Supplementary

Table S1 Summary table for whether the reporting items were reported or not

Reporting items	Reported	Not reported
MM-YY when the enrollment begins and ends	The months and years of interest were specified in the main text (Methods section or Results section)	The months and years of interest cannot be found in the main text
MM-YY when the treatment begins and ends	The months and years of interest were specified in the main text (Methods section or Results section)	The months and years of interest cannot be found in the main text
MM-YY of data cutoff	The months and years of interest were specified in the main text, such as the Results section	The months and years of interest cannot be found in the main text
Length of Treatment	Surgery: Not applicable Chemotherapy and radiotherapy: Relevant information was provided either in the form of (I) whole treatment duration or (II) cycle counts along with the length of each cycle	Surgery: Not applicable Chemotherapy and radiotherapy: Either the cycle number or the length of each cycle were not provided
Locations where patients were treated	Reported in supplementary material: The authors stated that readers should refer to the supplementary materials for further information Reported in the main text: If relevant information can be found in the main text, the articles will be subclassified into Region-level", "Country-Level", or "Site-level" based on the reported information	No information about where patients were treated can be found in the main text and/or in the supplementary material
Treatment discontinuation	Descriptions such as "treatment discontinuation" and "patients were removed from the treatment arm" were found in the Results section, with numbers (or percentages) being provided. Articles will be further classified as "with reasons" or "without reasons" based on whether the reasons were mentioned or not	No information about treatment discontinuation can be found in the main text and/or in the supplementary material
Treatment delay	Descriptions such as "dose delay", "dose interruption", "treatment delay", and "treatment interruption" were found in the Results section, with numbers (or percentages) being provided. Articles will be further classified as "with reasons" or "without reasons" based on whether the reasons were mentioned or not	No information about treatment delay can be found in the main text and/or in the supplementary material

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Table S2 Key takeaways from recent literatures on impact of COVID-19 on clinical trials

Key takeaways from recent literatures on impact of COVID-19 on clinical trials	Reference + page/paragraph
Study sites/locations were affected by the pandemic	(Boughey *et al.*, 2021) (12): Page 2, paragraph 3
Remote data capture and collection	(Boughey *et al.*, 2021) (12): Page 5, paragraph 2 (Ali and Riches, 2021) (13): Page 4, paragraph 2
Changes to protocol interventions due to COVID-19	(Ali and Riches, 2021) (13): Page 4, paragraph 2 (Boughey *et al.*, 2021) (12): Page 2, paragraph 3 (Onesti *et al.*, 2021) (14): Page 7, paragraph 1
Changes to trial outcomes happen before or after a pre-planned interim analysis	(Meyer *et al.*, 2020) (7): Page 5, paragraph 9
The need for sensitivity analyses	(Meyer *et al.*, 2020) (7): Page 6, table 3
The need to address missing data	(Meyer *et al.*, 2020) (7): Page 8, paragraph 1
Participants experienced treatment delay	(Boughey *et al.*, 2021) (12): Page 2, paragraph 5
Treatment period can be impacted by lockdowns	(Sathian *et al.*, 2020) (22): Page 7, paragraph 3
COVID-19 impacted the study accrual rate	(Boughey *et al.*, 2021) (12): Page 1, paragraph 1
Relevant adverse events can be associated with COVID-19	(Ali and Riches, 2021) (13): Page 4, paragraph 3
Laboratory test delays can impact adverse events assessments	(Boughey *et al.*, 2021) (12): Page 3, paragraph 6

References

22. Sathian B, Asim M, Banerjee I, et al. Impact of COVID-19 on clinical trials and clinical research: a systematic review. Nepal Journal of Epidemiology 2020;10:878.

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Table S3 Full checklist integrated with the CONSORT[1,^]

Section/Topic	Item No.	Checklist item
Title and abstract		
	1a	Identification as a randomised trial in the title
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)
	1c	Indicate whether this trial was conducted during the force majeure event in the abstract
Introduction		
Background and objectives	2a	Scientific background and explanation of rationale
	2b	Specific objectives or hypotheses
Methods		
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons
Participants	4a	Eligibility criteria for participants
	4b	Settings and locations where the data were collected
	4c	Specify the study locations (such as community clinics and academic hospitals) in the supplement, including whether the study sites were affected by the force majeure event after trial commencement
	4d	If 4b includes remote data capture, describe the data collection process
Interventions	5a	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered
	5b	Any changes to protocol interventions due to COVID-19, with reasons
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed
	6b	Any changes to trial outcomes after the trial commenced, with reasons
Sample size	7a	How sample size was determined
	7b	When applicable, explanation of any interim analyses and stopping guidelines
	7c	If yes to 6b and if 7b is applicable, did the changes to trial outcomes happen before or after a pre-planned interim analysis
Randomisation:		
Sequence generation	8a	Method used to generate the random allocation sequence
	8b	Type of randomisation; details of any restriction (such as blocking and block size)
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes
	12b	Methods for additional analyses, such as subgroup analyses, adjusted analyses, and sensitivity analyses
	12c	Methods for addressing missing data
Results		
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome
	13b	For each group, losses and exclusions after randomisation, together with reasons
	13c	For each group, the numbers of participants experiencing treatment delay, with reasons
Recruitment	14a	Dates defining the periods of recruitment, treatment, and follow-up
	14b	Why the trial ended or was stopped
	14c	Indicate whether the force majeure event impacted the study accrual rate
Baseline data	15a	A table showing baseline demographic and clinical characteristics for each group
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses, adjusted analyses, sensitivity analyses, distinguishing pre-specified from exploratory
Harms	19a	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)
	19b	If applicable, are the adverse events associated with the force majeure event
	19c	If applicable, for each group, the numbers of participants experiencing laboratory test delays for assessing adverse events, with reasons
Discussion		
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses
Generalisability	21	Generalizability (external validity, applicability) of the trial findings
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence and the impact of the force majeure event
Other information		
Registration	23	Registration number and name of trial registry
Protocol	24	Where the full trial protocol can be accessed, if available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders

[1] Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. Journal of Pharmacology and Pharmacotherapeutics 2010;1:100-107. ^ New and modified items are listed in *Table 3*.

