Response-adaptive design for clinical trials with recurrent events data

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Abstract: In long‑term clinical studies, recurrent event data are sometimes collected and used to compare the efficacies of two different treatments. The event reoccurrence rates can be compared using the popular negative binomial model, which allows heterogeneity among patients. It is popular that a balanced design in which equal sample sizes are obtained for both treatments is employed. However, it may be desirable to allocate fewer subjects to be assigned to the less‑effective treatment by using a sequential response‑adaptive treatment allocation procedure. Our proposed treatment allocation schemes have been shown to be able to reduce the number of subjects receiving the inferior treatment while at the same time maintains a test power level that is comparable to that of a balanced design. A clinical trial is redesigned to demonstrate the advantages of using our procedure.