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Liu, YY; Zhong, LJ; Sun, ZY; Feng, Y; Ding, QL; Zhang, YJ.

Corresponding author:

Yujian Zhang

zhangyujian@scszlyy.org.cn

Author Affiliation:

Sichuan Cancer Hospital & Institute.

ADMINISTRATIVE INFORMATION**Support** - None.**Review Stage at time of this submission** - Completed but not published.**Conflicts of interest** - None declared.**INPLASY registration number:** INPLASY202450131**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 May 2024 and was last updated on 29 May 2024.**INTRODUCTION**

Review question / Objective The objective was to evaluate the effects of maternal and infant n-3 PUFA supplementation on childhood psychomotor and cognitive development.

Rationale Long-chain n-3 polyunsaturated fatty acid (PUFA) consumption of maternal and infant has been positively associated with cognitive and visual development. Tails even meta-analysis showed mixed results.

Condition being studied Effects of maternal and infant n-3 PUFA supplementation on childhood psychomotor and cognitive development.

METHODS

Search strategy We performed supplemented electronic searches of PubMed, Embase, the Cochrane Library, PsycINFO and clinicaltrials.gov .

To avoid missing any trials, we included several common language terms in addition to Medical Subject Heading terms. The main search terms related to following searched strategy: ((omega-3 fatty acids) or (polyunsaturated fatty acids) or (docosahexaenoic acid) or (eicosapentaenoic acid) or (fish) or (seafood)) and ((neurodevelopment) or (cognition) or (development) or (vision)) and ((child) or (infant) or (pregnancy) or (lactation)).

Participant or population Pregnant mothers, nursing mothers, or children aged <2 years, generally healthy subjects.

Intervention With supplementation or fortification with n-3 PUFA (DHA, EPA, or a combination, or with other n-3 or n-6 PUFAs) for a minimum duration of 3 months.

Comparator Without supplementation or fortification with n-3 PUFA (DHA, EPA, or a combination, or with other n-3 or n-6 PUFAs) for a minimum duration of 3 months.

Study designs to be included Randomized controlled trials.

Eligibility criteria Studies were excluded if 1) subjects with a specifically defined health problem or received supplementation as a treatment or secondary prevention; 2) trials with supplements that contained additional active ingredients in addition to n-3 PUFA only and were given to the intervention group, included trials that compared breastfed to formula-fed infants; 3) not offer essential or clear information of reported findings to determine differences in group mean values at follow-up.

Information sources PubMed, Embase, the Cochrane Library, PsycINFO and clinicaltrials.gov.

Main outcome(s) Assessment of cognitive development using quantitative and standardized measures. The relevant infant development measures included Bayley Scales of Infant Development (BSID-II18 or BSID-III19), Intelligence quotient (IQ) based on the Wechsler Intelligence Scale for Children (WISC), the Wechsler Preschool and Primary Scale of Intelligence (WPPSI), and the Wechsler Abbreviated Scale of Intelligence (WASI).

Quality assessment / Risk of bias analysis

Quality assessment: according to the Cochrane Risk of Bias tool, assessed from following items: generation of a randomization sequence, allocation concealment, blinding, incomplete outcome data, selective reporting and other bias, calculated with a score of low (+1), high (-1), or unclear (0) risk of bias, and summed to generate the overall quality score.

Strategy of data synthesis Stata (version 15.0) software was used to statistical analyses and meta-analysis. The mean differences (MD) with 95% confidence intervals (95% CIs) at follow-up between the intervention and control groups were utilized for individual and pooled statistics. If a significant statistical heterogeneity was present ($I^2 > 50\%$), the outcomes were combined using the random-effect model assuming that studies were drawn from unequal populations. Otherwise, the fixed-effect model was used.

Subgroup analysis For maternal, subgroup analyses were grouped according to period of supplementation (pregnancy and/or lactation). And for infant, we detected separately the effects of n-3 PUFA supplementation for preterm infant and term infant.

Sensitivity analysis None.

Language restriction English.

Country(ies) involved China.

Keywords long-chain n-3 polyunsaturated fatty acids, infant formula, cognition, development, Bayley Scales of Infant Development, global intelligence, childhood, meta-analysis.

Contributions of each author

Author 1 - Yingyu Liu.

Email: liuyingyu2018@163.com

Author 2 - Lijun Zhong.

Author 3 - Zhouyang Sun.

Author 4 - Yuan Feng.

Author 5 - Qianlu Ding.

Author 6 - Yujian Zhang.

Email: zhangyujian@scszlyy.org.cn