OFFICIAL TITLE: **Oral Health Educational Methods in Adolescence**

NCT n/umber: **03216746**
Date:17/07/2018

Study Protocol and Statisical Analysis Plan

Study population and sample size

The investigation followed the parameters of the Declaration of Helsinki and was approved by the Human Ethics Committee of the Federal University of Paraná (case number 51712315.4.0000.0102). The description of this clinical trial followed the recommendations made by CONSORT and the extension to cluster randomized trials[19]. The study was registered in the clinicaltrials.gov database under number NCT03216746.

Clinical trial randomized by clustering involving four arms in a 1: 1: 1: 1 ratio to the four intervention groups. The randomized allocation was performed using the classes as sample units. The courses were ordered alphabetically by name and allocation was generated by the software *Stata* version 12.0. A total of 28 classes were selected and randomly allocated to an interventional group by a blinded investigator, which did not participate in the study. The analysis was done in the individual unit. Adolescents of both sexes, aged 14 to 19 years, enrolled in a technical high school in the city of Curitiba, Paraná, Brazil were evaluated. Written informed consent was obtained prior to randomization from the participant or from the legal guardian when the age of the participant was less than 18 years.

Exclusion criteria were: adolescents with some physical or mental condition that made interventions impossible and those using fixed orthodontic devices at the time of clinical examination. Cluster unit areas of technical education related to the

health area, including dental technician, were excluded. The duration of the study was from July to December 2016.

The comparison between two independent groups was used for the sample calculation considering the unequal variances. For this calculation, the outcome was considered the "knowledge score" (KS). In a pilot study, it was found that the standard deviation of the KS from the "oral guidance" group was 2.56, while in the "video" group it was 1.96. In the same study, the difference detected between the groups was 0.53 points in the knowledge score. Therefore, considering a 5% significance level and 80% statistical power, a sample value of 108 individuals was found for each group, totaling 216 participants. Estimating a loss of 35% for each group, the final sample totaled 317 individuals.

Pilot study

A pilot study was carried out with the objective of testing the suitability and methodological applicability of the instruments used. In addition, this step allowed us to verify the application dynamics of the instruments and the average time spent with each participant. Fifteen adolescents aged 14 to 19 years, with the same socioeconomic characteristics as the study population, were selected who did not participate in the main study. The methodological design was adequate; however, some terms of the questionnaire were modified to allow greater understanding on the part of the adolescents.

Interventions

Interventions were performed at the individual level within each cluster. The study included four phases (Figure 1), and the educational interventions or their different associations were evaluated through the knowledge score (KS) and oral

clinical indexes. In Phase I/baseline, the participants answered a questionnaire (pre-test) and were evaluated clinically. In phase II, the 28 classes were randomly allocated into two groups: 14 classes received oral guidance (OG) and 14 classes received video guidance (VG). Both methods (oral guidance and guidance by video) had the same thematic content. In the next phase (III), the groups were again divided into four groups (7 groups in each group), and for two of them, a smartphone App was developed so that reinforcement messages were sent during a period of 30 days. Shortly after this period (phase IV), the participants answered the questionnaire again (follow-up test) and were reassessed clinically.

Oral guidance with standardized content was performed by one of the researchers (GM) previously trained, and included aspects on general, oral health and, especially, on periodontal diseases. This guidance was carried out in the classroom, in a group, with aproximately 20 adolescents, providing an environment of discussions on the subjects addressed. The duration was aproximately 15 minutes. The elaboration of the video had the participation of three actors, two acting as adolescents and the third as a dental surgeon. The video had a total duration of 14 minutes and was applied in the classroom itself, in a group, with Aproximately 20 adolescents, without, however, allowing a later discussion of the subject.

The "Oral Health" App was specially developed for this research and developed for the Android system version 4.4 (*Kitkat*) API level 19 with JAVA language (JDK 1.8.0) in the environment Android Studio 2.1.2, having 27.90 megabytes. The App has been made available for free on Google Play for 12,199 cellphone models. This tool was aimed at transmitting knowledge in oral health in a didactic, simple and relaxed way to its target audience over a period of 30 days. To this end, 60 messages were developed, based on the contents previously exposed in the educational activities, of which they were sent twice a day to each participant: the first with information in written form and the second in the form of videos, which had an average

duration of one minute, developed especially for this research and aiming to reinforce the content of the first tip.

The participant received messages developed through the Android notification bar. The standard tone and vibration of the phone were activated when receiving the messages. For the execution of these functionalities some permissions of the cellphone were necessary: permission to access the internet, to vibrate the cell phone, to keep the screen on while running the video and permission for the App start when the phone was turned on. The App performed its functions even when the cellphone was offline, requiring access to the Internet only at the time of downloading the App. The App source code can be obtained through the address in GitHub (https://github.com/willianmuniz/saudebucal) and can be accessed and used by any user.

