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CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement

Enhancing the Reporting and Impact of Pediatric Randomized Trials

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IMPORTANCE Randomized controlled trials (RCTs) in children and adolescents provide evidence for patients, families, researchers, clinicians, regulators, funders, policymakers, and other interest holders to inform decisions about health care interventions and improve outcomes for young patients and their families. To critically evaluate, interpret, and apply trial results, readers require access to a complete and transparent report of what was planned, done, and found, taking unique considerations specific to children and adolescents into account. Harmonized guidance based on evidence and consensus is needed to optimize standardized reporting and reduce research waste in pediatric RCTs.

OBJECTIVE To develop a pediatric reporting guideline extension to the Consolidated Standards of Reporting Trials (CONSORT) 2025 guideline, CONSORT-Children and Adolescents (CONSORT-C) 2026, that supports comprehensive reporting and enhances the transparency, reproducibility, accuracy, and utility of published pediatric RCT reports.

EVIDENCE REVIEW The Enhancing the Quality of Transparency of Health Research (EQUATOR) Network's published framework primarily informed the development of CONSORT-C 2026. A literature review was conducted to generate a list of candidate reporting items. To obtain direct input from young people and family caregivers throughout the project, a Youth Advisory Group and a Family Caregiver Advisory Group were formed. An international Delphi study with a priori consensus thresholds, consensus meeting, group writing of the explanation and elaboration paper, and pilot testing were conducted.

MAIN OUTCOMES AND MEASURES Harmonized guidance based on evidence and consensus is needed to optimize standardized reporting and reduce research waste in pediatric RCTs. As an extension to the CONSORT 2025 statement, the CONSORT-C 2026 reporting guideline aims to improve the quality and completeness of reporting of pediatric RCTs that involve participants aged 0 to 19 years.

FINDINGS The new CONSORT-C 2026 guideline is an extension to the updated CONSORT 2025 statement and adds reporting items applicable to pediatric RCT reports involving children and adolescents aged 0 to 19 years. Developed in partnership with young people (aged 10-24 years) and family caregivers, CONSORT-C 2026 comprises 13 new items recommended to be reported in pediatric RCT reports in addition to the CONSORT 2025 items. The 13 new reporting items include 1 youth-generated and 6 youth-endorsed items. CONSORT-C 2026 can be considered a minimum set of reporting items applicable to pediatric RCT reports reflecting the priorities of clinicians, researchers, young people, family caregivers, and other interest holders.

CONCLUSIONS AND RELEVANCE Widespread implementation and uptake of CONSORT-C 2026 should optimize the usability of trial results for these populations, improve the reproducibility of trial results, and reduce research waste.

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Editor's Note

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Appropriately designed, well-conducted, and comprehensively reported randomized controlled trials (RCTs) are important to support and communicate transparent, evidence-informed health care decisions. RCTs contribute to a robust evidence base on the effects of interventions that is indispensable to patients, families, researchers, funders, policymakers, health care providers, and other interest holders. As well documented in the literature, children are often underrepresented in RCTs,[1] and the rate of RCTs conducted and published in pediatric populations is relatively stagnant compared with RCTs conducted and published in adult populations.[2,3] Studies show that many pediatric RCTs are not completed and therefore are not published,[4,5] and among those that eventually are published, suboptimal reporting is common.[6,7] For instance, critical information on the consent and assent process,[8] details of comparator interventions,[9,10] randomization and blinding,[11,12] trial procedure–associated pain and harms prevention, sources of missing data,[13] choice and measurement of age-appropriate primary trial outcomes,[14,15] and patient and family engagement is often inadequately reported. This makes it difficult for readers to critically appraise the research and interpret the studies' findings. Although the dearth of pediatric RCTs is due to many contributing factors and challenges,[16-18] when combined with poor reporting, patients and families are left with a lack of available, good-quality evidence specific to infants, children, and adolescents. This lack of evidence also has negative consequences on the innovation of interventions critical to improving the care and health outcomes of pediatric patients.

Guidance has been developed to help authors improve the quality of their research reporting so that end users can benefit from new evidence and research waste is reduced.[19] Empirical studies suggest that the quality of reporting in RCTs improves with the use or endorsement of reporting guidelines.[20,21] As a result, the development, endorsement, and use of such guidelines has vastly increased in recent years.[20-22] The Consolidated Standards of Reporting Trials (CONSORT) statement was updated in 2025 and currently provides a checklist of essential reporting items for all RCTs.[23] While numerous extensions to CONSORT that focus on various trial designs, interventions, outcomes, and data types exist, no reporting guidelines provide guidance specifically for RCTs involving participants aged 0 to 19 years. This group of children and adolescents, from extremely premature newborns to 19-year-olds, is a much more diverse population than adults. The pediatric population is heterogeneous, comprising subpopulations who differ considerably in their biology, anatomy, pharmacokinetics, pharmacodynamics, cognitive abilities, and psychology.[16,24] Therefore, pediatric RCTs come with their own unique nuances and considerations, such as age-appropriate trial interventions and formulations, considerations around consent and assent that may vary from one jurisdiction to another, and differences in treatment effects depending on the age, development, and growth of the children or adolescents.[25] Given mounting evidence showing deficient research reporting in pediatric RCTs,[6,7,25,26] there have been calls for specific guidance and a need to improve reporting in this area.[25,27-30]

