

Block randomization with real-time participant assignment: A low-tech approach

Block randomization and real-time group assignment are helpful design features for randomized controlled trials. While block randomization guarantees a balanced group split throughout the data collection process, real-time group assignment fosters assignment transparency and allows for on-the-spot group orientation. Some on-line applications offer these simultaneous features, but you have to pay and host your randomization information with them. In this Methodology Bits we describe an alternative paper-based solution, which can be implemented for free and hosted in-house. This solution works well on small and medium size studies with detailed-oriented and well-trained staff.

Randomization number	Block number	Block size	Group assigned
R001	1	4	C
R002			C
R003			I
R004			I
R005	2	2	I
R006			C
R007	3	6	I
R008			I
R009			C
R010			C
R011			I
R012			C
R013	4	2	C
R014			I
R015	5	2	I
R016			C

What is block randomization?

Block randomization is a randomization technique that randomizes study participants in blocks instead of randomizing each individual case. It is especially helpful for projects with sample sizes below 100, where group distribution has the potential to be uneven.

The table on your left illustrates an example of a block randomization master list where a sample of 16 participants has been randomized into two groups using random block sizes of two, four and six. You can see that there are an equal number of control and intervention participants in each block.

How to choose the optimal block size?

- Block sizes must be divisible by the number of study groups. In the example above, where you have two groups (intervention and control), the block sizes selected were multiples of the number two.
- The goal is to choose block sizes small enough to minimize an uneven group split and big enough to make it impossible for research staff to guess the randomization pattern (since this could incentivize selection bias).
- Choosing more than one block size and randomizing the block sizes further helps prevent selection bias since research staff will not know the block size sequence, making it virtually impossible to predict group allocation.

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Creating the randomization master list

In order to develop a randomization master list you need to know the following: your sample size, how many groups you have, the randomization group sizes you want and whether you want to randomize the block sizes or not. There are several online applications that can assist you with the creation of the master list. We have used sealedenvelope.com in the past, which works well and allows for strata designations (in case you want to stratify your sample) and for the utilization of a seed number, which makes it possible to reproduce the randomization procedure.

Preparing and sealing the envelope

Popular Education Study PI: Dr. Paulo Freire Randomization ID: R045	
Participant ID: ___-___-___	
Date opened <small>(mm/dd/yyyy)</small> ___-___-___	Staff opening envelope: _____
Time opened <small>(mm/dd/yyyy)</small> ___:___:___	Staff signature: _____

Once you have your randomization master list you need to prepare the materials that will be used in the field. These include: the randomization envelope, the randomization insert and the randomization group information letter.

The *randomization envelope* should be printed with the study name, principal investigator (PI) name, randomization number, as well as space for staff to enter the participant ID, date and time of the randomization and the name and signature of the staff opening the envelope with the participant.

The *randomization insert* is individualized (it is unique to each randomization ID). This insert reveals the randomized group allocation to the study staff to provide to the participant. The insert should contain the study name, participant randomization ID and group allocation information (e.g. control or intervention). The insert should also have space for staff to enter the participant ID.

The *randomization group information letter* also goes inside the randomization envelope. The letter should include information related to the respective group assignment (e.g., intervention or control) for that participant, such as actions required and what it means to be in the selected group. You should have one letter for each group type and include only the letter for the selected group type in the envelope. The participant keeps the letter for future reference.

Group assignment

It is essential to carefully explain the randomization process to participants prior to opening the envelope. To avoid selection bias it is important to make sure the research staff opening the randomization envelope is unaware of the group assignment prior to opening the envelope. For this reason, they should receive sealed envelopes to be used in sequential order (based on randomization ID) and should not have access to the master randomization list.

Documentation and quality control

Make sure you document each step of the randomization process, from the creation of the list to group assignment. It is important to:

- Always track the randomization envelopes (by randomization ID), documenting date created, date assigned to staff, date opened, etc.
- Document the randomization allocation on the spot. One way to do that is to take a picture of the randomization insert and envelope after adding the participant ID and then upload the picture to a secure server.
- Verify tasks that require a lot of attention to detail. For some tasks, it is prudent to have two staff members involved (e.g. verification of the randomization envelope before sealing it).

Reference

- Boston Children's Hospital (2014). Guideline for Developing Randomization Procedures – RPG-03
- Efird J. (2010). Blocked randomization with randomly selected block sizes. *International journal of environmental research and public health*, 8(1), 15-20.
- Shen D & Lu Z. (2006) Randomization in Clinical Trial Studies. *SAS Conference Proceedings*, Bonita Springs, Florida.

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