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Impact of a short version of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published in biomedical journals: study protocol for a randomised controlled trial

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3 1 **Impact of a short version of the CONSORT checklist for peer reviewers to improve the**
4
5 2 **reporting of randomised controlled trials published in biomedical journals: study**
6
7 3 **protocol for a randomised controlled trial**
8

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39
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43
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45
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47
48 52 study, or analysing and reporting study results.
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50

51 53

52
53 54 **Keywords:** CONSORT; reporting guidelines; randomised controlled trials as topic; peer
54
55 55 review; meta-research
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56 **Abstract**

57 **Introduction:** Transparent and accurate reporting is essential for readers to adequately
58 interpret the results of a study. Journals can play a vital role in improving the reporting of
59 published randomised controlled trials (RCTs). We describe an RCT to evaluate our
60 hypothesis that asking peer reviewers to check whether the most important and poorly reported
61 CONSORT (CONsolidated Standards for Reporting Trials) items are adequately reported, will
62 result in higher adherence to CONSORT guidelines in published RCTs.

63 **Methods and Analysis:** Manuscripts presenting the primary results of RCTs submitted to
64 participating journals will be randomised to either the intervention group (peer reviewers will
65 receive a reminder and short explanation of the ten most important and poorly reported
66 CONSORT items; they will be asked to check if these items are reported in the submitted
67 manuscript) or a control group (usual journal practice). The primary outcome will be the mean
68 proportion of the ten items that are adequately reported in the published articles. Peer
69 reviewers and manuscript authors will not be informed of the study hypothesis, design, or
70 intervention. Outcomes will be assessed in duplicate from published articles by two data
71 extractors (at least one blinded to the intervention). We will enrol eligible manuscripts until a
72 minimum of 83 articles per group (166 in total) are published.

73 **Ethics and Dissemination:** This pragmatic RCT was approved by the Medical Sciences
74 Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001). If this
75 intervention is effective, it could be implemented by all medical journals without requiring large
76 additional resources at journal level. Findings will be disseminated through presentations in
77 relevant conferences and peer-reviewed publications. This trial is registered on the Open
78 Science Framework (<https://osf.io/c4hn8>).

79

80 **Strengths and limitations of this study**

- 81 • Pragmatic randomised controlled trial (RCT) with individual randomisation of real
82 manuscripts describing RCTs submitted to a variety of journals.
- 83 • If this simple intervention is effective, it could be implemented by journals without
84 requiring large additional resources at a journal level.
- 85 • We could not include the intervention within the journals' agreement to review letter or
86 all peer reviewers would receive the intervention due to the automated processes of
87 the journals' editorial systems. This risks peer reviewers potentially ignoring the
88 separate email containing the CONSORT reminder.

90 Introduction

91 Background and rationale

92 There is substantial agreement that well conducted and reported randomised controlled trials
93 (RCTs) generate the most trustworthy evidence when evaluating newly developed or existing
94 clinical interventions.¹⁻³ For clinicians, scientists and decision makers, published articles are
95 often the only way to know how a study was conducted. In order to judge the internal and
96 external validity of RCTs, it is crucial that these articles present transparent, accurate and
97 unbiased information about the methods and conduct of the RCT.

98
99 To improve the quality and transparency of clinical and epidemiological research, the
100 EQUATOR (Enhancing the Quality and Transparency of Research) Network was founded in
101 2006.⁴⁻⁹ This international network, which assists in the development of reporting guidelines
102 and actively promotes their use, consists of methodologists, epidemiologists, reporting
103 guideline developers, statisticians, clinicians and journal editors.

104
105 The CONSORT Statement (CONsolidated Standards of Reporting Trials) is perhaps the most
106 prominent reporting guideline, designed to help improve the transparency and quality of
107 reporting of RCTs.¹⁰⁻¹² It guides authors, peer reviewers and journal editors on the minimum
108 information to be included in published reports of RCTs to facilitate critical judgment and
109 interpretation of results and consists of 25 items and a flow diagram. The last update of the
110 CONSORT Statement was published simultaneously in 10 leading medical journals in 2010¹²
111 and currently CONSORT is endorsed by over 600 journals worldwide.¹³

112
113 Despite some improvement in reporting following the endorsement of the CONSORT
114 Statement, there remain major reporting deficiencies in published RCTs.^{3 14-20} For example, a
115 study of 1122 RCTs indexed in PubMed in December 2012 found that many did not define the
116 primary outcome (31%), state the sample size calculation (45%), or explain the method of

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2
3 117 allocation concealment (50%).²¹ This lack of transparency is a major limiting factor for readers
4
5 118 who assess an article in order to find the answer to a specific question; it is also a major
6
7 119 problem for scientists who perform systematic reviews and meta-analyses.
8

9 120

11 121 **Evidence to date**

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14 122 Journals can play a vital role in improving the reporting of published RCTs. For example, a
15
16 123 survey of journals' 'Instructions to Authors' in 2014 found that 63% (106 of 168) of biomedical
17
18 124 journals mentioned CONSORT;²² however of those journals only 38 (36%) required a
19
20 125 completed CONSORT checklist on submission. Such implementation indicates some
21
22 126 improvement over time compared to an assessment in 2007 when only 17 of 62 (27%) journals
23
24 127 requested the CONSORT checklist on submission.²³ A study using interrupted time series
25
26 128 analysis and assessing if the CONSORT checklist for reporting abstracts of RCTs had an effect
27
28 129 on reporting quality found that results were better reported in journals which had an active
29
30 130 editorial policy to implement the checklist.²⁴
31

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33 131

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35 132 A scoping review conducted in 2017 by Blanco and colleagues summarised different
36
37 133 interventions aimed at improving adherence to reporting guidelines.²⁵ They identified a number
38
39 134 of different interventions, some of which had been evaluated at journals. However, all the
40
41 135 interventions, except requesting submission of checklists from authors, required additional
42
43 136 resources from the journal (e.g. internal peer review by editorial assistants or inviting an
44
45 137 additional statistical peer-reviewer^{26 27}). Therefore, it is unlikely that these interventions will be
46
47 138 implemented in the majority of journals, especially smaller journals with limited resources.
48
49 139 Another study found that providing authors with a web-based CONSORT tool, which combined
50
51 140 different CONSORT extensions and provided authors with a customised checklist, did not
52
53 141 improve reporting when used at the manuscript revision stage.²⁸ However, a study examining
54
55 142 "the nature and extent of changes made to manuscripts after peer review, in relation to the
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3 143 reporting of methodological aspects of RCTs” and “the type of changes requested by peer
4
5 144 reviewers” found that peer review did lead to some improvement in reporting.²⁶
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7 145

8
9 146 The role of peer reviewers and expectations of them is varied.²⁹ While CONSORT checklists
10
11 147 are sometimes available for peer reviewers to check, they are not typically instructed to assess
12
13 148 this information as part of their review and there have been no studies evaluating the effect of
14
15 149 asking them to do this. We plan to evaluate the impact of giving peer reviewers a short version
16
17 150 of the CONSORT checklist together with a brief explanation of the items and asking them to
18
19 151 check if they are adequately reported.
20
21 152

22 23 24 25 153 **Methods**

26 27 154 **Objective**

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29
30 155 The objective of this study is to evaluate the impact of giving peer reviewers, during the
31
32 156 standard peer review process, a short version of the CONSORT checklist (C-short) together
33
34 157 with a brief explanation of the items and asking them to check if they are adequately reported
35
36 158 in the manuscript.
37
38 159

39 40 41 42 160 **Study design**

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44
45 161 This study is a multicentre RCT with submitted manuscripts as the unit of randomisation
46
47 162 (Figure 1; allocation ratio 1:1).
48
49 163

50 51 164 **Study setting and eligibility criteria**

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53 165 The population will be defined on two levels: included journals and included manuscripts.
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55 166

56 57 167 Inclusion criteria for journals: 58 59 60

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3 168 Included journals must: i) endorse the CONSORT Statement by mentioning it in the journals'
4
5 169 Instruction to Authors; ii) have published primary results of at least five RCTs in 2017 (identified
6
7 170 using a PubMed search). To be efficient, we plan to contact (via email) the editors of eligible
8
9 171 journals from specific publishers (e.g. BMJ Publishing Group; Public Library of Science
10
11 172 [PLOS]) instead of separate journals. A description of the requirements for participation and a
12
13 173 short summary information sheet will be included as part of the email invitation sent to journal
14
15 174 editors. If a journal is eligible, and the editor agrees to take part, the editor will need to provide
16
17 175 access to their editorial system (e.g. ScholarOne, Editorial Manager) to enable the external
18
19 176 researcher (BS) to screen and randomise eligible manuscripts. In cases where this is not
20
21 177 possible, we will explore with individual journals if it would be possible to grant limited access
22
23 178 (e.g. only rights to screen studies) or to handle the different steps without access to the editorial
24
25 179 system (e.g. screening through automated reports; intervention provided by a journal staff
26
27 180 member) and that the emails for the intervention would be sent by a member of the editorial
28
29 181 team.
30
31

32 182

33 34 35 183 Inclusion criteria for manuscripts

- 36
37 184 • All new manuscript submissions reporting the primary results of RCTs, which the
38
39 185 journal editor has decided to send out for external peer review. Since the 10 chosen
40
41 186 CONSORT checklist items (C-short) are applicable to different study designs, we will
42
43 187 include all manuscripts reporting the primary results of RCTs regardless of study design
44
45 188 (e.g. parallel group trial, cluster trial, superiority trial, non-inferiority/equivalence trials).

46 47 189 Exclusion criteria for manuscripts

- 48
49 190 • Manuscripts clearly presenting secondary trial results, additional time points, economic
50
51 191 analyses, or any other analyses.
- 52
53 192 • Manuscripts which are clearly labelled as a pilot or feasibility study or animal studies.
- 54
55 193 • Manuscripts not sent for peer review.

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3 195 Details of journal manuscript submission and peer review processes, including consent and
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5 196 potential confidentiality issues will be discussed in detail with each journal by teleconference
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7 197 and/or face to face prior to the journal agreeing to take part to ensure that randomisation of
8
9 198 manuscripts is feasible.

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13 200 In participating journals, the external researcher (BS) will check at least twice a week (by
14
15 201 screening automated submission lists) all research manuscripts that are sent out for external
16
17 202 peer review. As soon as the first invited peer reviewer accepts the invitation to review, the
18
19 203 manuscript will be randomised to the intervention or control arm (see “Randomisation” for more
20
21 204 details). It is possible that this process might be slightly different amongst different included
22
23 205 journals (e.g. that team members of a journal might be involved in the screening if limited or
24
25 206 no access to the journal’s editorial system is granted).

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29 208 **Interventions**

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32 210 Control group: Usual practice

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35 211 After accepting to review a manuscript, peer reviewers will receive the automated, journal
36
37 212 specific standard email with general information as per each journal’s usual practice (e.g.
38
39 213 where to access the manuscript, date the peer review report is due).

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41 214

42 215 Intervention group: C-short plus usual practice

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45 216 After accepting to review a manuscript, peer reviewers will receive the automated, journal
46
47 217 specific standard email with general information (identical to control group). In addition, peer
48
49 218 reviewers will receive an additional email from the editorial office that includes a short version
50
51 219 of the CONSORT checklist (C-short) together with a brief explanation of the items either as a
52
53 220 table within the email or as an attachment - based on the preferences and possibilities of the
54
55 221 journal (Table 1, appendix 1). Peer reviewers will be asked to check whether the items in the

1
2
3 222 C-short checklist are addressed in the manuscript and to request authors to include these
4
5 223 items if they are not adequately reported. This second email (see appendix 1), containing the
6
7 224 C-short checklist together with a brief explanation, is not generated automatically within the
8
9 225 existing journal editorial systems (e.g. ScholarOne or Editorial Manager); it will be sent
10
11 226 manually by a researcher (BS) from the journal's editorial system or by a member of the
12
13 227 journal's staff. In both cases the email will appear to have come from the editorial office (not
14
15 228 the researcher).

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18 229

20 230 Development of the C-short checklist and explanation of items

21
22 231 For the development of C-short we chose the 10 most important and poorly reported
23
24 232 CONSORT items as identified by a group of CONSORT experts in a previous study conducted
25
26 233 by Hopewell and colleagues.²⁸ The selection of the items was based on expert opinion and
27
28 234 empirical evidence whenever available.²⁸ In addition, to enable peer reviewers to better
29
30 235 understand the items, we added a short explanation for each of the 10 items. These short
31
32 236 explanations were extracted and amended from the CONSORT explanation and elaboration
33
34 237 paper¹⁰ and from COBWEB which is an online writing aid tool.³⁰ The short explanation was
35
36 238 discussed and adapted by the scientific committee.

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41 240 **Outcomes**

44 241 Primary outcome

45
46 242 The primary outcome of this study will be the difference in the mean proportion of adequately
47
48 243 reported C-short items in published articles between the two groups.

49
50 244

52 245 Secondary outcomes

53
54 246 Secondary outcomes will include the following:

- 56 247 • Mean proportion of adequately reported C-short items in published articles considering
57
58 248 each item separately.

- 1
2
3 249 • Difference in mean proportion of adequately reported C-short items in published
4
5 250 articles considering each sub-item (see “Assessment of outcomes”) as a separate item.
6
7 251 • Time from assigning an editor to the first decision (as communicated to the author after
8
9 252 the first round of peer-review).
10
11
12 253 • Proportion of manuscripts rejected after the first round of peer review.
13
14 254 • Proportion of manuscripts that will be published in the journal under study.
15
16 255

17
18 256 Additional outcomes:

- 19
20 257 • Exploratory analysis of available peer reviewer comments (i.e. any references to
21
22 258 CONSORT).

23
24 259 For journals where peer reviewers’ comments are subsequently published alongside the
25
26 260 published article, we will examine the peer reviewers’ comments for any reference to
27
28 261 CONSORT and trial reporting. We will contact those journals which do not make peer
29
30 262 reviewers’ comments publicly available, to see if reviews could be provided for such analyses
31
32 263 under the condition that only anonymised data will be published.
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34 264

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37 265 Assessment of outcomes:

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39 266 The outcomes will be assessed independently by two (blinded or at least partially blinded; see
40
41 267 “blinding”) outcome assessors with expertise in the design and reporting of clinical trials. Any
42
43 268 disagreement will be resolved by consensus or if necessary by consulting a third assessor. To
44
45 269 ensure consistency between reviewers, we will first pilot the data extraction form; any
46
47 270 disparities in the interpretation will be discussed and the data extraction form will be modified
48
49 271 accordingly.
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52 272
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54 273 Adequate reporting of items will be assessed in duplicate from published full-text publications
55
56 274 following the same instructions as provided by the CONSORT C-short checklist.¹⁰ The
57
58 275 following checklist items have, due to their complexity, sub-items which will be extracted
59
60

1
2
3 276 separately. The sub-items are highlighted in the short explanation of the intervention (see
4
5 277 Table 1 and appendix 1):

- 7 278 • Outcomes (item 6a): (i) Define primary outcome, (ii) how it was measured, (iii) at what
8
9 279 time point, and (iv) the analysis metric (e.g. change from baseline, final value).
11 280 • Sample size (item 7a): (i) The estimated outcomes in each group, (ii) the α (type I) error
13 281 level, (iii) the statistical power (or the β (type II) error level), (iv) for continuous
15 282 outcomes, the standard deviation of the measurements
17
18 283 • Blinding (item 11a): Is the blinding status clear for the following persons: (i) Healthcare
19 284 provider, (ii) patients, and (iii) outcome assessors.
21
22 285 • Funding (item 25): (i) The funding source, and (ii) the role of funder in the design,
23 286 conduct, analysis, and reporting.

26 287 All items will be judged as either “yes” meaning adequately reported, “no” meaning not
27
28 288 adequately reported or not reported at all, or “NA” meaning that this sub-item is not applicable
29
30 289 for this RCT. Items with different sub-items will only be judged as adequately reported if all
31
32 290 relevant sub-items were adequately reported.
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37 292 The outcomes “time from assigning an editor to the first decision”, “proportion of manuscripts
38
39 293 rejected after the first round of peer-review”, and “proportion of manuscripts that will be
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41 294 published in the journal under study” will be extracted directly from the journal’s editorial system
42
43 295 or provided by the journal.
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45

46 296
47 297 **Participant timeline**

49 298 The overview of the study schedule, including enrolment, intervention and assessments is
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51 299 presented in Table 2.
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301 **Sample size**

302 For the sample size calculation, we hypothesised in a first scenario (Table 3) that the
303 intervention C-short will result in a 25% relative increase in adequate reporting compared to
304 the control (meaning that 70% of items will be adequately reported in the intervention group
305 and 56% in the control group). This is based on a proportion of adequate reporting of 0.56 for
306 the 10 most important and poorly reported items found in the control group of a previous study
307 (meaning that a mean of 56% of the 10 most important and poorly reported items were
308 reported).²⁸ The standard deviation (SD) in the same study was 0.23. However, we calculated
309 our sample size to account for a slightly larger variability in our data (SD = 0.25). To
310 demonstrate a significant difference with a power of 90% and a type 1 error at 5%, a total of
311 136 published articles will be required in this scenario (68 per treatment arm; based on a two
312 sided t-test).

313
314 Two authors of this protocol, working for *PLOS ONE* (IP and AC), one of the participating
315 journals, pointed out that 3 out of the 10 assessed items (i.e. item “Registration”, “Protocol”,
316 and “Funding”) should always be implemented in submissions to their journal given their policy
317 requirements for clinical trials. Assuming that this journal will recruit a high proportion of
318 manuscripts, and that also other journals might update their templates, we increased the
319 sample size in a second scenario, in which all these 3 items would have an overall adherence
320 of 90% in the control arm (Table 3). This would entail an overall baseline adherence with the
321 10 C-short items of 71%. Based on a two sided t-test, a sample size of 166 (83 per treatment
322 arm) will have a power of 80% to find a 15% relative increase (71% adherence in control group;
323 82% adherence in intervention group; SD = 0.25; a type 1 error at 5%).

324 Since the final sample size will be based on the number of articles published, rather than on
325 the number of manuscripts randomised, eligible manuscripts will be randomised until 83
326 articles are published in each arm (resulting in no less than 166 articles), to avoid loss of power
327 due to potential imbalance between arms. Recruitment will be stopped as soon as both arms

1
2
3 328 reach the sample size of 83. After recruitment has stopped we will wait three months so that
4
5 329 manuscripts, which are still in production, can be published. Manuscripts which are published
6
7 330 after the three month period will be excluded
8

9 331

10 332 **Randomisation and blinding**

11
12
13
14 333 Manuscripts meeting the eligibility criteria and sent out for external peer review by the journals
15
16 334 will be randomised into one of the two groups (allocation 1:1). The randomisation list will be
17
18 335 created by the Study-Randomizer[®] system³¹ using random block sizes between 2 and 8 and
19
20 336 stratified by journal. As soon as the first peer reviewer accepts the invitation, the manuscript
21
22 337 will be included and randomised to one of the two study arms. One of the investigators (BS)
23
24 338 will log onto the Study-Randomizer[®] system³¹ and enter the study identification number (ID;
25
26 339 provided by the journal), the study title, and the journal the study was submitted to.
27
28 340 Subsequently, all additional peer reviewers accepting the invitation to review the same
29
30 341 manuscript will receive the same group assignment as the first peer reviewer.
31

32 342

33
34
35 343 Authors will be blinded to the intervention. Editors will not be actively informed about the
36
37 344 randomisation (possible exception listed under “Interventions”). To avoid potential bias, peer
38
39 345 reviewers and manuscript authors will not be informed of the study hypothesis, design and
40
41 346 intervention.
42

43 347

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45 348 Outcomes will be assessed in duplicate (see “Assessment of outcomes”). At least one outcome
46
47 349 assessor will be blinded. Due to restricted resources the investigator conducting the
48
49 350 randomisation (BS) might be involved in the data-extraction from published manuscripts.
50

51 351

52 352 **Data analysis**

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3 353 All quantitative variables will be described using means and standard deviations, or medians
4
5 354 and interquartile ranges in case severe departures from a normal distribution are identified.
6
7 355 Data distributions will be inspected visually (i.e. by histograms) instead of performing formal
8
9 356 statistical tests for normality. Categorical variables will be described using frequencies and
10
11 357 percentages. For the primary and secondary outcomes, we will estimate the mean difference
12
13 358 between the two groups and report them with respective 95% confidence intervals. No interim
14
15 359 analysis will be conducted.

16 360

17 18 19 20 21 361 Populations of analysis

22
23
24 362 The main population for analysis will be all manuscripts randomised and accepted for
25
26 363 publication in the participating journals. In contrast to RCTs conducted with patients, where
27
28 364 losses to follow-up need to be carefully considered (e.g. multiple imputation of missing data),
29
30 365 we are only interested in the reporting adherence of RCTs that are published. Hence we will
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32 366 exclude randomised manuscripts that were not published from the main analysis. All outcomes
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34 367 will be calculated based on the main population. The secondary outcome “Time to the first
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36 368 decision”, will additionally be calculated considering all randomised manuscripts (including the
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38 369 ones which were not published). For all analyses a p-value of 0.05 (5% significance level) will
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40 370 be used to indicate statistical significance. Exact p-values will be presented up to three decimal
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42 371 places. We anticipate there will be no missing data in this study, neither at the individual C-
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44 372 short items, nor at the manuscript level. This is due to the study design, which will include only
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46 373 the randomised manuscripts that are accepted for publication. We will analyse if the rate of
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48 374 manuscripts rejected after the first round of peer-review and if the proportion of manuscripts
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50 375 that will be published differentiate amongst the two study arms (both secondary results).

