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Definitions of blinding in randomized controlled trials of interventions published in high-impact anesthesiology journals: a methodological study and survey of authors

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3 **Definitions of blinding in randomized controlled trials of interventions published in**
4 **high-impact anesthesiology journals: a methodological study and survey of authors**
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Abstract

Objectives: To analyze completeness of reporting of blinding in randomized controlled trials (RCTs) of interventions in the field of anesthesiology, the actual blinding status of various persons associated with an RCT and trial authors' interpretation of blinding terminology related to RCTs.

Study design: Methodological (research-on-research) study and cross-sectional survey.

Setting: We analyzed reporting related to blinding in published RCTs of interventions published from the beginning of 2014 to the end of 2017 in seven highly cited anesthesiology journals, as well as registered protocols of those RCTs.

Participants: We surveyed corresponding authors of included RCTs about their definitions of blinding.

Primary and secondary outcome measures: Primary outcome was the number of RCTs that clearly described who was blinded in a trial. Secondary outcomes were definitions of blinding terminology in the trials and trial authors' interpretation of blinding terminology.

Results: Out of 622 analyzed RCTs; 38% were not explicitly described as either open-label or blinded studies and 10% did not report any information about blinding or lack of blinding.

Only one manuscript fully reported status of blinding for various individuals that may be involved with a trial. The most common descriptor was that a trial was double-blind. We found discrepant information regarding blinding in the majority of registered trial protocols. In most of protocol-manuscript pairs without discrepancies within a protocol, we found discrepancy regarding reporting of blinding between the protocol and published manuscript. The survey of authors of analyzed RCTs showed that they differed in how they defined different levels of blinding in trials.

Conclusions: Reporting of the blinding status of key individuals involved in anesthesiology RCTs published from 2014 to 2017 was inadequate. Reporting guidelines, peer-reviewers and

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3 editors need to insist on avoiding usage of the term double-blind, and request authors to
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5 clarify who was blinded.
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11 **Keywords:** blinding, randomized controlled trial, participants, personnel, methodology
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Strengths and limitations

- We analyzed large group of randomized controlled trials published within four years in the seven high-impact anesthesiology journals
- Reporting about blinding was inadequate in the majority of analyzed trials
- Term “double-blind” is ambiguous and researchers interpret it in different ways
- We focused on anesthesiology trials as a specific research field
- Future studies should monitor whether reporting about blinding in trials will improve

Introduction

Available evidence about efficacy and safety of interventions in medicine includes observational studies and studies with a randomized experimental design, i.e. randomized controlled trials (RCTs) [1]. RCTs are considered the highest level of primary evidence for analyzing medical interventions because randomization ensures allocation of participants by chance, and not by choice, which minimizes bias [2]. Apart from method of allocating participants into study arms, there are number of other methodological aspects of an RCT that can contribute to a risk of bias, including performance bias (blinding of participants and personnel) and detection bias (blinding of outcome assessors) [3].

The term “double-blind” is sometimes taken as a token of validity of an RCT [4]. However, it has been shown that the definitions of blinding may vary. Devereaux et al. analyzed how physicians interpret RCT blinding terminology and how textbooks define it [5]. Their study included 91 internal medicine physicians and analysis of 25 textbooks. For single blinding, physicians identified 10 and textbooks 5 different definitions, for double-blinding physicians provided 17 and textbooks 9 different definitions, while for triple blinding physicians gave 15 and textbooks 7 different definitions [5]. That study indicated that both physicians and textbooks provided highly inconsistent interpretations of the blinding terminology used in clinical trials, and suggested that the current ambiguous terminology should be replaced by specific descriptions of who was blinded [5]. According to the CONSORT checklist for reporting RCTs, the following should be reported for blinding: “If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how” [6].

The aim of this study was to analyze completeness of reporting of blinding in RCTs of interventions in the field of anesthesiology, the actual blinding status of various persons

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3 associated with an RCT, information about blinding reported in trial protocols, and the
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5 contemporary trial authors' interpretation of blinding terminology related to RCTs.
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Methods

Study design

We conducted a cross-sectional study of published RCTs and survey of trials' corresponding authors.

Ethics

Research protocol for the survey of trials' corresponding authors was approved by the Ethics Committee of the University of Split School of Medicine (Klasa: 003-08/18-03/0001, Ur. br.: 2181-198-03-04-18-0049; date: October 12, 2018). All invited study participants received information that the study was approved by the Ethics Committee. Continuation to the survey from the invitation e-mail was considered as consent to participate in the study.

Inclusion criteria

We included RCTs of interventions published from January 2014 to December 2017 in the seven first-quartile journals from the Journal Citation Reports (JCR) category Anesthesiology. Based on the 2017 JCR journal impact factor (JIF) those seven journals were (in alphabetic order) Anaesthesia, Anesthesia and Analgesia, Anesthesiology, Pain, British Journal of Anaesthesia, European Journal of Anaesthesiology, Regional Anesthesia and Pain Medicine. We excluded RCTs published as letters to the editor.

Search

We searched PubMed by combining journal name, 2014-2017 time-frame and the filter for RCTs. We exported titles and abstracts into the EndNote reference management software (Clarivate Analytics, Boston, MA, USA). Two authors independently analyzed titles and abstracts to screen them for eligibility. We retrieved potentially eligible manuscripts in full texts and two authors screened them independently. We resolved any disagreements through discussion.

Outcomes

Primary outcome was the number of RCTs that clearly described who was blinded in a trial. Secondary outcomes were definitions of blinding terminology in the trials (how did the authors define in the manuscript what is single-blinding, double-blinding and triple-blinding) and trial authors' interpretation of blinding terminology related to RCTs.

Data extraction

We extracted data into Microsoft Excel sheet (Microsoft Inc., Redmond, WA, USA) after the data extraction table was piloted with ten studies. We analyzed the whole text of an RCT to see whether it was mentioned that the trial was blinded/masked, and in which part of the manuscript. We then analyzed the methods' section of each included RCT and extracted information about blinding terminology (single-blind, double-blind, triple-blind, no such definition) and whether the trial authors explicitly elaborated who was blinded in a trial.

We checked whether the RCTs mentioned explicitly that they used CONSORT checklist for reporting, or mentioned CONSORT as a reference. We analyzed whether there were any discrepancies in reporting of blinding between abstracts and the body of the manuscript. We

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3 also checked for the occurrence of the term ‘double-dummy’ in the RCTs to assess the
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5 blinding in comparisons of drugs that are administered by different routes [7].
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8 We analyzed whether RCTs mentioned protocol registration, and if yes, we copied the
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10 protocol number and name of the registry. We excluded retrospectively registered protocols
11
12 from further analysis. For prospectively registered trials, we analyzed whether there was any
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14 description of blinding in the registered protocol. If we found description of blinding, we
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16 compared whether there were any discrepancies between details about blinding reported in the
17
18 registered protocol and in the published manuscript(s).
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25 *Author survey*

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27 For the author survey we extracted e-mail address of a corresponding author. We contacted via
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29 e-mail corresponding authors of included trials, which contained information about the study
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31 and a list of questions. After the initial e-mail invitation, potential participants received four
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33 subsequent reminders, one week apart if they did not respond, or indicated that they do not wish
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35 to participate. All surveys and reminders were sent between November 1, 2018 and January 9,
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37 2019.
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42 Participants received the following questions together with information about the name of their
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44 trial we studied:
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- 47 1. For authors who only indicated that study was blinded, or double-blind, single-blind,
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49 triple-blind, with no further details: Who exactly was blinded in the trial (participants,
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51 healthcare providers such as physicians or nurses taking care of a participant, data
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53 collectors, outcome assessors, data analysts, manuscript writers) – categorical answers
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2. What is authors' personal opinion what does it mean single-blind, double-blind and triple-blind by providing them the same categories from above, as well as response "any two types of trial participants" [8].
3. The authors were asked to assess the frequency of publication of double-blind trials in the literature adhering with their preferred definition. For example, if a participant characterized 'double-blind' as meaning blinding of participants and personnel, that author was subsequently asked to assess the frequency of 'double-blind' trials in which participants and personnel were blinded. The question did not refer to the publications of the participants, but their estimation about the literature.

We emphasized to the survey participants that only aggregate data will be published. In case when we had identical corresponding authors for more than one manuscript included in the study, we contacted them for the most recent manuscript only.

Analysis

We used descriptive statistics, including frequencies and percentages, as well as median and 95% (CI) confidence interval. Data were analyzed using MedCalc statistical software, v 15.2.1 (MedCalc Software bvba, Ostend, Belgium).

Results

Descriptors about blinding

In this study we analyzed 622 RCTs. Study design of 29 (4.7%) trials was explicitly described as non-blinded or open-label, while 357 (57%) were explicitly described as blinded, using terms blinded, single-blinded, double-blinded, triple-blinded or masked in description of study design. Study design of the remaining 236 (38%) trials was not explicitly described as blinded or non-blinded.

In 116 (19%) trials information about blinding status was mentioned in the study title. Descriptors used for blinding in trial titles are shown in Table 1. The most common descriptor was ‘double-blind’, followed by simply ‘blinded’. Statements about blinding were found in 283 (45%) of abstracts. The most common category of descriptor in trial abstracts was ‘double-blind’ (n=183 out of 283; 65%); some abstracts had more than one category of descriptor (Table 2).

Statements about blinding were found in the section Methods in 470 (76%) of analyzed trials. The most common statement about blinding in the Methods was ‘double-blind’ (n=191 out of 470; 41%). Categorized statements about blinding found in the Methods are shown in Table 3.

Regarding blinding vs masking terminology, the most common term used in the analyzed trials was blinding (n=477, 76%). Term masking alone was used in 9 (1.4%) trials, while in 45 (7.2%) trials both blinding and masking terms were used. In 91 (15%) trials neither word blinding nor masking was used. Term ‘double-dummy’ was found in 7 trials, and ‘triple-dummy’ in 1 trial.

Blinding of individuals involved in trials

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3 Analysis of who was blinded in trials was done for 531 trials where we found at least some
4 descriptors for blinding; the remaining trials were excluded from this analysis because they
5 were described as open-label, or were not described as neither blinded nor open-label. Table 4
6 indicates prevalence of blinding of various individuals that may be involved in a trial. For all
7 seven categories of individuals in the majority of trials it was unclear whether these individuals
8 were blinded. In 89 (14%) of 622 trials it was clearly reported whether the three key groups of
9 individuals, i.e. participants, healthcare providers and data collectors, were blinded or not.
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23 *Other analyses related to blinding*

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25 Among the analyzed trials, 47 (8%) explicitly mentioned that they used CONSORT checklist
26 for reporting, or mentioned CONSORT as a reference.
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30 We found discrepancies in reporting of blinding between abstracts and the body of the
31 manuscript in only one trial, which reported in the abstract that the study was double-blind,
32 and in the body of the manuscript that the study was single-blind.
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38 There were 384 (62%) trials that reported protocol trial registration and unique protocol
39 identifier. After searching for those protocols online, we were able to find 315 of those 384
40 protocols (82%); we were unable to retrieve the rest by searching for the reported protocol
41 identifier. Of the 315 protocols we managed to access, 174 (55%) were registered
42 prospectively, and as many as 141 (45%) were registered retrospectively, i.e. after the study
43 start date reported in a clinical trials register.
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52 Detailed analysis of the 174 prospectively registered protocols was conducted. The majority
53 of the protocols were registered in the ClinicalTrials.gov (n=157; 90%), while the remaining
54 protocols were registered on ACTRN – The Australian and New Zealand Clinical Trial
55 Registry (n=8), UMIN - University Hospital Medical Information Network registry of Japan
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3 (n=7), Netherlands Trial Register – NTR (n=1) and ChiCTR – Chinese Clinical Trial Registry
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5 (n=1). Two studies from our cohort were registered on ClinicalTrials.gov as observational
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7 studies, and did not have information about blinding. The remaining 155 trials registered on
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9 ClinicalTrials.gov had 14 different categories of the study status in the protocol section Study
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11 design, which contains pre-determined field called Masking (Table 5).
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15 In the protocols registered on ClincialTrials.gov, the most common descriptor in the sub-
16
17 section Masking was ‘Quadruple (Participant, Care Provider, Investigator, Outcomes
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19 Assessor)’, found in 39 protocols of the 155 registered on ClinicalTrials.gov. The second
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21 most common descriptor was ‘None (Open label)’ (Table 5). Besides this field, we also
22
23 analyzed full text of the protocol to find any other descriptions of blinding/masking. Among
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25 157 protocols, 92 did not have any other terminology related to blinding/masking other than
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27 information in the pre-determined field Masking. In the remaining 65 trial protocols, 47
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29 (72%) protocols had additional information about blinding that were different from the
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31 descriptor provided in the field Masking. The majority of discrepancies accounted for
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33 protocols which described the trial as quadruple-blind or triple-blind in the Masking field, but
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35 also described it as double-blind in another part of the protocol.
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41 In the other trial registries few trials were registered (Table 6) and we found only one
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43 discrepancy; in a trial registered in NTR it was described both that the study used ‘single
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45 masking’ and that it was ‘double-blind’ (Table 6).
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49 When we compared registered protocols and published manuscripts of the 126 registered
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51 trials that did not have discrepancies in the protocol, for 88 (70%) trials we found differences
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53 between protocol and published manuscript in description of blinding. The most common
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55 differences were in the description of who was blinded, the extent of blinding and whether
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57 there was any blinding at all (Table 7).
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Survey results

For 362 trials that were described as double-blind, there were 275 unique corresponding authors, and 264 email addresses available. There were 33 e-mails that returned undelivered because they were no longer in use. From the remaining 231 corresponding authors, we received 40 responses (17% response rate). Authors' responses regarding individuals that were blinded in their trials, as well as their opinions about who was blinded in single-, double- and triple-blinded trial are shown in Table 8. One participant who answered the question about blinding in their trial, provided a personal definition for the single-blind trial, but stated the following for the remaining questions: *"I cannot answer the rest of the questions. I don't use "double-blind" or "single-blind" any longer, as I think they are ambiguous. I adhere to Annals of Internal Medicine guidelines that advises authors to avoid those terms, but to specifically note who was blinded."*

Whereas 34 of 40 (85%) authors responded that participants were blinded in their own double-blinded trial, all authors that responded to the third question defined that in a double-blind trial participants are blinded (Table 8). For a single-blind trial, surveyed authors chose at least one from five of six individuals as targets for blinding; only manuscript writers were never considered as individual that could be blinding in a trial. When asked about their personal definition, in respondents' choices of blinded individuals in double- and triple-blind trial, all six types of individuals were chosen. Outcome assessors, data analysts and manuscript writers were more commonly mentioned as individual who could be blinded in a triple-blind trial (Table 8).

In addition, 25 participants estimated the percentage of how often is their personal definition of a double-blind trial used in published trials: this percentage ranged from 20% to 100%, with the median of 80% (95% CI 60% to 80%).

Discussion

We found that only one fifth of analyzed trials reported information about blinding or lack of blinding in the title. Most common description related to blinding, both in the title and in the manuscript, was that study was double-blind. Regarding terminology, blinding as a term was used in the majority of trials, whereas only a few trials used term masking. In the majority of trials described as blinded it was unclear whether participants and other relevant individuals were blinded or not. For less than half of the trials we identified registered protocols, and in the majority of those protocols we found discrepant information about blinding – both within the protocol, and between the protocol and published manuscript.

Blinding is very important for the results of RCTs. Saltaji et al. reported significant differences in effect size of treatment estimates between oral health trials, depending on the use of patient and assessor blinding. Treatment effect size estimates in their methodological study were 0.19 and 0.14 higher in trials with lack of blinding of both patients and assessors or concurrent blinding of patients, assessors, and personnel [9]. Juni et al. reported that trials described as double-blind on average reported 14% lower effects compared to studies that were not described as double-blind [10]. Armijo-Olivo et al. found that physical therapy trials without appropriate blinding of participants and assessors had a tendency to underestimate treatment effect. Although the difference was not statistically significant the authors warn that this does not mean that there is no impact of blinding in physical therapy trials [11].