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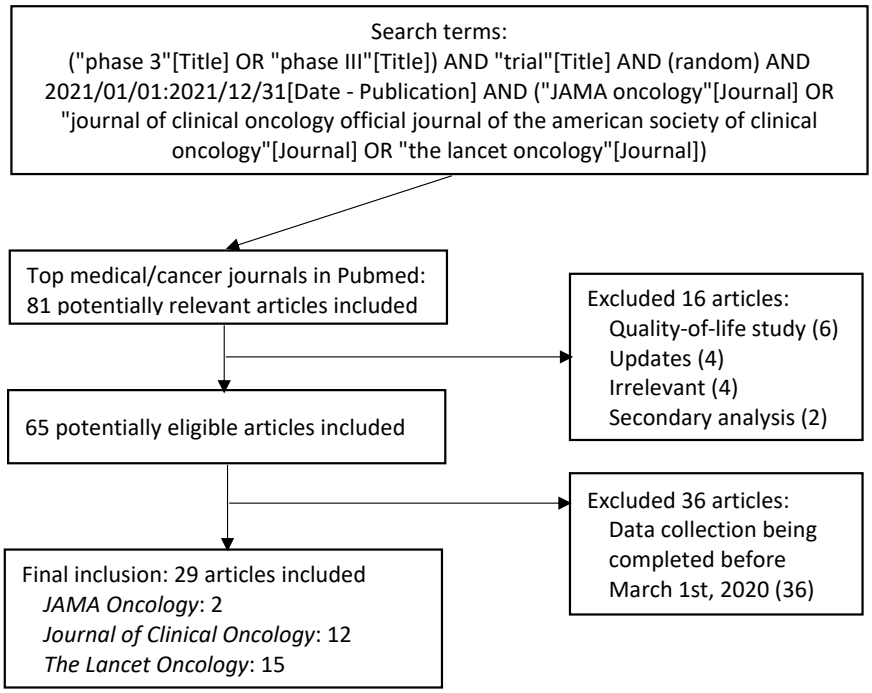

Figure S1 Process for literature search on trials impacted by COVID-19.

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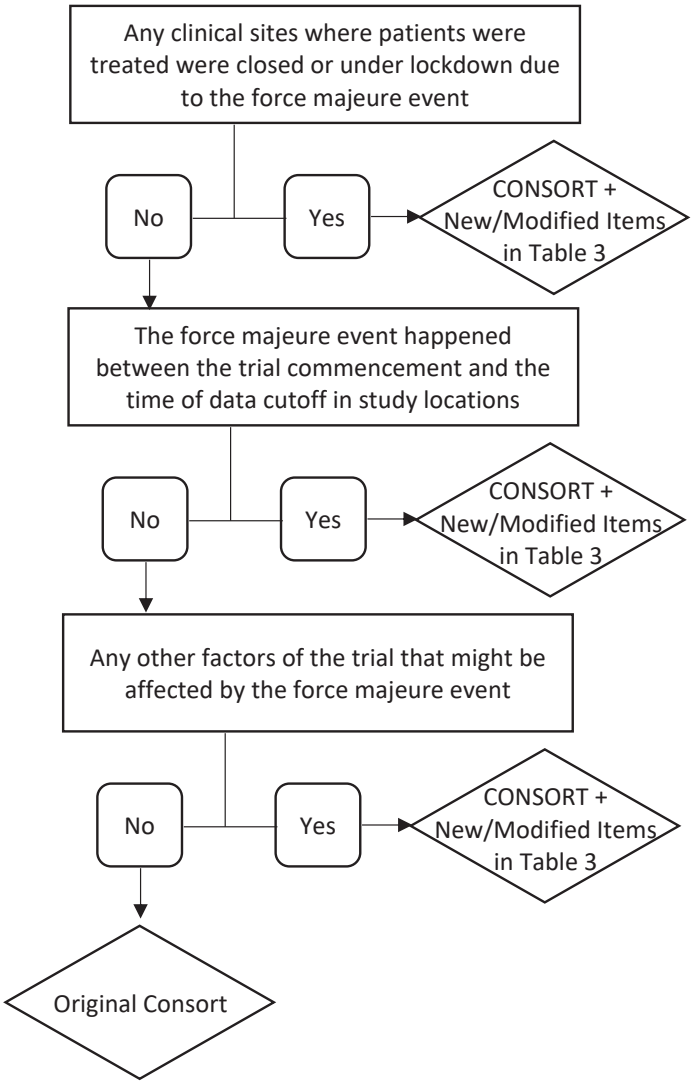

Figure S2 Flow diagram to assist in the decision-making process on whether to follow the new recommendations.

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