Auditory Versus Visual vs Kinesthetic Learning Hygiene Education in Adolescents with Orthodontic Braces: A Randomized Controlled Trial. Trial Acronyme: MAHO.

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Study protocol

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Abstract

1.1 Background

Fixed orthodontics appliances hamper oral hygiene procedures. The consequences are gingivitis and white spot lesions. 50 to 70% of patients treated with braces encounter these problems. Their care in the USA represents an annual cost of five hundred million dollars. Initial education and motivation for oral hygiene depend on two categories of factors. First, practical prophylactic measures (instruments and medication, professional care). Secondly, the educational component: choice of communication technique, frequency and nature of hygiene instructions. This trial aims to study this last component. Its main objective is to compare three method's effectiveness of oral hygiene education in adolescent patients treated with braces in terms of biofilm (plaque) control. The secondary objectives are the evaluation of these methods' effectiveness regarding gingival inflammation and the maintenance of hygiene during the first six months of treatment.

1.2 Methods

This study is a prospective randomized controlled trial of superiority. It evaluates the effectiveness of three hygiene education techniques. A total of 90 patients from the University Hospital Center of Rennes will be randomized into 3 parallel groups with a 1:1:1 ratio. Each will benefit from a different educational method: oral and / or practical. The main outcome will be the average plaque index for each group after 6 months of treatment. Additional outcomes will be the average gingival index for each group and the plaque and gingival indeces over 6 months.

1.3 Discussion

The effectiveness of preventive procedures for optimizing oral hygiene during orthodontics is based on ambiguous literature. As a result, it is difficult to draw conclusions and to translate them into everyday practice. 68% of the orthodontists support the development of guidelines for education. The aim of this study is to standardize methods of oral hygiene education during orthodontic fixed treatment. The purpose of this study would be to provide practitioners with a concrete education program through guidelines dedicated to the method having the best results.

1.4 Trial registration

This trial is registered with the ClinicalTrial.gov under number NCT04444154, registration date 06/22/2020. It is also regristered in SI CNRIPH with ID 8011N° 20.04.27.58337.

Introduction

2.1 Background and rationale {6a}

The medical relevance of orthodontic treatment no longer needs to be demonstrated today. The aim of orthodontic treatment is to restore oro-facial health, i.e. a "state of physical, mental and social well-being" as defined by the WHO [1]. The Oral Health-related Quality of Life Index (OHrQoL) is a multidimensional concept that includes a subjective assessment of oral health, functional well-being, emotional well-being, expectations and satisfaction with care, and sense of self [2]. Several scores are used to establish the OHrQoL index. The lower is the score, better is the quality of life. This index is negatively impacted by malocclusions in both adolescents and adults, making sense to begin orthodontic treatment [3].

As with any medical treatment, the balance between the expected benefits and the involved risks must remain positive. With bonded braces, major iatrogenic effects are gingivitis and enamel demineralization [4,5]. These adverse consequences affect 50 to 70% of patients treated with braces [6]. Gingivitis, a reversible inflammatory disease of the superficial periodontium (gums) and enamel demineralization are both linked to the accumulation of bacterial biofilm induced by orthodontic braces [7,8]. Indeed, these last lead to a change in the quantity and quality of the bacterial flora [9,10]. From a quantitative point of view, the colonization of hard surfaces, such as braces, proves to be faster [11]. In addition, orthodontic appliances create a highly retentive surface. From a qualitative point of view, the appliance bonding results in an increase in Gram + and Gram - aggressive bacteria such as *S. Mutans*, *Lactobacillus* spp., *P. gingivalis*, *T. forsythia*, and *T. denticola* [12]. These are closely associated with the development of carious lesions and periodontal disease [13].

Regardless of gender and age, a significant relation has already been demonstrated between bad oral hygiene measures and carious lesions formation [14]. Moreover, without early treatment, 15% of patients with a dental appliance will suffer of irreversible lesions of both iatrogenic effects. In the USA, these treatments cost the health system five hundred million dollars a year [15]. In this macro-economic context, a real benefit should be expected from multi-professional consultation. Regarding the literature, many preventive strategies have been developed to optimize oral hygiene during treatment. Unfortunately, study protocols are at high risk of bias: problems with randomization, maintenance of blindness and short-term follow-up [16,17]. It is therefore difficult to draw evidence-based conclusions and to translate them into everyday practice. Even today, no guideline is available for the orthodontists to standardise oral hygiene education during braces treatment. This problem appears to be international. A recent survey reports that 68% of the Dutch orthodontists are in favor of developing such recommendations [18].

