**A hypothesis test of feasibility for external pilot trials assessing recruitment, follow-up and adherence rates**

Introduction: The power of a large clinical trial can be adversely affected by low recruitment, follow-up and adherence rates. External pilot trials, conducted before a planned definitive trial but on a smaller scale, can be used to estimate these parameters and identify any issues. Pilot trials commonly specify decisions rules which use these estimates to determine if the definitive trial is feasible and should go ahead, but there is little methodological research underpinning how they, or the pilot sample size, should be chosen.

Methods: We argue that recruitment, follow-up and adherence rates are of interest primarily in how they affect the power of the definitive trial, and use this power as a quantitative measure of feasibility which can be used in a hypothesis test of pilot data. Considering a two-arm parallel group definitive trial with a single normally distributed primary endpoint, we show how appropriate hypotheses for this test can be defined. We suggest a test statistic and provide its sampling distribution, thus defining type I and II error rates, and show how these can be used to inform the choice of pilot trial sample size and stop/go decision rule.

Results: We use our method to re-design the TIGA-CUB trial, a pilot trial comparing a psychotherapy with treatment as usual for children with conduct disorders. Our results show that error rates around the conventional levels of 0.05 (type I) and 0.2 (type II) can be obtained using typical pilot sample sizes of between 30 and 50 participants per arm. In comparison to the proposed method, using several independent progression criteria leads to a substantial loss of efficiency.

Discussion: A formal, hypothesis testing approach to the design and analysis of external pilot trials could lead to improved decision making without requiring any substantial increase in pilot sample size.