**Official title**

Evaluating the impact of assessing during peer review the CONSORT checklist submitted by authors: protocol for a randomised controlled trial

**NCT Number**

NCT03751878

**Date of the document**

07/12/2018

**Title (SPIRIT i1*)**

Evaluating the impact of assessing during peer review the CONSORT checklist submitted by authors: protocol for a randomised controlled trial.

*All items corresponding to *Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) and key applicable items of the *Guidelines for the Content of Statistical Analysis Plans* are referenced in brackets.

**Authors**

David Blanco[1, 2] (ORCID: 0000-0003-2961-9328), Sara Schroter[3] (ORCID: 0000-0002-8791-8564), Adrian Aldcroft[3] (ORCID: 0000-0003-0106-720X), David Moher[4] (ORCID: 0000-0003-2434-4206), Isabelle Boutron[5] (ORCID: 0000-0002-5263-6241), Jamie J Kirkham[6**](ORCID: 0000-0003-2579-9325) and Erik Cobo[1**](ORCID: 0000-0002-3534-5602).

[1]Statistics and Operations Research Department, Universitat Politècnica de Catalunya - Barcelona Tech, Barcelona, Spain.

[2]INSERM, U1153 Epidemiology and Biostatistics Sorbonne Paris Cité Research Center (CRESS), Methods of Therapeutic Evaluation of Chronic Diseases (METHODS) Team, Paris Descartes University, Sorbonne Paris Cité, Paris F-75014, France.

[3]The BMJ, London, UK

[4]Centre for Journalology, Ottawa Hospital Research Institute, Ottawa, Canada.

[5]Centre d'Epidémiologie Clinique, Paris Descartes University, Paris, France.

[6]Department of Biostatistics, University of Liverpool, Liverpool, UK.

Correspondence to David Blanco; david.blanco.tena@upc.edu

**JJK and EC are joint senior authors.

**Trial registration (SPIRIT i2)**

The trial has been registered in ClinicalTrials.gov (Identifier: NCT03751878).

**Protocol version (SPIRIT i3)**

Issue date: 28/11/2018

Protocol amendment number: -

**Funding (SPIRIT i4)**

This study is part of the ESR 14 research project from the Methods in Research on Research (MiRoR) project (http://miror-ejd.eu/), which has received funding from the European Union's Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 676207. DM is supported through a University Research Chair (University of Ottawa).

**Roles and responsibilities (SPIRIT i5)**

A) **Contributorship:** Protocol drafted by David Blanco (DB) and commented by Sara Schroter (SS), David Moher (DM), Isabelle Boutron (IB), Jamie J Kirkham (JJK) and Erik Cobo (EC). Details on the implementation of the intervention within Scholar One discussed among DB, SS, and Adrian Aldridge (AA). Randomisation process designed and performed by José Antonio González (JAG).
B) **Sponsor contact information:** Universitat Politècnica de Catalunya: Statistics and Operations Research Department, Edificio C5, Planta 2, Campus Nord, C\ Jordi Girona, 1-3, 08034, Barcelona, Spain.
C) **Sponsor and funder:** The sponsor and the funding source had no role in the design of this study and will not have any role during its execution, analyses, interpretation of the data, or decision to submit results.
D) **Committees**: **Lead Investigator**: David Blanco. **Steering Committee**: DB, SS, AA, DM, IB, JJK, and EC. **Data quality**: DB, JJK, and EC.

## Introduction

**Background and rationale (SPIRIT i6, SAP i7 & i12)**

In recent years, different stakeholders have acted to boost the completeness of reporting of the published randomised trials, and therefore their transparency and reproducibility. In a recently completed scoping review, we identified and classified 31 interventions to improve adherence to reporting guidelines. Our study revealed that biomedical journals that taken different actions to improve the completeness of reporting of randomised trials – although most of these have been shown not to have the desired effect (1–3).

One of the most popular strategies used by journals to improve adherence to CONSORT (4) requires authors to submit a populated checklist together with their manuscript indicating page numbers corresponding to each item (2). However, journals usually lack further actions throughout the editorial process to ensure that the corresponding information to each item is reported in the randomised trial manuscript. This has been hypothesized to be one of the reasons why this editorial strategy has not achieved optimal results (1–3).