Studies that investigated the effect of blinding of certain group of individuals in a trial were also conducted. Hrobjartsson et al. showed that trials in the field of complementary and alternative medicine have pronounced bias in patient-reported outcome if participants were not blinded. They analyzed 12 trials with 3869 participants and found that the average difference in effect size for patient-reported outcomes was -0.56 (95% confidence interval -0.71 to -0.41),

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3 indicating that non-blinded participants exaggerated the effect size by an average of 0.56
4 standard deviation, but with the considerable variation of result [12].
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8 Noseworthy et al. analyzed multiple sclerosis trials and reported in 1994 that trials with blinded
9 raters had lower function scores compared to trials with raters that were not blinded [13].
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13 Multiple earlier studies analyzed in detail who was blinded in RCTs. In 2006, Haar and
14 Hjobjartsson analyzed 200 random RCTs that were published in 2001 in the Cochrane's
15 database Central Register of Controlled Trials (CENTRAL), which indexes only clinical trials.
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18 They found that 78% of manuscripts described trials as double-blind. Only in three, i.e. 2% of
19 the analyzed trials, the blinding status of participants, health care providers and data collectors
20 was explicitly reported [8]. In our study this finding was better; we found that the blinding
21 status of these three groups of individuals was explicitly reported in 14% of the analyzed trials.
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24 Haar and Hjobjartsson reported that 56% of trials they analyzed did not report blinding status
25 of any group of participants associated with a trial, and 26% reported no information relevant
26 to blinding beyond indicating that the trial was 'double-blind' [8].
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30 Even though that study was published twelve years ago, results of our study were worse
31 compared to Haar and Hjobjartsson's study, as we found that 57% of analyzed trials were
32 explicitly described as blinded, using terms *blinded*, *single-blinded*, *double-blinded*, *triple-*
33 *blinded*) or a term *masked*.
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37 In terms of completeness of reporting, in the study of Haar and Hjobjartsson, among the 156
38 manuscripts describing double-blind trials, they did not find a single manuscript with 'complete
39 reporting'. They found only three (2%) manuscripts with 'partial reporting, 65 (42%)
40 manuscripts with 'minimal reporting', and 88 (56%) manuscripts with 'no reporting' [8].
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44 However, it has been emphasized already that assessment of bias associated with blinding, or
45 lack of blinding, in clinical trials, is hampered with poor reporting [14]. In 2002 Montori et al.
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3 analyzed reporting of quality about blinding in RCTs published in five leading journals, and
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5 found that under 25% of RCTs reported explicitly blinding status of the six relevant groups of
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7 individuals associated with conduct of a trial. In 83 trials that were described as double-blind,
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9 the authors found 8 different combinations of blinded groups of those individuals. Therefore,
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11 already sixteen years ago Montori et al. warned that journals should abandon the term double-
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13 blind and require explicit reporting of the blinding status of relevant groups of participant that
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15 are involved in a clinical trial [14].
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19 In our study, we found that the term double-blind was the most commonly used term related to
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21 blinding, i.e. masking. Therefore, it is obvious that warnings aimed towards journal editors [14]
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23 were not successful in the efforts to reduce the use of ambiguous term double-blind.
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27 Feys et al. studied whether RCTs with inadequate reporting of blinding enhanced placebo
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29 effects for intervention groups and nocebo effects for placebo groups. Their analysis included
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31 110 studies with a total of 23877 participants included. They found unclear risk of bias for
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33 allocation concealment in 93 (85%) of trials, for blinding of participants in 51 (46%), blinding
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35 of caregiver in 93 (85%) and blinding of outcome assessor in 93 (85%) of analyzed trials [15].
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37 Because of the poor overall reporting in analyzed trials, and small number of trials that the
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39 authors could rate as either adequately or inadequately blinded, the authors reported that they
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41 could not provide robust conclusions regarding presence or absence of nocebo and enhanced
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43 placebo effects [15].
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51 *Discrepancies in blinding descriptors within trial protocols, and between protocols and* 52 53 *published manuscripts* 54

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56 One of the striking findings of our study was related to the discrepancies in blinding/masking
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58 information within different registration fields for registered trial protocols, and between
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3 those protocols and published manuscripts. Firstly, we managed to find registered protocols
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5 for only about half of trials in our cohort, either because the authors did not report protocol
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7 registration in their manuscripts, or because the reported trial protocol was not retrievable.
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10 Furthermore, analysis of trial protocols that we managed to find showed that 45% of them
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12 were registered retrospectively, i.e. after the study has already started, judging by the study
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14 start date that was reported in a clinical trial registry. When we analyzed information about
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16 blinding/masking, we found that the majority of protocols had discrepant information about
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18 the blinding of the study in their protocols. Analysis of trials in which we did not find
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20 discrepancies within a protocol indicated that the majority of those trials had differences
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22 between reporting of blinding in a registered protocol and published manuscript.
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27 ClinicalTrials.gov was the most commonly used clinical trial registry. This is in line with the
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29 finding that ClinicalTrials.gov contains the majority of the global trial registrations [16]. It has
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31 a mandatory field called Masking that individuals registering studies need to fill, and this field
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33 offers to study authors an option to choose between five options in a menu. First four options
34
35 in the menu are individuals involved within a trial: Participant, Care Provider, Investigator
36
37 and Outcomes Assessor. The fifth option is 'None (Open Label)'. Study authors are invited to
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39 'Check all roles that are masked or check None (Open Label)'. Below this menu is a blank
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41 field called 'Masking description', in which trialists can fill out additional information about
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43 blinding. Based on the number of participants that were checked as blinded, a trial will get a
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45 descriptor about being single, double, triple or quadruple blinded. The most common
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47 discrepancy within registered protocols was that the study was described as quadruple or
48
49 triple blind by ClinicalTrials.gov, but trialists themselves called the study 'double-blind'.
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Meaning of double-blind

Suggestion of Montori et al. that vague term double-blind should be abandoned [14] was also repeated later in the literature by other authors. Haar and Hjobjartsson also conducted a survey of corresponding authors of the analyzed trials, with high response rate of 65%. Based on the authors' responses, 20(19%) trials that were described as double-blind in the manuscript did not blind either patients, health care providers or data collectors. therefore, the authors concluded that it is not appropriate to presume blinding of key trial persons based only on the ambiguous term such as double-blind [8]. Survey responders provided 15 different operational meanings of the term double-blind, and typically felt that their preferred definition was the most widely used [8]. Before those two studies, Devereaux et al. reported that hospital physicians used 17 different definitions of the meaning of double-blind [5].

Our survey of authors showed that authors have varying definitions of who should be blinded in a single-blind, double-blind and triple-blind trial. Authors' response about who was blinded in their own double-blind trial did not always match their response about who should be blinded in a double-blind trial generally. Based on the participants' responses that the majority of published trials correspond to their personal definition of a double-blind trial, it appears that the surveyed researchers are not aware of the high heterogeneity of definitions of blinding in clinical trials. This is a further argument for ceasing the use of ambiguous terminology such as single-blind, double-blind and triple-blind, and to require that authors should report specifically who was blinded in their study.

Limitations

Our study had several limitations. We limited our analysis to a recent period, and to seven high-ranking anesthesiology journals, because those should be the ones that will be role models for

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2
3 the rest of the journals. Furthermore, we did not scrutinize in detail additional online material,
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5 such as supplements and appendices, where, theoretically, additional details about blinding
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7 could have been located. But, we did analyze all mentions of blinding in the analyzed
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9 manuscript, and we did not find a single case where the authors indicated that additional details
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11 about blinding were available in a supplement. We used PubMed to search for targeted articles,
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13 and we did not search journals' website; theoretically, some articles may have therefore been
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15 missed. However, we consider that the likelihood for this was small because these journals are
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17 indexed on PubMed, and searching of the journal websites would be more troublesome because
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19 of usual lack of search filters that are available on PubMed. Furthermore, we did not attempt to
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21 do comparison between the journals that we analyzed, because the focus here was not on
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23 individual journals, but the field. Also, we did not do analysis of all medical fields, and we
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25 focused on one field of interest.

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31 Another thing that would be worthwhile to explore is journals' instructions for author in terms
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33 of reporting requirements. We included studies published over a long period of time, that there
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35 is time lag between submission and publication, and that journal web sites only provide
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37 information about current instructions for authors, and not also history of their changes, i.e.
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39 previous versions of instructions for authors. Therefore, the only proper way to study influence
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41 of instructions for authors on reporting in manuscript would be to do it prospectively, having
42
43 in mind current instructions for authors and current submissions.

44 45 46 47 48 49 50 **Conclusion**

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53 Explicit and complete reporting of the blinding status of key individuals involved in RCTs is
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55 suboptimal. Anesthesiology trials rarely report who was blinded, and mostly use ambiguous
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57 term double-blind, which if not sufficiently informative for readers. Furthermore, we found
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59 many discrepancies about reporting of blinding within registered trial protocols, and between
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3 protocols and published manuscripts. Our survey of authors showed that authors differed in
4
5 their opinion of who was blinded in their own trial and who could be blinded in trials with
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7 different levels of blinding. Thus, poor reporting and heterogeneous definitions of ambiguous
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9 terminology hinders proper risk of bias assessment and analysis of impact of blinding of
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11 certain groups of participants on the study outcomes. Interventions for improving reporting
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13 about blinding are warranted.
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Declarations

Funding statement

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Competing interests

The authors declare that they have no competing interests.

Authorship contribution

Study design: LP, AM

Data acquisition: AP, DB, KB, MK, LP

Data analysis and interpretation: LP, AM

Writing manuscript draft: LP, AM

Agreeing to submission of the manuscript: AP, DB, KB, MK, AM, LP

Agree to be accountable for all aspects of the work: AP, DB, KB, MK, AM, LP

Reporting checklist

STROBE; checklist is enclosed as a Supplementary file 1

Participant consent form

All participants consented to participate in the study; there are no identifiable information about participants in the manuscript.

Data sharing statement

Data collected during the study are available from the corresponding author on reasonable request.

Patient and public involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

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3 **List of supplementary files**
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7 **Supplementary file 1: STROBE checklist**
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Table 1. Descriptors for blinding status of the study in titles of analyzed trials, N=116

Blinding status descriptors	N (%)
Double-blind	89 (76)
Blinded	8 (6.8)
Single-blinded	6 (5.1)
Triple-masked	3 (2.6)
Triple-blind	3 (2.6)
Open-label	1 (0.9)
Observer-blinded	1 (0.9)
Blinded evaluation	1 (0.9)
Blinded trial	1 (0.9)
Nonblinded	1 (0.9)
Double-masked	1 (0.9)
Masked	1 (0.9)

Table 2. Descriptors about blinding found in abstracts of analyzed trials; N= 294 descriptors from 283 abstracts

Categories of descriptors	N (%)
Double-blind	183 (62)
Single-blind	25 (8.5)
Blinded personnel	22 (7.5)
Blinded	20 (6.8)
Outcome assessors blinded	14 (4.7)
Open label	8 (2.7)
Patient and assessor blinded	4 (1.4)
Triple-masked	3 (1.0)
Blinded intervention application	3 (1.0)
Unmasked intervention	2 (0.7)
Blinded patients	2 (0.7)
Triple blind	2 (0.7)
Patients and personnel blinded	2 (0.7)
Clinicians not blinded	1 (0.3)
Unblinded assessment	1 (0.3)
Blinded monitoring	1 (0.3)
Success of patients' blinding	1 (0.3)

Table 3. Categorized statements about blinding found in Methods of analyzed trials; N=470

Categories of descriptors	N (%)
Double-blind	191 (41)
Personnel blinded	75 (16)
Single-blind	38 (8.1)
Patients and personnel blinded	37 (7.9)
Outcome assessor blinded	26 (5.5)
Data collectors blinded	19 (4.0)
Non-blinded personnel	17 (3.6)
Patients blinded	16 (3.4)
Blinded	14 (3.0)
Open-label	8 (1.7)
Data analysts blinded	8 (1.7)
Partially blinded	3 (0.6)
Unmasked patients and investigators	3 (0.6)
Non-blinded patients	2 (0.4)
Blinded interventions	2 (0.4)
Triple-blind	1 (0.2)
Unmasking information	1 (0.2)
Non-masked patients and personnel	1 (0.2)
Rater-blinded	1 (0.2)
Masked assignment	1 (0.2)
Masking	1 (0.2)
Outcome assessors and data analysts blinded	1 (0.2)
Data collector and data analysts blinded	1 (0.2)
Data collector and outcome assessor blinded	1 (0.2)

Table 4. Prevalence of blinding of individuals involved in trials described as blinded; N=622

Individual	Yes, N (%)	No, N (%)	Unclear, N (%)
Participants	227 (37)	46 (7)	349 (56)
Personnel; healthcare providers such as physicians or nurses taking care of a participant	225 (36)	55 (9)	342 (55)
Data collectors	161 (26)	29 (5)	432 (69)
Outcome assessors	130 (21)	21 (3)	471 (76)
Data analysts	43 (7)	20 (3)	559 (90)
Manuscript writers	0 (0)	16 (3)	606 (97)
Investigators	104 (17)	31 (5)	487 (78)

Table 5. Descriptors in the field Study design/Masking in the analyzed protocols that were registered on ClinicalTrials.gov (N = 157)

Blinding terminology used in analyzed clinical trial protocols	N
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)	39
None (Open Label)	22
Single (Participant)	15
Double (Participant, Investigator)	14
Double (Participant, Outcomes Assessor)	14
Triple (Participant, Investigator, Outcomes Assessor)	13
Triple (Participant, Care Provider, Investigator)	12
Single (Outcomes Assessor)	8
Single (Investigator)	6
Double (Participant, Care Provider)	5
Triple (Participant, Care Provider, Outcomes Assessor)	4
Study described as observational, without information about blinding/masking	2
Double (Investigator, Outcomes Assessor)	1
Masking: Triple (Participant, Care Provider, Investigator)	1
Single (Care Provider)	1

Table 6. Descriptors of blinding/masking in other clinical trial registries

Descriptors	N
ACTRN (N=8)	
Blinded (masking used)	4
Open (masking not used)	2
Subject and observer blinded	1
Blinded	1
UMIN (N=7)	
Single blind -participants are blinded	3
Single blind -investigator(s) and assessor(s) are blinded	2
Double blind -all involved are blinded	2
NTR (N=1)	
Single masking; double blind	1
ChiCTR (N=1)	
No statement about blinding	1

ACTRN = The Australian and New Zealand Clinical Trial Registry, UMIN = University Hospital Medical Information Network registry of Japan; NTR = Nederlands Trial Register, ChiCTR = Chinese Clinical Trial Registry

Table 7. Differences between protocol and manuscript, in the group of trials that did not have discrepancies within the protocol itself (N of trials = 88)

Differences between protocol and published manuscript	N (%)
Different individuals described as blinded between protocol and manuscript	30 (34)
Protocol reported who was blinded; manuscript did not	10 (11)
Protocol: triple blind; manuscript: double-blind	9 (10)
Protocol reported who was blinded; manuscript only that it was double-blind	9 (10)
Protocol: open label, manuscript: blinding of one or more groups of individuals	8 (9)
Protocol has description of blinding; manuscript no description of blinding	7 (8)
Protocol: quadruple-blind; manuscript: double-blind	6 (7)
Protocol double-blind, manuscript single-blind	2 (2)
Study described as observational on ClinicalTrials.gov	2 (2)
Protocol: quadruple-blind; manuscript: triple-blind	2 (2)
Protocol: no information about blinding; manuscript reported information about blinding	1 (1)
Protocol: open-label; manuscript only reported that participants were not blinded	1 (1)
Protocol: single-blind; manuscript: double-blind	1 (1)

Table 8. Information obtained from surveyed corresponding authors regarding who was blinded in their trials that were described as double-blind, and what is their personal definition of who is blinded in a single-blind, double-blind and triple-blind trial (total N of participants = 40)

Blinding scenarios	Participants, N	Healthcare providers such as physicians or nurses taking care of a participant, N	Data collectors, N	Outcome assessors, N	Data analysts, N	Manuscript writers, N
Who was blinded in your trial described as a double-blind?	34	31	32	28	18	10
What is your personal definition of a single-blind trial?	30	5	5	7	4	0
What is your personal definition of a double blinded trial?	37	33	30	25	12	4
What is your personal definition of a triple-blind trial?	34	34	31	31	26	12

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	3-4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6-7
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA

Results			Page
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	9-12
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Definitions of blinding in randomized controlled trials of interventions published in high-impact anesthesiology journals: a methodological study and survey of authors

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Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Research methods
Keywords:	Clinical trials < THERAPEUTICS, STATISTICS & RESEARCH METHODS, EPIDEMIOLOGY

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3 **Definitions of blinding in randomized controlled trials of interventions published in**
4 **high-impact anesthesiology journals: a methodological study and survey of authors**
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Abstract

Objectives: To analyze completeness of reporting of blinding in randomized controlled trials (RCTs) of interventions in anesthesiology, the actual blinding status of various persons associated with an RCT and trial authors' interpretation of blinding terminology related to RCTs.

Study design: Methodological study and cross-sectional survey.

Setting: We analyzed reporting related to blinding in published RCTs of interventions published from the beginning of 2014 to the end of 2016 in seven highly cited anesthesiology journals, and protocol registrations in ClinicalTrials.gov.

