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Nurse Researcher and Allocation Concealment

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Abstract

Allocation concealment is defined as the procedure for protecting the randomisation process so that the treatment to be allocated is not known before the patient enters into the study. Hiding the allocation sequence from those performing randomization is known as "Allocation Concealment". The primary purpose of randomizing patients into treatment arms is to prevent researchers, clinicians and patients from predicting and thus influencing, upcoming group assignments. Allocation concealment is a strict implementation of the schedule must be secured through an assignment mechanism that prevents biases that could stem from foreknowledge of treatment assignment.

Enclosing assignments in sequentially numbered, opaque, sealed envelopes can be a good allocation concealment mechanism if it is developed and monitored diligently.

Unpredictability is assured through the process of concealment which is critical in preventing selection bias that is the potential for investigators to manipulate who gets what treatment such manipulation in clinical trials has been well documented. Unclearly concealed and inadequately concealed trials compared to adequately concealed trials, exaggerated the estimates of an intervention's effectiveness by 30% to 40%, on average. Finally note that the issues of randomization and concealment should be kept separate from blinding and they are completely different.

Keywords: Randomization; Allocation concealment; Sequentially numbered opaque sealed envelopes; Nurse researcher.

Introduction

Concealment of randomisation is specified in the design section of Evidence Based Nursing abstracts of treatment studies. Concealing the knowledge of upcoming group assignments prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group [1].

Allocation concealment refers to the stringent precautions taken to ensure that the group assignments of patients are not revealed prior to definitively allocating them to their respective groups [9]. Concealment has been shown to be more important in preventing bias than other components of allocation such as generation of the allocation sequence [2]. Persons creating the allocation scheme should not be involved in ascertaining eligibility, administering treatment or assessing outcome.

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The actual process of generating the randomization scheme and the steps taken to ensure concealment should be described in detail. Whether it is a simple coin toss or the use of sealed opaque envelopes or a sophisticated off- site centralized randomization centre [5].

Although there are many approaches to randomize that are known to effectively conceal the randomization sequence, the use of sequentially numbered, opaque, sealed envelopes (SNOSE) is an effective and cheap method [3].

Enclosing assignments in sequentially numbered, opaque, sealed envelopes can also be a good allocation concealment mechanism if it is developed and monitored diligently. Investigators should ensure that the containers or envelopes are opened sequentially and only after the participant's name and other details are written on the appropriate label or envelope [9].

Definition

Concealment allocation can be defined as the process by which the researcher is blinded to the randomized sequence which was generated. The person who enrols participants in the trial should not be the same person who generates the allocation sequence [7].

Methods or schemes of allocation concealment

1. Sequentially numbered, opaque, sealed envelopes (SNOSE)
2. Sequentially numbered containers
3. Pharmacy controlled
4. Central randomisation

Sequentially numbered, opaque, sealed envelopes (SNOSE)

Randomizing participants using sequentially numbered, opaque, sealed envelopes (SNOSE) is the most accessible and straightforward method of maintaining allocation concealment and does not require the use of specialized technology.

Methods used to preserve SNOSE allocation concealment

a) Unrestricted (simple) randomization
b) Stratifies randomisation on one factor
c) Permuted blocks
d) Conducted at more than one study site.

Materials required [For a typical 50 patient trial]

Obtain 50 identical, opaque, letter-sized envelopes, 50 sheets of standard size paper, 25 letter size sheets of single sided carbon paper and two rolls of household aluminium cooking foil. Complete the kit by purchasing a tupperware-style plastic container large enough to hold all 50 envelopes.

Steps involved in SNOSE method

Step 1: Initial preparation

Cut the aluminium foil into 50 sheets that are the same width as the envelope and twice its height. The carbon paper should be cut into 50 envelope sized sheets. Separate the 50 sheets of standard size paper into two sets of 25 sheets. On one set of 25, print or write Treatment A and on the second set, print or write Treatment B. If the trial is not blinded (Treatment A vs. Treatment B) to avoid confusion you should write the exact name of the assigned treatment (instead of Treatment A or B).

Step 2a: Preparing 'Treatment A' envelopes

Select one sheet of standard sized paper marked 'Treatment A' and fold to fit the envelope. Next place one sheet of carbon paper on top of the folded 'Treatment A' allocation paper with carbon side facing the paper and fold one sheet of foil over both sides of the carbon-'Treatment A' paper combination. Place the completed insert into a blank envelope

with the carbon paper closest to the front of the envelope. If the completed insert is placed into the envelope properly, the double foil wrapper ensures the envelope is truly opaque and cannot be read by holding it up against a strong light source. If the carbon paper is positioned properly, writing on the front of the envelope is transferred to the actual treatment allocation paper inside. The carbon paper is important for establishing an audit trail that can be used to prevent violations of allocation concealment. Complete all 25 'Treatment A' envelopes, seal each envelope and sign your name in pen over top of the envelope seal.

