Enhancing the reporting and impact of paediatric randomised trials: CONSORT-Children and Adolescents (CONSORT-C) 2026 extension

Web Appendix 1-2

Note: *eAppendix 1, eAppendix 2, eAppendix 3, eAppendix 4, eTable 1, and eTable 2* also apply to *SPIRIT-Children and Adolescents 2026* and are published in the *SPIRIT-Children and Adolescents 2026 Statement's* Supplementary Materials.

Web Appendix 1: Supplementary Materials

APPENDICES

eAppendix 1. Protocol amendments and added procedures in the development of CONSORT-Children and Adolescents (CONSORT-C) 2026

Note: Adjustments from the published Protocol[1] as listed below are the same between *SPIRIT-Children and Adolescents* (SPIRIT-C) *2026* and *CONSORT-Children and Adolescents* (CONSORT-C) *2026*

- Throughout the protocol, we mention using the most updated versions of the SPIRIT and CONSORT checklists. At the time of protocol publication, we referred to these most recent versions as the 2023 version. However, as the SPIRIT and CONSORT update continued, we closely followed the updates and used the most up-to-date draft version, and subsequently, accepted and published 2025 versions.[2 3]
- In the protocol, we stated that young people ages 12-24 years would be involved in the development of SPIRIT-C 2026 and CONSORT-C 2026. As described in the protocol, we selected this age range for several reasons, such as the World Health Organization (WHO)'s definition of young people, and the age ranges of members of the involved Young Persons Advisory Groups (YPAGs). As the project continued, we changed the target age group to include young people ages 10-24 years, as the age range of the YPAG members had shifted to include young people as young as 10 years old.
- While we aimed to include family caregivers outside of Canada, despite efforts through our international networks, only family caregivers from Canada signed up to contribute to the international Delphi study.
- While we did not formally apply and utilize the Public Involvement Impact Assessment Framework (PiiAF) to develop an impact assessment plan, we worked with several key partners with extensive experience in developing a meaningful strategy to involve young people and family caregivers in research, and so elements of the PiiAF (e.g., values, approaches, research focus/design, practical issues, and impacts of public involvement) were carefully considered.[4] We also referred to and closely followed the 17 "blueprint" recommendations for patient and public involvement in reporting guideline development.[5] We documented how each recommendation was applied and their corresponding impact of young people and family caregiver's involvement in a separate publication.[6] We also collected evaluation feedback after every stage involving young people and family caregivers to assess impact, and reported this in the same publication.
- In the Delphi study, candidate reporting items that were classified as "Base item" or "SPIRIT/CONSORT-Outcomes item" were rated by panellists on a 3-point scale: "No, exclude", "Unsure", and "Yes, keep". An "I'm opting out" option was also offered. These items were voted on a 3-point scale as they have gone through a consensus process in previous projects – as described in the protocol.
- As outlined in the main Statement text, during Round 1, some panellists expressed concerns over the guideline comprising items that are relevant but are not necessarily specific to paediatrics. We reviewed each item to assess their specificity and relevance, and - from Round 2 onwards - labelled each candidate item as either specific (S) or relevant (R). After Round 2, we removed many items from consideration as a standalone reporting item, to instead incorporate it as paediatric detail in the E&E.
- In identifying pilot testers, we did not reach out to paediatric clinical trialists from Clinical Trials.gov, but to colleagues of the core project team, paediatric trial networks, and paediatric research organizations.
- We did not hold a two-day final project meeting. Instead, prior to finalisation of the guidelines, we had a final core project team meeting, as detailed in the main Statement text.

eAppendix 2. Contributors to the Development of CONSORT-Children and Adolescents (CONSORT-C) 2026

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*Indicates those who completed all three rounds of the Delphi study.
†Indicates those who attended the Consensus Meeting.

eAppendix 3. Detailed Methods

Generation of candidate reporting items

To generate a candidate list of reporting items, we first studied a confidential copy of the updated SPIRIT 2025 items and CONSORT 2025 items.[3 7] We then reviewed candidate items generated during the initial development efforts of SPIRIT | CONSORT-C, which were informed by two systematic reviews published in 2015;[8] these initial items are referred to as the "base checklist". To capture new candidate items following these publications, and to identify the need for modifications or removal of items from the "base checklist", we conducted a literature search to identify and review newly published articles and guidance. Articles pertaining to *reporting in pediatric clinical trials*, *clinical trial reporting in children*, *pediatric clinical trial reporting guidelines*, and *pediatric trial reporting guidelines*, were searched on Google Scholar and Google Search periodically between April and August 2023 (**eAppendix 4**, Web Appendix 1). An additional and more structured search was conducted on Ovid MEDLINE to identify articles published between January 2014 – September 1, 2023 (details in **eAppendix 4**, Web Appendix 1). One Core Project Team member (AB) conducted the literature search and reviewed all articles and documents to identify relevant candidate reporting items. More articles and regulatory guidance documents were provided by experts who were consulted during project meetings. We also considered topics – such as the importance of elaborating on trial next steps and the extent of patient and family engagement – raised by youth and family caregivers during the development of CommuniKIDS, a plain language paediatric trial results communication template.[9]

A first version of the *Candidate Items* list comprised reporting items from the "base checklist", some of which were modified based on the literature search, and newly identified items. Two members of the Core Project Team (AB, MO) reviewed and supplemented the list with items of all existing SPIRIT | CONSORT extensions available (as of July 2023) that may be applicable to paediatric trials. We then organized the candidate items based on the topic/sections as per the updated SPIRIT | CONSORT 2025 checklists.[2 3] All members of the Core Project Team reviewed the potential candidate items, and refined the final list of candidate items to be included in Delphi Round 1.

Young Person Reporting Guideline (YPRG) workshops were conducted between December 2023 and January 2024. These workshops were created to provide an opportunity for young people to share what they thought would be important to be reported in a paediatric RCT trial protocol or report. All workshops were held with members of established Young Person Advisory Groups (YPAGs) in England, France, Scotland, and Spain, led by their respective youth facilitators (see acknowledgments). Two additional workshops were held in Canada with a group of young people from various Canadian YPAGs and interested members of the Youth Advisory Group. Discussion points from all workshops were reviewed with the eYPAGnet leaders to see if any new candidate reporting items had emerged that could be included for voting in the Delphi Study. New candidate items suggested by youth at the workshop were labelled as "Youth Generated", while candidate items suggested by the youth at the workshops that were already in the existing candidate item list were labelled as "Youth Endorsed". Further details on the YPRG workshops are published elsewhere.[6]

International Delphi Study

The candidate list of items was refined, and consensus was obtained on a "minimum set" of essential items, to be reported in a paediatric trial protocol or trial report, through a three-round, international web-based Delphi study conducted between January and May 2024. The Delphi study combined the rating of items for both SPIRIT-C 2026 and CONSORT-C 2026, enabling panellists to see if a candidate reporting item was

relevant to both and vote accordingly. We utilized the Research Electronic Data Capture (REDCap) platform to deliver each survey round.[10]

Individuals with expertise and knowledge of paediatric RCTs and trial methods were identified internationally. Specifically, eligible Delphi panellists had to have experience in at least one of the following: a) authoring or reviewing paediatric trial protocols or reports; b) conducting systematic reviews/evidence synthesis of paediatric trials; c) designing and/or statistical planning of paediatric trials; d) developing reporting guidelines relevant to paediatric trials and/or core outcome sets; or e) consulting paediatric trial literature to inform clinical-decision making. Potential Delphi panellists were identified through the Core Project Team's contacts and paediatric research networks, the International Advisory Group's contacts and trial networks, past collaborators on methodology projects, and Standards for Research in Child Health (StaR) steering committee members and authors.[11 12] We utilized snowball sampling to reach a wide group of potential panellists globally, encouraging those who registered to invite and circulate the registration form to colleagues with the stated relevant expertise. Journal editors from paediatric academic journals (i.e., *JAMA Pediatrics*, *The Lancet Child and Adolescent Health*, *Archives of Disease in Childhood*, *Pediatrics*, *Journal of Pediatrics*) were directly invited. We also opened a general online interest form for individuals interested in contributing to the project, which was shared at academic conferences (44th Annual Society for Clinical Trials Meeting (2023), Maternal Infant Child and Youth Research Network (MICYRN) Annual Retreat 2023) and in a Viewpoint published in *JAMA Pediatrics*.[13] Those who filled out this general interest form indicating interest in being a Delphi panellist were contacted and sent the registration form, which collected data about their professional background and their relevant expertise. This online registration form was completed by all individuals interested in being a Delphi panellist. Core Project Team members did not participate as panellists.