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3 377 Analysis of primary endpoint
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5 378 The effect of the intervention will be estimated as the mean difference in the proportion of C-
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7 379 short items adequately reported between the study arms. If the data on the primary outcome
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9 380 is normally distributed, groups will be compared using an unpaired Student's t-test. If the data
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11 381 is not normally distributed, comparisons will be performed using a non-parametric equivalent
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13 382 test (i.e. Wilcoxon-Mann-Whitney test).
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17 383 Analysis of secondary endpoints
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20 384 To investigate the effect of the intervention on the secondary outcomes, mean differences with
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22 385 respective 95% confidence intervals will be reported. If normality is not observed for any of the
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24 386 continuous secondary outcomes, the same strategy adopted for the primary outcome (use of
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26 387 a non-parametric equivalent to the Student's t-test) will be used.
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32 389 Pre-specified subgroup analysis
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35 390 No formal subgroup comparative analysis is planned for the primary or secondary outcomes.
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37 391 However, the effect of the intervention on the primary outcome within subgroups will be
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39 392 presented using forest plots to visually examine whether it may differ according to some
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41 393 variables, such as: (1) Journals that actively implement the CONSORT Statement (defined as
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43 394 requiring authors to submit a completed CONSORT checklist alongside their manuscript) vs.
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45 395 journals that are not actively implementing the CONSORT Statement; (2) sample size of
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47 396 included RCTs ($n < 100$ vs. $n \geq 100$); and (3) impact factor (<5 , $5.1-10$; >10) as there is
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49 397 evidence that higher impact factor as well as higher sample size are associated with higher
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51 398 adherence to reporting guidelines.³² These analyses will be exploratory, with the aim of
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53 399 supporting new hypothesis generation, rather than being conclusive.
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3 401 **Data management and confidentiality**

4 402 Outcomes from publications will be assessed and extracted in duplicate. Since this information
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6 403 is not confidential, we will use freely available online forms (e.g. Google forms) for data
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9 404 extraction from published RCTs. Data entered will be validated for completeness.

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11 405 Data from the journal's editorial system (e.g. title of manuscript, first author, randomisation ID,
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13 406 journal, date when manuscript was assigned to an editor, date when the final decision was
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15 407 made, final editorial decision, number of peer reviewers who reviewed the manuscript, the peer
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17 408 review reports [if available]) will be extracted (by BS or a member of the journal's staff),
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19 409 anonymised and entered in password protected files which are saved on a server from the
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21 410 University of Oxford. Data will be managed and curated according to University of Oxford
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23 411 regulations, which includes regular back-up (on a daily basis) of the virtual drives where the
24
25 412 data are stored. No auditing or data monitoring is planned (as outcomes are directly extracted
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27 413 from journal's editorial system or in duplicate from published RCTs).

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31 414 The raw data extracted from the included published manuscripts can be made openly
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33 415 accessible in an anonymised way (i.e. giving the included RCT a number instead of identifying
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35 416 them). Derived/aggregated data, including anonymised information generated from the
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37 417 journal's editorial system, will be stored and made available to the research community when
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39 418 the project ends (see also "Publication policy and access to data"). Where appropriate, the
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41 419 researcher who has access to the journal's editorial system (BS) and anyone else who will see
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43 420 the identifiable data will sign a confidentially agreement with the participating journals,
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45 421 confirming that they will not share identifiable data with any other party. Publishers such as the
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47 422 BMJ state in their Company Privacy Statement that reviews and manuscripts may be used for
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49 423 quality improvement purposes and that is the nature of this research. Furthermore, peer
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51 424 reviewers for all BMJ journals receive the following statement in their invitation letter "*We are*
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53 425 *constantly trying to find ways of improving the peer review system and have an ongoing*
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55 426 *programme of research. If you do not wish your review entered into a study please let us know*
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57 427 *by emailing [...] as soon as possible.*"
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429 **Trial registration**

430 This trial was denied registration on ClinicalTrials.gov as the study is not a clinical study that
431 assesses a health outcome in human subjects. Instead we registered the trial on the Open
432 Science Framework (<https://osf.io/c4hn8>). The first manuscript was randomised in July 2019.
433 We expect that recruitment will be finished in summer 2021.

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435 **Patient and public involvement**

436 Given the specific study topic, the steering committee agreed that patient or public involvement
437 is not needed for this study.

438

439 **Discussion**

440 RCTs are the current gold standard for evaluating any new intervention in evidence-based
441 medicine. Unfortunately, not all RCTs are of high quality. In fact, there are several well-known
442 shortcomings with respect to reporting.^{3 14-19} It is important to note that adhering to the
443 CONSORT Statement does not mean that the study is of high quality. However, reporting all
444 items from the CONSORT checklist will enable readers to adequately judge the quality of
445 RCTs.

446

447 In this RCT we will test if a simple intervention in the form of asking peer reviewers to check
448 whether selected CONSORT items are adequately addressed will increase the proportion of
449 reporting completeness in the published RCTs in the participating journals. A multicentre
450 parallel arm RCT with randomisation at the individual manuscript level was chosen instead of
451 a cluster RCT because the risk of “contamination” at journal level was judged as low as the

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3 452 intervention will be implemented by an external researcher (i.e. BS) or a member of the journal
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5 453 staff (e.g. personnel from Editorial services). The likelihood of contamination due to peer
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7 454 reviewers being invited to assess several RCTs and therefore becoming exposed to both
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9 455 intervention arms was judged small and therefore we do not plan to adjust for clustering by
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11 456 journal. Originally we planned to implement the intervention within the original instruction to
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13 457 peer reviewer email which is sent out as soon as a peer reviewer accepts the invitation from
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15 458 the journal. However, as these emails are sent automatically by the journal's editorial system
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17 459 we would have needed to modify the software from each journal to make sure that only half of
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19 460 the manuscripts administered the intervention. After our first discussion with journal editors
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21 461 and journal staff, we realised that this approach is not feasible and therefore decided to
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23 462 implement the intervention in the form of a separate email. We intended to conduct this RCT
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25 463 in a pragmatic way so that results "would also be relevant to [...] people who decide whether
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27 464 to implement the intervention on the basis of its results".³³ Hence we chose to assess outcomes
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29 465 from published articles and not from manuscripts after the first round of revisions. Ideally, the
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31 466 full impact of the intervention would also be measured including all versions of randomised
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33 467 manuscripts in the final statistical analysis. However, due to confidentiality issues and limited
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35 468 resources we will not be able to evaluate manuscript versions prior to publication.
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470 A selection of CONSORT items was chosen instead of the entire CONSORT checklist as we
471 did not want to put too high a burden on peer reviewers, which could increase the risk that
472 peer reviewers ignore our reminder.

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474 Should the proposed intervention be successful in improving the reporting quality of published
475 RCTs, as measured by the adherence to CONSORT, the intervention could be implemented
476 at the journal level without requiring a large amount of additional resources. In addition, very

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3 477 similar interventions for other article types (e.g. systematic reviews, trial protocols) and
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5 478 corresponding guidelines (e.g. PRISMA, SPIRIT) could be easily implemented too.
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11 480 **Authors' contributions**

12 481 SH, BS, IB, MB, DM, and PR had the study idea and designed the study. SS, IP and AC
13 482 provided expertise to ensure implementation at the journal level was possible. MMS was
14 483 responsible for statistical aspects, including the sample size calculation and the data analysis
15 484 plan. BS and SH wrote the first draft of the study protocol. All authors critically revised the
16 485 protocol and approved the final version.
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23 487 **Roles and responsibilities**

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26 488 The principal investigator (BS) is responsible for the preparation and the revisions of the study
27 489 protocol, organising meetings of the steering committee, recruiting and randomising eligible
28 490 manuscripts as well as the publication of study reports. The steering committee (IB, MB, SH,
29 491 DM, PR, BS, MMS, and SS) is responsible for revising the protocol, defining and validating the
30 492 additional short explanation for each CONSORT item, advising on study implementation, and
31 493 for publishing the results of this study. MMS is responsible for the sample size calculation and
32 494 the statistical analyses.
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41 496 **Ethical approval**

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44 497 Ethical approval has been obtained from the Medical Sciences Interdivisional Research Ethics
45 498 Committee of the University of Oxford (R62779/RE001). The original approved study protocol
46 499 is available in Appendix 2. The WHO Trial Registration Data Set is available in Appendix 3.
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50 500

52 501 **Competing interests**

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55 502 SS is employed by the British Medical Journal (BMJ). IP and AC are employed by the Public
56 503 Library of Science (PLOS). DM, SH, and IB are members of the CONSORT executive and
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3 504 authors of the CONSORT 2010 Statement. DM and PR are members of the EQUATOR
4
5 505 network steering group. MMS is a meta-researcher and reporting guideline developer,
6
7 506 enthusiast, and disseminators, he may therefore overestimate the importance of this project.
8
9 507 All authors have declared that no other competing interests exist.
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13 509 **Publication policy and access to data**

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15 510 The results from this study will be published in a peer reviewed journal irrespective of the study
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17 511 results. Authorship of publications will be granted according to the criteria of the International
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19 512 Committee of Medical Journal Editors (ICMJE). We plan to make the anonymised dataset,
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21 513 including the data from the published articles, available as a supplementary file of the main
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23 514 publication.
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620 **Figure legend**

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622 **Figure 1: Study flowchart**

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For peer review only

Table 1: The ten most important and poorly reported CONSORT items as defined by a group of experts on the CONSORT statement.²⁸ For better understanding key features were summarised within a short explanation (extracted from the CONSORT explanation and elaboration paper¹⁰ as well as from the COBWEB tool³⁰).

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when it was assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the “assigned intervention is determined by a chance process and cannot be predicted”?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or “third-party” assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as “double-blind” without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of the funder(s) described?

630 **Table 2:** Study schedule

	Enrolment	Allocation and intervention	Intervention	Post-intervention	
Time-point	<i>Studies which are sent out for peer-review</i>	<i>After first peer-reviewer accepts invitation</i>	<i>Whenever an additional peer-reviewer accepts invitation</i>	<i>First decision by journal</i>	<i>Published manuscripts</i>
Eligibility screen	X				
Allocation		X			
Intervention:					
C-short + usual care		X	X		
Usual care		X	X		
Assessment of trial characteristics:					
Funding source					X
Study centres (single centre or multicentre)					X
Sample size					X
Study design (e.g. parallel arm, crossover)					X
Hypothesis (e.g. superiority, non-inferiority)					X
Medical field					X
Intervention tested					X
Number of trial arms					X
Number of peer-reviewers					X
Journal which published the manuscript					X
Number of journals requesting CONSORT adherence (submission of checklist mandatory)					X
Assessment of outcomes:					
Time from assigning an academic editor until the first decision				X	
Proportion of manuscripts directly rejected after the first round of peer-review				X	
Proportion of manuscripts that will be published in the journal under study					X
Adherence to CONSORT items and sub-items					X

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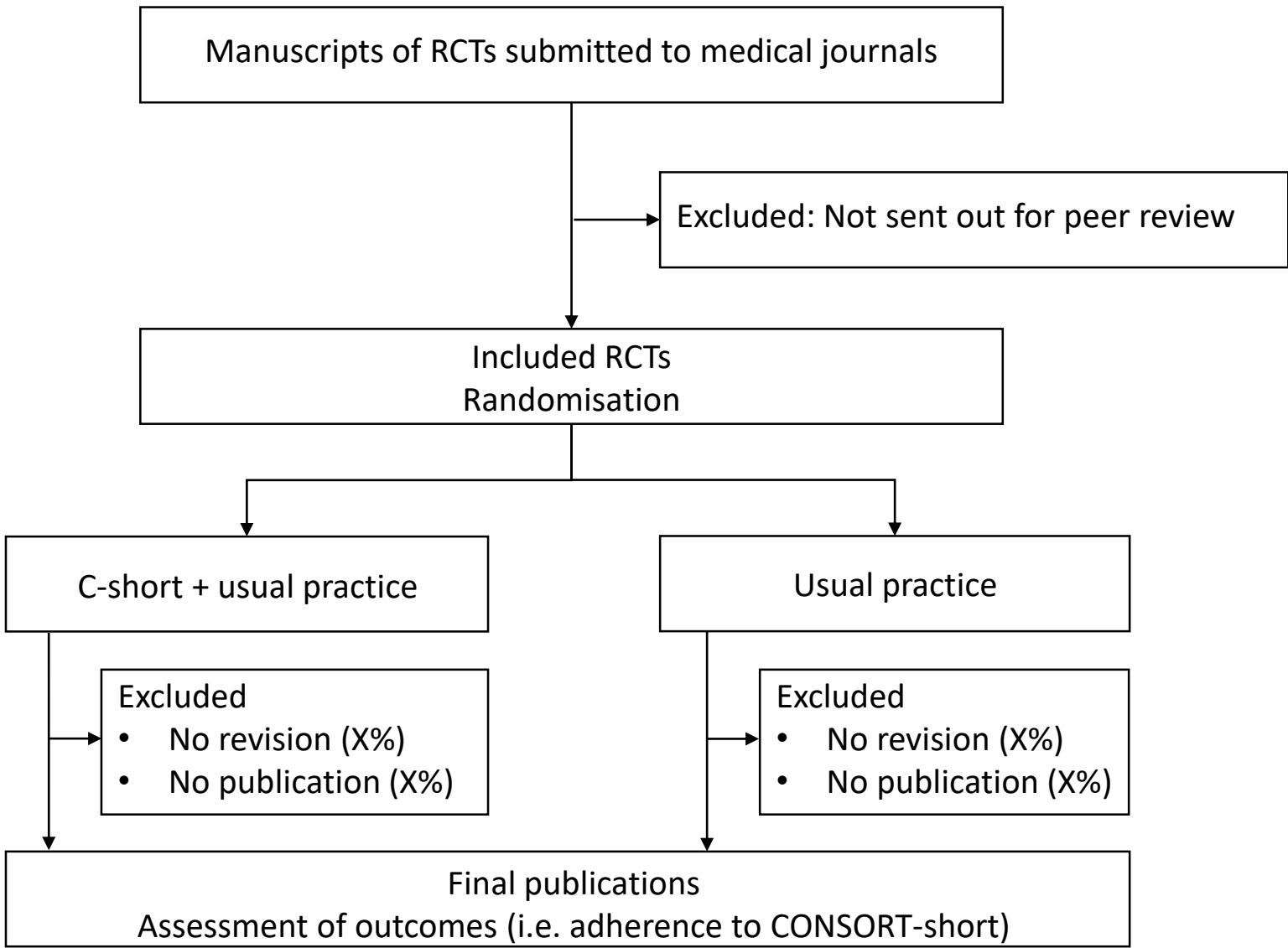
632 **Table 3:** Assumptions for sample size calculations in two different scenarios.

Item	CONSORT item	Scenario 1. Adequate reporting as published in WebCONSORT ²⁸	Scenario 2. Adapted from Scenario 1
1	Outcomes (6a)	77% (79 of 103)	77% (79 of 103)
2	Sample size (7a)	83% (85 of 103)	83% (85 of 103)
3	Sequence generation (8a)	76% (78 of 103)	76% (78 of 103)
4	Allocation concealment (9)	55% (57 of 103)	55% (57 of 103)
5	Blinding (11a)	35% (36 of 103)	35% (36 of 103)
6	Outcomes and estimation (17a)	44% (45 of 103)	44% (45 of 103)
7	Harms (19)	71% (73 of 103)	71% (73 of 103)
8	Registration (23)	69% (71 of 103)	90%
9	Protocol (24)	19% (20 of 103)	90%
10	Funding (25)	34% (35 of 103)	90%
Overall		56%	71%

633 Abbreviation: CONSORT= CONSolidated Standards for Reporting Trials

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3 **Impact of a short version of the CONSORT checklist for peer reviewers to improve the**
4 **reporting of randomised controlled trials published in biomedical journals: study**
5 **protocol for a randomised controlled trial**
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10 Benjamin Speich, Sara Schroter, Matthias Briel, David Moher, Iratxe Puebla, Alejandra Clark,
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12 Michael M Schlusser, Philippe Ravaud, Isabelle Boutron, Sally Hopewell
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18 **Appendix**
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22 **Appendix 1:** Example of the email which will be sent out in the intervention arm (C-Short).
23 The exact wording might be slightly adapted according to the journal preferences.
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27 **Appendix 2:** Original study protocol as it was approved by the Medical Sciences
28 Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001).
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30 *Page 3*
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32 **Appendix 3:** WHO Trial Registration Data Set (Version 1.3.1)
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Appendix 1: Example of the email which will be sent out in the intervention arm (C-Short).
The exact wording might be slightly adapted according to the journal preferences.

Dear **Title, Name**,

We thank you for accepting to peer-review a manuscript for **journal name**. As we are trying to improve the reporting for randomised controlled trials according to the CONSORT guidelines, we would like to ask if you could check whether the following most important and poorly reported items are adequately implemented as indicated in the *table below/attached table*.

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the "assigned intervention is determined by a chance process and cannot be predicted"?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or "third-party" assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as "double-blind" without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of funder(s) described?

Your efforts are highly appreciated.

Kind regards,

journal name-Team

Appendix 2: Original study protocol as it was approved by the Medical Sciences Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001).



Impact of a short form of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published in biomedical journals: a randomised controlled trial

Short title: CONSORT for Peer Review (CONSORT-PR)

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Trial registration: This trial will be prospectively registered under clinicaltrials.gov.

Protocol version: Version 1.1 2019-05-21

Funding: Benjamin Speich is supported by an Advanced Postdoc.Mobility grant from the Swiss National Science Foundation (P300PB_177933). David Moher is supported by a University Research Chair, Ottawa. The funders had no role in designing the study and will also have no role in conducting the study as well as in analysing and reporting study results.

Roles and responsibilities:

Contributors: SH, BS, IB, MB, DM, PR, had the study idea and designed the study. SS provided expertise to ensure implementation at the journal level was possible. MMS was responsible for statistical aspects, including the sample size calculation and the data analysis plan. BS and SH wrote the first draft of the study protocol. All authors critically revised the protocol and approved the final version.

Sponsor and contact information: Centre for Statistics in Medicine, Botnar Research Centre, University of Oxford, Windmill Road, Oxford OX3 7LD. Principal investigator: Benjamin Speich (Email: Benjamin.speich@ndorms.ox.ac.uk)

Sponsor and funders: The funders had no role in designing the study and will also have no role in conducting the study as well as in analysing and reporting study results.

Roles and responsibilities: The principal investigator (BS) is responsible for the preparation and the revisions of the study protocol, organising meetings of the steering committee, recruiting and randomizing eligible manuscripts as well as the publication of study reports. The steering committee (IB, MB, SH, DM, PR, BS, MMS, and SS) is in charge of participating in the elaboration of the protocol, defining and validating the additional short explanation for each CONSORT item, following the evolution of the committed study and for publishing the results of this study. MMS is responsible for the sample size calculation and the statistical analyses.

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1. Background and rational

1.1 Need for clinical research and epidemiologic transparency

There is substantial agreement that well conducted and reported randomised controlled trials (RCTs) generate the most trustworthy evidence when newly developed or already existing clinical interventions are evaluated (1-3). Besides the complexity and the high associated costs of conducting RCTs (4-6), there are major issues with their reporting that often make it difficult for researchers, clinicians, patients or policymakers to interpret the current evidence on a specific topic (7, 8). Chronologically, the most prominent difficulties in reporting consist of (i) poor reporting in study protocols for RCTs (9-12); (ii) a substantial fraction of trials are not registered, prematurely discontinued (most common due to difficulties with recruitment) and not published (13, 14); and (iii) that published RCTs are often poorly reported (7).

For clinicians, scientists and decision makers, published articles are often the only way to know how a study was conducted. In order to judge the internal and external validity of RCTs, it is crucial that these articles present transparent, accurate and unbiased information about the methods and conduct of the RCT.

1.2 Transparency in published randomised controlled trials

To improve the transparency in clinical and epidemiological research the international organisation called the EQUATOR (Enhancing the Quality and Transparency of Research) Network was founded in 2006 (15-20). This international network consists of researchers, epidemiologists, people in charge of recommendations for the presentation of articles or "reporting guidelines", statisticians, clinicians and editors from some of the most prestigious journals (e.g., *Lancet*, *JAMA*, *Annals of Internal Medicine*, *BMJ*).

The CONSORT Statement (CONsolidated Standards for Reporting Trials), is perhaps the most important reporting guideline designed to help improve the transparency and quality of reporting of RCTs (21, 22). The CONSORT Statement, consisting of 25 items and a flow diagram which should be reported in papers describing RCTs. The last update of the CONSORT Statement was published simultaneously in 10 leading medical journals in 2010 (23). Currently CONSORT is endorsed by 585 journals (24). The CONSORT Statement guides authors, peer reviewers and journal editors on what information should be included in published reports of RCTs in order to facilitate critical judgment and interpretation of results. It is important to note, that adhering to the CONSORT Statement does not mean that the study is of high quality. However, reporting all items from the CONSORT list will enable readers to adequately judge the quality of RCTs.