Initial hygiene education and motivation as well as the maintenance of a minimal plaque index throughout orthodontic treatment depend on two factors. First, practical prophylactic measures: instruments and medication, professional care. Secondly, the educational component: choice of communication technique, frequency and nature of hygiene instructions.

2.2 Objectives {7}

This trial aims to study the educational component. The main objective is to compare three methods' effectiveness of oral hygiene education in adolescent patients treated with braces in terms of biofilm control. The secondary objectives are the evaluation of the effectiveness of these methods regarding

gingival inflammation and the maintenance of hygiene during the first six months of treatment. The trial will evaluate the hypothesis that the plaque index after six months of treatment will be the lowest in the visual + kinesthetic learning method group. The goal of this study would be to provide practitioners with guidelines dedicated to the method having obtained the best results.

3.3 Trial design {8}

This study is a six-month, monocentric, randomized controlled trial (Fig. 1). Patients from the University Hospital Center of Rennes will be randomized into three groups running in parallel and an allocation ratio of 1:1:1. Each will benefit from a different educational method: oral and/or practical. This study adheres to the Consolidated Standards of Reporting Trials (CONSORT) 2010 Statement.

Methods: Participants, Interventions And Outcomes

3.1 Study setting {9}

As it is a monocentric trial, all patients will come from the University Hospital Center of Rennes. The orthodontic department of this Hospital Center is composed of two full-time hospital practitioners and 10 residents. The patients will be treated by all ten residents under the supervision of the professors or by one of these professors. All residents will participate in the study and each of them will be provided with a binder describing the study protocol and showing the key steps to include patients.

3.2 Eligibility criteria {10}

To be included in the study, patients must meet the following criteria:

- Aged from 11 to 17;
- Stable adolescent or young adult or adult dentition;
- Requiring fixed orthodontic treatment without extraction (except wisdom teeth) at least at the maxillary arch;
- Affiliated himself or through his parents with a social security scheme;
- Having received (as well as his parents) information about the protocol and having given free, informed and written consent.

Exclusion criteria are as follows:

- Periodontal disease or progressive carious lesions;
- Smokers;
- Prosthetic crown or restoration on a maxillary incisor;
- Systemic disease, syndrome or cleft palate;
- Dental structural abnormality (e.g. fluorosis, MIH, amelogenesis imperfecta...);

- Long term medications influencing periodontal health (corticosteroids, anti-epileptics...);
- Physical or mental disabilities avoiding autonomous teeth brushing;
- Refusal to use products and instruments prescribed as part of the study;
- Dental agenesis;
- Low skills on mastering the French language.

3.3 Who will take informed consent? {26a}

Patients and parents will receive an information letter describing the objectives, the process of the study and the benefits and risks involved. They will be required to sign an informed consent prior to begin the trial. This consent will be collected by the principal investigator (DB).

3.4 Additional consent provisions for collection and use of participants data and biological specimens {26b}

Not applicable

4 Interventions

4.1 Explanation for the choice of comparators {6b}

In this study, several learning styles will be compared. The methods are those described by Barbe. These are commonly used in pedagogy and teaching and identified by the acronym VAK: visual, auditory and kinesthetic [19].

4.2 Intervention description {11a}

4.2.1 Pre-inclusion appointment

Patients meeting the selection criteria will be offered the opportunity to participate in the study during the visit prior to the orthodontic appliance placement. The children and their parents will receive oral information about the study and a written information letter.

The free informed and written consent of the child and of both parents will be collected by the investigator before final inclusion in the study. Each patient will be followed for 6 months.

4.2.2 Inclusion appointment (D0)

During this visit, the inclusion criteria are checked again. The patient is also randomized to one of the following groups according to the hygiene education technique he will receive. Group 1 (control): the recommendations are given orally, in a chair, by a resident. They are issued during the bonding appointment and at each follow-up appointment. Group 2: the same recommendations as for group 1 are given, completed by a demonstration of dental brushing method at the sink with active participation of the child (more particularly: use of plate developer and then the Oral B electric toothbrush with special orthodontic head; this is done during the bonding appointment and at each inspection appointment). Group 3: the same recommendations as for group 1 are given, but associated with an additional appointment, between the device bonding and the first check-up: i.e. within 15 days of bonding. This is a 15-minutes session dedicated to teaching oral hygiene. This will include the viewing of an educational video followed by a quiz. Then an application to the sink is carried out as in group 2.