We also invited young people (eligible ages 19-24 years) and family caregivers with lived experience related to paediatric RCTs (e.g., personal experience as paediatric trial participants or of their child, users of paediatric RCT protocols or reports) to contribute as Delphi panellists. Identification of family caregivers and young people was done with assistance from members of our Family Caregiver Advisory Group, who work with various patient groups and research institutes, such as the Canadian PKU and Allied Disorders (CanPKU+), Children's Hospital of Eastern Ontario (CHEO) Research Family Leader Program, and the Youth Engagement in Research Instagram account (@youth_in_research). Additionally, we reached out to other Canadian research and patient partner groups, such as INFORM RARE, Centre for Addiction and Mental Health (CAMH) National Youth Advisory Council (NYAC), Maternal Infant Child and Youth Research Network (MICYRN) KidsCan Young Persons' Advisory Group (YPAG), SickKids Pain Centre Patient Advisory Committee, Pediatric Outcome Improvement through Coordination of Research Networks (POPCORN), Solutions for Kids in Pain (SKIP), Winnipeg Advisory Group, and TARGet! Kids, who circulated information and the registration link to their groups. All interested family caregivers and young people attended a 1-hour virtual onboarding session to learn more about the project and the Delphi study to become familiar with their roles and the process before committing to being a panellist. Further details on this patient-partnering process are provided in a separate publication.[6]

We pilot tested the Round 1 survey with two PhD students, one research fellow, three research staff, and one family advisor; these pilot testers possessed experience with Delphi studies or reporting guideline development but also included those with no expertise in research methodology. We asked pilot testers to evaluate whether the glossary accompanying the Delphi study was clear and understandable, and whether they found the Round 1 survey to be functional, clear, and understandable. Pilot testing was done for the Round 2 survey with two family advisors, who again provided feedback on the clarity of the survey instructions and format. Feedback from pilot testers were reviewed and incorporated prior to the launch of Round 1 and 2. The Round 3 survey was considerably shorter than the earlier rounds and similar in

instruction and format to Round 2, so no pilot testing was done. The pilot testing informed the estimated completion time for each survey round to be approximately 1 hour.

Those who registered as a Delphi panellist were emailed a link to access the Round 1 survey. Two reminders were sent for each round, the first going out around 10 days prior to the end date, and the second in the final week. There was a 3 to 4-week gap between each round for analysis of Delphi round results and survey development. After Round 1, family caregiver and young people panellists were offered the opportunity to join an optional virtual check-in session in case they had any questions or concerns, and were encouraged to reach out to the team should they need support at any point throughout the Delphi study.

In the Delphi study, panellists were presented three different types of items: a) "Base items" from the initial development of the SPIRIT | CONSORT-C guidelines; b) "SPIRIT | CONSORT-Outcomes items" from the SPIRIT | CONSORT-Outcomes 2022 checklists;[14 15] and c) "New/modified items", which were new items or modified "Base items", generated, as a result of the literature search or the international YPRG workshops. When voting, we asked panellists to rate the importance of including the item in a paediatric RCT protocol or report. Panellists were provided with different rating scales for different item types: items labelled as "Base items" or "SPIRIT | CONSORT-Outcomes items" were provided the options of "No, exclude", "Unsure", or "Yes, keep". This nominal scale was used as these items had gone through a consensus process in earlier projects. For items that were labelled as "New/Modified", a 9-point Likert scale was provided, with ratings of 1-3 indicating *limited importance* for the item's inclusion, 4-6 indicating *important but not critical*, and 7-9 indicating *critical* for inclusion. All items also had the option of "I'm opting out", for panellists who preferred not to rate an item. In addition, panellists were asked to vote on the clarity of the wording for each candidate item on a 5-point bipolar Likert scale (Strongly disagree, Disagree, Neutral, Agree, Strongly Agree). For every item, the Delphi study provided panellists an optional text box for feedback and comments on the item's wording, suggestions for item division or merging, or explaining their vote. According to the protocol,[1] for an item to meet consensus criteria to be included, the item was voted on at least twice, a threshold of ≥70% of panellists endorsed "Yes, keep" or assigned a score of 7-9, and <15% of panellists recommended exclusion or assigned a score of 1-3. For an item to meet consensus criteria to be excluded was defined as the reverse, with at least two rounds of voting, a threshold of ≥70% of panellists endorsed "No, exclude" or assigned a score of 1-3, and <15% of panellists recommended inclusion or assigned a score of 7-9.

In Round 1, in addition to rating candidate items, panellists were able to suggest new items for consideration. "Base items" and "SPIRIT | CONSORT-Outcomes" items that reached the consensus "in" threshold in Round 1 were not considered in Round 2; having gone through a prior consensus process and reaching inclusion threshold in Round 1, we considered their importance reaffirmed. In Round 2, we added the new, panellist-suggested items and items generated during the YPRG workshops (see above) for rating. Panellists also voted on three potential guideline's names and could suggest alternatives. In Round 3, items that had not yet been voted on twice were brought forward for voting. For both Rounds 2 and 3, panellists could review the scores from the previous round for items that were carried forward to inform their vote, including their own vote for the item, the percentage of panellists that had voted for including the item, and a list of summarized anonymous comments on the item from other Delphi panellists. Panellists were also shown how family caregivers and young people (as a group) had voted for each item in contrast with other panellist groups. Therefore, we required panellists to complete the preceding round's survey in its entirety to receive access to the next round. Only complete responses were included in the analysis. After each round, we analysed Delphi results by calculating the voting frequencies for each reporting item for all panellists and by separate groups (i.e., academia, non-academic healthcare, family caregivers, young people). Comments and feedback left in the open text box for each item were reviewed; key comments

that argued for or against the inclusion of an item were summarized, and any wording suggestions were reviewed and applied as proposals in the next Delphi round. All Delphi analysis was done by the project lead (AB); results were compiled in a summary report and were sent to all panellists prior to the start of the next round.

International Consensus Meeting

A virtual, five-hour Consensus Meeting was held in June 2024 over Zoom to a) discuss candidate reporting items that had not reached consensus in the Delphi study for both SPIRIT-C 2026 and CONSORT-C 2026, b) vote on the final guidelines' title, and c) discuss the subsequent E&E paper writing process. We invited members of the International Advisory Group, International Young Person Involvement Committee including the eYPAGnet leaders, experienced reporting guideline developers, and Delphi panellists who had completed all three rounds of the Delphi study and indicated their interest and availability to attend at the end of the Round 3 survey. Ultimately, Consensus Meeting attendees were purposively invited by members of the Core Project Team (AB, MO) to achieve diversity in expertise, roles, and geographic locations represented.

We provided a Pre-Consensus "Meeting Package" with information on logistics, instructions, and background information on candidate items that would be discussed at the meeting to all attendees a week prior to the meeting. Two days before the meeting, we held a separate preparatory meeting for Family Caregiver Advisors who were attending the Consensus Meeting, to go over the purpose of the Consensus Meeting and E&E writing process in more depth, their roles and how they could contribute, and to answer any questions.

The Consensus Meeting was recorded, along with meeting notes. Each Core Project Team member chaired one to three of the eight meeting sessions. Two sessions were dedicated to discussing the candidate reporting items; session chairs summarized the Delphi study results for the item and presented summarized comments, then opened for discussion by first inviting the family advisors, and then the wider group, to share their thoughts. At the "real time" group voting session, attendees could vote "Include", "Exclude", or "Abstain" for each item; the consensus criteria for inclusion or exclusion were at least 70% of votes. Items that did not reach the inclusion/exclusion threshold were discussed after the meeting by select core team members (AB, MO) to decide on their inclusion in the E&E writing phase and in the pre-final draft checklist. The other 5 sessions addressed young people and family caregiver involvement, Delphi study overview, options for the reporting guidelines' title, writing process for the E&E papers, and next project steps.

E&E Group Writing

We implemented a group-writing approach for the E&E writing process. The E&E is a pedagogical paper that provides the rationale and evidence for including each checklist item along with examples to demonstrate each item's optimal reporting. We invited all Consensus Meeting attendees to be part of the writing team, and International Advisory Group members, regardless of if they had attended the Consensus Meeting. International Advisory Group members could elect to either be a writer/reviewer as part of the writing team, as a reviewer for the entire E&E papers once both were drafted, or not participate in the E&E writing and review process.

Those interested in being part of the writing team signed up to be a writer, reviewer, or both for a minimum of five reporting items of their choice from July – August 2024. For each reporting item, we required a team of at least two writers and two reviewers and asked writing team members to sign up to contribute to a minimum of five items. The writing team worked on a shared online Google document, and had access to several resources, including instructions, pre-final checklists, reports of 50 paediatric RCTs published in 2022, and a list of key elements for each reporting item.

Once the writing and review process was completed, the project lead and principal investigator (AB, MO) reviewed and edited all drafts by the writing team, drafted additional text, and identified additional reporting examples. We also drafted E&E text and identified examples for CONSORT 2025 Item 1b to provide guidance for Abstracts. Revised versions of the E&E were then circulated to the International Advisory Group Members and other colleagues who signed up to be a reviewer for the drafted E&E papers. After review of the additional comments and feedback, the E&E papers were finalised.

Pilot testing of checklist, E&E, and finalisation

To assess the usability, feasibility, and acceptability of the new guidelines in practice, we pilot tested the new CONSORT-C 2026 items and accompanying E&E paper in October and November 2024. We recruited pilot testers by reaching out to the same paediatric trial networks and research organizations contacted to identify Delphi panellists, as well as through colleagues and networks of the Core Project Team. Those who were in the process of drafting, (re)submitting, or had recently published a paediatric RCT report (i.e., in 2023 or 2024) during the pilot testing dates were eligible to pilot test CONSORT-C 2026. Those reviewing an RCT report as a peer reviewer (e.g., journal editor) were also eligible.

We gave pilot testers access to the CONSORT-C 2026 checklist and E&E and asked them to assess or enhance reporting in their trial manuscript by applying the guidance. We then asked them to provide feedback through an online survey. For each CONSORT-C 2026 reporting item, this survey asked respondents to indicate whether the item was reported, and whether it was understandable and relevant. We asked pilot testers to indicate if they used the E&E paper for the reporting item, and if yes, whether the E&E was perceived helpful in understanding the item. They also had the option to suggest improvements to the item or its corresponding E&E text in a free text box.

