

Observational Study

In epidemiology and statistics, an observational study draws conclusions about the possible effect of a treatment on participants, where the assignment of participants into a treatment group versus a control group is outside the control of the investigator.

However, in some cases observational studies are the most appropriate design for example if the condition being studied is rare. Additionally, non-interventional observational studies are sometimes the only ethical approach. For example, if the effect of an environmental risk factor (such as asbestos) is being studied, it is unethical to deliberately expose participants to that risk factor.

In a non-interventional observational study, no additional diagnostic or monitoring procedures are applied to the participants, and epidemiological methods are used for the analysis of collected data (as per Article 2(c) of 2001/20/EC). A non-interventional observational study is not a randomised, controlled trial (RCT).