Title

Pre-publication abstracts compared to full-text reports: A systematic review protocol

Authors

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Contributions of authors

Pairs of authors will independently screen all search results at a title/abstract screening stage followed by a full-text screening stage. They will then perform data extraction as pairs and finally carry out the analysis. Any disagreements at all stages will be resolved by a third author. VS and MG will prepare the final manuscript.

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None.

Declaration of interests

None.

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None currently.

Background

Randomised controlled trials (RCTs) are the gold standard for the assessment of efficacy of medical interventions. RCT findings are most often initially published in abstract form for one or more conferences in their respective medical fields, followed by a peer-reviewed full-text report in a scientific journal later in time.

Abstract reports have been found to report data that are inconsistent with or absent from the main article's body, even in large-circulation general medical journals (1-3).

However, they are routinely used in systematic review analyses and evidence syntheses for guidelines, during the time full-text reports are not available. As abstract publications can be at risk of substandard peer review (4, 5) which may mean abstract data used in evidence synthesis could be inaccurate.

The aim of this systematic review is to assess whether the outcomes, data and conclusions reported in an abstract match those published in the same RCTs full-text report, in the field of IBD treatment. We will also assess whether there are justifications for potential mismatches.

Objectives

We will examine whether the reporting of primary outcomes, primary outcome data and author conclusions, in IBD RCTs from 2012 to date, is consistent between full text reports and their pre-publication abstract reports.

Methods

A systematic search via MEDLINE, CENTRAL and EMBASE will be conducted. Secondly, RCTs full text reports missing from the first search will be identified by hand via the references lists of Cochrane published systematic reviews for treatments in IBD.

Once the primary trial list has been identified each included trial will have a targeted search for a pre-publication abstract meeting the criteria below. Additionally, corresponding pre-publication abstracts will be identified by hand searching the DDW, ECCO and UEGW registers.

Inclusion criteria for RCTs:

We will include all RCTs for treatments in IBD in the 10-year period (1 January 2012 – 30 Dec 2021).

Type of participants: IBD patients of all age groups and any disease state/type.
Types of interventions: Interventions for the induction, maintenance, or management of symptoms. Studies could involve any medical or surgical intervention compared to any other intervention, placebo, no treatment or usual care. Studies could include any outcome measures.

Exclusion criteria for RCTs: Non-randomised trials or quasi-randomised trials will be excluded. Non-medical interventions such as service evaluation, delivery, safety, education, and drug or symptom monitoring trials will be excluded.

Inclusion criteria for abstracts:

Abstract reports on one of the RCTs that meets the above criteria. The abstract must have been published prior to the full text trial publication. Abstracts must have the goal of reporting the protocol planned data. Any abstract that states its reporting post-hoc unplanned or additional analysis rather than the primary goals of the study will not be considered. Long-term follow up reports will not be considered.
If more than one abstract is published with similar text in different output forms the first published abstract will be included.

Search methods for identification of studies

All RCTs in that period will be uploaded to Ryaan for dual screening.
All included texts will be downloaded as PDF files. Once the primary search is completed hand searching of the Cochrane published reviews.
We will include one primary full text report and one abstract that reports on the primary findings that's closest to date to the full report. In case of interim reports we will only include them in the absence of full dataset reports.

Searching for abstracts will be done by targeted searches in the same search databases as well as hand searching in abstract publications from DDW, ECCO, UEGW.

Data collection and analysis

Data collection:

Two authors will independently screen all titles of potential trials and then potential included titles will be accessed in full text. Any disagreements will be resolved by a third author. All journal articles chosen for full-text review will be evaluated independently again by two authors to assess for inclusion, with the third author resolving differences.

Data extraction:

Two authors will perform data extraction. A third author will resolve any disagreements.

For each full-text and abstract report, we will extract:

- Primary outcomes. If an outcome is reported and it is not stated whether this is primary or secondary all outcomes will be reported (dichotomous outcome, yes or no matching between abstract and full report)
- Trial registration numbers, if reported (dichotomous outcome, yes or no matching between abstract and full report)
- Numbers of randomised patients per intervention group (continuous outcome)
- Numbers of participants reaching end of study per intervention group (continuous outcome)
- Primary outcome data per intervention group (dichotomous outcome, yes or no matching between abstract and full report; if there is a match continuous outcome data will also be reported)

- Author conclusions: no difference, difference favouring intervention group or difference favouring control group (dichotomous outcome, yes or no matching between abstract and full report)
- We will also look for explicit or implied justifications for absence of any of the above items (dichotomous outcome, yes or no matching between abstract and full report)

Analysis

For our dichotomous outcomes, we will report the median and range (1-7) of the appropriately reported items in each of the 7 extraction categories. We will calculate descriptive statistics and conduct Chi-squared tests for statistical differences between abstracts and full reports.

For our continuous outcomes, we will perform meta-analyses by pooling together the data for matching outcomes and calculate MDs or SMDs with 95% CIs.

Sub-group analyses will be considered according to the following:

- Year of publication (first 5 years vs last 5 years 2012-2016 versus 2017-2021)
- IF of full-report journal (top 1% IF vs others)
- By source of abstract (different international meetings verus each other)
- Children vs adults
- Induction vs maintenance vs other

Ethics

Patients will not be involved at any stage of this study's design or outcome as data will be collected from previously published studies and at no point will patients be recruited.

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