (79% of all RCTs that were rated as low RoB in the envelopes-related categories) were rated as having low RoB for allocation concealment (Table 2), despite the guidance from the Cochrane Handbook.

Eight of those categories indicated that something related to envelope method was missing or potentially missing, such as categories "envelopes not numbered" or "opaque sealed envelopes, not numbered." These eight categories described only 13 RCTs (Table 2).

3.5. Comments for allocation concealment describing randomization

Twenty categories were related to randomization, not allocation concealment. The most common of those randomization-related categories were comments indicating that study was randomized (346 RCTs), that a trial had central randomization (251 RCTs) or that a trial was randomized

Table 1. Twenty most common categories of supporting comments used for judging risk of bias related to allocation concealment in trials included in analyzed Cochrane systematic reviews

Category	Total *N* (%) of all analyzed reviews, *N* = 10,280	Correct judgment for this comment according to the Cochrane Handbook	*N* of low risk (%) within the category	*N* of unclear risk (%) within the category	*N* of high risk (%) within the category
Not described/unclear	5,947 (58)	Unclear risk	69 (1)	5,710 (96)	168 (3)
Sealed envelopes	523 (5)	Unclear risk	387 (74)	131 (25)	5 (1)
Randomized	346 (3)	Unclear risk	256 (74)	80 (23)	10 (3)
Sequentially numbered opaque sealed envelopes	267 (2.6)	Low risk	266 (99)	1 (1)	0 (0)
Opaque sealed envelopes	261 (2.5)	Unclear risk	245 (94)	14 (5)	2 (1)
Central randomization	251 (2.4)	Unclear risk	240 (96)	11 (4)	0 (0)
Third party	239 (2)	Unclear risk	214 (90)	22 (9)	3 (1)
Allocation predictable	163 (1.5)	High risk	4 (3)	7 (4)	152 (93)
Open allocation	153 (1.4)	High risk	9 (6)	5 (3)	139 (91)
Central allocation	151 (1.4)	Low risk	149 (99)	2 (1)	0 (0)
Blinded	131 (1)	Unclear risk	120 (92)	11 (8)	0 (0)
Interactive voice response system	103 (1)	Low risk	102 (99)	1 (1)	0 (0)
Concealed	97 (0.9)	Unclear risk	92 (95)	4 (4)	1 (1)
Envelopes	89 (0.8)	Unclear risk	52 (58)	32 (36)	5 (6)
See quote above	84 (0.8)	Unclear risk	60 (72)	17 (20)	7 (8)
Central allocation by telephone	82 (0.7)	Low risk	82 (100)	0 (0)	0 (0)
Adequate	81 (0.7)	Unclear risk	80 (99)	0 (0)	1 (1)
Opaque envelopes	80 (0.7)	Unclear risk	75 (94)	2 (2)	3 (4)
Central allocation by pharmacy	68 (0.6)	Low risk	65 (96)	3 (4)	0 (0)
Access to randomization code restricted	65 (0.6)	Unclear risk	63 (97)	1 (1.5)	1 (1.5)

and blinded (23 RCTs; Table 3). Those categories belong to the domain related to random sequence generation because randomization is not the same as allocation concealment.

3.6. Comments for allocation concealment describing blinding

There were 13 categories related to blinding, where the most common was category of comment that simply indicated that blinding was used in a trial (131 RCTs), whereas the other blinding-related categories were seldom used. In these other categories, Cochrane authors indicated that physicians were blinded, that the study was double-blind, or that there was no blinding (Supplementary Table 1).

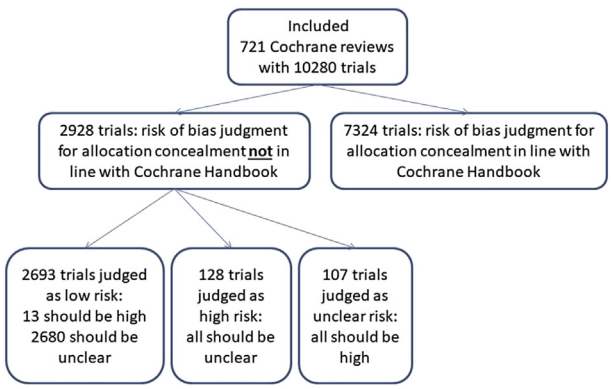

Fig. 1. Flowchart of trials included in analyzed Cochrane reviews and their adherence to instructions from the Cochrane Handbook.

