

Central Lancashire Online Knowledge (CLoK)

Title	Pre-publication abstract-only reports compared to full-text manuscripts for randomised controlled trials in inflammatory bowel disease: a systematic review
Type	Article
URL	https://clock.uclan.ac.uk/50678/
DOI	##doi##
Date	2024
Citation	Sinopoulou, Vasiliki orcid iconORCID: 0000-0002-2831-9406, Gordon, Morris orcid iconORCID: 0000-0002-1216-5158, Moran, Gordan William, Egiz, Abdullah Mohammed abousaleh ma orcid iconORCID: 0000-0003-0304-7982, Phlananthachai, Sanjana, Rane, Aditi Bhupendra and Al-tameemi, Ahmed Hussein Ali (2024) Pre-publication abstract-only reports compared to full-text manuscripts for randomised controlled trials in inflammatory bowel disease: a systematic review. <i>BMJ Open Gastroenterology</i> .
Creators	Sinopoulou, Vasiliki, Gordon, Morris, Moran, Gordan William, Egiz, Abdullah Mohammed abousaleh ma, Phlananthachai, Sanjana, Rane, Aditi Bhupendra and Al-tameemi, Ahmed Hussein Ali

It is advisable to refer to the publisher's version if you intend to cite from the work. ##doi##

For information about Research at UCLan please go to <http://www.uclan.ac.uk/research/>

All outputs in CLoK are protected by Intellectual Property Rights law, including Copyright law. Copyright, IPR and Moral Rights for the works on this site are retained by the individual authors and/or other copyright owners. Terms and conditions for use of this material are defined in the <http://clock.uclan.ac.uk/policies/>

Prepublication abstract-only reports compared with full-text manuscripts for randomised controlled trials in inflammatory bowel disease: a systematic review

Vassiliki Sinopoulou ,¹ Morris Gordon ,² Gordon William Moran,³ Abdullah Mohammed Abousaleh ma Egiz,¹ Sanjana Phlananthachai,¹ Aditi Rane,¹ Ahmed Hussein Ali Al-Tameemi¹

To cite: Sinopoulou V, Gordon M, Moran GW, *et al*. Prepublication abstract-only reports compared with full-text manuscripts for randomised controlled trials in inflammatory bowel disease: a systematic review. *BMJ Open Gastroenterol* 2024;**11**:e001334. doi:10.1136/bmjgast-2023-001334

► Additional supplemental material is published online only. To view, please visit the journal online (<https://doi.org/10.1136/bmjgast-2023-001334>).

Received 22 December 2023
Accepted 16 February 2024



© Author(s) (or their employer(s)) 2024. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

¹University of Central Lancashire, Preston, UK

²BEST Unit, University of Central Lancashire, Preston, UK

³Nottingham University Hospitals NHS Trust - City Campus, Nottingham, UK

Correspondence to
Professor Morris Gordon;
MGordon@uclan.ac.uk

ABSTRACT

Introduction Randomised controlled trials (RCTs) of key therapies in inflammatory bowel disease (IBD) are often presented and available as abstracts for significant periods of time prior to full publication, often being employed to make strategic and clinical prescribing decisions. We compared the concordance of prepublication abstract-only reports and their respective full-text manuscripts.

Methods Pairs of full-text manuscripts and their respective prepublication abstract-only reports for the same RCT outcomes, at the same time point of analysis were included. The RCTs were on treatments for IBD with full-text manuscripts published between 2010 and 2023.

Results We found 77 pairs of full-text manuscripts and their prepublication abstract-only reports. There were significant mismatches in the reporting of stated planned outcomes (65/77 matched, $p<0.001$) and primary outcomes reported in their results sections (67/77, $p<0.001$); trial registrations (34/65, $p<0.001$); the number of randomised participants (49/77, $p=0.18$); participants reaching end of study (21/71, $p<0.001$) and primary outcome data (40/73, $p<0.001$). Authors conclusions matched (75/77, $p=0.157$). Authors did not provide explicit or implied justifications for the absence or non-concordance for any of the above items.

Conclusions Abstract-only reports have consistent issues with both limited reporting of key information and significant differences in data when compared with their later full-text publications. These are not related to further recruitment of patients or word count limitations and are never explained. As abstracts are often used in guidelines, reviews and stakeholder decision-making on prescribing, caution in their use is strongly suggested. Further work is needed to enhance minimum reporting standards in abstract-only works and ensure consistency with final published papers.

INTRODUCTION

Randomised controlled trials (RCTs) are the gold standard for the assessment of efficacy

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Data from abstract-only reports of randomised controlled trials are often used as evidence sources for clinical and strategic decision-making in inflammatory bowel disease. It is not known whether they are up to par for this purpose.

WHAT THIS STUDY ADDS

⇒ Our findings suggest that abstract-only reports are often inconsistent in their reporting, compared with their respective full-text manuscripts, especially in areas such as flow of participants and primary outcome data. These are not related to further recruitment of patients or word count limitations and are never explained.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Caution is advised when abstract-only reports are used as evidence sources. Enhanced minimum reporting standards for abstract-only reports need to be employed.

of medical interventions.¹ Systematic reviews (SRs) will often only include RCTs during the systematic search and evidence synthesis process, in order to eliminate biases and quality concerns related to other research designs. Recent years have seen an exponential increase in the number of SRs published, which use RCTs as their main source of evidence. SRs and RCTs are in turn prioritised in decision-making and the development of guideline recommendations in all medical fields, including gastroenterology.^{2,3}

RCT findings are often initially published in abstract-only form, as proceedings of conferences of their respective medical fields, before the publication of a peer-reviewed



full-text manuscript report in a scientific journal. These can be associated with press releases and interest, as well as presentations at major international meetings, often with the same work being presented repeatedly across the globe at different congresses to achieve maximum saturation of key stakeholders. Full-text manuscript publications undergo lengthy peer-review and editorial rounds, meaning that a number of years can pass between the publication of RCT findings in full-text manuscript form. It is also possible that a full-text manuscript may never come to fruition, in cases of publication bias, when final RCT findings are not what was initially expected. However, abstract-only reports are routinely used in evidence synthesis, during the period full-text manuscripts are not available, or when they do not exist. This is also key for guideline development and prescribing decision-making and given the risk of publication bias involved with excluding such works, the null position is very often to consider them.⁴ They are also used often by clinicians who want to stay updated with new findings in their field and prescribing decisions, and the press for the communication of these findings to the public. It has been demonstrated in other medical fields that abstract-only reports have both methodological and outcome data reporting flaws compared with full-text manuscripts. Abstract-only reports have been found to report data that are inconsistent with or absent from the full-text manuscript's body, even in large-circulation general medical journals.⁵⁻⁷ Abstract-only reports can be at risk of substandard peer review,^{8,9} which could mean abstract outcome data used in evidence synthesis could be inaccurate. Additionally, methodological issues, such as whether allocation concealment has been reported or not, have been found to be associated with exaggerated effect estimates.¹⁰

Within the field of inflammatory bowel disease (IBD), methodological flaws have been identified even within full-text RCT manuscripts, with issues related to risk of bias¹¹ and sample size estimation.^{12,13}

Consistency of reporting between abstract-only and the respective full-text RCT manuscripts has not been investigated within the field of gastroenterology. The aim of this SR was to compare the concordance of prepublication abstract-only reports and their respective full-text manuscripts in outcome, attrition and magnitude of effect reporting for IBD RCTs, and to assess whether study authors provided justifications for potential mismatches.

METHODS

This review is reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses.¹⁴ A protocol for the review was uploaded to an institutional online repository before commencement of data collection.¹⁵

Inclusion and exclusion criteria

Full-text RCT manuscript selection

Inclusion criteria for full-text RCT manuscripts were as follows: (1) Full-text RCT manuscripts published between January 2010 and June 2023. The date range was chosen based on the year the Consolidated Standards of reporting trials (CONSORT) statement for the reporting of RCTs was reported until 6 months prior to data collection for this SR;¹⁶ (2) Full-text manuscripts of RCTs including patients with IBD of all age groups and any disease state or type; (3) Full-text manuscripts on RCT interventions for the induction, maintenance or management of symptoms, involving any pharmacological or non-pharmacological intervention compared with any other intervention, placebo, no treatment or usual care and (4) Full-text manuscripts which aimed to report the RCT's protocol planned primary outcome data. There were no limitations on outcome measure, language or region.

Exclusion criteria were as follows: (1) manuscripts of non-randomised or quasi-randomised trials; (2) non-medical interventions such as service evaluation, delivery, safety, education and drug or symptom monitoring trials; (3) manuscripts without outcome results (eg, protocols); (4) manuscripts which only reported outcome data for non-randomised long-term RCT extensions and (5) manuscripts which only reported post hoc outcome data were excluded.

Abstract-only RCT report selection

Inclusion criteria for abstract-only RCT reports were as follows: (1) Abstract-only RCT reports published prior to the full-text trial RCT manuscript date; (2) Abstract-only reports of RCTs including patients with IBD of all age groups and any disease state or type; (3) Abstract-only reports on RCT interventions for the induction, maintenance or management of symptoms, involving any pharmacological or non-pharmacological intervention compared with any other intervention, placebo, no treatment or usual care and (4) Abstract-only reports which aimed to report the RCT's protocol planned primary outcome data. Interim-results abstract-only reports were only included in the absence of finalised dataset reports. If more than one abstracts meeting the above criteria were identified, we included the abstract published closest to the date of publication of the full-text manuscript. If more than one abstract was published with similar text in different output forms, the first published abstract was included.

Exclusion criteria for abstract-only RCT reports matched those for full-text manuscript RCT reports.

Screening and pairing of full-text manuscript to abstract-only reports

We conducted a systematic search via MEDLINE, EMBASE and CENTRAL for all potential full-text manuscripts and abstract-only reports (online supplemental appendix) in March 2022. An update search was conducted on July

2023. Search results were uploaded to a Microsoft Excel database for screening.

Screening and study selection took place in three stages. In the first stage (title screening), we discarded all duplicate and non-RCT reports. In the second stage (abstract screening), we identified reports which met our inclusion criteria, and separated them into two databases, one for full-text manuscripts and one for abstract-only reports. In the third stage (full-text screening), we identified all potential full-text manuscripts and abstract-only reports that met our criteria, and we formed pairs of full-text manuscripts and abstract-only reports for each RCT.

Eligibility of full-text RCT manuscripts was assessed by pairs of reviewers independently (AHAA-T, NS, AMAmE and SP) at all stages. Disagreement was resolved by discussion and consensus. A third author (MG or VS) resolved cases in which consensus was not reached.

Eligibility of abstract-only RCT reports was assessed in the same way, at all stages. Pairs of reviewers (AHAA-T, NS, SP and AMAmE) independently assessed all available abstract-only reports for eligibility and disagreement was resolved by discussion and consensus, or by a third author (MG or VS), when consensus could not be reached.