To address this gap, we developed a CONSORT extension specific to pediatric RCTs involving newborns, infants, children, and adolescents to provide harmonized guidance based on evidence and international consensus. We aimed to identify and recommend a minimum set of essential reporting items: CONSORT–Children and Adolescents (CONSORT-C) 2026. This article describes the scope and development of this CONSORT 2025 extension and presents a checklist with recommended items to report in pediatric RCT reports. In the explanation and elaboration paper,[31] we provide good reporting examples and an explanation of all recommended reporting items.

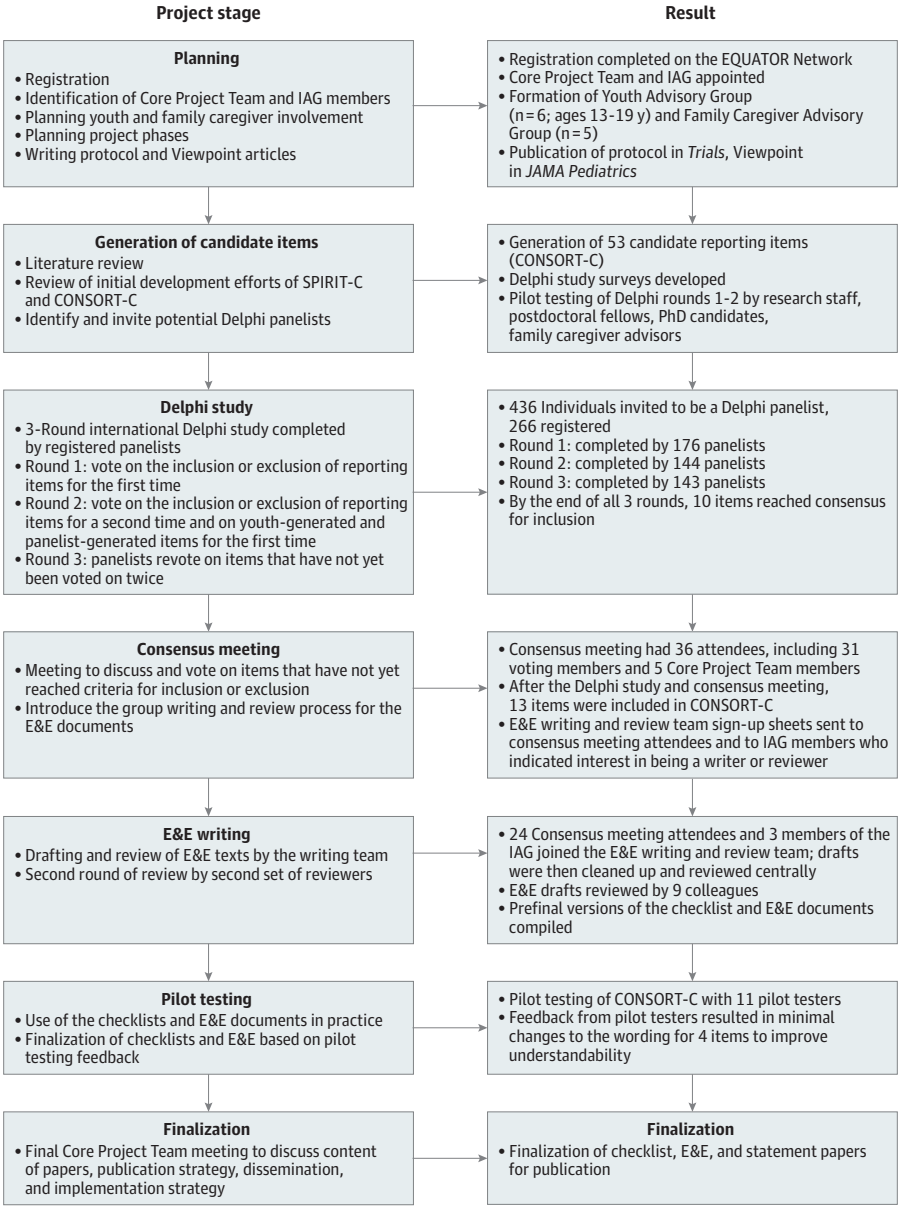
Methods

The CONSORT-C 2026 extension was developed simultaneously with the Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents (SPIRIT-C) extension.[32] We initially registered our intent to develop both guidelines with the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network in 2014,[33] and both registrations were updated in 2023 and 2024 to reflect the development process described throughout this article. For the purposes of this project, the term *pediatric* encompasses child and adolescent health, and the guidance pertains to trials that evaluate any interventions (ie, drug and nondrug, including public and population health) in newborns, infants, children, and adolescents. Although heterogeneity exists in what constitutes *pediatric* and how different age groups are defined in the literature,[34,35] the CONSORT-C 2026 extension pertains to newborns, infants, children, and adolescents (aged 0-19 years), which we based on published ranges by the United Nations Convention on the Rights of the Child and the World Health Organization.[36-39] In the context of this project, the term *children* includes newborns and infants.

