Research Made Easy

This article will help you understand how double-blind, randomised controlled trials allow the specific effects of an intervention to be differentiated from non-specific effects.

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SPECIFIC AND NON-SPECIFIC EFFECTS IN RANDOMISED CONTROLLED TRIALS

Double-blind randomised controlled trials (see previous article in this series) are used to evaluate new interventions such as medications or surgery. This is because this methodology enables the specific effect of an intervention to be measured independently from non-specific effects.

Specific effects are due to the effect of an active ingredient on a particular condition (e.g., the effect of acetylsalicylic acid, the active ingredient of aspirin, on headaches).

Non-specific effects are due to additional factors, e.g., beliefs about the intervention’s effectiveness, or to interaction with the clinician. These are often labelled the placebo effect, although the use of this term is controversial.1

Placebo: ‘a substance or procedure that is without specific activity for the condition being treated.’2

The double-blind, randomised, controlled trial was developed in 1937 by Gold and colleagues while evaluating the effect of xanthines on angina pectoris.3 Patients were allocated to receive either xanthine or placebo, and blinded to group allocation to prevent their beliefs from affecting the results.

The investigators collecting the data were not blinded, and Gold noticed that patients in the intervention group were asked leading questions about their pain severity. As this might bias the results, Gold stopped the investigators knowing which group patients were in, thereby ensuring that all patients were treated consistently.

Any differences between groups could then be attributed to the specific effects of treatment. No differences were found, and the use of xanthine for angina pectoris was discontinued. This methodology gradually became the gold standard for evaluating new drugs.


Evidence in Practice

EATING A MEDITERRANEAN DIET COULD PROTECT AGAINST RESPIRATORY ALLERGIES AND ASTHMA

Eating a diet high in fruits, vegetables and nuts is associated with lower risk of respiratory allergies and asthma, according to a study of children brought up in rural Crete.

Atopy is not uncommon among children living in rural Crete; but wheeze and rhinitis are rare. So researchers looked at whether this discrepancy could be attributed to a high consumption of fresh fruit and vegetables. They carried out a cross-sectional survey of 690 children aged 7-18 years in rural Crete. Parents completed a questionnaire on the child’s respiratory and allergic symptoms, and a 58-item food frequency questionnaire. Children underwent skin prick tests with 10 common allergens.

Results showed that 80% of children ate fresh fruit (and 68% vegetables) at least twice a day. The intake of grapes, oranges, apples, and fresh tomatoes – the main local products in Crete – had no association with atopy but was protective for wheezing and rhinitis. Children with high consumption of nuts were half as likely to suffer wheezing as those eating lower amounts (OR, 0.46; 95% CI, 0.20-0.98), whereas margarine increased the risk of both wheeze (OR, 2.19; 95% CI, 1.01-4.82) and allergic rhinitis (OR, 2.10; 95% CI, 1.31-3.37).

Overall, children with a high level of adherence to the Mediterranean diet were two-thirds less likely to have allergic rhinitis than those with lower adherence (OR, 0.34; 95% CI, 0.18-0.64) while a more modest protection was observed for wheezing and atopy.

ACTION

Daily consumption of fruits, vegetables and nuts (obviously ensuring no nut allergy!) and a high adherence to a traditional Mediterranean diet (high in fruit, vegetables, bread, olive oil and fish) during childhood seems to reduce symptoms of asthma and rhinitis. These findings add to existing evidence that a healthy diet could help reduce the risk of asthma symptoms by providing beneficial vitamins and antioxidants.


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