



## Journal of Neurotherapy: Investigations in Neuromodulation, Neurofeedback and Applied Neuroscience

### Can the Balanced Placebo Design Benefit Neurotherapy?

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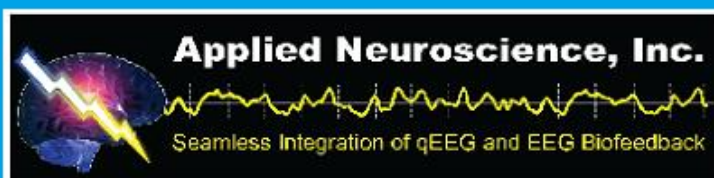
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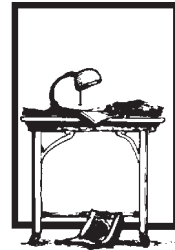
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*EDITORIAL*



Can the Balanced Placebo  
Design Benefit Neurotherapy?

This issue of the *Journal of Neurotherapy* presents outcome data from a variety of treatment modalities. The review article by Gilula and Kirsch presents data to show how cranial electrotherapy stimulation (CES) can offer patients a method of treatment for depression, anxiety and sleep. The outcome data for CES compared to medication outcome data shows a similar if not stronger effect across several studies and with different measures. The second outcome article by Burkett, Cummins, Dickson, and Skolnick is a study of neurofeedback implemented in an inpatient treatment program for persons dependent on cocaine. The addition of neurofeedback resulted in a large decline in relapse after 12 months. The third article by Olmstead shows some intriguing data with auditory and visual stimulation (AVS) treatment. Finally, in our Current Concepts section, the fourth article by Overcash is a case study in which multiple treatments were implemented in a single case design. Clinical Corner is once again loaded with valuable information on treatment techniques as

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Susan Othmer describes the steps utilized to develop treatment and how experience over time leads to more effective treatment techniques. David Kaiser offers an excellent review of research on brain connectivity and synchronization to provide a theoretical basis for clinical intervention.

While this issue shows numerous treatment outcomes with many treatment techniques, I often ask the question, “How do we measure treatment”? A brief search of “treatment outcome” on Medline found 10,721 references; a Google search found 504,000 references, and a search on Amazon.com resulted in 157 references to books. Clearly, these two words have a significant influence on how we guide new treatment in this developing area of neurotherapy and neurofeedback.

As a young undergraduate student in psychology, I was taught the rational approach to measure treatment outcome was a double-blind design. In Introduction to Psychology classes, I taught many students that in the double-blind design, the recipient of the treatment does not know what treatment they are getting and the experimenter does not know what treatment they are administering. In just a few words, the experimenter and the participant are “blind” so extraneous variables will not confound the treatment effect. The experimenter only wants to measure the effect of the treatment, not an interaction between the treatment and other variables, by holding all other variables constant.

Many other professions use the double-blind method as a means of measuring treatment effectiveness or outcome. Specifically, the researchers in medication have used this treatment design to measure the “effect” of medication on a prescribed illness. This design has almost become the “golden rule” to show the effectiveness of a new drug or medication so the researcher does not have to worry about the influence of expectation, a desire to get better, or thoughts that you will get better. In other words, this design is advantageous in research designs, but perhaps if we examine the disadvantages of this design, we find there are more problems than solutions with this design because of “external validity.” The double-blind placebo method has great internal validity (measures what it says it will measure) and has very good external validity in a laboratory situation, where everything is controlled. But, a double-blind procedure has poor external validity for medication treatment outcome because I have never received a treatment for a cold or virus when the doctor said, “I am not sure what I am giving you and you will have no idea what you are receiving, but take the medicine and let’s see if it helps you.” This simply does not happen in the real world and the double-blind method is not a valid measure of real world medication use. The problem is low external validity with medication due to the limitations of the dou-

ble-blind placebo design. We are constantly bombarded with information from the media or other professionals that says a medication will help your cold or pain which creates an expectation.

