SPIRIT | CONSORT CHILDREN & ADOLESCENTS
Reporting Guidelines for Child Health Trials

CONSORT-C 2026

Item 12a.1: Eligibility criteria

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

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale *Prevalence/incidence*
	6.2	Background and rationale *Efficacy/effectiveness*
	6.3	Background and rationale *Research question or aim*
Methods	12a.1	Eligibility criteria *Justification for including multiple age groups*
	12a.2	Eligibility criteria *Age-appropriate trial information*
	13.1	Intervention and comparator *Dose/formulation*
	13.2	Intervention and comparator *Intervention delivery*
	14.1	Outcomes
	15.1	Harms
Results	25.1	Baseline data
	28.1	Ancillary analyses
Discussion	29.1	Interpretation

Key elements for reporting this item:

- Age groups of eligible and included participants, and justification on how the selected age range(s) will enable the trial to meet its objective
- Specific and defined developmental stages of eligible and included participants
- Hypothesised 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.

Examples:

"In 2014, Zimmerman and colleagues first reported that [Sulforaphane] SF significantly improved the clinical symptoms of autistic teens and young adults with [autism spectrum disorder] ASD[reference]. Awareness, communication, stereotyped behavior and hyperactivity of individuals in SF group improved significantly during the 18 weeks treatment period, and symptoms returned during the follow-up period (4 week) off SF. Furthermore, a 3 year follow-up of this study using the subjective impressions of caregivers noted that many caregivers felt SF was beneficial and continued to use it[reference]. However, subsequent published studies with small samples did partially but not fully replicate these findings[reference]. (. . .) Accordingly, we examined the effect of sulforaphane in a broader age range of young children and adolescents with ASD through a randomized controlled trial in a new ethnic group, a Chinese Han population. To our knowledge, this is the largest sample size used to date in a study of effects on SF in ASD. Our more diverse sample allowed us to include evaluation of level of cognitive deficit and age as moderators of response to SF. (. . .) Inclusion of children as young as 3 years allows probing of treatment effects in earlier developmental cohorts (. . .) Children with ASD were recruited if they met the following criteria: (1) age 3-15 years; (2) met Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) diagnostic criteria for ASD; (3) met instrument classification as ASD via validated Chinese versions of the Autism Diagnostic Interview-Revised (ADI-R) and Autism Diagnostic Observation Schedule (ADOS)."

Ou J, Smith RC, Tobe RH, et al. Efficacy of Sulforaphane in Treatment of Children with Autism Spectrum Disorder: A Randomized Double-Blind Placebo-Controlled Multi-center Trial. J Autism Dev Disord 2024;54:628-41.

See the E&E for more examples.

Statement (co-published in *The BMJ, JAMA Pediatrics, and The Lancet Child and Adolescent Health*): Baba A, Smith M, Potter BK, et al. CONSORT-Children and Adolescents (CONSORT-C) 2026 Extension Statement: Enhancing the Reporting and Impact of Paediatric Randomised Trials. BMJ 2026;392:e085061. doi: 10.1136/bmj-2025-085061

Explanation and Elaboration: Baba A, Smith M, Potter BK, et al. CONSORT-C 2026 explanation and elaboration: recommendations for enhancing the reporting and impact of paediatric randomised trials. BMJ 2026;392:e085063. doi: 10.1136/bmj-2025-085063