Effects of oily fish intake on cardiovascular risk markers, cognitive function, and behavior in school-aged children: study protocol for a randomized controlled trial

Background
Most children in Western populations do not meet recommendations for fish consumption. Oily fish is an important source of n-3 long-chain polyunsaturated fatty acids (LCPUFA), which reduce blood pressure and plasma triacylglycerol in adults and may affect cognitive development and behavior. However, to our knowledge, the potential effects of oily fish on cardiometabolic health, cognitive function, and behavior in children have not been investigated. The aim of the FiSK Junior study is to investigate the effects of oily fish consumption on cardiovascular risk markers, cognitive function, and behavior in healthy children.

Methods/design
We are conducting a randomized controlled trial with 8- to 9-year-old Danish children, comparing the effect of consuming 300 g/week of oily fish with poultry (control) for 12 weeks between August 2016 and June 2017. The primary outcomes are blood pressure and fasting plasma triacylglycerol, which will be measured at baseline and endpoint. In addition, we will assess erythrocyte fatty acid composition (compliance), heart rate, plasma cholesterol, markers of glucose homeostasis, growth and body composition, dietary intake, and physical activity and sleep. We will also examine effects on cognitive function (attention, memory, and executive functions) by using standardized tests, behavior and emotions by administering parent-rated questionnaires and child interviews, and we will measure physiological stress response and cortisol levels. We need 150 children to complete the trial to detect a between-groups difference of 2.7 mmHg in diastolic blood pressure and 0.13 mmol/L in plasma triacylglycerol; thus, we aim to recruit 200 children. All outcomes will be analyzed in completer analysis supplemented with sensitivity analyses for the primary outcomes, and attention will be given to potential sex and genotype specificity.

Discussion
The results of the FiSK Junior study are expected to fill important gaps in the current knowledge about the importance of dietary fish and n-3 LCPUFA for children’s health and development, and may be used when setting dietary recommendations.