

NUTRITIONAL INTERVENTIONS

No evidence for the benefits of commonly recommended supplements from a gold standard trial

For many years, there has been a search for supplements that might improve the development of children with Down syndrome. Following a careful review of the literature^[1], this team designed and conducted a randomised control trial to investigate the effects of two of the substances which have been suggested as having potentially beneficial effects, antioxidants and folic acid. The paper reviews the theoretical and research evidence for the possible effectiveness of these supplements.

The team recruited 156 infants with Down syndrome under 7 months of age (mean 4.2 months) and randomly assigned them to one of four groups. One group received a daily oral dose of antioxidants (selenium, zinc, vitamin A, vitamin E and vitamin C), one group received folic acid, one group received both antioxidants and folic acid and one group received a placebo. All the supplements were made up to look identical and only the pharmacists knew which children were in each group. No one in the families or in the research team knew this information until the end of all the data collection (at the end of the trial only 11 of 138 parents guessed correctly – consistent with chance). The supplements were taken for 18 months unless side-effects were an issue (17 had side-effects which led to them stopping, 15 of these on anti-oxidants). There was evidence of good compliance with the daily supplementation.

Outcome measures included developmental measures and biochemical outcomes. The developmental measures were the Griffiths mental development scales and the MacArthur communicative inventory. There were no significant differences in developmental, motor or language outcomes for any of the groups at the end of the study (mean age 22.9 months). There were also no significant differences between the groups on any of the biochemical markers measuring enzyme activities or markers of oxidative stress.

This was a large well designed trial. A randomised control trial is the gold standard for testing the outcomes of interventions. The sample size was adequate to detect small but significant changes as a result of treatment if they occurred. In the discussion, the authors point out that they did not use the large doses used in some commercially marketed products claiming (without evidence) to benefit children with Down syndrome. They used the doses considered safe for this age group of infants, pointing out that there is no evidence of the safety of higher doses used over long periods. They draw attention to evidence that refutes the widely held beliefs that vitamins are harmless. In the words of the authors:

"this study provides no evidence to support the use of antioxidant or folic acid supplements in children with Down's syndrome. Parents who choose to give supplements to their children need to weigh their hope of unproved benefits against potential adverse effects from high dose, prolonged supplementation".

Sue Buckley

Original research paper

Ellis JM, Tan HK, Gilbert RE, Muller DPR, Henley W, Moy R, Pumphrey R, Ani C, Davies S, Edwards V, Green H, Salt A, Logan S. Supplementation with antioxidants and folic acid for children with Down's syndrome: randomised control trial. *British Medical Journal*. 2008; 336: 594-597. doi:10.1136/bmj.39465.544028

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doi:10.3104/highlights.2122

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Colours of the Soul, Colours of the Wind

Colours of the Soul, artwork by the students of the Mexican School of Down Art at the John Langdon Down Foundation, Mexico, has been exhibited throughout Europe over the past three years, and continues its itinerary in 2009. Meanwhile, the *Colours of the Wind* exhibition will be on display in Tokyo at the Cervantes Centre recently inaugurated by the King of Spain. It will then travel to Beijing and Shanghai.

See the next issue of DSRP for more information, dates and locations of these exhibitions.