At the inclusion appointment, the Loë and Silness Plaque Index (LSPI) and the Loë and Silness Gingival Inflammation Index (GI) will be assessed just prior to placement of the orthodontic appliance by a blind investigator. Both will be performed clinically using a periodontal probe on all 4 sides (buccal, lingual, mesial and distal) of each maxilar tooth.

At the end of this appointment, each patient will leave with a hygiene kit including an electric toothbrush with two orthodontic heads, Oral B toothpaste, orthodontic wax and the prescription for pain relief associated with the placement of the appliance.

4.2.3 Follow-up appointment (day 0, D45, D90, D135, D180)

Patients in groups 1 and 2 will have 5 appointments (D0, D45, D90, D135, D180). Patients in group 3 will have 6 appointments (D0, between D15, D45, D90, D135, D180).

There will be a check-up appointment (routine practice visits dedicated to arch wire changes and the implementation of different mechanics depending on the dysmorphias) every month and a half for 6 months.

During these 4 following check-ups, standardized photographs will be taken after removal of the orthodontic archwires for a later evaluation of the modified orthodontic plaque index (MOP) and the GI will be recorded by an external blinded ratter. After this examination, the oral hygiene advice will be repeated by the resident according to the patient's randomization group.

4.3 Criteria for discontinuing or modifying allocated interventions {11b}

If biofilm control is very insufficient (generalized visible deposit associated with visible gingival inflammation) the resident will check brushing with the patient using a visual control to limit loss of chance.

4.4 Strategies to improve adherence to interventions {11c}

Patients will only have an oral reminder of the benefit of brushing during follow-up so as not to create a bias.

4.5 Relevant concomitant care permitted or prohibited during the trial {11d}

This research does not require an exclusion period during which the subject cannot participate in another clinical research protocol after the end of the study or after his premature termination.

4.6 Provisions for post-trial care {30}

Not applicable

4.7 Outcomes {12}

4.7.1 Primary Outcome

Our main objective is to compare three method's effectiveness of oral hygiene education in adolescent patients treated with braces in terms of biofilm control. For that, the average plaque index for the maxillary arch after 6 months of treatment will be measured. The index used is the MOP (Modified Orthodontic Plaque Index) [20]. This index will be evaluated on photographs by one of two independent and blind examiner of the patient's randomization arm. The two examiners (DB and ALF) will have previously calibrated on 10 patients. The calibration will be considered sufficient when the inter-rater reproducibility evaluated by Cohen's Kappa is greater than 0.85.

4.7.2 Secondary Outcome

The secondary objectives are the effectiveness comparison of the methods for the control of gingival inflammation and the effectiveness comparison of these three methods over time. Two secondary outcomes were chosen. For the evaluation of the control of the inflammation, the average gingival index of Loë and Silness (GI) will be measured 6 months after the installation of the device. For the evaluation of the maintenance of the hygiene control during the treatment, the MOP and the GI scores recorded at each of the control appointments for each group will be compared.

4.8 Participant timeline {13}

A time schedule of enrolment, interventions, assessments, and visits for participants is proposed in the form of a diagram (Fig. 2).

4.9 Sample size {14}

The sample size calculation is based on the primary outcome: comparison of the mean MOP between the 3 experimental groups after 6 months of treatment. For a risk alpha = 5%, a power of 80%, an effect size of 0.35, with an ANOVA type analysis and 3 groups, a total of 81 subjects is necessary (27 per group). To consider possible dropouts, we plan to recruit 30 patients per group, *i.e.* 90 patients in total.

4.10 Recruitment {15}

To achieving adequate participants enrollment to reach target sample size it is expected that all residents and practitioners of the department will participate. A total around 30 bondings is made weekly in the department. It would allow to obtain the complete sample in 3-4 weeks of inclusion.

5 Assignment of interventions: allocation

5.1 Sequence generation {16a}

Randomisation will be carried out beforehand by a computerized system using R program and organised by an independent person. The library used is "blockrand" with the blockrand function. The script is: blockrand (n = 90, num.levels = 1, block.sizes = 1, levels = c ("Gr1", "Gr2", "Gr3")).

5.2 Concealment mechanism {16b}

The sequence is generated beforehand. When enrolling a patient, the resident or practitioner will randomly draw a sealed, opaque envelope containing the patient assignment group.

5.3 Implementation {16c}

The creation of the sequence is carried out by a person external to the study. Enrollment is done by residents and practitioners. The assignment to a group is also carried out by the practitioners or resident who treat the patient.

