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

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Title (SPIRIT i1*)

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

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

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Trial registration (SPIRIT i2)

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

Protocol version (SPIRIT i3)

Issue date: 15/05/2019

Protocol amendment number: 2 (changes marked in blue)

Funding (SPIRIT i4)

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

Roles and responsibilities (SPIRIT i5)

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

Introduction

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

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

One of the most popular strategies used by journals to improve adherence to CONSORT (4) requires authors to submit a populated checklist together with their manuscript indicating page numbers

corresponding to each item (2). However, journals usually lack further actions throughout the editorial process to ensure that the corresponding information to each item is reported in the randomised trial manuscript. This has been hypothesized to be one of the reasons why this editorial strategy has not achieved optimal results (1–3).

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

Objectives (SPIRIT i7)

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

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

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

Methods

Trial design (SPIRIT i8)

Two-arm parallel group, randomised trial.

Study setting (SPIRIT i9)

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

Eligibility criteria (SPIRIT i10, SAP i22)

Manuscripts will be eligible for our study if (i) they have been submitted to BMJ Open, (ii) they are original research submissions reporting the results of a randomised trial, (iii) they have passed the first editorial filter and have been subsequently sent out for peer review, and (iv) authors of these manuscripts have provided a completed CONSORT checklist. The last criterion was not included in the first version of the protocol but we incorporated it before recruitment started.

According to the official CONSORT extensions, we will also consider other study designs (cluster, non-inferiority and equivalence, pragmatic, N-of-1 trials, Pilot and feasibility, and within person trials) (5–10), and different intervention types (Herbal, non-pharmacologic, acupuncture and Chinese herbal medicine formulas) (11–14) in all areas of clinical specialty. Secondary trial analysis studies will be excluded.

Interventions (SPIRIT i11)

The intervention will consist of three steps that have been co-designed with the BMJ Publishing Group. First, the completed CONSORT checklist submitted by authors of manuscripts randomised to the intervention group will be assessed by the lead investigator (DB) as to whether it is consistent with the information that was actually reported in the manuscript. To determine what information authors are expected to report, we will rely on the CONSORT Explanation and Elaboration document (15) or the corresponding Explanation and Elaboration documents for each of the extensions considered (5–14). In a second step, the lead investigator (DB) will produce a standardised report containing precise requests to be addressed by authors in order to improve the completeness of reporting of the items where reporting inconsistencies were found. This report will consist of a brief introduction followed by a point by point description of the inconsistencies found together with precise requests related to the information missing and examples extracted from CONSORT (see an example in Box 1). The lead investigator (DB) will upload this report to the submission on the managing system of the journal (ScholarOne) to make it accessible to the handling editor of the manuscript. Finally, this editor will include our report in the letter to authors alongside the standard peer review reports. Manuscripts randomised to the control group will undergo the usual peer review process. Figure 1 describes the manuscript flow of the study.

Our intervention has not been previously evaluated (16). One potential facilitator of the intervention is that it can be implemented and evaluated in a real editorial context with no disruption to normal manuscript submission, peer review and editorial procedures.