We analysed pilot testing results descriptively, and compiled suggestions for possible changes to the guidelines based on pilot tester feedback. Results and feedback were independently reviewed by two Core Project Team members (AB, MO). Consensus was reached among AB and MO on the final changes to be made to item wording and explanation text based on the feedback, and the need to identify additional examples.

We conducted the final project meeting with all members of the Core Project Team present to discuss the content of the papers, publication, and dissemination strategies in December 2024. We then drafted this report; all co-authors contributed to the final version of this report.

eAppendix 4. Literature search strategy

OVID Medline Search Terms (search date: September 1, 2023)

Search terms	**Yield**
1. pediatrics.mp. or exp Pediatrics/	99074
2. clinical trials.mp. or exp Clinical Trial/	1381605
3. reporting.mp.	278355
4. exp Randomized Controlled Trials as Topic/ or trial reporting.mp. or exp Clinical Trials as Topic/	384343
5. randomized clinical trial.mp.	40234
6. RCT.mp.	34875
7. 1 and 2 and 3 and 4 and 5 and 6	1
8. 1 and 3 and 4	96
9. limit 8 to yr=’2014 – Current’	50

Other searches (Google Scholar, Google Search):

April 20, 2023: “Pediatric trial reporting guidelines”, Google Scholar, Since 2023
May 12, 2023: “pediatric clinical trials reporting guidelines”, Google Search
May 18, 2023: “scoping review for trials with PPI”, Google Search
June 12, 2023: “clinical trial reporting children”, Google Scholar, Since 2023
June 12, 2023: “clinical trial reporting children”, Google Search
August 25, 2023: “reporting pediatric trials”, Google Search

eAppendix 5. Item flow in Delphi Rounds 1-3

To start with, 53 candidate items pertinent to CONSORT-C 2026 were voted on in Round 1. Based on comments from panellists in Round 1 and voting results, we removed 7 items as they were redundant; 3 items were merged with other items. Six items met the consensus criteria to be included, and as these items were “Base items”, their importance was reaffirmed and met the consensus criteria to be included after Round 1. Sixteen items were carried forward to Round 2 for voting, with some items being modified based on suggestions from panellists, and one item was split into three based on panellist comments.

Items voted on in Round 1 included items that are specific to paediatric RCTS, as well as items that are particularly relevant to paediatric RCTs but not necessarily specific (e.g., establishment of a Data Safety Monitoring Board). However, in Round 1, some panellists expressed concerns over the feasibility of a guideline that includes reporting items that are relevant to paediatric RCTs, but not paediatric specific (e.g., establishment of a Data Safety Monitoring Board), in addition to reporting items that clearly are specific to paediatric RCTs. Both *relevant* and *specific* items were initially included for consideration to develop guidance that would comprehensively cover all key information needed for readers to be able to interpret, replicate, and synthesize what is published in a paediatric RCT. Yet, given these concerns, we labelled each candidate reporting item as either *specific* (S) or *relevant* (R) from Round 2 onwards. Considering the guideline’s scope in which we aimed to develop a **minimum** set of essential reporting items for paediatric clinical trials, we removed most reporting items that were *relevant* (R) from consideration as a standalone reporting item. Therefore, 21 items were removed from consideration as standalone reporting items after Round 1, and the content of these items was decided to be best included in the E&E for related CONSORT 2025 items regarding patient and public involvement, interventions, harms, outcomes, participant flow, baseline demographics and clinical characteristics.

In Round 2, panellists voted on 22 candidate items: 16 items carried over from Round 1, two Youth Generated items from the YPRG workshops attended by 42 youth (ages 10-21 years), two panellist-suggested items from Round 1, and two items resulting from a split of one item that was voted on in Round 1. After voting, three of these items reached the consensus criteria for inclusion. Six items did not meet consensus criteria for inclusion or exclusion after two rounds of voting and were carried forward to the Consensus Meeting. Based on panellist comments and voting results, we removed one item due to redundancy and found seven items to be better suited as detail in the E&E instead of being standalone reporting items, as above. Further rewording was done on select items based on panellist comments.

In Round 3, panellists voted on five candidate items *specific* to paediatric RCTs. One item met consensus criteria for inclusion, and 4 items did not reach consensus. In total, after the Delphi study, 10 items pertinent to CONSORT-C 2026 met the consensus “in” criteria, and 10 items did not meet consensus criteria for inclusion or exclusion and were carried over to the Consensus Meeting for discussion.

eTable 1. Characteristics of Delphi panellists

Characteristics	Round 1 (N = 176)	Round 2 (N = 144)	Round 3 (N = 143)
Panellist identification	**N (%)**	**N (%)**	**N (%)**
Self-selected/part of the snowball process	104 (59)	77 (53)	77 (54)
Invited by the team	72 (41)	67 (47)	66 (46)
Primary perspective	**N = 176**	**N = 144**	**N = 143**
Academia	132 (75)	106 (74)	105 (74)
Non-academic healthcare	16 (9)	12 (8)	12 (8)
Family caregiver (e.g., parent, guardian)	10 (6)	10 (7)	10 (7)
Non-profit	5 (3)	4 (3)	4 (3)
Young person (ages 19-24)	4 (2)	4 (3)	4 (3)
Regulatory agency	1 (1)	1 (1)	1 (1)
Industry	1 (1)	1 (1)	1 (1)
Other[a]	7 (4)	6 (2)	6 (2)
Location	**N = 176**	**N = 144**	**N = 143**
Europe	92 (52)	68 (47)	68 (47)
North America	63 (36)	57 (40)	56 (40)
South America	1 (1)	1 (1)	1 (1)
Oceania	8 (5)	7 (5)	7 (5)
Asia	8 (5)	7 (5)	7 (5)
Africa	2 (1)	2 (1)	2 (1)
Middle East	2 (1)	2 (1)	2 (1)
Highest level of education[b]	**N = 162**	**N = 130**	**N = 129**
MD (Medical degree) & PhD	69 (43)	53 (41)	53 (41)
MD (Medical degree)	31 (19)	27 (20)	26 (20)
PhD	37 (23)	31 (24)	31 (24)
Master's degree	17 (10)	12 (9)	12 (9)
Bachelor's degree	3 (2)	2 (2)	2 (2)
Other[c]	5 (3)	5 (4)	5 (4)
Interest-holder group[d]	**N = 176**	**N = 144**	**N = 143**
Child health researcher	95 (54)	79 (55)	78 (55)
Paediatrician	83 (47)	70 (49)	69 (48)
Paediatric/child health trial protocol author	82 (47)	68 (47)	67 (47)
Paediatric/child health clinician scientist	77 (44)	62 (43)	61 (43)
Paediatric/child health trial report author	71 (40)	60 (42)	59 (41)
Paediatric/child health clinical trialist	69 (39)	59 (41)	58 (41)
Systematic review author	68 (39)	57 (40)	56 (39)
Journal editor	41 (23)	37 (26)	37 (26)
Reporting guideline developer	20 (11)	15 (10)	15 (10)
Methodologist	33 (19)	26 (18)	25 (17)
Epidemiologist	31 (18)	28 (19)	28 (20)
Research ethics committee member that reviews trial protocols	22 (13)	20 (14)	20 (14)
Core outcome set developer	16 (9)	13 (9)	13 (9)
Biostatistician	13 (7)	12 (8)	12 (8)
Family caregiver (e.g., parent, guardian)	10 (6)	10 (7)	10 (7)
Student of trainee working on a paediatric/child health clinical trial	7 (4)	6 (4)	6 (4)
Young people (ages 19-24)	4 (2)	4 (3)	4 (3)
Funder	1 (1)	1 (1)	1 (1)

Paediatric specialty[e]	**N = 106**	**N = 87**	**N = 86**
Adolescent Medicine	1 (1)	0 (0)	0 (0)
Allergology	1 (1)	1 (1)	1 (1)
Anaesthesia	1 (1)	1 (1)	1 (1)
Community Paediatrics	1 (1)	1 (1)	1 (1)
Critical/Intensive Care	3 (3)	3 (3)	3 (4)
Epidemiology	1 (1)	1 (1)	1 (1)
General Paediatrics	4 (4)	4 (5)	4 (5)
Hepatology	1 (1)	1 (1)	1 (1)
Hospital Paediatrics	1 (1)	1 (1)	1 (1)
Infectious Disease	7 (7)	5 (6)	5 (6)
Neonatology	26 (25)	22 (26)	22 (26)
Neurodevelopment	1 (1)	1 (1)	1 (1)
Neurorehabilitation	1 (1)	1 (1)	1 (1)
Orthopaedic Surgery	1 (1)	1 (1)	1 (1)
Emergency medicine	9 (9)	8 (9)	7 (8)
Gastroenterology	6 (6)	4 (5)	4 (5)
Oncology	2 (2)	2 (2)	2 (2)
Cardiology	1 (1)	1 (1)	1 (1)
Nephrology	2 (2)	2 (2)	2 (2)
Neurology	4 (4)	3 (3)	3 (3)
Psychiatry	2 (2)	2 (2)	2 (2)
Pharmacology	1 (1)	1 (1)	1 (1)
Psychology	1 (1)	1 (1)	1 (1)
Respirology/Pulmonology	4 (4)	3 (3)	3 (3)
Rheumatology	2 (2)	2 (2)	2 (2)
Other[f]	22 (21)	15 (17)	15 (17)
Level of expertise on paediatric/child health clinical trials[b,g]	**N = 162**	**N = 130**	**N = 129**
High	93 (57)	76 (58)	75 (58)
Average	63 (39)	50 (38)	50 (39)
Low	6 (4)	4 (3)	4 (3)
Level of expertise on the SPIRIT statement[b,h]	**N = 162**	**N = 130**	**N = 129**
High	37 (23)	30 (23)	29 (22)
Average	91 (56)	76 (58)	76 (59)
Low	34 (21)	24 (18)	24 (19)
Level of expertise on the CONSORT statement[b,i]	**N = 162**	**N = 130**	**N = 129**
High	62 (38)	55 (42)	54 (42)
Average	85 (52)	68 (52)	68 (53)
Low	15 (9)	7 (5)	7 (5)
Number of paediatric/child health trial reports written/co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	26 (16)	18 (14)	18 (14)
< 3	50 (31)	41 (32)	41 (32)
3-6	40 (25)	29 (22)	29 (22)
7-10	16 (10)	15 (12)	15 (12)
>10	30 (18)	27 (21)	26 (21)
Number of paediatric/child health trial protocols written/co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	24 (15)	18 (14)	18 (14)
< 3	57 (35)	45 (35)	45 (35)
3-6	46 (28)	38 (29)	38 (29)
7-10	10 (6)	8 (6)	8 (6)