Questionnaires

Primary outcome was the knowledge score (KS) regarding etiology, treatment and forms of prevention of periodontal diseases. Data was obtained from a self-administered questionnaire, tested in a pilot study, using five statements: 1: If I have good oral hygiene I have less possibility of having gingival bleeding; 2: Whoever brushes their teeth very well does not need to floss; 3: It is not possible to remove the calculus or tartar with dental brushing; 4: Mouthwashes with mouth rinses may render flossing needless; and 5: A person may lose his teeth because he has problems in the periodontium. The answers were arranged in a three-point Likert scale, being *I agree*, *disagree* and *neither disagree nor disagree*. Correct answers were scored 1 (one), and incorrect and "do not know" score 0 (zero). Scores ranged from five (higher knowledge) to zero (less knowledge).

Those responsible for adolescents also answered a questionnaire containing socioeconomic and demographic information according to criteria of the Brazilian Association of Research Companies[20].

Oral clinical examination

Clinical examination was performed by a single examiner calibrated (K≥0.83) and blinded as to the intervention used and which verified the presence of dental biofilm through the simplified oral hygiene index (OHI-S)[21] and gingival bleeding (GBI)[22]. The tests were performed in two stages: Phase I and 20 weeks after in Phase V (Figure 1). The subjects were examined in a classroom where they were seated in chairs, and the evaluations were done individually, using gauze, artificial light and a millimeter probe.

Statistical analysis

Statistical analysis was performed on an individual level. Chi-square test was used to analyze the categorical variables. The numerical variables were submitted to the *Kolmogorov-Smirnov* test to verify the normality of the data, obtaining values of $P<0.05$. Thus, non-parametric tests were used to verify the association between the means of KS, OHI-S and GBI among the different intervention groups. The OHI-S variable was dichotomized in: OHI-S>1 (high dental biofilm index) and OHI-S≤1 (low dental biofilm index). *Kruskal Wallis* and *Mann-Whitney* tests were used for independent samples and *Wilcoxon's* test for paired samples. The level of significance adopted for all analyzes was 5%. The analyzes were performed using SPSS software version 20.0 (SPSS Inc., Chicago, IL, USA).