3.7. Other common categories of comments related to allocation concealment

Other categories worth noting were those related to a person who conducted allocation concealment, often describing third persons who were not involved with a trial, without specifying the method of allocation concealment. Frequent categories of comments were related to baseline characteristics of participants and timing of allocation concealment, but, again, without specifying methods of allocation concealment (Supplementary Table 1).

3.8. Contacting trial authors for clarification

In the total sample of 10,280 included trials, Cochrane authors indicated for 261 (2.5%) of comments for RoB regarding allocation concealment that they contacted trial authors to obtain clarification for judging this risk. Among 5,947 trials for which Cochrane authors used category *Not described/unclear* regarding allocation concealment, in 86 comments (1.4%), it was indicated that the Cochrane authors contacted trial authors for clarification.

Table 2. Ten most frequent categories related to using envelopes for allocation concealment

Category	Total *N* (%) of reviews using envelope method, *N* = 1,529	*N* of low risk (%) within the category	*N* of unclear risk (%) within the category	*N* of high risk (%) within the category
Sealed envelopes	523 (34)	387 (74)	131 (25)	5 (1)
Sequentially numbered, opaque, sealed envelopes (SNOSE)	268 (17.5)	266 (99)	2 (1)	0 (0)
Opaque sealed envelopes	261 (17)	245 (94)	14 (5)	2 (1)
Envelopes	89 (6)	52 (58)	32 (36)	5 (6)
Opaque envelopes	80 (5)	75 (94)	2 (2)	3 (4)
Sequentially numbered sealed envelopes	57 (4)	52 (91)	5 (9)	0 (0)
Numbered sealed envelopes	47 (3)	42 (89)	5 (11)	0 (0)
Closed envelopes	38 (2.5)	27 (71)	11 (29)	0 (0)
Sequentially numbered opaque envelopes	28 (1.8)	24 (86)	4 (14)	0 (0)
Numbered envelopes	23 (1.5)	18 (78)	5 (22)	0 (0)

According to the Cochrane Handbook, only sequentially numbered, opaque, sealed envelopes (SNOSE) methods should be judged as low risk of bias, whereas all other incomplete descriptions of envelope method should be judged as unclear risk of bias.

4. Discussion

In this study, we found that in almost one-third of trials included in 721 Cochrane reviews, assessment of RoB for allocation concealment was not in line with recommendations from Cochrane Handbook. Most of the discrepancies were made in trials that were judged as having a low RoB for allocation concealment, which ultimately may lead to misrepresentation of evidence included in those reviews.

Allocation concealment methods mentioned in the analyzed supporting comments most commonly mentioned envelope-related methods, and this was the most common category of explanatory comment in our analysis. However, of 66 categories related to envelope methods, only one—SNOSE—should have been judged as low RoB for allocation concealment. Therefore, discrepancies in RoB judgment related to insufficiently described envelope methods were the most common problems we found in this study.

The other most common categories of comments were related to randomization, blinding, baseline characteristics of participants, persons who conducted allocation concealment and timing of allocation concealment, but without actually providing information or sufficient information about allocation concealment methods. The sixth most common category used in our study was "central randomization." Randomization may have been done centrally, but allocation concealment is the next step, which may not have been done properly, even with central randomization. However, one can also find different opinions in the literature, indicating that only proper central randomization is low RoB for allocation concealment [7].

The findings of this study are very important for several reasons. First, individual RoB judgments in CSRs are used to generate judgments of overall quality or overall RoB in systematic reviews [1]. Therefore, if individual judgments are not in line with recommendations, then the overall conclusions about a systematic review in question may be flawed. By making discrepant judgments of RoB, Cochrane authors may propagate mistakes about the adequacy of evidence included in systematic reviews. We found that the overwhelming majority of the discrepancies in judging RoB for allocation concealment were made for trials that were judged as having low RoB for this domain. This means that Cochrane authors are sending the wrong signals about the methodological adequacy of analyzed evidence, indicating that these trials may have a better methodology than they actually do and higher level of quality of evidence.