In developing CONSORT-C 2026, we followed the EQUATOR Network's guidelines on development of reporting guidelines,[40] reviewed how recent reporting guideline extensions were developed,[23,41-53] and considered methodological limitations attributed to the development of reporting guidelines.[54] The study protocol, detailing the development process of SPIRIT-C 2026 and CONSORT-C 2026, including the composition of the development group (ie, Core Project Team, International Advisory Group, young people [aged 10-24 years], and family caregivers [ie, parents, guardians]) and the various project stages, is published elsewhere.[55] Briefly, the Core Project Team comprised 6 individuals with expertise in the development of reporting guidelines, child health research, pediatric rare diseases, trial methodology, and patient and public involvement. The International Advisory Group consisted of 14 pediatric clinical trialists, clinician scientists, epidemiologists, statisticians, and pediatric trial network representatives from Canada, the UK, the US, and the Netherlands. The International Youth Involvement Steering Committee was established, comprising 3 members of the Core Project Team and youth facilitator experts from the European Young Person Advisory Group Network from England, Spain, France, and Scotland, who were instrumental in developing appropriate methods for involving young people in the project.

We involved young people (aged 10-24 years) and family caregivers throughout the project. The protocol details the rationale for the selected age range and the required experience of young people who were involved in the project.[55] We describe the involvement and impact of the contribution of young people and family caregivers in this project in a separate publication.[56] Briefly, we formed a pan-Canadian Youth Advisory Group comprising 6 young people

Figure 1. Development Process of the Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026 Checklist Items and Explanation and Elaboration (E&E) Paper



EQUATOR indicates Enhancing the Quality and Transparency of Health Research; IAG, International Advisory Group; SPIRIT-C, Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents.

(advisors aged 13-19 years) and a Family Caregiver Advisory Group with 5 family caregivers of children with lived experiences related to pediatric RCTs. Both groups were actively involved as contributors and as advisors at various project stages, including the Young Person Reporting Guideline workshops, Delphi study, writing of an explanation and elaboration paper, and the development of knowledge translation outputs.

eAppendix 1 in Supplement 1 describes minor amendments from the protocol. eAppendix 2 in Supplement 1 details all contributors to the development of SPIRIT-C 2026 and CONSORT-C 2026. eAppendix 3 in Supplement 1 describes the methods used in the generation of candidate reporting items, the Delphi study, the consensus meeting, the group writing process of the explanation and elaboration, and pilot testing and finalization.

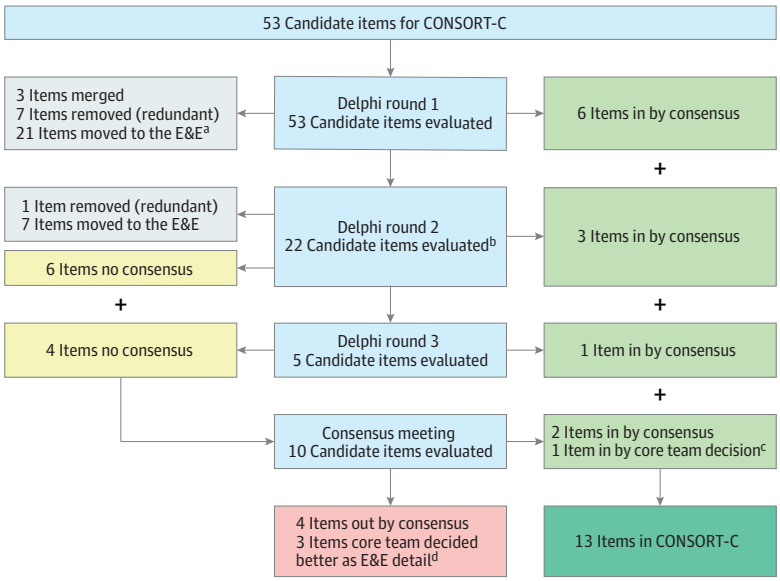
Results

The project was completed as planned from July 2023 to January 2025. We worked closely with the developers of the CONSORT update to ensure that the final CONSORT-C 2026 checklist was harmonized with the CONSORT 2025 statement.[23] **Figure 1** depicts the development process of CONSORT-C 2026.

Delphi Study

Of 436 people invited to take part in the Delphi study, 266 responded (response rate 61%). eTable 1 in Supplement 1 shows the number of panelists who completed rounds 1 through 3, including their characteristics and whether they were directly invited or self-

Figure 2. Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026 Item Flow Diagram



eTable 6 in Supplement 1 shows the detailed flow of each item. E&E indicates explanation and elaboration.

[a]The 21 items include 15 Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) | CONSORT-Outcomes items and 1 base item that met consensus criteria to be included after round 1, which affirmed their importance, as detailed in the statement paper. However, after concerns raised in round 1 by some panelists about the inclusion of items not specific to pediatrics, these items were considered better as detail for the E&E and did not appear again in the Delphi study.