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3 A number of research studies have identified serious limitations in the reporting of published
4 RCTs (3, 25-30). Despite some improvement in reporting following the implementation of the
5 CONSORT Statement, there still remain major reporting deficiencies in published RCTs (31).
6 For example, Odutayo and colleagues showed that a large proportion of RCTs published in
7 December 2012 in PubMed did not define the primary outcome (31%), did not state the sample
8 size calculation (45%) and did not explain the method of allocation concealment (50%) (32).
9 This lack of transparency is a major limiting factor for the reader who assesses an article in
10 order to find the answer to a specific question; it is also a major problem for scientists who
11 perform systematic reviews and meta-analyses. Thus, some published trials may not be
12 included in the meta-analysis because of their lack of transparency. Chan showed (25, 33) that
13 50% of efficacy outcomes and 65% of safety outcomes could not be included in meta-analyses
14 because of how they were reported. Furthermore, even if these trials are included in systematic
15 reviews and meta-analyses, an adequate risk of bias assessment is often not possible due to
16 the poor reporting quality. Nevertheless, the main consequence of the lack of transparency is
17 the risk of accepting treatments that are ineffective or cause serious adverse events (34).
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28 1.3 Journal attempts to improve reporting in published randomised controlled trials

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30 Journals can play a vital role in improving the reporting of published reports of RCTs. For
31 example, a survey of authors' instructions on journal websites revealed that in 2014 63% (106
32 of 168) of biomedical journals mentioned CONSORT within their "Instructions to Authors" (35).
33 Of those journals 38 (36%) required a CONSORT checklist as a condition of RCT report
34 submission. Such implementation indicates some improvement over time compared to an
35 assessment in 2007 when only 17 journals requested the CONSORT checklist (36). An
36 interrupted time series analysis which assessed if the CONSORT for Abstracts guideline had
37 an effect on the reporting quality, found that results are better reported in Journals which
38 enforce the policy (37).
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46 In a study published in 2016 authors of RCTs were asked by journal editors to use the web-
47 based CONSORT tool at the manuscript revision stage (38). Authors who were randomly
48 allocated to the intervention had access to a tool which allowed them to combine different
49 CONSORT extensions (according to study design, medical field) to generate customised
50 checklists. In the control group, authors had access to a CONSORT flow diagram generator.
51 The goal was to improve the reporting of CONSORT items with a simple webtool. However, a
52 quarter of all authors either wrongly selected a CONSORT extension or failed to select an
53 extension, indicating that further education is needed in terms of when and how to implement
54 CONSORT extensions.
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3 A systematic scoping review conducted in 2017 by Blanco and colleagues summarised
4 different interventions aimed to improve adherence to reporting guidelines (39) (manuscript
5 with results currently under review. Draft received via personal communication). A number of
6 different interventions were identified and some had also been tested at journals. However,
7 the interventions, besides requesting submission of checklists from authors, required
8 additional resources at the journal level (e.g. internal peer review by editorial assistants or
9 inviting an additional statistical peer-reviewer (40, 41)). Therefore, it is unlikely that these
10 interventions will be implemented in the vast majority of journals, especially not in smaller
11 journals with limited resources. A study examining “the nature and extent of changes made to
12 manuscripts after peer review, in relation to the reporting of methodological aspects of RCTs”
13 and “the type of changes requested by peer reviewers” found that peer review did lead to some
14 improvement in reporting (40).

15
16 Building on these findings we plan to evaluate the impact of inviting peer reviewers to explicitly
17 use a short version of the CONSORT checklist (including a short explanation of those items)
18 as part of their review process. If this intervention deems to be effective, it could be easily
19 implemented by all medical journals without needing additional resources at a journal level.

2. Hypothesis

20
21 We propose an RCT to evaluate the impact of asking peer reviewers to use a short version of
22 the CONSORT checklist when reviewing a manuscript of an RCT and whether it improves the
23 completeness of reporting. Our hypothesis is that reminding peer reviewers of the CONSORT
24 items (including a short explanation of those items) will result in higher adherence to
25 CONSORT guidelines in published RCTs. We only selected a limited number of the CONSORT
26 items because we did not want to deter peer reviewers with too much information. Since peer
27 reviewing in general can be burdensome, we felt that this approach is more promising than
28 listing all items, risking that the information will be ignored. The short version of the CONSORT
29 checklist is based on the same items described in a previous study as the 10 most important
30 and underreported CONSORT items (38).

3. Objective

3.1 Main objective

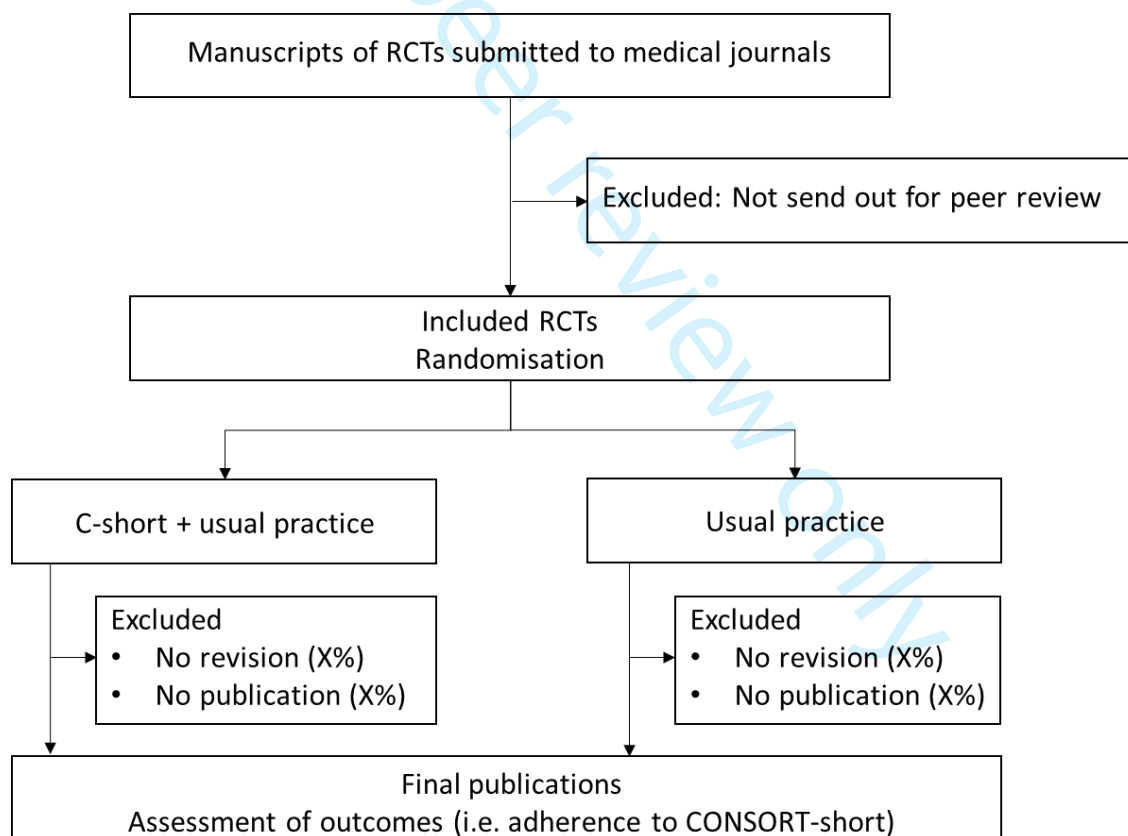
31
32 The main objective of this study is to evaluate the impact of asking peer reviewers during the
33 standard peer-review process to ask them to use a short version of the CONSORT checklist
34 (C-short) and whether it will improve the reporting in published RCTs compared to manuscripts
35 where the peer reviewers underwent usual practice.

4. Methods

4.1 Trial design

This study is a multicentre RCT with articles being the unit of randomisation (Figure 1; allocation ratio 1:1). A multicentre parallel arm RCT with randomisation at the individual article level was chosen instead of a cluster RCT because the risk of any “contamination” on journal level is not given as the intervention will be implemented by an external researcher (i.e. BS). The possibility of contamination due to the possibility that peer reviewer are invited to assess several RCTs and are randomised into both arms was judged as relatively small and therefore we do not plan to adjust for clustering by journal. The journal staff (i.e. editors) will not be actively told which manuscript was allocated to the proposed intervention and which to the control group.

Figure 1: Study flowchart



4.2 Study setting and eligibility criteria

The population will be defined on two levels. Included journals and included articles.

Included journals must: i) endorse the CONSORT Statement (e.g. assessed via journals Instruction to Authors); ii) publish primary results of at least five RCTs in 2017 (identified in a brief PubMed search as publishing RCTs in 2017). To be efficient, we plan to contact (via

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3 email) the editors of eligible journals within a publishing house (i.e. journals which are part of
4 the BMJ series, BMC series, PLoS, Lancet, JAMA) instead of separate journals. A description
5 of the requirements for participation and a short summary information sheet will be included
6 as part of the email invitation sent to journal editors. If a journal is eligible, and agrees to take
7 part, the journal will also need to provide access to their journal editorial system (e.g.
8 ScholarOne, Editorial Manager) to enable the external researcher (i.e. BS) to screen and
9 randomise eligible manuscripts. In cases this is not possible, we will explore with separate
10 journals if it would be possible to grant limited access (e.g. only rights to screen studies) and
11 that the emails from the intervention would be sent by a person from the editorial team.
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19 We will include all submitted manuscripts reporting RCTs for which the journal decides to send out for
20 external peer review. Since the 10 chosen CONSORT checklist items are applicable to different study
21 designs, we will include all RCTs regardless of study design (e.g. parallel group trial, cluster trial,
22 superiority trial, non-inferiority trial). Articles presenting clearly secondary trial results, additional time
23 points, economic analyses, or any other analyses derived from an RCT dataset not including the study's
24 main results will be excluded. Furthermore, RCTs which are clearly labelled as a pilot or feasibility study
25 or randomise animals or cells instead of individuals will be excluded.
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30 Details of journal manuscript submission and peer review processes, including, consent and
31 potential confidentiality issues will be discussed in detail with each journal by teleconference
32 and/or face to face prior to the journal agreeing to take part to ensure that randomisation of
33 manuscripts is feasible. We considered conducting randomisation at the level of the journal
34 (i.e. cluster RCTs). However, in order to make the intervention as easy and simple to
35 implement (and with little or no additional effort from the journal) we believe that randomisation
36 at the manuscript level - with an external researcher implementing the intervention within the
37 existing journal management systems - will be the most efficient study design.
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45 In participating journals, the external investigator (BS) will have access to the editorial
46 management software (e.g. ScholarOne or Editorial Manager) and will check at least twice a
47 week (using automated report lists) all research manuscripts that are sent out for external peer
48 review. As soon as the first peer-reviewer accepts the invitation to review, the manuscript will
49 be randomised to the intervention or control arm (see "Randomisation" for more details). It is
50 possible that this process might be slightly different amongst different included journals.
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56 4.3 Interventions

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59 Experimental group: C-short plus usual practice
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3 After accepting to review an article, peer reviewers will receive the automated, journal specific
4 standard email with general information as per each journal's usual practice (e.g. where to
5 access the manuscript, date when the peer review report is due). In addition, peer-reviewers
6 who received a manuscript which was randomised to C-short will receive an additional email
7 including a short version of the CONSORT checklist (C-short) (either within the email or as
8 an attachment; based on the preferences and possibilities of the journal) focusing on the 10
9 most important and most poorly reported items (Table 1; as previously defined by a group of
10 experts of the CONSORT Group (38)). Peer-reviewers will be asked to pay particular attention
11 to items in the C-short checklist and request authors to report on these items, if not already
12 adequately reported. This second email, containing the C-short checklist, is not generated
13 automatically within the existing journal editorial management system (e.g. ScholarOne or
14 Editorial Manager); it will be sent by the investigator who has access to the journal editorial
15 system (BS). An example of this additional email is presented within the appendix (appendix
16 1; the exact wording might be changed according to the preferences of the participating
17 journals). At least twice a week the editorial management system will be checked for each
18 journal and if a peer reviewer has accepted an invitation to review, an email containing the C-
19 short intervention will be generated and sent. It might be possible that some journals will only
20 provide the right to access and read manuscripts in the editorial management system, but not
21 to send emails. If this is the case, the corresponding Editor (or designated person within the
22 journal) will be informed to send the emails.
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Development and testing of the short explanation of the C-short items:

36 We chose the 10 most important and poorly reported CONSORT items as identified by a group
37 of CONSORT experts in a previous study conducted by Hopewell and colleagues (38). The
38 selection of the items was based on expert opinion and empirical evidence whenever available
39 (38). In addition, we have added a short explanation for each of the 10 items. These short
40 explanations were extracted and amended from the CONSORT explanation and elaboration
41 paper (21) and from COBWEB which is online writing aid tool (42). The short explanation was
42 discussed and adapted by the scientific committee.
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Control group: Usual practice:

50 After accepting to review an article, peer reviewers will receive the automated, journal specific
51 standard email with general information as per each journal's usual practice (e.g. where to
52 access the manuscript, date until when the peer review report is due). However, they will not
53 receive the second email, sent by the investigator who has access to the journal editorial
54 system (BS) which contains the C-short checklist.
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Table 1: The ten most important and poorly reported CONSORT items as defined by a group of experts on the CONSORT statement (38). For better understanding key features were summarised within a short explanation (extracted from the CONSORT explanation and elaboration paper (21) as well as from the COBWEB tool (42)).

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the “assigned intervention is determined by a chance process and cannot be predicted”?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or “third-party” assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as “double-blind” without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of the funder(s) described?

4.4 Outcomes

Primary outcome:

The primary outcome of this study will be the difference of the mean proportion of adequately reported items of the 10 most important and poorly reported CONSORT items between the two intervention arms.

Secondary outcomes:

Secondary outcomes will include the following:

- Mean proportion of adequate reporting of the 10 most important and poorly reported CONSORT items, considering each sub-item (see also “Assessment of outcomes”) as a separate item.
- Mean proportion for each of the 10 most important and poorly reported CONSORT items separately (including also separate analysis of sub-items).
- Time from assigning an academic editor until the first decision (as communicated to the author after the first round of peer-review).
- Proportion of articles directly rejected after the first round of peer-review.
- Proportion of articles published.

Additional outcomes:

For journals where peer reviewer comments are subsequently published alongside the published article, we will examine the peer reviewer comments for any reference to CONSORT and trial reporting. We will contact those journals which do not make peer reviewer comments publicly available, to see if they still could be used for such an analyses under the condition that only anonymised data will be published.

Data collection methods:

The outcomes will be assessed independently by two (blinded or at least partially blinded; see “blinding”) outcome assessors with expertise in the design and reporting of clinical trials. Any disagreement will be resolved by consensus or if necessary by consulting a third assessor. To ensure consistency between reviewers, we will first pilot the data extraction form; any disparities in the interpretation will be discussed and the data extraction form will be modified accordingly.

Adequate reporting of items will be assessed from published full-text publications adhering to the CONSORT C-short checklist (21). The following included items have sub-items which will be extracted separately:

- Outcomes (item 6a): (i) Define primary outcome, (ii) how it was measured, (iii) at what time point, and (iv) the analysis metric (e.g. change from baseline, final value).
- Sample size (item 7a): (i) The estimated outcomes in each group, (ii) the α (type I) error level, (iii) the statistical power (or the β (type II) error level), (iv) for continuous outcomes, the standard deviation of the measurements
- Blinding (item 11a): Is the blinding status clear for the following persons: (i) Healthcare provider, (ii) patients, and (iii) outcome assessors.
- Funding (item 25): (i) The funding source, and (ii) the role of funder in the design, conduct, analysis, and reporting.

All items will be judged as either “yes” meaning adequately reported, “no” meaning not adequately reported, or “NA” meaning that this sub-item is not applicable for this RCT. Items with different sub-items will only be judged as adequately reported if all relevant sub-items were adequately reported.

- Time from assigning an academic editor until the first decision: The day when the academic editor was assigned and the day of the first decision (e.g. major revision, minor revision, rejected) will be extracted to calculate the number of days until the first decision.
- Proportion of articles directly rejected after the first round of peer-review: Articles which were not invited for re-submission will be labelled and counted.
- Proportion of articles published: Articles which will be published will be counted and collected for data extraction.

The outcomes “time from assigning an academic editor until the first decision”, “proportion of articles directly rejected after the first round of peer-review”, and “proportion of articles published” will be extracted directly from editorial management software of the journal.

4.5 Participant timeline

The overview of the study schedule, including enrolment, intervention and assessments is presented in Table 2.

Table 2: Study schedule

	Enrolment	Allocation and intervention	Intervention	Post-intervention	
Time-point	<i>Studies which are sent out for peer-review</i>	<i>After first peer-reviewer accepts invitation</i>	<i>Whenever an additional peer-reviewer accepts invitation</i>	<i>First decision by journal</i>	<i>Published manuscripts</i>
Eligibility screen	X				
Allocation		X			
Intervention:					
C-short + usual care		X	X		
Usual care		X	X		
Assessment of trial characteristics:					
Funding source					X
Study centres (single centre or multicentre)					X
Sample size					X
Study design (e.g. parallel arm, crossover)					X
Hypothesis (e.g. superiority, non-inferiority)					X
Medical field					X
Intervention tested					X
Number of trial arms					X
Number of peer-reviewers					X
Journal which published the manuscript					X
Number of journals requesting CONSORT adherence (submission of checklist mandatory)					X
Assessment of outcomes:					
Time from assigning an academic editor until the first decision				X	
Proportion of articles directly rejected after the first round of peer-review				X	
Proportion of articles published					X
Adherence to CONSORT items and sub-items					X

4.6. Sample size

For the sample size calculation we hypothesise in a first scenario (Table 3) that the intervention C-Short will result in a 25% relative increase in adequate reporting compared to the control (meaning that 70% of items will be adequately reported in the intervention group and 56% in the control group). This is based on the rate of reporting of the 10 most important and poorly reported items was 0.56 (meaning that a mean of 56% of the 10 most important and poorly reported items were reported) in the control group of a previous study called WebCONSORT (38). The standard deviation (SD) in the same study was 0.23. However, we calculated our sample size to account for a slightly bigger variability in our data (SD = 0.25). To demonstrate a significant difference with a power of 90% and a type 1 error at 5% a total of 136 articles will be required in this scenario (68 per treatment arm; based on a two sided t-test).

The staff from one journal which will most likely be included (i.e. *PLoS One*) pointed out that 3 out of the 10 assessed items (i.e. item "Registration", "Protocol", and "Funding") should always be implemented given their template. Assuming that this journal will recruit a high proportion, and that also other journals might update their templates, we increased the sample size in a second scenario, in which all these 3 items would have an overall adherence of 90% in the control arm (Table 3). This would entail an overall baseline adherence with the 10 CONSORT-short items of 71%. Based on a two sided t-test, a sample size of 166 (83 per treatment arm) will have a power of 80% to find a 15% relative increase (71% adherence in control group; 82% adherence in intervention group; SD = 0.25; a type 1 error at 5%).

Since the final sample size will be based on the number of articles published, rather than on the number of manuscripts randomised, eligible RCTs will be included and randomised until the number of 83 published RCTs is reached in each arm (resulting in no less than 166 articles), to avoid loss of power due to potential imbalance between arms. Recruitment will be stopped as soon as both arms reach the sample size of 83. After recruitment stop we will wait three month so that manuscripts which are still in production can be published. Manuscripts which are published after the three month period will be excluded.

Table 3: Assumptions for sample size calculations in two different scenarios.

Item	CONSORT item	Scenario 1. Adequate reporting as published in WebCONSORT	Scenario 2. Adapted from Scenario 1
1	Outcomes (6a)	77% (79 of 103)	77% (79 of 103)
2	Sample size (7a)	83% (85 of 103)	83% (85 of 103)
3	Sequence generation (8a)	76% (78 of 103)	76% (78 of 103)
4	Allocation concealment (9)	55% (57 of 103)	55% (57 of 103)
5	Blinding (11a)	35% (36 of 103)	35% (36 of 103)
6	Outcomes and estimation (17a)	44% (45 of 103)	44% (45 of 103)
7	Harms (19)	71% (73 of 103)	71% (73 of 103)
8	Registration (23)	69% (71 of 103)	90%
9	Protocol (24)	19% (20 of 103)	90%
10	Funding (25)	34% (35 of 103)	90%
Overall		56%	71%

Abbreviation: CONSORT= CONSolidated Standards for Reporting Trials

4.7 Randomisation and blinding

Articles, which meet the eligibility criteria as a primary report of an RCT, for which the journal decides to send out for external peer review will be randomised into one of the two groups (allocation 1:1). The randomisation list will be created by the study-randomizer system (43) using random block sizes between 2 and 8 and stratification by journal. As soon as the first peer-reviewer accepts the invitation, the manuscript will be included and randomised to one of the two intervention arms. One of the investigators (BS) will log onto the study randomizer-system (43) entering the study identification number (ID; provided from the Journal), the study title, as well as the journal the study was submitted to. Subsequently, all additional peer-reviewers accepting the invitation to review the same manuscript will receive the same intervention (C-short plus usual practice or usual practice only) as the first peer-reviewer.