In an effort to take full advantage of requiring the submission of populated checklists, we intend to evaluate in a real editorial context whether assessing during peer review the consistency between the submitted CONSORT checklist and the information reported in the manuscripts of randomised trials, as well as to provide feedback to authors on the inconsistencies found, improves the completeness of reporting of published trials.

**Objectives (SPIRIT i7)**

The objective of this study is to investigate the impact of the following actions on the completeness of reporting of randomised trials submitted to a biomedical journal:

(i) Assessing during peer review the consistency between the fulfilled CONSORT checklist submitted by authors together with their manuscript and the information that was actually reported in the manuscript, and

(ii) Asking authors for changes in relation to the inconsistencies found as part of the peer review process of their manuscript.

## Methods

**Trial design (SPIRIT i8)**

Two-arm parallel group, randomised trial.

**Study setting (SPIRIT i9)**

The study will be performed in collaboration with the BMJ Publishing Group. The intervention will be implemented at the peer review process of BMJ Open. We believe this journal to be appropriate for this study because (i) it requires authors to submit a completed CONSORT checklist together with their randomised trial manuscript indicating page numbers corresponding to each item and (ii) adherence to reporting guidelines through the editorial process might be more of an issue since they have less resources than top medical journals.

**Eligibility criteria (SPIRIT i10, SAP i22)**

Manuscripts will be eligible for our study if (i) they have been submitted to BMJ Open, (ii) they are original research submissions reporting the results of a randomised trial and (iii) they have passed the first editorial filters and have been subsequently sent out for peer review.

According to the official CONSORT extensions, we will also consider other study designs (cluster, non-inferiority and equivalence, pragmatic, N-of-1 trials, Pilot and feasibility, and within person trials), and different intervention types (Herbal, non-pharmacologic, acupuncture and Chinese herbal medicine formulas) in all areas of clinical specialty. Secondary trial analysis studies will be excluded.

**Interventions (SPIRIT i11)**

The intervention will consist of three steps that have been co-designed with the BMJ Publishing Group. First, the completed CONSORT checklist submitted by authors of manuscripts randomised to the intervention group will be assessed by the lead investigator (DB) as to whether it is consistent with the information that was actually reported in the manuscript. To determine what information authors are expected to report, we will rely on the CONSORT Explanation and Elaboration document (5) or the corresponding Explanation and Elaboration documents for each of the extensions considered [REF]. In a second step, the lead investigator (DB) will produce a standardised report containing precise requests to be addressed by authors in order to improve the completeness of reporting of the items where reporting inconsistencies were found. This report will consist of a brief introduction followed by a point by point description of the inconsistencies found together with precise requests related to the information missing and examples extracted from CONSORT (see an example in Box 1). The lead investigator (DB) will upload this report to the submission on the managing system of the journal (Scholar One) to make it accessible to the handling editor of the paper. Finally, this editor will include our report in the letter to authors alongside the standard peer review reports. Manuscripts randomised to the control group will undergo the usual peer review process. Figure 1 describes the manuscript flow of the study.

Our intervention has not been previously evaluated [Scoping review by Blanco et al. - not yet published]. One potential facilitator of the intervention is that it can be implemented and evaluated in a real editorial context with no disruption to normal manuscript submission, peer review and editorial procedures.

