How to select study designs and parameters to investigate the effect of mouthrinses? Part I: rationale and background.

In the literature and in the daily study routine, a wide range of study designs exists to test the efficacy of mouthrinses. Within these various designs, a considerable number of parameters is applied. Due to the different protocols currently used the outcome of these investigations is hardly to compare. Therefore, it was the aim of the present investigation to assess suitable study designs of different durations, to select and compare parameters, and to find suitable study participants in order to finally recommend more standardized protocols for future studies on oral antiseptics. Eight-hour substantivity studies, four-day plaque re-growth studies, 21-day experimental gingivitis studies, and six-month home-use studies were performed either cross-over or parallel. The clinical studies were randomized, controlled, and investigator-blinded. From most often applied clinical and laboratory parameters, two plaque indices, bacterial vitality, three gingivitis indices, gingival crevicular fluid, colony forming units, and the discoloration index were selected to assess plaque inhibition, gingivitis development, tooth staining, and possible bacterial shifts in the oral cavity. Four or five, respectively, treatment groups were formed that rinsed with the following solutions: chlorhexidine digluconate 0.06%, 0.12%, 0.20%, amine fluoride/stannous fluoride, and a negative control. In addition, all study designs were tested on two different study populations. Population alpha consisted of persons who had a gingival index <0.8 while population beta participants presented a mean gingival index of >/=0.8. Pearson correlation coefficients were calculated between parameters and between subsets of teeth and full-mouth recording. T-tests were applied to compare between populations alpha and beta.