

## Compliance with the dietary regimen in a five-year trial of the primary prevention of asthma

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The Childhood Asthma Prevention Study is a randomised controlled trial designed to measure the effectiveness of house dust mite allergen reduction and supplementation with omega-3 fatty acids, both separately and in combination, for the primary prevention of atopy and asthma (1). Poor compliance may compromise the successful outcome and validity of CAPS results.

Pregnant women whose unborn children were at high risk of developing asthma due to family history were randomised prenatally into active and placebo groups (n = 616). The active dietary intervention requires mothers to add tuna oil capsules to the infant's food from six months, and use Canola margarine and oil. The placebo diet involves the use of Sunola oil capsules, polyunsaturated margarine and sunflower oil. Data are collected quarterly in the first year and then half yearly until five years. Compliance is assessed by self-rating (all visits) and plasma phospholipids at 18 months. Data are currently available for 251 children (41% of total).

This study sought to 1) assess differences in plasma phospholipids between active and placebo groups, as a biomarker for compliance with the dietary regimen 2) evaluate the validity of self-reported compliance compared with plasma phospholipids.

The active group had significantly higher plasma omega-3 fatty acid levels and significantly lower omega-6 fatty acid levels than the placebo group.

Fatty acid	Active (n = 125) mean (%) (95%CI)	Placebo (n = 126) mean (%) (95%CI)	P value
Total omega-3	7.07 (6.71-7.42)	5.05 (4.83-5.26)	< 0.001
Total omega-6	32.7 (32.20-33.24)	35.21 (34.69-35.72)	< 0.001

Self-reported compliance was related to plasma phospholipids in the expected direction, that is, omega-3 fatty acids were significantly higher among self-rated good compliers with capsule taking than in self-rated poor compliers (P < 0.001). Nearly half of the subjects were correctly classified into tertiles of plasma omega-3 fatty acids according to self-rated compliance. Only 12.5% were grossly misclassified (Kappa = 0.18).

Significant differences between plasma fatty acids in the intervention groups reflected high compliance with the dietary regimen of CAPS. Self-reported compliance was significantly associated with plasma fatty acids. However, self-reported compliance was not an accurate basis for classification into tertiles of omega-3 fatty acids.

1. Miharshahi S, Peat JK, Webb K, Tovey ER, Marks GB, Mellis CM, Leeder SR. The Childhood Asthma Prevention Study (CAPS): Design and Research Protocol of a Randomized Trial for the Primary Prevention of Asthma. *Controlled Clinical Trials* 2001; 22: 333-354.