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The effect of providing peer reviewers with registry information on consistency between registered and published outcomes

Submission date 24/10/2018	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/10/2018	**Overall study status** Completed	
Last Edited 29/09/2022	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Clinical trials play an important role in advancing medical knowledge. However, for the data from trials to be reliable it is important to ensure that the primary outcome remains consistent throughout the course of the study. Selective outcome reporting, in which pre-planned outcomes are not reported at the time of manuscript publication or unplanned outcomes are newly reported in study publications is common throughout medical literature. Trial registries include a record of pre-specified trial outcomes, and can therefore help identify and stop selective outcome reporting if they are utilized effectively during the peer review process. This study will test whether providing peer reviewers with a summary of registered, pre-specified primary trial outcomes will decrease the number of inconsistencies observed between pre-planned trial outcomes and the outcomes that are published in trial manuscripts.

Who can participate?
This study does not involve human subjects; instead, the study cohort consists of manuscripts submitted for publication at participating journals that describe the results from clinical trials

What does the study involve?
Eligible manuscripts will be placed in either the control group or the intervention group. No change in the usual peer review and editorial practices will occur for manuscripts in the control group. For manuscripts in the intervention group, the study team will identify registry entries that match each trial manuscript. Information from these registries describing the timing of registration and the definition of any registered primary outcomes will be emailed to peer reviewers or editors assigned to evaluate each manuscript. Peer reviewers will be free to use this information to assist with their evaluation of the manuscript in question.

What are the possible benefits and risks of participating?
This study does not involve human subjects; therefore there are no possible benefits or risks to participating in this study.

Where is the study run from?
Cooper University Hospital, Camden, New Jersey (USA)

When is the study starting and how long is it expected to run for?
February 2018 to May 2020

Who is funding the study?
U.S. Department of Health and Human Services, Office of Research Integrity (USA)

Who is the main contact?
Christopher Jones
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
ORIIR180039

Study information

Scientific Title
Peer Review Evaluation of Registered End-Points of Randomized Trials

Acronym
PRE-REPORT

Study objectives

Providing peer reviewers with a summary of registered, pre-specified primary trial outcomes will decrease the incidence of inconsistencies between prospectively registered and published primary outcomes among clinical trials published in participating journals.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Cooper Health System Institutional Review Board has determined that this study does not constitute human subjects research as defined by the U.S. Code of Federal Regulations, and is therefore exempt from further IRB oversight.

Study design
Interventional stepped wedge cluster randomised trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Internet/virtual

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Consistency of published primary outcomes with prospectively registered outcomes for manuscripts describing clinical trial results

Interventions
As this trial uses a stepped wedge design, participating journals will all begin the study in the control arm. Beginning in month 3, the participating journals will be crossed over into the intervention arm in random order. By the end of month 10 all journals will be in the intervention arm.
The tested intervention will consist of a brief email describing the timing of registration and definitions of any prospectively registered primary outcomes, which peer reviewers will receive after they agree to review a clinical trial manuscript under consideration at one of the participating journals. This email will be distributed to peer reviewers/editors of included studies that are sent for peer review during the intervention phase.
The control arm will consist of current peer review and editorial practices at the participating journals.

Intervention Type
Other

Primary outcome measure

Presence of a clearly defined, prospectively registered primary trial outcome that is consistent with the primary outcome in the published manuscript, as determined by two independent outcome assessors. This measure is recorded as a dichotomous variable: the registered and published primary outcomes are either consistent or not. This will be determined after all of the included manuscripts that are accepted for publication by participating journals have been published.

We use the following definitions to make this determination:

We define prospective registration as registration of a primary outcome with ClinicalTrials.gov or any of the Primary Registries in the WHO Registry Network prior to enrollment of the trial's first participant.

A clearly defined outcome provides sufficient information to reasonably allow its identification on review of the study results and to allow an independent investigator to design a study measuring the same parameter.