[b]The 22 items comprise 16 items carried over from round 1 for a second-round vote, 2 youth-generated items from Young Person Reporting Guideline workshops, 2 new panelist-suggested items from round 1, and 2 additional items as a result of splitting an item from round 1.

[c]No consensus was determined for this item even after voting at the consensus meeting. The core team decided to include this item.

[d]No consensus was determined even after voting at the consensus meeting. The core team decided to exclude these items and instead include them as detail in the E&E.

selected through snowball sampling. Overall, 176 of the 266 panelists (response rate 66%) completed round 1, 144 (54%) completed round 2, and 143 (54%) completed round 3. In total, 10 family caregivers expressed interest in being a Delphi panelist; 5 were members of the Family Caregiver Advisory Group. Four young people (aged 19-24 years) each signed up to be a Delphi panelist.

Figure 2 depicts the flow of candidate reporting items that pertain to CONSORT-C 2026; eAppendix 5 in Supplement 1 provides details on the flow of items in rounds 1 through 3. eTable 6 in Supplement 1 shows the results of the Delphi study.

Consensus Meeting

Of 38 individuals invited to the consensus meeting, 31 attended as voting members (82%); 4 of the attendees (13%) were family caregiver advisors. Additionally, although ineligible to vote, 5 Core Project Team members and 1 notetaker attended. eTable 2 in Supplement 1 shows the characteristics of the consensus meeting attendees.

During the consensus meeting, we discussed and voted on 10 candidate reporting items pertaining to CONSORT-C 2026. After discussing each item, we voted out 4 items and voted in 2 items. Four items were neither voted in nor out, even after 2 rounds of voting at the consensus meeting. Members of the Core Project Team subsequently discussed these 4 items, and based on the discussions at the consensus meeting, the content of the item, and considering the full context of both SPIRIT-C 2026 and CONSORT-C 2026, we included 1 item as a stand-alone reporting item and removed 3 items as stand-alone items; we deemed these to be better placed as detail in the explanation and elaboration. eTable 7 in Supplement 1 shows the voting results from the consensus meeting for each item.

After this stepwise process, the final CONSORT-C 2026 checklist contained 13 reporting items for pediatric RCTs, of which 1 (item 13.2) is a youth-generated item and 6 (items 1a.1, 6.2, 6.3, 13.1, 15.1, 29.1) are youth-endorsed items.

Group Writing of the Explanation and Elaboration

Twenty-four of 31 consensus meeting attendees and 3 members of the International Advisory Group who had not attended the consensus meeting signed up to be part of the explanation and elaboration writing team to draft material for 21 items. The 21 items addressed in the explanation and elaboration paper comprise the 13 new CONSORT-C 2026 items and 8 CONSORT 2025 items (items 1b, 8, 13, 14, 15, 22a, 25, 26). The latter items were supplemented with pediatric details on the abstract; patient and public involvement; intervention and comparator; outcomes; harms; participant flow; baseline data; and numbers analyzed, outcomes, and estimation. All 4 members of the Family Caregiver Advisory Group who attended the consensus meeting signed up for the writing team. Seventeen of 27 team members (63%) signed up to be both a writer and a reviewer; on average, each writing team member agreed to contribute to 6 items.

Once the writing and review process was completed, 2 members of the Core Project Team (A.B., M. Offringa) reviewed and

revised all drafts by the writing team. Subsequently, 5 members of the International Advisory Group, 1 core team member (B.K.P.), and 3 colleagues reviewed the complete explanation and elaboration papers. All feedback was reviewed and incorporated into the final version of the explanation and elaboration papers that were used during pilot testing.

Pilot Testing and Finalization

Eleven pilot testers evaluated the CONSORT-C 2026 checklist and explanation and elaboration paper, of whom 5 (45%) also piloted SPIRIT-C 2026. eTable 3 in Supplement 1 shows the characteristics of the pilot testers. After independent review of the feedback from pilot testers, 2 members of the Core Project Team (A.B., M. Offringa) made minimal changes to the wording of 4 items (eTable 8 in Supplement 1) to improve understandability. A few additional examples were identified and included. No modifications were made to the content of the checklists. After a meeting of the Core Project Team in December 2024, this statement paper and explanation and elaboration paper were drafted and finalized with input from all coauthors.

Scope and Use of CONSORT-C 2026

As an extension to the CONSORT 2025 guideline, CONSORT-C 2026 adds 13 essential reporting items that are relevant to all pediatric RCTs for any disease, condition, intervention, and outcome that involve children and adolescents (aged 0-19 years) (**Table 1**); aligning with the CONSORT 2025 statement, CONSORT-C 2026 is most focused on reporting parallel-group RCTs.[23] eTable 4 in Supplement 1 includes an expanded checklist outlining all key elements for reporting each CONSORT-C 2026 item.

The new reporting items address the title, background and rationale, eligibility criteria, intervention and comparator, outcomes, harms, baseline data, ancillary analyses, and interpretation. The **Box** describes the structure and use of CONSORT-C 2026.