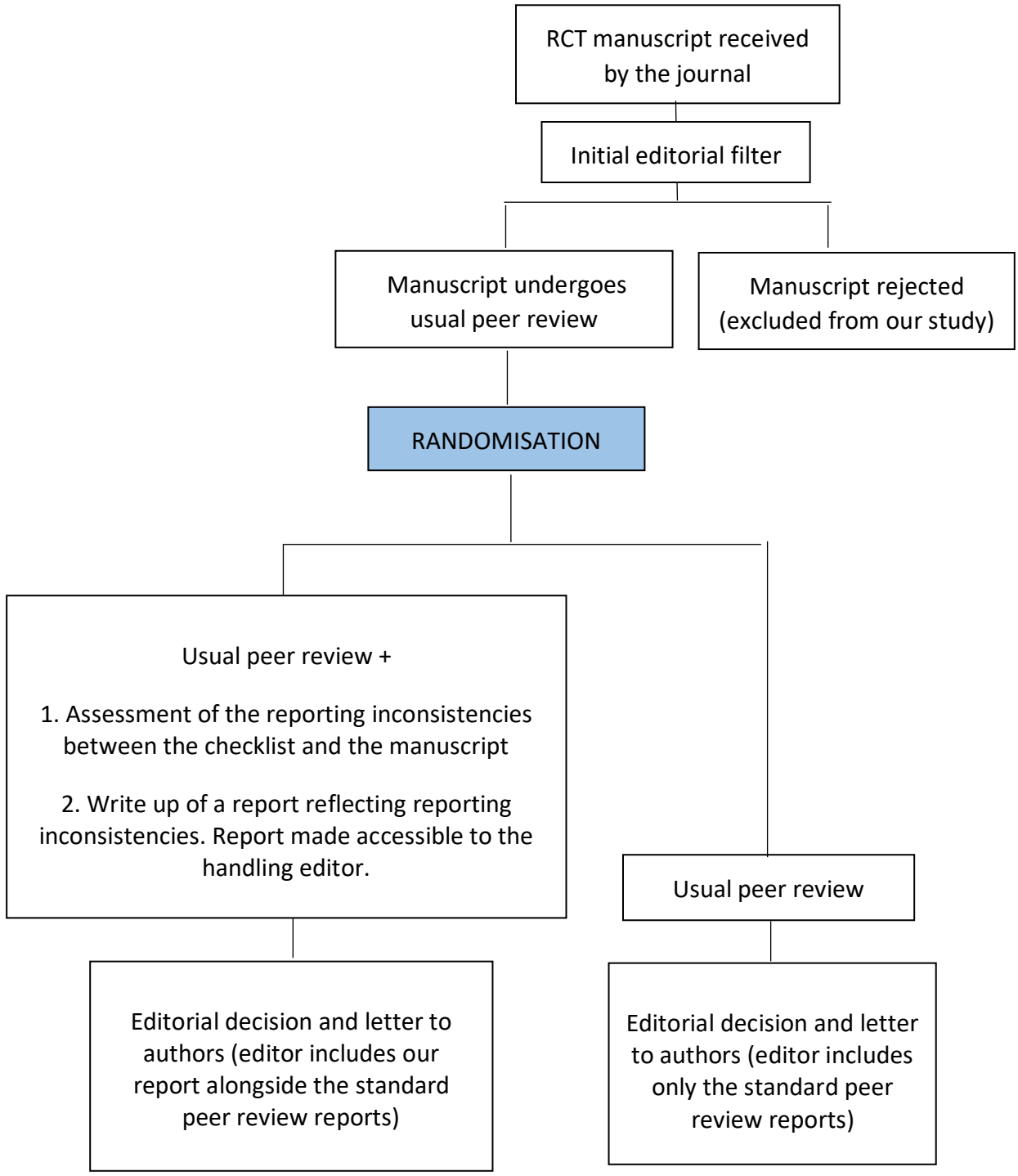
**Box 1. Example of report on the reporting inconsistencies found**

*This report shows the results of an evaluation of the consistency between the CONSORT checklist you submitted and the information that was reported in the manuscript.*

*Please, make the following revisions:*

- *For CONSORT Item 8a ("Method used to generate the random allocation sequence"), please report the method used to generate the random allocation sequence.*
    - *Example from CONSORT: "Randomization sequence was created using Stata M.N (StataCorp, College Station, TX) statistical software".*
- *For CONSORT Item 13b ("For each group, losses and exclusions after randomisation, together with reasons"), please provide the exact reasons why some participants in your study withdrew.*
    - *Example from CONSORT: "There was only one protocol deviation, in a woman in the study group. She had an abnormal pelvic measurement and was scheduled for elective caesarean section. However, the attending obstetrician judged a trial of labour acceptable; caesarean section was done when there was no progress in the first stage of labour."*