>10	25 (15)	21 (16)	20 (16)
Number of paediatric/child health trials conducted	**N = 162**	**N = 130**	**N = 129**
None	24 (15)	20 (15)	20 (15)
< 3	45 (28)	35 (27)	35 (27)
3-6	38 (23)	28 (22)	28 (22)
7-10	20 (12)	16 (12)	16 (12)
>10	35 (22)	31 (24)	30 (24)
Number of paediatric/child health trial reports reviewed for funding agency or medical journal[b]	**N = 162**	**N = 130**	**N = 129**
None	27 (17)	18 (14)	18 (14)
< 3	25 (15)	19 (15)	19 (15)
3-6	31 (19)	29 (22)	29 (22)
7-10	20 (12)	16 (12)	16 (12)
>10	59 (36)	48 (37)	47 (37)
Number of paediatric/child health trial protocols reviewed for a funding agency or medical journal[b]	**N = 162**	**N = 130**	**N = 129**
None	33 (20)	23 (18)	23 (18)
< 3	32 (20)	27 (21)	27 (21)
3-6	40 (25)	34 (26)	34 (26)
7-10	21 (13)	16 (12)	16 (12)
>10	36 (22)	30 (23)	29 (23)
Number of paediatric/child health trials involved in the design and/or statistical planning of[b]	**N = 162**	**N = 130**	**N = 129**
None	13 (8)	11 (8)	11 (8)
< 3	54 (33)	42 (32)	42 (32)
3-6	34 (21)	26 (20)	26 (20)
7-10	23 (14)	18 (14)	18 (14)
>10	38 (23)	33 (25)	32 (25)
Number of core outcome sets developed and/or co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	73 (45)	55 (42)	54 (42)
< 3	48 (30)	38 (29)	38 (29)
3-6	23 (14)	21 (16)	21 (16)
7-10	8 (5)	7 (5)	7 (5)
>10	10 (6)	9 (7)	9 (7)
Number of reporting guidelines relevant to trials developed and/or co-authored[b]	**N = 162**	**N = 130**	**N = 129**
None	95 (59)	71 (55)	71 (55)
< 3	47 (29)	41 (32)	40 (32)
3-6	12 (7)	11 (8)	11 (8)
7-10	6 (4)	6 (5)	6 (5)
>10	2 (1)	1 (1)	1 (1)
Number of systematic reviews and/or evidence synthesis of trials conducted[b]	**N = 162**	**N = 130**	**N = 129**
None	38 (23)	26 (20)	26 (20)
< 3	47 (29)	37 (28)	37 (28)
3-6	40 (25)	33 (25)	33 (25)
7-10	14 (9)	14 (11)	14 (11)
>10	23 (14)	20 (15)	19 (15)
Frequency of reading and/or consulting trial literature to inform clinical decision-making practices[b]	**N = 162**	**N = 130**	**N = 129**
Never	4 (2)	2 (1)	2 (1)

Occasionally	17 (10)	13 (8)	13 (8)
Often	128 (79)	104 (64)	103 (64)
Not applicable	13 (8)	11 (7)	11 (7)

[a] Other consisted of those who indicated: publishing (n = 1), academia and regulatory agency (n = 1), associate editor and chair of paediatrics (n = 1); paediatric emergency medicine (n = 1); student and person with a paediatric-onset rare disease (n = 1); healthcare with academia (n = 1); ethics committee (n = 1). Panellist who indicated ethics committee did not complete Rounds 2 and 3.

[b] Denominator excludes family caregivers (n = 10) and young people (ages 19-24) (n = 4). Round 1 (n = 162); Round 2 (n = 130); Round 3 (n = 129).

[c] PharmD/PhD; Clinical Doctorate; MBBS; MBChB; MRCP, MRCPCH

[d] Panellist could select more than one option, so percentages do not add up to 100%

[e] Limited to those who selected “paediatrician” or “clinician-scientists” as their interest-holder groups (Round 1: n = 106; Round 2: n = 87; Round 3: n = 86)

[f] Other consisted of a mix of specialties: all trials/anaesthesia (n = 1, Round 1); allergy and immunology (n = 2, Round 1; n = 1, Rounds 2-3); infectious diseases and immunology (n = 1, Rounds 1-3); infectious diseases and pulmonology (n = 1, Round 1); inherited genetic conditions, emergency medicine (n = 1; Rounds 1-3); n/a (n = 1, Rounds 1-3); neonatal intensive care nurse, advanced neonatal nurse practitioner (n = 1, Round 1); neonatology and clinical pharmacology (n = 1, Rounds 1-3); neurodisability, child protection (n = 1, Rounds 1-3); paediatric and neonatal intensive care (n = 1, Round 1); paediatric gastroenterology, hepatology, and nutrition (n = 2, Round 1; n = 1, Rounds 2-3); paediatric nephrologist, clinical pharmacologist, and clinical trials lead (n = 1, Rounds 1-3); paediatric oncology, child health outcomes (n = 1, Round 1); paediatrics, paediatric cardiology (n = 1, Rounds 1-3); paediatric critical care and clinical pharmacology (n = 1, Rounds 1-3); pharmacovigilance and drug safety (n = 1, Rounds 1-3); pulmonology and allergology (n = 1, Rounds 1-3); respiratory and high dependency care (n = 1, Rounds 1-3); respiratory and sleep medicine (n = 1, Rounds 1-3); rheumatology, physiology (n = 1, Rounds 1-3)

[g] Panellists’ self-rated expertise (e.g., designing, conducting, reporting, understanding, and using) paediatric/child health clinical trials

[h] Panellists’ self-rated expertise on using the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement

[i] Panellists’ self-rated expertise on using the Consolidated Standards of Reporting Trials (CONSORT) statement

eTable 2. Characteristics of Consensus Meeting panellists

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Ami Baba, MRes	**Project Lead,** SPIRIT | CONSORT-C project **Senior Project Manager,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Child health researcher Reporting guideline developer Systematic review author
Martin Offringa, MD, PhD	**Project Principal Investigator,** SPIRIT | CONSORT-C project **Senior Scientist,** Staff Neonatologist **Associate editor,** Cochrane Neonatal	The Hospital for Sick Children	Canada	Trial report author Trial protocol author Child health researcher Clinical trialist Clinician-scientist Paediatrician Reporting guideline developer Core outcome set developer Methodologist Epidemiologist Journal editor Systematic review author
Karel Allegaert, MD, PhD	**Professor,** KU Leuven **Senior consultant,** Erasmus MC Rotterdam **Associate Editor**, Archives of Disease in Childhood **Associate Editor,** Archives of Disease in Childhood – Fetal and Neonatal Edition **Deputy Editor in Chief,** BMJ Paediatrics Open	KU Leuven, Eramus MC, Rotterdam	Belgium, the Netherlands	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Neonatologist, Clinical Pharmacologist Reporting guideline developer Core outcome set developer Journal editor Systematic review author
Katelynn E. Boerner, PhD RPsych	**Assistant Professor,** University of British Columbia & BC Children's Hospital Research Institute **Registered Psychologist,** BC Children's Hospital	University of British Columbia	Canada	Trial protocol author Trial report author Clinician scientist Child health researcher Journal editor Systematic review author

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Nancy J. Butcher, PhD	**Co-Director,** Increasing Capacity for Maternal and Paediatric Trials (IMPaCT) **Assistant Professor,** University of Toronto	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Reporting guideline developer Core outcome set developer Methodologist Systematic review author
Tanya Chute Nagy	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project **Vice President,** Canadian PKU and Allied Disorders (CanPKU+)	Canadian PKU and Allied Disorders (CanPKU+)	Canada	Family caregiver
Jérémie F. Cohen, MD, PhD	**Professor,** Necker Hospital for Sick Children	Necker Hospital for Sick Children, Université Paris Cité, France	France	Paediatrician Reporting guideline developer Methodologist Epidemiologist Journal editor Systematic review author
Kimberly Courtney, MSc, CCLS, RECE	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project **Family Engagement in Research Facilitator**, Child Life Specialist, CHEO	CHEO	Canada	Family caregiver
Yan Défossés	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project	N/A	Canada	Family caregiver
Amanda Doherty-Kirby, PhD	**Family Caregiver Advisor,** SPIRIT | CONSORT-C project	N/A	Canada	Family caregiver
Reinhard Feneberg, MD	**Medical Director,** ICON plc	ICON Plc	Germany	Trial protocol author Trial report author Clinician-scientist Child health researcher Paediatrician Biostatistician