Although focused mostly on 2-arm, parallel-design RCTs, CONSORT-C 2026 can also be used with the existing CONSORT extensions, depending on the condition, design, intervention, and outcome (eTable 5 in Supplement 1). CONSORT-C 2026 can also be broadly applied to the reporting of nonrandomized pediatric trials. Authors are invited to consider these guidelines for any type of pediatric trial and apply reporting items as appropriate.

Additionally, CONSORT-C 2026 items should be considered when reporting pediatric adaptive trials, cluster RCTs, multiarm RCTs, multistage RCTs, n-of-1 trials, and pilot and feasibility trials. CONSORT-C 2026 can also be used to report trials that include a mixed population—for example, adolescents and adults, or in trials that enrolled parents or caregivers, or both (ie, to deliver or receive the intervention) but assessed outcomes in children or adolescents, or when parent-child dyads are recruited. Users of CONSORT-C 2026 should use the guidance alongside CONSORT 2025.[23]

Although primarily a reporting guideline to assist authors of trial reports, CONSORT-C 2026 can also be used by journal editors and publishers; journal peer reviewers; academic institutions; research funders; patients, public, and trial participants; trainees; trial or research staff; and systematic reviewers and meta-researchers. **Table 2** details all key user groups and the expected benefits resulting from implementation of CONSORT-C 2026.

Discussion

When implemented by authors and journals, clear guidance on how to comprehensively and transparently report pediatric RCT reports will enable knowledge users to critically appraise, synthesize, and interpret trial findings. Recently, a child-centered research checklist was developed; however, this checklist is not specific to RCTs and is limited in focus to informed consent, assent, and dissent; code of conduct; and child-focused methods; it did not provide guidance on research reporting.[57] We developed CONSORT-C 2026 using the updated CONSORT 2025, which integrates important elements from existing extensions applicable to all RCTs,[23] with input from future users and beneficiaries of the guideline—for example, young people, family caregivers, clinicians, pediatricians, child health researchers, regulatory agencies, methodologists, trainees, trial authors, and journal editors. Based on evidence and international consensus, CONSORT-C 2026 comprises a minimum set of essential items that are meaningful to end users of pediatric trial reports. As a result, CONSORT-C 2026 directly reflects the priorities of young people, family caregivers, and their health providers, resulting in guidance that is relevant and meaningful to all key users.

CONSORT-C 2026 aims to facilitate authors in adequately including specific trial information, yielding transparent, clear, and comprehensive reporting so that key details are not missed. Congruent with other reporting guidelines such as CONSORT 2025, CONSORT-C 2026 is not prescriptive in terms of where the information for each reporting item should be reported. Authors should clearly indicate where the information can be found, either in the main text or supplementary material, and if published elsewhere, a citation or link to the source.

Typically, CONSORT extensions are based on specific conditions, designs, interventions, or outcomes. The defining characteristic that makes CONSORT-C 2026 unique from other reporting guideline extensions is that it focuses on a specific population: children and adolescents (aged 0-19 years; Box). However, depending on the trial design, interventions, or outcomes, users of CONSORT-C 2026 may also consider reporting items from other extensions, as appropriate to their trial (eTable 5 in Supplement 1). Additionally, for describing interventions in pediatric RCTs, we recommend users refer to the Template for Intervention Description and Replication (TIDieR)–Children and Adolescents (TIDieR-C),[58] also detailed in the accompanying explanation and elaboration paper.[31]

Changing Reporting Practice: Downstream and Upstream Effects

The widespread uptake and implementation of CONSORT highlight the importance of endorsement by medical journals.[23,59] Beyond endorsement, mandating the submission of completed CONSORT-C 2026 checklists as part of the submission may also be effective.[60] Published articles in journals that endorse reporting guidelines have shown improved reporting and better adherence to reporting guidelines.[59,61,62] Verification of adherence by editorial staff (eg, for completeness) and peer reviewers (eg, for content) may be necessary, as reporting completeness in submitted checklists may not always be consistent.[63] To support these verification efforts, some journals have implemented specific editorial roles—including protocol editors or assistant editors for transparent reporting.[64,65]

Table 1. Recommended Items to Report in Pediatric (Aged 0-19 Years) Trial Reports From Consolidated Standards of Reporting Trials (CONSORT) 2025 and CONSORT-Children and Adolescents (CONSORT-C) 2026 Checklists

