

Item 13.2: Intervention and comparator

Describe whether the trial interventions were delivered with help from a support person

Title and abstract	1a.1	Title and structured abstract
Introduction	6.1	Background and rationale <i>Prevalence/incidence</i>
	6.2	Background and rationale <i>Efficacy/effectiveness</i>
	6.3	Background and rationale <i>Research question or aim</i>
Methods	12a.1	Eligibility criteria <i>Justification for including multiple age groups</i>
	12a.2	Eligibility criteria <i>Age-appropriate trial information</i>
	13.1	Intervention and comparator <i>Dose/formulation</i>
	13.2	Intervention and comparator <i>Intervention delivery</i>
	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:

- ✓ 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 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.

Examples:

- ✓ *“Parents were told to administer 5 ml of study medication up to 6 times per day every 4–6 h as needed to treat cold symptoms during the first 3 days after the initial visit.”*

✓ Jacobs J, Taylor JA. A randomized controlled trial of a homeopathic syrup in the treatment of cold symptoms in young children. *Complement Ther Med* 2016;29:229-34. doi:10.1016/j.ctim.2016.10.013.

- ✓ *“Teachers administered two capsules daily (one early in the morning and another at lunchtime). The afternoon capsule and the weekend and holiday doses were administered by the parents. Both parents and teachers were given a calendar to mark the supplement intake of each child; this calendar was delivered every two weeks. This information was completed with unused capsule counts.”*

✓ Portillo-Reyes V, Pérez-García M, Loya-Méndez Y, Puente AE. Clinical significance of neuropsychological improvement after supplementation with omega-3 in 8-12 years old malnourished Mexican children: a randomized, double-blind, placebo and treatment clinical trial. *Res Dev Disabil* 2014;35:861-70. doi:10.1016/j.ridd.2014.01.013.

- ◀ *“During intervention delivery, the class leader’s and yoga / [physical training] PT teachers helped in the demonstration of yoga postures along with the yoga teacher. They also helped to correct the student’s postures during practice sessions. The student leaders helped build peer support. The idea of involving the school teachers and peers as part of intervention delivery was to ensure long term sustainability of the yoga program in the schools.”*

✓ Ranjani H, Jagannathan N, Rawal T, et al. The impact of yoga on stress, metabolic parameters, and cognition of Indian adolescents: Cluster randomized controlled trial. *Integr Med Res* 2023;12:100979. doi:10.1016/j.imr.2023.100979.

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