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Ségolène Gaillard	**Project Manager,** Hospices Civils de Lyon **PhD Student,** Claude Bernard University	Hospices Civils de Lyon eYPAGnet	France	Member of the Youth Involvement International Steering Committee
Lisa Hartling, PhD	**Professor,** University of Alberta **Director**, Alberta Research Centre for Health Evidence (ARCHE) **Canada Research Chair,** Knowledge Synthesis and Translation	University of Alberta	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Reporting guideline developer Methodologist Epidemiologist Systematic review author
Terry P. Klassen, MD	**Provincial Department Head of Paediatrics,** University of Saskatchewan **Adjunct Professor**, University of Manitoba	University of Saskatchewan	Canada	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Methodologist Systematic review author
Niina Kolehmainen, PhD	**Professor in Child Health Research,** Newcastle University	Newcastle University	UK	Trial protocol author Allied health clinician Child health researcher Systematic review author
Menelaos Konstantinidis, MSc	**PhD Student,** University of Toronto **Chief Statistician,** Emory University School of Medicine	St. Michael's Hospital, Unity Health Toronto	Canada	Child health researcher Reporting guideline developer Methodologist Biostatistician Epidemiologist Journal editor Systematic review author Student/trainee
Thierry Lacaze-Masmonteil, MD, PhD	**Scientific Director,** Maternal Infant and Child Youth Research Network (MICYRN)	Maternal Infant and Child Youth Research Network (MICYRN)	Canada	Clinician scientist
Esther Lau, MA	**Editor-in-Chief,** The Lancet Child & Adolescent Health	The Lancet Child & Adolescent Health	UK	Journal editor

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Patricia Longmuir, PhD	**Senior Scientist,** CHEO Research Institute	CHEO Research Institute	Canada	Trial protocol author Trial report author Child health researcher
Kayur Mehta, MD	**Assistant Scientist,** Johns Hopkins Bloomberg School of Public Health	Johns Hopkins University	USA	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Epidemiologist Systematic review author
David Moher, PhD	**Professor,** University of Ottawa	University of Ottawa	Canada	Clinical epidemiologist Reporting guidelines Publication scholarship
Shaun Morris, MD	**Senior Scientist and Infectious Disease Physician,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Clinician scientist Child health researcher Paediatrician Systematic review author
Begonya Nafria Escalera, PhD Candidate	**Head of the Patient Engagement in Research Department,** Institut de Recerca Sant Joan de Deu **PhD Student,** Universitat Internacional de Catalunya	Institut de Recerca Sant Joan de Deu eYPAGnet	Spain	Member of the Youth Involvement International Steering Committee Patient involvement expert Systematic review author
Kim An Nguyen, MD, PhD	**Associate Professor, Neonatologist,** Hospices Civils de Lyon Claude Bernard University Lyon 1	Hospices Civils de Lyon LBBE/Claude Bernard University Lyon 1	France	Trial protocol author Trial report author Clinical trialist Clinician scientist Paediatrician Methodologist Epidemiologist Systematic review author Research ethics committee member
Michal Odermarsky, MD, PhD	**Senior Pediatric Cardiologist,** Children Heart Centre, Skane University Hospital	Children Heart Centre, Skane University Hospital	Sweden	Trial protocol author Child health researcher Paediatrician

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Wes Onland, MD, PhD	**Neonatologist,** Emma Children's Hospital, Amsterdam UMC	Emma Children's Hospital, Amsterdam UMC	The Netherlands	Trial protocol author Trial report author Clinical trialist Clinician scientist Paediatrician Systematic review author
Ramesh Poluru, PhD	**Senior Program Officer,** The INCLEN Trust International	The INCLEN Trust International	India	Trial protocol author Trial report author Clinical trialist Child health researcher Methodologist Biostatistician Epidemiologist Journal editor
Beth Potter, PhD	**Professor,** University of Ottawa **Co-Investigator**, SPIRIT | CONSORT-C project	University of Ottawa	Canada	Epidemiologist Child Health Researcher Trial protocol author Systematic review author
Jennifer Preston, PhD Candidate, BA Hons	**Patient and Public Involvement Policy Manager**	University of Liverpool eYPAGnet	UK	Member of the Youth Involvement International Steering Committee Patient and Public Involvement Expert Systematic review author
Diane Purper-Ouakil, MD, PhD	**Professor,** University Hospital of Montpellier **Head of Child and Adolescent Psychiatry Department,** University Hospital of Montpellier	University Hospital of Montpellier	France	Clinician scientist Clinical trialist Trial protocol author Systematic review author
Giorgio Reggiardo, PhD	**Head of Biostatistics Unit,** TEDDY European Network of Excellence for Paediatric Research	TEDDY European Network of Excellence for Paediatric Research	Italy	Methodologist Biostatistician Epidemiologist Systematic review author
Amy Slogrove, MD PhD	**Senior Editor,** The Lancet Child & Adolescent Health	The Lancet Child & Adolescent Health	South Africa	Paediatrician Epidemiologist Journal editor
Maureen Smith, MEd	**Patient Engagement Expert,** SPIRIT | CONSORT-C project	N/A	Canada	Patient Partner

Name[a]	Title(s)	Institution(s)	Location	Self-reported interest-holder group
Catherine Stratton, MPH	**PhD Student,** University of Toronto	University of Toronto	Canada	Student/trainee
Alene Toulany, MD	**Adolescent Medicine Specialist,** The Hospital for Sick Children	The Hospital for Sick Children	Canada	Paediatrician
Julia Upton, MD, MPH	**Clinical Immunologist & Allergist**	The Hospital for Sick Children	Canada	Trial protocol author Trial report author Clinical trialist Child health researcher Paediatric subspecialist Journal editor Systematic review author

[a]SPIRIT | CONSORT-Children and Adolescents team members also in attendance to facilitate meeting: Adrian Sammy (notetaker)
Note: The consensus meeting was held virtually on 20 June 2024.

eTable 3. Characteristics of Pilot Testers

Self-reported characteristics	**CONSORT-C 2026 Pilot testers (n = 11)**
Country of workplace	**N (%)**
Australia	6 (55)
Netherlands	3 (27)
Canada	1 (9)
France	1 (9)
Highest level of education	
MD/PhD	6 (55)
PhD	3 (27)
PharmD/PhD	1 (9)
Master's degree	1 (9)
Participated in the Delphi study	
Yes	2 (18)
No	9 (82)
Participated in the Explanation and Elaboration (E&E) Writing Process	
Yes	1 (9)
No	10 (91)
Use of the guideline*	
As a checklist	7 (64)
As a writing tool	4 (36)
As a peer review or assessment of someone else's trial report	2 (18)
As a teaching tool	2 (18)
Trial report used for pilot testing	
Published	4 (36)
Not yet published	7 (64)
Role in trial report used for pilot testing	
First author	5 (45)
Principal investigator/senior author	4 (36)
Co-author	2 (18)
Trial report specialty	
Respirology/pulmonology	2 (18)
Neonatology	1 (9)
Allergy	1 (9)
Emergency medicine	1 (9)
Surgery	1 (9)
Anaesthesia	1 (9)
Undisclosed	4 (36)

*Respondents were able to select more than one option, so percentages add up to over 100%

eTable 4. *CONSORT-Children and Adolescents (CONSORT-C) 2026* Expanded Checklist with Summary of Key Elements

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
Title and abstract					
Title and structured abstract	1a	Identification as a randomised trial	1a.1*	Identify that it is a paediatric trial, and include age group(s)/range(s), interventions, and, if applicable, trial acronym	• Clearly indicate it is a paediatric trial with relevant terms (e.g., paediatric, newborn, infants, children, young children, adolescents, etc.) • (Sub) population accompanied by age range(s) • Intervention(s) • Acronym, if used
	1b	Structured summary of the trial design, methods, results, and conclusions		• Eligible age group(s) and developmental stage(s) of participants • Appropriateness of intervention dose and formulation for the trial participants age, weight, or body surface area • Need for support person for intervention delivery • Justification for trial being undertaken in children/adolescents • Number of children/adolescents randomised and analysed by age group(s) • Results for each age group(s) • Important harms for different age group(s) included • Specific age group(s) to which results are applicable	
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 de-identified 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*†	Describe the prevalence/incidence of the disease or condition in children/adolescents	• Prevalence and/or incidence of the condition in the designated trial population • Known variability in prevalence or incidence for each included (sub)group

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
					• Paediatric (sub)groups most affected by the disease or condition
			6.2	Describe available evidence on the efficacy/effectiveness of the intervention in children/adolescents	• Existing evidence of efficacy/effectiveness of intervention in children and adolescents • Whether paediatric evidence is available, yet uncertainty exists for children/adolescents overall or for specific age subgroups • Whether evidence is only available in adults
			6.3*	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents	• Need for the trial in the context of existing paediatric evidence • Rationale for including specific age range(s) • Whether the trial was done for regulatory purposes
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		• Whether children, adolescents, family caregivers (i.e., parents, guardians), family member, and/or adults with relevant lived paediatric experiences were involved as research partners • Level of involvement of patient or public partners in the design, conduct, reporting, and dissemination of trial results, with details on the timing of involvement and activities • Outcome and impact of children/adolescents and families on trial design, conduct, reporting; if no or unknown impact, state this • Any permissions, research ethics aspects, compensation, and privacy considerations related to patient and public involvement	
Trial design	9	Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, 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*†	Provide a justification for including multiple age groups or children/adolescents at different developmental stages, and address potential	• Age groups of eligible and included participants, and justification on how the selected age range(s) will enable the trial to meet its objective