	CONSORT 2025 statement		CONSORT-C 2026 extension	
Section and topic	Item No.	CONSORT 2025	Item No.	CONSORT-C 2026
Title and abstract				
Title and structured abstract	1a	Identification as a randomized trial	1a.1[a]	Identify that it is a pediatric trial, and include age group(s)/range(s), interventions, and, if applicable, trial acronym
	1b	Structured summary of the trial design, methods, results, and conclusions		
Open science				
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration		
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed		
Data sharing	4	Where and how the individual deidentified participant data (including data dictionary), statistical code, and any other materials can be accessed		
Funding and conflicts of interest	5a	Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis, and reporting of the trial		
	5b	Financial and other conflicts of interest of the manuscript authors		
Introduction				
Background and rationale	6	Scientific background and rationale	6.1[a,b]	Describe the prevalence/incidence of the disease or condition in children/adolescents
			6.2	Describe available evidence on the efficacy/effectiveness of the intervention in children/adolescents
			6.3[a]	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents
Objectives	7	Specific objectives related to benefits and harms		
Methods				
Patient and public involvement	8	Details of patient or public involvement in the design, conduct, and reporting of the trial		
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)		
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason		
Trial setting	11	Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted		
Eligibility criteria	12a	Eligibility criteria for participants	12a.1[a,b]	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential age or development-related differences in treatment effects
			12a.2	Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists)		
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed	13.1[a,b]	Describe whether there is an intervention dose and/or formulation appropriate for the trial population, and if there were any adjustments made based on age, weight, or body surface area
			13.2[a,b]	Describe whether the trial interventions were delivered with help from a support person
Outcomes	14	Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome	14.1[a]	Explain evidence supporting validity of selected outcomes and outcome measurement instruments in age group(s) included
Harms	15	How harms were defined and assessed (eg, systematically, nonsystematically)	15.1[a,b]	Describe whether trial interventions and/or procedures induced fear, pain, distress, or were invasive, and what measures were taken to mitigate this

(continued)

Table 1. Recommended Items to Report in Pediatric (Aged 0-19 Years) Trial Reports From Consolidated Standards of Reporting Trials (CONSORT) 2025 and CONSORT-Children and Adolescents (CONSORT-C) 2026 Checklists (continued)

	CONSORT 2025 statement		CONSORT-C 2026 extension	
Section and topic	Item No.	CONSORT 2025	Item No.	CONSORT-C 2026
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation		
	16b	Explanation of any interim analyses and stopping guidelines		
Randomization:				
Sequence generation	17a	Who generated the random allocation sequence and the method used		
	17b	Type of randomization and details of any restriction (eg, stratification, blocking, and block size)		
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned		
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence		
Blinding	20a	Who was blinded after assignment to interventions (eg, participants, care providers, outcome assessors, data analysts)		
	20b	If blinded, how blinding was achieved and description of the similarity of interventions		
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms		
	21b	Definition of who is included in each analysis (eg, all randomized participants), and in which group		
	21c	How missing data were handled in the analysis		
	21d	Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing prespecified from post hoc		
Results				
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analyzed for the primary outcome		
	22b	For each group, losses and exclusions after randomization, together with reasons		
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms		
	23b	If relevant, why the trial ended or was stopped		
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])		
	24b	Concomitant care received during the trial for each group		
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	25.1[b]	Report number of children/adolescents in the trial by prespecified age group(s)
Numbers analyzed, outcomes, and estimation	26	For each primary and secondary outcome, by group: The number of participants included in the analysis The number of participants with available data at the outcome time point Result for each group, and the estimated effect size and its precision (such as 95% confidence interval) For binary outcomes, presentation of both absolute and relative effect size		
Harms	27	All harms or unintended events in each group		
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing prespecified from post hoc	28.1[b]	For each primary and secondary outcome, report results for each prespecified age group studied
Discussion				
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	29.1	Highlight unanswered and new questions, and discuss potential future research
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalizability, and, if relevant, multiplicity of analyses		

[a] New item pertains to both Standard Protocol Items: Recommendations for Interventional Trials–Children and Adolescents 2026[32] and CONSORT-C 2026.

[b] Report item if applicable or state explicitly that it is not applicable.

Box. Structure and Use of the Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026 Extension

Structure

The CONSORT-C 2026 extension comprises a checklist (**Table 1**) and an explanation and elaboration paper. The explanation and elaboration paper is presented separately.[31] Users of the CONSORT-C 2026 checklist are strongly encouraged to use it alongside the CONSORT-C 2026 explanation and elaboration paper, as this contains full explanations, rationale, and examples of good reporting for each CONSORT-C 2026 item. Reporting all items is recommended, with the exception of 7 items with footnote b (items 6.1, 12a.1, 13.1, 13.2, 15.1, 25.1, and 28.1), which should then only be reported if applicable; if an item is not applicable, an explicit statement "not applicable" with an explanation, if relevant, is helpful. As an extension, CONSORT-C 2026 is integrated within CONSORT 2025; therefore, users should report CONSORT 2025 items along with the CONSORT-C 2026 items.

Intended Users

CONSORT-C 2026, although primarily a writing tool, can be used by individuals other than authors of pediatric randomized controlled trials. Key users, such as journal editors, funders, peer reviewers, and evidence end users (eg, young people, family caregivers, and health care providers), can use and potentially benefit from the CONSORT-C 2026 extension. **Table 2** details all users and resulting benefits.

Fillable Checklist

The downloadable, fillable checklist is available in Supplement 2. It is also available on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/), Enhancing the Quality and Transparency of Health Research (EQUATOR) Network website (https://www.equator-network.org/), and new SPIRIT | CONSORT website (https://www.consort-spirit.org/).

