Stepped Wedge Randomized Trial: a simulation study.

Naiara Santos[1], *Cristian Tebe*[1]

[1]nsantos@idibell.cat, Biostatistics Unit, Bellvitge Biomedical Research Institute (IDIBELL), Barcelona, Catalonia, Spain

Background: A stepped wedge trial is a type of crossover trial in which patients are not randomised to one treatment or another, but the groups receive the intervention at different times according to a staggered schedule. The design involves the random and sequential crossover of clusters from control to intervention until all clusters are exposed. The order in which clusters receive treatment is randomised. We will conduct a stepped wedge trial to investigate whether stopping any type of medication intervention for 90 days in terminally ill patients could improve their quality of life without significantly increasing mortality.

Methods: A stepped-wedge, non-superiority, cluster-randomised trial was planned to assess the impact of a tool for adjusting diagnostic and therapeutic intensity compared to traditional clinical practice on the cumulative incidence of 90-day all-cause in-hospital mortality after discharge. Mortality was expected to be 4 in 100 in the control group and 5 in 100 in the intervention group, with a margin of non-superiority for the 5% difference in rates. A generalised linear mixed model with a binomial distribution and log link function was used to estimate relative risk as the measure of effect. We will use the R package swCRTdesign, a package that allows the design and analysis of stepwise studies in an effective way.

Results: The researchers identified 20 eligible doctors and planned to randomise them into 4 sequences and 5 periods, with the first period serving as the baseline. Each doctor would recruit between 20 and 30 subjects at each observed time point. To assess the plausibility of the study and the power of the contrast, a simulation will be performed using the previous assumptions. The simulation results would indicate both the feasibility of the project in terms of the number of patients and doctors to be recruited and the percentage of times that the study hypotheses will be successfully tested.

Conclusions: Stepwise studies are a useful tool for evaluating interventions that cannot be implemented simultaneously in all groups, particularly those that require a training period beforehand. In addition, these types of studies have proven to be more ethical, as all groups receive the intervention at some point in time. Another advantage is that, in addition to allowing comparison between clusters, each group also serves as its own control group.

Keywords: Stepped wedge trial, R package swCRTdesign, Simulation.