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
				age or development-related differences in treatment effects	• Specific and defined developmental stages of eligible and included participants • Hypothesized treatment effects, risk-benefit profile, and pharmacology, related to age or developmental stage(s) • If any relevant (sub)group was excluded from the trial, include the reason for exclusion
			12a.2	Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age	• Age group(s) or developmental stage(s) that the material was prepared for • How information was prepared to be developmentally appropriate for the target population • Where the developmentally appropriate materials can be found, or whether available on request
	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		• All 12 TIDieR reporting items with corresponding paediatric considerations from TIDieR-C	
			13.1*†	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	For both the "experimental" and "comparator" intervention: • How the dose and/or formulation was deemed appropriate for the trial population • Provide any available dose/exposure data from paediatric studies or regulatory agencies to support the choice • Adjustments made to the intervention dose or formulation, based on trial participants' age, weight, or body surface area

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
					• Information or efforts made to make the formulation palatable and acceptable for participants, or how this was assessed • Possible palatability and bio-availability differences between different formulations
			13.2*†	Describe whether the trial interventions were delivered with help from a support person	• Details on who the support person was • If there was any specific training for the support person(s) to deliver the intervention, or to support the participant during intervention delivery • To what extent is assistance was required from a support person and how they were involved • Who determined the requirement for help and who the support person would be • Whether help was required only for the intervention during trial conduct, or also afterwards if the intervention continued post-trial
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		• Pre-specifying the primary and secondary outcomes, including their specific measurement variable, who assessed/gathered the outcome data, time point(s), analysis metric, method of aggregation, and time point, and clearly specific if this was the same or different in each prespecified age group • Whether children, adolescents, or family caregivers were involved in defining the target difference (e.g., minimal important difference, smallest worthwhile effect), and how they were involved in defining this • Whether a family caregiver, support person, or child/adolescent assessed the primary outcome, and whether any training was given to facilitate this • Evidence of the validity, reliability, and responsiveness of the outcome measurement instrument used to measure the trial primary and secondary outcomes in children/adolescents	
			14.1	Explain evidence supporting validity of selected outcomes and outcome measurement instruments in age group(s) included	• Justification of the relevance and importance of trial outcomes to the participating age/developmental group(s) • Validity of the outcome measurement instrument for the pre-specified age group(s)

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
					• Any (known) variability in validity of outcome measures across age ranges / age-subgroups of trial participants; rationale for the selection of different outcome measures for each age-subgroups • Describe who assesses the outcomes, and whether the outcome measurement instrument(s) are child/adolescent-centred (e.g., if parent-reported outcome, clearly specify if the measure is a parent-proxy report of child outcomes, or a parent self-report)
Harms	15	How harms were defined and assessed (eg, systematically, non-systematically)		• Definitions of the potential harms and if there are expected differences by paediatric sub-groups • How the harms, including pain, procedural pain, and anxiety were assessed and treated • How the trial proceeded if harms occurred • Whether the observed harms including pain or anxiety are reversible and can be treated in children/adolescents • Corrective actions taken for individual participants experiencing the harms • Whether the observed harms can have lasting impact in children/adolescents	
			15.1*†	Describe whether trial interventions and/or procedures induced fear, pain, distress, or were invasive, and what measures were taken to mitigate this	• Efforts taken to reduce harms such as fear, pain, or distress in both the experimental and comparator groups • Specific strategies applied to reduce pain, discomfort, distress, and invasiveness of procedures • If available, evidence on interventions and procedures used to mitigate any potential harms of participation
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			
Randomisation:					
Sequence generation	17a	Who generated the random allocation sequence and the method used			
	17b	Type of randomisation and details of any restriction (eg, stratification, blocking and block size)			

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
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 randomised 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 analysed for the primary outcome		• For those (children/adolescents/caregivers) who declined to participate, reasons for non-participation • Number of participants assigned to each intervention for each age group or other classification (e.g., grade/school year) • Number of participants for each age group who received the intervention and reasons why the children/adolescents did not receive the intervention • Number of participants assigned to each intervention for each age group who completed the study • Assent/consent rates	
	22b	For each group, losses and exclusions after randomisation, 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		• Baseline characteristics of participants, and, if relevant, characteristics of parents, guardians or caregivers	

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
		characteristics for each group		• Data on age distribution of participants and if there are imbalances, rationale, explanation or reasoning whether such an imbalance could have an influence on the study results, endpoint interpretation, or harms considerations	
			25.1†	Report number of children/adolescents in the trial by prespecified age group(s)	• Number of children/adolescents in trial by pre-defined age subgroups, total and for each study arm • If the trial used developmental stage or another related factor for defining eligibility, number of children/adolescents according to this factor, total and by study arm
Numbers analysed, 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		• Results for all prespecified outcome analyses • Criteria for excluding any outcome data from the analysis and reporting	
Harms	27	All harms or unintended events in each group			
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified	28.1†	For each primary and secondary outcome, report results for each prespecified age group studied	• Results for each prespecified age subgroup • If age groups were not used, results as per applicable categorization based on eligibility criteria (e.g., developmental stages)

Section/Topic	Item No.	CONSORT 2025 Statement	Item No.	CONSORT-Children and Adolescents (CONSORT-C) 2026 extension	Summary of Key Elements
		from post hoc			
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	• What are unanswered questions regarding other paediatric age groups, other developmental stages, short- or long-term developmental impacts • What are unanswered questions specific to children/adolescents with explanation of the reasons for not clarifying these issues within this trial • What are questions arising from current study, especially those with potential impact on safety short- or long-term developmental impacts, implying limitations for paediatric use • Next steps in the evaluation of the intervention studied before it can be recommended for clinical practice or in other paediatric age groups, other developmental stages • Need for long term (developmental) follow up studies, future trial phases, further pre-clinical studies
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses			

* New item pertains to both SPIRIT-C 2026[16] and CONSORT-C 2026; † Report item if applicable; otherwise, state explicitly that it is not applicable

eTable 5. Existing CONSORT Extensions Relevant to Paediatric Trials*

Topic	Available CONSORT extensions	Year
Condition	Pain Specific Supplement[17]	2019
	MARE[18] (Medical abortion)	2016
	CONSORT-Application within orthodontic trials[19]	2015
	CONSORT-IMPRINT[20] (Infertility treatments)	2014
Intervention	TIDieR-C[21] (Paediatric trial interventions)	2025
	CONSORT-iNeurostim[22] (Implantable neurostimulation devices)	2024
	CONSORT-STRICTOC[23] (Cupping)	2020
	CONSORT-CENT for TCM[24] (N-of-1 for Traditional Chinese Medicine)	2019
	CONSORT-SPI[25] (Social and Psychological Interventions)	2018
	CONSORT-Nonpharmacological Treatments[26]	2017
	CONSORT-Chinese Herbal Medicine Formulas[27]	2017
	TIDieR[28] (Template for Intervention Description and Replication)	2014
	CONSORT-STRICTA[29] (Acupuncture)	2010
	CONSORT Herbal Interventions[30]	2006
Trial design	CONSORT CRXO[31] (Cluster randomised crossover trials)	2025
	CONSORT-DEFINE[32] (Early Phase Dose-Finding)	2023
	CONSORT Factorial[33] (Factorial Randomised Trials)	2023
	CONSERVE[34] (Modifications due to extenuating circumstances)	2021
	CONSORT-ROUTINE[35] (Cohort and routinely collected data)	2021
	CONSORT-AI[36] (Artificial Intelligence)	2020
	CONSORT-ACE[37] (Adaptive Designs)	2020
	CONSORT-Randomised Crossover Trials[38]	2019
	CONSORT-Multi-Arm Parallel Group Trials[39]	2019
	CONSORT-Stepped Wedge Cluster Trials[40]	2018
	CONSORT-Equity[41]	2017
	CONSORT-Within Person Randomised Trials[42]	2017
	CONSORT-Health Care Simulation Research[43]	2016
	CONSORT-Pilot and Feasibility[44]	2016
	CONSORT CENT[45] (n-of-1)	2015
	CONSORT Cluster Randomised Trials[46]	2012
	CONSORT Noninferiority and Equivalence Randomised Trials[47]	2012
	CONSORT E-HEALTH[48]	2011
	CONSORT Abstracts[49]	2008
	CONSORT Pragmatic Trials[50]	2008
Outcomes	CONSORT-Surrogate[51]	2024
	CONSORT-Outcomes[15]	2022
	CONSORT-Harms[52]	2022
	CONSORT-PRO[53] (Patient Reported Outcomes)	2013

*as of August 2025

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Web Appendix 2: Data Supplement