When an abstract-only report met the selection criteria, the assessors matched them with the full-text manuscript of the same RCT. Full-text RCT manuscripts and abstract-only RCT reports that were found to have no eligible matches at this stage were discarded.

When a single report was reporting on results of more than one RCTs (eg, randomised induction followed by a re-randomised maintenance of remission phase), we only considered relevant the parts of the report that were also reported in its matching pair. When both matching full-text manuscripts and abstract-only reports reported data from more than one RCTs, we included them twice (eg, as one induction pair and as one maintenance pair).

The systematic search and screening eliminated the risk of selection bias. Other forms of bias such as performance and detection bias were not relevant for the outcomes of this review, as they were not related to the effects of the performed interventions.

Data extraction

Pairs of reviewers (AMAmE, ABR, SP and AHAA-T) independently performed data extraction using pre-designed data extraction forms. A third author (MG or VS) resolved any disagreements.

The extracted reporting item data for full-text manuscript were the following: (1) Whether primary outcomes were stated; (2) Whether results for the stated primary outcomes were reported in any numerical form. If an outcome was reported but not stated whether it was primary or secondary, we considered all stated outcomes as primary; (3) Whether a trial registration was reported; (4) Whether a number of randomised patients per intervention group were reported; (5) Whether a number of participants reaching end of study per intervention group were reported; (6) Were the primary outcome

data reported in a form where they could be used in a meta-analysis per intervention group and what were they; (7) What were the author conclusions (no difference, difference favouring intervention group or difference favouring control group) and (8) Explicit or implied justifications for the absence or non-concordance of any of the above items.

The extracted reporting item data for the matching abstract-only reports were the following: (1) Whether primary outcomes were stated and matched full-text; (2) Whether primary outcome results were reported in any form and matched full-text; (3) Whether a trial registration was reported and matched full text; (4) Whether a number of randomised patients per intervention group were reported and matched full-text; (5) Whether a number of participants reaching end of study per intervention group were reported and matched full-text; (6) Were the primary outcome data reported in a form where they could be used in a meta-analysis per intervention group and did they match the full-text; (7) What were the author conclusions (no difference, difference favouring intervention group or difference favouring control group) and if they matched full-text and (8) Explicit or implied justifications for the absence or non-concordance of any of the above items.

The reviewers chose a judgement of 'yes' when the reported item matched in both full-text manuscript and abstract-only publication, 'no' when the reported item did not match or that was not possible to determine due to unclear reporting in one of the two publications, or 'missing' when the item was not reported in both publications or it was not possible to determine due to unclear reporting in both publications, for each pair of full-text manuscript and abstract-only report, for each reporting item. Unclear reporting was ruled when there was not enough information to extract an item without contacting the authors. 'No' was only chosen when the reporting items clearly did not match, and not in cases of minimal mismatches, or when it was clear from context that the items matched.

AMAmE, ABR, SP and AHAA-T were not aware of the full-text manuscripts' and abstract-only reports' impact factor or abstract-only report's source during data extraction.

After extraction of the reporting item data, publication characteristics for publication year, pharmacological or non-pharmacological intervention, impact factor of full-text manuscript and abstract-only report source were also extracted.

Data analysis

We calculated descriptive statistics as absolute numbers and percentages for dichotomous outcomes, and mean (SD) for continuous. We conducted McNemar's test for two related samples, with a binomial distribution used for missing data—when one of the two datapoints in a matching pair, for a given outcome, was missing—to test statistical differences between the abstract-only reports

and full-text manuscripts. For pairs where both datapoints for a matching pair, for a given outcome, were missing, they were removed from the analysis of that outcome. We used SPSS V.28.0.

Subgroup analyses were performed for the following: period of publication (on or before 2016 vs 2017 or later—this was chosen as the midpoint between the beginning of our systematic search and when data analysis occurred); pharmacological versus non-pharmacological

interventions; Impact factor of full-report journal (more or less than 20) and source of abstract-only report (different international conferences and meetings).

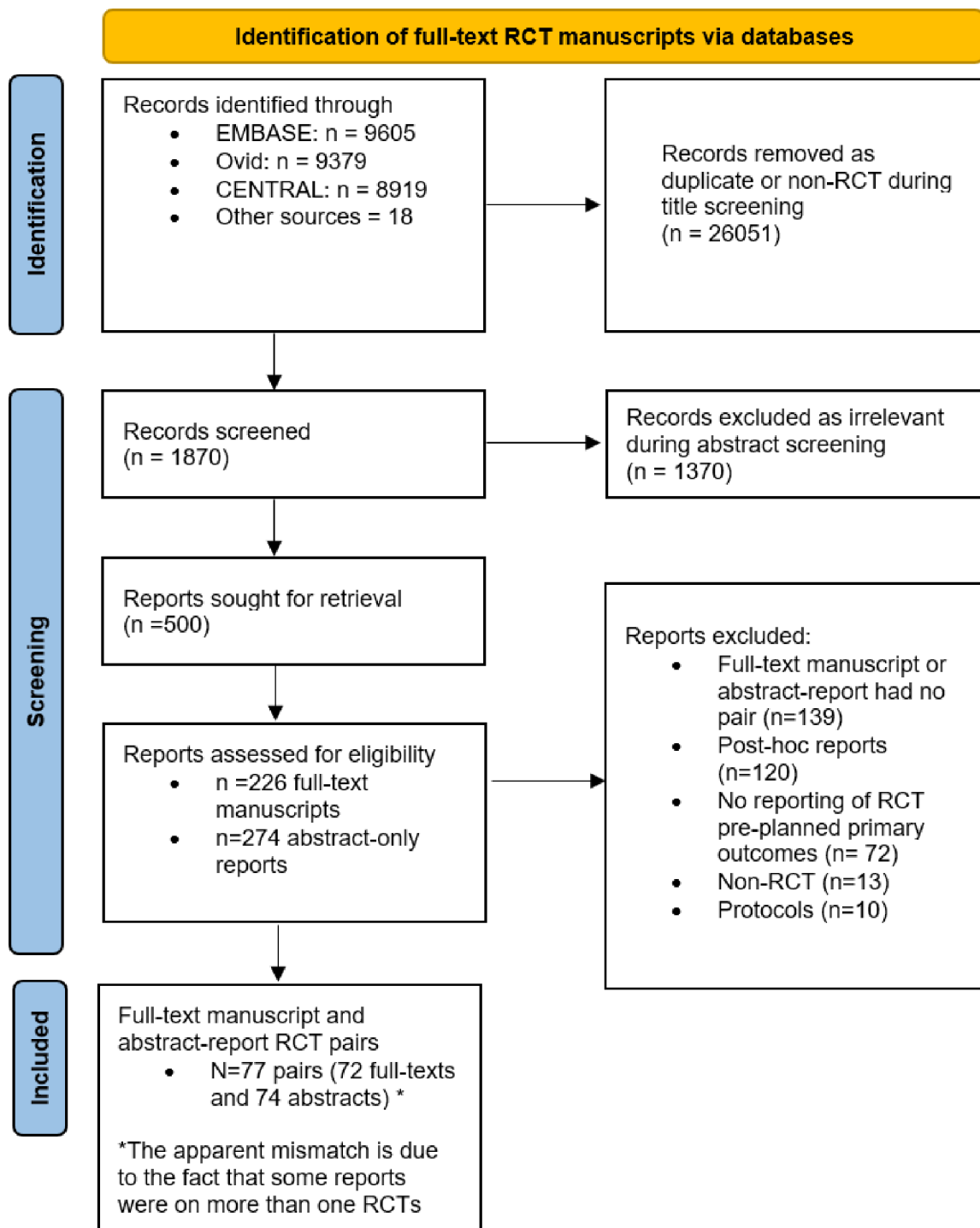


Figure 1 PRISMA flow diagram. RCTs, randomised controlled trials; PRISMA, Preferred reporting items for systematic reviews and meta-analysis.

Table 1 Characteristics of included manuscripts and records

	Pharmacological/ non- pharmacological	Year of publication of full-text manuscript	Year gap between full text and abstract	5-year impact factor of full- text journal	Impact factor more or less than 20	Abstract source (JCC, GastroJ, other)
Pairs, n (%) (total=77)	63 (82%) pharma 14 (17.9%) non- pharma	Reported for all	Reported for all	Retrieved for all	41 (53.8%) >20 36 (46.2%) <20	30 (38.5%) JCC 32 (42.3) GastroJ 15 (19.2) Other
Mean/ median/ mode	n/a	2017 (median) 2019 (mode)	1.19 (mean)	42.85 (mean)	n/a	n/a
Range/SD	n/a	2010–2022 (range)	1.1 (SD) 0–6 (range)	48.9 (SD) 0–130 (range)	n/a	n/a

GastroJ, *Gastroenterology Journal* (publishes the Digestive Diseases Week conferences' abstracts); JCC, *Journal of Crohn's and Colitis* (publishes the European Crohn's and Colitis Organisation's conferences' abstracts); n/a, not available.

RESULTS

Characteristics of included full-text manuscript and abstract-only report pairs

The search and screening results are presented in [figure 1](#). We were able to form 77 pairs of matching full-text manuscripts and abstract-only reports meeting our inclusion criteria (online supplemental file for references). Six full-text manuscripts and three abstract-only reports were included twice, as they reported results of separate RCTs (randomised induction of remission phases followed by re-randomised maintenance phases) ([figure 1](#)). The full list of references for all pairs is presented in online supplemental material. Descriptive characteristics are presented in [table 1](#).

Comparison of reporting items

[Figure 2](#) is a visual presentation of the results.

Are the planned primary outcomes stated and reported?

Primary outcomes were stated in 76/77 full-text manuscripts (1 did not report) and matched in 64 abstract-only reports (3 were not matching, 10 did not report). Results for the stated primary outcomes were reported in any numerical form in 76/77 (1 did not report) full-text manuscripts and matched in 66 abstract-only reports (2 did not match, 9 did not report). Both reporting items were significantly mismatched ($p<0.001$, $p=0.002$).

Are trial registrations reported?

Trial registrations were reported in 65/77 full-text manuscripts (13 did not report) and matched in 33 abstract-only reports (44 did not report). There was only one pair where a trial registration was reported in the abstract-only report and not in the full-text manuscript. This reporting item was significantly mismatched ($p<0.001$).

Do the flow of participants and outcome data match?

The number of randomised patients per intervention group was reported in 76/77 full-text manuscripts (1 did not report) and matched in 48 abstract-only reports (14 did not match, 15 did not report).

The number of randomised participants reaching the end of the study was reported in 71/77 full-text manuscripts (9 did not report) and matched in 20 abstract-only reports (5 did not match, 52 did not report).

Outcome data per intervention group was reported in 73/77 full-text manuscripts (5 did not report) and matched in 39 abstract-only reports (18 did not match, 20 did not report).

The reporting of these items was significantly mismatched ($p<0.001$).

Do authors' conclusions match?

