## Methodological Note

# Blindness in Randomized Controlled Trials

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In combination with randomization, blinding or masking is an important factor in randomized controlled trials (RCTs), particularly in trials that assess therapeutic effects. Here an attempt is made to explain blindness and why it is important. In clinical trials, blinding is defined as the condition imposed on a study in which study participants, health care providers and assessors collecting outcome data are unaware of the assigned intervention throughout the study. A single-blind trial means that usually one of three above mentioned categories of individuals remains unaware of the intervention assignment throughout the trial. The optimal approach, however, is the double-blind trial in which neither the participant nor the health care providers and assessors involved in implementation of the intervention, evaluation or measurement of outcomes are aware of the treatment received. Additionally, nomenclature such as triple-blind or quadruple-blind exist in the literature which offer different and confusing interpretations and definitions. Thus what is very important in reporting the clinical trial is that researchers should clearly state those who are blinded and unblinded in their trial rather than solely labeling their trial as single-blind, double blind, etc. This issue is quite useful for the reader to judge the effects of blinding on bias reduction. Knowledge of treatment allocation can affect patients' responses since participants who know that they have received a new intervention may report symptoms differently from blinded participants. Another risk of unblinding in the therapeutic trial is unequal cointervention in which patients receive a wide range of other treatments that will, on average, favorably affect their outcomes. This phenomenon may cause confusion in determining whether any outcome differences are due to the experimental treatment or to unequal cointervention. Furthermore, lack of blinding can cause ascertainment bias.

Ascertainment bias is more important in subjective outcome assessments such as pain scores. Under these circumstances, if individuals are not successfully blinded, psychological responses to intervention could affect the measure of association. The last risk of unblinding that should be considered in designing of trials is contamination of the control group. When the clinician or the patient is pretty suspicious that the experimental treatment is better than standard treatment one or both of them may take some actions leading to access of control group to the experimental treatment. This contamination results in a decrease in any difference in outcomes between the two groups. Other essential topics that should be taken into account in the blinding procedure are the methods to maintain blinding of participants and health care providers, assessment of success of blinding and the difference between blinding and allocation concealment. We will consider these topics in future notes (1-2).

## References

1. Schulz KF, Grimes DA. Blinding in randomised trials: hiding who got what. Lancet, 2002; 359(9307): 696-700.

2. Haynes RB, Sackett DL, Guyatt GH, Tugwell P. Clinical epidemiology: how to do clinical practice research. 3th ed. Canada: Lippincott Williams & Wilkins; 2006; 495.