Authors will be blinded to the intervention allocation. Editors will not be actively informed about the randomisation (possible exception listed under "4.3 Interventions"). To avoid potential bias, peer reviewers and manuscript authors will not be informed of the study hypothesis, design and intervention.

Outcomes will be assessed in duplicate (see assessment of outcomes). At least one outcome assessors will be blinded. Due to restricted resources it might be possible that the investigator conducting the randomisation (BS) will be included in the data-extraction from published manuscripts.

4.7 Data management and confidentiality

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3 Outcomes from publications will be assessed and extracted in duplicate. Since this information
4 is not confidential, we will use Google Forms for data extraction from published RCTs. Data
5 entered will be validated for completeness.
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9 Data from the editorial manager software (e.g. Title of manuscript, first author, randomisation
10 ID, Journal, date when manuscript was accepted by and academic editor, date when the final
11 decision was made, final decision, number of peer-reviewers who peer reviewed the
12 manuscript, the peer review) will be extracted, anonymised and entered in a password
13 protected database which is saved on a server from the University of Oxford. Data will be
14 managed and curated according to University of Oxford regulations, which includes regular
15 back-up (on a daily basis) of the virtual drives where the data are stored.
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21 The raw data extracted from the included manuscripts can be made openly accessible in an
22 anonymised way (i.e. giving the included RCT a number instead of identifying them).
23 Derived/aggregated data, including anonymised information generated from the journals'
24 editorial manager software, will be stored and made available to the research community when
25 the project ends (see also "8. Publication policy and access to data"). Where appropriate, the
26 researcher who has access to the editorial manager software (BS) and anyone else who will
27 see the identifiable data will sign a confidentially agreement with the participating journals,
28 confirming that they will not share identifiable data with any other party. Journals such as the
29 BMJ series state in their Company Privacy Statement that research programmes for quality
30 improvement might be in place. Furthermore, peer reviewers for all BMJ journals receive the
31 following statement in their invitation letter "*We are constantly trying to find ways of improving
32 the peer review system and have an ongoing programme of research. If you do not wish your
33 review entered into a study please let us know by emailing [...] as soon as possible.*"
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44 4.8 Statistical methods

45 4.8.1 Populations of analysis

46 The main population for analysis will be all manuscripts randomised and accepted for
47 publication in the participating journals. Differently from RCTs conducted with patients, where
48 drop outs need to be carefully considered (e.g. multiple imputation of missing data), we are
49 only interested in the reporting adherence of RCTs that are published. All outcomes will be
50 calculated based on the main population for analysis. The secondary outcome "Time to the
51 first decision", will additionally be calculated considering all randomised manuscripts (including
52 the ones which were not published).
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4.8.2 Data analysis

All quantitative variables will be described using means and standard deviations, or median and interquartile ranges in case severe departures from a normal distribution are identified. Data distribution will be inspected visually (i.e. by histograms) instead of performing formal statistical tests for normality. Categorical variables will be described using frequencies and percentages. For the primary and secondary outcomes, we will estimate the difference between means between the two groups and report them with respective 95% confidence intervals.

4.8.3 Analysis of primary endpoint

The primary outcome will be the difference of the mean proportion of adequately reported items of the 10 most important and poorly reported CONSORT items. If the data on the primary outcome is normally distributed then the two groups (i.e. C-short plus usual practice vs. usual practice) will be compared using an unpaired Student's *t*-test to compare the unadjusted mean proportion of adequate reporting. If the data is not normally distributed, comparisons will be performed using a non-parametric equivalent test (i.e. Wilcoxon-Mann-Whitney test for testing whether the population medians of the two groups are the same).

For the analyses of the primary outcomes a *p*-value of 0.05 (5% significance level) will be used to indicate statistical significance and treatment effect (mean difference) reported with 95% confidence intervals (or median and respective interquartile ranges, in case of asymmetric distribution). Exact *p*-values will be presented up to three decimal places. We anticipate there will be no missing data in this study, neither at the individual C-short items, nor at the manuscript level. This is due to the study design, which will include only the randomised manuscripts that are accepted for publication.

4.8.4 Analysis of secondary endpoints

To investigate the effect of the intervention on the secondary outcomes, mean differences with respective 95% confidence intervals will also be reported for these outcomes. If normality is not observed for any of the continuous secondary outcomes, the same strategy adopted for the primary outcome (use of a non-parametric equivalent to the Student's *t*-test) will be used.

A *p*-value of 0.05 will indicate statistical significance for the observed treatment effect on the secondary outcomes. Exact *p*-values will be presented up to three decimal places. Similarly to the primary outcome, we anticipate there will be no missing data for any of the secondary

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3 outcomes, as we will have access to the Editorial Management system of the included
4 journals, where all relevant information is automatically reported.
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7 4.8.5 Pre-specified subgroup analysis 8

9 No formal subgroup comparative analysis is planned for the primary or secondary outcomes.
10 However, the effect of the intervention on the primary outcome within subgroups, will be
11 presented using forest plots to visually examine whether it differs according to some variables,
12 such as: (1) Journals that actively implement the CONSORT Statement (defined as requiring
13 authors to submit a completed CONSORT checklist alongside their manuscript) vs. journals
14 that are not actively implementing the CONSORT Statement; (2) sample size ($n < 100$ vs. $n \geq$
15 100); and (3) impact factor (<5 , $5.1-10$; >10) as there is evidence that higher impact factor as
16 well as higher sample size are associated with higher adherence to reporting guidelines (44).
17 These analyses will be exploratory, with the aim of supporting new hypothesis generation,
18 rather than conclusive.
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27 **5 Legal and general logistics** 28

29 5.1. Organisation of study 30 31

32 5.1.1 Coordinating centre 33

34 The coordinating centre's, will be the Centre for Statistics in Medicine at the University of
35 Oxford under the responsibilities of Dr Sally Hopewell and Dr Benjamin Speich.
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37 The coordinating centre's will ensure the following missions:
38

- 39 • Training of the staff
- 40 • Implementation of quality control
- 41 • Logical controls of data
- 42 • Follow-up on requests for correction/validation
- 43 • Statistical analysis
- 44 • Archiving of data
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50 5.1.2 Scientific committee 51

52 The scientific committee is composed of:

- 53 • Prof Isabelle Boutron: Centre D'Épidémiologie Clinique Hôtel-Dieu, Paris Descartes
54 University, France
- 55 • Prof Matthias Briel, University of Basel, Switzerland
- 56 • Associate Prof Sally Hopewell: Centre for Statistics in Medicine, University of Oxford,
57 UK
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- Prof David Moher: Centre for Journalology, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Canada
- Prof Philippe Ravaud: Centre d'Épidémiologie Clinique Hôtel-Dieu, Paris Descartes University, France
- Dr Benjamin Speich, Centre for Statistics in Medicine, University of Oxford, UK
- Dr. Michael M Schlusser, Centre for Statistics in Medicine, University of Oxford, UK
- Dr Sara Schroter, The BMJ, London, UK

The scientific committee is in charge of:

- Participating in the elaboration of the protocol
- Defining and validating the additional short explanation for each CONSORT item.
- Following the evolution of the committed study
- Publishing the results of this study

5.2. Regulatory aspects

Ethical approval for this study will be sought from the Central University Research Ethics Committee (CUREC) of the University of Oxford. Any amendments in the conduct of the study, collection of outcomes or analysis will be reported to the CUREC. The tested intervention has the goal to improve the quality of published journals (i.e. the adherence to CONSORT) and could also be implemented as usual practice without testing at the journal level. In agreement with another study, testing a similar intervention (45), we think that it is ethical to conduct this study without obtaining written consent. The main reason for this procedure are the following:

- Informing the authors and peer-reviewers would make it impossible to measure the effect of our intervention. In short, informing peer-reviewers and authors would create an artificial context which would not be comparable any more to the “real world context”. Authors and peer-reviewers would most likely be much more aware of CONSORT if they received information about the study. Furthermore, being aware to participate in a study could strongly influence the natural behaviour of peer-reviewers (e.g. putting more effort into reviewing a manuscript than under “real world conditions”) but also of authors.
- The intervention does not pose any risk of harms for authors and peer-reviewers.
- The intervention is not a medical intervention but rather tries to improve the research quality and journal processes.
- Several journal series (e.g. BMJ series) have Company Privacy Statements in place which clearly mention that research programmes might be in place for quality improvement.

- The intervention could be part of the routine at any Journal without previous assessment of its efficacy.
- No data which identifies participating manuscripts will be published.

6 Publication policy and access to data

The results from this study will be published in a peer-reviewed journal irrespective of the study results. Authorship to publications will be granted according to the rules of the International Committee of Medical Journal Editors (ICMJE). We plan to publish the full anonymised dataset as a supplementary file together with the main publication.

For peer review only

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For peer review only

Appendix

Appendix 1: Example of the email which will be sent out in the intervention arm (C-Short).
The exact wording might be slightly adapted according to the journal preferences.

Dear **Title, Name**,

We thank you for accepting to peer-review a manuscript for **journal name**. As we are trying to improve the reporting for randomised controlled trials according to the CONSORT guidelines, we would like to ask if you could check whether the following most important and poorly reported items are adequately implemented as indicated in the *table below/attached table*.

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the "assigned intervention is determined by a chance process and cannot be predicted"?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or "third-party" assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as "double-blind" without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of funder(s) described?

Your efforts are highly appreciated.

Kind regards,

journal name-Team

Appendix 3: WHO Trial Registration Data Set (Version 1.3.1)

Statement was filled out on the 01. October 2019.

1. Primary Registry and Trial Identifying Number

This trial was denied registration on ClinicalTrials.gov as the study is not a clinical study that assesses a health outcome in human subjects. Instead we registered the trial on the Open Science Framework (<https://osf.io/c4hn8>).

2. Date of Registration in Primary Registry

21. June 2019

3. Secondary Identifying Numbers

Not applicable

4. Source(s) of Monetary or Material Support

No specific funding was acquired for this study. Benjamin Speich is supported by an Advanced Postdoc.Mobility grant from the Swiss National Science Foundation (P300PB_177933). David Moher is supported by a University Research Chair, Ottawa. Michael M Schlüssel is funded by Cancer Research UK. The funders had no role in designing the study and will also have no role in conducting the study, or analysing and reporting study results.

5. Primary Sponsor

Sponsor:	University of Oxford
Principal Investigator/Sponsor Investigator:	Benjamin Speich, PhD Postdoctoral Researcher Centre for Statistics in Medicine (CSM) Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) University of Oxford Windmill Road Oxford OX3 7LD Tel: +44 1865 737904 Email: benjamin.speich@ndorms.ox.ac.uk

6. Secondary Sponsor(s)

Not applicable

1
2
3 **7. Contact for Public Queries**

4 Dr. Benjamin Speich

5
6 Tel: +44 1865 737904

7
8 Email: benjamin.speich@ndorms.ox.ac.uk

9
10
11 **8. Contact for Scientific Queries**

12
13 Sponsor: University of Oxford
14 Principal Investigator/Sponsor Benjamin Speich, PhD
15 Investigator: Postdoctoral Researcher
16 Centre for Statistics in Medicine (CSM)
17 Nuffield Department of Orthopaedics, Rheumatology and
18 Musculoskeletal Sciences (NDORMS)
19 University of Oxford
20 Windmill Road
21 Oxford OX3 7LD
22 Tel: +44 1865 737904
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24 Email: benjamin.speich@ndorms.ox.ac.uk
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30 **9. Public Title**

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32 Impact of checklists to improve the reporting of randomised controlled trials published in
33 biomedical journals

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35 **10. Scientific Title**

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37 Impact of a short version of the CONSORT checklist for peer reviewers to improve the
38 reporting of randomised controlled trials published in biomedical journals: a randomised
39 controlled trial

40 Running title: CONSORT for Peer Review (CONSORT-PR)

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43 Study identifier: CONSORT-PR

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47 **11. Countries of Recruitment**

48 Multinational (Centres are Biomedical journals)

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50 **12. Health Condition(s) or Problem(s) Studied**

51 Reporting in published randomised controlled trials

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56 **13. Intervention(s)**

57 Control group: Usual practice
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3 After accepting to review a manuscript, peer reviewers will receive the automated, journal
4 specific standard email with general information as per each journal's usual practice (e.g.
5 where to access the manuscript, date the peer review report is due).
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10 Intervention group: C-short plus usual practice

11 After accepting to review a manuscript, peer reviewers will receive the automated, journal
12 specific standard email with general information (identical to control group). In addition, peer
13 reviewers will receive an additional email from the editorial office that includes a short
14 version of the CONSORT checklist (C-short) together with a brief explanation of the items
15 either as a table within the email or as an attachment. Peer reviewers will be asked to check
16 whether the items in the C-short checklist are addressed in the manuscript and to request
17 authors to include these items if they are not adequately reported.
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23 **14. Key Inclusion and Exclusion Criteria**

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25 The population will be defined on two levels: included journals and included manuscripts.
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27 Inclusion criteria for journals:

28
29 Included journals must: i) endorse the CONSORT Statement by mentioning it in the journals'
30 Instruction to Authors; ii) have published primary results of at least five RCTs in 2017
31 (identified using a PubMed search).
32

33 Inclusion criteria for manuscripts

34
35 • All new manuscript submissions reporting the primary results of RCTs, which the
36 journal editor has decided to send out for external peer review. Since the 10 chosen
37 CONSORT checklist items (C-short) are applicable to different study designs, we will include
38 all manuscripts reporting the primary results of RCTs regardless of study design (e.g. parallel
39 group trial, cluster trial, superiority trial, non-inferiority/equivalence trials).
40
41

42 Exclusion criteria for manuscripts

- 43
44 • Manuscripts clearly presenting secondary trial results, additional time points, economic
45 analyses, or any other analyses.
46
47 • Manuscripts which are clearly labelled as a pilot or feasibility study or animal studies.
48
49 • Manuscripts not sent for peer review.
50
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54

55 **15. Study Type**

56
57 This study is a multicentre RCT with submitted manuscripts as the unit of randomisation
58 (allocation ratio 1:1).
59
60

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2
3 **16. Date of First Enrollment**
4

5 22. July 2019
6
7
8

9 **17. Sample Size**

10 166 Since the final sample size will be based on the number of articles published, rather than
11 on the number of manuscripts randomised, eligible manuscripts will be randomised until 83
12 articles are published in each arm (resulting in no less than 166 articles), to avoid loss of power
13 due to potential imbalance between arms.
14
15

16 **18. Recruitment Status**
17

18 Recruiting
19

20 **19. Primary Outcome(s)**

- 21
- 22 • The primary outcome of this study will be the difference in the mean proportion of
23 adequately reported C-short items in published articles between the two groups.
24

25 **20. Key Secondary Outcomes**
26

- 27 • Mean proportion of adequately reported C-short items in published articles
28 considering each item separately.
29
- 30 • Difference in mean proportion of adequately reported C-short items in published
31 articles considering each sub-item (see "Assessment of outcomes") as a separate item.
32
- 33 • Time from assigning an editor to the first decision (as communicated to the author
34 after the first round of peer-review).
35
- 36 • Proportion of manuscripts rejected after the first round of peer review.
37
- 38 • Proportion of manuscripts that will be published in the journal under study.
39
40
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42
43

44 **21. Ethics Review**

45 Ethical approval has been obtained from the Medical Sciences Interdivisional Research
46 Ethics Committee of the University of Oxford (R62779/RE001).
47
48

49 **22. Completion date**

50 We expect that recruitment will be finished in summer 2021.
51

52 **23. Summary Results**

53 Not applicable
54

55 **24. IPD sharing statement**
56

57 We plan to make the anonymised dataset, including the data from the published articles,
58 available as a supplementary file of the main publication.
59
60

1 **Impact of a short form of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published**
 2 **in biomedical journals: study protocol for a randomised controlled trial**
 3
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 5
 6

7 Benjamin Speich^{1,2,*}, Sara Schroter³, Matthias Briel^{2,4}, David Moher⁵, Michael M Schlusser¹, Philippe Ravaud^{6,7}, Isabelle Boutron^{6,7}, Sally Hopewell¹
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18
 19
 20 SPIRIT 2013 Checklist: Recommended
 21 and related documents*
 22

items to address in a clinical trial protocol

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3_____
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix 3
Protocol version	3	Date and version identifier	Appendix 1
Funding	4	Sources and types of financial, material, and other support	2_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 and 19-20__
	5b	Name and contact information for the trial sponsor	1 and Appendix 1_

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	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	2_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	20_____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	5-6_____
	6b	Explanation for choice of comparators	5-6 (comparator, usual practice)_____
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	7-9_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	7-9_
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-10, Table 1, Appendix_____

1		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	NA (one time intervention)
2				
3				
4		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA (one time intervention)
5				
6				
7		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA_____
8				
9	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-12_____
10				
11				
12				
13				
14				
15	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1 and Table Table 2_____
16				
17				
18	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14_____
19				
20				
21	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8, 13-14____
22				
23				

Methods: Assignment of interventions (for controlled trials)

Allocation:

27				
28	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14_____
29				
30				
31				
32				
33	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14_____
34				
35				
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37				
38	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14_____
39				
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42				

1	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14_____
2				
3				
4		17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	NA_____
5				
6				
7				

8 **Methods: Data collection, management, and analysis**

9				
10	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	11-12__
11				
12				
13				
14				
15		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14 (no missing data expected)___
16				
17				
18	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16__
19				
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21				
22				
23	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13-15_____
24				
25				
26		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	16_____
27				
28		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	15 (no missing data expected)___
29				
30				
31				

32 **Methods: Monitoring**

33				
34	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	17_____
35				
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40		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	13_____
41				
42				

1	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	NA__
2				
3				
4	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	17_____
5				
6				
7				
8	Ethics and dissemination			
9				
10	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20_____
11				
12				
13	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20_
14				
15				
16				
17	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Appendix 2_____
18				
19				
20		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA_____
21				
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23				
24	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17_
25				
26				
27	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	20_____
28				
29				
30	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	21__
31				
32				
33	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA__
34				
35				
36	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	21_____
37				
38				
39				
40				
41		31b	Authorship eligibility guidelines and any intended use of professional writers	21_____
42				
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1	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Intend to publish in BMJ open (protocol), dataset: page 21
2			
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Appendices

9	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 2 (no consent)_
10			
11			
12	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular	NA_____
13		analysis in the current trial and for future use in ancillary studies, if applicable	
14			

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](#) license.

Pre-review only

BMJ Open

Impact of a short version of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published in biomedical journals: study protocol for a randomised controlled trial

Journal:	<i>BMJ Open</i>
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Article Type:	Protocol
Date Submitted by the Author:	05-Feb-2020
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Primary Subject Heading:	Medical publishing and peer review
Secondary Subject Heading:	Medical education and training, Medical publishing and peer review, Research methods
Keywords:	Protocols & guidelines < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING, STATISTICS & RESEARCH METHODS

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3 1 **Impact of a short version of the CONSORT checklist for peer reviewers to improve the**
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5 2 **reporting of randomised controlled trials published in biomedical journals: study**
6
7 3 **protocol for a randomised controlled trial**

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9 4 Benjamin Speich^{1,2,*}, Sara Schroter³, Matthias Briel^{2,4}, David Moher^{5,6}, Iratxe Puebla⁷,
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11 5 Alejandra Clark⁷, Michael M Schlusser^{1,8}, Philippe Ravaud^{9,10}, Isabelle Boutron^{9,10}, Sally
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35
36 46 **Running title:** CONSORT for Peer Review (CONSORT-PR)
37

38 47 **Keywords:** CONSORT; reporting guidelines; randomised controlled trials as topic; peer
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40 48 review; meta-research
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3 49 **Abstract**
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6 50 **Introduction:** Transparent and accurate reporting is essential for readers to adequately
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8 51 interpret the results of a study. Journals can play a vital role in improving the reporting of
9
10 52 published randomised controlled trials (RCTs). We describe an RCT to evaluate our
11
12 53 hypothesis that asking peer reviewers to check whether the most important and poorly reported
13
14 54 CONSORT (CONsolidated Standards for Reporting Trials) items are adequately reported, will
15
16 55 result in higher adherence to CONSORT guidelines in published RCTs.
17

18
19 56 **Methods and Analysis:** Manuscripts presenting the primary results of RCTs submitted to
20
21 57 participating journals will be randomised to either the intervention group (peer reviewers will
22
23 58 receive a reminder and short explanation of the ten most important and poorly reported
24
25 59 CONSORT items; they will be asked to check if these items are reported in the submitted
26
27 60 manuscript) or a control group (usual journal practice). The primary outcome will be the mean
28
29 61 proportion of the ten items that are adequately reported in the published articles. Peer
30
31 62 reviewers and manuscript authors will not be informed of the study hypothesis, design, or
32
33 63 intervention. Outcomes will be assessed in duplicate from published articles by two data
34
35 64 extractors (at least one blinded to the intervention). We will enrol eligible manuscripts until a
36
37 65 minimum of 83 articles per group (166 in total) are published.
38
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40
41 66 **Ethics and Dissemination:** This pragmatic RCT was approved by the Medical Sciences
42
43 67 Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001). If this
44
45 68 intervention is effective, it could be implemented by all medical journals without requiring large
46
47 69 additional resources at journal level. Findings will be disseminated through presentations in
48
49 70 relevant conferences and peer-reviewed publications. This trial is registered on the Open
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51 71 Science Framework (<https://osf.io/c4hn8>).
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73 **Strengths and limitations of this study**

- 74 • Pragmatic randomised controlled trial (RCT) with individual randomisation of real
75 manuscripts describing RCTs submitted to a variety of journals.
- 76 • Main outcomes will be assessed from publicly available sources (i.e. published
77 articles).
- 78 • If this simple intervention is effective, it could be implemented by journals without
79 requiring large additional resources at journal level.
- 80 • The intervention could not be included within the email from journal with the link to the
81 manuscript for review, risking peer reviewers will potentially ignore the separate email
82 containing the CONSORT reminder.