Author's conclusions were reported in 77/77 full-text manuscripts and matched in 75 abstract-only reports (2 did not match, $p=0.157$).

Are mismatch justifications provided?

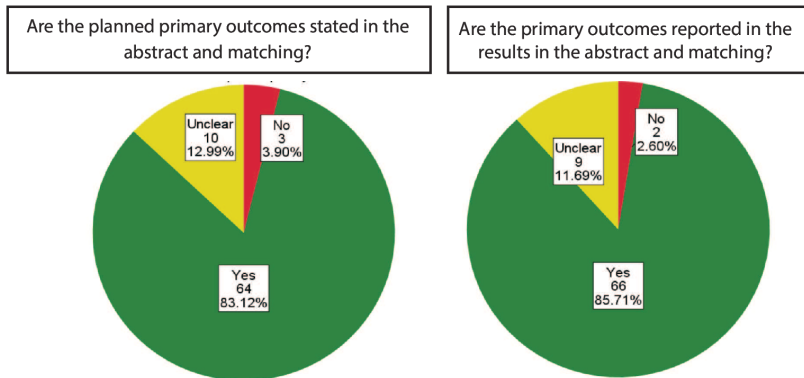
We did not come across any instances of explicit or implied justifications for the absence or non-concordance for any of the items we compared between full-text manuscripts and abstract-only reports.

Subgroup analyses

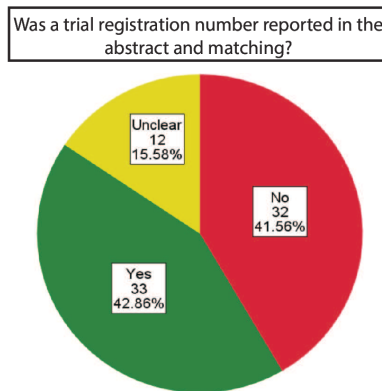
For the 48 pairs with full-text manuscript published in 2017 and later, there was no difference from the main analysis. For the 29 pairs with full-text manuscript published in 2016 or earlier, there was no statistical difference for primary outcome stating and reporting ($p=0.5$, $p=0.125$). For the other items, there was no difference from the main analysis.

For the 63 pharmacological RCTs, there were no differences from the main results. For the 14

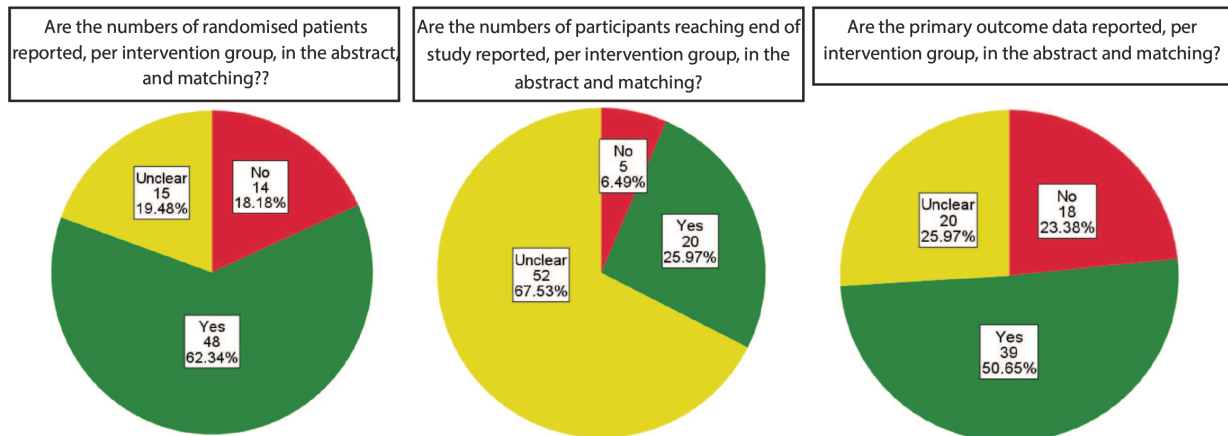
1. DO THE PLANNED PRIMARY OUTCOMES MATCH?



2. DO THE TRIAL REGISTRATIONS MATCH?



3. DO THE FLOW OF PARTICIPANTS AND OUTCOME DATA MATCH?



4. DO AUTHORS' CONCLUSIONS MATCH?

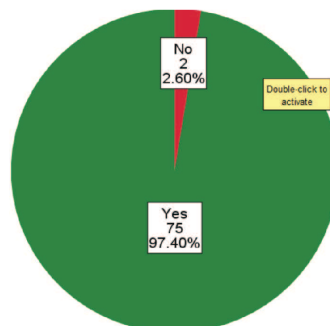


Figure 2 Reporting items compared between full-text manuscripts and abstract-only report pairs.



non-pharmacological RCTs there was no statistical difference for primary outcome stating and reporting, trial registration reporting, and reporting of randomised numbers ($p=0.125$, $p=0.125$, $p=0.125$, $p=0.063$). For the other items, there was no difference from the main analysis.

For the 42 pairs with impact factor of the full-text publication more than 20, there was no statistical difference for primary outcome stating ($p=0.063$). For the 36 pairs with impact factor of the full-text publication less than 20, there was no statistical difference for primary outcome reporting ($p=0.125$). For everything else, there was no difference from the main analysis.

For the 30 pairs with abstract-only reports published for the proceedings of the European Crohn's and Colitis Organisation (ECCO) conference, there was no statistical difference for primary outcome stating and reporting ($p=0.063$, $p=0.125$). For the 32 pairs with abstract-only reports published for the proceedings of the Digestive disease week (DDW) conference, there was no statistical difference for primary outcome stating and reporting ($p=0.25$, $p=0.25$). For the 15 pairs with abstract-only reports published elsewhere, there was no statistical difference for primary outcome stating and reporting ($p=0.125$, $p=0.25$). For everything else, there was no difference from the main analysis.

DISCUSSION

Principal findings

We found significant mismatches and omissions between full-text manuscripts and prepublication abstract-only reports of IBD RCTs, for all reporting items apart from authors' conclusions.

Our methodology has ensured these are not related to the use of different phases of a trial where data would not be expected to match, different follow-up time frames or even different subgroups and outcomes. Rather, the differences have remained unexplained by the authors, and in key areas which impact interpretation and associated quality assessment of the work.

The most stark finding is that in almost a quarter of paired texts, the main outcome data reported did not match for unexplained reasons (and for a further quarter it was unclear so a judgement could not even be made). Rather than obscure or experimental treatments, these paired publications included many treatments that are of significance to the field, often with much impact on practical prescribing level. Given the common use of these abstract texts for a significant period time by the international IBD community, this is a highly relevant finding that must be considered by all clinicians when reading such abstract forms of an RCT. While many of the differences could be explainable, the fact that this is not considered within the final publication and the abstract form is never amended or removed in the way that an RCT with incorrect data may be, forms a considerable risk to the use of such forms of evidence.

From a quality appraisal perspective, sparse or inconsistent reporting for randomised participant numbers and participant numbers reaching the end of an RCT, per intervention group, can increase the risk of reported attrition bias. For primary outcome data, it can increase the risk of selective reporting and misreporting of magnitude of effect. Insufficient statements for which outcomes an RCT planned to explore and which are actually reported, as well as for trial registration numbers in abstract-only reports, can also increase the risk of selective reporting, as it makes it difficult to ascertain whether the abstract reporting followed the plan of the RCT protocol. A common consideration is, of course, word count and readers may consider these requirements not feasible due to this reason. We believe that the minor clarification needed in several key areas is not explainable due to such issues. Rather, a lack of focus on the potential impact of such sparse reporting and how this echoes forward within the evidence base is a likely hypothesis, from both the perspective of the writer and the peer reviewer.

Combined, the issues of inconsistent key data and sparse quality reporting leave a significant source of evidence for clinicians, patients and wider stakeholders at significant risk when used in core activities to guide immediate and medium-term shifts in the ever-evolving portfolio of therapies for IBD.

Abstract-only reports are not always indexed in a fashion that highlights how they link to the many other forms of published outputs from the same single trial. This lack of a unified system that links together all published material for RCTs risks dual consideration of patient populations.

Strengths and weaknesses of the present review

This is the first study of its kind to review the concordance between full-text manuscripts and abstract-only reports in gastroenterology RCTs. It highlights key reporting areas in need of improvement, which require minimal word space, which can improve risk of bias assessments, and increase quality of RCT reporting. In turn, this will increase the precision and consistency of evidence synthesis in subsequent SRs, guidelines and clinical decision-making. Due to the already mentioned issues with a lack of a unified method of identifying trials published in different mediums, there are possible matches of full-text manuscripts and abstract-only reports we might have missed. Additionally, there are more reporting items that can be compared in addition to the ones chosen that could further illuminate the issue.

Strengths and weaknesses in relation to other studies

As far as we are aware, the topic of this review has not been reviewed in other medical areas by pairing full-text manuscripts and abstract-only reports. However, there have been other studies and reviews which have assessed the use of abstracts and abstract-only reports and their adherence to reporting standards and peer review, and have found them suboptimal^{5-9 17-20}. A recent review on trustworthiness assessment for SRs found that 25% or



RCTs included in 18 Cochrane SRs should not have been included in the reviews, due to issues around research governance, study feasibility and the plausibility of the results and reported baseline characteristics.²¹ The authors propose a formal trustworthiness assessment as part of the screening process and an inclusion criterion.

Our review focused on the role prepublication abstract-only reports play in SRs and guidelines, continuing previous work highlighting methodological flaws that can compromise evidence synthesis findings.^{11–13} Our findings add to the existing literature, suggesting there are serious issues with the trustworthiness of abstract reporting. Our subgroup analyses comparing newer to older RCTs suggest that abstract-only reporting of RCTs has may be only minimally improved with time. Further subgroup analyses suggest that whether an RCT is pharmacological or non-pharmacological, the impact factor of the full-text journal and the source of the abstract-only report, make no major difference.

Other studies could adopt our review approach in other fields gastroenterology or other medical fields, to establish the interpretability of our results more generally.

Explanations and implications for clinicians and policy-makers

The implications for clinicians and policy-makers, who rely on SRs and guidelines for decision-making, is that the certainty of the available evidence is compromised, and timely updates of the evidence basis are difficult. The use of abstract-only reports is vital for evidence synthesis and updating, as they can be the only data source from RCTs that never get fully published due to publication bias, and they are the only available data source until a full-text manuscript gets published and becomes accessible. We found that it can take up to 6 years between the publication of an abstract-only report and its full-text manuscript, while sometimes a full-text manuscript never gets published. Even when an accessible full-text manuscript is available, abstract-only reports are still accessible and might be used instead. Our findings suggest, however, that abstract-only reporting is highly capricious and calls into question whether they should be trusted and used.

