> *If the referring health care provider is aware of the next allocation, he…may (even unknowingly) influence enrollment or selection of participating subjects. For example, if the referring health care provider knows the next subject will be allocated to* Slimmenow, *he…may be inclined to try to help a certain patient he/she thinks may benefit more. Or perhaps knowing the next subject is to be allocated to placebo, he/she refers someone who really does not need to lose much weight.*

Pildal et al. (10) characterized the failure to conceal allocation as, "[w]ithout concealment the person in charge of enrolment might channel patients with a better prognosis into his…preferred treatment."

Schulz (11) describes a number of intentional attempts to subvert allocation, thereby resulting in unblinding of clinical trials. These include attempts to obtain the master randomization list, and using X-rays to screen sealed envelopes containing the patient's allocation to drug or placebo. In another publication, Schultz et al. (12) identified a few clinical studies where allocation was poorly controlled, and where there appeared to be consequent bias in the results.

According to Torgerson and Roberts (13), "[a] trial which has had its randomisation compromised may apparently show a treatment effect that is entirely due to biased allocation. The results of such a study are more damaging than an explicitly unrandomised study, as bias in the latter is acknowledged."

Randomization is a consequence of proper allocation. The reverse circumstance is not the case. According to Gluud (14), "[a]dequate randomization requires that the allocation of the next patient be unpredictable."

b. Simple randomization

Simple randomization refers to the act of flipping a coin for each person enrolling in the trial, and using the coin flip to allocate the person to Treatment A or Treatment B. But according to Schultz and Grimes (15), this method of randomization can lead to errors, especially when the total number of people enrolling in the trial is small. For a clinical trial containing only 16 subjects, where 8 are men and 8 are women, the ideal clinical trial is one where 4 men and 4 women receive Treatment A, and 4 men and 4 women receive Treatment B. But it is intuitively obvious that imbalances are expected. The laws of probability inform us that it is quite possible for the coin-flipping technique to assign most, or even all, of the subjects to Treatment B. Other methods of

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