
Summary sheet

RANDOMIZED CONTROLLED TRIAL (RCT)

Abstract

A randomized controlled trial (RCT) is a technique that randomly selects, from an eligible population, an experimental group that will receive an intervention and a control group that will serve as the comparison in order to assess the effect of an intervention (White, Sabarwal, & Thomas, 2014, p. 1). The technique is highly valued and used in science, medicine and increasingly in the social sciences because of its ability to minimize certain biases, earning it the moniker “gold standard.” In the context that characterizes most social economy organizations, however, the conditions required to implement this method are difficult to meet (Cupitt, 2015).



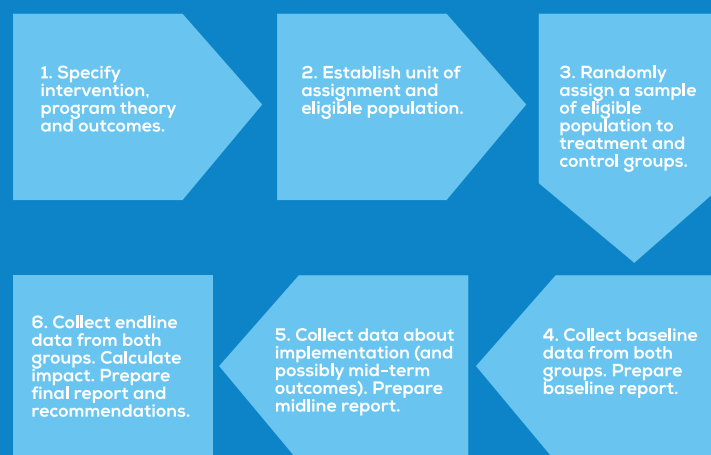
History

The concept of designing an experiment with a control group was first applied in 1747 by James Lind in a study on the treatment of scurvy. However, it was not until the 1920s that the practice of randomly assigning subjects to a treatment or control group became widespread, thanks in part to the publications of the statistician Ronald Fisher. The application of RCTs to government social programs began in the 1960s as part of the rapid expansion of a social welfare system and the debates surrounding its merits (J-PAL, 2017, pp. 22-23). After a rapid expansion in the 1970s, enthusiasm for the use of these techniques in the public policy field seems to have waned in the 1980s, only to resurge in the early 2000s due, in part, to debates in the international aid sector (Labrousse, 2016). Recently, this approach gained even more pre-eminence as the co-founders of the Abdul Latif Jameel Poverty Action Lab (J-PAL), Abhijit Banerjee and Esther Duflo as well as J-PAL affiliate Michael Kremer, were awarded the 2019 Sveriges Riksbank Prize in Economic Sciences in Memory of Alfred Nobel for “their experimental approach to alleviating global poverty” (J-PAL, 2019).

Method

To implement a randomized controlled trial, a methodological note published by UNICEF suggests the following steps (White et al., 2014, pp. 5-7).

Overview of conducting an RCT



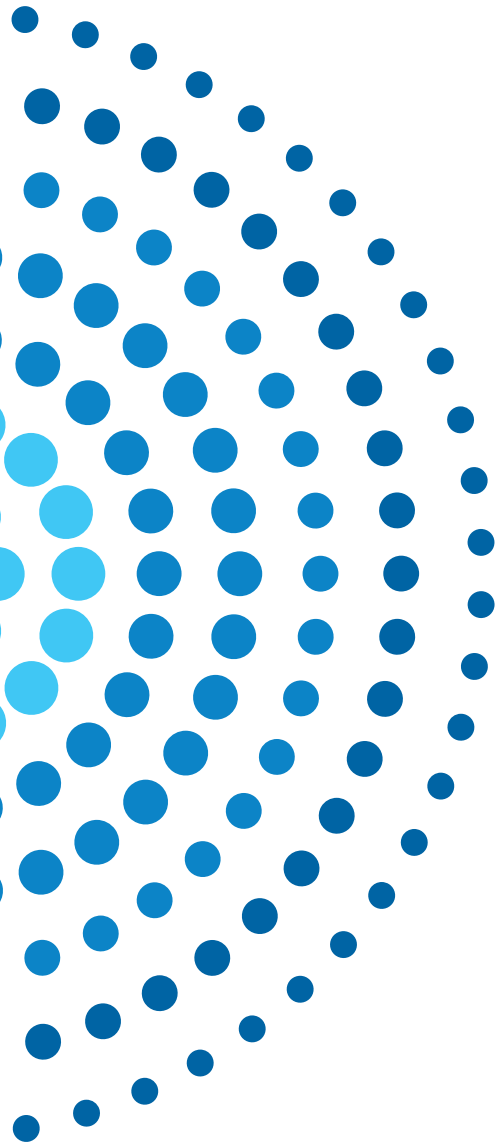
Source: White et al., 2014, p.5

In practice, there are many variants of the RCT depending on the choices made at each stage. This document is not intended to be exhaustive. For more information, readers may consult guides from UNICEF (White et al., 2014), the World Bank (Gertler & World Bank, 2011) or the Network of Networks for Impact Evaluation (NONIE) (Leeuw & Vaessen, 2009, pp. 22-29), among others.