Recommendations for the future

A number of simple practice changes could be implemented by different members of the research and clinical community. We believe the mandatory inclusion of trial registration numbers in all forms of trial presentation would allow easy cross-referencing and unification with little to no barriers to implementation. We also believe that the peer review systems for abstract-only publishing forums, predominately scientific meetings, could use their guidance documents or even checklists when RCTs are being submitted to ensure these bare minimum quality indices are reported. In the meantime, we would encourage all involved in evidence synthesis works and publishing reviews to consider comparisons

that are mindful of the risk from abstract-only publication to ensure that risk is mitigated at the clinical practice level. Finally, editors and peer reviewers could ensure that previous abstracts are referenced in full-text publications and differences explained. This is key as it not only helps the clinical reader but also aids transparency is a key source of trial bias (selective reporting) further enhancing the quality of the trial publication. Research could produce a simple tool to aid this reporting for use across the field. At this point in time, guideline developers and policy-makers should not make recommendations based on abstract-only reporting. However, this can still occur, which makes our recommendations even more pertinent.

Differences between protocol and review

We had originally planned to do meta-analyses for the continuous data we collected, however, we did not perform this due to the heterogeneity of the outcomes in the RCTs. We had also planned to do additional subgroup analyses for age (children vs adults), and primary outcome (induction vs maintenance vs other), however, these were not possible due to lack of adequate data. The subgroup analysis for pharmacological versus non-pharmacological interventions was planned retrospectively.

Conclusions

Abstract-only reports were demonstrated to have consistent issues with both limited reporting of key information to judge quality and significant difference in data when compared with their later full-text publications. These are not related to further recruitment of patients or word count limitations and are never explained. As abstracts are often used by clinicians and in guidelines, reviews and stakeholder decision-making on prescribing, caution when using such sources of evidence is strongly suggested. Further work is needed to enhance minimum reporting standards in abstract-only works and ensure inconsistency with final published papers is highlighted.

Acknowledgements We'd like to thank Ms Negar Sharafi for her contribution to record screening.

Contributors VS led at all stages and write-up of the project. MG conceived the project idea and led at all stages of the project and is guarantor for the data. He provided advice and feedback at all stages of the project. GWM provided advice and feedback at all stages of the project. AMAmE, SP, AR and AHAA-T contributed to screening and data extraction.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient consent for publication Not applicable.

Ethics approval This review used publicly available data and no ethics approval was necessary.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Please contact the corresponding author for data requests.

Supplemental material This content has been supplied by the author(s). It has not been vetted by BMJ Publishing Group Limited (BMJ) and may not have been

peer-reviewed. Any opinions or recommendations discussed are solely those of the author(s) and are not endorsed by BMJ. BMJ disclaims all liability and responsibility arising from any reliance placed on the content. Where the content includes any translated material, BMJ does not warrant the accuracy and reliability of the translations (including but not limited to local regulations, clinical guidelines, terminology, drug names and drug dosages), and is not responsible for any error and/or omissions arising from translation and adaptation or otherwise.

Open access This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

ORCID iDs

Vassiliki Sinopoulou <http://orcid.org/0000-0002-2831-9406>

Morris Gordon <http://orcid.org/0000-0002-1216-5158>

REFERENCES

- 1 Hariton E, Locascio JJ. Randomised controlled trials—the gold standard for effectiveness research. *BJOG* 2018;125:1716.
- 2 Raine T, Bonovas S, Burisch J, *et al.* ECCO guidelines on therapeutics in ulcerative colitis: medical treatment. *J Crohns Colitis* 2022;16:2–17.
- 3 Lamb CA, Kennedy NA, Raine T, *et al.* British society of gastroenterology consensus guidelines on the management of inflammatory bowel disease in adults. *Gut* 2019;68(Suppl 3):s1–106.
- 4 Darie A-M, Sinopoulou V, Ajay V, *et al.* BSG 2024 IBD guidelines protocol (standard operating procedures). *BMJ Open Gastroenterol* 2023;10:e001067.
- 5 Pitkin RM, Branagan MA, Burmeister LF. Accuracy of data in abstracts of published research articles. *JAMA* 1999;281:1110–1.
- 6 Mills I, Sheard C, Hays M, *et al.* Professional medical writing support and the reporting quality of randomized controlled trial abstracts among high-impact general medical journals. *F1000Res* 2017;6:1489.
- 7 Ghimire S, Kyung E, Kang W, *et al.* Assessment of adherence to the CONSORT statement for quality of reports on randomized controlled trial abstracts from four high-impact general medical journals. *Trials* 2012;13:77:1–7.
- 8 Hays M, Andrews M, Wilson R, *et al.* Reporting quality of randomised controlled trial abstracts among high-impact general medical journals: a review and analysis. *BMJ Open* 2016;6:e011082.
- 9 Janackovic K, Puljak L. Reporting quality of randomized controlled trial abstracts in the seven highest-ranking anesthesiology journals. *Trials* 2018;19:591.
- 10 Wood L, Egger M, Gluud LL, *et al.* Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study. *BMJ* 2008;336:601–5.
- 11 Gordon M, Akobeng A. The quality of reporting inflammatory bowel disease randomized control trials: a systematic review. *None* 2020.
- 12 Iheozor-Ejiogor Z, Lakunina S, Gordon M, *et al.* Sample-Size estimation is not reported in 24% of randomised controlled trials of inflammatory bowel disease: a systematic review. *United European Gastroenterol J* 2021;9:47–53.
- 13 Gordon M, Lakunina S, Sinopoulou V, *et al.* Minimum sample size estimates for trials in inflammatory bowel disease: a systematic review of a support resource. *World J Gastroenterol* 2021;27:7572–81.
- 14 Moher D, Liberati A, Tetzlaff J, *et al.* Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *Int J Surg* 2010;8:336–41.
- 15 Sinopoulou V. Pre-publication abstracts compared to full-text reports: a systematic review protocol. Clouk University of Central Lancashire depository; 2022.
- 16 Antes G. The new consort statement. *BMJ* 2010;340:bmj.c1432.
- 17 Marcelo A, Gavino A, Isip-Tan IT, *et al.* A comparison of the accuracy of clinical decisions based on full-text articles and on Journal abstracts alone: a study among residents in a tertiary care hospital. *Evid Based Med* 2013;18:48–53.
- 18 Berwanger O, Ribeiro RA, Finkelsztejn A, *et al.* The quality of reporting of trial abstracts is suboptimal: survey of major general medical journals. *J Clin Epidemiol* 2009;62:387–92.
- 19 Khan MS, Shaikh A, Ochani RK, *et al.* Assessing the quality of abstracts in randomized controlled trials published in high impact cardiovascular journals. *Circ Cardiovasc Qual Outcomes* 2019;12:e005260.
- 20 Villa M, Le Pera M, Cassina T, *et al.* Reporting quality of abstracts from randomised controlled trials published in leading critical care nursing journals: a methodological quality review. *BMJ Open* 2023;13:e070639.
- 21 Alfirevic Z, Weeks J, Cuthbert A. Trustworthiness assessment as an inclusion criterion for systematic reviews -- what is the impact on results? *Preprints* [Preprint] 2023.

Supplementary material. Full references of paired full-text manuscripts and abstract-only reports

Study ID	Full-text reference	Pre-publication abstract-only reference
Ankersen 2019	Ankersen, D.V., et al., <i>Individualized home-monitoring of disease activity in adult patients with inflammatory bowel disease can be recommended in clinical practice: A randomized-clinical trial</i> . World Journal of Gastroenterology, 2019. 25 (40): p. 6158.	Ankersen, D.V., et al., <i>DOP031 Individualised home-monitoring of disease activity in adult patients with inflammatory bowel disease can be recommended implemented in clinical practice</i> . Journal of Crohn's and Colitis, 2018. 12 (supplement_1): p. S052-S053
Armuzzi 2013	Armuzzi, A., et al., <i>Prevention of postoperative recurrence with azathioprine or infliximab in patients with Crohn's disease: an open-label pilot study</i> . Journal of Crohn's and Colitis, 2013. 7 (12): p. e623-e629	Armuzzi, A., et al., <i>Tu1231 Prevention of Postoperative Recurrence With Azathioprine or Anti-TNF Alpha in Patients With Crohn's Disease: an Open-Label Pilot Study</i> . Gastroenterology, 2012. 142 (5): p. S-780
Assa 2019 (PAILOT)	Assa, A., et al., <i>Proactive monitoring of adalimumab trough concentration associated with increased clinical remission in children with Crohn's disease compared with reactive monitoring</i> . Gastroenterology, 2019. 157 (4): p. 985-996. e2	Assa, A., et al., <i>OP18 Proactive adalimumab trough measurements increase corticosteroid-free clinical remission in paediatric patients with Crohn's disease: the paediatric Crohn's disease adalimumab-level-based optimisation treatment (PAILOT) trial</i> . Journal of Crohn's and Colitis, 2019. 13 (Supplement_1): p. S012-S013
Berding 2017	Berding, A., et al., <i>Beneficial effects of education on emotional distress, self-management, and coping in patients with inflammatory bowel disease: a prospective randomized controlled study</i> . Inflammatory intestinal diseases, 2016. 1 (4): p. 182-190	<i>P547. Effectiveness of patient education in inflammatory bowel disease</i> . Journal of Crohn's and Colitis, 2016. 10 (suppl_1): p. S378-S378
Buhl 2022	Buhl, Sine, et al. "Discontinuation of infliximab therapy in patients with Crohn's disease." <i>NEJM Evidence</i> 1.8 (2022): EVIDoA2200061. [26]	[27] Buhl, Sine, et al. "742 DISCONTINUATION OF INFLIXIMAB THERAPY IN PATIENTS WITH CROHN'S DISEASE IN SUSTAINED, COMPLETE CLINICAL-BIOCHEMICAL-ENDOSCOPIC REMISSION: A DOUBLE-BLINDED, PLACEBO-CONTROLLED, RANDOMIZED CLINICAL TRIAL."

