

The stratified micro-randomized trial design: sample size considerations for testing nested causal effects of time-varying treatments

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Technological advancements in the field of mobile devices and wearable sensors have helped overcome obstacles in the delivery of care, making it possible to deliver behavioral treatments anytime and anywhere. Increasingly the delivery of these treatments is triggered by predictions of risk or engagement which may have been impacted by prior treatments. Furthermore the treatments are often designed to have an impact on individuals over a span of time during which subsequent treatments may be provided.

I will discuss work on the design of a mobile health smoking cessation experimental study in which two challenges arose. First the randomizations to treatment should occur at times of stress and second the outcome of interest accrues over a period that may include subsequent treatment. To address these challenges we develop the “stratified micro-randomized trial,” in which each individual is randomized among treatments at times determined by predictions constructed from outcomes to prior treatment and with randomization probabilities depending on these outcomes. We define both conditional and marginal proximal treatment effects. Depending on the scientific goal these effects may be defined over a period of time during which subsequent treatments may be provided. We develop a primary analysis method and associated sample size formulae for testing these effects.

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