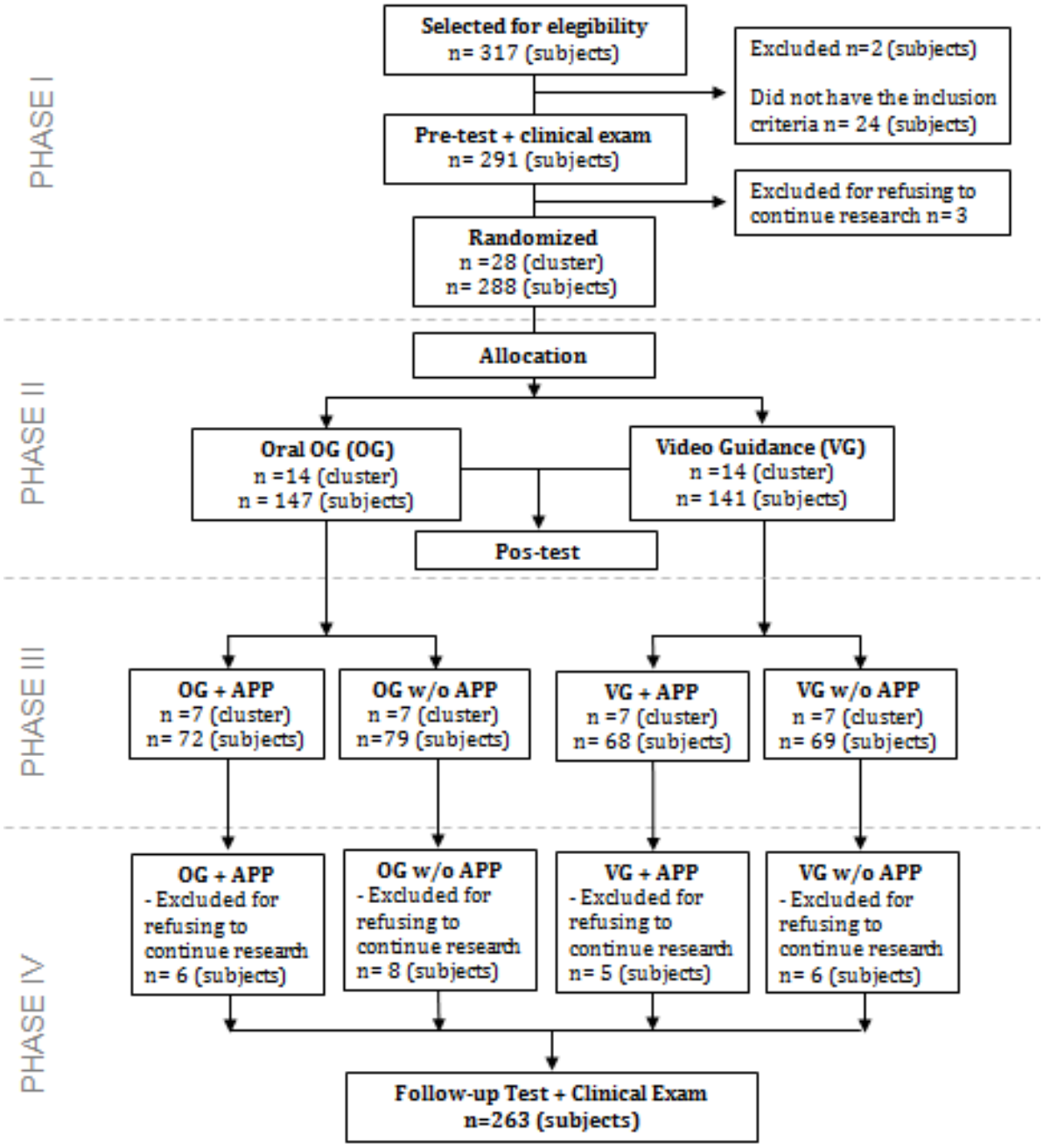

Figure 1. Flow chart demonstrating the different phases of the study.

INFORM CONSENT FORM

We, Luciana Reichert Assunção Zanon and Gisele Marchetti - Professor and Graduate Student of the Federal University of Paraná - invite you, student of the Federal Institute of Paraná (IFPR) to participate in a study, entitled "Knowledge in oral health by adolescents". The importance of this study lies in the fact that adolescence is an important period of life for health education, since the learning acquired during this phase strongly influences future customs and behaviors. Therefore, the development of an adequate health care at this stage becomes, in the long term, a self-care mentality.

The objective of this research is to evaluate the acquisition and retention of knowledge about oral health among students between the ages of 14 and 18 years, enrolled in the IFPR, in the city of Curitiba - PR.

If you participate in the survey, you will need to answer one questionnaire, in three different phases, containing oral health questions. You will also participate in a clinical evaluation to check the oral hygiene index, gingival alterations and index decayed, missing and filled teeth and get an application free of charge for smartphone that will contain tips and instructions on oral hygiene and gum disease. This application, during the research, will be used only by participants drawn to compose one of the samples, at the end of the survey all participants will have access and can use it.

The research will be conducted at the IFPR at a predetermined time during the class period. The research will be conducted in three stages, on three different days, and the duration of each intervention will be approximately 15 minutes. The total search time will be 1 (one) month.

You may experience some discomforts, mainly related to intra-oral examinations and fatigue when responding to questionnaires. If you experience any of these discomforts the search may be interrupted.

If you have any changes in the mouth that indicate treatment, you will be notified and you can look for the free dental care service of the Federal University of Paraná.

The expected benefits of this research are the acquisition of knowledge about gum disease, proper brushing and flossing, and the free availability of a smartphone application containing tips and instructions on oral hygiene and gum disease, as well as contributing for the advancement of science.

The researchers, Luciana Reichert Assunção Zanon and Gisele Marchetti, responsible for this study, can be found at the Botanical Campus of the Federal University of Paraná (Av. Prefeito Lothário Meissner, 632 - Jardim Botânico, Curitiba - PR, CEP 80210-170) or at e-mail: lurassuncao@yahoo.com.br and / or gimarchetti155@yahoo.com.br. Also, in order to clarify any doubts that you may have and to provide you with the information you want, before, during or after the end of the study, it will be possible to contact you by phone at (41) 3360-4025, between 8:00 and 17:00:00 hours from Monday to Friday.

Your participation in this study is voluntary and you may stop attending at any time, and may request that you return this signed and signed Consent Form.

The information related to the study will be known by authorized persons - the researcher and counselor. However, if any information is disclosed in a report or publication, this will be done in codified form, so that your identity is preserved and kept confidential.

The expenses necessary for carrying out the research, such as transportation of researchers, materials used for clinical analysis, printing of questionnaires and creation of software for the smartphone application are the responsibility of the researchers, and there will be no remuneration for the respondents or those responsible participation.

If you have any questions about your rights as a participant of this research, you may also contact the Ethics Committee on Research in Human Beings (CEP / SD) of the Sector of Health Sciences of the Federal University of Paraná by telephone (41) 3360-7259.

I, _____ I read this Consent Form and understood the nature and purpose of the study that I agreed to participate in. The explanation I received mentions the risks and benefits. I understand that I am free to discontinue my participation at any time without warranting my decision and without any prejudice to me and without this decision affecting my possible referral for treatment.

I voluntarily agree to participate in this study.

Curitiba - PR, date

_____

Signature of the Participant

_____

Signature of the Researcher Responsible or collaborator who applied the TCLE

Committee on Ethics in Research with Humans of the Sector of Health Sciences of UFPR | CEP / SD Rua Padre Camargo, 285 | ground floor | South Africa | Curitiba / PR | CEP 80060-240 | cometica.saude@ufpr.br - telephone (041) 3360-7259