		<i>Gastroenterology</i> 160.6 (2021): S-151.
Carlsen 2017	Carlsen, K., et al., <i>Self-managed eHealth disease monitoring in children and adolescents with inflammatory bowel disease: a randomized controlled trial.</i> <i>Inflammatory bowel diseases</i> , 2017. 23 (3): p. 357-365	<i>DOP044. Self-administered telemedicine reduces number of outpatient visits and days of absence from school in paediatric and adolescent patients with inflammatory bowel disease.</i> <i>Journal of Crohn's and Colitis</i> , 2016. 10 (suppl_1): p. S53-S53
Chen 2020 (FERGlor)	Chen, B., et al., <i>Efficacy and safety of adalimumab in Chinese patients with moderately to severely active Crohn's disease: results from a randomized trial.</i> <i>Therapeutic advances in gastroenterology</i> , 2020. 13 : p. 1756284820938960	Chen B, G.X., Zhong J, Ren J, Zhu X, Liu Z, Wu K, Kalabic J, Huang B, Doan T, Robinson AM, Chen M, <i>P0335 EFFICACY AND SAFETY OF ADALIMUMAB IN CHINESE PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE.</i> <i>United European Journal of Gastroenterology</i> , 2018. 6 : p. A240
Colombel 2010 (SONIC)	Colombel, J.F., et al., <i>Infliximab, azathioprine, or combination therapy for Crohn's disease.</i> <i>New England journal of medicine</i> , 2010. 362 (15): p. 1383-1395	Colombel, J., P. Rutgeerts, and W. Reinisch, <i>One year data from the sonic study: A randomized, double-blind trial comparing infliximab and infliximab plus azathioprine to azathioprine in patients with Crohn's disease naive to immunomodulators and biologic therapy.</i> <i>Gut</i> , 2009. 58 (Suppl II): p. A69
Cosnes 2013	Cosnes, J., et al., <i>Early administration of azathioprine vs conventional management of Crohn's disease: a randomized controlled trial.</i> <i>Gastroenterology</i> , 2013. 145 (4): p. 758-765. e2.	Cosnes, J., A. Bourrier, and Y. Bouhnik, <i>Accelerated step-care therapy with early azathioprine vs. conventional step-care therapy in Crohn's disease. A randomized study.</i> <i>Gastroenterology</i> , 2012. 142 : p. S161
Cross 2012 (UC-HAT)	Cross, R.K., et al., <i>Randomized, controlled trial of home telemanagement in patients with ulcerative colitis (UC HAT).</i> <i>Inflammatory bowel diseases</i> , 2012. 18 (6): p. 1018-1025	Cross, R., et al., <i>T1240 A Randomized, Controlled Trial of Home Telemanagement in Patients With Ulcerative Colitis (UC HAT).</i> <i>Gastroenterology</i> , 2010. 138 (5): p. S-519
D'Haens 2022 (ADVANCE)	D'Haens, Geert, et al. "Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials." <i>The Lancet</i> 399.10340 (2022): 2015-2030.	D'Haens, Geert R., et al. "775a Risankizumab induction therapy in patients with moderate-to-severe Crohn's disease with intolerance or inadequate

	[38]	response to conventional and/or biologic therapy: results from the phase 3 ADVANCE study." <i>Gastroenterology</i> 161.2 (2021): e28.[39]
D'Haens 2022 (MOTIVATE)	D'Haens, Geert, et al. "Risankizumab as induction therapy for Crohn's disease: results from the phase 3 ADVANCE and MOTIVATE induction trials." <i>The Lancet</i> 399.10340 (2022): 2015-2030	Panaccione, Remo, et al. "S754 Risankizumab as induction therapy in patients with moderately to severely active Crohn's disease who failed 1 vs> 1 prior biologic treatment: results from the MOTIVATE study." <i>Official journal of the American College of Gastroenterology ACG</i> 116 (2021): S348.[40]
D'Haens 2023 (LUCENT)	[41] D'Haens, Geert, et al. "Mirikizumab as induction and maintenance therapy for ulcerative colitis." <i>New England Journal of Medicine</i> 388.26 (2023): 2444-2455.	Andrews, J. M., et al. "Efficacy and safety of mirikizumab as induction therapy in patients with moderately to severely active ulcerative colitis: Results from the Phase 3 LUCENT-1 study." <i>JOURNAL OF GASTROENTEROLOGY AND HEPATOLOGY</i> . Vol. 37. 111 RIVER ST, HOBOKEN 07030-5774, NJ USA: WILEY, 2022.[42]
Danese 2017 (ANDANTE - induction)	Danese, S., et al., <i>Randomised trial and open-label extension study of an anti-interleukin-6 antibody in Crohn's disease (ANDANTE I and II)</i> . <i>Gut</i> , 2019. 68 (1): p. 40-48	OP015. Results of ANDANTE, a randomised clinical study with an anti-IL6 antibody (PF-04236921) in subjects with Crohn's disease who are anti-tumour necrosis factor inadequate responders. <i>Journal of Crohn's and Colitis</i> , 2016. 10 (suppl_1): p. S12-S13.
Del Hoyo 2018 (TECCU)	Del Hoyo, J., et al., <i>A web-based telemanagement system for improving disease activity and quality of life in patients with complex inflammatory bowel disease: pilot randomized controlled trial</i> . <i>Journal of medical Internet research</i> , 2018. 20 (11): p. e11602	Aguas, M., et al., <i>P227 A web-based telemanagement system for patients with complex Inflammatory Bowel Disease (TECCU): Results of a randomised controlled clinical trial</i> . <i>Journal of Crohn's and Colitis</i> , 2018. 12 (supplement_1): p. S214-S215
Evstatiev 2011	Evstatiev, R., et al., <i>FERGICor, a randomized controlled trial on ferric carboxymaltose for iron deficiency anemia in inflammatory bowel disease</i> . <i>Gastroenterology</i> , 2011. 141 (3): p. 846-853. e2	Evstatiev, R., et al., <i>Intravenously administered ferric carboxymaltose and iron sucrose significantly improve quality of life in patients with IBD-associated iron deficiency</i>

		<i>anaemia</i> . J Crohns Colitis, 2011. 5 : p. S91.
Feagan 2013 (GEMINI 1 - induction)	Feagan, B.G., et al., <i>Vedolizumab as induction and maintenance therapy for ulcerative colitis</i> . New England Journal of Medicine, 2013. 369 (8): p. 699-710	Feagan, B.G., et al., <i>943b Induction Therapy for Ulcerative Colitis: Results of GEMINI I, a Randomized, Placebo-Controlled, Double-Blind, Multicenter Phase 3 Trial</i> . Gastroenterology, 2012. 142 (5): p. S-160-S-161
Feagan 2013 (GEMINI 1 - maintenance)	Feagan, B.G., et al., <i>Vedolizumab as induction and maintenance therapy for ulcerative colitis</i> . New England Journal of Medicine, 2013. 369 (8): p. 699-710	Feagan, B., et al., <i>Vedolizumab Maintenance Therapy for Ulcerative Colitis: Results of GEMINI I, a Randomized, Placebo-Controlled, Double-Blind, Multicenter Phase 3 Trial: 1522</i> . Official journal of the American College of Gastroenterology ACG, 2012. 107 : p. S609-S610
Feagan 2014	Feagan, B.G., et al., <i>Methotrexate in combination with infliximab is no more effective than infliximab alone in patients with Crohn's disease</i> . Gastroenterology, 2014. 146 (3): p. 681-688. e1	Feagan, B., et al., <i>A randomized trial of methotrexate in combination with infliximab for the treatment of Crohn's disease</i> . Gastroenterology, 2008. 135 (1): p. 294-295
Feagan 2017	Feagan, B.G., et al., <i>Induction therapy with the selective interleukin-23 inhibitor risankizumab in patients with moderate-to-severe Crohn's disease: a randomised, double-blind, placebo-controlled phase 2 study</i> . The Lancet, 2017. 389 (10080): p. 1699-1709	Feagan, B., et al., <i>Efficacy and safety of induction therapy with the selective IL-23 inhibitor risankizumab (BI 655066), in patients with moderate-to-severe Crohn's disease: results of a randomized, double-blind, placebo-controlled phase II study</i> . Digestive Disease Week, San Diego, USA, 2016.
Flourié 2013 (MOTUS)	<i>Randomised clinical trial: once-vs. twice-daily prolonged-release mesalazine for active ulcerative colitis</i> . Alimentary pharmacology & therapeutics, 2013. 37 (8): p. 767-775	Flourie, B., et al., <i>1097 Once-Daily Versus Twice-Daily Mesalazine for Active Ulcerative Colitis: Efficacy Results From MOTUS, a Multicentre, Controlled, Randomised, Investigator-Blinded Study</i> . Gastroenterology, 2012. 5 (142): p. S-197
Gasche 2015	Gasche, C., et al., <i>Ferric maltol is effective in correcting iron deficiency anemia in patients with inflammatory bowel disease: results from a phase-3 clinical trial program</i> . Inflammatory bowel diseases, 2015. 21 (3): p. 579-588	Gasche, C., et al., <i>DOP079 Correcting iron deficiency anaemia in IBD: A pivotal phase 3 study of a novel oral ferric iron</i> . Journal of Crohn's and

		Colitis, 2014. 8 (Supplement_1): p. S53-S53.
Hanauer 2021 (VOLTAIRE-CD)	Hanauer, S., et al., <i>Safety and efficacy of BI 695501 versus adalimumab reference product in patients with advanced Crohn's disease (VOLTAIRE-CD): a multicentre, randomised, double-blind, phase 3 trial</i> . The Lancet Gastroenterology & Hepatology, 2021. 6 (10): p. 816-825.	[61] Hanauer, S.B., et al., <i>Tu1862 BI 695501 DEMONSTRATES SIMILAR EFFICACY AND COMPARABLE SAFETY TO ADALIMUMAB REFERENCE PRODUCT IN PATIENTS WITH ACTIVE CROHN'S DISEASE: FINAL ANALYSIS OF THE PHASE III VOLTAIRE-CD STUDY</i> . Gastroenterology, 2020. 158 (6): p. S-1192-S-1193
Hawthorne 2012	Hawthorne, B.A., et al., <i>One-year investigator-blind randomized multicenter trial comparing Asacol 2.4 g once daily with 800 mg three times daily for maintenance of remission in ulcerative colitis</i> . Inflammatory Bowel Diseases, 2012. 18 (10): p. 1885-1893.	Hawthorne, A.B., et al., <i>Once daily mesalazine as maintenance therapy for ulcerative colitis (UC): a one-year single-blind randomised trial</i> . Gastroenterology, 2011. 5 (140): p. S-65
Heida 2018	Heida, A., et al., <i>Efficacy of home telemonitoring versus conventional follow-up: a randomized controlled trial among teenagers with inflammatory bowel disease</i> . Journal of Crohn's and Colitis, 2018. 12 (4): p. 432-441.	Heida A, D.A., Muller Kobold A, Kindermann A, Kokke F, de Meij T, Norbruis O, Wessels M, Hummel T, Escher H, van Wering H, Hendriks D, Mearin L, Groen H, Verkade H, van Rheenen P, <i>OP05. Telemonitoring versus usual care: a multicenter trial among teenagers with inflammatory bowel disease</i> . 4th International Symposium on Pediatric Inflammatory Bowel Disease, 2017. 65 : p. S3
Herfarth 2018 (MERIT-UC)	Herfarth, H., et al., <i>Methotrexate is not superior to placebo in maintaining steroid-free response or remission in ulcerative colitis</i> . Gastroenterology, 2018. 155 (4): p. 1098-1108. e9	Herfarth, H., et al., <i>P390 Methotrexate is not superior to placebo in maintaining remission in patients with ulcerative colitis: results from the MERIT-UC study</i> . Journal of Crohn's and Colitis, 2018. 12 (supplement_1): p. S300-S301
Howaldt 2022	Howaldt, Stefanie, et al. "Long-Term effectiveness of oral ferric maltol vs intravenous ferric carboxymaltose for the treatment of iron-deficiency anemia in patients with inflammatory bowel disease: a randomized controlled Noninferiority trial."	Howaldt, S., et al. "Oral ferric maltol versus intravenous ferric carboxymaltose for the treatment of iron-deficiency anaemia in patients with inflammatory bowel disease: a multicentre phase 3b, open-