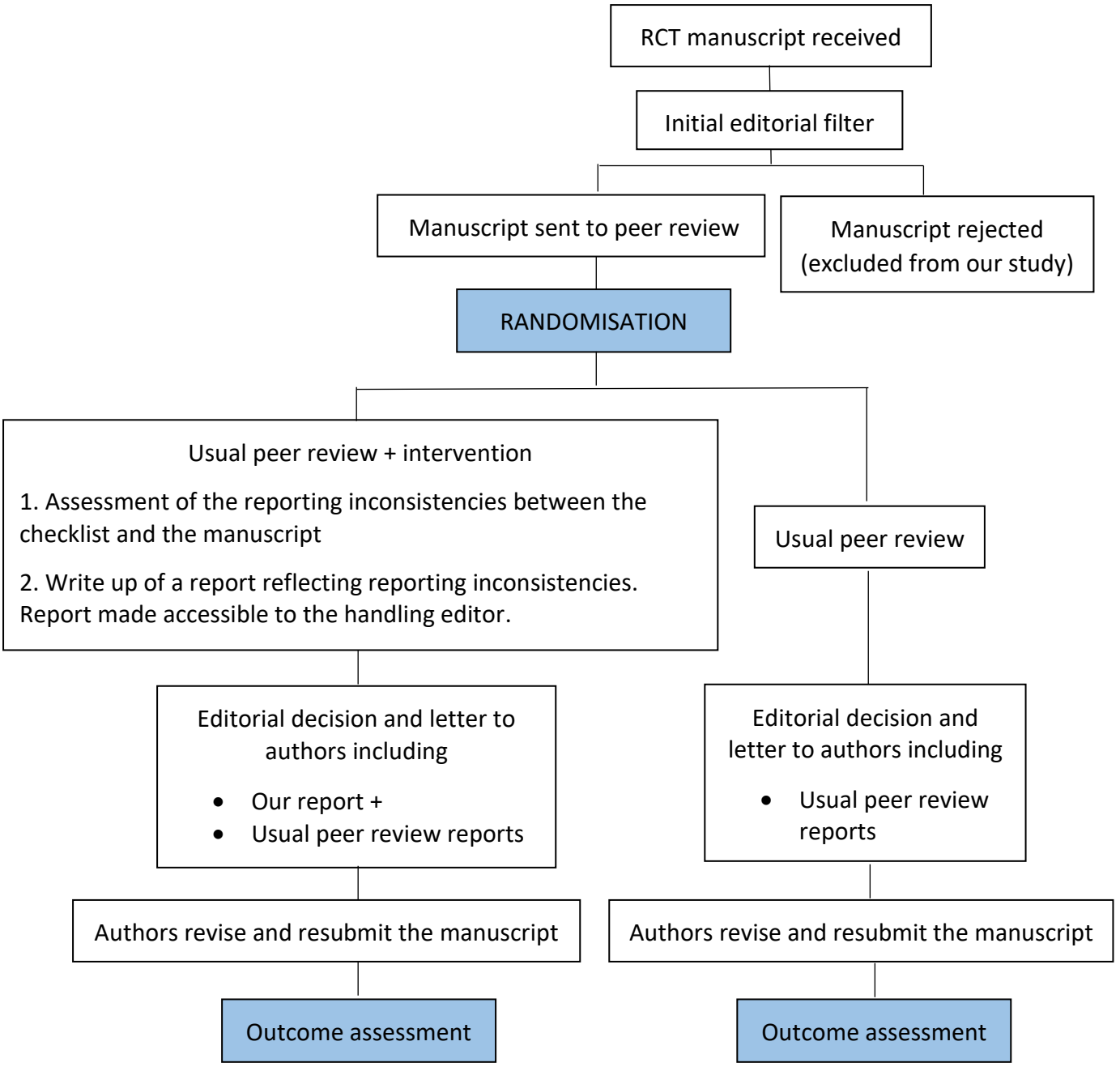
Box 1. Example of report on the reporting inconsistencies found

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

Please, make the following revisions:

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

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



After a pilot evaluation of the completeness of reporting of randomised trials published in BMJ Open (see Sample Size section for more details), we decided to focus on 8 core CONSORT items where reporting issues were detected and which are essential for systematic reviewers when evaluating the risk of bias and recording the outcome data (17). These items are:

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

In the case of manuscripts where the CONSORT extensions considered in this study are applicable, we will use the corresponding extensions for each of these items, no matter whether the authors have submitted the appropriate extension checklist(s) or not. All extension items will be assessed in addition to the standard CONSORT items, except those of the Pilot and Feasibility extension, which will substitute the standard ones (9).

If authors report N/A for a certain item, we will consider it appropriate (i) if the item does not apply and therefore it is not reported, and (ii) if the item applies and it is actually reported although the page number is not given. In contrast, we will evaluate it negatively if the item applies but it is not adequately reported. Regarding the specific case of item 11a ('If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how'), it will be considered as inadequately reported if blinding was not performed and authors do not specify so in the paper.

