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Study Design in Clinical Trials

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Abstract: *The purpose of a double-blind, placebo-controlled trial is to compare the efficacy of a specific treatment or treatments with that of placebo for patients identified according to a priori criteria. The typical design of such a trial involves the parallel comparison of one or more treatments with placebo, with sample sizes considered adequate to detect a therapeutic response, given the expected placebo response rates in that specific population. As the term is commonly used, placebo response represents an apparent improvement in the clinical condition of patients randomly assigned to the placebo treatment.*

Key Words: *clinical trials, blinding, drug effects.*

1. INTRODUCTION:

Over the past 30 years, negative double-blind, placebo controlled trials – trials that have failed to confirm the expected superiority of a drug over a placebo condition – have become the rule more than the exception in clinical research. Negative findings are often assumed to be the result of some failure of 'assay sensitivity' of the trial. As pointed out by Otto and Nierenberg, this reasoning has the potential of distorting the scientific process, such that the adequacy of the trial is judged not by the design but, instead, by the results of the trial itself. Blinding is a procedure in which one or more parties in a trial are kept unaware of which treatment arms participants have been assigned to, i.e. which treatment was received in order to avoid bias. Blinding is an important aspect of any trial. How a trial was blinded should be accurately recorded in order to allow readers to interpret the results of a study. If blinding is broken during a trial on individual patients, it needs to be statistically and/or ethically explained at the end.

2. DISCUSSION:

Our field's traditional view on placebo-controlled trials in clinical trials has been that design issues are not significant contributing factors to the problem of the gradual but steady increase in placebo response rates across clinical trials. This view primarily derives from the fact that our field has accepted standard parallel comparisons between treatment or treatments and placebo as the only method to study the efficacy of new and standard treatments in disorders, as concerns about carry over effects have limited the use of intensive design approaches, despite the successful use of these techniques in studies of drug effects. One may argue that the rigid use of standard trial designs has in fact contributed to the placebo problem and has prevented investigators from exploring and testing novel approaches to study design. Blinding is important in other types of research too. For example, in studies to evaluate the performance of a diagnostic test those performing the test must be unaware of the true diagnosis. In studies to evaluate the reproducibility of a measurement technique the observers must be unaware of their previous measurement(s) on the same individual. Blinding Trials can be divided in to 4 types. **1. Unblinded Trials, 2. Single Blind Trials, 3. Double Blind Trials, 4. Triple Blind Trials.**

- **Unblinded Trials:**In un biased or open trials both investigator and patient aware of the treatment given. Most trials involving surgical treatment, acupuncture and physio therapy can only be carried out in open form. The advantages are simple to conduct and it reflects the real life clinical practice. Doctors are more comfortable in making decisions to continue or stop the therapy. The disadvantage of open trial is possibility of introducing bias. Patients are likely to loose interest in trial and drop out if they know they are receiving placebo.
- **Single Blind Trials:** Here only the Investigators are of the treatment and the patient is blinded. It is very simply to carry out compared to double blind trial. The disadvantage of single blind trial is similar to that of unbiased

trials. Here the knowledge of intervention of clinician can influence the therapeutic response. Doctors can give supplementary therapy if they know who is getting placebo and who is not. Supplementary therapy is likely to influence the outcome.

- **Double Blind Trial:** Here neither the patient nor the investigator know the identity of intervention. This design is followed in clinical trials. The main advantage of this trial is avoidance of in measuring out comes. It is a standard therapy known to be beneficial instead of placebo to one group, both groups can be treated with two different therapies and finally we can compare the efficacy of the drugs. Here third person Principle investigator monitor the response and side effects.
- **Triple blind Trials:** It is a double blind trial involves monitoring of the response by a committee which is blinded. This design give advantage over double blind study in that the monitoring committee can evaluate the response. The triple blind trial ensures freedom from bias. Therefore, triple blind trial may be counterproductive.

3. CONCLUSION:

We have emphasised the risks of bias if adequate blinding is not used. This may seem to be challenging the integrity of researchers and patients, but bias associated with knowing the treatment is often subconscious. On average, randomised trials that have not used appropriate levels of blinding show larger treatment effects than blinded studies. Similarly, diagnostic test performance is overestimated when the reference test is interpreted with knowledge of the test result. Blinding makes it difficult to bias results intentionally or unintentionally and so helps ensure the credibility of study conclusions.

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