6 Assignment of interventions: Blinding

6.1 Who will be blinded {17a}

Participants cannot be blinded in this study given the nature of the interventions. Children and their parents will know they are taking part in a trial. The practionners and the resident who treat patient are not blind. The photos taken for the evaluation of the primary outcome will be taken by the resident ensuring the treatment of the patient. The evaluators will be blind because the evaluation of the main outcome is done on these photographs at a distance from the patient by a foreign examiner of the project.

The evaluation of the secondary outcomes is done in the chair by an evaluator external to the project. To avoid bias, the patient is informed not to communicate about his randomization arm and a resident or pratcionner will always be present with him to avoid leaks. Moreover, a photographic retractor will be placed in the mouth to limit the dialogue with the patient.

6.2 Procedure for unblinding if needed {17b}

The lifting of the blind will then be able to be carried out by the resident or the practitioner who treats the patient.

7 Data collection and management

7.1 Plans for assessment and collection of outcomes {18a}

LSPI will only be used once per patient during the bonding appointment. It will be read with a periodontal probe on the 4 sides of each tooth from 16 to 26 (12 teeth so 48 measurements in total per patient). Then, to evaluate the plaque control, the MOP will be used at each appointment. Its evaluation is done on 3 intra-oral photographs in occlusion after removal of the orthodontic archwires. They will be calibrated using a spreader with green marks to have the same magnification. The camera used is a Nikon D7000 model with an AF-S Micro Nikkor 60mm lens. The settings used will be manual mode, F32 aperture, shutter speed 200, 1: 3 magnification. The photographs will be taken by the resident, but the posterior evaluation will be carried out by one of the two examiners, blind to the allocation of the patient to one of the three groups.

The GI will be evaluated at each appointment and for each patient using a periodontal probe on the four faces of the teeth from 16 to 26 (48 measurements per patient). All clinical measurements will be performed by one of the study’s two ratters.

7.2 Plans to promote participant retention and complete follow-up {18b}

Subjects may withdraw their consent and request to exit the study at any time and for any reason. Data prior to this withdrawal of consent will be collected unless the participant objects in writing. The investigator may temporarily or permanently interrupt the participation of a subject in the study for any reason that would best serve the subject's interests. In the event of premature exit, the investigator must document the reasons as completely as possible. Leaving a participant's study should not change their usual care in relation to their illness. In the event of a subject lost to follow-up, the investigator will make every effort to resume contact with the person.

7.3 Data management {19} and Confidentiality {27}

All clinical data will be collected in anonym / individual case report form (CRF). The data will then be compiled in an Excel spreadsheet meeting the requirements of the FDPA (French Data Protection Authority).

The Excel file including the anonymized data and that of the correspondence table will be protected by a password and saved on the secure server of the Rennes hospital. They will not be transmitted outside the establishment. The files will be accessible only to the investigators and examiners. Photo shoots will be kept in the patient's CRF.

7.4 Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable

8 Statistical methods

8.1 Statistical methods for primary and secondary outcomes {20a}

The statistical analysis will have a descriptive and an inferential part. The descriptive statistical analysis of the quantitative variables will be done by giving for each variable the positional parameters (mean, median, minimum, maximum, first and third quartiles) as well as the dispersion parameters (variance, standard deviation, range, interquartile range). The Gaussian character of the data will be tested by the

Shapiro-Wilk test and by QQ-plot diagrams. The qualitative variables will be described by giving the contingency and proportions of each modality in the sample.

For the first outcomes (comparisons of final MOP between the 3 groups) and for inflammation outcome (gingival index) analyses will be made either by an analysis of variance (Gaussian case) or by its non-parametric equivalent, namely the Kruskall-Wallis test (non-Gaussian data). For the evolution of the MOP and of the LSPI in the 3 groups will be graphically represented (on average and per individual) and analysed by mixed models (random patient effect) allowing in particular to study the effect of the interventions over time (introduction of the time*group interaction term).

8.2 Interim analyses {21b}

Not applicable

8.3 Methods for additional analyses (e.g. subgroup analyses) {20b}

For all these analyses, when the data are not Gaussian, the possibility of transforming the variable (via the Box-Cox method or by a "classical" transformation of the square root or logarithmic type) will be studied before using a non-parametric test.

8.4 Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The analysis will be carried out with the intention to treat (whatever the subjects benefited from the intervention in their group). Analyses will be performed with the R software in its most up-to-date version at the time of analysis and with all the packages required to perform the analyses.