Outcomes (SPIRIT i12 & i18a, SAP i15)

- **Primary outcome**: Proportion of adequately reported items in the first revised manuscript [Time frame: Following manuscript revision (usually 2-3 months)]. An item will be considered as adequately reported if all subparts of the item (including all possible extensions, where relevant) are adequately reported [e.g. for CONSORT item 6a: A) completely prespecified primary and secondary outcomes, B) how each of these outcomes is assessed, and C) when each of these outcomes is assessed].
- **Secondary outcomes**: i) Proportion of manuscripts where each item is adequately reported [Time frame: Following manuscript revision (usually 2-3 months)], and ii) Average time to perform the assessment of reporting inconsistencies and to produce the report [Time frame: Following the evaluation of reporting inconsistencies by the lead investigator (1 week)].

Outcome evaluation will be performed independently and in duplicate by two masked outcome assessors (EC, JJK) with extensive experience in reporting and methodological issues of randomised trials. Outcome assessors will also collect baseline measures of compliance between the CONSORT checklist and the manuscript in order to adjust for these in the analysis (see "Statistical methods" section). Outcome evaluation will start on 17 May 2019.

To ensure that the evaluations of the two outcome assessors are consistent, they appraised 6 random randomised trials published in BMJ Open between April 2018 and September 2018. Discrepancies among evaluators were discussed.

We consider two potential scenarios that could lead to missing data on the study outcomes: (i) when a manuscript is rejected after peer review and therefore not returned to authors for revision, and (ii) when authors do not return the revised manuscript within the established time (28 days plus, if necessary, the extra time that the handling editor of each manuscript considers appropriate) after a "Minor revision" or "Major revision" editorial decision. Methods to handle missing data are reported below (see "Statistical methods" section).

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

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

Recruitment of manuscripts started in 7th December 2018.

Sample size (SPIRIT i14, SAP i11)

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

If we expect the intervention to manuscripts in the intervention group adequately report 7 and 8 items 50% and 50% of the times, respectively, a sample size of 24 articles (12 per arm) would be enough to detect such increase with 85% of power.

To relax the strong assumptions behind the t-test, which was initially used, we re-defined the main analysis and used bootstrapping calculations (see "Statistical methods" section and Box 3), after which we checked that the power did not decrease (see Box 2 for the final power calculation).

Box 2: Power calculation

```
na = 12
nb = 12
A = 0:8
B = 0:8
pra = c(0,0,0,0,0,0,0,5,5)
pra = pra/sum(pra)
prb = c(0,0,0,0,0,2,4,4,2)
prb = prb/sum(prb)
nboot <- 1000
N = 1000
ma = matrix(sample(A, pr=pra, replace=TRUE, siz=N*na), ncol=N)
mb = matrix(sample(B, pr=prb, replace=TRUE, siz=N*nb), ncol=N)
sign1 <- c()
for (i in 1:N) {
  reporting <- data.frame(
    score = c(ma[,i],mb[,i]),
    group = factor(rep(c("Control", "Intervention"), c(na, nb)))
  )
  diff.mean1 <- c()
  for (k in 1:nboot){
    sel <- sample(1:(na+nb),na+nb,rep=TRUE)  # selected articles
    reporting.boot <- reporting[sel,]
    diff.mean1[k]<- with(reporting.boot,diff(tapply(score,group,mean)))
  }
  conf.int1 <- quantile(diff.mean1,c(0.025,0.975))
  sign1[i] <- conf.int1[1]>0 | conf.int1[2]<0
}
sum(sign1)/N
```

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

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

The folder containing the manuscript allocations and PDFs will remain unavailable to authors of included manuscripts and outcome assessors, who will be masked to allocation. Every time the lead investigator (DB) detects that an editorial decision has been made on a manuscript and that authors have revised it, he will first make available to the outcome assessors (JJK, EC) the first submitted version of the manuscript. Then, they will have to complete the evaluation form for the manuscript independently and in duplicate. This form will include the CONSORT extensions to be used. Once this is done, DB will inform the outcome assessors of the discrepancies, if any, so that they can solve them by consensus via Skype call and agree on a final joint score. Afterwards, DB will share the first revised manuscript and the outcome assessors will evaluate it. Again, DB will point out discrepancies, they will solve them and assign a final score to the manuscript.