Participants: We surveyed corresponding authors of included RCTs about their definitions of blinding.

Primary and secondary outcome measures: Primary outcome was the number of RCTs that explicitly described who was blinded in a trial. Secondary outcomes were definitions of blinding terminology in the trials and trial authors' interpretation of blinding terminology.

Results: Out of 622 analyzed RCTs, 38% were not explicitly described as either open-label or blinded studies and 10% did not report any information about blinding or lack of blinding. Only one manuscript fully reported status of blinding for various individuals that may be involved with a trial. The most common descriptor was that a trial was double-blind. We found discrepant information regarding blinding in the majority of protocol registrations. Even when there were no discrepancies in the registration, we found discrepancy in the reporting of blinding between the majority of protocol registration and published manuscripts. The survey of authors (40 responses from 231 eligible authors; 17% response rate) of analyzed RCTs showed that they differed in how they defined different levels of blinding in trials.

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3 **Conclusions:** Reporting of the blinding status of key individuals involved in analyzed
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5 anesthesiology RCTs was insufficient. Reporting guidelines, peer-reviewers and editors need
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7 to insist clear information on who was blinded in a trial instead of using the “double-blind”
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9 term for different blinding practices.
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15 **Keywords:** blinding, randomized controlled trial, participants, personnel, methodology
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Strengths and limitations

- We analyzed large group of randomized controlled trials published in seven high-impact anesthesiology journals
- Reporting about blinding was insufficient in the majority of analyzed trials
- Term “double-blind” is ambiguous and researchers interpret it in different ways
- We focused on anesthesiology trials as a specific research field
- Future studies should monitor whether reporting about blinding in trials will improve

Introduction

Available evidence about efficacy and safety of interventions in medicine includes observational studies and studies with a randomized experimental design, i.e. randomized controlled trials (RCTs) [1]. RCTs are considered the highest level of primary evidence for analyzing medical interventions because randomization ensures allocation of participants by chance, and not by choice, which minimizes bias [2]. Apart from the method of allocating participants into study arms, there are other methodological aspects of an RCT that can contribute to a risk of bias, including performance bias (blinding of participants and personnel) and detection bias (blinding of outcome assessors) [3].

Blinding is very important for the validity of RCT results. Multiple studies reported significant differences in effect size of treatment estimates depending on the use of blinding of key individuals [4-8].

The term “double-blind” is sometimes taken as a token of validity of an RCT [9]. However, it has been shown that the definitions of blinding may vary. Devereaux et al. showed that both physicians and textbooks provided highly inconsistent interpretations of the blinding terminology used in clinical trials, and suggested that the current ambiguous terminology should be replaced by specific descriptions of who was blinded [10]. According to the CONSORT checklist for reporting RCTs, the following should be reported for blinding: “If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how” [11].

The aim of this study was to analyze the completeness of reporting of blinding in RCTs of interventions in the field of anesthesiology, the actual blinding status of various persons associated with an RCT, information about blinding reported in the trial protocol registrations, and the trial authors’ interpretation of blinding terminology related to RCTs. The study focused specifically on the field of anesthesiology because pain is a subjective outcome and

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2
3 there is no objective method for analyzing pain. The analgesic placebo effect has been well
4 documented [12]. In the area of placebo effects, expectations play a major role, triggering a
5 cascade of endogenous opioids and non-opioids, and altering the experience of pain [12]. For
6 this reason, the field of anesthesiology and pain research is likely biased if blinding is not
7 used adequately.
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Methods

Study design

We conducted a cross-sectional study of published RCTs and registered data about their protocols in public trial registries, and a survey of trials' corresponding authors.

Ethics

Research protocol for the survey of trials' corresponding authors was approved by the Ethics Committee of the University of Split School of Medicine (Klasa: 003-08/18-03/0001, Ur. br.: 2181-198-03-04-18-0049; date: October 12, 2018). All invited study participants received information that the study was approved by the Ethics Committee. Continuation to the survey from the invitation e-mail was considered as consent to participate in the study. The data were fully anonymized for analysis.

Inclusion criteria

We included RCTs of interventions published from January 2014 to December 2016 in the seven first-quartile journals from the Journal Citation Reports (JCR) category Anesthesiology. Based on the 2015 JCR journal impact factor (JIF) those seven journals were (in alphabetic order) Anaesthesia, Anesthesia & Analgesia, Anesthesiology, British Journal of Anaesthesia, European Journal of Anaesthesiology, Pain, and Regional Anesthesia and Pain Medicine. We excluded RCTs published as letters to the editor.

Search

1
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3 We searched PubMed by combining journal name, 2014-2016 time-frame, and the publication
4 type filter for RCTs. We exported titles and abstracts into the EndNote reference management
5 software (Clarivate Analytics, Boston, MA, USA). Two authors independently analyzed titles
6 and abstracts to screen them for eligibility. We retrieved potentially eligible manuscripts in full
7 texts and two authors screened them independently. We resolved any disagreements through
8 discussion.
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20 *Outcomes*

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23 Primary outcome was the number of RCTs that explicitly described who (which individuals or
24 group/s of individuals) was blinded in a trial. Secondary outcomes were the definitions of
25 blinding terminology in the trials (how the authors defined in the manuscript what was
26 blinding terminology in the trials (how the authors defined in the manuscript what was
27 “single-blinding”, “double-blinding”, and “triple-blinding”) and trial authors’ interpretation of
28 blinding terminology related to RCTs.
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38 *Data extraction*

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40 We extracted data into a Microsoft Excel sheet (Microsoft Inc., Redmond, WA, USA) after
41 the data extraction table was piloted with ten studies. Data from each trial were extracted
42 independently by two authors (three authors participated in data extraction: AP, KB, MK).
43 Independent extractions were compared for consistency, and discrepancies were resolved via
44 consensus.
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52 For each publication, we analyzed the abstract, full body of the manuscript (and
53 supplementary files if the authors indicated that additional details about methods were in
54 supplementary files) to see whether it was mentioned that the trial was blinded/masked, and in
55 which part of the manuscript. We then analyzed the methods’ section of each included RCT
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3 and extracted information about blinding terminology (“single-blind”, “double-blind”, “triple-
4 blind”, no such definition) and whether the trial authors explicitly elaborated who was blinded
5 in a trial.
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10 We checked whether the RCTs mentioned explicitly that they used CONSORT checklist for
11 reporting, or mentioned CONSORT as a reference. We analyzed whether there were any
12 discrepancies in reporting of blinding between abstracts and the body of the manuscript. If the
13 abstract described the study as “double-blind”, but body of the manuscript provided more
14 details about who was blinded, we considered this a discrepancy. We also checked for the
15 occurrence of the term “double-dummy” in the RCTs to assess the blinding in comparisons of
16 drugs that are administered by different routes [13].
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27 We analyzed whether RCTs mentioned trial protocol registration, and if yes, we recorded the
28 protocol registration number and the name of the registry. We excluded trials registered after
29 the trial was open for recruitment from further analysis. For trials registered before
30 participants’ recruitment, we analyzed whether there was any description of blinding in the
31 protocol registration. If we found description of blinding, we compared whether there were
32 any discrepancies between details about blinding reported in the protocol registration and in
33 the published manuscript(s). We also searched whether RCTs mentioned protocol as a
34 supplementary file, or as a publication in a scholarly journal.
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49 *Author survey*

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51 For the author survey, we extracted e-mail addresses of corresponding authors. We contacted
52 via e-mail corresponding authors of included trials, including the information about the study
53 and a list of questions. One author (DB) sent all the emails. After the initial e-mail invitation,
54 potential participants received four subsequent reminders, one week apart if they did not
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3 respond, or indicated that they do not wish to participate. All surveys and reminders were sent
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5 between November 1, 2018 and January 9, 2019.
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8 We conducted the survey based on the questions described previously [14]. Participants
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10 received the following questions, together with the title of their trial:
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- 13 1. For authors who only indicated that study was blinded, or double-blind, single-blind,
14 triple-blind, with no further details: Who exactly was blinded in the trial [six categories
15 of participants, as used by Haahr and Hrobjartsson [14]: (i) participants, (ii) healthcare
16 providers such as physicians or nurses taking care of a participant, (iii) data collectors,
17 (iv) outcome assessors, (v) data analysts, (vi) manuscript writers] – categorical answers,
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19 2. What authors' personal opinion was about what single-blind, double-blind and triple-
20 blind mean, by providing them the same categorical answers from above, as well as
21 response "any two types of trial participants" [14].
22
23 3. The authors were asked to assess the frequency of publication of double-blind trials in
24 the literature adhering with their preferred definition. For example, if a participant
25 characterized "double-blind" to represent blinding of participants and personnel, that
26 author was subsequently asked to assess the frequency of "double-blind" trials in which
27 participants and personnel were blinded. The question did not refer to the publications
28 of the participants, but their estimation about the literature.
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46 We emphasized to the survey participants that only anonymized data would be published. The
47 exact text of the survey is presented in Supplementary file 1. In cases when we had identical
48 corresponding authors for more than one manuscript included in the study, we contacted them
49 for the most recent manuscript only. Two authors (DB, LP) independently categorized the
50 responses obtained via survey.
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3 *Analysis*
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6 We used descriptive statistics, including frequencies and percentages, as well as median and
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8 95% (CI) confidence interval. Data were analyzed using MedCalc statistical software, v 15.2.1
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10 (MedCalc Software bvba, Ostend, Belgium).
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Results

Descriptors about blinding

We analyzed 622 RCTs; study flow chart is shown in Figure 1. The list of included studies is presented in Supplementary file 2. The study design of 29 (4.7%) trials was explicitly described as non-blinded or open-label, while 357 (57%) were explicitly described as blinded, using terms “blinded”, “single-blinded”, “double-blinded”, “triple-blinded” or “masked” in the description of study design. Study design of the remaining 236 (38%) trials was not explicitly described as blinded or non-blinded.

The information about the blinding status was found in 116 (19%) titles; 283 (45%) abstracts and 470 (76%) Methods sections. The most common descriptor for blinding in titles (Table 1), abstracts (Table 2) and section Methods (Table 3) was “double-blind”.

Regarding blinding vs masking terminology, the most common term used in the analyzed trials was “blinding” (n=477, 76%). Term masking alone was used in 9 (1.4%) trials, while in 45 (7.2%) trials both blinding and masking terms were used. In 91 (15%) trials neither word blinding nor masking was used. The term “double-dummy” was found in 7 trials, and “triple-dummy” in 1 trial.

Blinding of individuals involved in trials

The analysis of who was blinded in trials was done for 531 trials, where we found at least some descriptors for blinding; the remaining trials were excluded from this analysis because they were described as open-label, or were not described as either blinded or open-label. Table 4 presents the prevalence of blinding of various individuals that may be involved in a trial. For all six categories of individuals in the majority of trials it was unclear whether these individuals were blinded.

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3 In 89 (17%) of 531 trials (14% from the overall sample of 622 trials) it was explicitly reported
4 whether the three key groups of individuals, i.e. participants, healthcare providers and data
5 collectors, were blinded or not. This percentage improved over analyzed time, as it was 10% in
6 year 2014 (25/203), 15% in year 2015 (31/203) and 26% in year 2016 (33/125).
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12 Among the analyzed trials, 47 (8%) explicitly mentioned that they used CONSORT checklist
13 for reporting, or cited CONSORT as a reference.
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17 18 19 20 21 *Discrepancies between abstracts and body of manuscript*

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23 We found discrepancies in the reporting of blinding between abstracts and the body of the
24 manuscript in a single trial, which reported in the abstract that the study was double-blind, but
25 that is was single-blind in the body of the manuscript.
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30 31 32 33 34 *Reporting of blinding in protocol registrations*

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36 There were 384 (62%) trials that reported trial registration and unique registration identifier.
37 After searching for those protocol registrations online, we were able to find 315 of those 384
38 (82%); we were unable to retrieve the rest by searching for the reported trial protocol registry
39 identifier. Of the 315 protocol registrations we managed to access, 174 (55%) were registered
40 prospectively, and as many as 141 (45%) were registered after the study start date reported in
41 a clinical trials register.
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51 Detailed analysis of 174 prospectively registered trials in registries was conducted. The
52 majority of the trial protocols were registered in the ClinicalTrials.gov (n=157; 90%). Two
53 studies from our cohort were registered on ClinicalTrials.gov as observational studies, and did
54 not have information about blinding. The remaining 155 trials registered on ClinicalTrials.gov
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3 had 14 different categories of the study status in the section Study design, which contains pre-
4
5 determined Masking registration field (Table 5).
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8 In the protocol registrations on ClinicalTrials.gov, the most common descriptor in the sub-
9
10 section Masking was “Quadruple (Participant, Care Provider, Investigator, Outcomes
11
12 Assessor)” (Table 5). Besides this field, we also analyzed full text of the protocol registration
13
14 to find any other descriptions of blinding/masking. Among 157 protocol registrations, 92 did
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16 not have any other terminology related to blinding/masking other than information in the pre-
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18 determined field Masking. In the remaining 65 trial protocol registrations, 47 (72%) protocol
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20 registrations had additional information about blinding that were different from the descriptor
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22 provided in the field Masking. The majority of discrepancies accounted for protocol
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24 registrations which described the trial as quadruple-blind or triple-blind in the Masking
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26 registration field, but also described it as double-blind in another part of the protocol
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28 registration.
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34 In the other trial registries few trials were registered (Table 6) and we found only one
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36 discrepancy; in a trial registered in NTR a study was described to use “single masking” but
37
38 that it was “double-blind” (Table 6).
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41 Among 126 registered trials that did not have discrepancies in the protocol registration, for 88
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43 (70%) trials we found differences between protocol registration and published manuscript in
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45 description of blinding. The most common differences were in the description of who was
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47 blinded, the extent of blinding and whether there was any blinding at all (Table 7). We did not
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49 find trial protocols published as supplementary files or as a manuscript in a scholarly journal.
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56 *Survey results*

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3 For 362 trials that were described as double-blind, there were 275 unique corresponding
4 authors, and 264 email addresses available. There were 33 e-mails that returned undelivered
5 because they were no longer in use. From the remaining 231 corresponding authors, we
6 received 40 responses (17% response rate). Authors' responses regarding individuals that
7 were blinded in their trials, as well as their opinions about who was blinded in single-, double-
8 and triple-blinded trial are shown in Table 8. One participant who answered the question
9 about blinding in their trial, provided a personal definition for the single-blind trial, but stated
10 the following for the remaining questions: *"I cannot answer the rest of the questions. I don't*
11 *use "double-blind" or "single-blind" any longer, as I think they are ambiguous. I adhere to*
12 *Annals of Internal Medicine guidelines that advises authors to avoid those terms, but to*
13 *specifically note who was blinded."*

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29 Whereas 34 of 40 (85%) authors responded that participants were blinded in their own
30 double-blinded trial, all authors that responded to the second question stated that in a double-
31 blind trial participants are blinded. Table 8 shows the summary of responses, and
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Supplementary file 3 contains detailed anonymized responses. For a single-blind trial,
surveyed authors chose at least one from five of six individuals as targets for blinding; only
manuscript writers were never considered as individual that could be blinding in a trial. When
asked about their personal definition, in respondents' choices of blinded individuals in
double- and triple-blind trial, all six types of individuals were chosen. Outcome assessors,
data analysts and manuscript writers were more commonly mentioned as individual who
could be blinded in a triple-blind trial (Table 8).

In addition, 25 participants estimated the percentage of how often their personal definition of
a double-blind trial is used in trials they published: this percentage ranged from 20% to 100%,
with the median of 80% (95% CI 60% to 80%).

Discussion

We found that only a quarter of analyzed trials reported explicitly whether three key groups of individuals were blinded. One fifth reported the information about blinding or lack of blinding in the title. Most common description related to blinding, both in the title and in the manuscript, was that study was double-blind. Regarding terminology, “blinding” as a term was used in the majority of trials, whereas only a few trials used term masking. In the majority of trials described as blinded, it was unclear whether participants and other relevant individuals were blinded or not. For less than half of the trials we identified that they registered their protocols in public trial registries, and in the majority of those protocol registrations we found discrepant information about blinding – both in different fields in the protocol registration and between the protocol registration and published manuscript.

In 2006, Haar and Hjobjartsson analyzed 200 random RCTs and showed that the blinding status of participants, health care providers and data collectors was explicitly reported in 2% of those trials [14]. In our study this finding was better; we found that the blinding status of these three groups of individuals was explicitly reported in 14% of the analyzed trials.