Furthermore, our results directly impact studies in which various conclusions are drawn based on RoB of analyzed studies. Dechartres et al. in 2017 reported that poor reporting and inadequate methods have decreased over time, by analyzing RoB in more than 20,000 trials included in Cochrane reviews [8], but their analysis relied on judgments of Cochrane authors, which may not be in line with Cochrane recommendations, as our study showed.

In this study, we analyzed only CSRs, which are usually reported as having better methodological and reporting quality compared with non-Cochrane reviews [9–12]. Therefore, we can only speculate that the results would be at least similar or even worse, in terms of prevalence of discrepancies, in non-CSRs, but this assumption should be tested on a cohort of non-Cochrane reviews.

The most common category of explanatory comments indicated that the method of allocation concealment was not described or it was unclear. However, only 1.4% of Cochrane authors indicated that they contacted trial authors to receive further information for judging this RoB domain. The Cochrane Handbook recognizes that attempts to assess RoB may be hampered by incomplete reporting of the

Table 3. Categories related to using randomization when explaining risk of bias associated with allocation concealment

Category	Total *N* (%) of reviews mentioning randomization, *N* = 1,529	*N* of low risk (%) within the category	*N* of unclear risk (%) within the category	*N* of high risk (%) within the category
Randomized	346 (54)	256 (74)	80 (23)	10 (3)
Central randomization	251 (39)	240 (96)	11 (4)	0 (0)
Randomized and blinded	23 (36)	19 (83)	4 (17)	0 (0)
Central randomization probably performed	4 (1)	0 (0)	4 (100)	0 (0)
Randomization blinded	2 (0.3)	2 (100)	0 (0)	0 (0)
Randomization performed after informed consent obtained	2 (0.3)	2 (100)	0 (0)	0 (0)
Random number table allocation	1 (0.2)	0 (0)	0 (0)	1 (100)
It was stated that the randomization occurred while ''applying concealed allocation (with respect to gender)''	1 (0.2)	1 (100)	0 (0)	0 (0)
Adequate randomization	1 (0.2)	1 (100)	0 (0)	0 (0)
Concealed randomization	1 (0.2)	1 (100)	0 (0)	0 (0)
Investigators were unable to influence randomization	1 (0.2)	1 (100)	0 (0)	0 (0)
Likely entered into trial before randomization	1 (0.2)	1 (100)	0 (0)	0 (0)
Numbered randomization cards	1 (0.2)	0 (0)	1 (100)	0 (0)
Potential problems with randomization	1 (0.2)	0 (0)	0 (0)	1 (100)
Randomization method unclear	1 (0.2)	0 (0)	1 (100)	0 (0)
Randomization was not revealed to recruiters	1 (0.2)	1 (100)	0 (0)	0 (0)
Randomized after enrollment	1 (0.2)	1 (100)	0 (0)	0 (0)
Randomized before Intention-to-treat participants were identified	1 (0.2)	1 (100)	0 (0)	0 (0)
Partly randomized	1 (0.2)	0 (0)	0 (0)	1 (100)
Study not randomized	1 (0.2)	0 (0)	0 (0)	1 (100)

primary studies and suggests that an option for obtaining missing information is contacting the primary study investigators [1]. The Cochrane Handbook also warns that this approach may yield overly positive results and that study investigators may not respond to a query, and that Cochrane authors should approach primary study investigators with open-ended questions [1].

Therefore, Cochrane authors do have explicit guidance to try to obtain missing information from primary study authors. It is possible that Cochrane authors tried to contact the primary study authors but did not receive a response and failed to mention that in the RoB table. Alternatively, it is possible that Cochrane authors are discouraged in contacting study authors because of known fact that primary study investigators rarely provide answers, and that the e-mail addresses of corresponding authors may not be available, or they may be outdated [13].