I learned about an alternative research design from personal experience when I completed my dissertation. In this study, I gave a placebo and the hormone Desmopressin Acetate (DDAVP) to college students to examine the effect on memory for prose passages (Tinius, 1991). During my dissertation proposal meeting my advisor, Bill Beckwith, PhD, proposed that I add a no-treatment control group. This group would complete the same steps as the placebo and DDAVP groups except inhale placebo or DDAVP through their sinuses from a needleless syringe. Our assumption was that the placebo group should have performed like the no-treatment control group, but this was not the case. The no-treatment control group performed very different than either the placebo or DDAVP group. I went to the library to look up treatment effects to understand these results and stumbled upon several studies suggesting problems with the double-blind research design. The articles suggested that when subjects were given a placebo or medication and told they may or may not be receiving the medication there could be a significant change in their performance because of a change in their expectancy about the experiment. Marlatt and Rohsenow (1980) suggested that what the investigator tells the subject she or he is receiving (instructions) may be the most important determinant of the subject's expectancy, regardless of the actual ingredients in the drug. This phenomenon in which subjects suspect they have received the drug and their performance changes accordingly is called expectancy. The subject's expectancy or beliefs about the pharmacological agent or drug and the situational factors are important variables that mediate the effect of a drug (Marlatt & Rohsenow, 1980).

A change in psychological or physiological performance due to the expectations about a drug is a placebo effect (Shapiro & Morris, 1978). Placebo effects generally correspond to people's knowledge or beliefs about the kind of drug they are receiving (Kirsch, 1985). Ross and Olson (1982) suggested that subjects who receive a placebo do not truly perceive changes in their condition, but simply follow the demands of the situation, may know the effects that the placebos should have, or may feel that it is important, either for the sake of science or for their own well-being that the experimenter's prognosis be affirmed. Most importantly, when subjects have an expectancy that is contrary to the pharmacological effects of the active drug, their response is consistent with their expectations instead of with the drug's pharmacological effects (Kirsch, 1985).

According to this theory, the no-treatment group in my dissertation had a completely different set of expectations and clearly showed the limitations of the double-blind design. Marlatt and Rohsenow (1980) suggested several problems with the double-blind procedure used to test the effects of pharmacological agents. First, there may be a guessing game for the subject. They may focus attention inwards (paying attention to physical or psychological cues) in an attempt to discover whether an active or an inert substance was administered. They may be left wondering what exactly they received. Second, the subject is told on the consent form that the medicine has been shown to influence some physiological process. This knowledge from the consent form and possible prior knowledge about the effects of other medications may influence the expectations of subjects. Third, this procedure is an excellent method to control for experimenter expectancy or bias, but not an acceptable design to control for subject's expectancy. Fourth, this procedure does not resemble the real world in terms of receiving medications. Medications are given by health professionals with the expectation they will cure conditions or improve health. In order to generalize the results from the laboratory to the naturalistic environment in which subjects take medications, the subject must be led to believe that the placebo is the real thing. Fifth, this procedure did not provide a mechanism to test for the "pure" pharmacological effects of the drug alone unconfounded by the subject's expectancy of receiving the drug.

In response to these problems with the double-blind design, the balanced placebo design (Marlatt & Rohsenow, 1980) can evaluate drug effects, expectancy effects, and their interaction. This design has a  $2 \times 2$  matrix composing four conditions in which the subjects are:

- a. told they will get the drug and receive the drug
- b. told they will get the drug and receive the placebo
- c. told they will not get the drug and receive the drug
- d. told they will not get the drug and receive the placebo

Conditions a, b, and d correspond to administration of a pharmacologically effective drug, administration of an ineffective drug, and no treatment. Condition c allows for the direct evaluation of pure pharmacological effects, which are usually inferred indirectly. Conditions a and b permit evaluation of the degree to which the combined psychological (expectancy) and pharmacological effect of drug administration exceeds the effects of expectancy when subjects are given placebo in condition b.

Conditions c and d permit evaluation of purely pharmacological effects. Conditions b and d evaluate expectancy effects.

The balance placebo design will evaluate the expectation of medication and can be applied to research in neurotherapy or neurofeedback. Proponents of medication for treatment of ADHD have often criticized neurotherapy because the expectation of a person getting better from neurotherapy will result in improved performance; however, the research with treatment effects of medication clearly is confounded by expectancy effects. Most importantly, a balance placebo design has a place in neurotherapy research to evaluate the effects of expectancy from treatment. Researchers in neurotherapy may want to utilize the balanced placebo design as a way to measure the effect of expectancy in their treatment.

*Tim Tinius, PhD*  
*Editor*

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