Data eTable 1. Delphi item flow of candidate CONSORT-C 2026 items

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
Base	S	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and, if applicable, trial acronym	98% *Consensus reached after R1*	N/A	N/A	N/A	N/A
Base	S	Describe the state of evidence of efficacy/effectiveness of the intervention in children	89% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	S	Describe, if any, plans of involving patient or public partners, or children's advisory groups, in planning and supporting the dissemination of trial results (e.g., determining timing and frequency of sharing trial results, providing feedback on plain language summaries, co-creating infographics, co-authoring manuscripts, co-presenting results	49% *Reworded based on feedback, moved onto R2*	Describe, if applicable, any plans to involve, or how patient or public partners (e.g., children, young people, or families), or family/children's advisory groups have been involved in planning and supporting the dissemination of trial results	53% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	R	Describe how patient or public partners, or children's advisory groups were involved in the dissemination of results and findings (e.g., development of plain language results summary, co-creating infographics, co-authoring manuscripts, co-presenting results)	54% *Item merged with above item*	N/A	N/A	N/A	N/A
New / modified	S	Describe how plain language summaries will meet the recommended reading age of Grade 6 (or 11-12 years) for healthcare information (e.g., by using the Simplified	28% *Reworded based on feedback, moved onto R2*	Describe how plain language summaries will be/have been prepared to be accessible to the trial's participants and their families	17% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		Measure of Gobbledygook (SMOG) readability scale)					
New / modified	R	Describe plans for piloting and obtaining feedback on the understandability and appropriateness of the plain language summary with patient and public members	29% *Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	Scientific background and rationale, including a description of the research question and justification for undertaking the trial in the pre-specified age group, including summary of relevant studies (published and unpublished) or a systematic review examining benefits and harms for each intervention	96% *Reworded based on feedback, moved onto R2*	Include a description of the research question and justification for undertaking the trial in the pre-specified population, cohort, or age group(s)	97% *Consensus reached after R2*	N/A	N/A
New / modified	R	Report race and ethnicity for groups who are most affected by the disease or condition that is being investigated in the trial	57% *Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	Describe the disease prevalence and/or aetiology of disease and (long term developmental) impact of the disease in children	75% *Item split into 3, voted on in R2*	Describe, if applicable and known, the prevalence/incidence of the disease or condition in children	70% *Moved onto R3*	Describe, if applicable and known, the prevalence/incidence of the disease or condition in children	82% *Consensus reached after R3*
New / modified	S	N/A	N/A	Describe, if applicable and known, the aetiology of the disease or condition in children	56% *Reworded based on feedback, moved onto R3*	Describe, if applicable and known, the aetiology (cause) of the disease or	27% *No consensus after two rounds of voting, to discuss at Consensus Meeting*

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
						condition in the paediatric sub-population of interest	
New / modified	S	N/A	N/A	Describe, if applicable and known, the developmental impact of the disease or condition on children	60% *Reworded based on feedback, moved onto R3*	Describe, if applicable and known, the impact of the disease or condition on children	56% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
New / modified	S	Describe, if any, the standard of care including definitions, diagnosis, and available treatments	81% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified	R	Explain and detail the choice of comparator(s), whether comparator(s) are the standard of care, and, if applicable, evidence for the active comparator's effectiveness	92% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified	R	Describe if the trial was done for regulatory purposes	67% *Reworded based on feedback, moved onto R2*	Describe if the trial was done for regulatory purposes (e.g., seeking marketing authorization for a new indication in children)	70% *Item removed (E&E)*	N/A	N/A
New / modified	R	Provide demographics (e.g., gender, age, ethnicity, health condition) of patient or public members involved in the design, conduct, or reporting of the trial	50% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified	R	If no patient or public members were involved in the design, conduct, or	50% *Item removed (redundant)*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		reporting of the trial, describe rationale on why there was no patient and public involvement					
New / modified	S	If the eligible population crossed childhood developmental stages, provide a justification of the selected age/developmental stage groups, addressing potential age/development-related differences in treatment effects	65% *Reworded based on feedback, moved onto R2*	If multiple age groups or children at multiple developmental stages are eligible to participate, provide a justification for including each and if applicable, address potential age or development-related differences in treatment effects	56% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified	S	Provide the rationale for the eligible age/developmental stage range(s) selected for the trial	85% *Item merged with earlier item*	N/A	N/A	N/A	N/A
New / modified	S	Describe whether the trial intervention will affect the child's quality of life (e.g., ability to go to school, vacation, holiday, travel) and if interventions are associated with fear and pain	58% *Reworded based on feedback, moved onto R2*	Describe the anticipated impact of trial participation on the child's daily life (e.g., time off school, social activities)	44% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified [Youth Generated]	S	N/A	N/A	Describe whether taking the intervention requires help from a parent or caregiver, and if they need to take time off work to help their child	35% *Reworded based on feedback, moved onto R3*	Describe, if applicable, whether taking the intervention as part of the trial requires help from a parent or caregiver	22% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
Base	S	Give rationale for extrapolation or adaptation of adult interventions (for	66%	If applicable, give rationale for adapting interventions used in	51% *No consensus after two rounds of*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		specific guidance see TIDieR checklist and guide)	*Reworded based on feedback, moved onto R2*	other paediatric populations or adults (for specific guidance see ADAPT guidance)	*voting, to discuss at Consensus Meeting*		
New / modified	S	Justify, if applicable, either the fixed intervention drug dose or developmental stage-based dose adjustments	80% *Reworded based on feedback, moved onto R2*	Describe, if applicable, whether there is an intervention dose and/or formulation appropriate for the trial population, and if there are any adjustments made based on age, weight, or body surface area	91% *Consensus reached after R2*	N/A	N/A
New / modified	S	Describe, if applicable, the availability of an age-appropriate drug formulation	67% *Item merged with above item*	N/A	N/A	N/A	N/A
New / modified	R	If more than one formulation will be used, discuss how quality control measures will be put in place to mitigate any possible differences between the different formulations, and whether the approach is appropriate for the study's medication administration strategy	55% *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Provide a rationale for the selection of the domain for the trial's primary outcome	88% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If the analysis metric for the primary outcome represents within-participant change, define and justify the minimal	81% *Originally consensus for inclusion reached in Round 1, but*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		important change in individuals	*Item removed (E&E)*				
SPIRIT | CONSORT-Outcomes	R	If the outcome data collected are continuous, but will be analysed as categorical (method of aggregation), specify the cutoff values to be used	86% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If outcome assessments will be performed at several time points after randomization, state the time points that will be used for the analysis, and justify the time points used	85% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If a composite outcome is used, define all individual components of the composite outcome	89% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Describe who assessed the outcome (e.g., nurse, parent) and any qualifications or trial-specific training necessary to administer the study instruments to assess the outcome	77% *Originally consensus for inclusion reached in Round 1, but* *Item removed (E&E)*	N/A	N/A	N/A	N/A
Base	S	Validity of selected outcomes in age group(s) included	84% *Consensus reached after R1*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Provide a description of the study instruments used to assess the outcome (e.g., questionnaires, laboratory tests) along with reliability, validity, and responsiveness	85% *Originally consensus for inclusion reached in Round 1, but*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		in a population similar to the study sample	*Item removed (E&E)*				
SPIRIT | CONSORT-Outcomes	R	Identify any outcomes that were not prespecified in a trial registry or trial protocol	81% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Describe any processes used to promote outcome data quality during data collection (e.g., duplicate measurements) and after data collection (e.g., range checks of outcome data values), or state where these details can be found	75% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	R	Describe the anticipated and unanticipated adverse events and side effects experienced because of the trial procedures (e.g., pain, impact to participants or family caregivers)	85% *Reworded based on feedback, moved onto R2*	Describe adverse events and side effects from the trial procedures that may occur or were experienced	98% *Item removed (E&E)*	N/A	N/A
New / modified	S	Describe the efforts to reduce the child's risk of participation including ways to reduce distress, i.e., pain, anxiety, fear to children	57% *Reworded based on feedback, moved onto R2*	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures are taken to reduce potential harms of participation	61% *No consensus after two rounds of voting, to discuss at Consensus Meeting*	N/A	N/A
New / modified [Youth Generated]	R	N/A	N/A	Describe whether occurring adverse events can be treated	49% *Item removed (E&E)*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
SPIRIT | CONSORT-Outcomes	R	Define and justify the target difference between treatment groups (e.g., the minimal important difference)	91% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	S	Describe stakeholders (e.g., patients, caregivers, healthcare providers) that were involved in defining the minimal important difference	46% *Reworded based on feedback, moved onto R2*	Describe, if applicable, research partners (e.g., patients, caregivers, healthcare providers) involved in defining the target difference (e.g., minimal important difference, smallest worthwhile effect)	25% *Item removed (E&E)*	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Describe any planned methods to account for multiplicity in the analysis or interpretation of the primary and secondary outcomes (e.g., coprimary outcomes, same outcome assessed at multiple time points, or subgroup analyses of an outcome)	85% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Provide a definition of the outcome analysis population relating to nonadherence of the trial protocol (e.g., as a randomized analysis)	78% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	State and justify any criteria for excluding any outcome data from the analysis and reporting, or report that no outcome data were excluded	94% *Originally consensus for inclusion reached in Round 1, but*	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
			Item removed (E&E)				
SPIRIT | CONSORT-Outcomes	R	Describe the methods used to assess patterns of missingness (e.g., missing not at random), and describe the methods used to handle missing outcome items or entire assessments	86% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
Base	R	Describe, if applicable, establishment of a Data Safety Monitoring Board and its composition	85% *Originally consensus for inclusion reached in Round 1, but Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified [Panellist suggested]	S	N/A	N/A	Describe any accommodations (e.g., communication aids, environmental adjustments) to support children's participation and inclusion	39% *Reworded based on feedback, moved onto R3*	Describe, if applicable, any adaptations put in place to support inclusion and participation of children (e.g., communicatio n aids, environmental adjustments)	39% *No consensus after two rounds of voting, to discuss at Consensus Meeting*
New / modified [Panellist suggested]	S	N/A	N/A	Describe, if applicable, any experiences and outcomes collected from trial participant's parents or guardians	48% *Item removed (redundant)*	N/A	N/A
New / modified	R	Provide details on research ethics committee / institutional review board approval obtained	89% *Reworded based on feedback, moved onto R2*	Include the project/reference number and the name of the research ethics committee/institutional	92% *Item removed (E&E)*	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
				review board that provided approval			
Base	S	Describe whether information about the trial was provided to children and assent given, if appropriate for age	87% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	R	Report consent and assent rates, including number of individuals approached, number of individuals who declined to provide consent, number of those who withdrew consent, and if available, basic characteristics about those who did not provide consent/assent and reasons for non-participation and consent withdrawal	69% *Reworded based on feedback, moved onto R2*	Report consent and assent rates, including number of individuals approached, number of individuals who declined to participate, and number of those who withdrew consent or assent	78% *Item removed (E&E)*	N/A	N/A
New / modified	R	Report any discontinuation of participation due to adverse events, unexplained withdrawals, or death	96% *Moved onto R2*	Report any discontinuation of participation due to adverse events, unexplained withdrawals, or death	99% *Item removed (E&E)*	N/A	N/A
Base	S	Report number of children in the trial by age group(s)	93% *Consensus reached after R1*	N/A	N/A	N/A	N/A
New / modified	R	Report aggregate, deidentified information of trial participants (e.g., sex, socioeconomic indicators), including race and ethnicity of enrolled trial participants using specific racial and ethnic categories	79% *Item removed (E&E)*	N/A	N/A	N/A	N/A
New / modified	R	Describe who identified (e.g., self, caregiver, investigator,	39%	N/A	N/A	N/A	N/A