Outcomes will be considered to be consistent if every primary outcome described in the registry is reported as a primary outcome in the manuscript, and every primary outcome reported in the manuscript is described as a primary outcome in the registry. Two investigators will independently assess all registered and published outcomes for consistency. Both investigators will be blinded to whether the manuscript was in the control or intervention phase and to the content of the manuscript draft sent for initial peer review. Any discrepancies will be resolved by consensus after having both authors review the full text of the manuscript and registry; persistent disagreements will be adjudicated by a third investigator. Trials not prospectively registered will be considered to have inconsistent outcomes, as these publications will introduce new outcomes by definition.

Secondary outcome measures

The following will be assessed after all the included manuscripts that are accepted for publication by participating journals have been published:

1. Acceptance rate, assessed by recording the final editorial decision for clinical trial manuscripts sent for peer review during the study period
2. Number of manuscripts that disclose an outcome change within the published manuscript. Among trial manuscripts with primary outcome discrepancies present, we will determine whether the manuscript disclosed the outcome change
3. Number of trials with changes to the primary outcome between the initial submitted manuscript and the published manuscript. For manuscripts which are published we will assess the consistency between primary trial outcomes described in the initial manuscript submitted for peer review and the primary trial outcomes described in the published version of the manuscript.
4. Number of manuscripts with consistent outcomes between the registered and published primary outcome when the registered primary outcome is not clearly defined. Among trials with registered primary outcomes that were registered prospectively but unclearly, we will determine whether the registered outcomes are consistent with the published outcomes.
5. Statistical significance of outcome changes. Manuscripts with inconsistencies between the prospectively registered and published primary outcomes will be assessed to determine whether the change in outcomes affected the statistical significance (as defined in each included manuscript) of published outcomes.
6. Discrepancies in secondary outcomes. We will assess included manuscripts to determine whether discrepancies are present between prospectively registered secondary outcomes and published secondary outcomes and will describe the nature of identified discrepancies.

7. Time elapsed between initial submission and publication. We will measure the impact of the intervention on the delay between initial submission and publication for included trials that are accepted for publication.

Overall study start date
01/02/2018

Completion date
01/05/2020

Eligibility

Key inclusion criteria
Manuscripts:
1. Sent for peer review during the one year study period by any of the participating journals
2. Include human subjects or groups of humans (e.g. cluster randomised trials)
3. Report results from an interventional study which prospectively assigns participants to one or more arms consisting of health-related interventions in order to evaluate an effect on health outcomes

Participant type(s)
Other

Age group
Other

Sex
Both

Target number of participants
The study will include 13 participating journals (clusters). We anticipate that on average 2 trial manuscripts per month will be accepted for publication at each participating journal.

Key exclusion criteria
Manuscripts:
1. Describe a planned trial without reporting trial results
2. Clearly state that the manuscript is not intended to report on the trial's primary outcome (i.e. manuscript describes only secondary or subgroup analyses)
3. Resubmitted manuscripts which have already completed the first round of peer review.
Manuscripts sent for peer review from multiple participating journals during the study will be analysed in the first journal’s cluster, and will not be included a second time if resubmitted to a different participating journal.

Date of first enrolment
01/11/2018

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
United States of America

Study participating centre
Cooper University Health System
One Cooper Plaza
Camden, New Jersey
United States of America
08103

Sponsor information

Organisation
Cooper University Health System

Sponsor details
One Cooper Plaza
Camden, New Jersey
United States of America
08103

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/056nm0533

Funder(s)

Funder type
Government

Funder Name
US Department of Health and Human Services, Office of Research Integrity

Results and Publications

Publication and dissemination plan

Trial results will be submitted to a peer reviewed journal for publication following the completion of data collection. Results will also be made available as part of the registration record.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available because the editors of the collaborating journals have requested that the information collected during the course of the study should remain confidential as a condition of participation for these journals.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2019	19/05/2020	Yes	No
Results article		28/09/2022	29/09/2022	Yes	No