Haar and Hjobjartsson reported that 56% of trials they analyzed did not report blinding status of any group of participants associated with a trial, and 26% reported no information relevant to blinding beyond indicating that the trial was “double-blind” [14]. Even though that study was published twelve years ago, the results of our study are even worse, as we found that 57% of analyzed trials were explicitly described as blinded, using terms “blinded”, “single-blinded”, “double-blinded”, “triple-blinded”) or a term “masked”.

In terms of completeness of reporting, Haar and Hjobjartsson, among the 156 manuscripts describing double-blind trials, did not find a single manuscript with “complete reporting”. They found only three (2%) manuscripts with “partial reporting”, 65 (42%) manuscripts with “minimal reporting”, and 88 (56%) manuscripts with “no reporting” [14].

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3 However, it has been emphasized already that the assessment of bias associated with blinding,
4 or lack of blinding, in clinical trials, is hampered by poor reporting [15]. Already sixteen years
5 ago Montori et al. warned that journals should abandon the term double-blind and require
6 explicit reporting of the blinding status of relevant groups of participant that are involved in a
7 clinical trial [15]. Our study shows that warnings aimed towards journal editors [15] were not
8 successful in the efforts to reduce the use of ambiguous term double-blind.
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20 *Discrepancies in blinding descriptors within trial protocol registrations, and between protocol*
21 *registrations and published manuscripts*
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25 One of the striking findings of our study was related to the discrepancies in blinding/masking
26 information within different registration fields for trial protocol registrations, and between
27 those protocol registrations and published manuscripts.
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31 Firstly, we were able to identify protocol registrations for only about half of trials in our
32 cohort, either because the authors did not report trial registration in their manuscripts, or
33 because the reported trial protocol registration was not retrievable. Since 2005, International
34 Committee of Medical Journal Editors (ICMJE) recommends that journals require prospective
35 registration of clinical trials, i.e. before or at the time of first patient enrolment [16].
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44 Therefore, it is unfortunate that so many recently published trials do not report trial
45 registration in the manuscript, but this is not an isolated finding. In our recent study of
46 osteoarthritis trials published between 2012 and 2017, we found that 57% of 334 analyzed
47 trials reported that trial was registered [17]. Another recent study showed that 28% of trials
48 published in six high-impact general medicine journals did not comply with ICMJE policy on
49 prospective trial registration [18]. Therefore, even though we analyzed high-impact journals
50 in the field, our results are similar to previous findings, which showed that many trials still do
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3 not report trial registration and adhere to ICMJE policy, even though they were published
4 recently and in high-impact journals.
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8 Furthermore, the analysis of trial protocol registrations that we were able to identify showed
9 that 45% of them were registered after the study has already started, judging by the study start
10 date that was reported in the trial registry. When we analyzed the information about
11 blinding/masking, we found that the majority of protocol registrations had discrepant
12 information about the blinding of the study in different registration fields. The analysis of
13 trials in which we did not find discrepancies between registration fields showed that the
14 majority of those trials had differences between reporting of blinding in a protocol registration
15 and a published manuscript.
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ClinicalTrials.gov was the most commonly used clinical trial registry. This is in line with the finding that ClinicalTrials.gov contains the majority of the global trial registrations [19]. It has a mandatory field called “Masking”, which offers to study authors to choose among five options in a menu. The first four options in the menu are individuals involved within a trial: Participant, Care Provider, Investigator and Outcomes Assessor. The fifth option is “None (Open Label)”. Study authors are invited to “Check all roles that are masked or check None (Open Label)”. Below this menu is a blank field called “Masking description”, in which trialists can fill out additional information about blinding. Based on the number of participants that were checked as blinded, a trial will get a descriptor about being single, double, triple or quadruple blinded. The most common discrepancy within protocol registrations was that the study was described as quadruple or triple blind by ClinicalTrials.gov, but trialists themselves called the study “double-blind”.

Meaning of “double-blind”

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3 Suggestion of Montori et al. that vague term “double-blind” should be abandoned [15] was also
4
5 repeated later in the literature by other authors [14]. Even before that, Devereaux et al. reported
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7 that hospital physicians used 17 different definitions of the meaning of double-blind [10].
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10 Our survey of authors showed that authors have varying definitions of who should be blinded
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12 in a single-blind, double-blind and triple-blind trial. Authors’ response about who was blinded
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14 in their own double-blind trial did not always match their response about who should be blinded
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16 in a double-blind trial generally. Based on the participants’ responses that the majority of
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18 published trials correspond to their personal definition of a double-blind trial, it appears that the
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20 surveyed researchers are not aware of the high heterogeneity of definitions of blinding in
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22 clinical trials. This is an additional argument for ceasing the use of ambiguous terminology such
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24 as “single-blind”, “double-blind” and “triple-blind”, and to require that authors should report
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26 specifically who was blinded in their study.
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34 **Limitations**

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37 Our study had several limitations. We limited our analysis to a recent period and to seven high-
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39 ranking journals, because those should be the ones with best publishing practices and role
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41 models for the rest of the journals. Furthermore, we did not scrutinize in detail additional online
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43 material, such as supplements and appendices, where, theoretically, additional details about
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45 blinding could have been located. But we did analyze all mentions of blinding in the analyzed
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47 manuscripts, and we did not find a single case where the authors indicated that additional details
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49 about blinding were available in a supplement.
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54 We used PubMed to search for articles instead of journals’ website, and we used simple search
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56 consisting of journal name, publication type and chosen time frame. Theoretically, some articles
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58 may have therefore been missed. However, we consider that the likelihood for this was small
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3 because these journals are all indexed on PubMed, and searching of the journal websites would
4
5 be more troublesome because of the lack of search filters that are available on PubMed.
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8 We used JIF to define high-impact journals. The use of JIF as a measure of “quality” has been
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10 criticized in the research community, specifically due to the asymmetry between the numerator
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12 and the denominator, differences across various disciplines, the insufficient citation window,
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14 the skewness of the underlying citation distributions, and opaque method of its calculation [20].
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16 However, there is no perfect bibliometric indicator, and we used it because JIF is highly
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18 prevalent, and most researchers are familiar with this metrics [21]. Also, we did not analyze all
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20 medical fields, but focused on one field of interest. Our survey had response rate of 17%, which
21
22 carries a high risk of non-responder bias.
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26
27 Another thing that would be worthwhile to explore is journals’ instructions for author in terms
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29 of reporting requirements. However, we included studies published over a long period of time,
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31 and it has to be taken into account that there is a time lag between submission and publication,
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33 and that journal web sites only provide the information about current instructions for authors,
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35 and not also the history of their changes, i.e. previous versions of instructions for authors.
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37 Therefore, the only proper way to study influence of instructions for authors on reporting in
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39 manuscript would be to do it prospectively, having in mind current instructions for authors and
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41 current submissions.
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46 It could be argued that perhaps we should not have judged it as discrepancy if an abstract
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48 reported that a study was “double-blind”, but body of the manuscript reported more details
49
50 about who was blinded. However, a reporting extension CONSORT for Abstracts explicitly
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52 requires authors to report in the abstract [quote]: “*Whether or not participants, care givers, and*
53
54 *these assessing the outcomes were blinded to group assignment*“. Therefore, if authors want to
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56 report their study adequately, adherence to the relevant reporting guideline would also preclude
57
58 usage of the term “double-blind” in an abstract [22].
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Recommendations

The authors should stop using ambiguous term “double-blind”, and editors, and peer-reviewers can help in achieving this by requiring clear reporting about blinding. Additionally, editors and peer-reviewers can require authors to provide a CONSORT checklist for both abstract (in line with the extension CONSORT for Abstracts) and the body of the manuscript. In this way, the authors may be compelled into investing more attention to proper reporting.

Conclusion

Explicit and complete reporting of the blinding status of key individuals involved in RCTs is suboptimal. Anesthesiology trials rarely report who was blinded, and mostly use ambiguous term double-blind, which if not sufficiently informative for readers. Furthermore, we found many discrepancies about reporting of blinding within trial protocol registrations, and between protocol registrations and published manuscripts. Our survey of authors showed that authors differed in their opinion of who was blinded in their own trial and who could be blinded in trials with different levels of blinding. Thus, poor reporting and heterogeneous definitions of ambiguous terminology hinders proper risk of bias assessment and analysis of impact of blinding of certain groups of participants on the study outcomes. Interventions for improving reporting about blinding are necessary.

Declarations

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Competing interests

The authors declare that they have no competing interests.

Authorship contribution

Study design: LP, AM

Data acquisition: AP, DB, KB, MK, LP

Data analysis and interpretation: LP, AM

Writing manuscript draft: LP, AM

Agreeing to submission of the manuscript: AP, DB, KB, MK, AM, LP

Agree to be accountable for all aspects of the work: AP, DB, KB, MK, AM, LP

Reporting checklist

STROBE; checklist is enclosed as a Supplementary file 4

Participant consent form

All participants consented to participate in the study; there are no identifiable information about participants in the manuscript.

Data sharing statement

Data collected during the study are available from the corresponding author on reasonable request.

Patient and public involvement statement

Patients or the public were not involved in the design, or conduct, or reporting, or dissemination of our research.

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Word count

4190

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3 **Figure legend**
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5 **Figure 1. Study inclusion flow chart**
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10 **List of supplementary files**
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14 **Supplementary file 1. Survey sent to the study participants**

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17 **Supplementary file 2. List of included studies**
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19 **Supplementary file 3. Detailed responses of survey participants**
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21 **Supplementary file 4: STROBE checklist**
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For peer review only

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Table 1. Descriptors for blinding status of the study in titles of analyzed trials, N=116

Blinding status descriptors	N (%)
Double-blind	89 (76)
Blinded	8 (6.8)
Single-blinded	6 (5.1)
Triple-masked	3 (2.6)
Triple-blind	3 (2.6)
Open-label	1 (0.9)
Observer-blinded	1 (0.9)
Blinded evaluation	1 (0.9)
Blinded trial	1 (0.9)
Nonblinded	1 (0.9)
Double-masked	1 (0.9)
Masked	1 (0.9)

Table 2. Descriptors about blinding found in abstracts of analyzed trials; N= 294 descriptors from 283 abstracts

Categories of descriptors	N (%)
Double-blind	183 (62)
Single-blind	25 (8.5)
Blinded personnel	22 (7.5)
Blinded	20 (6.8)
Outcome assessors blinded	14 (4.7)
Open label	8 (2.7)
Patient and assessor blinded	4 (1.4)
Triple-masked	3 (1.0)
Blinded intervention application	3 (1.0)
Unmasked intervention	2 (0.7)
Blinded patients	2 (0.7)
Triple blind	2 (0.7)
Patients and personnel blinded	2 (0.7)
Clinicians not blinded	1 (0.3)
Unblinded assessment	1 (0.3)
Blinded monitoring	1 (0.3)
Success of patients' blinding	1 (0.3)

Table 3. Categorized statements about blinding found in Methods of analyzed trials; N=470

Categories of descriptors	N (%)
Double-blind	191 (41)
Personnel blinded	75 (16)
Single-blind	38 (8.1)
Patients and personnel blinded	37 (7.9)
Outcome assessor blinded	26 (5.5)
Data collectors blinded	19 (4.0)
Non-blinded personnel	17 (3.6)
Patients blinded	16 (3.4)
Blinded	14 (3.0)
Open-label	8 (1.7)
Data analysts blinded	8 (1.7)
Partially blinded	3 (0.6)
Unmasked patients and investigators	3 (0.6)
Non-blinded patients	2 (0.4)
Blinded interventions	2 (0.4)
Triple-blind	1 (0.2)
Unmasking information	1 (0.2)
Non-masked patients and personnel	1 (0.2)
Rater-blinded	1 (0.2)
Masked assignment	1 (0.2)
Masking	1 (0.2)
Outcome assessors and data analysts blinded	1 (0.2)
Data collector and data analysts blinded	1 (0.2)
Data collector and outcome assessor blinded	1 (0.2)

Table 4. Prevalence of blinding of individuals involved in trials described as blinded; N=622

Individual	Yes, N (%)	No, N (%)	Unclear, N (%)
Participants	227 (37)	46 (7)	349 (56)
Personnel; healthcare providers such as physicians or nurses taking care of a participant	225 (36)	55 (9)	342 (55)
Data collectors	161 (26)	29 (5)	432 (69)
Outcome assessors	130 (21)	21 (3)	471 (76)
Data analysts	43 (7)	20 (3)	559 (90)
Manuscript writers	0 (0)	16 (3)	606 (97)
Investigators	104 (17)	31 (5)	487 (78)

Table 5. Descriptors in the field Study design/Masking in the analyzed trial protocol registrations on ClinicalTrials.gov (N = 157)

Blinding terminology used in analyzed clinical trial protocol registrations	N
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)	39
None (Open Label)	22
Single (Participant)	15
Double (Participant, Investigator)	14
Double (Participant, Outcomes Assessor)	14
Triple (Participant, Investigator, Outcomes Assessor)	13
Triple (Participant, Care Provider, Investigator)	12
Single (Outcomes Assessor)	8
Single (Investigator)	6
Double (Participant, Care Provider)	5
Triple (Participant, Care Provider, Outcomes Assessor)	4
Study described as observational, without information about blinding/masking	2
Double (Investigator, Outcomes Assessor)	1
Masking: Triple (Participant, Care Provider, Investigator)	1
Single (Care Provider)	1

Table 6. Descriptors of blinding/masking in other clinical trial registries

Descriptors	N
ACTRN (N=8)	
Blinded (masking used)	4
Open (masking not used)	2
Subject and observer blinded	1
Blinded	1
UMIN (N=7)	
Single blind -participants are blinded	3
Single blind -investigator(s) and assessor(s) are blinded	2
Double blind -all involved are blinded	2
NTR (N=1)	
Single masking; double blind	1
ChiCTR (N=1)	
No statement about blinding	1

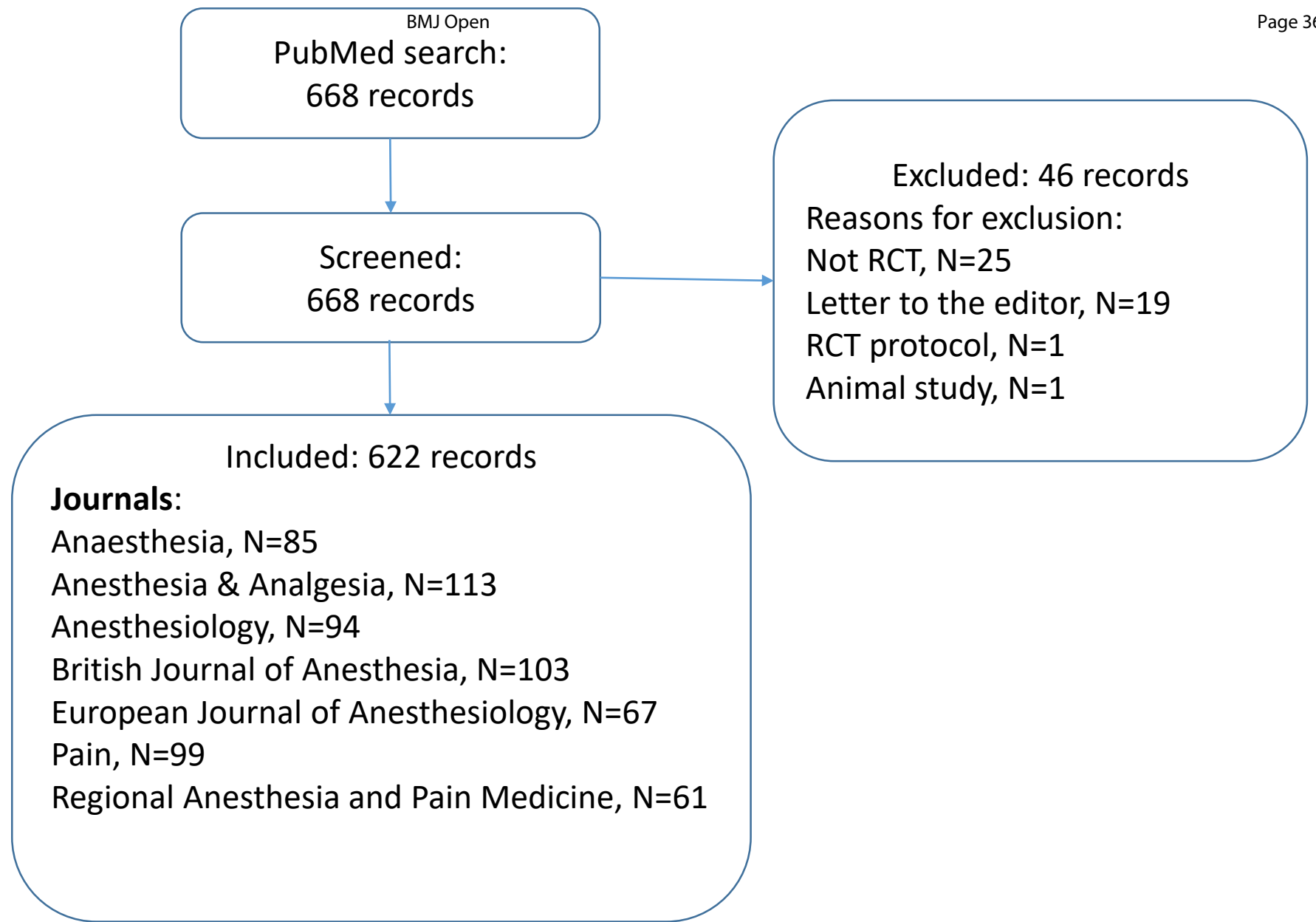
ACTRN = The Australian and New Zealand Clinical Trial Registry, UMIN = University Hospital Medical Information Network registry of Japan; NTR = Nederlands Trial Register, ChiCTR = Chinese Clinical Trial Registry