Item type	Specific/ Relevant	Round 1 Items (n = 53)	Consensus in Round 1*	Round 2 Items (n = 22)	Consensus in Round 2*	Round 3 Items (n = 5)	Consensus in Round 3*
		research staff) racial and ethnic categories, how racial and ethnic categories were defined, and groups classified as "Other"	*Item removed (E&E)*				
Base	S	For each primary and secondary outcome, report results for each age group studied	86% *Consensus reached after R1*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	Report the results for all prespecified outcome analyses or state where the results can be found if not in this report	94% *Item removed (E&E)*	N/A	N/A	N/A	N/A
Base	R	Describe measures taken to reduce pain, distress, invasiveness, and potential harm of research methods	69% *Item removed (redundant)*	N/A	N/A	N/A	N/A
Base	R	Describe plans, if any, for assessing harms beyond the formal study completion date	58% *Item removed (redundant)*	N/A	N/A	N/A	N/A
SPIRIT | CONSORT-Outcomes	R	If there were any analyses that were not prespecified, explain why they were performed	91% *Item removed (redundant)*	N/A	N/A	N/A	N/A
New / modified	S	Highlight unanswered and new questions, and discuss potential future research	72% *Moved onto R2*	Highlight unanswered and new questions, and discuss potential future research	78% *Consensus reached after R2*	N/A	N/A

Note: Numbering for items is not included as it changed throughout the project.
*Defined as percentage of Delphi panellists who voted the item as a score of 7-9 (critical for inclusion) for "New/modified items" or "Yes, keep" for "Base" or "SPIRIT | CONSORT-Outcomes" items

Data eTable 2. Consensus meeting results for CONSORT-C 2026 relevant items that were voted on

Item	Voting Results n (%)*	Consensus status	Core team decision
Describe, if applicable and known, the aetiology (cause) of the disease or condition in the paediatric sub-population of interest	Include: 1 (4%) Exclude: 27 (96%) Total voters: 28	Consensus out	N/A
Describe, if applicable and known, the impact of the disease or condition on children	Include: 12 (40%) Exclude: 18 (60%) Total voters: 30	No consensus	Include in E&E as detail
Describe, if applicable, any plans to involve, or how patient or public partners (e.g., children, young people, or families), or family/children's advisory groups have been involved in planning and supporting the dissemination of trial results	Include: 7 (23%) Exclude: 24 (77%) Total voters: 31	Consensus out	N/A
Describe how plain language summaries will be/have been prepared to be accessible to the trial's participants and their families	Include: 3 (10%) Exclude: 28 (90%) Total voters: 31	Consensus out	N/A
If multiple age groups or children at multiple developmental stages are eligible to participate, provide a justification for including each and if applicable, address potential age or development-related differences in treatment effects	Include: 22 (73%) Exclude: 8 (27%) Total voters: 30	Consensus in	N/A
Describe the anticipated impact of trial participation on the child's daily life (e.g., time off school, social activities)	Include: 8 (26%) Exclude: 23 (74%) Total voters: 31	Consensus out	N/A
If applicable, give rationale for adapting interventions used in other paediatric populations or adults (for specific guidance see ADAPT guidance)	Include: 14 (45%) Exclude: 17 (55%) Total voters: 31	No consensus	Include in E&E as detail
Describe, if applicable, whether taking the intervention as part of the trial requires help from a parent or caregiver	Include: 13 (43%) Exclude: 17 (57%) Total voters: 30	No consensus	Include
Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures are taken to reduce potential harms of participation	Include: 22 (71%) Exclude: 9 (29%) Total voters: 31	Consensus in	N/A
Describe, if applicable, any adaptations put in place (e.g., communication aids, environmental adjustments) to support inclusion and participation of children	Include: 14 (48%) Exclude: 15 (52%) Total voters: 29	No consensus	Include in E&E as detail

Note 1: Numbering for items is not included as it changed throughout the project.
Note 2: "Consensus in" means that the item met consensus criteria to be included. "Consensus out" means that the item met consensus criteria to be excluded.
* Max voting members at the meeting (n = 31); however, there is variability in the total voters across items as some panellists did not vote before we had to move on. For items that reached no consensus, two rounds of voting took place; results depicted are of the second vote.

Data eTable 3. Item wording evolution after the Consensus Meeting

Final item #	E&E writing/review	Pilot testing	Final wording
1a.1	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and if applicable, trial acronym	Identify that it is a paediatric clinical trial, and include age group(s), interventions, and if applicable, trial acronym	Identify that it is a paediatric trial, and include age group(s)/range(s), interventions, and, if applicable, trial acronym
6.1	Describe, if applicable and known, the prevalence/incidence of the disease or condition in children	Describe, if applicable and known, the prevalence/incidence of the disease or condition in children and adolescents	Describe the prevalence/incidence of the disease or condition in children/adolescents
6.2	Describe the state of evidence of efficacy/effectiveness of the intervention in children	Describe the state of evidence of efficacy/effectiveness of the intervention in children and adolescents	Describe available evidence on the efficacy/effectiveness of the intervention in children/adolescents
6.3*	Include a description of the research question and justification for undertaking the trial in the pre-specified population, cohort, or age group(s)	Include a description of the research question and justification for undertaking the trial in the pre-specified population or age group(s)	Include a description of the research question or aim with a justification for undertaking the trial in children/adolescents
12a.1	Provide, if applicable, a justification for including multiple age groups or children at different developmental stages, and address potential age or development-related differences in treatment effects	Provide, if applicable, 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	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 children and assent given, if appropriate for age	Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age	Describe whether information about the trial was provided to participating children/adolescents and assent given/consent obtained, if appropriate for age
13.1	Describe, if applicable, 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	Describe whether there is an intervention dose and/or, if applicable, formulation appropriate for the trial population, and if there were any adjustments made based on age, weight, or body surface area	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	Describe, if applicable, whether taking the intervention as part of the trial required help from a support person	Describe, if applicable, whether taking the intervention as part of the trial required help from a support person	Describe whether the trial interventions were delivered with help from a support person
14.1*	Validity of selected outcomes in age group(s) included	Validity of selected outcomes and outcome measures in age group(s) included	Explain evidence supporting validity of selected outcomes and outcome measurement instruments

Final item #	E&E writing/review	Pilot testing	Final wording
			in age group(s) included (updated also based on feedback during writing of papers)
15.1	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures were taken to reduce potential harms of participation	Describe, if applicable, whether trial interventions and/or procedures are associated with fear, pain, distress, or are invasive, and what measures were taken to reduce potential harms of participation	Describe whether trial interventions and/or procedures induced fear, pain, distress, or were invasive, and what measures were taken to mitigate this
25.1	Report number of children in the trial by age group(s)	Report number of children/adolescents in the trial by age group(s)	Report number of children/adolescents in the trial by prespecified age group(s)
28.1*	For each primary and secondary outcome, report results for each age group studied	For each primary and secondary outcome, report results for each age group studied	For each primary and secondary outcome, report results for each prespecified age group studied
29.1	Highlight unanswered and new questions, and discuss potential future research	Highlight unanswered and new questions, and discuss potential future research	Highlight unanswered and new questions, and discuss potential future research

*Item wording changed slightly during drafting of Statement and E&E papers.

Note 1: Between the E&E writing/review and pilot testing phase, we edited the phrasing “children” to “children/adolescents” to align with the scope of the guidelines

Note 2: Between the pilot testing and final wording, we removed all instances of “if applicable”, and these items are labelled with a dagger in the final checklist to indicate that it should only be reported if applicable.

Note 3: Other than the global changes applied in Note 1 and 2, items with wording evolution based on feedback from the E&E writing/review stage that are subsequently reflected in the wording used during pilot testing are in blue boxes. Similarly, items with wording evolutions from pilot testing feedback are in the green boxes. Items with wording changes based on feedback from the editorial process are in pink boxes.