**Fig 1. Manuscript flow in the context of the intervention proposed.**



After a pilot evaluation of the completeness of reporting of randomised trials published in BMJ Open (see Sample Size section for more details), we decided to focus on 8 core CONSORT items where reporting issues were detected and which are essential for systematic reviewers when evaluating the risk of bias and recording the outcome data (6). These items are:

- Five items in the methods section (outcomes (6a), randomisation/sequence generation (8a), allocation concealment mechanism (9), blinding (11a, 11b)) and
- Three items in the results section (participant flow (13a, 13b), outcomes and estimation (17a)).

In the case of manuscripts where the CONSORT extensions considered in this study are applicable, we will use the corresponding extensions for each of these items.

**Outcomes (SPIRIT i12 & i18a, SAP i15)**

- **Primary outcome**: Proportion of adequately reported items in the first revised manuscript [Time frame: Following manuscript revision (usually 2-3 months)]. An item will be considered as adequately reported if subparts of the item (including all possible extensions, if relevant) are adequately reported [e.g. for CONSORT item 6a: A) Completely prespecified primary and secondary outcomes, B) how each of these outcomes is assessed, and C) when each of these outcomes is assessed].

  The evaluation of the first revised manuscripts will be performed independently and in duplicate by two masked independent outcome assessors (EC, JJK) with extensive experience on reporting and methodological issues of randomised trials. Discrepancies in the evaluation of any of the items will be solved by consensus via Skype call.

  To ensure that the evaluations of the two outcome assessors are consistent, they have appraised 6 random randomised trials published in BMJ Open between April 2018 and September 2018. Discrepancies among evaluators were discussed.
- **Secondary outcomes**: i) Percentage of compliance between the checklist and the manuscript for the trials in the intervention arm [Time frame: Following the evaluation of reporting inconsistencies by the lead investigator (1 week)], ii) Proportion of manuscripts where each item is adequately reported [Time frame: Following manuscript revision (usually 2-3 months) ], and iii) Average time to perform the assessment of reporting inconsistencies and to produce the report [Time frame: Following the evaluation of reporting inconsistencies by the lead investigator (1 week)].

**Participant timeline and recruitment (SPIRIT i13 & i15, SAP i21)**

Prior to recruitment, the lead investigator (DB) and one of the study investigators (SS) have set up a report in Scholar One that shows a list of original research paper submissions to BMJ Open, including their ID, date of submission, title, abstract, and different parameters related to their peer review status. This report will be automatically sent on a daily basis to the lead investigator (DB), who will check it for randomised trials (based on given title and abstract) being sent out for peer review.

Recruitment of manuscripts will start in 1st December 2018 and it will last until the planned sample size is achieved (probably around June-July 2019).

**Sample size (SPIRIT i14, SAP i11)**

In order to estimate the proportion of adequately reported items in the control group, the lead investigator (DB) performed a pilot evaluation of 12 random randomised trials published in BMJ Open between April 2018 and September 2018, which was verified by the two CONSORT experts (EC and JJK). According to it, the estimated probabilities of the control group adequately reporting (0, 1, 2, …, 8) items would be (0, 0, 0, 0, 0, 0.17, 0.33, 0.33, 0.17).

If we expect the intervention to lead authors of papers in the intervention group to adequately report 7 and 8 items 50% and 50% of the times, respectively, a sample size of 24 articles (12 per arm) would be enough to detect such increase with 85% of power (see Box 2 for the power calculation in R Software).