8.5 Plans to give access to the full protocol, participant level-data and statistical code {31c}

Upon simple request by email, we will communicate the data collected as well as our analysis method.

9 Oversight and monitoring

9.1 Composition of the coordinating center and trial steering committee {5d}

The Rennes University Hospital is the promoter of this clinical trial. It transmits to the National Agency for the Safety of Medicines and Health Products the favorable opinion of the Personal Protection Committee and the summary of the study. Trial steering committee is composed by the investigator (DB) and the representative of the Research and Innovation Department.

9.2 Composition of the data monitoring committee, its role and reporting structure {21a}

The data will be processed by the two investigators (DB and ALF) of the study and the signed consents will be retrieved and processed by the representative of the Research and Innovation Department of the Rennes University Hospital.

9.3 Adverse event reporting and harms {22}

Adverse events, undesirable effects and incidents will be declared to the various health vigilance circuits applicable to each product or practice concerned (care vigilance, pharmacovigilance, materiovigilance, hemovigilance, cosmetovigilance, etc.) in accordance with the regulation's laws. It will be specified that the patient is included in a clinical trial and to identify precisely the clinical trial concerned.

9.4 Frequency and plans for auditing trial conduct {23}

The investigators (DB and ALF) and associated persons agree to accept any quality assurance audits carried out by the sponsor of the study as well as the inspections carried out by the competent authority. All data, documents and reports can be subject to regulatory audits and inspections without medical confidentiality being enforceable.

9.5 Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

Any substantial modification to the study protocol would be notified to the Personal Protection Committee in order to verify that the proposed modifications do not affect the guarantees given to people who lend themselves to research. A substantial change to the protocol by the investigators must be approved by the promoter. The latter must obtain, prior to the implementation of this modification, a favorable opinion from the Personal Protection Committee. If necessary, a new consent from the people participating in the research will be collected.

9.6 Dissemination plans {31a}

As a reminder, the objective of this study is to compare three teaching methods for oral hygiene education. This is part of a particularly vague context on communication with young patients. The aim of this project is to provide clinicians with recommendations for good practice in terms of motivation methodology and hygiene education. The ideal is to minimize white spots and gum damages.

Abbreviations

MOP
Modified orthodontic plaque index
GI
Loë and Silness gingival inflammation index
LSPI
Loë and Silness plaque index

Declarations

13.1 Acknowledgements

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13.2 Authors' contributions {31b}

ALF: methodology, conceptualization, investigation, writing draft, project administration.

SJ: writing editing, conceptualization.

OS: writing editing.

DB: conceptualization, data curation, investigation, formal analysis, funding acquisition, supervision, writing draft.

13.3 Funding {4}

This clinical trial is funded by the budget of the research and innovation department of the Rennes hospital. This ensures the recruitment and monitoring of patients, the collection and analysis of data as well as compulsory insurance. Only the material for the oral hygiene of the patients is provided free of

charge by the company Procter and Gamble. The design, management, analysis and reporting of the study are entirely independent of the Procter and Gamble company.

13.4 Availability of data and materials {29}

All investigators will have access to the cleaned data sets. The project datasets will be hosted on the hospital's secure network and all datasets will be password protected. To ensure confidentiality, the data disseminated to the members of the project team will be deprived of any information identifying the participants.

13.5 Ethics approval and consent to participate {24}

According to The Declaration of Helsinki, free informed and written consent from the patient’s parents will be collected by the investigators, before final inclusion in the study. A copy of the information letter and the consent form signed by the parents will be given to them, the investigator will keep the original. The parents of the minor patient will be fully and fairly informed, in understandable terms, of the objectives and constraints of the study, of the possible risks incurred, of their rights to refuse to participate in the study or of the possibility of retract at any time. All this information can be found on the information letter and the consent form given to the parents. The minor patient will also receive information adapted to their age and understanding. From 11 to 14 years old: oral and written information understandable by the child. The information provided will be included in a written document which will also be given to him. From 15 to 17 years old: complete and understandable oral and written information. The information provided will be included in a written document which will also be given to him. The consent of a minor aged 15 to 17 is required on the parents' information and consent form.

13.6 Consent for publication {32}

Not applicable.

13.7 Competing interests {28}

None of the authors have any paid consultancies with companies related to this research.

