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Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial.

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Abstract

BACKGROUND: We undertook a randomised, double-blinded, placebo-controlled, crossover trial to test whether intake of artificial food colour and additives (AFCA) affected childhood behaviour.

METHODS: 153 3-year-old and 144 8/9-year-old children were included in the study. The challenge drink contained sodium benzoate and one of two AFCA mixes (A or B) or a placebo mix. The main outcome measure was a global hyperactivity aggregate (GHA), based on aggregated z-scores of observed behaviours and ratings by teachers and parents, plus, for 8/9-year-old children, a computerised test of attention. This clinical trial is registered with Current Controlled Trials (registration number ISRCTN74481308). Analysis was per protocol.

FINDINGS: 16 3-year-old children and 14 8/9-year-old children did not complete the study, for reasons unrelated to childhood behaviour. Mix A had a significantly adverse effect compared with placebo in GHA for all 3-year-old children (effect size 0.20 [95% CI 0.01-0.39], $p=0.044$) but not mix B versus placebo. This result persisted when analysis was restricted to 3-year-old children who consumed more than 85% of juice and had no missing data (0.32 [0.05-0.60], $p=0.02$). 8/9-year-old children showed a significantly adverse effect when given mix A (0.12 [0.02-0.23], $p=0.023$) or mix B (0.17 [0.07-0.28], $p=0.001$) when analysis was restricted to those children consuming at least 85% of drinks with no missing data.

INTERPRETATION: Artificial colours or a sodium benzoate preservative (or both) in the diet result in increased hyperactivity in 3-year-old and 8/9-year-old children in the general population.

PMID: 17825405 [PubMed - indexed for MEDLINE]

Arch Dis Child. 2004 Jun;89(6):506-11.

The effects of a double blind, placebo controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children.

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Abstract

AIMS: To determine whether artificial food colourings and a preservative in the diet of 3 year old children in the general population influence hyperactive behaviour.

METHODS: A sample of 1873 children were screened in their fourth year for the presence of hyperactivity at baseline (HA), of whom 1246 had skin prick tests to identify atopy (AT). Children were selected to form the following groups: HA/AT, not-HA/AT, HA/not-AT, and not-HA/not-AT (n = 277). After baseline assessment, children were subjected to a diet eliminating artificial colourings and benzoate preservatives for one week; in the subsequent three week within subject double blind crossover study they received, in random order, periods of dietary challenge with a drink containing artificial colourings (20 mg daily) and sodium benzoate (45 mg daily) (active period), or a placebo mixture, supplementary to their diet. Behaviour was assessed by a tester blind to dietary status and by parents' ratings.

RESULTS: There were significant reductions in hyperactive behaviour during the withdrawal phase. Furthermore, there were significantly greater increases in hyperactive behaviour during the active than the placebo period based on parental reports. These effects were not influenced by the presence or absence of hyperactivity, nor by the presence or absence of atopy. There were no significant differences detected based on objective testing in the clinic.

CONCLUSIONS: **There is a general adverse effect of artificial food colouring and benzoate preservatives on the behaviour of 3 year old children which is detectable by parents but not by a simple clinic assessment.** Subgroups are not made more vulnerable to this effect by their prior levels of hyperactivity or by atopy.

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Do artificial food colors promote hyperactivity in children with hyperactive syndromes? A meta-analysis of double-blind placebo-controlled trials.

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Abstract

Burgeoning estimates of the prevalence of childhood attention-deficit/hyperactivity disorder (ADHD) raise the possibility of a widespread risk factor. We seek to assess whether artificial food colorings (AFCs) contribute to the

behavioral symptomatology of hyperactive syndromes. We searched ten electronic databases for double-blind placebo-controlled trials evaluating the effects of AFCs. Fifteen trials met the primary inclusion criteria. Meta-analytic modeling determined the overall effect size of AFCs on hyperactivity to be 0.283 (95% CI, 0.079 to 0.488), falling to 0.210 (95% CI, 0.007 to 0.414) when the smallest and lowest quality trials were excluded. Trials screening for responsiveness before enrollment demonstrated the greatest effects. **Despite indications of publication bias and other limitations, this study is consistent with accumulating evidence that neurobehavioral toxicity may characterize a variety of widely distributed chemicals.** Improvement in the identification of responders is required before strong clinical recommendations can be made.

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J Paediatr Child Health. 2002 Aug;38(4):373-6.

Controlled trial of cumulative behavioural effects of a common bread preservative.

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Abstract

OBJECTIVE: Many anecdotes and one scientific report describe cumulative behavioural effects of bread preservative on children.

METHODOLOGY: Twenty-seven children, whose behaviour improved significantly on the Royal Prince Alfred Hospital diet, which excludes food additives, natural salicylates, amines and glutamates, were challenged with calcium propionate (preservative code 282) or placebo through daily bread in a double-blind placebo-controlled crossover trial.

RESULTS: Due to four placebo responders, there was no significant difference by ANOVA of weighted placebo and challenge Rowe Behaviour Rating Inventory means, but a statistically significant difference existed in the proportion of children whose behaviours 'worsened' with challenge (52%), compared to the proportion whose behaviour 'improved' with challenge (19%), relative to placebo (95% confidence intervals 14-60%).

CONCLUSIONS: **Irritability, restlessness, inattention and sleep disturbance in some children may be caused by a preservative in healthy foods consumed daily. Minimizing the concentrations added to processed foods would reduce adverse reactions. Testing for behavioural toxicity should be included in food additive safety evaluation.**

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