

Randomized Controlled Studies

What Is a Randomized Controlled Trial (RCT)?

The goal of conducting a RCT is to test whether an intervention works. It is often referred to as the gold standard of research designs. This is because it creates two groups that should be equivalent in every way, except that one group receives the experimental intervention while the other does not. Any differences between the two groups should be attributable to the intervention.

Cases can be randomly assigned in a number of ways. There are computer programs that will randomly generate the output of “experimental” or “control.” The individual making the assignment can flip a coin or consult a table of random numbers. If these approaches are not practical, researchers can assign cases based on some factor that should not introduce any systematic biases. For example, cases with Social Security numbers (SSN) ending in 0 to 5 can be control group cases, while an SSN ending in 6 to 9 would put the case in the experimental group. Or individuals with birthdates in January through June can be experimental, while July through December are control. While this is not truly random (because every case does not have an equal possibility of being in the experimental or control group), there should not be any systematic differences between people based on the last digit of their SSN or month of birth. In fact, using this approach allows the researcher to double-check that cases are being appropriately assigned and not placed into the experimental or control group based on how well the individual making the assignments believes the person will perform.

If random assignment is strictly adhered to, the two groups should be similar on characteristics that might influence outcomes such as regularity of contact between father and child. If the two groups varied significantly on age, race/ethnicity, level of education, or income, it might be argued that these factors contributed to different levels of parent-child contact.

What Are the Benefits of a Randomized Controlled Study?

The primary benefit has been alluded to above:

Random assignment increases the likelihood that differences between two groups are due to the intervention or service being studied by minimizing differences between the two groups prior to intervention.

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In addition:

- Using an RCT study design can also help identify factors that influence the effects of the intervention (called moderators) or the processes through which an intervention influences change (called mediators).
- Good randomization will generally decrease the chances of population bias.
- The results can be analyzed with well-known statistical tools.

Are There any Disadvantages of Using this Study Design?

- There is often temptation on the part of those making assignments to put cases into the experimental group if they are seen as especially “needy” or motivated.
- If the study requires that individuals volunteer to take part, randomly assigning volunteers to the experimental and control group will not rule out the possibility that volunteers are systematically different from non-volunteers. This means that the results of the study can be generalized only to volunteers — not to the whole population.
- An RCT study will not reveal causation or prove that one variable directly caused changes in the other. Even if the experimental group (that received six sessions on fathering) reports more contact with their children a year later relative to the control group, it is not accurate to report that receiving six sessions on fathering causes fathers to visit more frequently.
- If there is a small group of individuals to be studied, creating two groups (randomly or non-randomly) can result in a comparison of very small groups.
- RCT can sometimes be expensive in terms of time and money.
- RCT may not be feasible for all interventions or settings, such as those where judges must be allowed to send an individual for services in return for the court’s active participation in the study.
- There may be questions raised about whether serving only half of the population is ethical. Of course, this is a problem only if the study has sufficient funds to serve all cases.

Examples of Randomized Controlled Studies

Example 1: In the field of fatherhood research, the most notable randomized study is undoubtedly the Parents’ Fair Share (PFS) Demonstration. The final report of this project described the research design as follows:

The PFS Demonstration operated in seven sites: Los Angeles, California; Jacksonville, Florida; Springfield, Massachusetts; Grand Rapids, Michigan; Trenton, New Jersey; Dayton, Ohio; and Memphis, Tennessee. From 1994 to 1996, over 5,500 noncustodial parents who were found eligible for PFS were randomly assigned either to a PFS group

that was referred to the program or to a control group that was not. The effects of the program are estimated by comparing the two groups' outcomes over time. The random assignment research design provided a powerful and reliable method for estimating the program's effects: Because each father was assigned at random to one or the other group, the two groups did not differ in terms of employment, child support, or parental involvement when the program started.

The study reached the following conclusions:

- PFS increased employment rates and earnings for the most-disadvantaged men.
- Most of the men participated in job search services, but fewer than expected participated in skill-building activities.
- PFS did not generally affect fathers' level of involvement with their children, but it did increase involvement among those who were least involved initially.
- Bringing in low-income noncustodial fathers to assess their eligibility for PFS increased child support payments. For the fathers who were found eligible, PFS also increased child support payment rates.

