SPECIFIC COMMISSION OF THE DOCTORAND - RESEARCH PLAN
4. RESEARCH PROTOCOL

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Main Researcher: -
Secondary Researcher: -
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Departament: Periodontics
Research Line: Diagnóstico, prevención y tratamiento de las enfermedades periodontales y periimplantarias.
Research Title: Pain Perception during Supportive Periodontal Therapy – impact in compliance

Peri-Implant Diseases

In the last decades, replacement of teeth with dental implants became a very frequent procedure, and it is associated with high rates of implant survival (Albrektsson and Donos, 2012). However, the incidence of technical and biological complications seems to be frequent (Scwartz et al., 2018). Since the number of subjects receiving dental implants is growing continuously (Schimmel et al., 2017), preventing and effectively resolving peri-implant diseases on the long-term without compromising esthetic results have become one of the major endeavors of this field.

In 2017, the World Workshop jointly held by the European Federation of Periodontology and the American Academy of Periodontology on the classification of Periodontal and Peri-Implant Diseases, defined peri-implant disease as a pathological condition occurring in tissues around dental implants, characterized by inflammation in the peri-implant connective tissue (ie, peri-implant mucositis - PM), and progressive loss of supporting bone (ie, peri-implantitis - PI) (Schwarz et al., 2018). The onset of peri-implant diseases is characterized by the presence of etiological factors similar to those involved in the etiology of periodontal diseases and it might occur within the first three years of function in a non-linear and accelerating pattern (Derks et al., 2016).

A recent systematic review and meta-analysis, performed by Jan Derks and colleagues in 2015, found a prevalence of 43% for PM and 22% of PI. Later on, in Spain, Rodrigo et al. (2018) observed similar PI prevalence's with 24% of the subjects presenting bleeding on probing and radiographic bone loss ≥ 2mm after at least 5 years of function.

The predictability of treatment of PI remains controversial, with evidence of results from several controlled clinical studies pointing out that nonsurgical treatment appears to be unpredictable with potential beneficial clinical outcomes limited to a period of 6–12 months (Renvert et al., 2008). However, in the last years, two 12-month follow-up case studies demonstrated a novel protocol to address PI, with improved outcomes (Stein et al., 2018; Nart et al., 2019). Notwithstanding the above, at the moment, surgical treatment is still the standard of care, with a resective or regenerative approach depending on the morphology and anatomy of

the bone defects resulting from the disease (Claffey et al. 2008). In spite of that, the predictability and long-term stability of these procedures are still a matter of controversy (Teughels et al., 2006; Renvert et al., 2012; Chan et al., 2014; Serino et al., 2015). Therefore, efforts from the research community should be more directed towards prevention.

Compliance to supportive periodontal therapy and prevention of peri-implantitis

In the 3rd World Workshop, all the efforts taken after completion of the dental implant therapy were defined as supportive periodontal therapy (SPT), as opposed to periodontal maintenance, to highlight the importance of this phase of treatment. Moreover, in the same workshop, factors such as patients with history of chronic periodontitis, poor bacterial plaque control skills, and absence of regular maintenance care after implant therapy were recognized as being more likely to develop peri-implant diseases (Schwarz et al., 2018). This stress the idea that SPT is mandatory to prevent future breakdown of the disease.

The rational for doing SPT is due to three main facts: i) bacterial plaque and its byproducts represent the primary etiological factor for further breakdown (Lang et al., 2008); ii) after being exposed to inflammation, tissues are more susceptible due to changes in gene expression that are not encoded by DNA itself (Martins et al., 2016); iii) recolonization with putative bacteria such as spirochetes and motile rods occurs as soon as 4 to 8 weeks after active periodontal treatment (Mousques et al., 1980; Magnusson et al., 1984), highlighting the importance of frequent disruption of the biofilm.

In this context, SPT can determine the failure to meet oral hygiene standards (Morrison et al., 1979). Several studies conducted in the 1980's have clearly demonstrated that long-term therapeutic outcomes can be achieved if patients practice good oral hygiene and enroll in a regular supportive periodontal treatment after active periodontal therapy (Becker et al., 1984a; Becker et al., 1984b; Axelsson et al., 2004). Moreover, other studies concluded that without effective oral hygiene skills and a regular SPT program, the beneficial effects of various periodontal therapies would be compromised (Nyman et al., 1977; Axelsson et al., 1981).