Step 2b: Preparing 'Treatment B' envelopes

Prepare the 'Treatment B' envelopes as in Step 2a. After Step 2b is complete, there should be one pile of 25 sealed 'Treatment A' envelopes and a second pile of 25 sealed 'Treatment B' envelopes. Do not mix 'Treatment A' envelopes with 'Treatment B' envelopes and do not write on the envelopes except for signing your name over the seal.

Step 3a: Unrestricted (simple) randomization

Combine the 25 sealed 'Treatment A' envelopes with the 25 sealed 'Treatment B' envelopes and shuffle as you would a deck of cards. Once you are satisfied that the deck of envelopes is shuffled very thoroughly, with a firm hand mark a unique number on the front of each envelope sequentially from one to fifty in pen. The carbon paper inside the envelope will transfer this number to the allocation paper inside. Place these envelopes into the plastic container in numerical order, ready for use.

Step 3b: Stratified randomization one factor

Stratified randomization is used to ensure that important prognostic factors such as age, disease severity or other patient characteristics are balanced across intervention groups. First create and seal 25 'Treatment A' envelopes and 25 'Treatment B' envelopes as outlined in Step 1, Step 2a and Step2b. Next obtain two Tupperware style plastic containers and mark one as 'Treatment A' and the other as 'Treatment B'.

Assume the previous research documents and shuffle 'Treatment A' and 'Treatment B' thoroughly. Once you are satisfied that envelops are shuffled very thoroughly mark a unique identifier on the front of each envelope sequentially. The carbon paper inside the envelope will transfer the identifier to the allocation paper inside. Place the envelopes in numerical order in the container marked 'Treatment A', ready for use. Follow the same procedure for 'Treatment B'.

Step 3c: Permuted block randomization in a stratified trial

Block randomization is simply a process that can be used to ensure balance in a clinical trial after the enrolment of each block of patients. In Step 3a, because one prepared 25 'Treatment A' envelopes and 25 'Treatment B' envelopes at trial completion (after enrolling 50 patients) one would be certain of having similar numbers in each group.

Permuted blocks are useful for maintaining similar treatment group sizes in small, stratified or multi-centred trials when the number of patients that will be recruited within each strata or centre is uncertain. Unfortunately recent research suggests that it may be possible to subvert or anticipate the randomization sequence in unblinded trials that are block randomized using a uniform block size [2]. For this reason, the researchers strongly recommend using at least two or more different block sizes.

Step 3d: Permuted blocks in a stratified trial with two (or more) study sites

The patient trial will be conducted at two sites which will be stratified on one factor and will use permuted block randomization within strata. First based on the best guess estimate the maximum number of patients any one site will enrol in any single strata. It is better to over-estimate than to run out of envelopes half way through the trial. To set up the

randomization kit for Site 1 repeat Step 1, Step 2a and Step 2b. For Site 2 repeat the same procedure. Note that four Tupperware-style plastic containers will be required to hold the randomization kits.

Block randomization will not guarantee that an identical number of patients will be enrolled into each arm of the trial but it will ensure that similar numbers of patients are enrolled into each arm. There are no requirements that group sizes must be identical. The primary purpose of varying the block size is to prevent the study participants from guessing the upcoming randomization sequence.

Advantages of SNOSE method

- Low cost
- High reliability
- Allocation details received quickly
- Audit trail created (allocation paper)

Disadvantages of SNOSE method

- Research assistant must be able to access envelopes consistently
- Vulnerable to breach of allocation sequence
- Participant personal information transferred to allocation paper

Nurse researcher's role in allocation concealment

Beginning with the October 1999 issue of *Evidence-Based Nursing*, allocation concealment and blinding have been given more attention. *Allocation concealment,* shields those involved in a trial from knowing upcoming assignments in advance. Without this protection, investigators have been known to change who gets the next assignment, making the comparison groups less equivalent.

Nurse researcher should know the steps and process involved in allocation concealment in order to prevent the bias. Nurses should not confuse allocation concealment with blinding. Allocation concealment concentrates on preventing selection and confounding biases, safeguards the assignment sequence *before and until* allocation, and can *always* be successfully implemented. By comparison, blinding concentrates on preventing study participants and personnel from determining the group to which participants have been assigned (which leads to ascertainment bias), safeguards the sequence *after* allocation, and cannot always be implemented [4].

Prompt exercise and implementation of allocation concealment would bring strong evidence based practice in nursing.

Conclusion

By describing assessments of allocation concealment and blinding, abstracts included in *Evidence-Based Nursing* will help readers to discern those trials that have made superior efforts to minimise bias. Judging the quality of allocation concealment and blinding reflects current empirical research and to apply the principles of evidence-based practice to reporting of study findings. Adequate allocation concealment emerges from the analyses as crucial to reducing bias. Without it the whole point of randomization vanishes and bias may distort results.

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