When the design of an RCT significantly departs from the standard protocol (usually for practical reasons such as time constraints, budget, data availability, etc.), it is referred to as a quasi-experimental design. As compiled by Leeuw and Vaessen (2009, p. 30), examples of such methodological trade-offs include:

- the creation of an a posteriori control group according to certain criteria that one tries to control, rather than distributing participants randomly (propensity score matching);
- the comparison of changes observed in a group before and after the intervention without a control group (before-after study);
- the comparison of the final state of two groups without having previously collected data.

Each of these studies is likely to generate relevant information while being vulnerable to certain biases regarding its validity (Champagne, Brousselle, Contandriopoulos, & Hartz, 2011, pp. 180-198).



Scope and limitations

Because of its ability to attribute a causal link between an intervention and an effect while minimizing several potential biases, the RCT is often referred to as the gold standard for judging the quality of a research design. In fact, the establishment of a comparison group makes it possible to establish a “counterfactual,” that is, a portrait of what would have happened in the absence of the intervention. The trial (experiment) is therefore considered controlled. Random assignment of participants to one group or another minimizes statistical bias and allows probability rules to be applied to the interpretation of results. The trial (experiment) is therefore considered randomized.

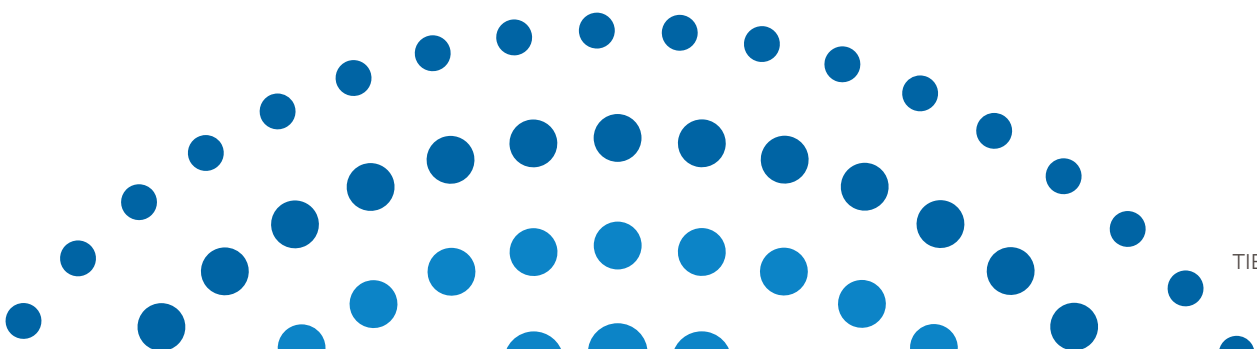
This preference for RCTs in the evaluation of social programs such as those characterizing the social economy is, however, contested. The reason is that there are a number of obstacles, at times difficult to overcome, to the implementation of an RCT. The following are some examples of these difficulties:

- **Data** – It is first necessary to have reliable data on the state of the situation before (baseline) and after (endline) the intervention (Leeuw & Vaessen, 2009, p. 21);
- **Resources** – There must also be the resources (time and budget) to plan and implement such a methodology (Cupitt, 2015, p. 6);
- **Context** – An impact assessment, to be complete, must also consider other factors that may have had an impact on the observed results and the context (Leeuw & Vaessen, 2009, p. 21). These factors are multiple and sometimes difficult to quantify (Bamberger, Rugh, & Mabry, 2011, p. 20);

- **Ethics** – The creation of a control group, which causes unequal treatment between two groups of citizens, is often ethically delicate to implement in a public policy or international development context (Cupitt, 2015, pp. 6-7) and may also provoke resistance among some participants (Labrousse, 2016, pp. 3-5).
- **Reactivity** – Humans are likely to change their behaviour when experiments are conducted on them. Thus, even if the way of determining who will be treated is randomized, there may be biases in the type of participants who are willing to take part into the experiment in the first place (Heckman, 2020, p. 22-23).

These limitations and many others are known to proponents of RCTs and a significant amount of guidance is devoted to defining the contexts in which it is appropriate to implement such a method (J-PAL, 2017, pp. 12-13; White et al., 2014, pp. 2-4), the ethical issues to be considered (White et al., 2014, pp. 8-9) and methodological tips to overcome some technical challenges (Gertler & World Bank, 2011, pp. 31-228).

Finally, while RCT makes it possible to assess the effect of an intervention, its impact, with a greater degree of rigour and certainty than most other methods, it is unable to explain how this effect occurred (attribution issue) (Labrousse, 2016, p. 5). Worse, even if this approach is generally presented as atheoretical, the methodological details of its application mean that several choices are likely to guide the conclusions (Heckman, 2005). For this reason, many foundations and international development actors prefer methods that allow participants to explain these steps, such as the Theory of Change (ToC) or Outcome Mapping.





Uses

RCT has been applied with some success to social interventions in international development (Banerjee & Duflo, 2009). However, critics of the method have observed that these applications are largely limited to simple interventions, which lend themselves well to this type of experimentation, such as the distribution of mosquito nets to combat malaria (Cupitt, 2015, p. 5).

Social impact bonds require protocols comparable to the RCT¹ for the evaluation of their results. Some recent experiences have been documented by Avise (Boscaro, Rodrigues, Mounier-Saintoyant, & Baudet, 2017; Dahlab, 2016; Mounier-Saintoyant, Dahlab, Sebag, & Baudet, 2016).

¹ See, on this subject, the TIESS blog article, <http://www.tiess.ca/tag/obligation-impact-social/>, and the corresponding section on the Evaluation and Impact Measurement Web Portal.

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