Table 7. Differences between protocol registration and manuscript, in the group of trials that did not have discrepancies within the protocol registration itself (N of trials = 88)

Differences between protocol and published manuscript	N (%)
Different individuals described as blinded between protocol registration and manuscript	30 (34)
Protocol registration reported who was blinded; manuscript did not	10 (11)
Protocol registration: triple blind; manuscript: double-blind	9 (10)
Protocol registration reported who was blinded; manuscript only that it was double-blind	9 (10)
Protocol registration: open label, manuscript: blinding of one or more groups of individuals	8 (9)
Protocol registration has description of blinding; manuscript no description of blinding	7 (8)
Protocol registration: quadruple-blind; manuscript: double-blind	6 (7)
Protocol registration double-blind, manuscript single-blind	2 (2)
Study described as observational on ClinicalTrials.gov	2 (2)
Protocol registration: quadruple-blind; manuscript: triple-blind	2 (2)
Protocol registration: no information about blinding; manuscript reported information about blinding	1 (1)
Protocol registration: open-label; manuscript only reported that participants were not blinded	1 (1)
Protocol registration: single-blind; manuscript: double-blind	1 (1)

Table 8. Information obtained from surveyed corresponding authors regarding who was blinded in their trials that were described as double-blind, and what is their personal definition of who is blinded in a single-blind, double-blind and triple-blind trial (total N of participants = 40)

Blinding scenarios	Participants, N	Healthcare providers such as physicians or nurses taking care of a participant, N	Data collectors, N	Outcome assessors, N	Data analysts, N	Manuscript writers, N
Who was blinded in your trial described as a double-blind?	34	31	32	28	18	10
What is your personal definition of a single-blind trial?	30	5	5	7	4	0
What is your personal definition of a double-blinded trial?	37	33	30	25	12	4
What is your personal definition of a triple-blind trial?	34	34	31	31	26	12



Supplementary file 1. Survey sent to the study participants via e-mail

Dear ...*[insert title and name]*,

My name is Dinka Begic, and I am conducting a study about blinding in randomised controlled trials. Together with Prof. Livia Puljak from Cochrane Croatia and our research team, we are trying to further investigate who exactly was blinded in trials described as „double blinded“, and what is the definition of double blinding that researchers use in clinical trials.

We would kindly ask you to participate in our research by answering three quick questions, which should take approximately five minutes of your time. The protocol of our research was approved by the Ethics committee of the University of Split School of Medicine on October 12th, 2018. Your response to this message will be considered as informed consent for participating in this study. We aim to publish anonymized data.

You are receiving invitation to participate in this research because you were a corresponding author for the RCT, which was described as double-blind: *[insert title of the study]*

These questions refer to that particular trial.

Questions

1. Who was blinded in your trial described as a double-blind? Please delete from the list below all of the persons in your trial that were NOT blinded, so that the remaining list contains only those who were blinded.
 - a. *participants*
 - b. *healthcare providers such as physicians or nurses taking care of a participant*
 - c. *data collectors*
 - d. *outcome assessors*
 - e. *data analysts*
 - f. *manuscript writers*
- 2.1 *What is your personal definition of a single-blind trial? Please delete from the list below all of the persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only individuals who are blinded in a single-blind trial.*
 - a. *participants*
 - b. *healthcare providers such as physicians or nurses taking care of a participant*
 - c. *data collectors*
 - d. *outcome assessors*
 - e. *data analysts*
 - f. *manuscript writers*

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6 2.2 What is your personal definition of a double blinded trial? Please delete from the list below all of
7 the persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only
8 individuals who are blinded in a double-blind trial.

- 9 a. *participants*
10
11 b. *healthcare providers such as physicians or nurses taking care of a participant*
12
13 c. *data collectors*
14
15 d. *outcome assessors*
16
17 e. *data analysts*
18
19 f. *manuscript writers*

20 2.3 What is your personal definition of a triple-blind trial? Please delete from the list below all of the
21 persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only
22 individuals who are blinded in a triple-blind trial.

- 23 a. *participants*
24
25 b. *healthcare providers such as physicians or nurses taking care of a participant*
26
27 c. *data collectors*
28
29 d. *outcome assessors*
30
31 e. *data analysts*
32
33 f. *manuscript writers*

34 3. How often is your personal definition of a double-blind trial used in published trials? Can you please
35 estimate using percentages:

36 _____
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38 Thank you very much for participating in this study.
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40 Sincere regards,
41 Dinka Begic, MD
42 Prof. Livia Puljak, MD, PhD, Cochrane Croatia
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Supplementary file 2. List of included studies

1. Nader A, Kendall MC, Manning DW, Beal M, Rahangdale R, Dekker R, De Oliveira GS Jr, Kamenetsky E, McCarthy RJ. Single-Dose Adductor Canal Block With Local Infiltrative Analgesia Compared With Local Infiltrate Analgesia After Total Knee Arthroplasty: A Randomized, Double-Blind, Placebo-Controlled Trial. *Reg Anesth Pain Med*. 2016 Nov/Dec;41(6):678-684.
2. Mohamed SA, Abdel-Ghaffar HS, Kamal SM, Fares KM, Hamza HM. Effect of Topical Morphine on Acute and Chronic Postmastectomy Pain: What Is the Optimum Dose? *Reg Anesth Pain Med*. 2016 Nov/Dec;41(6):704-710.
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4. Barrington MJ, Gledhill SR, Kluger R, Clarke AL, Wong DM, Davidson H, Thomas R. A Randomized Controlled Trial of Ultrasound Versus Nerve Stimulator Guidance for Axillary Brachial Plexus Block. *Reg Anesth Pain Med*. 2016 Nov/Dec;41(6):671-677.
5. Cerezo-Téllez E, Torres-Lacomba M, Fuentes-Gallardo I, Perez-Muñoz M, Mayoral-Del-Moral O, Lluch-Girbés E, Prieto-Valiente L, Falla D. Effectiveness of dry needling for chronic nonspecific neck pain: a randomized, single-blinded, clinical trial. *Pain*. 2016 Sep;157(9):1905-17. doi: 10.1097/j.pain.0000000000000591.
6. Kendigelen P, Tutuncu AC, Emre S, Altindas F, Kaya G. Pudendal Versus Caudal Block in Children Undergoing Hypospadias Surgery: A Randomized Controlled Trial. *Reg Anesth Pain Med*. 2016 Sep-Oct;41(5):610-5. doi: 10.1097/AAP.0000000000000447.
7. Dhir S, Sondekoppam RV, Sharma R, Ganapathy S, Athwal GS. A Comparison of Combined Suprascapular and Axillary Nerve Blocks to Interscalene Nerve Block for Analgesia in Arthroscopic Shoulder Surgery: An Equivalence Study. *Reg Anesth Pain Med*. 2016 Sep-Oct;41(5):564-71. doi: 10.1097/AAP.0000000000000436.
8. Kim JS, Lee J, Soh EY, Ahn H, Oh SE, Lee JD, Joe HB. Analgesic Effects of Ultrasound-Guided Serratus-Intercostal Plane Block and Ultrasound-Guided Intermediate Cervical Plexus Block After Single-Incision Transaxillary Robotic Thyroidectomy: A Prospective, Randomized, Controlled Trial. *Reg Anesth Pain Med*. 2016 Sep-Oct;41(5):584-8. doi: 10.1097/AAP.0000000000000430.

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6 9. Maalouf DB, Dorman SM, Sebeo J, Goytizolo EA, Gordon MA, Yadeau JT, Dehipawala
7 SS, Fields K.

8 Prospective, Randomized Double-Blind Study: Does Decreasing Interscalene Nerve
9 Block Volume for Surgical Anesthesia in Ambulatory Shoulder Surgery Offer
10 Same-Day Patient Recovery Advantages?

11 Reg Anesth Pain Med. 2016 Jul-Aug;41(4):438-44. doi:
12 10.1097/AAP.0000000000000418.
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16 10. Schreiber KL, Chelly JE, Lang RS, Abuelkasem E, Geller DA, Marsh JW, Tsung A,
17 Sakai T.

18 Epidural Versus Paravertebral Nerve Block for Postoperative Analgesia in Patients
19 Undergoing Open Liver Resection: A Randomized Clinical Trial.

20 Reg Anesth Pain Med. 2016 Jul-Aug;41(4):460-8. doi: 10.1097/AAP.0000000000000422.
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23 11. Teunkens A, Vermeulen K, Van Gerven E, Fieuws S, Van de Velde M, Rex S.
24 Comparison of 2-Chloroprocaine, Bupivacaine, and Lidocaine for Spinal Anesthesia
25 in Patients Undergoing Knee Arthroscopy in an Outpatient Setting: A Double-Blind
26 Randomized Controlled Trial.

27 Reg Anesth Pain Med. 2016 Sep-Oct;41(5):576-83. doi:
28 10.1097/AAP.0000000000000420.
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31 12. Cappelleri G, Cedrati VL, Fedele LL, Gemma M, Camici L, Loiero M, Gallazzi MB,
32 Cornaggia G.

33 Effects of the Intraneural and Subparaneural Ultrasound-Guided Popliteal Sciatic
34 Nerve Block: A Prospective, Randomized, Double-Blind Clinical and
35 Electrophysiological Comparison.

36 Reg Anesth Pain Med. 2016 Jul-Aug;41(4):430-7. doi: 10.1097/AAP.0000000000000413.
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40 13. Broderick JE, Keefe FJ, Schneider S, Junghaenel DU, Bruckenthal P, Schwartz
41 JE, Kaell AT, Caldwell DS, McKee D, Gould E.

42 Cognitive behavioral therapy for chronic pain is effective, but for whom?
43 Pain. 2016 Sep;157(9):2115-23. doi: 10.1097/j.pain.0000000000000626.
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46 14. Andresen SR, Bing J, Hansen RM, Biering-Sørensen F, Johannesen IL, Hagen EM,
47 Rice AS, Nielsen JF, Bach FW, Finnerup NB.

48 Ultramicronized palmitoylethanolamide in spinal cord injury neuropathic pain: a
49 randomized, double-blind, placebo-controlled trial.

50 Pain. 2016 Sep;157(9):2097-103. doi: 10.1097/j.pain.0000000000000623.
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54 15. Miki K, Murakami M, Oka H, Onozawa K, Yoshida S, Osada K.

55 Efficacy of mirtazapine for the treatment of fibromyalgia without concomitant
56 depression: a randomized, double-blind, placebo-controlled phase IIa study in
57 Japan.

58 Pain. 2016 Sep;157(9):2089-96. doi: 10.1097/j.pain.0000000000000622.
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5 16. Hanling SR, Hickey A, Lesnik I, Hackworth RJ, Stedje-Larsen E, Drastal CA,
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7 Stellate Ganglion Block for the Treatment of Posttraumatic Stress Disorder: A
8 Randomized, Double-Blind, Controlled Trial.
9 Reg Anesth Pain Med. 2016 Jul-Aug;41(4):494-500. doi:
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13 17. Runge C(1), Børglum J, Jensen JM, Kobborg T, Pedersen A, Sandberg J, Mikkelsen
14 LR, Vase M, Bendtsen TF.
15 The Analgesic Effect of Obturator Nerve Block Added to a Femoral Triangle Block
16 After Total Knee Arthroplasty: A Randomized Controlled Trial.
17 Reg Anesth Pain Med. 2016 Jul-Aug;41(4):445-51. doi:
18 10.1097/AAP.0000000000000406.
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22 18. Arendt-Nielsen L, Harris S, Whiteside GT, Hummel M, Knappenberger T, O'Keefe
23 S, Kapil R, Kyle D.
24 A randomized, double-blind, positive-controlled, 3-way cross-over human
25 experimental pain study of a TRPV1 antagonist (V116517) in healthy volunteers and
26 comparison with preclinical profile.
27 Pain. 2016 Sep;157(9):2057-67. doi: 10.1097/j.pain.0000000000000610.
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31 19. Dewinter GB, Teunkens A, Vermeulen K, Al Tmimi L, Van de Velde M, Rex S.
32 Systemic Lidocaine Fails to Improve Postoperative Pain, But Reduces Time to
33 Discharge Readiness in Patients Undergoing Laparoscopic Sterilization in Day-Case
34 Surgery: A Double-Blind, Randomized, Placebo-Controlled Trial.
35 Reg Anesth Pain Med. 2016 May-Jun;41(3):362-7. doi: 10.1097/AAP.0000000000000398.
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42 20. Smith SM(1), Amtmann D, Askew RL, Gewandter JS, Hunsinger M, Jensen MP,
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49 PROTECCT system.
50 Pain. 2016 May;157(5):1056-64. doi: 10.1097/j.pain.0000000000000502.
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4 Evaluation of a New Needle Guidance System for Ultrasound: Results of a
5 Prospective, Randomized, Blinded Study.
6 Reg Anesth Pain Med. 2016 May-Jun;41(3):356-61. doi:
7 10.1097/AAP.0000000000000390.
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12 sensorimotor integration using a complex typing task.
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Supplementary file 3. Detailed survey responses

Participant code	Who was blinded in your trial described as a double-blind?	What is your personal definition of a <u>single-blind</u> trial?	What is your personal definition of a <u>double blinded</u> trial?	What is your personal definition of a <u>triple-blind</u> trial?	How often is your personal definition of a double-blind trial used in published trials?
1	participants healthcare providers such as physicians or nurses taking care of a participant data collectors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	No answer
2	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	50%
3	data analysts manuscript writers	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	I am unable to respond ; in RCTs of rTMS this is less than 50 %

4	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	100%
5	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	I suppose that in the prospective clinical trials, nowadays, it will be used in a high percentage (80%?), if it is possible to perform the masking in the study area in question. But, of the total of studies that exist, I suspect that it will not be more than 20% of the total, taking into account the high number of retrospective studies.
6	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	1. participants OR 2. healthcare providers such as physicians or nurses taking care of a participant	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5.	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts 6.	25%

7	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	participants	> 1. participants > 2. healthcare providers such as physicians or nurses taking care of a participant > 3. data collectors > 4. outcome assessors > 5. data analysts > 6. manuscript writers	Never heard of this term?	Not sure I would hope at least 80%
8	a. participants b. data collectors c. outcome assessors d. data analysts	1. data collectors 2. outcome assessors 3. data analysts	1. participants 2. data collectors 3. outcome assessors 4. data analysts	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	20%
9	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	No response?	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	In trials performed by pharmaceutical companies ph 1 trials are often single blinded whereas all other trials are called double-blinded but are often triple blinded.....or moreas the only unblinded person(s) is a pharmacist or an assessor who may be unblinded by side effect reports. Those unblinded folks would be clearly specified in the protocol and would not be involved in collection of efficacy data.
10	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors manuscript writers	No response?	I cannot answer the rest of the questions. I don't use "double-blind" or "single-blind" any longer, as I think they are ambiguous. I adhere to Annals of Internal Medicine guidelines that advises authors to avoid those terms, but to specifically note		No answer

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			who was blinded.		
11	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	1. healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analyst	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	I don't specify my personal definition in my trials
12	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	100%
13	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	90%

14	data collectors outcome assessors	participants data collectors outcome assessors data analysts	participants data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	60%
15	participants * healthcare providers such as physicians or nurses taking care of a participant * outcome assessors	participants 4. outcome assessors	1. participants and/or 2. healthcare providers such as physicians or nurses taking care of a participant 4. outcome assessors	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 5. outcome assessors	90%
16	participants data collectors	participants	a. participants b. data collector	participants data collectors healthcare providers such as physicians or nurses taking care of a participant	70%
17	participants * healthcare providers such as physicians or nurses taking care of a participant * data collectors * outcome assessors * data analysts	healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	_I do not know

18	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	This is very hard to estimate. It probably depends on the field of interest and will widely vary between e.g. Oncology, Anesthesiology, Pain, Surgery, Internal Medicine etc.
19	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	90%
20	healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	20%

1 2 3 4 5 6 7 8 9 10 11 12 13 14	21	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts	No answer
15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31	22	participants data collectors outcome assessors data analysts	data collectors outcome assessors	participants data collectors outcome assessors	participants data collectors outcome assessors data analysts	50%
32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	23	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	95%

24	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	either participants or healthcare providers such as physicians or nurses taking care of a participant, but generally participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	just a and b probably 90%, with the addition of assessors probably around 40%.
25	participants healthcare providers such as physicians or nurses taking care of a participant	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants b. healthcare providers such as physicians or nurses taking care of a participant d. outcome assessors	80%

For peer review only

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1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	26	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants, healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	90%
26 27 28 29 30 31 32 33 34 35 36	27	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data analystist	From my point of view, data collector does not "take part" inthe definition of single/double/triple blind trial,because the data colector always is blinded. In my research is very difficult to use a double or triple blind trial. I have only used in research with drugs (5% of my reserach).
37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	28	* participants * healthcare providers such as physicians or nurses taking care of a participant * data collectors * outcome assessors * data analysts	participants	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	Sorry, can't answer. However I rarely see "triple-blind" used, despite my answer to 3...and that many of my own "double-blind" trials were "triple-blind"

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29	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	Do not know. Do you mean what I read or what I have published? I have publishes only one trial.
30	participants ALL healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors data analysts		80%

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31	outcome assessors data analysts manuscript writers	a. participants b. data collectors c. outcome assessors d. data analysts	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	70%
32	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	80%
33	participants healthcare providers such as physicians or nurses taking care of a participant data collectors Note that the healthcare providers were at the same time the data collectors and the outcome assessors in our trial.	participants	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors	a. Participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors	90%
34	participants data collectors outcome assessors data analysts manuscript writers	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	I do not have a personal definition. double blind is any two of the patient, the clinician, the outcome/data collectors. Many trials cannot be truly blinded, including the one you refer to above, where the administering physician is targeting a certain depth of anaesthesia.