	Inflammatory Bowel Diseases 28.3 (2022): 373-384.[68]	label randomised controlled trial." <i>United European Gastroenterol J</i> 7 (2019).[69]
Jørgensen 2017 (NOR-SWITCH)	Jørgensen, K.K., et al., <i>Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial</i> . The Lancet, 2017. 389 (10086): p. 2304-2316	Goll GL, O.I., Jorgensen KK, Lorentzen M, Bolstad N, Haavardsholm EA, Lundin KE, Mork C, Jahnsen J, Kvien TK, <i>Biosimilar Infliximab (CT-P13) Is Not Inferior to Originator Infliximab: Results from a 52-Week Randomized Switch Trial in Norway [abstract]</i> . Arthritis Rheumatol, 2016. 68
Lawrance 2017	Lawrance, I.C., et al., <i>Efficacy of rectal tacrolimus for induction therapy in patients with resistant ulcerative proctitis</i> . Clinical Gastroenterology and Hepatology, 2017. 15 (8): p. 1248-1255	Lawrance, I.C., et al., <i>OP007 A multi-centre double blind randomised placebo-controlled study of the use of rectal tacrolimus in the treatment of resistant ulcerative proctitis</i> . Journal of Crohn's and Colitis, 2017. 11 (suppl_1): p. S4-S5
Levine 2019	Levine, A., et al., <i>Crohn's disease exclusion diet plus partial enteral nutrition induces sustained remission in a randomized controlled trial</i> . Gastroenterology, 2019. 157 (2): p. 440-450. e8	van Limbergen, J.E., et al.; <i>Crohn's Disease Exclusion Diet is Equally Effective But Better Tolerated Than Exclusive Enteral Nutrition for Induction of Remission in Mild-To-Moderate Pediatric Crohn's Disease: A Prospective Randomized Controlled Trial</i> . Gastroenterology, 2019. 156 (6): p. S-59
Lie 2020	Lie, M.R., et al., <i>No superiority of tacrolimus suppositories vs beclomethasone suppositories in a randomized trial of patients with refractory ulcerative proctitis</i> . Clinical Gastroenterology and Hepatology, 2020. 18 (8): p. 1777-1784. e2	Kreijne, J.E., et al., <i>DOP022 Tacrolimus suppositories as induction therapy for refractory ulcerative proctitis: a randomised controlled trial</i> . Journal of Crohn's and Colitis, 2018. 12 (supplement_1): p. S045-S045
Luglio 2020 (SuPREMe-CD)	Luglio, G., et al., <i>Surgical prevention of anastomotic recurrence by excluding mesentery in Crohn's disease: the SuPREMe-CD study-a randomized clinical trial</i> . Annals of surgery, 2020. 272 (2): p. 210-217	Luglio, G., et al., <i>OP18 Surgical prevention of anastomotic recurrence by excluding mesentery in Crohn's disease: The SuPREMe-CD study</i> . Journal of Crohn's and Colitis, 2020. 14 (Supplement_1): p. S015-S016
Mañosa 2013	Mañosa, M., et al., <i>Addition of metronidazole to azathioprine for the prevention of postoperative recurrence of</i>	Mañosa, M., et al., <i>P210 Azathioprine versus azathioprine plus metronidazole</i>

	<i>Crohn's disease: a randomized, double-blind, placebo-controlled trial.</i> Inflammatory Bowel Diseases, 2013. 19 (9): p. 1889-1895	<i>for the prevention of postoperative endoscopic recurrence of Crohn's disease: A randomized, placebo-controlled trial.</i> Journal of Crohn's and Colitis, 2012. 6 (Supplement_1): p. S93-S93
Matsumoto 2016	Matsumoto, Takayuki, et al. "Adalimumab monotherapy and a combination with azathioprine for Crohn's disease: a prospective, randomized trial." <i>Journal of Crohn's and Colitis</i> 10.11 (2016): 1259-1266. [82]	[83] Matsumoto, T., et al. "Comparison of adalimumab monotherapy and a combination with azathioprine for patients with Crohn's disease: a prospective, multicentre, open-labelled clinical trial (DIAMOND study)." <i>J Crohns Colitis</i> 10 (2016): S8.
McCombie 2020	McCombie, A., et al., <i>A noninferiority randomized clinical trial of the use of the smartphone-based health applications IBDsmart and IBDoc in the care of inflammatory bowel disease patients.</i> Inflammatory bowel diseases, 2020. 26 (7): p. 1098-1109	Walmsley, R., et al., <i>P630 A non-inferiority randomised clinical trial of the use of the smartphone-based health applications IBDsmart and IBDoc® in the care of inflammatory bowel disease patients.</i> Journal of Crohn's and Colitis, 2019. 13 (Supplement_1): p. S432-S433
Mowat 2016 (TOPPIC)	Mowat, C., et al., <i>Mercaptopurine versus placebo to prevent recurrence of Crohn's disease after surgical resection (TOPPIC): a multicentre, double-blind, randomised controlled trial.</i> The lancet Gastroenterology & hepatology, 2016. 1 (4): p. 273-282	Arnott, I., et al. <i>The TOPPIC Trial: a randomised, double-blind parallel-group trial of mercaptopurine versus placebo to prevent recurrence of Crohn's disease following surgical resection in 240 patients.</i> in <i>JOURNAL OF CROHNS & COLITIS</i> . 2016. OXFORD UNIV PRESS GREAT CLARENDON ST, OXFORD OX2 6DP, ENGLAND
Motoya 2019 (induction)	Motoya, S., et al., <i>Vedolizumab in Japanese patients with ulcerative colitis: a phase 3, randomized, double-blind, placebo-controlled study.</i> PLoS One, 2019. 14 (2): p. e0212989	Watanabe, M., et al., <i>Sa1751 - A Phase 3 Study of Vedolizumab for Induction and Maintenance Therapy in Japanese Patients with Moderately to Severely Active Ulcerative Colitis.</i> Gastroenterology, 2018. 154 (6): p. S-380-S-381
Motoya 2019 (maintenance)	Motoya, S., et al., <i>Vedolizumab in Japanese patients with ulcerative colitis: a phase 3, randomized, double-blind, placebo-</i>	Watanabe, M., et al., <i>Sa1751 - A Phase 3 Study of Vedolizumab for Induction and Maintenance Therapy in Japanese Patients</i>

	<i>controlled study</i> . PLoS One, 2019. 14 (2): p. e0212989	<i>with Moderately to Severely Active Ulcerative Colitis</i> . Gastroenterology, 2018. 154 (6): p. S-380-S-381
Naganuma 2017 (INDIGO)	Naganuma, M., et al., <i>Efficacy of indigo naturalis in a multicenter randomized controlled trial of patients with ulcerative colitis</i> . Gastroenterology, 2018. 154 (4): p. 935-947.	Naganuma M, S.S., Mitsuyama K, Kobayashi T, Yoshimura N, Matsuoka K, Hisamatsu T, Watanabe K, Abe T, Suzuki Y, Hibi T, Kanai T, <i>OP098 INDIGO NATURALIS IS EFFECTIVE FOR INDUCING CLINICAL REMISSION AND MUCOSAL HEALING IN PATIENTS WITH ULCERATIVE COLITIS (INDIGO STUDY)</i> . United European Journal of Gastroenterology, 2017. 5 : p. A41-2
Nikolaus 2017	Nikolaus, S., et al., <i>Patient education in a 14-month randomised trial fails to improve adherence in ulcerative colitis: influence of demographic and clinical parameters on non-adherence</i> . Journal of Crohn's and Colitis, 2017. 11 (9): p. 1052-1062	Nikolaus, S., et al., <i>DOP044 Patient education in a 14 month randomized trial fails to improve adherence in ulcerative colitis: Influence of demographic and clinical parameters on non-adherence</i> . Journal of Crohn's and Colitis, 2014(8): p. S36
Ozgursoy-Uran 2019	Uran, B.N.O., S. Aykar, and Y. Yildirim, <i>The effect of web-based education on disease activity, symptom management and quality of life in patients with inflammatory bowel disease: randomized-controlled study</i> . Medical Science, 2019. 23 (98): p. 415-431	Ozgursoy Uran, B.N., et al., <i>N031 The effect of web-based education on disease activity, symptom management, and quality of life on patients with inflammatory bowel disease</i> . Journal of Crohn's and Colitis, 2018. 12 (supplement_1): p. S582-S582
Panes 2017	Panés, J., et al., <i>Tofacitinib for induction and maintenance therapy of Crohn's disease: results of two phase IIb randomised placebo-controlled trials</i> . Gut, 2017. 66 (6): p. 1049-1059.	Panés, J., et al., <i>855 Efficacy and Safety of Tofacitinib for Oral Induction Therapy in Patients With Moderate to Severe Crohn's Disease: Results of a Phase 2B Randomized Placebo-Controlled Trial</i> . Gastroenterology, 2016. 150 (4): p. S182-S183.
Panes 2022	Panés, J., Colombel, J. F., D'Haens, G. R., Schreiber, S., Panaccione, R., Peyrin-Biroulet, L., ... & Sandborn, W. J. (2022). Higher vs standard adalimumab induction and maintenance dosing regimens for treatment of ulcerative colitis: SERENE UC trial results. <i>Gastroenterology</i> , 162 (7), 1891-1910.	[99] Colombel, J. F., et al. "OP01 Higher vs. standard adalimumab maintenance regimens in patients with moderately to severely active ulcerative colitis: Results from the SERENE-UC maintenance study." <i>Journal of Crohn's and Colitis</i>

