



INTERDENTAL CLEANING TO PREVENT AND TREAT GUM DISEASE: STATE OF THE EVIDENCE

APPENDIX I

A BRIEF GUIDE TO ORAL HYGIENE RANDOMIZED CONTROLLED STUDIES (RCTS)

Oral hygiene RCT studies can be grouped into two types

- Studies of oral hygiene status in relation to dental caries and periodontal disease – usually contain large numbers of patients
- Studies of the effectiveness of the use of various techniques, procedures and devices for cleaning the teeth – usually contain smaller numbers of patients; the key studies in this document fall under this type

Study Design for Oral Hygiene

In oral hygiene studies it is not possible to use the normally-desirable “double-blind” design, as patients clearly know which device they are using. However, a single-blind design is possible, where the examiner is blinded to the treatment used. This is the design used in the best oral hygiene RCTs.

Patients can be randomized into separate treatment groups, including a control group, with the results in one group compared against the other. More frequently, a “**half-“ or “split-mouth” design** is used, where patients act as their own controls (thereby reducing interindividual variability) and use a different product for each side of the mouth.

Study Design for Prevention Studies

In “prevention” studies in orally-healthy people, “**experimental gingivitis**” is induced by asking patients to refrain from oral hygiene for a set period of time (from hours to a week or two) before they begin treatment (baseline).

Outcome Measures

In all studies, outcomes are measured at baseline and at the end of the study and compared to see whether there are any significant differences – i.e. whether differences are due to an actual treatment effect rather than to chance. This is represented by the p-value. Usually, if the difference between the treatments results in a p-value of less than 0.05, it is regarded as significant (e.g. $p < 0.01$ is significant, but $p = 0.06$ is not significant).