35	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	50%
36	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	No answer
37	participants healthcare providers such as physicians or nurses taking care of a participant (ATTEMPTED BUT SUCCESS UNCERTAIN) data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	SORRY, BUT I HAVE NO IDEA.

38	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	80%
39	healthcare providers such as physicians or nurses taking care of a participant - after first day only [nurses in preadmission clinic were actually part of the intervention] data collectors outcome assessors data analysts manuscript writers	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	75
40	No answer	No answer	No answer	No answer	90

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	3-4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6-7
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA

Results			Page
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	9-12
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Definitions of blinding in randomized controlled trials of interventions published in high-impact anesthesiology journals: a methodological study and survey of authors

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Primary Subject Heading:	Epidemiology
Secondary Subject Heading:	Research methods
Keywords:	Clinical trials < THERAPEUTICS, STATISTICS & RESEARCH METHODS, EPIDEMIOLOGY

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3 **Definitions of blinding in randomized controlled trials of interventions published in**
4 **high-impact anesthesiology journals: a methodological study and survey of authors**
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9 Livia Puljak⁴
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Abstract

Objectives: To analyze completeness of reporting of blinding in randomized controlled trials (RCTs) of interventions in anesthesiology, the actual blinding status of various persons associated with an RCT and trial authors' interpretation of blinding terminology related to RCTs.

Methods: This was a methodological study and cross-sectional survey. We analyzed reporting related to blinding in published RCTs of interventions published in seven highly cited anesthesiology journals from 2014 to 2016, and registered protocols in ClinicalTrials.gov. We surveyed corresponding authors of included RCTs about their definitions of blinding. Primary outcome was the number of RCTs that explicitly described who was blinded in a trial. Secondary outcomes were definitions of blinding terminology in the trials; trial authors' interpretation of blinding terminology; discrepancies in blinding description within registered protocols, and between registered protocols and publications.

Results: Out of 622 analyzed RCTs, 38% were not explicitly described as either open-label or blinded studies and 10% did not report any information about blinding or lack of blinding. Only one manuscript fully reported status of blinding for various individuals that may be involved with a trial. The most common descriptor was that a trial was double-blind. We found discrepant information regarding blinding in the majority of registered protocols. Even when there were no discrepancies in the registration, we found discrepancies in the reporting of blinding between the majority of registered protocols and published manuscripts. The survey of authors (40 responses from 231 eligible authors; 17% response rate) of analyzed RCTs showed that they differed in how they defined different levels of blinding in trials.

Conclusions: Reporting of the blinding status of key individuals involved in analyzed anesthesiology RCTs was insufficient. Reporting guidelines, peer-reviewers and editors

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3 should insist on clear information on who was blinded in a trial instead of using the term
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5 “double-blind” for different blinding practices.
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11 **Keywords:** blinding, randomized controlled trial, participants, personnel, methodology
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Strengths and limitations

- We analyzed a large group of randomized controlled trials published in seven high-impact anesthesiology journals
- Reporting about blinding was insufficient in the majority of analyzed trials
- The term “double-blind” is ambiguous and researchers interpret it in different ways
- We focused on anesthesiology trials as a specific research field
- Future studies should monitor whether reporting about blinding in trials will improve

Introduction

The available evidence about the efficacy and safety of interventions in medicine includes observational studies and studies with a randomized experimental design, i.e., randomized controlled trials (RCTs) [1]. RCTs are considered the highest level of primary evidence for analyzing medical interventions because randomization ensures the allocation of participants by chance, and not by choice, which minimizes bias [2]. Apart from the method of allocating participants into study arms, there are other methodological aspects of an RCT that can contribute to a risk of bias, including performance bias (blinding of participants and personnel) and detection bias (blinding of outcome assessors) [3].

Blinding is very important for the validity of RCT results. Multiple studies reported significant differences in the effect size of treatment estimates depending on the use of blinding of key individuals [4-8].

The term “double-blind” is sometimes taken as a token of validity of an RCT [9]. However, it has been shown that the definitions of blinding may vary. Devereaux et al. showed that both physicians and textbooks provided highly inconsistent interpretations of the blinding terminology used in clinical trials, and suggested that the current ambiguous terminology should be replaced by specific descriptions of who was blinded [10]. According to the CONSORT checklist for reporting RCTs, the following should be reported for blinding: “If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how” [11].

The aim of this study was to analyze the completeness of the reporting of blinding in RCTs of interventions in the field of anesthesiology, the actual blinding status of the various persons involved in an RCT, information about the blinding reported in the registered trial protocol, and the trial authors’ interpretation of the blinding terminology related to RCTs. The study focused specifically on the field of anesthesiology because pain is a subjective outcome and

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2
3 there is no objective method for analyzing pain. The analgesic placebo effect has been well
4 documented [12]. In the area of placebo effects, expectations play a major role, triggering a
5 cascade of endogenous opioids and non-opioids, and altering the experience of pain [12]. For
6 this reason, the field of anesthesiology and pain research is likely biased if blinding is not
7 used adequately.
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Methods

Study design

We conducted a cross-sectional study of published RCTs and registered data from their protocols in public trial registries. Additionally, we surveyed the trials' corresponding authors.

Ethics

The research protocol for the survey of trials' corresponding authors was approved by the Ethics Committee of the University of Split School of Medicine (Klasa: 003-08/18-03/0001, Ur. br.: 2181-198-03-04-18-0049; date: October 12, 2018). All invited study participants received information that the study was approved by the Ethics Committee. The participants' continuation on to the survey from the invitation e-mail was considered as consent to participate in the study. The data were fully anonymized for analysis.

Inclusion criteria

We included RCTs of interventions published from January 2014 to December 2016 in the seven first-quartile journals from the Anesthesiology category in Journal Citation Reports (JCR). Based on the 2015 JCR journal impact factor (JIF), those seven journals were (in alphabetic order) Anaesthesia, Anesthesia & Analgesia, Anesthesiology, British Journal of Anaesthesia, European Journal of Anaesthesiology, Pain, and Regional Anesthesia and Pain Medicine. We excluded RCTs published as letters to the editor.

Search

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3 We searched PubMed by combining the journal name, the 2014-2016 time-frame, and the
4 publication type filter for RCTs. We exported titles and abstracts into the EndNote reference
5 management software (Clarivate Analytics, Boston, MA, USA). Two authors independently
6 analyzed titles and abstracts to screen them for eligibility. We retrieved potentially eligible full
7 text manuscripts and two authors screened them independently. We resolved any disagreements
8 through discussion.
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20 *Outcomes*

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23 The primary outcome was the number of RCTs that explicitly described who (which
24 individuals or group/s of individuals) was blinded in a trial. Secondary outcomes were the
25 definitions of the blinding terminology in the trials (how the authors defined “single-
26 blinding”, “double-blinding”, and “triple-blinding” in the manuscript), trial authors’
27 interpretation of the blinding terminology related to RCTs, as well as discrepancies in the
28 blinding description within registered protocols, and between registered protocols and
29 publications.
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42 *Data extraction*

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45 We extracted data into a Microsoft Excel sheet (Microsoft Inc., Redmond, WA, USA) after
46 the data extraction table was piloted with ten studies. Data from each trial were extracted
47 independently by two authors (three authors participated in data extraction: AP, KB, MK).
48 Independent extractions were compared for consistency and discrepancies were resolved via
49 consensus.
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57 For each publication, we analyzed the abstract, the full body of the manuscript (and
58 supplementary files if the authors indicated that additional details about the methods were in
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3 supplementary files) to see whether and in which part of the manuscript there was an explicit
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5 mention that the trial was blinded/masked. We then analyzed the Methods section of each
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7 included RCT and extracted information about the blinding terminology (“single-blind”,
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9 “double-blind”, “triple-blind”, or no such definition) and whether the trial authors explicitly
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11 elaborated on who was blinded in a trial.
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15 We checked whether the RCTs explicitly mentioned using the CONSORT checklist for
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17 reporting or mentioned CONSORT as a reference. We analyzed whether there were any
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19 discrepancies in the reporting of blinding between abstracts and the body of the manuscript. If
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21 the abstract described the study as “double-blind”, but the body of the manuscript provided
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23 more details about who was blinded, we considered this a discrepancy. We also checked for
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25 the occurrence of the term “double-dummy” in the RCTs to assess the blinding in
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27 comparisons of drugs that are administered by different routes [13].
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31 We analyzed whether the RCTs mentioned trial protocol registration, and if yes, we recorded
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33 the protocol registration number and the name of the registry. We excluded trials registered
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35 after the trial was open for recruitment from further analysis. For trials registered before
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37 participants’ recruitment, we analyzed whether there was any description of blinding in the
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39 registered protocol. If we found a description of blinding, we compared whether there were
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41 any discrepancies between the details about blinding reported in the registered protocol and in
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43 the published manuscript(s). We also searched whether the RCTs mentioned a protocol as a
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45 supplementary file or as a publication in a scholarly journal.
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53 *Author survey*

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56 For the author survey, we extracted e-mail addresses of corresponding authors. We contacted
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58 corresponding authors of the included trials via e-mail, wherein they received information about
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3 the study and a list of questions. One author (DB) sent all the emails. After the initial e-mail
4 invitation, potential participants received four subsequent reminders one week apart if they did
5 not respond or indicated that they did not wish to participate. All surveys and reminders were
6 sent between November 1, 2018 and January 9, 2019.
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10 We conducted the survey based on questions described previously [14]. Participants received
11 the following questions together with the title of their trial:
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- 15 1. For authors who only indicated that the study was blinded, double-blind, single-blind,
16 triple-blind, or provided no further details: “Who exactly was blinded in the trial [six
17 categories of participants, as used by Haahr and Hrobjartsson [14]: (i) participants, (ii)
18 healthcare providers such as physicians or nurses taking care of a participant, (iii) data
19 collectors, (iv) outcome assessors, (v) data analysts, (vi) manuscript writers]” –
20 categorical answers.
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- 32 2. What were authors’ personal opinions about the definitions of single-blind, double-blind
33 and triple-blind by providing them the same categorical answers from above, as well as
34 the response of “any two types of trial participants” [14].
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- 39 3. The authors were asked to assess the frequency of the publication of double-blind trials
40 in the literature adhering to their preferred definition. For example, if a participant
41 characterized “double-blind” to represent blinding of participants and personnel, that
42 author was subsequently asked to assess the frequency of “double-blind” trials in which
43 participants and personnel were blinded. The question did not refer to the publications
44 of the participants, but their estimation of the use of the term in the literature.
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53 We emphasized to the survey participants that only anonymized data would be published. The
54 exact text of the survey is presented in Supplementary file 1. In cases when we had identical
55 corresponding authors for more than one manuscript included in the study, we contacted them
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3 for the most recent manuscript only. Two authors (DB, LP) independently categorized the
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5 responses obtained via survey.
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10 11 *Analysis*

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13 We used descriptive statistics including frequencies and percentages, as well as medians and
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15 95% (CI) confidence intervals. Data were analyzed using MedCalc statistical software, v 15.2.1
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17 (MedCalc Software bvba, Ostend, Belgium).
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Results

Descriptors about blinding

We analyzed 622 RCTs; the study flow chart is shown in Figure 1. The list of included studies is presented in Supplementary file 2. In the description of the study design, 29 (4.7%) trials were explicitly described as non-blinded or open-label, while 357 (57%) were explicitly described as blinded, using terms “blinded”, “single-blinded”, “double-blinded”, “triple-blinded” or “masked” in the description of study design. The study design of the remaining 236 (38%) trials was not explicitly described as blinded or non-blinded.

The information about the blinding status was found in 116 (19%) titles; 283 (45%) abstracts and 470 (76%) Methods sections. The most common descriptor for blinding in titles (Table 1), abstracts (Table 2) and Methods sections (Table 3) was “double-blind”.

Regarding the blinding vs masking terminology, the most common term used in the analyzed trials was “blinding” (n=477, 76%). Masking as a term alone was used in 9 (1.4%) trials, while in 45 (7.2%) trials both blinding and masking terms were used. In 91 (15%) trials, neither the word blinding nor masking was used. The term “double-dummy” was found in 7 trials and “triple-dummy” in 1 trial.

Blinding of individuals involved in trials

We analyzed 531 trials to determine who was blinded in the trials. Concerning these trials, we found at least some descriptors for blinding, while the remaining trials were excluded from this analysis because they were described as open-label, or were not described as either blinded or open-label. Table 4 presents the prevalence of the blinding of various individuals that may be involved in a trial. For all six categories of individuals in the majority of trials, it was unclear whether these individuals were blinded.