Nevertheless, even though SPT is considered to be crucial to maintain peri-implant health, classic studies have shown that patient's adherence to SPT is not satisfactory (Wilson et al., 1984). Several studies have been carried out in different settings involving a considerable variety of cohorts of patients coming from both university and private practices in order to assess the factors that are associated with the lack of compliance with SPT (Ramseier et al., 2014, Perrell-Jones and Ireland, 2016). Identifying patients who are more likely to present a non-compliant pattern would help clinicians to focus their attention on these particular subjects, who mostly require a motivational strategy tailored to each individual risk profile (Amerio et al., 2019). The same publication pointed out that smoking habit and history of periodontal disease were found to be associated with patients´ compliance. Inadequate information/motivation was found as the main patient-reported reason for non-compliance.

Addressing the main reason for patients' non-compliance is a research priority; however, studies in the literature are scarce. It's crucial that clinicians understand the importance of supportive periodontal treatment to prevent the development and progression of peri-implant diseases (Schwarz et al., 2018). Therefore,

missing or inadequate information given to patients after finishing the active periodontal treatment or the dental implant therapy is condemned to end. Patient motivation, nevertheless, is something external and depends mainly on patients' phycological factors and personality traits (Komarraju et al., 2009). The main reason is going to be addressed in the first part of this research project. The second most frequent reason for patients to fail SPT on these questionnaires was **bad experiences and dissatisfaction**. It has been demonstrated that peri-implant probing, even in healthy tissues, caused significantly more pain/discomfort than periodontal probing (Ringeling et al., 2016; Stanner et al., 2017; Parvini et al., 2017). Such finding might be due to: 1) differences between periodontal and peri-implant tissues or, 2) on average, higher levels of inflammation are observed around dental implants than around teeth (Meyer et al., 2017).

Considering these premises, one might suspect that a SPT visit to the dental office can be associated with a bad experience (Si et al., 2016), especially when these patients have one or more implants. Several debridement methods have been associated with better experiences around teeth. Less treatment discomfort was reported when comparing laser therapy with conventional therapy (Tomasi et al., 2006; Ratka-Kruger et al., 2012). Also, around teeth, air-polishing devices (APD) has been described as being significantly more comfortable and less painful than conventional instrumentation (Petersilka et al., 2003a; Petersilka et al., 2003; Möene et al., 2010; Wennström et al., 2011; Muller et al., 2014). An erythritol based air-polishing powder (Electro Medical Systems, Nyon, CH) have been recently introduced as a low abrasive powder (Hagi et al., 2013). Erythritol is a polyol used in food industry as an artificial sweetener. Its physical properties were shown to be comparable to glycine (Hagi et al., 2015). Moreover, when used during SPT, similar results in terms of clinical and microbiological outcome were demonstrated in comparison with hand instrumentation (Hagi et al., 2015). The efficacy of APD as monotherapy around dental implants, in the treatment of peri-implant diseases, have been addressed in a recent systematic review (Schwarz et al., 2015) – comparable results were found between conventional devices and APD in terms of mucositis treatment and better outcomes regarding peri-implantitis. However, only one of the studies included in the review observed that "no complains or discomfort" were reported by any of the patients investigated (Ji et al., 2014) – even though, no visual analog scale or other measurement scale was used for this purpose.

To our knowledge, only one study compared pain/discomfort during SPT around dental implants (Menini et al., 2019). This study included only full-mouth implant-supported restoration and compared three debridement approaches: 1) glycine air polishing; 2) sodium bicarbonate air polishing and, 3) manual scaling with carbon-fiber curettes. Since they didn't use a control group with ultrasonic devices, and no teeth were included in the study, it reduces its external validity. Nevertheless, they observed statistically significant better VAS scores for glycine group when compared with sodium bicarbonate air polishing. Leading to a possible effect of the size of the powder particles in the pain perception, which could be improved with the erythritol due to its even smaller particle size (Hagi et al., 2013).

2. Background and current status of the topic:

Implants have become a popular and widely used treatment option for treating partial and total edentulism. As the number of implants placed increases, so does the incidence of peri-implant mucositis and peri-

implantitis. Placing patients under SPT/maintenance care has been shown to prevent and treat such conditions. Despite SPT's importance in prevention and infection control, adherence to scheduled SPT visits have been unsatisfactory. Understanding the reasons for non-compliance can help both the clinician and research community to address them by improving communication and/or patients experience to those visits thereby increasing compliance.