	[98]	14.Supplement_1 (2020): S001-S001.
Park 2019	Park, S.-K., et al., <i>Adherence to Asacol once daily versus divided regimen for maintenance therapy in ulcerative colitis: a prospective, multicenter, randomized study.</i> Intestinal research, 2019. 17 (3): p. 349-356	Park, S.-K., et al., <i>P517 The effects and adherence of Asacol® comparing 2.4 g once daily with 800 mg three times or 1200 mg twice daily for maintain therapy in the ulcerative colitis: Prospective multicentre randomised study.</i> Journal of Crohn's and Colitis, 2018. 12 (supplement_1): p. S367-S367
Petersen 2014	Petersen, A.M., et al., <i>Ciprofloxacin and probiotic Escherichia coli Nissle add-on treatment in active ulcerative colitis: a double-blind randomized placebo controlled clinical trial.</i> Journal of Crohn's and Colitis, 2014. 8 (11): p. 1498-1505	Petersen, A.M., et al., <i>Mo1227 Ciprofloxacin and Probiotic Escherichia coli Nissle As Add-on Treatment in Active Ulcerative Colitis; a Double-Blinded Randomized Placebo Controlled Clinical Trial.</i> Gastroenterology, 2014. 146 (5): p. S-591
Reich 2019 (Mychart-Epic)	Reich, J., et al., <i>The use of An EHR patient portal (Mychart-Epic) in patients with inflammatory bowel disease.</i> Crohn's & Colitis 360, 2019. 1 (3): p. otz039.	Reich, J., et al., <i>The Use of an EMR Patient Portal (MYCHART-EPIC) in Patients With Inflammatory Bowel Disease: Preliminary Results of a Randomized Clinical Trial: 609.</i> Official journal of the American College of Gastroenterology ACG, 2018. 113 : p. S349
Roblin 2019	Roblin, X., et al., <i>Addition of azathioprine to the switch of anti-TNF in patients with IBD in clinical relapse with undetectable anti-TNF trough levels and antidrug antibodies: a prospective randomised trial.</i> Gut, 2020. 69 (7): p. 1206-1212	Roblin, X., et al., <i>345 - Interest in the Addition of Azathioprine (AZA) to the Switch of Anti-TNF in IBD Patients in Clinical Relapse with Undetectable Anti-TNF trough Levels and Anti-Drug Antibodies: A Prospective Randomized Trial.</i> Gastroenterology, 2018. 154 (6): p. S-84.
Rutgeerts 2012 (EXTEND)	Rutgeerts, P., et al., <i>Adalimumab induces and maintains mucosal healing in patients with Crohn's disease: data from the EXTEND trial.</i> Gastroenterology, 2012. 142 (5): p. 1102-1111. e2.	Colombel, J.-F., et al., <i>T1239 Adalimumab Treatment Results in Deep Remission for Patients With Moderate to Severe Ileocolonic Crohn's Disease: Results</i>

		From <i>EXTEND</i> . Gastroenterology, 2010. 138 (5): p. S-518.
Sandborn 2010 (WELCOME)	Sandborn, W.J., et al., <i>Certolizumab pegol in patients with moderate to severe Crohn's disease and secondary failure to infliximab</i> . Clinical Gastroenterology and Hepatology, 2010. 8 (8): p. 688-695. e2	Sandborn, W.J., et al., <i>143 Welcome: A Randomized, Double-Blind, Controlled Trial Comparing Certolizumab Pegol 400 Mg Every 2 Weeks with Every 4 Weeks for Maintenance of Response and Remission in Patients with Moderate to Severe Crohn's Disease with Secondary Failure to Infliximab</i> . Gastroenterology, 2009. 5 (136): p. A-27
Sandborn 2011	Sandborn, W.J., et al., <i>Certolizumab pegol for active Crohn's disease: a placebo-controlled, randomized trial</i> . Clinical gastroenterology and hepatology, 2011. 9 (8): p. 670-678. e3	Sandborn, W., et al., <i>Induction Therapy with Certolizumab Pegol in Patients with Moderate to Severe Crohn's Disease: A Placebo-Controlled Trial: 1156</i> . Official journal of the American College of Gastroenterology ACG, 2010. 105 : p. S419
Sandborn 2012	Sandborn, W.J., et al., <i>Once-daily budesonide MMX[®] extended-release tablets induce remission in patients with mild to moderate ulcerative colitis: results from the CORE I study</i> . Gastroenterology, 2012. 143 (5): p. 1218-1226. e2	Sandborn, W.J., et al., <i>Budesonide Mxx[®] 9 mg for the Induction of Remission of Mild-to-Moderate Ulcerative Colitis (UC): Data From a Multicenter, Randomized, Double-Blind Placebo-Controlled Study in North America and India</i> . Gastroenterology, 2011. 5 (140): p. S-124.
Sandborn 2012 (CERTIFI- induction)	Sandborn, W.J., et al., <i>Ustekinumab induction and maintenance therapy in refractory Crohn's disease</i> . New England Journal of Medicine, 2012. 367 (16): p. 1519-1528	Sandborn, W.J., et al., <i>A multicenter, randomized, double-blind, placebo-controlled phase2b Study of Ustekinumab, a human monoclonal antibody to IL-12/23p40, in patients with moderately to severely active Crohn's disease: results through week 22 from the certifi trial</i> . Gastroenterology, 2011. 140 (5): p. S109-S109
Sandborn 2012 (CERTIFI- maintenance)	Sandborn, W.J., et al., <i>Ustekinumab induction and maintenance therapy in refractory Crohn's disease</i> . New England Journal of Medicine, 2012. 367 (16): p. 1519-1528	Sandborn, W.J., et al., <i>A multicenter, randomized, double-blind, placebo-controlled phase2b Study of Ustekinumab, a human monoclonal antibody to IL-12/23p40, in patients with</i>

		<i>moderately to severely active Crohn's disease: results through week 22 from the certifi trial. Gastroenterology, 2011. 140(5): p. S109-S109</i>
Sandborn 2013 (GEMINI 2-induction)	Sandborn, W.J., et al., <i>Vedolizumab as induction and maintenance therapy for Crohn's disease. New England Journal of Medicine, 2013. 369(8): p. 711-721</i>	Hanauer, S.B., et al., <i>Tu1138 Efficacy of Vedolizumab in Crohn's disease by prior treatment failure in Gemini II, a randomized, placebo-controlled, double-blind, multicenter study. Gastroenterology, 2013. 5(144): p. S-772.</i>
Sandborn 2013 (GEMINI 2maintenance)	Sandborn, W.J., et al., <i>Vedolizumab as induction and maintenance therapy for Crohn's disease. New England Journal of Medicine, 2013. 369(8): p. 711-721</i>	Rutgeerts, P.J., et al., <i>Sustained Therapeutic Benefit of Vedolizumab Throughout 1 Year in Crohn's Disease in Gemini II, a Randomized, Placebo-Controlled, Double-Blind, Multicenter Study. Gastroenterology, 2013. 144(5): p. S21-S21</i>
Sandborn 2019	Sandborn, W.J., et al., <i>Efficacy and safety of mirikizumab in a randomized phase 2 study of patients with ulcerative colitis. Gastroenterology, 2020. 158(3): p. 537-549. e10.</i>	Sandborn, W.J., et al., <i>882-Efficacy and safety of anti-interleukin-23 therapy with mirikizumab (Ly3074828) in patients with moderate-to-severe ulcerative colitis in a phase 2 study. Gastroenterology, 2018. 154(6): p. S-1360-S-1361</i>
Sandborn 2020 (CELEST)	[123] Sandborn, W.J., et al., <i>Efficacy and safety of upadacitinib in a randomized trial of patients with Crohn's disease. Gastroenterology, 2020. 158(8): p. 2123-2138. e8</i>	Panes, J., et al., <i>P273 Efficacy and safety of upadacitinib maintenance treatment for moderate to severe Crohn's disease: Results from the CELEST study. Journal of Crohn's and Colitis, 2018. 12(supplement_1): p. S238-S239</i>
Sandborn 2022 (GALAXI-1)	Sandborn, W.J., et al., <i>Guselkumab for the treatment of Crohn's disease: induction results from the phase 2 GALAXI-1 study. Gastroenterology, 2022. 162(6): p. 1650-1664. e8.</i>	Sandborn, W., et al., <i>The efficacy and safety OF guselkumab induction therapy IN patients with moderately to severely active CROHN'S disease: week 12 interim analyses from the phase 2 GALAXI 1 study. United Eur</i>

		Gastroenterol J, 2020. 8 (8S): p. 64.
Sandborn 2022 (BERGAMOT Cohort 1)	[127] Sandborn, William J., et al. "Etrolizumab as induction and maintenance therapy in patients with moderately to severely active Crohn's disease (BERGAMOT): a randomised, placebo-controlled, double-blind, phase 3 trial." <i>The Lancet Gastroenterology & Hepatology</i> 8.1 (2023): 43-55.	William, Sandborn, et al. "Etrolizumab as Induction Therapy in Moderate to Severe Crohn's Disease: Results From BERGAMOT Cohort 1: P-011." <i>Official journal of the American College of Gastroenterology ACG 113</i> (2018): S3. [128]
Sands 2014 (GEMINI 3)	Sands, B.E., et al., <i>Effects of vedolizumab induction therapy for patients with Crohn's disease in whom tumor necrosis factor antagonist treatment failed.</i> <i>Gastroenterology</i> , 2014. 147 (3): p. 618-627. e3	Sands, B., et al., <i>11 Vedolizumab induction therapy for patients with Crohn's disease and prior anti-tumour necrosis factor antagonist failure: a randomised, placebo-controlled, double-blind, multicentre trial.</i> <i>Journal of Crohn's and Colitis</i> , 2013. 7 (Supplement_1): p. S5-S6.
Sands 2019 (UNIFI)	Sands, B.E., et al., <i>Ustekinumab as induction and maintenance therapy for ulcerative colitis.</i> <i>New England Journal of Medicine</i> , 2019. 381 (13): p. 1201-1214.	Sands, B., et al., <i>Safety and efficacy of ustekinumab induction therapy in patients with moderate to severe ulcerative colitis: results from the Phase 3 UNIFI study.</i> <i>United European Gastroenterol J</i> , 2018. 6 (8 suppl).
Sands 2019 (VARSITY)	Sands, B.E., et al., <i>Vedolizumab versus adalimumab for moderate-to-severe ulcerative colitis.</i> <i>New England Journal of Medicine</i> , 2019. 381 (13): p. 1215-1226	Schreiber, S., et al., <i>OP34 VARSITY: a double-blind, double-dummy, randomised, controlled trial of vedolizumab versus adalimumab in patients with active ulcerative colitis.</i> <i>Journal of Crohn's and Colitis</i> , 2019. 13 (Supplement_1): p. S612-S613.
Sands 2022 (SEAVUE - maintenance)	Sands, Bruce E., et al. "Ustekinumab versus adalimumab for induction and maintenance therapy in biologic-naive patients with moderately to severely active Crohn's disease: a multicentre, randomised, double-blind, parallel-group, phase 3b trial." <i>The Lancet</i> 399.10342 (2022): 2200-2211.[135]	Sands, Bruce E., et al. "775d Ustekinumab versus adalimumab for induction and maintenance therapy in moderate-to-severe Crohn's disease: the SEAVUE study." <i>Gastroenterology</i> 161.2 (2021): e30-e31.[136]
Schreiber 2018	Schreiber, S., et al., <i>A phase 2, randomized, placebo-controlled study evaluating matrix</i>	Schreiber S, S.C., Friedenber K, Seidler U, Bhandari BR ,Younes