83

84 Introduction

85 Background and rationale

86 There is substantial agreement that well conducted and reported randomised controlled trials
87 (RCTs) generate the most trustworthy evidence when evaluating newly developed or existing
88 clinical interventions.¹⁻³ For clinicians, scientists and decision makers, published articles are
89 often the only way to know how a study was conducted. In order to judge the internal and
90 external validity of RCTs, it is crucial that these articles present transparent, accurate and
91 unbiased information about the methods and conduct of the RCT.

92
93 To improve the quality and transparency of clinical and epidemiological research, the
94 EQUATOR (Enhancing the Quality and Transparency of Research) Network was founded in
95 2006 and officially launched in 2008.⁴⁻¹⁰ This international network, which assists in the
96 development of reporting guidelines and actively promotes their use, consists of
97 methodologists, epidemiologists, reporting guideline developers, statisticians, clinicians and
98 journal editors.

99
100 The CONSORT Statement (CONsolidated Standards of Reporting Trials) is perhaps the most
101 prominent reporting guideline, designed to help improve the transparency and quality of
102 reporting of RCTs.¹¹⁻¹³ It guides authors, peer reviewers and journal editors on the minimum
103 information to be included in published reports of RCTs to facilitate critical judgment and
104 interpretation of results and consists of 25 items and a flow diagram. The last update of the
105 CONSORT Statement was published simultaneously in 10 leading medical journals in 2010¹³
106 and currently CONSORT is endorsed by over 600 journals worldwide.¹⁴

107
108 Despite some improvement in reporting following the endorsement of the CONSORT
109 Statement, there remain major reporting deficiencies in published RCTs.^{3 15-21} For example, a
110 study of 1122 RCTs indexed in PubMed in December 2012 found that many did not define the

1
2
3 111 primary outcome (31%), state the sample size calculation (45%), or explain the method of
4
5 112 allocation concealment (50%).²² This lack of transparency is a major limiting factor for readers
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7 113 who assess an article in order to find the answer to a specific question; it is also a major
8
9 114 problem for scientists who perform systematic reviews and meta-analyses.
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13 116 **Evidence to date**

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16 117 Journals can play a vital role in improving the reporting of published RCTs. For example, a
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18 118 survey of journals' 'Instructions to Authors' in 2014 found that 63% (106 of 168) of biomedical
19
20 119 journals mentioned CONSORT;²³ however of those journals only 38 (36%) required a
21
22 120 completed CONSORT checklist on submission. Such implementation indicates some
23
24 121 improvement over time compared to an assessment in 2007 when only 17 of 62 (27%) journals
25
26 122 requested the CONSORT checklist on submission.²⁴ A study using interrupted time series
27
28 123 analysis and assessing if the CONSORT checklist for reporting abstracts of RCTs had an effect
29
30 124 on reporting quality found that results were better reported in journals which had an active
31
32 125 editorial policy to implement the checklist.²⁵
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37 127 A scoping review conducted in 2017 by Blanco and colleagues summarised different
38
39 128 interventions aimed at improving adherence to reporting guidelines.²⁶ They identified a number
40
41 129 of different interventions, some of which had been evaluated at journals. However, all the
42
43 130 interventions, except requesting submission of checklists from authors, required additional
44
45 131 resources from the journal (e.g. internal peer review by editorial assistants or an additional
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47 132 peer-reviewer round conducted by a senior statistician using appropriate reporting guidelines²⁷⁻
48
49 133 ²⁹). Therefore, it is unlikely that these interventions will be implemented in the majority of
50
51 134 journals, especially smaller journals with limited resources. Another study found that providing
52
53 135 authors with a web-based CONSORT tool, which combined different CONSORT extensions
54
55 136 and provided authors with a customised checklist, did not improve reporting when used at the
56
57 137 manuscript revision stage.³⁰ However, a study examining "the nature and extent of changes
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3 138 made to manuscripts after peer review, in relation to the reporting of methodological aspects
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5 139 of RCTs” and “the type of changes requested by peer reviewers” found that peer review did
6
7 140 lead to some improvement in reporting.²⁷
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9 141
10
11 142 The role of peer reviewers and expectations of them is varied.³¹ While CONSORT checklists
12
13 143 are sometimes available for peer reviewers to check, they are not typically instructed to assess
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15 144 this information as part of their review and there have been no studies evaluating the effect of
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17 145 asking them to do this. We plan to evaluate the impact of giving peer reviewers a short version
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19 146 of the CONSORT checklist together with a brief explanation of the items and asking them to
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21 147 check if they are adequately reported.
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27 149 **Methods and analysis**

30 150 **Objective**

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33 151 The objective of this study is to evaluate the impact of giving peer reviewers, during the
34
35 152 standard peer review process, a short version of the CONSORT checklist (C-short) together
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37 153 with a brief explanation of the items and asking them to check if they are adequately reported
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39 154 in the manuscript.
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44 156 **Study design**

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47 157 This study is a multicentre superiority RCT with submitted manuscripts as the unit of
48
49 158 randomisation (Figure 1; allocation ratio 1:1). This study protocol was written in adherence to
50
51 159 the SPIRIT guidelines (supplementary file).³²
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53 160

55 161 **Study setting and eligibility criteria**

56
57 162 The population will be defined on two levels: included journals and included manuscripts.
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3 1634
5 164 Inclusion criteria for journals:

6
7 165 Included journals must: i) endorse the CONSORT Statement by mentioning it in the journals'
8
9 166 Instruction to Authors; ii) have published primary results of at least five RCTs in 2017 (identified
10
11 167 using a PubMed search). To be efficient, we plan to contact (via email) the editors of eligible
12
13 168 journals from specific publishers (e.g. BMJ Publishing Group; Public Library of Science
14
15 169 [PLOS]) instead of separate journals. A description of the requirements for participation and a
16
17 170 short summary information sheet will be included as part of the email invitation sent to journal
18
19 171 editors. If a journal is eligible, and the editor agrees to take part, the editor will need to provide
20
21 172 access to their editorial system (e.g. ScholarOne, Editorial Manager) to enable the external
22
23 173 researcher (BS) to screen and randomise eligible manuscripts. In cases where this is not
24
25 174 possible, we will explore with individual journals if it would be possible to grant limited access
26
27 175 (e.g. only rights to screen studies) or to handle the different steps without access to the editorial
28
29 176 system (e.g. screening through automated reports; intervention provided by a journal staff
30
31 177 member) and that the emails for the intervention would be sent by a member of the editorial
32
33 178 team.

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37 17938
39 180 Inclusion criteria for manuscripts

- 40
41 181 • All new manuscript submissions reporting the primary results of RCTs, which the
42
43 182 journal editor has decided to send out for external peer review. Since the 10 chosen
44
45 183 CONSORT checklist items (C-short) are applicable to different study designs, we will
46
47 184 include all manuscripts reporting the primary results of RCTs regardless of study design
48
49 185 (e.g. parallel group trial, cluster trial, superiority trial, non-inferiority/equivalence trials).

50
51 186 Exclusion criteria for manuscripts

- 52
53 187 • Manuscripts clearly presenting secondary trial results, additional time points, economic
54
55 188 analyses, or any other analyses.
- 56
57 189 • Manuscripts which are clearly labelled as a pilot or feasibility study or animal studies.

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2
3 190 • Manuscripts not sent for peer review.
4
5 191

6
7 192 Details of journal manuscript submission and peer review processes, including consent and
8
9 193 potential confidentiality issues will be discussed in detail with each journal by teleconference
10
11 194 and/or face to face prior to the journal agreeing to take part to ensure that randomisation of
12
13 195 manuscripts is feasible.
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16 196
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18 197 In participating journals, the external researcher (BS) will check at least twice a week (by
19
20 198 screening automated submission lists) all research manuscripts that are sent out for external
21
22 199 peer review. As soon as the first invited peer reviewer accepts the invitation to review, the
23
24 200 manuscript will be randomised to the intervention or control arm (see “Randomisation” for more
25
26 201 details). It is possible that this process might be slightly different amongst different included
27
28 202 journals (e.g. that team members of a journal might be involved in the screening if limited or
29
30 203 no access to the journal’s editorial system is granted).
31
32

33 204

34 205 **Interventions**

35
36 206

37 207 Control group: Usual practice

38
39 208 After accepting to review a manuscript, peer reviewers will receive the automated, journal
40
41 209 specific standard email with general information as per each journal’s usual practice (e.g.
42
43 210 where to access the manuscript, date the peer review report is due).
44
45

46 211

47 212 Intervention group: C-short plus usual practice

48
49 213 After accepting to review a manuscript, peer reviewers will receive the automated, journal
50
51 214 specific standard email with general information (identical to control group). In addition, peer
52
53 215 reviewers will receive an additional email from the editorial office that includes a short version
54
55 216 of the CONSORT checklist (C-short) together with a brief explanation of the items either as a
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3 217 table within the email or as an attachment - based on the preferences and possibilities of the
4
5 218 journal (Table 1, appendix 1). Peer reviewers will be asked to check whether the items in the
6
7 219 C-short checklist are addressed in the manuscript and to request authors to include these
8
9 220 items if they are not adequately reported. This second email (see appendix 1), containing the
10
11 221 C-short checklist together with a brief explanation, is not generated automatically within the
12
13 222 existing journal editorial systems (e.g. ScholarOne or Editorial Manager); it will be sent
14
15 223 manually by a researcher (BS) from the journal's editorial system or by a member of the
16
17 224 journal's staff. In both cases the email will appear to have come from the editorial office (not
18
19 225 the researcher).
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226

227 Development of the C-short checklist and explanation of items

228 For the development of C-short we chose the 10 most important and poorly reported
229 CONSORT items as identified by a group of CONSORT experts in a previous study conducted
230 by Hopewell and colleagues.³⁰ The selection of the items was based on expert opinion and
231 empirical evidence whenever available.³⁰ In addition, to enable peer reviewers to better
232 understand the items, we added a short explanation for each of the 10 items. These short
233 explanations were extracted and amended from the CONSORT explanation and elaboration
234 paper¹¹ and from COBWEB which is an online writing aid tool.³³ The short explanation was
235 discussed and adapted by the scientific committee.

236

237 **Outcomes**

238 Primary outcome

239 The primary outcome of this study will be the difference in the mean proportion of adequately
240 reported C-short items in published articles between the two groups.

241

242 Secondary outcomes

243 Secondary outcomes will include the following:

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2
3 244 • Mean proportion of adequately reported C-short items in published articles considering
4
5 245 each item separately.
6
7 246 • Difference in mean proportion of adequately reported C-short items in published
8
9 247 articles considering each sub-item (see “Assessment of outcomes”) as a separate item.
10
11 248 • Time from assigning an editor to the first decision (as communicated to the author after
12
13 249 the first round of peer-review).
14
15
16 250 • Proportion of manuscripts rejected after the first round of peer review.
17
18 251 • Proportion of manuscripts that will be published in the journal under study.
19

20 252

21
22 253 Additional outcomes:

- 23
-
- 24 254 • Exploratory analysis of available peer reviewer comments (i.e. any references to
-
- 25
-
- 26 255 CONSORT).
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29 256 For journals where peer reviewers’ comments are subsequently published alongside the
30
31 257 published article, we will examine the peer reviewers’ comments for any reference to
32
33 258 CONSORT and trial reporting. We will contact those journals which do not make peer
34
35 259 reviewers’ comments publicly available, to see if reviews could be provided for such analyses
36
37 260 under the condition that only anonymised data will be published.
38

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40
41 262 Assessment of outcomes:42
43 263 The outcomes will be assessed independently by two (blinded or at least partially blinded; see
44
45 264 “blinding”) outcome assessors with expertise in the design and reporting of clinical trials. Any
46
47 265 disagreement will be resolved by consensus or if necessary by consulting a third assessor. To
48
49 266 ensure consistency between reviewers, we will first pilot the data extraction form; any
50
51 267 disparities in the interpretation will be discussed and the data extraction form will be modified
52
53 268 accordingly.
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3 270 Adequate reporting of items will be assessed in duplicate from published full-text publications
4
5 271 following the same instructions as provided by the CONSORT C-short checklist.¹¹ The
6
7 272 following checklist items have, due to their complexity, sub-items which will be extracted
8
9 273 separately. The sub-items are highlighted in the short explanation of the intervention (see
10
11 274 Table 1 and appendix 1):

- 12
13 275 • Outcomes (item 6a): (i) Define primary outcome, (ii) how it was measured, (iii) at what
14
15 276 time point, and (iv) the analysis metric (e.g. change from baseline, final value).
- 16
17 277 • Sample size (item 7a): (i) The estimated outcomes in each group, (ii) the α (type I) error
18
19 278 level, (iii) the statistical power (or the β (type II) error level), (iv) for continuous
20
21 279 outcomes, the standard deviation of the measurements
- 22
23 280 • Blinding (item 11a): Is the blinding status clear for the following persons: (i) Healthcare
24
25 281 provider, (ii) patients, and (iii) outcome assessors.
- 26
27 282 • Funding (item 25): (i) The funding source, and (ii) the role of funder in the design,
28
29 283 conduct, analysis, and reporting.

30
31 284 All items will be judged as either “yes” meaning adequately reported, “no” meaning not
32
33 285 adequately reported or not reported at all, or “NA” meaning that this sub-item is not applicable
34
35 286 for this RCT. Items with different sub-items will only be judged as adequately reported if all
36
37 287 relevant sub-items were adequately reported.

38
39 288
40
41 289 The outcomes “time from assigning an editor to the first decision”, “proportion of manuscripts
42
43 290 rejected after the first round of peer-review”, and “proportion of manuscripts that will be
44
45 291 published in the journal under study” will be extracted directly from the journal’s editorial system
46
47 292 or provided by the journal.

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49 293

50 294 **Participant timeline**

51
52 295 The overview of the study schedule, including enrolment, intervention and assessments is
53
54 296 presented in Table 2.

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56 297

298 **Sample size**

299 For the sample size calculation, we hypothesised in a first scenario (Table 3) that the
300 intervention C-short will result in a 25% relative increase in adequate reporting compared to
301 the control (meaning that 70% of items will be adequately reported in the intervention group
302 and 56% in the control group). This is based on a proportion of adequate reporting of 0.56 for
303 the 10 most important and poorly reported items found in the control group of a previous study
304 (meaning that a mean of 56% of the 10 most important and poorly reported items were
305 reported).³⁰ The standard deviation (SD) in the same study was 0.23. However, we calculated
306 our sample size to account for a slightly larger variability in our data (SD = 0.25). To
307 demonstrate a significant difference with a power of 90% and a type 1 error at 5%, a total of
308 136 published articles will be required in this scenario (68 per treatment arm; based on a two
309 sided t-test).

310
311 Two authors of this protocol, working for *PLOS ONE* (IP and AC), one of the participating
312 journals, pointed out that 3 out of the 10 assessed items (i.e. item “Registration”, “Protocol”,
313 and “Funding”) should always be implemented in submissions to their journal given their policy
314 requirements for clinical trials. Assuming that this journal will recruit a high proportion of
315 manuscripts, and that also other journals might update their templates, we increased the
316 sample size in a second scenario, in which all these 3 items would have an overall adherence
317 of 90% in the control arm (Table 3). This would entail an overall baseline adherence with the
318 10 C-short items of 71%. Based on a two sided t-test, a sample size of 166 (83 per treatment
319 arm) will have a power of 80% to find a 15% relative increase (71% adherence in control group;
320 82% adherence in intervention group; SD = 0.25; a type 1 error at 5%).

321 Since the final sample size will be based on the number of articles published, rather than on
322 the number of manuscripts randomised, eligible manuscripts will be randomised until 83
323 articles are published in each arm (resulting in no less than 166 articles), to avoid loss of power
324 due to potential imbalance between arms. Recruitment will be stopped as soon as both arms

1
2
3 325 reach the sample size of 83. After recruitment has stopped we will wait three months so that
4
5 326 manuscripts, which are still in production, can be published. Manuscripts which are published
6
7 327 after the three month period will be excluded
8

9 328

11 329 **Randomisation and blinding**

12
13
14 330 Manuscripts meeting the eligibility criteria and sent out for external peer review by the journals
15
16 331 will be randomised into one of the two groups (allocation 1:1). The randomisation list will be
17
18 332 created by the Study-Randomizer® system³⁴ using random block sizes between 2 and 8 and
19
20 333 stratified by journal. As soon as the first peer reviewer accepts the invitation, the manuscript
21
22 334 will be included and randomised to one of the two study arms. One of the investigators (BS)
23
24 335 will log onto the Study-Randomizer® system³⁴ and enter the study identification number (ID;
25
26 336 provided by the journal), the study title, and the journal the study was submitted to.
27
28 337 Subsequently, all additional peer reviewers accepting the invitation to review the same
29
30 338 manuscript will receive the same group assignment as the first peer reviewer.
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35 340 Authors will be blinded to the intervention. Editors will not be actively informed about the
36
37 341 randomisation (possible exception listed under “Interventions”). To avoid potential bias, peer
38
39 342 reviewers and manuscript authors will not be informed of the study hypothesis, design and
40
41 343 intervention.
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45 345 Outcomes will be assessed in duplicate (see “Assessment of outcomes”). At least one outcome
46
47 346 assessor will be blinded. Due to restricted resources the investigator conducting the
48
49 347 randomisation (BS) might be involved in the data-extraction from published manuscripts.
50

51 348

55 349 **Data analysis**

1
2
3 350 All quantitative variables will be described using means and standard deviations, or medians
4
5 351 and interquartile ranges in case severe departures from a normal distribution are identified.
6
7 352 Data distributions will be inspected visually (i.e. by histograms) instead of performing formal
8
9 353 statistical tests for normality. Categorical variables will be described using frequencies and
10
11 354 percentages. For the primary and secondary outcomes, we will estimate the mean difference
12
13 355 between the two groups and report them with respective 95% confidence intervals. No interim
14
15 356 analysis will be conducted.

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19 357

20 21 358 Populations of analysis

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24 359 The main population for analysis will be all manuscripts randomised and accepted for
25
26 360 publication in the participating journals. In contrast to RCTs conducted with patients, where
27
28 361 losses to follow-up need to be carefully considered (e.g. multiple imputation of missing data),
29
30 362 we are only interested in the reporting adherence of RCTs that are published. As such, we will
31
32 363 exclude randomised manuscripts that were not published from the main analysis. All outcomes
33
34 364 will be calculated based on the main population. The secondary outcome “Time to the first
35
36 365 decision”, will additionally be calculated considering all randomised manuscripts (including the
37
38 366 ones which were not published). For all analyses a p-value of 0.05 (5% significance level) will
39
40 367 be used to indicate statistical significance. Exact p-values will be presented up to three decimal
41
42 368 places. We anticipate there will be no missing data in this study, neither at the individual C-
43
44 369 short items, nor at the manuscript level. This is due to the study design, which will include only
45
46 370 the randomised manuscripts that are accepted for publication. We will analyse if the rate of
47
48 371 manuscripts rejected after the first round of peer-review and if the proportion of manuscripts
49
50 372 that will be published differentiate amongst the two study arms (both secondary results).

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3 374 Analysis of primary endpoint
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5 375 The effect of the intervention will be estimated as the mean difference in the proportion of C-
6
7 376 short items adequately reported between the study arms. If the data on the primary outcome
8
9 377 is normally distributed, groups will be compared using an unpaired Student's t-test. If the data
10
11 378 is not normally distributed, comparisons will be performed using a non-parametric equivalent
12
13 379 test (i.e. Wilcoxon-Mann-Whitney test).
14
15
16

17 380 Analysis of secondary endpoints
18

19
20 381 To investigate the effect of the intervention on the secondary outcomes, mean differences with
21
22 382 respective 95% confidence intervals will be reported. If normality is not observed for any of the
23
24 383 continuous secondary outcomes, the same strategy adopted for the primary outcome (use of
25
26 384 a non-parametric equivalent to the Student's t-test) will be used.
27
28

29 385
30

31
32 386 Pre-specified subgroup analysis
33

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35 387 No formal subgroup comparative analysis is planned for the primary or secondary outcomes.
36
37 388 However, the effect of the intervention on the primary outcome within subgroups will be
38
39 389 presented using forest plots to visually examine whether it may differ according to some
40
41 390 variables, such as: (1) Journals that actively implement the CONSORT Statement (defined as
42
43 391 requiring authors to submit a completed CONSORT checklist alongside their manuscript) vs.
44
45 392 journals that are not actively implementing the CONSORT Statement; (2) sample size of
46
47 393 included RCTs ($n < 100$ vs. $n \geq 100$); and (3) impact factor (<5 , $5.1-10$; >10) as there is
48
49 394 evidence that higher impact factor as well as higher sample size are associated with higher
50
51 395 adherence to reporting guidelines.³⁵ Sub-group analysis at the journal level will only be
52
53 396 conducted when sufficient journals are in each group so that no results of individual journals
54
55 397 are revealed. All analyses will be exploratory, with the aim of supporting new hypothesis
56
57 398 generation, rather than being conclusive.
58
59
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399

400 Data management and confidentiality

401 Outcomes from publications will be assessed and extracted in duplicate. Since this information
402 is not confidential, we will use freely available online forms (e.g. Google forms) for data
403 extraction from published RCTs. Data entered will be validated for completeness.