**Box 2: Power calculation**

```
na = 12
nb = 12
A = 0:8
B = 0:8
pra = c(0,0,0,0,0,2,4,4,2)
pra = pra/sum(pra)
prb = c(0,0,0,0,0,0,0,5,5)
prb = prb/sum(prb)
N = 100000  # No pasarse!
ma = matrix(sample(A, pr=pra, replace=TRUE, siz=N*na), ncol=N)
mb = matrix(sample(B, pr=prb, replace=TRUE, siz=N*nb), ncol=N)
pv = array(NA, dim=N)
for (i in 1:N) {
  reporting <- data.frame(
    score = c(ma[,i],mb[,i]),
    group = factor(rep(c("Control", "Intervention"), c(na, nb)))
  )
  T = t.test(score ~ group, data = reporting, conf.int = TRUE)
 pv[i] = T$p.value
}
a=table(cut(pv, c(0, 0.05, 1)))/N
power005=a[1]
```

**Assignment of interventions (SPIRIT i16 & i17, SAP i10 & i24) [sequence generation, allocation concealment mechanism, implementation, blinding]**

Every time the lead investigator (DB) detects in the submissions report a randomised trial that has at least one peer reviewer invited, he will transfer a PDF version of it to a Google Drive folder. The randomisation process of the manuscript will be performed using a Shiny applicative (R Software) created by one of the study collaborators (JAG). The lead investigator will introduce the manuscript ID into the applicative, which will randomise it with a 1:1 allocation ratio in blocks of 4. Moreover, manuscripts will be stratified according to whether there is an applicable extension for that study or not. An email will be received by the lead investigator indicating the manuscript allocation. To avoid

selection bias, the applicative will only allow to introduce each manuscript ID once and will record the times when allocations were performed.

The folder containing the manuscript allocations and PDFs will remain unavailable to authors of included manuscripts and outcome assessors, who will be blinded to allocation. Every time the lead investigator (DB) detects in the submissions report that one of the included studies has been revised and submitted to the journal, he will transfer a PDF copy of the revised manuscript to a Google Drive folder where outcome assessors will have access to it. If any of the included studies is not revised and submitted to the journal within the stipulated time frame (28 days after authors receive the first decision letter), it will be replaced by a new study that will be allocated to the same arm as the original one. Based on historical data of the journal, this only happens for around 5% of papers where authors are asked to make major or minor revisions.

Due to the nature of the intervention, handling editors of the included manuscripts and the lead investigator assessing the reporting inconsistencies (DB) cannot be blinded.

**Data management (SPIRIT i19)**

All data related to the study will be collated in a password protected spreadsheet file that will be stored in Google Drive.

**Statistical methods (SPIRIT i20, SAP i25, i27 & i31)**

Statistical analysis will be carried out using R software.

We will describe all outcomes using proportions, means, and standard deviations. For the primary outcome, we will calculate the difference of means between the two groups, as well as its two-sided 95% confidence interval (see in Box 3 the R code that will be used). The analysis will be stratified according to those manuscripts for which the standard CONSORT checklist was applicable and those that required the use of one or more of the extensions considered.

**Box 3: Primary outcome analysis** (*C_i* and *I_i* with *i in 1:12* represent the scores for completeness of reporting of the manuscripts in the control and the intervention group, respectively)

```
na = 12
nb = 12
control<-c(c_1, ... , c_12)
intervention<-c(i_1, ... , i_12)
mean(intervention)-mean(control)
reporting <- data.frame(
  score = c(intervention,control),
  group = factor(rep(c("Control", "Intervention"), c(na, nb)))
)
T=t.test(score ~ group, data = reporting, conf.int = TRUE)
T$conf.int
```

**Data monitoring (SPIRIT i21)**

The study will not have a formal data monitoring committee.

**Harms (SPIRIT i22)**

Not described.

**Auditing (SPIRIT i23)**

The trial will not be externally audited.

**Research ethics approval (SPIRIT i24)**

This study has been given ethics approval by the Universitat Politècnica de Catalunya Ethical Committee for ethics approval (Ref: EC 02).

**Protocol amendments (SPIRIT i25)**

Any important protocol amendments will be registered at ClinicalTrials.gov and communicated in the primary RCT report.

**Consent or assent & informed consent materials (SPIRIT i26 & i32)**

All submitting authors are informed that BMJ has a research programme and that they can opt out if they wish. Moreover, they are forced to read the BMJ Company Privacy Statement, which describes the fact that BMJ has a research programme for quality improvement.

