**Optimising hypothesis tests of efficacy in external pilot trials using Bayesian statistical decision theory**

Introduction: External pilot trials of complex interventions are often conducted in advance of a definitive trial to assess feasibility and to inform its design. The efficacy of the intervention is rarely assessed using a formal hypothesis test since it would have low power, given the small sample size of a pilot and assuming a conventional type I error rate (e.g. 0.025). By not testing efficacy, an external pilot will effectively have a type I error rate of 1, suggesting an infinite preference for type I errors over type II errors. As such a preference will never occur in practice, we consider methods for finding the optimal balance of between type I and II error rates in external pilots.

Methods: We consider the problem of determining the sample size and type I error rate which maximise the expected utility of an external pilot trial testing intervention efficacy. We introduce a utility function which accounts for improvement in primary outcome, the cost of sampling, treatment costs, and the decision-maker’s attitude to risk. We apply the method to the re-design of a pilot trial with a continuous primary outcome with known standard deviation and where uncertainty in the treatment effect is quantified using a normal prior distribution.

Timing of potential results: A study of the proposed method’s properties under a range of values for the utility function and prior distribution parameters is to be completed by August 2019.

Potential relevance and impact: By viewing external pilot trial design from a Bayesian decision-theoretic viewpoint, we will provide a method for finding the optimal balance of type I and II error rates in external pilots. In particular, we will identify in which (if any) settings the current approach of not assessing efficacy is the optimal course of action.