404 Data from the journal's editorial system (e.g. title of manuscript, first author, randomisation ID,
405 journal, date when manuscript was assigned to an editor, date when the final decision was
406 made, final editorial decision, number of peer reviewers who reviewed the manuscript, the peer
407 review reports [if available]) will be extracted (by BS or a member of the journal's staff),
408 anonymised and entered in password protected files which are saved on a server from the
409 University of Oxford. Data will be managed and curated according to University of Oxford
410 regulations, which includes regular back-up (on a daily basis) of the virtual drives where the
411 data are stored. No auditing or data monitoring is planned (as outcomes are directly extracted
412 from journal's editorial system or in duplicate from published RCTs).

413 The raw data extracted from the included published manuscripts can be made openly
414 accessible in an anonymised way (i.e. giving the included RCT a number instead of identifying
415 them). Derived/aggregated data, including anonymised information generated from the
416 journal's editorial system, will be stored and made available to the research community when
417 the project ends (see also "Publication policy and access to data"). Where appropriate, the
418 researcher who has access to the journal's editorial system (BS) and anyone else who will see
419 the identifiable data will sign a confidentially agreement with the participating journals,
420 confirming that they will not share identifiable data with any other party. Publishers such as the
421 BMJ state in their Company Privacy Statement that reviews and manuscripts may be used for
422 quality improvement purposes and that is the nature of this research. Furthermore, peer
423 reviewers for all BMJ journals receive the following statement in their invitation letter "*We are*
424 *constantly trying to find ways of improving the peer review system and have an ongoing*

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3 425 *programme of research. If you do not wish your review entered into a study please let us know*
4
5 426 *by emailing [...] as soon as possible.”*
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10 428 **Trial registration**

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14 429 This trial was denied registration on ClinicalTrials.gov as the study is not a clinical study that
15
16 430 assesses a health outcome in human subjects. Instead we registered the trial on the Open
17
18 431 Science Framework (<https://osf.io/c4hn8>). The first manuscript was randomised in July 2019.
19
20 432 We expect that recruitment will be finished in summer 2021.
21
22

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26 434 **Patient and public involvement**

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29 435 Given the specific study topic, the steering committee agreed that patient or public involvement
30
31 436 is not needed for this study.
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37 438 **Discussion**

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41 439 RCTs are the current gold standard for evaluating any new intervention in evidence-based
42
43 440 medicine. Unfortunately, not all RCTs are of high quality. In fact, there are several well-known
44
45 441 shortcomings with respect to reporting.^{3 15-20} It is important to note that adhering to the
46
47 442 CONSORT Statement does not mean that the study is of high quality. However, reporting all
48
49 443 items from the CONSORT checklist will enable readers to adequately judge the quality of
50
51 444 RCTs.
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56 446 In this RCT we will test if a simple intervention in the form of asking peer reviewers to check
57
58 447 whether selected CONSORT items are adequately addressed will increase the proportion of
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3 448 reporting completeness in the published RCTs in the participating journals. A multicentre
4
5 449 parallel arm RCT with randomisation at the individual manuscript level was chosen instead of
6
7 450 a cluster RCT because the risk of “contamination” at journal level was judged as low as the
8
9 451 intervention will be implemented by an external researcher (i.e. BS) or a member of the journal
10
11 452 staff (e.g. personnel from Editorial services). The likelihood of contamination due to peer
12
13 453 reviewers being invited to assess several RCTs and therefore becoming exposed to both
14
15 454 intervention arms was judged small and therefore we do not plan to adjust for clustering by
16
17 455 journal. Originally we planned to implement the intervention within the original instruction to
18
19 456 peer reviewer email which is sent out as soon as a peer reviewer accepts the invitation from
20
21 457 the journal. However, as these emails are sent automatically by the journal’s editorial system
22
23 458 we would have needed to modify the software from each journal to make sure that only half of
24
25 459 the manuscripts administered the intervention. After our first discussion with journal editors
26
27 460 and journal staff, we realised that this approach is not feasible and therefore decided to
28
29 461 implement the intervention in the form of a separate email. We intended to conduct this RCT
30
31 462 in a pragmatic way so that results “would also be relevant to [...] people who decide whether
32
33 463 to implement the intervention on the basis of its results”.³⁶ Hence we chose to assess outcomes
34
35 464 from published articles and not from manuscripts after the first round of revisions. Ideally, the
36
37 465 full impact of the intervention would also be measured including all versions of randomised
38
39 466 manuscripts in the final statistical analysis. However, due to confidentiality issues and limited
40
41 467 resources we will not be able to evaluate manuscript versions prior to publication.
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49 469 A selection of CONSORT items was chosen instead of the entire CONSORT checklist as we
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51 470 did not want to put too high a burden on peer reviewers, which could increase the risk that
52
53 471 peer reviewers ignore our reminder.
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3 473 Should the proposed intervention be successful in improving the reporting quality of published
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5 474 RCTs, as measured by the adherence to CONSORT, the intervention could be implemented
6
7 475 at the journal level without requiring a large amount of additional resources. In addition, very
8
9 476 similar interventions for other article types (e.g. systematic reviews, trial protocols) and
10
11 477 corresponding guidelines (e.g. PRISMA, SPIRIT) could be easily implemented too.
12

13
14 478

17 479 **Ethics and dissemination**

20 480 Ethical approval has been obtained from the Medical Sciences Interdivisional Research Ethics
21
22 481 Committee of the University of Oxford (R62779/RE001). The original approved study protocol
23
24 482 is available in Appendix 2. The WHO Trial Registration Data Set is available in Appendix 3.
25

27 483 The results from this study will be published in a peer reviewed journal irrespective of the study
28
29 484 results. Authorship of publications will be granted according to the criteria of the International
30
31 485 Committee of Medical Journal Editors (ICMJE). We plan to make the anonymised dataset,
32
33 486 including the data from the published articles, available as a supplementary file of the main
34
35 487 publication.
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For peer review only

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56 **600 Authors' contributions**

7 601 SH, BS, IB, MB, DM, and PR had the study idea and designed the study. SS, IP and AC
8 602 provided expertise to ensure implementation at the journal level was possible. MMS was
9 603 responsible for statistical aspects, including the sample size calculation and the data analysis
10 604 plan. BS and SH wrote the first draft of the study protocol. All authors critically revised the
11 605 protocol and approved the final version.
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22 611 conducting the study, or analysing and reporting study results.
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32 613 **Competing interests statement**

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34 614 SS is employed by the British Medical Journal (BMJ). IP and AC are employed by the Public
35 615 Library of Science (PLOS). DM, SH, and IB are members of the CONSORT executive and
36 616 authors of the CONSORT 2010 Statement. DM and PR are members of the EQUATOR
37 617 network steering group. MMS is a meta-researcher and reporting guideline developer,
38 618 enthusiast, and disseminators, he may therefore overestimate the importance of this project.
39 619 All authors have declared that no other competing interests exist.
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50 621 **Roles and responsibilities**

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53 622 The principal investigator (BS) is responsible for the preparation and the revisions of the study
54 623 protocol, organising meetings of the steering committee, recruiting and randomising eligible
55 624 manuscripts as well as the publication of study reports. The steering committee (IB, MB, SH,
56 625 DM, PR, BS, MMS, and SS) is responsible for revising the protocol, defining and validating the
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3 626 additional short explanation for each CONSORT item, advising on study implementation, and
4 627 for publishing the results of this study. MMS is responsible for the sample size calculation and
5 628 the statistical analyses.
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8 629 **Word count: 4408**

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3 632 **Figure legend**

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7 634 **Figure 1: Study flowchart**

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Table 1: The ten most important and poorly reported CONSORT items as defined by a group of experts on the CONSORT statement.³⁰ For better understanding key features were summarised within a short explanation (extracted from the CONSORT explanation and elaboration paper¹¹ as well as from the COBWEB tool³³).

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when it was assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the “assigned intervention is determined by a chance process and cannot be predicted”?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or “third-party” assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as “double-blind” without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of the funder(s) described?

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642 **Table 2:** Study schedule

	Enrolment	Allocation and intervention	Intervention	Post-intervention	
Time-point	<i>Studies which are sent out for peer-review</i>	<i>After first peer-reviewer accepts invitation</i>	<i>Whenever an additional peer-reviewer accepts invitation</i>	<i>First decision by journal</i>	<i>Published manuscripts</i>
Eligibility screen	X				
Allocation		X			
Intervention:					
C-short + usual care		X	X		
Usual care		X	X		
Assessment of trial characteristics:					
Funding source					X
Study centres (single centre or multicentre)					X
Sample size					X
Study design (e.g. parallel arm, crossover)					X
Hypothesis (e.g. superiority, non-inferiority)					X
Medical field					X
Intervention tested					X
Number of trial arms					X
Number of peer-reviewers					X
Journal which published the manuscript					X
Number of journals requesting CONSORT adherence (submission of checklist mandatory)					X
Assessment of outcomes:					
Time from assigning an academic editor until the first decision				X	
Proportion of manuscripts directly rejected after the first round of peer-review				X	
Proportion of manuscripts that will be published in the journal under study					X
Adherence to CONSORT items and sub-items					X

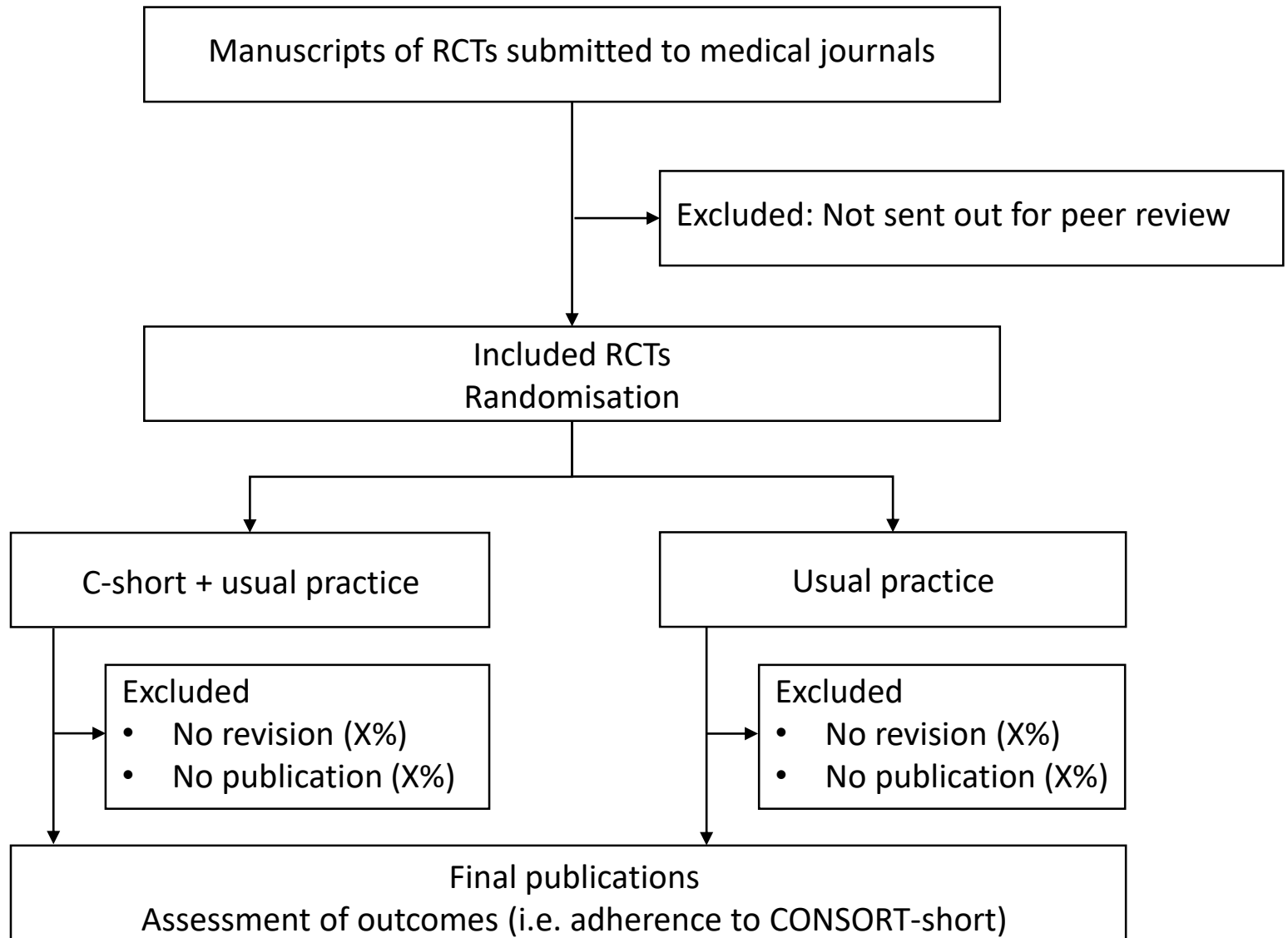
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644 **Table 3:** Assumptions for sample size calculations in two different scenarios.

Item	CONSORT item	Scenario 1. Adequate reporting as published in WebCONSORT ³⁰	Scenario 2. Adapted from Scenario 1
1	Outcomes (6a)	77% (79 of 103)	77% (79 of 103)
2	Sample size (7a)	83% (85 of 103)	83% (85 of 103)
3	Sequence generation (8a)	76% (78 of 103)	76% (78 of 103)
4	Allocation concealment (9)	55% (57 of 103)	55% (57 of 103)
5	Blinding (11a)	35% (36 of 103)	35% (36 of 103)
6	Outcomes and estimation (17a)	44% (45 of 103)	44% (45 of 103)
7	Harms (19)	71% (73 of 103)	71% (73 of 103)
8	Registration (23)	69% (71 of 103)	90%
9	Protocol (24)	19% (20 of 103)	90%
10	Funding (25)	34% (35 of 103)	90%
Overall		56%	71%

645 Abbreviation: CONSORT= CONSolidated Standards for Reporting Trials

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3 **Impact of a short version of the CONSORT checklist for peer reviewers to improve the**
4 **reporting of randomised controlled trials published in biomedical journals: study**
5 **protocol for a randomised controlled trial**
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10 Benjamin Speich, Sara Schroter, Matthias Briel, David Moher, Iratxe Puebla, Alejandra Clark,
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12 Michael M Schlusser, Philippe Ravaud, Isabelle Boutron, Sally Hopewell
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19 **Appendix**
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23 **Appendix 1:** Example of the email which will be sent out in the intervention arm (C-Short).
24 The exact wording might be slightly adapted according to the journal preferences.
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26 *Page 2*

27 **Appendix 2:** Original study protocol as it was approved by the Medical Sciences
28 Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001).
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32 **Appendix 3:** WHO Trial Registration Data Set (Version 1.3.1)
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Appendix 1: Example of the email which will be sent out in the intervention arm (C-Short).
The exact wording might be slightly adapted according to the journal preferences.

Dear **Title, Name**,

We thank you for accepting to peer-review a manuscript for **journal name**. As we are trying to improve the reporting for randomised controlled trials according to the CONSORT guidelines, we would like to ask if you could check whether the following most important and poorly reported items are adequately implemented as indicated in the *table below/attached table*.

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the "assigned intervention is determined by a chance process and cannot be predicted"?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or "third-party" assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as "double-blind" without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of funder(s) described?

Your efforts are highly appreciated.

Kind regards,

journal name-Team

Appendix 2: Original study protocol as it was approved by the Medical Sciences Interdivisional Research Ethics Committee of the University of Oxford (R62779/RE001).



CENTRE for STATISTICS in MEDICINE



Impact of a short form of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published in biomedical journals: a randomised controlled trial

Short title: CONSORT for Peer Review (CONSORT-PR)

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Dr Sara Schroter, The BMJ, London, UK

Trial registration: This trial will be prospectively registered under clinicaltrials.gov.

Protocol version: Version 1.1 2019-05-21

Funding: Benjamin Speich is supported by an Advanced Postdoc.Mobility grant from the Swiss National Science Foundation (P300PB_177933). David Moher is supported by a University Research Chair, Ottawa. The funders had no role in designing the study and will also have no role in conducting the study as well as in analysing and reporting study results.

Roles and responsibilities:

Contributors: SH, BS, IB, MB, DM, PR, had the study idea and designed the study. SS provided expertise to ensure implementation at the journal level was possible. MMS was responsible for statistical aspects, including the sample size calculation and the data analysis plan. BS and SH wrote the first draft of the study protocol. All authors critically revised the protocol and approved the final version.

Sponsor and contact information: Centre for Statistics in Medicine, Botnar Research Centre, University of Oxford, Windmill Road, Oxford OX3 7LD. Principal investigator: Benjamin Speich (Email: Benjamin.speich@ndorms.ox.ac.uk)

Sponsor and funders: The funders had no role in designing the study and will also have no role in conducting the study as well as in analysing and reporting study results.

Roles and responsibilities: The principal investigator (BS) is responsible for the preparation and the revisions of the study protocol, organising meetings of the steering committee, recruiting and randomizing eligible manuscripts as well as the publication of study reports. The steering committee (IB, MB, SH, DM, PR, BS, MMS, and SS) is in charge of participating in the elaboration of the protocol, defining and validating the additional short explanation for each CONSORT item, following the evolution of the committed study and for publishing the results of this study. MMS is responsible for the sample size calculation and the statistical analyses.

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1. Background and rational

1.1 Need for clinical research and epidemiologic transparency

There is substantial agreement that well conducted and reported randomised controlled trials (RCTs) generate the most trustworthy evidence when newly developed or already existing clinical interventions are evaluated (1-3). Besides the complexity and the high associated costs of conducting RCTs (4-6), there are major issues with their reporting that often make it difficult for researchers, clinicians, patients or policymakers to interpret the current evidence on a specific topic (7, 8). Chronologically, the most prominent difficulties in reporting consist of (i) poor reporting in study protocols for RCTs (9-12); (ii) a substantial fraction of trials are not registered, prematurely discontinued (most common due to difficulties with recruitment) and not published (13, 14); and (iii) that published RCTs are often poorly reported (7).

For clinicians, scientists and decision makers, published articles are often the only way to know how a study was conducted. In order to judge the internal and external validity of RCTs, it is crucial that these articles present transparent, accurate and unbiased information about the methods and conduct of the RCT.

1.2 Transparency in published randomised controlled trials

To improve the transparency in clinical and epidemiological research the international organisation called the EQUATOR (Enhancing the Quality and Transparency of Research) Network was founded in 2006 (15-20). This international network consists of researchers, epidemiologists, people in charge of recommendations for the presentation of articles or "reporting guidelines", statisticians, clinicians and editors from some of the most prestigious journals (e.g., *Lancet*, *JAMA*, *Annals of Internal Medicine*, *BMJ*).

The CONSORT Statement (CONsolidated Standards for Reporting Trials), is perhaps the most important reporting guideline designed to help improve the transparency and quality of reporting of RCTs (21, 22). The CONSORT Statement, consisting of 25 items and a flow diagram which should be reported in papers describing RCTs. The last update of the CONSORT Statement was published simultaneously in 10 leading medical journals in 2010 (23). Currently CONSORT is endorsed by 585 journals (24). The CONSORT Statement guides authors, peer reviewers and journal editors on what information should be included in published reports of RCTs in order to facilitate critical judgment and interpretation of results. It is important to note, that adhering to the CONSORT Statement does not mean that the study is of high quality. However, reporting all items from the CONSORT list will enable readers to adequately judge the quality of RCTs.