	<i>metalloproteinase-9 inhibitor, andecaliximab, in patients with moderately to severely active Crohn's disease.</i> Journal of Crohn's and Colitis, 2018. 12 (9): p. 1014-1020	Z, Wang K, Mckevitt M, Zhao S, Kanwar B, Sundry J, Lee SD, Loftus Jr EV, ANDECALIXIMAB (ANTI-MMP9) INDUCTION THERAPY FOR CROHN'S DISEASE: A DOUBLE-BLIND, RANDOMIZED, PLACEBO-CONTROLLED, PHASE 2 STUDY. United Eur Gastroenterol J, 2017. 5 : p. A302-3
Schwartz 2021 (ENTERPRISE)	Schwartz, D.A., et al., <i>Efficacy and safety of 2 vedolizumab intravenous regimens for perianal fistulizing Crohn's disease: ENTERPRISE study.</i> Clinical Gastroenterology and Hepatology, 2022. 20 (5): p. 1059-1067. e9.	Schwartz, D.A., et al. <i>Efficacy and Safety of 2 Vedolizumab Iv Regimens in Patients with Perianal Fistulizing Crohn's Disease: Results of the Enterprise Study.</i> in <i>Gastroenterology.</i> 2020
Travis 2014 (CORE II)	Travis, S.P., et al., <i>Once-daily budesonide MMX in active, mild-to-moderate ulcerative colitis: results from the randomised CORE II study.</i> Gut, 2014. 63 (3): p. 433-441.	Sandborn, W.J., et al. <i>Budesonide-MMx[®] 9 mg for induction of remission of mild-to-moderate ulcerative colitis (UC): data from a multicenter, randomized, double-blind placebo-controlled study in the Europe, Russia, Israel and Australia.</i> in <i>Gastroenterology: Conference on Digestive Disease Week 2011: Abstract Supplement: Chicago, IL, May 07-10, 2011/AGA (American Gastroenterological Association) Institute. Philadelphia, PA: WB Saunders, 2011, vol. 140, iss. 5, suppl. 1, May. 2011</i>
Turner 2017	Turner, D., et al., <i>Once-versus twice-daily mesalazine to induce remission in paediatric ulcerative colitis: a randomised controlled trial.</i> Journal of Crohn's and Colitis, 2017. 11 (5): p. 527-533.	Turner, D., et al. <i>Once versus twice daily mesalazine to induce remission in paediatric ulcerative colitis: an investigator-initiated randomised controlled trial.</i> in <i>JOURNAL OF CROHNS & COLITIS.</i> 2016
VanAssche 2012 (SWITCH)	Van Assche, G., et al., <i>Switch to adalimumab in patients with Crohn's</i>	Van Assche, G.A., et al., <i>645 Switch to Adalimumab in</i>

	<i>disease controlled by maintenance infliximab: prospective randomised SWITCH trial.</i> Gut, 2012. 61 (2): p. 229-234.	<i>Patients With Crohn's Disease Controlled by Maintenance Infliximab. the Prospective Randomized Switch Study.</i> Gastroenterology, 2010. 138 (5): p. S-85.
Vaz 2019 (NEAT)	Vaz, K.K., et al., <i>Evaluation of a novel educational tool in adolescents with inflammatory bowel disease: the neat study.</i> Journal of pediatric gastroenterology and nutrition, 2019. 69 (5): p. 564	Vaz KH, Z.Y., Denson LA, Hommel KA, <i>Evaluation of a Novel Educational Tool in Adolescents With Inflammatory Bowel Disease: The NEAT Study.</i> Journal of pediatric gastroenterology and nutrition, 2016. 63 : p. S66.
Vermeire 2017 (FITZROY)	Vermeire, S., et al., <i>Clinical remission in patients with moderate-to-severe Crohn's disease treated with filgotinib (the FITZROY study): results from a phase 2, double-blind, randomised, placebo-controlled trial.</i> The Lancet, 2017. 389 (10066): p. 266-275.	Vermeire, S., et al., <i>812c Filgotinib (GLPG0634), an Oral JAK1 Selective Inhibitor, Induces Clinical Remission in Patients With Moderate-to-Severe Crohn's Disease: Results From the Phase 2 FITZROY Study Interim Analysis.</i> Gastroenterology, 2016. 150 (4): p. S1267.
Vogelaar 2013	Vogelaar, L., et al., <i>Fatigue management in patients with IBD: a randomised controlled trial.</i> Gut, 2014. 63 (6): p. 911-918.	Vogelaar, L., et al., <i>P503 Fatigue in IBD patients decreases with psychotherapy: results of a randomized controlled trial.</i> Journal of Crohn's and Colitis, 2013(7): p. S211-S212.
Volz 2016	Volz, M.S., A. Farmer, and B. Siegmund, <i>Reduction of chronic abdominal pain in patients with inflammatory bowel disease through transcranial direct current stimulation: a randomized controlled trial.</i> Pain, 2016. 157 (2): p. 429-437.	Pruess, M., A. Farmer, and B. Siegmund. <i>Inflammatory bowel disease-induced chronic abdominal pain can be ameliorated by transcranial direct current stimulation.</i> in JOURNAL OF CROHNS & COLITIS. 2016.
Watanabe 2012	Watanabe, M., et al., <i>Adalimumab for the induction and maintenance of clinical remission in Japanese patients with Crohn's disease.</i> Journal of Crohn's and Colitis, 2012. 6 (2): p. 160-173.	Hibi, T., et al., <i>Efficacy and Safety of Adalimumab for the Treatment of Japanese Patients with Moderately to Severely Active Crohn's Disease: Results from a Randomized Controlled Trial: 1061.</i> Official journal of the American College of Gastroenterology ACG, 2008. 103 : p. S414-S415

Watanabe 2020 (induction)	Watanabe, K., et al., <i>Effects of vedolizumab in Japanese patients with Crohn's disease: a prospective, multicenter, randomized, placebo-controlled phase 3 trial with exploratory analyses</i> . Journal of gastroenterology, 2020. 55 : p. 291-306.	Ogata, H., et al., <i>Tu1746 &#x2013; A Phase 3 Study of Vedolizumab for Induction and Maintenance Therapy in Japanese Patients with Moderate to Severe Crohn's Disease</i> . Gastroenterology, 2019. 156 (6): p. S-1109.
Watanabe 2020 (maintenance)	Watanabe, K., et al., <i>Effects of vedolizumab in Japanese patients with Crohn's disease: a prospective, multicenter, randomized, placebo-controlled phase 3 trial with exploratory analyses</i> . Journal of gastroenterology, 2020. 55 : p. 291-306.	Ogata, H., et al., <i>Tu1746 &#x2013; A Phase 3 Study of Vedolizumab for Induction and Maintenance Therapy in Japanese Patients with Moderate to Severe Crohn's Disease</i> . Gastroenterology, 2019. 156 (6): p. S-1109.
Weizman 2019	Weizman, A.V., et al., <i>Providing Hospitalized Ulcerative Colitis Patients With Practice Guidelines Improves Patient-Reported Outcomes</i> . Journal of the Canadian Association of Gastroenterology, 2021. 4 (3): p. 131-136.	Weizman, A.V., et al., <i>Sa1863 &#x2013; Patient Empowerment Through an Educational Intervention Improves Patient Satisfaction and Trust in Physician Among Hospitalized Patients with Ulcerative Colitis</i> . Gastroenterology, 2019. 156 (6): p. S-432-S-433.
Ye 2019	Ye, B.D., et al., <i>Efficacy and safety of biosimilar CT-P13 compared with originator infliximab in patients with active Crohn's disease: an international, randomised, double-blind, phase 3 non-inferiority study</i> . The Lancet, 2019. 393 (10182): p. 1699-1707.	Ye, B.D., et al., <i>814 - Phase Iii Randomized Controlled Trial to Compare Biosimilar Infliximab (CT-P13) with Innovator Infliximab in Patients with Active Crohn's Disease: 1-Year Maintenance and Switching Results</i> . Gastroenterology, 2018. 154 (6): p. S-167-S-168.

Appendix

EMBASE search (n=9605)

- 1 exp *Inflammatory Bowel Disease/ or (Inflammatory Bowel Disease* or IBD or Crohn* or Colitis or Enteritis or Proctocolitis or Colorectitis or Ileocolitis).ti,ab.
- 2 Randomized controlled trial/ or Controlled clinical study/ or randomization/ or intermethod comparison/ or double blind procedure/ or human experiment/ or (random\$ or placebo or (open adj label) or ((double or single or doubly or singly) adj (blind or blinded or blindly)) or parallel group\$1 or crossover or cross over or ((assign\$ or match or matched or allocation) adj5 (alternate or group\$1 or intervention\$1 or patient\$1 or subject\$1 or participant\$1)) or assigned or allocated or (controlled adj7 (study or design or trial)) or volunteer or volunteers).ti,ab. or (compare or compared or comparison or trial).ti. or ((evaluated or evaluate or evaluating or assessed or assess) and (compare or compared or comparing or comparison)).ti,ab.
- 3 (random\$ adj sampl\$ adj7 ("cross section\$" or questionnaire\$1 or survey\$ or database\$1)).ti,ab. not (comparative study/ or controlled study/ or randomi?ed controlled.ti,ab. or randomly assigned.ti,ab.)
- 4 Cross-sectional study/ not (randomized controlled trial/ or controlled clinical study/ or controlled study/ or (randomi?ed controlled or control group\$1).ti,ab.)
- 5 (((case adj control\$) and random\$) not randomi?ed controlled).ti,ab.
- 6 (Systematic review not (trial or study)).ti.
- 7 (nonrandom\$ not random\$).ti,ab.
- 8 ("Random field\$" or (random cluster adj3 sampl\$)).ti,ab.
- 9 (review.ab. and review.pt.) not trial.ti.
- 10 "we searched".ab. and (review.ti. or review.pt.)
- 11 ("update review" or (databases adj4 searched)).ab.
- 12 (rat or rats or mouse or mice or swine or porcine or murine or sheep or lambs or pigs or piglets or rabbit or rabbits or cat or cats or dog or dogs or cattle or bovine or monkey or monkeys or trout or marmoset\$1).ti. and animal experiment/
- 13 Animal experiment/ not (human experiment/ or human/)
- 14 or/3-13
- 15 2 not 14
- 16 and/1-2,15
- 17 limit 16 to (embase and yr="2010 - 2021")

MEDLINE (Ovid) search (n=9379)

- 1 exp Inflammatory Bowel Diseases/ or (Inflammatory Bowel Disease* or IBD or Crohn* or Colitis or Enteritis or Proctocolitis or Colorectitis or Ileocolitis).ti,ab.
- 2 ((randomized controlled trial or controlled clinical trial).pt. or (randomi?ed or placebo or randomly or trial or groups).ab. or drug therapy.fs.) not (exp animals/ not humans.sh.)
- 3 "and/1-2".m_titl.
- 4 limit 3 to yr="2010 - 2021"

CENTRAL (n=8919)

[[mh "Inflammatory Bowel Diseases"] or (Inflammatory Bowel Disease* or IBD or Crohn* or Colitis or Enteritis or Proctocolitis or Colorectitis or Ileocolitis): with Publication Year from 2010 to 2021, in Trials

