

**The effect of motivational interviewing on oral hygiene behavior in patients with fixed orthodontic appliances: A randomised clinical trial**

**Document type:** Study protocol with SAP

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**Document date:** March 1<sup>st</sup>, 2021

**IRB approval:** June 6<sup>th</sup>, 2017

## **Objective**

To evaluate the effectiveness of motivational interviewing on improving oral hygiene behavior in patients with fixed orthodontics appliances.

## **Materials and Methods**

The present study was designed as a parallel-group randomized clinical trial. The approval number provided by UNIBE's Ethics Committee is CEI2017-06. The research was performed following the Declaration of Helsinki of 2013.

### **Sample and eligibility criteria**

A power analysis was carried out to determine the number of participants needed to achieve a Simplified Oral Hygiene Index (SOHI) significant interaction with the study groups when applying repeated measures ANOVA. The total number of completed patients needed to achieve power of 0.90 with an alpha ( $\alpha$ ) of 0.05, an effect size ( $f$ ) of at least .25 was determined to be 36; taking into consideration a possible 10% attrition rate, 45 participants were recruited, consented and randomized to either the experimental or control group.

Due to the matter that repeated measures ANOVA treats each measurement as a separate variable, and it's preferable to use listwise deletion, if one measurement is missing, the whole case gets dropped. For this reason and therefore the incontrovertible fact that the trial suffers attrition, the sample for the three measurements was reduced to 30 participants.

The clinical trial was carried out at the Orthodontic Clinic of UNIBE's Postgraduate Unit, Santo Domingo, Dominican Republic, from June 2017 to November 2018. The established inclusion criteria were patients with 18-40 years old, systemically healthy, without active dental caries lesions or periodontal diseases, who were candidates for fixed orthodontic appliances. Smokers and pregnant patients were excluded. Participants were discarded if they decided voluntarily to abandon the study of the orthodontic treatment or if they didn't attend to the periodical check-ups.

### **Randomization**

A simple randomization procedure was executed by the principal investigator to allocate the participants into one of the study groups. A computer-generated list of numbers was created using the software SPSS V21.0, with a 1:1.25 allocation ratio. The aforementioned researcher didn't participate in the data recollection process.

Two dentists were in charge of the study logistic. They enrolled and allocated the participants according to the order of arrival and following the list of random numbers. A coding system was used as a concealment mechanism, which consisted of colored labels attached to the participants' file. This system was only known by the logistics managers and the interviewer (the periodontist who provided OHI and MI). Thus, the participant and the evaluator (the periodontist who recorded the data) were masked.

### **Study intervention**

The patients were invited to participate in the research in their first appointment with the orthodontic postgraduate dentist. Then, on the second appointment, the fixed orthodontic appliance was placed and the intervention began. A questionnaire to collect sociodemographic information was administered by the interviewer.

The interviewer was also in charge of providing oral hygiene instructions for both groups. All the participants received a G.U.M. kit with special orthodontic hygiene tools. Then, the patients of the experimental group received a motivational interviewing session. It is important to point out that the periodontist was trained and evaluated by two expert psychologists in MI, who also supervised the interviewer to ensure that the intervention was properly applied. Additionally, all the staff related to the research was also trained.

Afterwards, the clinical parameters were measured by another periodontist. The primary endpoint with respect of the efficacy of MI was the Simplified Oral Hygiene Index (SOHI). Additional parameters were recorded, such as the Gingival Index (GI), Periodontal Probing Depth (PPD) and Bleeding on Probing (BoP), with the purpose of evaluating the periodontal stability.

Monthly follow-up appointments were scheduled for the orthodontic check-ups to deliver a new G.U.M. kit, to reinforce the OHI and MI and to register the periodontal parameters. The important data for this research was the one recorded at baseline, three and six months after the intervention.

### **Statistical analysis**

Mean SOHI, GI, PPD and BoP scores were compared between groups across three time points using repeated-measures mixed-model analysis of variance. Tests for equality of variances and sphericity to check for homoscedasticity were performed due to the problem of sample attrition. Nevertheless, it was not found any violation to these assumptions in any of the variables included

in the analysis. SPSS software was used for all calculations (IBM SPSS 25th version). Due to the nominal level of measurement of the variable BoP, it was performed a chi-squared test for each three time points to check if there were any differences between the two experimental conditions.