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

Data management (SPIRIT i19)

All data related to the study is being collated in a password protected spreadsheet file stored in Google Drive.

Statistical methods (SPIRIT i20, SAP i25, i27, i28 & i31)

Statistical analysis will be carried out using R software.

For the primary outcome, we will adjust a linear regression model with the baseline percentage of consistency between the manuscript and the checklist as the only covariate. The 95% confidence interval will be calculated using bootstrapping (see Box 3).

In case that we have missing data for the primary outcome for some of the manuscripts included, the scores will be imputed with a value of *1-b*, where *b* is the baseline score of the manuscript, regardless of the manuscript allocation. This would reflect that rejecting a manuscript with low baseline score could be considered as an editorial success. Multiple imputation of missing values was discarded because missingness could not entirely be due to observed variables (18). For example, a manuscript with excellent reporting quality could be rejected based on other reasons, such as poor methodological quality or the fact that it does not meet the scope of the journal. Secondarily, the robustness of the primary outcome results will be assessed by carrying out the complete case analysis.

Box 3: Primary outcome analysis (*The file 'Primary outcome analysis.txt' contains the baseline and final scores of each paper, as well as its allocation*)

```
data <- read.csv2('Primary outcome analysis.txt', header = TRUE, sep = '')
model1 <- lm(data$Final ~ data$Baseline + data$Group)
summary(model1)
na=12
nb=12
nboot <- 1000
diff.mean1 <- c()
for (k in 1:nboot){
  sel <- sample(1:(na+nb),na+nb,rep=TRUE)  # selected articles
  reporting.boot <- data[sel,]
  diff.mean1[k] <- coefficients(lm(reporting.boot$Final ~
reporting.boot$Group + reporting.boot$Baseline,reporting.boot))[2]
}
conf.int1 <- quantile(diff.mean1,c(0.025,0.975))
```

Data monitoring (SPIRIT i21)

The study will not have a formal data monitoring committee.

Harms (SPIRIT i22)

Not described.

Auditing (SPIRIT i23)

The trial will not be externally audited.

Research ethics approval (SPIRIT i24)

Ethics approval has been obtained from the Research Committee of the Governing Council of the Universitat Politècnica de Catalunya (UPC). Ref: EC 02. Date: 13 September 2018.

Protocol amendments (SPIRIT i25)

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

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

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

Confidentiality (SPIRIT i27)

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

Declaration of interests (SPIRIT i28)

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

Ancillary and post-trial care (SPIRIT i30)

Not applicable.

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

To ensure transparent and adequate reporting of the trial protocol, we referenced in brackets all items corresponding to Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) (19), as well as key applicable items of the Guidelines for the Content of Statistical Analysis Plans (20).

The results paper will be submitted for publication to a peer-reviewed journal, regardless of the direction of the results, and will be reported in accordance to CONSORT (4). Contributor roles in the trial will be reported according to the Contributor Roles Taxonomy (CRediT) (21).

The content of the intervention reports reflecting reporting inconsistencies will appear as part of the review history of the manuscripts included in the study. However, in order to protect confidentiality, we will not release any dataset including individual manuscript data or outcome data identifying the performance of individual participants. When the study is finished, DB will assign a study number to each paper and store that code with the manuscript ID, password protect it, and store it (File 1) in the BMJ Google Drive folder for the study. In this file, we will also include all identifying variables (Submission date, Trial registration number, Title, Latest editorial decision, applicable CONSORT extensions). For the file containing the content of the intervention and the study outcomes (File 2), DB will strip all identifying variables other than the study code and store that file separate from File 1 in the same folder. DB will stick File 1, File 2, and the peer review reports in one folder, compress this folder using WinZip, password protect it, and store it in the same Google Drive folder. DB will share the password with SS, who will keep DB's access to the folder active after the study.

Biological specimens (SPIRIT i33)

Not applicable.

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