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# Evaluation of the Effect of Neptune Krill Oil on Adult attention Deficit and Hyperactivity Disorder (ADHD)

## STUDY SYNOPSIS

| | |
|---|---|
| **Product candidate** | Neptune Krill Oil (NKO®) |
| **Sponsor** | Neptune technologies and Bioressources<br>International Organization of Attention Deficit Hyperactivity Disorder |
| **Indication** | **Adult attention Deficit and Hyperactivity Disorder (ADHD)** |
| **Phase** | Phase 1 pilot study |
| **Study design** | Open-label, non-randomized |
| **Multicenter** | Yes, Disability Services, Barry University (FL, USA) and clinics (QC, Canada) |
| **Country** | USA and CANADA |
| **Nb of study arms** | 1 |
| **Comparator** | No |
| **Treatment duration** | 24 wks |
| **Intervention** | NKO® 500 mg softgel QD during 24wks |
| **Total enrollement** | 30 |
| **First patient in** | 2005 |
| **Last patient out** | 2006 |
| **Primary outcome** | Change in a modified Barkley executive function scale (BEFS) at 12 and 24 wks |

## INTRODUCTION

Attention Deficit and Hyperactivity Disorder (ADHD) is described as one of the most chronic conditions of childhood and may affect adults as well. ADHD treatment usually implies both pharmacologic and behavioural therapies. Stimulant drugs (e.g. Ritalin) are the cornerstone of the pharmacologic treatment: drugs are prescribed over long periods of time fact that increases the risk of cumulative toxicity.

Previously published research revealed that natural extracts rich in n3PUFAs, among which DHA, can reduce the medication dose, improve quality of life and reduce treatment costs related with child and adult ADHD (Schachter, HM et al. 2005).

**NKO® is a rich source of omega-3 carried by phospholipids (PL)**. The uptake and physiological effects of n3PUFAs bounded to PL show several advantages over triglycerides (TG)-bounded fatty acids, predominant in fish oil, such as an increased uptake in specific tissues such as the brain (Lagarde, Bernoud et al. 2001; Wijendran, Huang et al. 2002; Werner, Havinga et al. 2004). PL like phosphatidylcholine (PC) is a superior carrier for DHA because it favours DHA accretion by erythrocytes (and putatively to the brain) to a greater extent as compared to TG-DHA (Lemaitre-Delaunay, Pachiaudi et al. 1999).

The objective of the study was to evaluate the effect of daily intake of 500 mg **NKO®** after 12 and 24 weeks on adult ADHD as measured by Barkley's Executive Function score of **behaviour inhibition**, **daily functional capacity** and **social behaviour**.

## SUMMARY OF STUDY STATUS and RESULTS

Thirty (30) otherwise healthy adults with a mean (SD) age of 23 (1.2) years and having a confirmed diagnosis of ADHD for an average of 7 years were originally enrolled in the study of whom 25 (83.3%) completed 6 months of treatment. The five (16.7%) subjects who did not complete the study were lost in follow-up. No adverse events were reported amongst the 30 subjects recruited. The treatment consisted of administration of NKO® as softgels (500 mg) once a day.

Overall, subjects showed significant improvement in all three categories Behavior (33.6%; $p<0.022$), Social Behavior (18.5%; $p<0.001$) and Daily functional capacity (16.2%; $p<0.05$).

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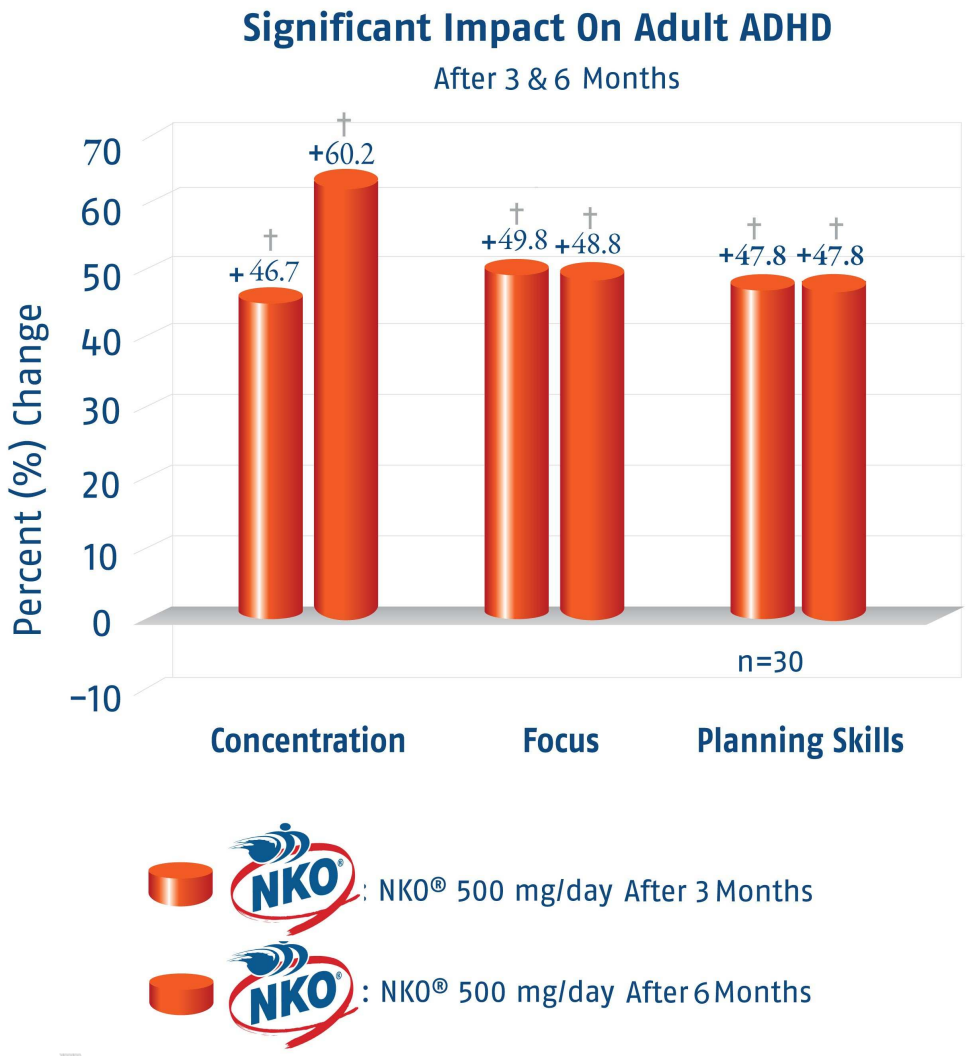
After 6 months of treatment the 25 subjects who completed the study showed a statistically significant improvement in all Barkley's Executive Function scores. In particular, a patients improved their ability to **concentrate** 60.2% (p<0.001), their ability to **focus** by 48.8% (p<0.001) and their **planning skills** by 47.8% (p=0.001).

## Cognitive Function




## CONCLUSION

NKO® can be considered a safe, and effective treatment able to improve brain executive function for adults having ADHD. NKO® diminishes the need for stimulant medication, decreases treatment costs and improves the quality of patients.

Further research is needed in order to better understand dosage and long term effects of the treatment in different physical and psychological conditions of adults and children.