Effect of fish oil supplementation in pregnancy on bone, lean, and fat mass at six years: randomised clinical trial

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RobotReviewer report

Risk of bias table

trial	design	n	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment
Kofod Vinding R, 2018	RCT	?? ?	+	+	+	+

Characteristics of studies

Kofod Vinding R, 2018

Population	1. However, in humans, randomised trials with n-3 LCPUFA supplementation in pregnancy have shown ambiguous results regarding anthropometric outcomes later in childhood WHAT THIS STUDY ADDS n-3 LCPUFA supplementation in pregnancy led to increased body mass index (BMI) in childhood, with sustained elevated BMI from age 1 year to 6 years 2. Anthropometry Anthropometry was assessed at the COPSAC research unit at age 1 week, 1 month, 3 months, and 6 months, then every sixth month until age 2 years, and thereafter every year until age 6 years. 3. 2 In humans, both observational studies on dietary intake of fish and randomised controlled trials of n-3 LCPUFA (fish oil) supplementation in pregnancy and during lactation have consistently shown higher birth weight in children born to women with higher n-3 LCPUFA intake; this is mainly explained by an increase in gestational age, but an increase in size for gestational age has not been excluded.
Intervention	1. The women were randomised 1:1 in a double blind design at pregnancy week 24 to either daily supplementation of 2.4 g n-3 LCPUFA (55% eicosapentaenoic acid (20:5 n-3) and 37% docosahexaenoic acid (22:6 n-3), Incromega TG33/22, Croda Health Care, UK) in triacylglycerol form or lookalike control supplementation capsules of olive oil (72% n-9 oleic acid and 12% n-6 linoleic acid, Pharmatech A/S, Norway).
Outcomes	1. No interaction existed between the intervention and sex, size for gestational age, or maternal preintervention blood concentrations of eicosapentaenoic acid and docosahexaenoic acid in relation to the body composition outcomes at 6 years (data not shown). 2. However, in humans, randomised trials with n-3 LCPUFA supplementation in pregnancy have shown ambiguous results regarding anthropometric outcomes later in childhood WHAT THIS STUDY ADDS n-3 LCPUFA supplementation in pregnancy led to increased body mass index (BMI) in childhood, with sustained elevated BMI from age 1 year to 6 years

3. Anthropometry Anthropometry was assessed at the COPSAC research unit at age 1 week, 1 month, 3 months, and 6 months, then every sixth month until age 2 years, and thereafter every year until age 6 years.

Bias	Judgement	Support for judgement
Random sequence generation	low	1. The total number of visits to our clinic was 11. 2. No difference was seen in fat percentage, but a proportional increase in lean mass, bone mass, and fat mass was seen at 6 years), in which we did a double blind, randomised controlled trail of n-3 LCPUFA (fish oil) versus control (olive oil) supplementation from week 24 of pregnancy to one week postpartum. 3. The number of participants completing the scans at 3.5 and 6 years was equal in the two supplementation groups (176 v 180 at 3.5 years; 263 v 260 at 6 years).
Allocation concealment	low	1. No pharmaceutical company was involved in the trial. 2. No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for recruitment, design, or implementation of the study. 3. The analyses were done for all children and stratified by sex.
Blinding of participants and personnel	low	1. No pharmaceutical company was involved in the trial. 2. No difference was seen in fat percentage, but a proportional increase in lean mass, bone mass, and fat mass was seen at 6 years), in which we did a double blind, randomised controlled trail of n-3 LCPUFA (fish oil) versus control (olive oil) supplementation from week 24 of pregnancy to one week postpartum. 3. The women were randomised 1:1 in a double blind design at pregnancy week 24 to either daily supplementation of 2.4 g n-3 LCPUFA (55% eicosapentaenoic acid (20:5 n-3) and 37% docosahexaenoic acid (22:6 n-3), Incromega TG33/22, Croda Health Care, UK) in triacylglycerol form or lookalike control supplementation capsules of olive oil (72% n-9 oleic acid and 12% n-6 linoleic acid, Pharmatech A/S, Norway).
Blinding of outcome assessment	low	1. Each growth measurement was made using the same equipment by trained COPSAC assistants on the basis of standard operating procedures, and the observed growth curves were similar to previous reports. 2. All analyses on body composition from the scans were adjusted for height+height 2 with regards to fat mass and lean mass and adjusted for height with regards to bone mineral content and bone mineral density. 3. No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for recruitment, design, or implementation of the study.