Additional Resources

One-page tip sheets for each reporting item, a short informational video on the guideline and its use, and resources aimed at the public will be made available on the SPIRIT | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/). An expanded version of CONSORT-C 2026 was also developed, which summarizes key elements of reporting for each item (eTable 4 in Supplement 1), similar to what was done for CONSORT 2025.[23]

Reference on Guidance Implementation

Users of the guidelines should state in their manuscript that their trial report has been reported in accordance with the CONSORT-C 2026 extension, in combination with other extensions as applicable.

However, nuances need to be considered in maximizing the uptake and implementation of reporting guidelines such as CONSORT-C 2026. Mere awareness of these guidelines is simply not enough to improve reporting. Endorsement is not consistent across different journals[66]; similarly, peer review is also not standardized.[67] Although CONSORT-C 2026 may be a useful tool to check for inclusion of minimum essential items, it is evident that to be able to effectively use these guidelines, first and foremost users need to understand what the reporting item entails and what constitutes good reporting. Training in responsible research practice, research integrity, and peer review should be integrated into academic curriculums.[68-70]

We believe that, aside from trial report authors, peer reviewers, and journals, CONSORT-C 2026 can also benefit other interest holders of pediatric RCTs, such as research funders and the public, who are knowledge users of research (Table 2).

The immediate intended downstream effects of CONSORT-C 2026 are the facilitation of research synthesis and end users' appraisal of pediatric RCTs and enhanced development of clinical practice guidelines, adding value to pediatric research.[30] Although not the primary purpose of reporting guidelines, CONSORT-C 2026 also may have upstream effects on the design, conduct, and analysis of pediatric RCTs, as the reporting items touch on these topics and may urge trialists to consider various elements. This is why we deliberately developed CONSORT-C 2026 simultaneously with a guideline for reporting pediatric trial protocols and focused on harmonizing reporting items. For trialists developing a pediatric RCT protocol, the use of CONSORT-C 2026 in tandem with SPIRIT-C 2026 will enable efficient, harmonized comprehensive reporting guidance at all trial stages. Thus, when coupled with use of SPIRIT-C 2026 upstream in reporting trial protocols, the use of both guidelines prospectively rather than retrospectively has the potential to enable good reporting from the trial planning stage to the reporting stage to ensure that all key elements are considered at the right time. We appreciate that improving research practice requires concerted effort and implementation of various strategies by all key users across numerous research stages.[69,71] Better RCT reporting may play a role, as it may eventually lead to growth in the usable pediatric evidence base, and specificity in knowing what needs more investigation and investment, to drive innovation in treatment and improve patient outcomes.

Limitations

The development of CONSORT-C 2026 had some limitations. First, although 2 systematic reviews were conducted in 2015 to support the development of SPIRIT-C and CONSORT-C,[25] we did not conduct a completely updated systematic review. Instead, we reviewed the recent literature to generate additional candidate items, building on the list of items generated from the 2 original systematic reviews. A single reviewer, however, conducted the updated search. Regardless, to avoid missing important candidate reporting items, we referred to other literature and consensus-based reporting guidelines, including the updated SPIRIT 2025 and CONSORT 2025 guidelines.[23,42] Subsequent project phases, such as the international Delphi study and consensus meeting, which involved diversity in expertise relevant to pediatric RCTs, reaffirmed the importance of the candidate items and yielded limited new or missed pediatric reporting items. Importantly, we added a process to capture reporting items that young people and family caregivers believed to be important, resulting in guidance that is meaningful and relevant to all key users.

Second, although we involved a diverse group of end users and experts in the development of CONSORT-C 2026, nonresponse bias cannot be excluded, as only those who were interested in the devel-

Table 2. Implementable Actions of Key User Groups and Resulting Benefits From Use of Consolidated Standards of Reporting Trials–Children and Adolescents (CONSORT-C) 2026[a]

