The DHA Oxford Learning and Behaviour (DOLAB) study: A Randomised Controlled Trial of DHA Supplementation in Healthy Children

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Introduction

The DOLAB study is a parallel group, fixed dose, randomised, double blind, placebo controlled trial of DHA supplementation (600 mg/day for 16 weeks) in n = 362 healthy children aged 7-9 years from mainstream schools (n = 74) in Oxfordshire, UK. (Clinical Trials.gov NCT01066182).

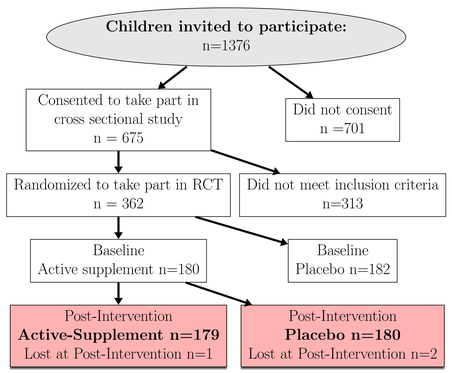
Research Question:

- Can supplementation with Omega-3 (DHA) improve reading, working memory and behaviour in underperforming but otherwise healthy children?

Methods

Eligibility Criteria:

- Children aged 7–9 years with English as a first language, no major physical or mental health problems.
- No omega-3 supplement use in previous 6 months, nor eating fish >2× a week.
- Reading performance $\leq 33^{rd}$ centile as confirmed at initial screening. NB: *Owing to anticipated problems there was a protocol amendment and recruitment was widened from the $\leq 20^{th}$ centile before the first child was randomised.*



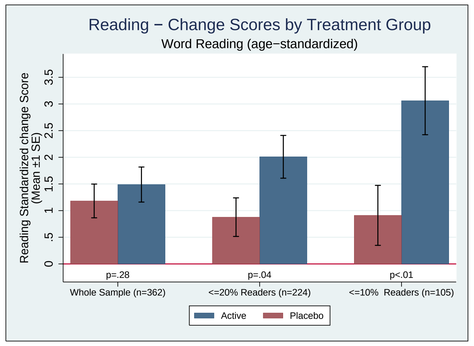
Study assessments:

These assessments were carried out on all children at the initial screening and repeated at the 16 week follow-up.

- Reading performance - (British Ability Scales single word reading)
- Working memory - (British Ability Scales Recall of Digits Forward and Backward)
- Behaviour Parent Ratings (Conner's Parent Rating Scales Long Version (CPRS-L)
- Behaviour Teacher Ratings (Conner's Teacher Rating Scales Long Version (CTRS-L)

DHA Omega-3 Supplementation and Reading Improvement

Change in Age-standardized Reading Scores



ITT analyses showed no effect of DHA on reading in the full sample, but significant effects in the pre-planned subgroup of 224 children whose initial reading performance was $\leq 20^{th}$ centile (the target population in our original study design), and these were even more pronounced in those $\leq 10^{th}$ centile.

Reading Age at baseline, and change scores

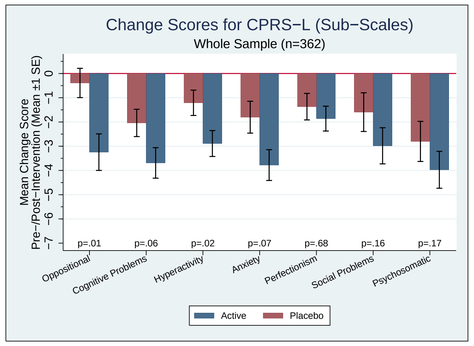
Months (Sd.)

	Baseline		Change scores	
	Active	Placebo	Active	Placebo
All randomized (n=362)	86.1 (10.0)	87.1 (9.7)	**4.7** (4.7)	**4.8** (4.6)
Reading $\leq 20^{th}$ centile (n=224)	82.5 (9.1)	84.1 (8.6)	**4.9** (4.7)	**4.1** (4.0)
Reading $\leq 10^{th}$ centile (n=105)	77.3 (7.3)	80.8 (7.9)	**5.7** (4.8)	**3.8** (4.1)

In children with initial reading $\leq 20^{th}$ centile, DHA led to an additional 0.8 months reading age gain compared with placebo, while in those initially reading $\leq 10^{th}$ centile, the *additional* reading age gain from treatment was 1.9 months.

Reading ages would typically increase by 4 months over a 16-week period, so the gains from DHA supplementation in these poorer readers were around 20% and 50% greater, respectively, than would normally be expected, helping these children to catch up with their peer group.

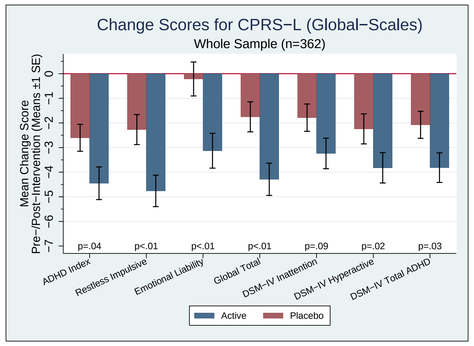
DHA Omega-3 Supplementation and Behaviour ADHD (Conner's Parent Rating Scales)



DHA Omega-3 supplementation reduced ratings on the Sub-Scales for:

- Oppositional (p=.01)
- Hyperactivity (p=.02)

Teacher reported outcomes (CTRS-L) indicated differences on perfectionism (p<0.03) but not on other outcomes.



DHA Omega-3 supplementation reduced ratings on the Global-Scales for:

- ADHD Index (p=.04)
- Restless Impulsive (p<.01)
- Emotional Liability (p<.01)
- Global Total (p<.01)
- DSM-IV Hyperactive (p=.02)
- DSM-IV Total ADHD (p=.03)

Acknowledgements:
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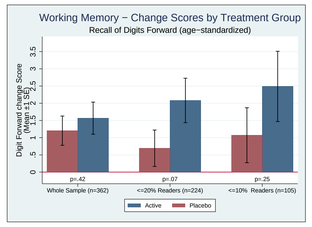
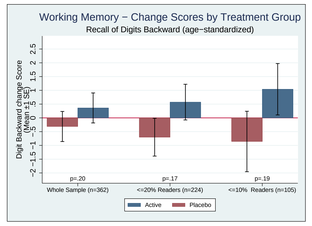
DHA Omega-3 Supplementation and Working Memory



There were no significant group differences on the primary outcome of change scores, although post-intervention scores on Recall of Digits Forward were higher in the active treatment group as a whole (Active Mean=42.6, Sd=8.4; Placebo Mean=41.2, Sd=7.7, p<0.04). There was also a suggestion that the slight group difference in favour of active treatment increased with the degree of reading impairment, as illustrated.



Conclusions

- **The effects of DHA on children's reading progress were found to vary with initial reading performance, with significant benefits found only for the poorest readers.**
- **Parent-rated behavior problems (ADHD-type symptoms) were significantly reduced by active treatment, but little or no effects were seen for either teacher-rated behaviour or working memory.**
- **DHA supplementation therefore appears to be a safe and effective way to improve reading and behaviour in healthy but underperforming children from mainstream schools.**
- **Since such children are known to be at risk of poorer educational and occupational outcomes, and in light of the promising findings from this trial, we are currently under-taking a replication study (DOLAB II), specifically targeting those children whose baseline reading performance is $\leq 20^{th}$centile.**