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Figures

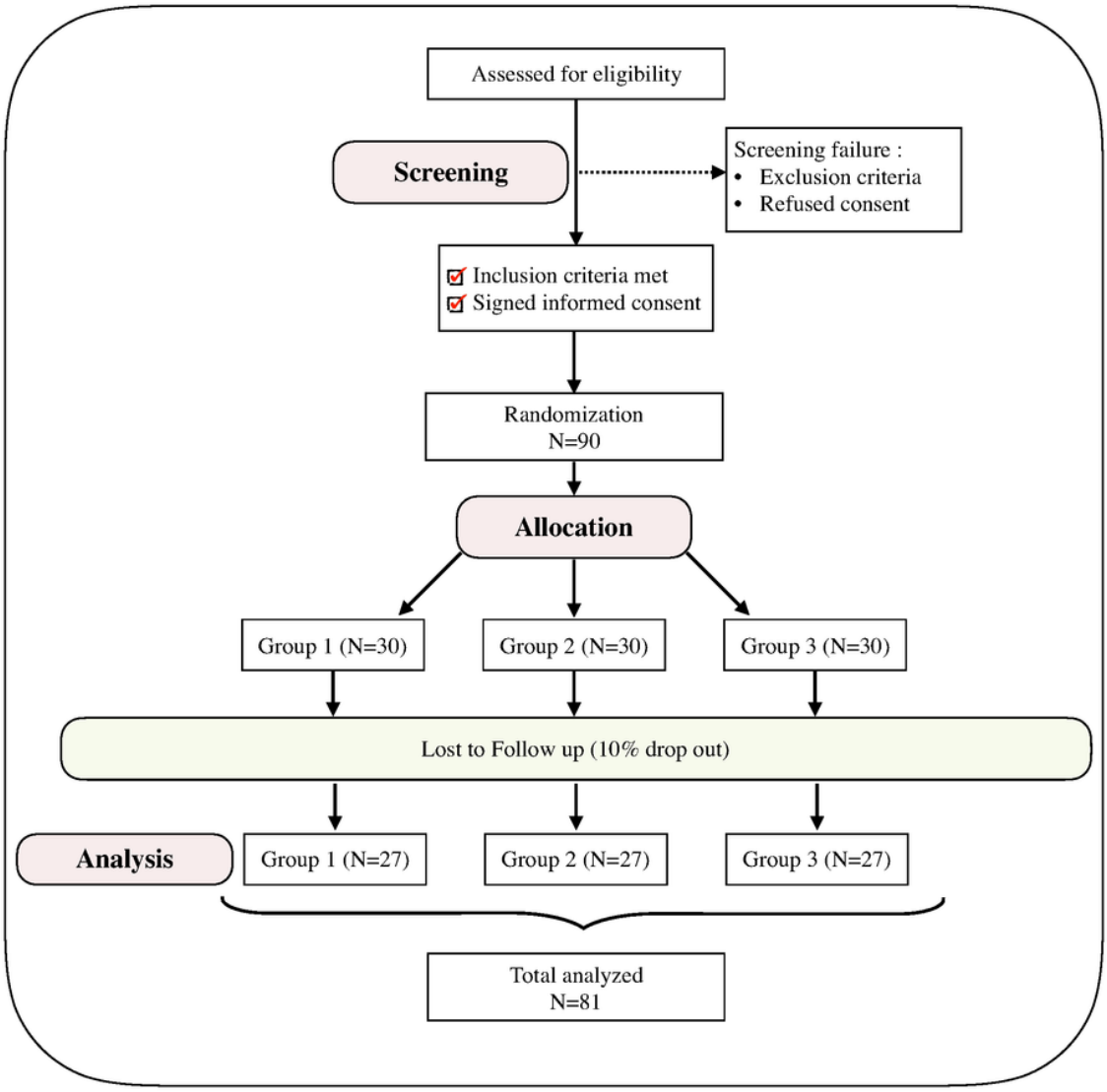

Figure 1

Trial protocol flow chart.

	STUDY PERIOD						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT (days)	*-20*	0	*15*	*45*	*90*	*135*	*180*
ENROLMENT:							
Eligibility screen	X	X					
Informed consent	X						
Medical history check	X						
Allocation		X					
INTERVENTIONS:							
Clinical examination	X	X		X	X	X	X
Bonding of braces		X					
Delivery of the hygiene kit		X					
Auditory learning		X		X	X	X	X
Kinesthetic learning			Gr 2 + Gr 3	Gr 2	Gr 2	Gr 2	Gr 2
Visual learning			Gr3				
ASSESSMENTS:							
LSPI		X					
MOP				X	X	X	X
GI		X		X	X	X	X

Figure 2

Time schedule of enrolment, interventions, and assessments.