

Alternative Medicine and Scientific Trials

We understand how much parents may want to try different treatment approaches to help their child when modern medicine cannot find a quick cure. Some parents ask us about complementary (or alternative or holistic) therapies, such as restrictive diets, herbs, and supplements. Some inquire after hearing claims on the Internet or in magazines that such therapies can work wonders.

Understandably, many parents of a child with a chronic disease desperately want something to work for their child. But we also do not want to waste your time and money on treatments that will do the child no good, and may even do harm. What we need is evidence—objective and unbiased—of therapeutic benefit. Such evidence requires large, randomized, double-blind placebo-controlled, trials (RCTs) that is the basis of modern science and medicine.

Why is it important for a study to be "controlled"? When investigators want to study the effects of a therapy objectively, they compare it against a "fake" treatment—or placebo—in 2 groups of patients. The researchers are not told which group is getting the active treatment and which is receiving the placebo. If they were told, their interpretation of the results could be biased because they might wish that the therapy would work better than the placebo.

Why is it important for patients to be randomly assigned to a therapy or to a placebo? The first step in testing a medicine or a particular diet or other therapy is to choose who will get the "real" treatment and who will get the placebo. Patients should be chosen randomly (by chance)—not at the whim of one person. Random selection eliminates that person's unknown or unconscious bias.

How large does a study need to be for results to be "scientific"? If the total number of patients in a particular study is small, the treatment groups could be divided unevenly. Unless a study has an adequate number of patients, the results may not tell the true story. Many of the studies of complementary or alternative treatments lack a control group and include fewer than 20 patients. Consequently, their results can't be considered reliable.

How does the placebo effect figure into a scientific study? The placebo effect is a fascinating concept. If a person is told that a medicine will make him or her feel better, the mere power of that suggestion can create a powerful positive response. This effect was noted during World Wars I and II when morphine supplies ran low: doctors injected saline or sugar water and told the soldiers that they were being given strong pain medicine. The power of the soldier's belief actually diminished their perception of pain.

Don't patients know they are receiving a placebo and not the real therapy? In an RCT; patients aren't told whether they are receiving active therapy or placebo. Researchers will strive to make placebo and active therapy "look alike". Placebo-controlled studies are difficult to conduct because parents need to sign a consent acknowledging that they are aware that their child could receive a fake pill.

What does "double-blind" mean? "Double-blind" means that neither investigators nor patients know who is receiving therapy or placebo during a study. It is extremely important to maintain a double blind throughout the study. However, occasionally, when preliminary data suggest that a treatment is potentially harmful or helpful, the blinding can be removed.

Tips on Assessing the Evidence About a Complementary or Alternative Therapy

1. Randomized, double-blind, placebo-controlled trials are the gold standard for assessing the safety and effectiveness of a treatment.
2. For an objective assessment of the benefit (or lack thereof) of a treatment, make sure it has been compared with a placebo—and that the treatment and control groups were randomly selected. Also, neither the researchers nor the patients should know whether they were given the active treatment or fake treatment.
3. A study must have an adequate number of patients; otherwise, the results may not tell the true story.
4. Testimonials are very uplifting but not very helpful when it comes to unbiased information. Be very careful about product or services that rely on testimonials in ads.
5. Some products claim scientific studies that 'prove' that their products work, but if one digs deeper into these claims, the scientific 'proof' may not be valid at all.
6. Remember, the US Food and Drug Administration (FDA) that controls medicines does not control food products or supplements such as herbs and vitamins. Therefore, the makers of these alternative therapies can claim all sorts of cures that really do not exist at all. In the Wild West such people were called 'Snake Oil' salesmen, or quacks.