Abstract:

The use of adaptive designs has been increasing in randomized clinical trials. Sample size re-estimation is a type of adaptation in which nuisance parameters are estimated at an interim point in the trial and the sample size re-computed based on these estimates. However, post-hoc evaluations of adaptations, including sample size re-estimations, have not frequently been performed, leaving questions about the gains that come from utilizing these procedures in practice. In this talk, I describe the statistical impact of implementing a sample size re-estimation in the Secondary Prevention of Small Subcortical Strokes (SPS3) study and describe the effect of the adaptation on the practical aspects of the study.