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3 A number of research studies have identified serious limitations in the reporting of published
4 RCTs (3, 25-30). Despite some improvement in reporting following the implementation of the
5 CONSORT Statement, there still remain major reporting deficiencies in published RCTs (31).
6 For example, Odutayo and colleagues showed that a large proportion of RCTs published in
7 December 2012 in PubMed did not define the primary outcome (31%), did not state the sample
8 size calculation (45%) and did not explain the method of allocation concealment (50%) (32).
9 This lack of transparency is a major limiting factor for the reader who assesses an article in
10 order to find the answer to a specific question; it is also a major problem for scientists who
11 perform systematic reviews and meta-analyses. Thus, some published trials may not be
12 included in the meta-analysis because of their lack of transparency. Chan showed (25, 33) that
13 50% of efficacy outcomes and 65% of safety outcomes could not be included in meta-analyses
14 because of how they were reported. Furthermore, even if these trials are included in systematic
15 reviews and meta-analyses, an adequate risk of bias assessment is often not possible due to
16 the poor reporting quality. Nevertheless, the main consequence of the lack of transparency is
17 the risk of accepting treatments that are ineffective or cause serious adverse events (34).
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28 1.3 Journal attempts to improve reporting in published randomised controlled trials

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30 Journals can play a vital role in improving the reporting of published reports of RCTs. For
31 example, a survey of authors' instructions on journal websites revealed that in 2014 63% (106
32 of 168) of biomedical journals mentioned CONSORT within their "Instructions to Authors" (35).
33 Of those journals 38 (36%) required a CONSORT checklist as a condition of RCT report
34 submission. Such implementation indicates some improvement over time compared to an
35 assessment in 2007 when only 17 journals requested the CONSORT checklist (36). An
36 interrupted time series analysis which assessed if the CONSORT for Abstracts guideline had
37 an effect on the reporting quality, found that results are better reported in Journals which
38 enforce the policy (37).
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46 In a study published in 2016 authors of RCTs were asked by journal editors to use the web-
47 based CONSORT tool at the manuscript revision stage (38). Authors who were randomly
48 allocated to the intervention had access to a tool which allowed them to combine different
49 CONSORT extensions (according to study design, medical field) to generate customised
50 checklists. In the control group, authors had access to a CONSORT flow diagram generator.
51 The goal was to improve the reporting of CONSORT items with a simple webtool. However, a
52 quarter of all authors either wrongly selected a CONSORT extension or failed to select an
53 extension, indicating that further education is needed in terms of when and how to implement
54 CONSORT extensions.
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3 A systematic scoping review conducted in 2017 by Blanco and colleagues summarised
4 different interventions aimed to improve adherence to reporting guidelines (39) (manuscript
5 with results currently under review. Draft received via personal communication). A number of
6 different interventions were identified and some had also been tested at journals. However,
7 the interventions, besides requesting submission of checklists from authors, required
8 additional resources at the journal level (e.g. internal peer review by editorial assistants or
9 inviting an additional statistical peer-reviewer (40, 41)). Therefore, it is unlikely that these
10 interventions will be implemented in the vast majority of journals, especially not in smaller
11 journals with limited resources. A study examining “the nature and extent of changes made to
12 manuscripts after peer review, in relation to the reporting of methodological aspects of RCTs”
13 and “the type of changes requested by peer reviewers” found that peer review did lead to some
14 improvement in reporting (40).

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16 Building on these findings we plan to evaluate the impact of inviting peer reviewers to explicitly
17 use a short version of the CONSORT checklist (including a short explanation of those items)
18 as part of their review process. If this intervention deems to be effective, it could be easily
19 implemented by all medical journals without needing additional resources at a journal level.

2. Hypothesis

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21 We propose an RCT to evaluate the impact of asking peer reviewers to use a short version of
22 the CONSORT checklist when reviewing a manuscript of an RCT and whether it improves the
23 completeness of reporting. Our hypothesis is that reminding peer reviewers of the CONSORT
24 items (including a short explanation of those items) will result in higher adherence to
25 CONSORT guidelines in published RCTs. We only selected a limited number of the CONSORT
26 items because we did not want to deter peer reviewers with too much information. Since peer
27 reviewing in general can be burdensome, we felt that this approach is more promising than
28 listing all items, risking that the information will be ignored. The short version of the CONSORT
29 checklist is based on the same items described in a previous study as the 10 most important
30 and underreported CONSORT items (38).

3. Objective

3.1 Main objective

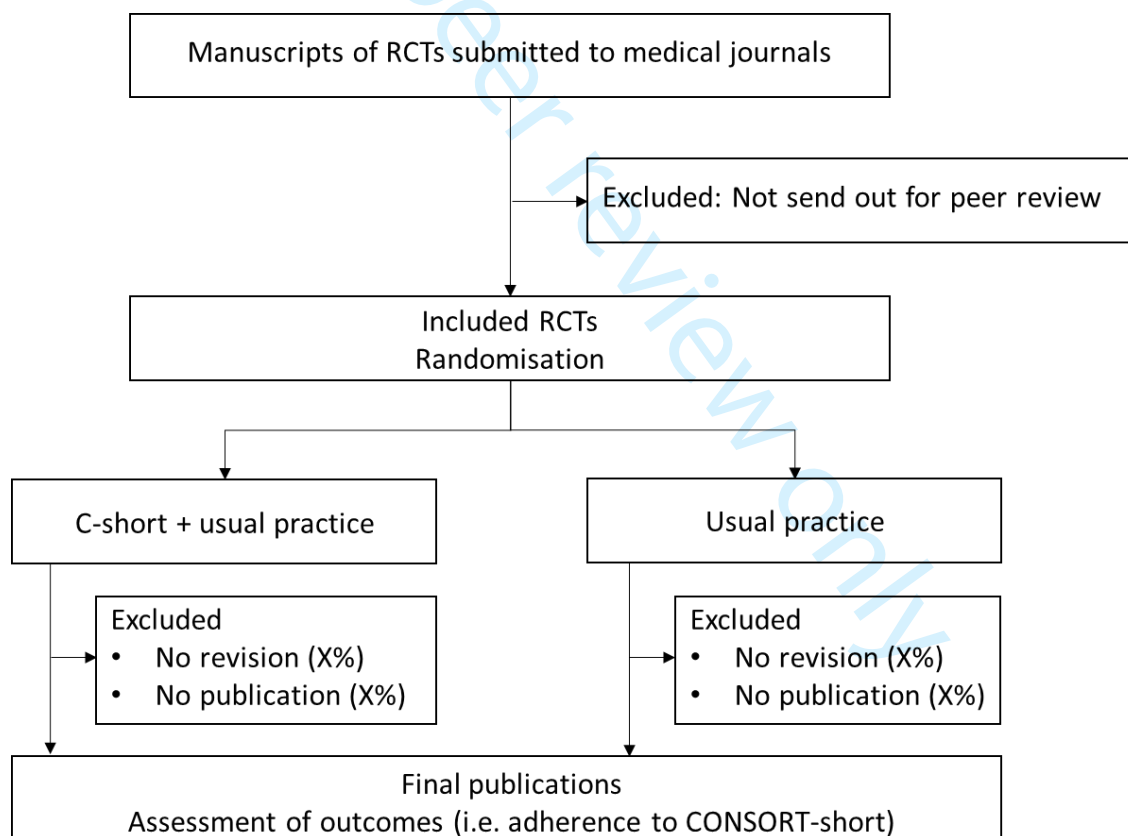
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32 The main objective of this study is to evaluate the impact of asking peer reviewers during the
33 standard peer-review process to ask them to use a short version of the CONSORT checklist
34 (C-short) and whether it will improve the reporting in published RCTs compared to manuscripts
35 where the peer reviewers underwent usual practice.

4. Methods

4.1 Trial design

This study is a multicentre RCT with articles being the unit of randomisation (Figure 1; allocation ratio 1:1). A multicentre parallel arm RCT with randomisation at the individual article level was chosen instead of a cluster RCT because the risk of any “contamination” on journal level is not given as the intervention will be implemented by an external researcher (i.e. BS). The possibility of contamination due to the possibility that peer reviewer are invited to assess several RCTs and are randomised into both arms was judged as relatively small and therefore we do not plan to adjust for clustering by journal. The journal staff (i.e. editors) will not be actively told which manuscript was allocated to the proposed intervention and which to the control group.

Figure 1: Study flowchart



4.2 Study setting and eligibility criteria

The population will be defined on two levels. Included journals and included articles.

Included journals must: i) endorse the CONSORT Statement (e.g. assessed via journals Instruction to Authors); ii) publish primary results of at least five RCTs in 2017 (identified in a brief PubMed search as publishing RCTs in 2017). To be efficient, we plan to contact (via

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3 email) the editors of eligible journals within a publishing house (i.e. journals which are part of
4 the BMJ series, BMC series, PLoS, Lancet, JAMA) instead of separate journals. A description
5 of the requirements for participation and a short summary information sheet will be included
6 as part of the email invitation sent to journal editors. If a journal is eligible, and agrees to take
7 part, the journal will also need to provide access to their journal editorial system (e.g.
8 ScholarOne, Editorial Manager) to enable the external researcher (i.e. BS) to screen and
9 randomise eligible manuscripts. In cases this is not possible, we will explore with separate
10 journals if it would be possible to grant limited access (e.g. only rights to screen studies) and
11 that the emails from the intervention would be sent by a person from the editorial team.
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19 We will include all submitted manuscripts reporting RCTs for which the journal decides to send out for
20 external peer review. Since the 10 chosen CONSORT checklist items are applicable to different study
21 designs, we will include all RCTs regardless of study design (e.g. parallel group trial, cluster trial,
22 superiority trial, non-inferiority trial). Articles presenting clearly secondary trial results, additional time
23 points, economic analyses, or any other analyses derived from an RCT dataset not including the study's
24 main results will be excluded. Furthermore, RCTs which are clearly labelled as a pilot or feasibility study
25 or randomise animals or cells instead of individuals will be excluded.
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30 Details of journal manuscript submission and peer review processes, including, consent and
31 potential confidentiality issues will be discussed in detail with each journal by teleconference
32 and/or face to face prior to the journal agreeing to take part to ensure that randomisation of
33 manuscripts is feasible. We considered conducting randomisation at the level of the journal
34 (i.e. cluster RCTs). However, in order to make the intervention as easy and simple to
35 implement (and with little or no additional effort from the journal) we believe that randomisation
36 at the manuscript level - with an external researcher implementing the intervention within the
37 existing journal management systems - will be the most efficient study design.
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45 In participating journals, the external investigator (BS) will have access to the editorial
46 management software (e.g. ScholarOne or Editorial Manager) and will check at least twice a
47 week (using automated report lists) all research manuscripts that are sent out for external peer
48 review. As soon as the first peer-reviewer accepts the invitation to review, the manuscript will
49 be randomised to the intervention or control arm (see "Randomisation" for more details). It is
50 possible that this process might be slightly different amongst different included journals.
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56 4.3 Interventions

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59 Experimental group: C-short plus usual practice
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3 After accepting to review an article, peer reviewers will receive the automated, journal specific
4 standard email with general information as per each journal's usual practice (e.g. where to
5 access the manuscript, date when the peer review report is due). In addition, peer-reviewers
6 who received a manuscript which was randomised to C-short will receive an additional email
7 including a short version of the CONSORT checklist (C-short) (either within the email or as
8 an attachment; based on the preferences and possibilities of the journal) focusing on the 10
9 most important and most poorly reported items (Table 1; as previously defined by a group of
10 experts of the CONSORT Group (38)). Peer-reviewers will be asked to pay particular attention
11 to items in the C-short checklist and request authors to report on these items, if not already
12 adequately reported. This second email, containing the C-short checklist, is not generated
13 automatically within the existing journal editorial management system (e.g. ScholarOne or
14 Editorial Manager); it will be sent by the investigator who has access to the journal editorial
15 system (BS). An example of this additional email is presented within the appendix (appendix
16 1; the exact wording might be changed according to the preferences of the participating
17 journals). At least twice a week the editorial management system will be checked for each
18 journal and if a peer reviewer has accepted an invitation to review, an email containing the C-
19 short intervention will be generated and sent. It might be possible that some journals will only
20 provide the right to access and read manuscripts in the editorial management system, but not
21 to send emails. If this is the case, the corresponding Editor (or designated person within the
22 journal) will be informed to send the emails.
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Development and testing of the short explanation of the C-short items:

36 We chose the 10 most important and poorly reported CONSORT items as identified by a group
37 of CONSORT experts in a previous study conducted by Hopewell and colleagues (38). The
38 selection of the items was based on expert opinion and empirical evidence whenever available
39 (38). In addition, we have added a short explanation for each of the 10 items. These short
40 explanations were extracted and amended from the CONSORT explanation and elaboration
41 paper (21) and from COBWEB which is online writing aid tool (42). The short explanation was
42 discussed and adapted by the scientific committee.
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Control group: Usual practice:

50 After accepting to review an article, peer reviewers will receive the automated, journal specific
51 standard email with general information as per each journal's usual practice (e.g. where to
52 access the manuscript, date until when the peer review report is due). However, they will not
53 receive the second email, sent by the investigator who has access to the journal editorial
54 system (BS) which contains the C-short checklist.
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Table 1: The ten most important and poorly reported CONSORT items as defined by a group of experts on the CONSORT statement (38). For better understanding key features were summarised within a short explanation (extracted from the CONSORT explanation and elaboration paper (21) as well as from the COBWEB tool (42)).

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the “assigned intervention is determined by a chance process and cannot be predicted”?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or “third-party” assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as “double-blind” without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio) and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of the funder(s) described?

4.4 Outcomes

Primary outcome:

The primary outcome of this study will be the difference of the mean proportion of adequately reported items of the 10 most important and poorly reported CONSORT items between the two intervention arms.

Secondary outcomes:

Secondary outcomes will include the following:

- Mean proportion of adequate reporting of the 10 most important and poorly reported CONSORT items, considering each sub-item (see also “Assessment of outcomes”) as a separate item.
- Mean proportion for each of the 10 most important and poorly reported CONSORT items separately (including also separate analysis of sub-items).
- Time from assigning an academic editor until the first decision (as communicated to the author after the first round of peer-review).
- Proportion of articles directly rejected after the first round of peer-review.
- Proportion of articles published.

Additional outcomes:

For journals where peer reviewer comments are subsequently published alongside the published article, we will examine the peer reviewer comments for any reference to CONSORT and trial reporting. We will contact those journals which do not make peer reviewer comments publicly available, to see if they still could be used for such an analyses under the condition that only anonymised data will be published.

Data collection methods:

The outcomes will be assessed independently by two (blinded or at least partially blinded; see “blinding”) outcome assessors with expertise in the design and reporting of clinical trials. Any disagreement will be resolved by consensus or if necessary by consulting a third assessor. To ensure consistency between reviewers, we will first pilot the data extraction form; any disparities in the interpretation will be discussed and the data extraction form will be modified accordingly.

Adequate reporting of items will be assessed from published full-text publications adhering to the CONSORT C-short checklist (21). The following included items have sub-items which will be extracted separately:

- Outcomes (item 6a): (i) Define primary outcome, (ii) how it was measured, (iii) at what time point, and (iv) the analysis metric (e.g. change from baseline, final value).
- Sample size (item 7a): (i) The estimated outcomes in each group, (ii) the α (type I) error level, (iii) the statistical power (or the β (type II) error level), (iv) for continuous outcomes, the standard deviation of the measurements
- Blinding (item 11a): Is the blinding status clear for the following persons: (i) Healthcare provider, (ii) patients, and (iii) outcome assessors.
- Funding (item 25): (i) The funding source, and (ii) the role of funder in the design, conduct, analysis, and reporting.

All items will be judged as either “yes” meaning adequately reported, “no” meaning not adequately reported, or “NA” meaning that this sub-item is not applicable for this RCT. Items with different sub-items will only be judged as adequately reported if all relevant sub-items were adequately reported.

- Time from assigning an academic editor until the first decision: The day when the academic editor was assigned and the day of the first decision (e.g. major revision, minor revision, rejected) will be extracted to calculate the number of days until the first decision.
- Proportion of articles directly rejected after the first round of peer-review: Articles which were not invited for re-submission will be labelled and counted.
- Proportion of articles published: Articles which will be published will be counted and collected for data extraction.

The outcomes “time from assigning an academic editor until the first decision”, “proportion of articles directly rejected after the first round of peer-review”, and “proportion of articles published” will be extracted directly from editorial management software of the journal.

4.5 Participant timeline

The overview of the study schedule, including enrolment, intervention and assessments is presented in Table 2.

Table 2: Study schedule

	Enrolment	Allocation and intervention	Intervention	Post-intervention	
Time-point	<i>Studies which are sent out for peer-review</i>	<i>After first peer-reviewer accepts invitation</i>	<i>Whenever an additional peer-reviewer accepts invitation</i>	<i>First decision by journal</i>	<i>Published manuscripts</i>
Eligibility screen	X				
Allocation		X			
Intervention:					
C-short + usual care		X	X		
Usual care		X	X		
Assessment of trial characteristics:					
Funding source					X
Study centres (single centre or multicentre)					X
Sample size					X
Study design (e.g. parallel arm, crossover)					X
Hypothesis (e.g. superiority, non-inferiority)					X
Medical field					X
Intervention tested					X
Number of trial arms					X
Number of peer-reviewers					X
Journal which published the manuscript					X
Number of journals requesting CONSORT adherence (submission of checklist mandatory)					X
Assessment of outcomes:					
Time from assigning an academic editor until the first decision				X	
Proportion of articles directly rejected after the first round of peer-review				X	
Proportion of articles published					X
Adherence to CONSORT items and sub-items					X

4.6. Sample size

For the sample size calculation we hypothesise in a first scenario (Table 3) that the intervention C-Short will result in a 25% relative increase in adequate reporting compared to the control (meaning that 70% of items will be adequately reported in the intervention group and 56% in the control group). This is based on the rate of reporting of the 10 most important and poorly reported items was 0.56 (meaning that a mean of 56% of the 10 most important and poorly reported items were reported) in the control group of a previous study called WebCONSORT (38). The standard deviation (SD) in the same study was 0.23. However, we calculated our sample size to account for a slightly bigger variability in our data (SD = 0.25). To demonstrate a significant difference with a power of 90% and a type 1 error at 5% a total of 136 articles will be required in this scenario (68 per treatment arm; based on a two sided t-test).

The staff from one journal which will most likely be included (i.e. *PLoS One*) pointed out that 3 out of the 10 assessed items (i.e. item “Registration”, “Protocol”, and “Funding”) should always be implemented given their template. Assuming that this journal will recruit a high proportion, and that also other journals might update their templates, we increased the sample size in a second scenario, in which all these 3 items would have an overall adherence of 90% in the control arm (Table 3). This would entail an overall baseline adherence with the 10 CONSORT-short items of 71%. Based on a two sided t-test, a sample size of 166 (83 per treatment arm) will have a power of 80% to find a 15% relative increase (71% adherence in control group; 82% adherence in intervention group; SD = 0.25; a type 1 error at 5%).

Since the final sample size will be based on the number of articles published, rather than on the number of manuscripts randomised, eligible RCTs will be included and randomised until the number of 83 published RCTs is reached in each arm (resulting in no less than 166 articles), to avoid loss of power due to potential imbalance between arms. Recruitment will be stopped as soon as both arms reach the sample size of 83. After recruitment stop we will wait three month so that manuscripts which are still in production can be published. Manuscripts which are published after the three month period will be excluded.

Table 3: Assumptions for sample size calculations in two different scenarios.

Item	CONSORT item	Scenario 1. Adequate reporting as published in WebCONSORT	Scenario 2. Adapted from Scenario 1
1	Outcomes (6a)	77% (79 of 103)	77% (79 of 103)
2	Sample size (7a)	83% (85 of 103)	83% (85 of 103)
3	Sequence generation (8a)	76% (78 of 103)	76% (78 of 103)
4	Allocation concealment (9)	55% (57 of 103)	55% (57 of 103)
5	Blinding (11a)	35% (36 of 103)	35% (36 of 103)
6	Outcomes and estimation (17a)	44% (45 of 103)	44% (45 of 103)
7	Harms (19)	71% (73 of 103)	71% (73 of 103)
8	Registration (23)	69% (71 of 103)	90%
9	Protocol (24)	19% (20 of 103)	90%
10	Funding (25)	34% (35 of 103)	90%
Overall		56%	71%

Abbreviation: CONSORT= CONSolidated Standards for Reporting Trials

4.7 Randomisation and blinding

Articles, which meet the eligibility criteria as a primary report of an RCT, for which the journal decides to send out for external peer review will be randomised into one of the two groups (allocation 1:1). The randomisation list will be created by the study-randomizer system (43) using random block sizes between 2 and 8 and stratification by journal. As soon as the first peer-reviewer accepts the invitation, the manuscript will be included and randomised to one of the two intervention arms. One of the investigators (BS) will log onto the study randomizer-system (43) entering the study identification number (ID; provided from the Journal), the study title, as well as the journal the study was submitted to. Subsequently, all additional peer-reviewers accepting the invitation to review the same manuscript will receive the same intervention (C-short plus usual practice or usual practice only) as the first peer-reviewer.

Authors will be blinded to the intervention allocation. Editors will not be actively informed about the randomisation (possible exception listed under "4.3 Interventions"). To avoid potential bias, peer reviewers and manuscript authors will not be informed of the study hypothesis, design and intervention.

Outcomes will be assessed in duplicate (see assessment of outcomes). At least one outcome assessors will be blinded. Due to restricted resources it might be possible that the investigator conducting the randomisation (BS) will be included in the data-extraction from published manuscripts.