Key groups	Implementable actions	Potential benefits
Trial report authors	Adhere to the CONSORT-C 2026 checklist and refer to the corresponding explanation and elaboration paper when writing trial reports	Improved reporting of minimum set of key elements, resulting in transparent, standardized, useful, and comprehensive trial reports that can be replicated and interpreted properly
		Inclusion of details that were identified as important by end users of trial reports, including young people and family caregivers
		Better understanding of the minimum set of reporting items that needs to be included in trial reports involving children and adolescents
		Upstream effects on design, conduct, and analysis of trials and writing protocols
		Improved detection of selective reporting
		Enhanced assessment of risk of bias
		Improved ability to collectively assess results to generate recommendations or guidelines
Journal editors and publishers	Endorse use of CONSORT-C 2026 in Instructions to Authors and in the submission process for trial reports that involve children and adolescents	Consistency in details reported across all submitted manuscripts, setting a minimum standard and fostering transparency and proper interpretation by readers
	Verify accuracy of submitted CONSORT-C 2026 checklists by authors who submitted their manuscript	Quality check of reporting accuracy to ensure proper understanding of reporting items that should be reported
		Improve efficiency in the peer review process
		Improve author's understanding of reporting items
Journal peer reviewers	Use CONSORT-C 2026 during peer review to assess comprehensiveness of reporting	Consistency in review process and in details reported across all submitted manuscripts
		Improved transparency and interpretation of trial reports
Academic institutions	Increase training and awareness of CONSORT-C 2026 to promote transparency in reporting, and motivate investigators to use them	Improved understanding of the minimum set of reporting items to be reported in trial reports that involve children and adolescents
	Endorse or mandate use of CONSORT-C 2026 for ethics and funding applications	Improved quality, accountability, reproducibility, replicability, and usefulness of produced research
		Fosters research integrity and transparency
Research funders	Endorse use of CONSORT-C 2026 in final report to funders	Consistency in details reported in work arising from funding, setting a minimum standard and fostering transparency and proper interpretation by readers
	Mandate the use of CONSORT-C 2026 in publications arising from funded work	Improved ability to collectively assess results to identify gaps and generate recommendations and priorities for allocation of funds or future funding
Patients, public, trial participants	Familiarize self with tools such as CONSORT-C 2026 to know what information to expect when reading a trial report	Improved understanding of content that should be reported in trial reports to facilitate knowledge and health care decision-making
	Empower family caregivers to fully understand what was done, found, and what the results mean to support their child	Increased awareness and empowerment of the general public in holding investigators and the research enterprise accountable for proper conduct of research, reporting, and appropriate spending of research funding
	Advocate for the use of reporting guidelines, such as CONSORT-C 2026, by authors, journals, funders, and institutions	Increased trust in research
Trainees (eg, graduate and medical students, residents, research fellows, clinical fellows)	Use CONSORT-C 2026 as a training tool to increase understanding and awareness of the design, planning, and reporting of pediatric trials	Increased familiarity with minimum set of reporting items to be reported in pediatric RCT reports
		Improved understanding and awareness by future generations in responsible research practices, including use of research reporting guidelines and importance of transparent and comprehensive reporting
Trial/research staff	Use CONSORT-C 2026 as a training tool to increase understanding and awareness of the design, planning, and reporting of pediatric trials	Improved understanding of trial concepts and reporting
		Reduce risk of bias that results from reporting
Systematic reviewers and metaresearchers	Use CONSORT-C 2026 to assess comprehensive reporting in included trial reports	Improved detection of selective reporting
		Enhanced assessment of risk of bias
		Improved ability to collectively assess results to generate recommendations or guidelines

Abbreviation: RCT, randomized controlled trial.

[a] Table adapted and modified from CONSORT-Outcomes 2022.[46]

opment of the guideline would have registered (ie, Delphi panelists, attendees of the Young Person Reporting Guideline workshop, advisory group members, pilot testers, and explanation and elaboration writers and reviewers). For example, although we extended our efforts through our international pediatric trial networks to include family caregivers from outside of Canada, only family caregivers from Canada expressed interest in being a Delphi panelist. We recognize that of those invited to take part in the Delphi study, only 61% registered and 54% completed all 3 rounds. We could, however, still integrate the pediatric expertise of a variety of interest holders in

the development of these guidelines. Relatedly, only 4 young people contributed as Delphi panelists despite our outreach efforts; this may be related to the time commitment needed. Additionally, despite efforts to involve a geographically diverse group of individuals in the project, individuals from Western countries were predominantly involved, and representation from low- and middle-income countries was relatively low. We tried to mitigate this through involving global health experts who conduct trials in low- and middle-income countries (eAppendix 2 in Supplement 1); however, perspectives of individuals from underrepresented areas may differ.

Future work should focus on combining reporting items from existing standards—for example, for early-phase trials in children and adolescents and n-of-1 trials that are likely to become more common in pediatric rare disease settings. Such integration of CONSORT-C 2026 items with reporting items recommended in existing CONSORT extensions (eTable 5 in Supplement 1) may facilitate further uptake of reporting guidelines and the usefulness of published trial reports.

Conclusions

The evidence- and consensus-based CONSORT-C 2026 extension provides recommendations for essential items to be included in pediatric clinical trial reports. These items reflect the priorities of researchers, young people, and family caregivers. To improve the reporting quality and impact of pediatric trials, we recommend that interest holders and reviewers adopt the CONSORT-C 2026 checklist and maximize the transparency, reproducibility, and utility of published pediatric RCT reports. This will enhance the uptake of research results, improve health outcomes of children and adolescents, and reduce research and resource waste.

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Additional Information: The CONSORT-C 2026 extension is being simultaneously published in *The BMJ*, *The Lancet Child and Adolescent Health*, and *JAMA Pediatrics*. Ethical approval was not required, as confirmed by The Hospital for Sick Children's research ethics committee. CONSORT-C 2026 will be disseminated to participants and related patient and public communities through the SPIRIT | CONSORT-C website (https://lab.research.sickkids.ca/enrich/reporting-standards/spirit-consort-c/), where materials for patients and public members will be freely accessible. This article was not commissioned and was externally peer reviewed.

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