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3 In 89 (17%) of 531 trials (14% from the overall sample of 622 trials), it was explicitly reported
4 whether the three key groups of individuals, i.e. the participants, healthcare providers and data
5 collectors, were blinded or not. This percentage seemed to improve over the analyzed time
6 frame, as it was 10% in 2014 (25/203), 15% in 2015 (31/203) and 26% in 2016 (33/125).
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12 Among the analyzed trials, 47 (8%) explicitly mentioned that they used the CONSORT
13 checklist for reporting or cited CONSORT as a reference.
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17 18 19 20 21 *Discrepancies between abstracts and the body of the manuscript*

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23 We found discrepancies in the reporting of blinding between abstracts and the body of the
24 manuscript in a single trial, which reported in the abstract that the study was double-blind, but
25 that is was single-blind in the body of the manuscript.
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30 31 32 33 34 *Reporting of blinding in registered protocols*

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36 There were 384 (62%) trials that reported trial registration and a unique registration identifier.
37 After searching for those registered protocols online, we were able to find 315 of those 384
38 (82%), but we were unable to retrieve the rest from our search using the reported trial registry
39 identifier. Of the 315 registered protocols we managed to access, 174 (55%) were registered
40 prospectively and as many as 141 (45%) were registered after the study start date reported in a
41 clinical trials registry.
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51 We conducted a detailed analysis of 174 prospectively registered trials in registries. The
52 majority of the trial protocols were registered in ClinicalTrials.gov (n=157; 90%). Two
53 studies from our cohort were registered on ClinicalTrials.gov as observational studies and did
54 not have information about blinding. The remaining 155 trials registered on ClinicalTrials.gov
55 had 14 different categories describing the design characteristics of the study in the Study
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3 design section, which contains the mandatory registration field for the selection of the
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5 masking type (Table 5).
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8 In the registered protocols on ClinicalTrials.gov, the most common descriptor in the Masking
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10 sub-section was “Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)”
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12 (Table 5). Besides this field, we also analyzed the full text of the registered protocol to find
13
14 any other descriptions of blinding/masking. Among 157 registered protocols, 92 did not have
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16 any other terminology related to blinding/masking other than the information in the
17
18 mandatory Masking field, and therefore no within-protocol discrepancies. In the remaining 65
19
20 registered trial protocols, 18 protocols had no discrepancies, while 47 (72%) registered
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22 protocols had additional information about the blinding that was different from the descriptor
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24 provided in the Masking field. Registered protocols that described the trial as quadruple-blind
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26 or triple-blind in the Masking registration field accounted for the majority of discrepancies,
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28 but the description of the trial as double-blind was also in another part of the registered
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30 protocol.
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36 In the 17 protocols registered in other trial registries, a few trials were registered (Table 6) and
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38 we found only one discrepancy in a trial registered in the Netherlands Trial Register (NTR)
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40 which indicated “single masking” but instead the masking was “double-blind” (Table 6). The
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42 remaining 16 registered protocols did not have any discrepancies related to blinding.
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46 Among 126 registered trials that did not have discrepancies in the registered protocols, for 88
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48 (70%) trials we found differences between the registered protocol and published manuscript
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50 in the description of blinding. The most common differences were in the description of who
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52 was blinded, the extent of blinding and whether there was any blinding at all (Table 7). We
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54 did not find trial protocols published as supplementary files or as a manuscript in a scholarly
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56 journal.
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Survey results

For 362 trials that were described as double-blind, there were 275 unique corresponding authors and 264 email addresses available. There were 33 undelivered e-mails because the addresses were no longer in use. From the remaining 231 corresponding authors, we received 40 responses (17% response rate). Authors' responses regarding individuals that were blinded in their trials, as well as their opinions about who was blinded in single-, double- and triple-blinded trials are shown in Table 8. One participant who answered the question about blinding in their trial provided a personal definition for the single-blind trial, but stated the following for the remaining questions: *"I cannot answer the rest of the questions. I don't use "double-blind" or "single-blind" any longer, as I think they are ambiguous. I adhere to Annals of Internal Medicine guidelines that advises authors to avoid those terms, but to specifically note who was blinded."*

Whereas 34 of 40 (85%) authors responded that participants were blinded in their own double-blinded trial, all authors that responded to the second question stated that participants are blinded in a double-blind trial. Table 8 shows the summary of responses, and Supplementary file 3 contains detailed anonymized responses. For a single-blind trial, surveyed authors chose at least one from five of six individuals as targets for blinding; only manuscript writers were never considered as individuals that could be blinded in a trial. When asked about their personal definition, respondents chose all six types of individuals given choices of blinded individuals in double- and triple-blind trials. Outcome assessors, data analysts and manuscript writers were more commonly mentioned as individuals who could be blinded in a triple-blind trial (Table 8).

In addition, 25 participants estimated the percentage of how often their personal definition of a double-blind trial is used in trials they published: this percentage ranged from 20% to 100%, with a median of 80% (95% CI 60% to 80%).

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Reporting checklist

This study was reported in line with the STROBE checklist, which is enclosed as a Supplementary file 4.

For peer review only

Discussion

We found that only a quarter of analyzed trials reported explicitly whether three key groups of individuals were blinded. One-fifth reported information about blinding or the lack of blinding in the title. The most common description related to blinding, both in the title and in the manuscript, was that the study was double-blind. Regarding terminology, “blinding” as a term was used in the majority of trials, whereas only a few trials used the term masking. In the majority of trials described as blinded, it was unclear whether participants and other relevant individuals were blinded or not. For less than half of the trials, we identified that they registered their protocols in public trial registries, and in the majority of those registered protocols we found discrepant information about blinding – both in different fields in the registered protocol and between the registered protocol and published manuscript.

In 2006, Haar and Hjobjartsson analyzed 200 random RCTs and showed that the blinding status of participants, health care providers and data collectors was explicitly reported in 2% of those trials [14]. In our study this finding was better; we found that the blinding status of these three groups of individuals was explicitly reported in 14% of the analyzed trials.

Twelve years ago it was indicated that 26% of trials reported no information relevant to blinding beyond indicating that the trial was “double-blind” [14]. We found that 57% of analyzed trials were explicitly described as blinded, using the terms “blinded”, “single-blinded”, “double-blinded”, “triple-blinded” or “masked”. Our study shows that warnings aimed towards journal editors [15] were not successful in the efforts to reduce the use of the ambiguous term double-blind.

Discrepancies in blinding descriptors within registered trial protocols and between registered protocols and published manuscripts

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3 One of the striking findings of our study was related to the discrepancies in blinding/masking
4 information within different registration fields for registered trial protocols, and between
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6 those registered protocols and published manuscripts.
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10 Firstly, we were able to identify registered protocols for only about half of the trials in our
11 cohort, either because the authors did not report trial registration in their manuscripts, or
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13 because the reported registered protocol was not retrievable. Since 2005, the International
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15 Committee of Medical Journal Editors (ICMJE) recommends that journals require prospective
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17 registration of clinical trials, i.e. before or at the time of first patient enrolment [16].
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20 Therefore, it is unfortunate that so many recently published trials do not report trial
21 registration in the manuscript, but this is not an isolated finding. In our recent study of
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23 osteoarthritis trials published between 2012 and 2017, we found that 57% of 334 analyzed
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25 trials reported their registration [17]. Another recent study showed that 28% of trials
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27 published in six high-impact general medicine journals did not comply with the ICMJE policy
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29 on prospective trial registration [18]. Therefore, even though we analyzed high-impact
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31 journals in the field, our results are similar to previous findings, which showed that many
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33 trials still do not report trial registration and adhere to ICMJE policy, even though they were
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35 published recently and in high-impact journals.
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43 Furthermore, the analysis of registered trial protocols that we were able to identify showed
44 that 45% of them were registered after the study has already started, judging by the study start
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46 date that was reported in the trial registry. When we analyzed the information about
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48 blinding/masking, we found that the majority of registered protocols had discrepant
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50 information about the blinding of the study in different registration fields. Our analysis of
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52 trials in which we did not find discrepancies between registration fields showed that the
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54 majority of those trials had differences between the reporting of blinding in a registered
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56 protocol and a published manuscript.
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3 ClinicalTrials.gov was the most commonly used clinical trial registry. This is in line with the
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5 finding that ClinicalTrials.gov contains the majority of global trial registrations [19]. Within
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7 the registry, the mandatory field called “Masking” offers study authors a choice of five
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9 options in a menu. The first four options in the menu are individuals involved in a trial:
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11 Participant, Care Provider, Investigator and Outcomes Assessor. The fifth option is “None
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13 (Open Label)”. Study authors are invited to “Check all roles that are masked or check None
14
15 (Open Label)”. Below this menu is a blank field called “Masking description”, in which
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17 trialists can fill out additional information about blinding. Based on the number of participants
18
19 that are checked as blinded, a trial will get a descriptor about being single, double, triple or
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21 quadruple blinded. The most common discrepancy within registered protocols was that the
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23 study was described as quadruple or triple blind by ClinicalTrials.gov, but trialists themselves
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25 called the study “double-blind”.
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33 *The meaning of “double-blind”*

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35 The suggestion by Montori et al. that the vague term “double-blind” should be abandoned [15]
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37 was also repeated later in the literature by other authors [14]. Even before that, Devereaux et
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39 al. reported that hospital physicians used 17 different definitions of the meaning of double-blind
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41 [10].
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45 Our survey of authors showed that authors have varying definitions of who should be blinded
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47 in a single-blind, double-blind and triple-blind trial. Authors’ response about who was blinded
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49 in their own double-blind trial did not always match their response about who should be blinded
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51 in a double-blind trial generally. Based on the participants’ responses that the majority of
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53 published trials correspond to their personal definition of a double-blind trial, it appears that the
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55 surveyed researchers are not aware of the high heterogeneity of the definitions of blinding in
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57 clinical trials. This is an additional argument for ceasing the use of ambiguous terminology such
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3 as “single-blind”, “double-blind” and “triple-blind”, and to require that authors should report
4 specifically who was blinded in their study.
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10 **Limitations**

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12 Our study had several limitations. We limited our analysis to a recent period and to seven high-
13 ranking journals. We did not scrutinize in detail additional online material, such as supplements
14 and appendices, where, theoretically, additional details about blinding could have been located.
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16 But we did analyze all mentions of blinding in the analyzed manuscripts and we did not find a
17 single case where the authors indicated that additional details about blinding were available in
18 a supplement.
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28 We used PubMed to search for articles instead of journals’ websites and we used a simple search
29 consisting of the journal name, publication type and chosen time frame. We used the JIF to
30 define high-impact journals. The use of the JIF as a measure of “quality” has been criticized in
31 the research community, specifically due to the asymmetry between the numerator and the
32 denominator, differences across various disciplines, the insufficient citation window, the
33 skewness of the underlying citation distributions, and the opaque method of its calculation [20].
34
35 However, there is no perfect bibliometric indicator and we used it because the JIF is highly
36 prevalent, and most researchers are familiar with this metrics [21]. Also, we did not analyze all
37 medical fields, but focused on one field of interest. Our survey had a response rate of 17%,
38 which carries a high risk of non-responder bias.
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51 Another thing that would be worthwhile to explore is the journals’ instructions for authors in
52 terms of reporting requirements. However, the only proper way to study the influence of
53 instructions for authors on reporting in a manuscript would be to conduct it prospectively,
54 having in mind the current instructions for authors and current submissions.
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3 It could be argued that perhaps we should not have judged an abstract as having a discrepancy
4 that reported therein that a study was “double-blind”, but the body of the manuscript reported
5 more details about who was blinded. However, the reporting extension to CONSORT for
6 Abstracts explicitly requires authors to report in the abstract [quote]: “*Whether or not*
7 *participants, care givers, and these assessing the outcomes were blinded to group assignment*“.
8 Therefore, if authors want to report their study adequately, adherence to the relevant reporting
9 guideline would also preclude the usage of the term “double-blind” in an abstract [22].
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22 **Recommendations**

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25 Authors of RCTs should stop using the ambiguous term “double-blind”, and editors and peer-
26 reviewers can help in achieving this by requiring clear reporting about the blinding.
27 Additionally, editors and peer-reviewers can require authors to provide a CONSORT checklist
28 for both the abstract (in line with the CONSORT extension for Abstracts) and the body of the
29 manuscript. In this way, authors of RCTs may be compelled to invest more attention to proper
30 reporting.
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42 **Conclusion**

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45 Explicit and complete reporting of the blinding status of key individuals involved in RCTs is
46 suboptimal. Anesthesiology trials rarely report who was blinded and mostly use the
47 ambiguous term double-blind, which is not sufficiently informative for readers. Furthermore,
48 we found many discrepancies about reporting of blinding within registered trial protocols, and
49 between registered protocols and published manuscripts. Our survey of authors showed that
50 authors differed in their opinion of who was blinded in their own trial and who could be
51 blinded in trials with different levels of blinding. Thus, poor reporting and heterogeneous
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3 definitions of ambiguous terminology hinders a proper risk of bias assessment and analysis of
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5 the impact of blinding of certain groups of participants on the study outcomes. Interventions
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7 for improving the reporting about blinding are necessary.
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For peer review only

Declarations

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Competing interests

The authors declare that they have no competing interests.

Authorship contribution

Study design: LP, AM

Data acquisition: AP, DB, KB, MK, LP

Data analysis and interpretation: LP, AM

Writing manuscript draft: LP, AM

Agreeing to submission of the manuscript: AP, DB, KB, MK, AM, LP

Agree to be accountable for all aspects of the work: AP, DB, KB, MK, AM, LP

Participant consent form

All participants consented to participate in the study; there is no identifiable information about participants in the manuscript.

Data sharing statement

Data collected during the study are available from the corresponding author on reasonable request.

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5 **Patient and public involvement statement**
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7 Patients or the public were not involved in the design, or conduct, or reporting, or
8 dissemination of our research.
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14 **Acknowledgements**
15

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17 Prof. Shelly Pranic, PhD, for proofreading final version of the manuscript.
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23 **Word count**
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3 **Figure legend**
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5 **Figure 1. Study inclusion flow chart**
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10 **List of supplementary files**
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14 **Supplementary file 1. Survey sent to the study participants**

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17 **Supplementary file 2. List of included studies**

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19 **Supplementary file 3. Detailed responses of survey participants**
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21 **Supplementary file 4: STROBE checklist**
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Table 1. Descriptors for blinding status of the study in titles of analyzed trials, N=116

Blinding status descriptors	N (%)
Double-blind	89 (76)
Blinded	8 (6.8)
Single-blinded	6 (5.1)
Triple-masked	3 (2.6)
Triple-blind	3 (2.6)
Open-label	1 (0.9)
Observer-blinded	1 (0.9)
Blinded evaluation	1 (0.9)
Blinded trial	1 (0.9)
Nonblinded	1 (0.9)
Double-masked	1 (0.9)
Masked	1 (0.9)

Table 2. Descriptors about blinding found in abstracts of analyzed trials; N= 294 descriptors from 283 abstracts

Categories of descriptors	N (%)
Double-blind	183 (62)
Single-blind	25 (8.5)
Blinded personnel	22 (7.5)
Blinded	20 (6.8)
Outcome assessors blinded	14 (4.7)
Open label	8 (2.7)
Patient and assessor blinded	4 (1.4)
Triple-masked	3 (1.0)
Blinded intervention application	3 (1.0)
Unmasked intervention	2 (0.7)
Blinded patients	2 (0.7)
Triple blind	2 (0.7)
Patients and personnel blinded	2 (0.7)
Clinicians not blinded	1 (0.3)
Unblinded assessment	1 (0.3)
Blinded monitoring	1 (0.3)
Success of patients' blinding	1 (0.3)

Table 3. Categorized statements about blinding found in the Methods section of analyzed trials; N=470

Categories of descriptors	N (%)
Double-blind	191 (41)
Personnel blinded	75 (16)
Single-blind	38 (8.1)
Patients and personnel blinded	37 (7.9)
Outcome assessor blinded	26 (5.5)
Data collectors blinded	19 (4.0)
Non-blinded personnel	17 (3.6)
Patients blinded	16 (3.4)
Blinded	14 (3.0)
Open-label	8 (1.7)
Data analysts blinded	8 (1.7)
Partially blinded	3 (0.6)
Unmasked patients and investigators	3 (0.6)
Non-blinded patients	2 (0.4)
Blinded interventions	2 (0.4)
Triple-blind	1 (0.2)
Unmasking information	1 (0.2)
Non-masked patients and personnel	1 (0.2)
Rater-blinded	1 (0.2)
Masked assignment	1 (0.2)
Masking	1 (0.2)
Outcome assessors and data analysts blinded	1 (0.2)
Data collector and data analysts blinded	1 (0.2)
Data collector and outcome assessor blinded	1 (0.2)

Table 4. Prevalence of blinding of individuals involved in trials described as blinded; N=622

Individual	Yes, N (%)	No, N (%)	Unclear, N (%)
Participants	227 (37)	46 (7)	349 (56)
Personnel; healthcare providers such as physicians or nurses taking care of a participant	225 (36)	55 (9)	342 (55)
Data collectors	161 (26)	29 (5)	432 (69)
Outcome assessors	130 (21)	21 (3)	471 (76)
Data analysts	43 (7)	20 (3)	559 (90)
Manuscript writers	0 (0)	16 (3)	606 (97)
Investigators	104 (17)	31 (5)	487 (78)

Table 5. Descriptors in the Study design/Masking field in the analyzed registered trial protocols on ClinicalTrials.gov (N = 157)

Blinding terminology used in analyzed registered clinical trial protocols	N
Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)	39
None (Open Label)	22
Single (Participant)	15
Double (Participant, Investigator)	14
Double (Participant, Outcomes Assessor)	14
Triple (Participant, Investigator, Outcomes Assessor)	13
Triple (Participant, Care Provider, Investigator)	12
Single (Outcomes Assessor)	8
Single (Investigator)	6
Double (Participant, Care Provider)	5
Triple (Participant, Care Provider, Outcomes Assessor)	4
Study described as observational, without information about blinding/masking	2
Double (Investigator, Outcomes Assessor)	1
Masking: Triple (Participant, Care Provider, Investigator)	1
Single (Care Provider)	1

Table 6. Descriptors of blinding/masking in other clinical trial registries

Descriptors	N
ACTRN (N=8)	
Blinded (masking used)	4
Open (masking not used)	2
Subject and observer blinded	1
Blinded	1
UMIN (N=7)	
Single blind -participants are blinded	3
Single blind -investigator(s) and assessor(s) are blinded	2
Double blind -all involved are blinded	2
NTR (N=1)	
Single masking; double blind	1
ChiCTR (N=1)	
No statement about blinding	1