Example 2: A second notable randomized study is the Supporting Father Involvement Preventative Intervention conducted by Cowan and colleagues. In this study, researchers worked with four separate Family Resource Centers to recruit participants across four California counties. The authors describe the research as such:

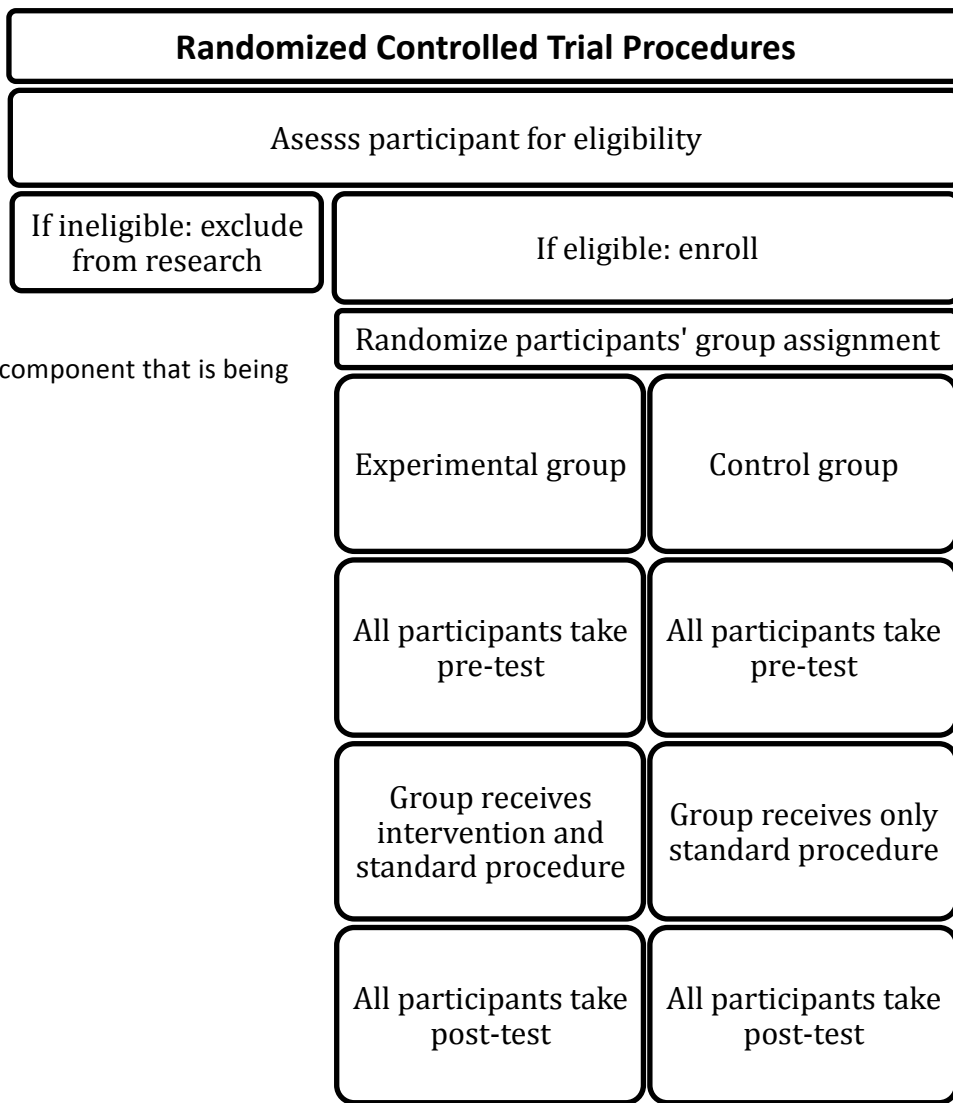
In this study, 289 couples from primarily low-income Mexican American and European American families were randomly assigned to one of three conditions and followed for 18 months: 16-week groups for fathers, 16-week groups for couples, or a 1-time informational meeting.

The study reached the following conclusions:

- Participation in a fathers' group or a couples' group was associated with an increase in fathers' engagement with their children and an increase in their sense of self as fathers.
- Participation in a fathers' or a couples' group was associated with stable levels of children's problem behaviors, while children of parents who participated in the 1-time informational meeting (or low-dose comparison option) had an increase in problem behaviors.
- Participants in the couples' group reported maintained satisfaction in their relationships as couples, while participants in the fathers' group and participants in 1-time informational meeting group did not maintain satisfaction in their relationship.

Setting Up a Randomized Controlled Study

If you are designing an RCT, ensure that the randomization is, in fact, “random.” There should be no key differences between the control group and the experimental group except the component that is being tested.



Randomized Controlled Study Resources

Research Randomizer

<http://www.randomizer.org/>

Parents' Fair Share

http://www.mdrc.org/project/parents-fair-share#featured_content

The National Center for Technology Intervention

<http://www.nationaltechcenter.org/index.php/products/at-research-matters/experimental-study-design/>

Herr Research Center for Children and Social Policy

Erikson Institute

Evaluating early care and education programs: A review of research methods and findings

<http://www.erikson.edu/wp-content/uploads/ECEreport.pdf>

Encyclopedia of Survey Research Methods

Paul J. Lavrakas

Sage Publications

<http://srmo.sagepub.com/view/encyclopedia-of-survey-research-methods/n102.xml>