4.7 Data management and confidentiality

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3 Outcomes from publications will be assessed and extracted in duplicate. Since this information
4 is not confidential, we will use Google Forms for data extraction from published RCTs. Data
5 entered will be validated for completeness.
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9 Data from the editorial manager software (e.g. Title of manuscript, first author, randomisation
10 ID, Journal, date when manuscript was accepted by and academic editor, date when the final
11 decision was made, final decision, number of peer-reviewers who peer reviewed the
12 manuscript, the peer review) will be extracted, anonymised and entered in a password
13 protected database which is saved on a server from the University of Oxford. Data will be
14 managed and curated according to University of Oxford regulations, which includes regular
15 back-up (on a daily basis) of the virtual drives where the data are stored.
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21 The raw data extracted from the included manuscripts can be made openly accessible in an
22 anonymised way (i.e. giving the included RCT a number instead of identifying them).
23 Derived/aggregated data, including anonymised information generated from the journals'
24 editorial manager software, will be stored and made available to the research community when
25 the project ends (see also "8. Publication policy and access to data"). Where appropriate, the
26 researcher who has access to the editorial manager software (BS) and anyone else who will
27 see the identifiable data will sign a confidentially agreement with the participating journals,
28 confirming that they will not share identifiable data with any other party. Journals such as the
29 BMJ series state in their Company Privacy Statement that research programmes for quality
30 improvement might be in place. Furthermore, peer reviewers for all BMJ journals receive the
31 following statement in their invitation letter "*We are constantly trying to find ways of improving
32 the peer review system and have an ongoing programme of research. If you do not wish your
33 review entered into a study please let us know by emailing [...] as soon as possible.*"
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44 4.8 Statistical methods

45 4.8.1 Populations of analysis

46 The main population for analysis will be all manuscripts randomised and accepted for
47 publication in the participating journals. Differently from RCTs conducted with patients, where
48 drop outs need to be carefully considered (e.g. multiple imputation of missing data), we are
49 only interested in the reporting adherence of RCTs that are published. All outcomes will be
50 calculated based on the main population for analysis. The secondary outcome "Time to the
51 first decision", will additionally be calculated considering all randomised manuscripts (including
52 the ones which were not published).
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4.8.2 Data analysis

All quantitative variables will be described using means and standard deviations, or median and interquartile ranges in case severe departures from a normal distribution are identified. Data distribution will be inspected visually (i.e. by histograms) instead of performing formal statistical tests for normality. Categorical variables will be described using frequencies and percentages. For the primary and secondary outcomes, we will estimate the difference between means between the two groups and report them with respective 95% confidence intervals.

4.8.3 Analysis of primary endpoint

The primary outcome will be the difference of the mean proportion of adequately reported items of the 10 most important and poorly reported CONSORT items. If the data on the primary outcome is normally distributed then the two groups (i.e. C-short plus usual practice vs. usual practice) will be compared using an unpaired Student's t-test to compare the unadjusted mean proportion of adequate reporting. If the data is not normally distributed, comparisons will be performed using a non-parametric equivalent test (i.e. Wilcoxon-Mann-Whitney test for testing whether the population medians of the two groups are the same).

For the analyses of the primary outcomes a p-value of 0.05 (5% significance level) will be used to indicate statistical significance and treatment effect (mean difference) reported with 95% confidence intervals (or median and respective interquartile ranges, in case of asymmetric distribution). Exact p-values will be presented up to three decimal places. We anticipate there will be no missing data in this study, neither at the individual C-short items, nor at the manuscript level. This is due to the study design, which will include only the randomised manuscripts that are accepted for publication.

4.8.4 Analysis of secondary endpoints

To investigate the effect of the intervention on the secondary outcomes, mean differences with respective 95% confidence intervals will also be reported for these outcomes. If normality is not observed for any of the continuous secondary outcomes, the same strategy adopted for the primary outcome (use of a non-parametric equivalent to the Student's t-test) will be used.

A p-value of 0.05 will indicate statistical significance for the observed treatment effect on the secondary outcomes. Exact p-values will be presented up to three decimal places. Similarly to the primary outcome, we anticipate there will be no missing data for any of the secondary

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3 outcomes, as we will have access to the Editorial Management system of the included
4 journals, where all relevant information is automatically reported.
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7 4.8.5 Pre-specified subgroup analysis

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9 No formal subgroup comparative analysis is planned for the primary or secondary outcomes.
10 However, the effect of the intervention on the primary outcome within subgroups, will be
11 presented using forest plots to visually examine whether it differs according to some variables,
12 such as: (1) Journals that actively implement the CONSORT Statement (defined as requiring
13 authors to submit a completed CONSORT checklist alongside their manuscript) vs. journals
14 that are not actively implementing the CONSORT Statement; (2) sample size ($n < 100$ vs. $n \geq$
15 100); and (3) impact factor (<5 , $5.1-10$; >10) as there is evidence that higher impact factor as
16 well as higher sample size are associated with higher adherence to reporting guidelines (44).
17 These analyses will be exploratory, with the aim of supporting new hypothesis generation,
18 rather than conclusive.
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27 **5 Legal and general logistics**

28 5.1. Organisation of study

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32 5.1.1 Coordinating centre

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34 The coordinating centre's, will be the Centre for Statistics in Medicine at the University of
35 Oxford under the responsibilities of Dr Sally Hopewell and Dr Benjamin Speich.
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37 The coordinating centre's will ensure the following missions:

- 38 • Training of the staff
- 39 • Implementation of quality control
- 40 • Logical controls of data
- 41 • Follow-up on requests for correction/validation
- 42 • Statistical analysis
- 43 • Archiving of data
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50 5.1.2 Scientific committee

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52 The scientific committee is composed of:

- 53 • Prof Isabelle Boutron: Centre D'Épidémiologie Clinique Hôtel-Dieu, Paris Descartes
54 University, France
- 55 • Prof Matthias Briel, University of Basel, Switzerland
- 56 • Associate Prof Sally Hopewell: Centre for Statistics in Medicine, University of Oxford,
57 UK
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- Prof David Moher: Centre for Journalology, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Canada
- Prof Philippe Ravaud: Centre d'Épidémiologie Clinique Hôtel-Dieu, Paris Descartes University, France
- Dr Benjamin Speich, Centre for Statistics in Medicine, University of Oxford, UK
- Dr. Michael M Schlusser, Centre for Statistics in Medicine, University of Oxford, UK
- Dr Sara Schroter, The BMJ, London, UK

The scientific committee is in charge of:

- Participating in the elaboration of the protocol
- Defining and validating the additional short explanation for each CONSORT item.
- Following the evolution of the committed study
- Publishing the results of this study

5.2. Regulatory aspects

Ethical approval for this study will be sought from the Central University Research Ethics Committee (CUREC) of the University of Oxford. Any amendments in the conduct of the study, collection of outcomes or analysis will be reported to the CUREC. The tested intervention has the goal to improve the quality of published journals (i.e. the adherence to CONSORT) and could also be implemented as usual practice without testing at the journal level. In agreement with another study, testing a similar intervention (45), we think that it is ethical to conduct this study without obtaining written consent. The main reason for this procedure are the following:

- Informing the authors and peer-reviewers would make it impossible to measure the effect of our intervention. In short, informing peer-reviewers and authors would create an artificial context which would not be comparable any more to the “real world context”. Authors and peer-reviewers would most likely be much more aware of CONSORT if they received information about the study. Furthermore, being aware to participate in a study could strongly influence the natural behaviour of peer-reviewers (e.g. putting more effort into reviewing a manuscript than under “real world conditions”) but also of authors.
- The intervention does not pose any risk of harms for authors and peer-reviewers.
- The intervention is not a medical intervention but rather tries to improve the research quality and journal processes.
- Several journal series (e.g. BMJ series) have Company Privacy Statements in place which clearly mention that research programmes might be in place for quality improvement.

- The intervention could be part of the routine at any Journal without previous assessment of its efficacy.
- No data which identifies participating manuscripts will be published.

6 Publication policy and access to data

The results from this study will be published in a peer-reviewed journal irrespective of the study results. Authorship to publications will be granted according to the rules of the International Committee of Medical Journal Editors (ICMJE). We plan to publish the full anonymised dataset as a supplementary file together with the main publication.

For peer review only

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For peer review only

Appendix

Appendix 1: Example of the email which will be sent out in the intervention arm (C-Short). The exact wording might be slightly adapted according to the journal preferences.

Dear **Title, Name**,

We thank you for accepting to peer-review a manuscript for **journal name**. As we are trying to improve the reporting for randomised controlled trials according to the CONSORT guidelines, we would like to ask if you could check whether the following most important and poorly reported items are adequately implemented as indicated in the *table below/attached table*.

Item	Section	CONSORT item	Short explanation
1	Outcomes (6a)	Completely defined pre-specified primary outcome measure, including how and when they were assessed	Is it clear (1) what the primary outcome is (usually the one used in the sample size calculation), (2) how it was measured (if relevant; e.g. which score used), (3) at what time point, and (4) what the analysis metric was (e.g. change from baseline, final value)?
2	Sample size (7a)	How sample size was determined	Is there a clear description of how the sample size was determined, including (1) the estimated outcomes in each group; (2) the α (type I) error level; (3) the statistical power (or the β (type II) error level); and (4) for continuous outcomes, the standard deviation of the measurements?
3	Sequence generation (8a)	Method used to generate random allocation sequence	Does the description make it clear if the "assigned intervention is determined by a chance process and cannot be predicted"?
4	Allocation concealment (9)	Mechanism used to implement random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Is it clear how the care provider enrolling participants was made ignorant of the next assignment in the sequence (different from blinding)? Possible methods can rely on centralised or "third-party" assignment (i.e., use of a central telephone randomisation system, automated assignment system, sealed containers).
5	Blinding (11a)	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes)	Is it clear if (1) healthcare providers, (2) patients, and (3) outcome assessors are blinded to the intervention? General terms such as "double-blind" without further specifications should be avoided.
6	Outcomes and estimation (17a/b)	For the primary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence intervals)	Is the estimated effect size and its precision (such as standard deviation or 95% confidence intervals) for each treatment arm reported? When the primary outcome is binary, both the relative effect (risk ratio, relative risk) or odds ratio and the absolute effect (risk difference) should be reported with confidence intervals.
7	Harms (19)	All-important harms or unintended effects in each group	Is the number of affected persons in each group, the severity grade (if relevant) and the absolute risk (e.g. frequency of incidence) reported? Are the number of serious, life threatening events and deaths reported? If no adverse event occurred this should be clearly stated.
8	Registration (23)	Registration number and name of trial registry	Is the registry and the registration number reported? If the trial was not registered, it should be explained why.
9	Protocol (24)	Where trial protocol can be accessed	Is it stated where the trial protocol can be assessed (e.g. published, supplementary file, repository, directly from author, confidential and therefore not available)?
10	Funding (25)	Sources of funding and other support (such as supply of drugs) and role of funders	Are (1) the funding sources, and (2) the role of funder(s) described?

Your efforts are highly appreciated.

Kind regards,

journal name-Team

Appendix 3: WHO Trial Registration Data Set (Version 1.3.1)

Statement was filled out on the 01. October 2019.

1. Primary Registry and Trial Identifying Number

This trial was denied registration on ClinicalTrials.gov as the study is not a clinical study that assesses a health outcome in human subjects. Instead we registered the trial on the Open Science Framework (<https://osf.io/c4hn8>).

2. Date of Registration in Primary Registry

21. June 2019

3. Secondary Identifying Numbers

Not applicable

4. Source(s) of Monetary or Material Support

No specific funding was acquired for this study. Benjamin Speich is supported by an Advanced Postdoc.Mobility grant from the Swiss National Science Foundation (P300PB_177933). David Moher is supported by a University Research Chair, Ottawa. Michael M Schlüssel is funded by Cancer Research UK. The funders had no role in designing the study and will also have no role in conducting the study, or analysing and reporting study results.

5. Primary Sponsor

Sponsor:	University of Oxford
Principal Investigator/Sponsor Investigator:	Benjamin Speich, PhD Postdoctoral Researcher Centre for Statistics in Medicine (CSM) Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) University of Oxford Windmill Road Oxford OX3 7LD Tel: +44 1865 737904 Email: benjamin.speich@ndorms.ox.ac.uk

6. Secondary Sponsor(s)

Not applicable

1
2
3 **7. Contact for Public Queries**

4 Dr. Benjamin Speich

5
6 Tel: +44 1865 737904

7
8 Email: benjamin.speich@ndorms.ox.ac.uk

9
10
11 **8. Contact for Scientific Queries**

12
13 Sponsor: University of Oxford
14
15 Principal Investigator/Sponsor Benjamin Speich, PhD
16 Investigator: Postdoctoral Researcher
17 Centre for Statistics in Medicine (CSM)
18 Nuffield Department of Orthopaedics, Rheumatology and
19 Musculoskeletal Sciences (NDORMS)
20 University of Oxford
21 Windmill Road
22 Oxford OX3 7LD
23 Tel: +44 1865 737904
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25 Email: benjamin.speich@ndorms.ox.ac.uk

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30 **9. Public Title**

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32 Impact of checklists to improve the reporting of randomised controlled trials published in
33 biomedical journals

34
35 **10. Scientific Title**

36
37 Impact of a short version of the CONSORT checklist for peer reviewers to improve the
38 reporting of randomised controlled trials published in biomedical journals: a randomised
39 controlled trial

40 Running title: CONSORT for Peer Review (CONSORT-PR)

41
42
43 Study identifier: CONSORT-PR

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46
47 **11. Countries of Recruitment**

48 Multinational (Centres are Biomedical journals)

49
50 **12. Health Condition(s) or Problem(s) Studied**

51 Reporting in published randomised controlled trials

52
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55
56 **13. Intervention(s)**

57
58 Control group: Usual practice

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2
3 After accepting to review a manuscript, peer reviewers will receive the automated, journal
4 specific standard email with general information as per each journal's usual practice (e.g.
5 where to access the manuscript, date the peer review report is due).
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10 Intervention group: C-short plus usual practice

11 After accepting to review a manuscript, peer reviewers will receive the automated, journal
12 specific standard email with general information (identical to control group). In addition, peer
13 reviewers will receive an additional email from the editorial office that includes a short
14 version of the CONSORT checklist (C-short) together with a brief explanation of the items
15 either as a table within the email or as an attachment. Peer reviewers will be asked to check
16 whether the items in the C-short checklist are addressed in the manuscript and to request
17 authors to include these items if they are not adequately reported.
18
19
20
21
22

23 **14. Key Inclusion and Exclusion Criteria**

24
25 The population will be defined on two levels: included journals and included manuscripts.
26

27 Inclusion criteria for journals:

28
29 Included journals must: i) endorse the CONSORT Statement by mentioning it in the journals'
30 Instruction to Authors; ii) have published primary results of at least five RCTs in 2017
31 (identified using a PubMed search).
32

33 Inclusion criteria for manuscripts

34
35 • All new manuscript submissions reporting the primary results of RCTs, which the
36 journal editor has decided to send out for external peer review. Since the 10 chosen
37 CONSORT checklist items (C-short) are applicable to different study designs, we will include
38 all manuscripts reporting the primary results of RCTs regardless of study design (e.g. parallel
39 group trial, cluster trial, superiority trial, non-inferiority/equivalence trials).
40
41

42 Exclusion criteria for manuscripts

- 43
44 • Manuscripts clearly presenting secondary trial results, additional time points, economic
45 analyses, or any other analyses.
46
47 • Manuscripts which are clearly labelled as a pilot or feasibility study or animal studies.
48
49 • Manuscripts not sent for peer review.
50
51
52
53
54

55 **15. Study Type**

56
57 This study is a multicentre RCT with submitted manuscripts as the unit of randomisation
58 (allocation ratio 1:1).
59
60

1
2
3 **16. Date of First Enrollment**
4

5 22. July 2019
6
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8

9 **17. Sample Size**

10 166 Since the final sample size will be based on the number of articles published, rather than
11 on the number of manuscripts randomised, eligible manuscripts will be randomised until 83
12 articles are published in each arm (resulting in no less than 166 articles), to avoid loss of power
13 due to potential imbalance between arms.
14

15
16 **18. Recruitment Status**
17

18 Recruiting
19

20 **19. Primary Outcome(s)**

- 21
- 22 • The primary outcome of this study will be the difference in the mean proportion of
23 adequately reported C-short items in published articles between the two groups.
24

25 **20. Key Secondary Outcomes**
26

- 27 • Mean proportion of adequately reported C-short items in published articles
28 considering each item separately.
- 29 • Difference in mean proportion of adequately reported C-short items in published
30 articles considering each sub-item (see “Assessment of outcomes”) as a separate item.
- 31 • Time from assigning an editor to the first decision (as communicated to the author
32 after the first round of peer-review).
- 33 • Proportion of manuscripts rejected after the first round of peer review.
- 34 • Proportion of manuscripts that will be published in the journal under study.
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44 **21. Ethics Review**

45 Ethical approval has been obtained from the Medical Sciences Interdivisional Research
46 Ethics Committee of the University of Oxford (R62779/RE001).
47
48

49 **22. Completion date**

50 We expect that recruitment will be finished in summer 2021.
51

52 **23. Summary Results**

53 Not applicable
54

55 **24. IPD sharing statement**
56

57 We plan to make the anonymised dataset, including the data from the published articles,
58 available as a supplementary file of the main publication.
59
60

1 **Impact of a short form of the CONSORT checklist for peer reviewers to improve the reporting of randomised controlled trials published**
 2 **in biomedical journals: study protocol for a randomised controlled trial**
 3
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7 Benjamin Speich^{1,2,*}, Sara Schroter³, Matthias Briel^{2,4}, David Moher⁵, Michael M Schlusser¹, Philippe Ravaud^{6,7}, Isabelle Boutron^{6,7}, Sally Hopewell¹
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 20 SPIRIT 2013 Checklist: Recommended
 21 and related documents*

items to address in a clinical trial protocol

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	3_____
	2b	All items from the World Health Organization Trial Registration Data Set	Appendix 3
Protocol version	3	Date and version identifier	Appendix 1
Funding	4	Sources and types of financial, material, and other support	24_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	1 and 24-25__
	5b	Name and contact information for the trial sponsor	1 and Appendix 1_

1		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and	24-25_____
2			interpretation of data; writing of the report; and the decision to submit the report for publication, including	
3			whether they will have ultimate authority over any of these activities	
4				
5		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint	24-25_____
6			adjudication committee, data management team, and other individuals or groups overseeing the trial, if	
7			applicable (see Item 21a for data monitoring committee)	
8				
9				
10				
11	Introduction			
12				
13	Background and	6a	Description of research question and justification for undertaking the trial, including summary of relevant	5-7_____
14	rationale		studies (published and unpublished) examining benefits and harms for each intervention	
15		6b	Explanation for choice of comparators	5-7 (comparator,
16				usual
17				practice)_____
18				
19				
20				
21	Objectives	7	Specific objectives or hypotheses	7
22				
23	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group),	7_____
24			allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	
25				
26				
27	Methods: Participants, interventions, and outcomes			
28				
29	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will	7-9_____
30			be collected. Reference to where list of study sites can be obtained	
31				
32	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and	7-9_
33			individuals who will perform the interventions (eg, surgeons, psychotherapists)	
34				
35	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be	9-10, Table 1,
36			administered	Appendix_____
37		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose	NA (one time
38			change in response to harms, participant request, or improving/worsening disease)	intervention)
39				
40				
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1		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	NA (one time intervention)
2				
3				
4		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	NA_____
5				
6	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	10-12_____
7				
8				
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10				
11	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 1 and Table Table 2_____
12				
13				
14	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13-14_____
15				
16				
17				
18	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7-8, 13-14____
19				

Methods: Assignment of interventions (for controlled trials)

Allocation:

24	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14_____
25				
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30	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14_____
31				
32				
33				
34	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14_____
35				
36				
37				
38	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14_____
39				
40				
41				
42				

1 17b If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's NA_____

2 allocated intervention during the trial

3

4

5 **Methods: Data collection, management, and analysis**

6 Data collection 18a Plans for assessment and collection of outcome, baseline, and other trial data, including any related 11-12__

7 methods processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of

8 study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known.

9 Reference to where data collection forms can be found, if not in the protocol

10

11

12 18b Plans to promote participant retention and complete follow-up, including list of any outcome data to be 15 (no missing

13 collected for participants who discontinue or deviate from intervention protocols data expected)___

14

15 Data management 19 Plans for data entry, coding, security, and storage, including any related processes to promote data quality 16-17__

16 (eg, double data entry; range checks for data values). Reference to where details of data management

17 procedures can be found, if not in the protocol

18

19

20 Statistical methods 20a Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the 14-16_____

21 statistical analysis plan can be found, if not in the protocol

22

23 20b Methods for any additional analyses (eg, subgroup and adjusted analyses) 16_____

24

25 20c Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any 15 (no missing

26 statistical methods to handle missing data (eg, multiple imputation) data expected)___

27

28

29 **Methods: Monitoring**

30

31 Data monitoring 21a Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of 24-25_____

32 whether it is independent from the sponsor and competing interests; and reference to where further details

33 about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not

34 needed

35

36

37 21b Description of any interim analyses and stopping guidelines, including who will have access to these interim 15_____

38 results and make the final decision to terminate the trial

39

40 Harms 22 Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse NA__

41 events and other unintended effects of trial interventions or trial conduct

42

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1	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	24-25_____
2				
3				
4	Ethics and dissemination			
5				
6	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	20_____
7				
8				
9	Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20_
10				
11				
12				
13				
14	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	Appendix 2_____
15				
16				
17		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	NA_____
18				
19				
20	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	17_
21				
22				
23	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	24_____
24				
25				
26				
27	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	20_
28				
29				
30	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	NA__
31				
32				
33	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	20_____
34				
35				
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37				
38		31b	Authorship eligibility guidelines and any intended use of professional writers	20_____
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1	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	Intend to publish in
2			BMJ open
3			(protocol), dataset:
4			page 20
5			
6			

Appendices

7			
8			
9	32	Model consent form and other related documentation given to participants and authorised surrogates	Appendix 2 (no
10		materials	consent)_
11			
12	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular	NA_____
13		specimens	
14		analysis in the current trial and for future use in ancillary studies, if applicable	

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons [“Attribution-NonCommercial-NoDerivs 3.0 Unported”](#) license.