ACTRN = The Australian and New Zealand Clinical Trial Registry, UMIN = University Hospital Medical Information Network registry of Japan; NTR = Nederlands Trial Register, ChiCTR = Chinese Clinical Trial Registry

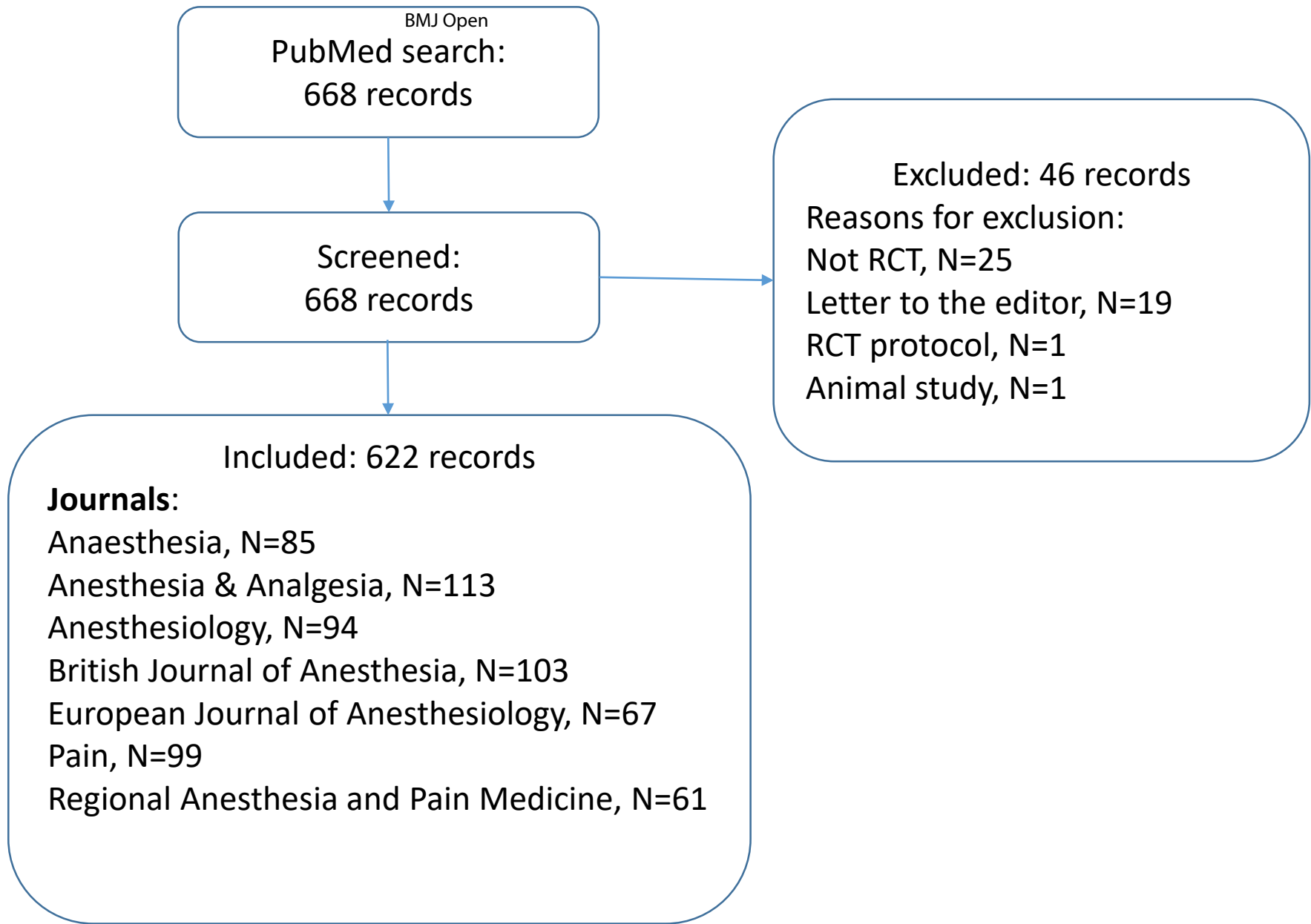
Table 7. Differences between the registered protocol and manuscript in the group of trials that did not have discrepancies within the registered protocol itself (N of trials = 88)

Differences between protocol and published manuscript	N (%)
Different individuals described as blinded between registered protocol and manuscript	30 (34)
Registered protocol reported who was blinded; manuscript did not	10 (11)
Registered protocol: triple blind; manuscript: double-blind	9 (10)
Registered protocol reported who was blinded; manuscript only that it was double-blind	9 (10)
Registered protocol: open label, manuscript: blinding of one or more groups of individuals	8 (9)
Registered protocol has description of blinding; manuscript no description of blinding	7 (8)
Registered protocol: quadruple-blind; manuscript: double-blind	6 (7)
Registered protocol double-blind, manuscript single-blind	2 (2)
Study described as observational on ClinicalTrials.gov	2 (2)
Registered protocol: quadruple-blind; manuscript: triple-blind	2 (2)
Registered protocol: no information about blinding; manuscript reported information about blinding	1 (1)
Registered protocol: open-label; manuscript only reported that participants were not blinded	1 (1)
Registered protocol: single-blind; manuscript: double-blind	1 (1)

Table 8. Surveyed corresponding authors' responses regarding who was blinded in their trials of those described as double-blinded and what is their personal definition of who is blinded in a single-blind, double-blind and triple-blind trial (total N of participants = 40)

Blinding scenarios	Participants, N	Healthcare providers such as physicians or nurses taking care of a participant, N	Data collectors, N	Outcome assessors, N	Data analysts, N	Manuscript writers, N
Who was blinded in your trial described as a double-blind?	34	31	32	28	18	10
What is your personal definition of a single-blind trial?	30	5	5	7	4	0
What is your personal definition of a double-blinded trial?	37	33	30	25	12	4
What is your personal definition of a triple-blind trial?	34	34	31	31	26	12

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Supplementary file 1. Survey sent to the study participants via e-mail

Dear ...*[insert title and name]*,

My name is Dinka Begic, and I am conducting a study about blinding in randomised controlled trials. Together with Prof. Livia Puljak from Cochrane Croatia and our research team, we are trying to further investigate who exactly was blinded in trials described as „double blinded“, and what is the definition of double blinding that researchers use in clinical trials.

We would kindly ask you to participate in our research by answering three quick questions, which should take approximately five minutes of your time. The protocol of our research was approved by the Ethics committee of the University of Split School of Medicine on October 12th, 2018. Your response to this message will be considered as informed consent for participating in this study. We aim to publish anonymized data.

You are receiving invitation to participate in this research because you were a corresponding author for the RCT, which was described as double-blind: *[insert title of the study]*

These questions refer to that particular trial.

Questions

1. Who was blinded in your trial described as a double-blind? Please delete from the list below all of the persons in your trial that were NOT blinded, so that the remaining list contains only those who were blinded.
 - a. *participants*
 - b. *healthcare providers such as physicians or nurses taking care of a participant*
 - c. *data collectors*
 - d. *outcome assessors*
 - e. *data analysts*
 - f. *manuscript writers*
- 2.1 *What is your personal definition of a single-blind trial? Please delete from the list below all of the persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only individuals who are blinded in a single-blind trial.*
 - a. *participants*
 - b. *healthcare providers such as physicians or nurses taking care of a participant*
 - c. *data collectors*
 - d. *outcome assessors*
 - e. *data analysts*
 - f. *manuscript writers*

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6 2.2 What is your personal definition of a double blinded trial? Please delete from the list below all of
7 the persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only
8 individuals who are blinded in a double-blind trial.

- 9 a. *participants*
10
11 b. *healthcare providers such as physicians or nurses taking care of a participant*
12
13 c. *data collectors*
14
15 d. *outcome assessors*
16
17 e. *data analysts*
18
19 f. *manuscript writers*

20 2.3 What is your personal definition of a triple-blind trial? Please delete from the list below all of the
21 persons who, in your personal opinion, are NOT blinded, so that the remaining list contains only
22 individuals who are blinded in a triple-blind trial.

- 23 a. *participants*
24
25 b. *healthcare providers such as physicians or nurses taking care of a participant*
26
27 c. *data collectors*
28
29 d. *outcome assessors*
30
31 e. *data analysts*
32
33 f. *manuscript writers*

34 3. How often is your personal definition of a double-blind trial used in published trials? Can you please
35 estimate using percentages:

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38 Thank you very much for participating in this study.
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40 Sincere regards,
41 Dinka Begic, MD
42 Prof. Livia Puljak, MD, PhD, Cochrane Croatia
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Supplementary file 2. List of included studies

1. Nader A, Kendall MC, Manning DW, Beal M, Rahangdale R, Dekker R, De Oliveira GS Jr, Kamenetsky E, McCarthy RJ. Single-Dose Adductor Canal Block With Local Infiltrative Analgesia Compared With Local Infiltrate Analgesia After Total Knee Arthroplasty: A Randomized, Double-Blind, Placebo-Controlled Trial. *Reg Anesth Pain Med*. 2016 Nov/Dec;41(6):678-684.
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7 SS, Fields K.
8 Prospective, Randomized Double-Blind Study: Does Decreasing Interscalene Nerve
9 Block Volume for Surgical Anesthesia in Ambulatory Shoulder Surgery Offer
10 Same-Day Patient Recovery Advantages?
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18 Epidural Versus Paravertebral Nerve Block for Postoperative Analgesia in Patients
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26 Randomized Controlled Trial.
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Randomized, Double-Blind, Controlled Trial.
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8 post-anaesthesia care unit: a randomized study.
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47 hypotension and tachycardia under spinal anaesthesia: a randomised controlled
48 trial.

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Supplementary file 3. Detailed survey responses

Participant code	Who was blinded in your trial described as a double-blind?	What is your personal definition of a <u>single-blind</u> trial?	What is your personal definition of a <u>double blinded</u> trial?	What is your personal definition of a <u>triple-blind</u> trial?	How often is your personal definition of a double-blind trial used in published trials?
1	participants healthcare providers such as physicians or nurses taking care of a participant data collectors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	No answer
2	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	50%
3	data analysts manuscript writers	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	I am unable to respond ; in RCTs of rTMS this is less than 50 %

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	4	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	100%
23 24 25 26 27 28 29 30 31 32 33 34	5	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	I suppose that in the prospective clinical trials, nowadays, it will be used in a high percentage (80%?), if it is possible to perform the masking in the study area in question. But, of the total of studies that exist, I suspect that it will not be more than 20% of the total, taking into account the high number of retrospective studies.
35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	6	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	1. participants OR 2. healthcare providers such as physicians or nurses taking care of a participant	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5.	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts 6.	25%

7	<p>participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers</p>	<p>participants</p>	<p>> 1. participants > 2. healthcare providers such as physicians or nurses taking care of a participant > 3. data collectors > 4. outcome assessors > 5. data analysts > 6. manuscript writers</p>	<p>Never heard of this term?</p>	<p>Not sure I would hope at least 80%</p>
8	<p>a. participants b. data collectors c. outcome assessors d. data analysts</p>	<p>1. data collectors 2. outcome assessors 3. data analysts</p>	<p>1. participants 2. data collectors 3. outcome assessors 4. data analysts</p>	<p>1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts</p>	<p>20%</p>
9	<p>participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers</p>	<p>No response?</p>	<p>participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers</p>	<p>participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers</p>	<p>In trials performed by pharmaceutical companies ph 1 trials are often single blinded whereas all other trials are called double-blinded but are often triple blinded.....or moreas the only unblinded person(s) is a pharmacist or an assessor who may be unblinded by side effect reports. Those unblinded folks would be clearly specified in the protocol and would not be involved in collection of efficacy data.</p>
10	<p>participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors manuscript writers</p>	<p>No response?</p>	<p>I cannot answer the rest of the questions. I don't use "double-blind" or "single-blind" any longer, as I think they are ambiguous. I adhere to Annals of Internal Medicine guidelines that advises authors to avoid those terms, but to specifically note</p>		<p>No answer</p>

			who was blinded.		
11	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	1. healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analyst	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	I don't specify my personal definition in my trials
12	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	100%
13	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	90%

14	data collectors outcome assessors	participants data collectors outcome assessors data analysts	participants data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	60%
15	participants * healthcare providers such as physicians or nurses taking care of a participant * outcome assessors	participants 4. outcome assessors	1. participants and/or 2. healthcare providers such as physicians or nurses taking care of a participant 4. outcome assessors	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 5. outcome assessors	90%
16	participants data collectors	participants	a. participants b. data collector	participants data collectors healthcare providers such as physicians or nurses taking care of a participant	70%
17	participants * healthcare providers such as physicians or nurses taking care of a participant * data collectors * outcome assessors * data analysts	healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	_I do not know

18	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	This is very hard to estimate. It probably depends on the field of interest and will widely vary between e.g. Oncology, Anesthesiology, Pain, Surgery, Internal Medicine etc.
19	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	90%
20	healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	20%

21	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts	No answer
22	participants data collectors outcome assessors data analysts	data collectors outcome assessors	participants data collectors outcome assessors	participants data collectors outcome assessors data analysts	50%
23	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	95%

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25	24	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	either participants or healthcare providers such as physicians or nurses taking care of a participant, but generally particiapnts	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	just a and b probably 90%, with the addition of assessors probably around 40%.
26 27 28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49	25	participants healthcare providers such as physicians or nurses taking care of a participant	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants b. healthcare providers such as physicians or nurses taking care of a participant d. outcome assessors	80%

26	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants, healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	90%
27	participants healthcare providers such as physicians or nurses taking care of a participant data collectors	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data analystist	From my point of view, data collector does not "take part" inthe definition of single/double/triple blind trial,because the data colector always is blinded. In my research is very difficult to use a double or triple blind trial. I have only used in research with drugs (5% of my reserach).
28	* participants * healthcare providers such as physicians or nurses taking care of a participant * data collectors * outcome assessors * data analysts	participants	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors	1. participants 2. healthcare providers such as physicians or nurses taking care of a participant 3. data collectors 4. outcome assessors 5. data analysts	Sorry, can't answer. However I rarely see "triple-blind" used, despite my answer to 3...and that many of my own "double-blind" trials were "triple-blind"

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27	29	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	Do not know. Do you mean what I read or what I have published? I have publishes only one trial.
28 29 30 31 32 33 34 35 36 37 38 39 40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	30	participants ALL healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors data analysts		80%

31	outcome assessors data analysts manuscript writers	a. participants b. data collectors c. outcome assessors d. data analysts	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	70%
32	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	80%
33	participants healthcare providers such as physicians or nurses taking care of a participant data collectors Note that the healthcare providers were at the same time the data collectors and the outcome assessors in our trial.	participants	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors	a. Participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors	90%
34	participants data collectors outcome assessors data analysts manuscript writers	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	I do not have a personal definition. double blind is any two of the patient, the clinician, the outcome/data collectors. Many trials cannot be truly blinded, including the one you refer to above, where the administering physician is targeting a certain depth of anaesthesia.

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	35	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	50%
24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 39	36	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	a. participants b. healthcare providers such as physicians or nurses taking care of a participant c. data collectors d. outcome assessors e. data analysts f. manuscript writers	No answer
40 41 42 43 44 45 46 47 48 49 50 51 52 53 54 55 56 57 58 59 60	37	participants healthcare providers such as physicians or nurses taking care of a participant (ATTEMPTED BUT SUCCESS UNCERTAIN) data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	SORRY, BUT I HAVE NO IDEA.

38	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors	participants healthcare providers such as physicians or nurses taking care of a participant data collectors outcome assessors data analysts	80%
39	healthcare providers such as physicians or nurses taking care of a participant - after first day only [nurses in preadmission clinic were actually part of the intervention] data collectors outcome assessors data analysts manuscript writers	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant	participants healthcare providers such as physicians or nurses taking care of a participant outcome assessors	75
40	No answer	No answer	No answer	No answer	90

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	3-4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants	5
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6-7
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6-7
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	6-7
		(b) Describe any methods used to examine subgroups and interactions	
		(c) Explain how missing data were addressed	
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy	
		(e) Describe any sensitivity analyses	NA

Results			Page
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	9
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	9
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time	
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure	
		<i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	9-12
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	9-12
		(b) Report category boundaries when continuous variables were categorized	
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	9-12
Discussion			
Key results	18	Summarise key results with reference to study objectives	13
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	13-17
Generalisability	21	Discuss the generalisability (external validity) of the study results	13-17
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.