**Confidentiality (SPIRIT i27)**

Since the lead investigator (DB) will need access to BMJ Publishing Group's manuscript tracking system, a confidentiality agreement with BMJ Publishing Group was signed to certify that (i) BMJ Publishing group wishes to disclose information to DB, and (ii) DB wishes to receive this information on a confidential basis.

Personal data related to the manuscripts included in the study will be kept separate from the main dataset and will not be shared in order to protect confidentiality before, during and after the trial.

**Declaration of interests (SPIRIT i28)**

AA is Editor in Chief of BMJ Open. SS is Senior Researcher at The BMJ. DM is Director of the Canadian EQUATOR Centre. IB is deputy director of French EQUATOR Centre.

**Ancillary and post-trial care (SPIRIT i30)**

Not applicable.

**Dissemination policy and access to data (SPIRIT i29 & i31)**

To ensure transparent and adequate reporting of the trial protocol, we referenced in brackets all items corresponding to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (7), as well as key applicable items of the Guidelines for the Content of Statistical Analysis Plans (8).

The results paper will be submitted for publication to a peer-reviewed journal, regardless of the direction of the results. the results paper will be reported in accordance to CONSORT (4). Contributor roles in the trial will be reported according to the Contributor Roles Taxonomy (CRediT) (9).

The content of the intervention reports reflecting reporting inconsistencies will appear as part of the review history of the papers included.

**Biological specimens (SPIRIT i33)**

Not applicable.

**References**


1. Stevens A, Shamseer L, Weinstein E, Yazdi F, Turner L, Thielman J, et al. Relation of completeness of reporting of health research to journals' endorsement of reporting guidelines: systematic review. BMJ [Internet]. 2014 Jun 25 [cited 2017 Jun 7];348(jun25 2):g3804–g3804. Available from: http://www.bmj.com/cgi/doi/10.1136/bmj.g3804

2. Turner L, Shamseer L, Altman DG, Schulz KF, Moher D, L. T, et al. Does use of the CONSORT Statement impact the completeness of reporting of randomised controlled trials published in medical journals? A Cochrane review. Syst Rev [Internet]. 2012 Nov 29 [cited 2017 Feb 24];1(1):60. Available from: http://systematicreviewsjournal.biomedcentral.com/articles/10.1186/2046-4053-1-60

3. Blanco D, Biggane AM, Cobo E. Are CONSORT checklists submitted by authors adequately reflecting what information is actually reported in published papers? Trials [Internet]. 2018 Dec 29 [cited 2018 Jan 31];19(1):80. Available from: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-018-2475-0

4. Schulz KF, Altman DG, Moher D, CONSORT Group. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ [Internet]. 2010 Mar 23 [cited 2018 Mar 3];340:c332. Available from: http://www.ncbi.nlm.nih.gov/pubmed/20332509

5. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 Explanation and Elaboration: Updated guidelines for reporting parallel group randomised trials. J Clin Epidemiol [Internet]. 2010 Aug [cited 2017 Feb 24];63(8):e1-37. Available from: http://linkinghub.elsevier.com/retrieve/pii/S0895435610001034

6. Chauvin A, Moher D, Altman D, Schriger DL, Alam S, Hopewell S, et al. A protocol of a cross-sectional study evaluating an online tool for early career peer reviewers assessing reports of randomised controlled trials. BMJ Open [Internet]. 2017 Sep 15 [cited 2018 Apr 26];7(9):e017462. Available from: http://www.ncbi.nlm.nih.gov/pubmed/28918414

7. Chan AW, Tetzlaff JM, G??tzsche PC, Altman DG, Mann H, Berlin JA, et al. SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. BMJ. 2013;346:1–42.

8. Gamble C, Krishan A, Stocken D, Lewis S, Juszczak E, Doré C, et al. Guidelines for the Content of Statistical Analysis Plans in Clinical Trials. JAMA [Internet]. 2017 Dec 19 [cited 2018 Jun 15];318(23):2337. Available from:

http://jama.jamanetwork.com/article.aspx?doi=10.1001/jama.2017.18556

9. Contributor Roles Taxonomy [Internet]. Available from: http://dictionary.casrai.org/Contributor_Roles