Our data should be compelling evidence for Cochrane that more needs to be done to ensure adequacy of data presented in Cochrane reviews. The findings of our study indicate that Cochrane should consider introducing interventions that will improve adequacy of RoB assessment for allocation concealment. Judging by the high prevalence of discrepancies in assessing allocation concealment methodology, Cochrane authors often may not be aware of the definition of allocation concealment, proper methodology for concealing allocation, or difference between allocation concealment and randomization.

Alternatively, it is possible that some authors caused discrepancies we identified using inaccurate comments and simplifying information that were present in the analyzed RCTs; for example, if an RCT contained information that the SNOSE was used, Cochrane authors may have only indicated in a comment for bias related to allocation concealment that the ''envelope method'' was used. This possibility could be verified in future studies by analyzing the data source, that is, individual trials that were included in analyzed reviews.

Jordan et al. analyzed RoB assessments in trials that were included in more than one Cochrane review in the field of subfertility, and they found large discrepancies in how RoB was evaluated for the same trial in different reviews. For allocation concealment domain, they found discrepancies in 41% of judgments across different reviews [14]. However, the authors of that study did not go to the included trials to verify information presented there, and they did not compare those judgments with instructions from the Cochrane Handbook.

A group of authors to whom we owe term allocation concealment [4] recently wrote that the usage of the term has increased considerably in the literature since 1994, but they suspect that the term might be used improperly and that "*many authors and editors define allocation concealment imprecisely, similar to their imprecise use of other trial terminology*" [9]. Our study indicates that their suspicions could be justified.

The problem of authors not using RoB judgments in line with Cochrane Handbook is present in other RoB domains as well. We made a series of analyses of other RoB domains so far, and we found that 12% of analyzed trials included in Cochrane reviews had a discrepant RoB judgment for a randomized sequence generation [15]. Likewise, we found many inconsistencies in judgments of attrition bias and other bias in CSRs [16,17]. Therefore, Cochrane should make an effort to prevent publication of reviews with such discrepancies and inconsistencies. This effort could include interventions aimed toward authors, peer reviewers and actions at the editorial level. An example of an intervention aimed toward Cochrane authors could include information technologies because Cochrane reviews are produced with a software called RevMan (The Nordic Cochrane Centre, Copenhagen, Cochrane, 2014); therefore, reminders for authors with links to specific parts of Cochrane Handbook or drop-down menus with predetermined responses and judgments could be considered. Alongside the RoB table, Cochrane authors can also use the text of the review to provide more information behind their RoB judgments.

The Cochrane is developing *a revised tool to assess risk of bias in randomized trials* (RoB 2.0) [18]. However, from the information available on the Website devoted to the new tool, we do not see that the new version of the Cochrane RoB tool itself will improve judgment for this specific item of RoB. In the RoB 2.0, authors are provided with instructions regarding allocation concealment that are similar to the instructions currently available in the Cochrane Handbook. Therefore, we believe that the mere availability of information for Cochrane authors is not sufficient.

In this study, only one author compared extracted judgments with recommendations from the Cochrane Handbook, which could be considered a limitation. Hartling et al. found that agreement between authors regarding assessing RoB is suboptimal [19]. However, we believe that this should not impact the quality of this analysis because of the transparency of our reporting—we explicitly indicated what we considered discrepant and, therefore, our work can be easily verified by comparing our assessments with the recommendations from the Cochrane Handbook. In addition, it has to be emphasized that some of the included reviews included a high number of included studies; and therefore, some discrepancies may have been repeated multiple times in the same systematic review.

In conclusion, we found that almost one-third of Cochrane reviews had judgments of RoB related to allocation concealment that were not in line with Cochrane's recommendations for authors. Most of the discrepancies were made by Cochrane authors judging a trial to have a low RoB for allocation concealment but with a supporting comment that indicates that the judgment should be unclear or high RoB for this domain. These discrepancies may misrepresent evidence included in Cochrane reviews by presenting many trials as having a better methodology than they deserve. Future studies should explore interventions that could be introduced to enable more accurate assessments of allocation concealment in Cochrane reviews, which will be in line with recommendations from the Cochrane Handbook.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2018.10.002.

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