3. Objectives:

a) General objective

Evaluate the patient reported outcomes to a different implant instrumentation method during SPT visits, as well as its impact in compliance rates.

b) Specific objective

1. To evaluate pain/discomfort during SPT around dental implants and teeth.
2. To evaluate patient reported outcomes and clinical variables by decontamination during SPT with erythritol based air polishing powder (Air Flow Master®, Air-Flow Plus®, EMS, Nyon, Switzerland), at the first SPT and after 2 years.
3. To evaluate the effect of erythritol based air polishing powder (Air Flow Master®, Air-Flow Plus®, EMS, Nyon, Switzerland) during SPT on the compliance rates after 1 and 2 years of follow-up.

4. Hypothesis:

a) General Hypothesis

The proposed protocols, focused on the prevention of peri-implantitis, will result in an increase adherence to SPT by better understanding the specific factors related to non-compliance, specifically by improving the experience of patients to SPT visits.

b) Specific Hypothesis

1. SPT with conventional ultrasonic device will result in more pain/discomfort around dental implants than in teeth.
2. SPT by means of an erythritol based air-polishing powder (Air Flow Master®, Air-Flow Plus®, EMS, Nyon, Switzerland) will result in better patient reported outcomes and same clinical outcomes, at the first SPT and after 2 years.
3. SPT by means of an erythritol based air-polishing powder (Air Flow Master®, Air-Flow Plus®, EMS, Nyon, Switzerland) will result in the increase of the compliance rates after 2 year of follow-up.

5. Materials and Methods:

Study Design

The present research project is designed as a randomized controlled double-blind clinical trial with a 2-year follow-up. The reporting of this clinical trial will follow the Consolidated Standards of Reporting (CONSORT) guidelines. It is registered in ClinicalTrials.gov (…)

Subject Selection

The study will be performed after the approval of the Ethics Committee of the Universitat Internacional de Catalunya (UIC) and will be conducted according to the principles outlined in the Declaration of Helsinki and Ethical Conduct for Research with Human Beings.

An aleatoric list of patients who have been enrolled in SPT at the Department of Periodontology of UIC and met the inclusion criteria will be generated – those patients will be called for SPT visit by the same investigator (E.R)

Criteria for subject selection will be as follows:

(1) Patients aged 18 to 80 years who are healthy;
(2) Partially edentulous patients, rehabilitated with at least one dental implant in the maxilla or mandible;
(3) No implant mobility;
(4) Treated periodontal disease;
(5) No systemic diseases that could influence the outcome of the therapy (i.e. uncontrolled diabetes, osteoporosis, bisphosphonate medication).
(6) Non-smoker or light smoking status in smokers (<10 cigarettes/day).

Pregnant, lactating women and non-collaborating patients will be excluded from the study.

Sample Size Calculation

The sample size will be calculated using changes in CAL as the primary outcome variable. Thirty patients (15 subjects in each group) were necessary to detect a difference of ≥ 1 mm in CAL assuming a mean standard deviation (SD) of 0.9. This calculation assumes an alpha error of 0.05, a beta error of 0.2, and a statistical power of 80%. In addition, 12% of loss to follow-up was considered.

Compliance Definition

Patients will be grouped as regular compliers (RC), erratic compliers (EC), or non-compliers (NC), as described by Monje and cols. (2017). Complete compliance will be based on the longest SPT recall interval possible for each group.

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Groups:

RC = 3- to 6-month recall interval (≥2 SPT/year)

EC = 7- to 12-month recall interval (<2 SPT/year)

NC = no recall interval program (no SPT/year)

Patients who participated in a recall schedule but discontinued SPT in future appointments will be categorized as EC or NC according to their complianceduring the following years

Considering the beginning of the COVID-19 Pandemic in early 2020 and the consequent lockdown between March and May of the same year, those patients unable to come to their programed SPT appointment due to the lockdown, but came right after the easing of the restrictions, will be consider as compliers – in a case-by-case evaluation from the authors of the study.

Study Visits

a) SPT visit

One calibrated investigator will consecutively call patients for SPT visits and will be responsible of enrolling the patients (T.R.A).

The study variables will be recorded in a case report form (CRF) specially designed for the study. Each study patient will be assigned a numerical code comprising a 3-digit patient code (assigned correlatively as they are included in the study). Only the study investigator will be able to identify the patient by their code.

Screening examination

The clinician will review with the patient the Information and Medication History Forms and record the anthropometric, socio-demographic and clinical information. Candidates will undergo an oral pathology examination and a full-mouth manual probing using a periodontal probe PCP-UNC 15 (HuFriedy®, Rockwell St, Chicago, IL) to determine their periodontal and peri-implant status. Presence or absence of plaque will be recorded after staining with an erythrosine disclosing dye (Plac-Control®, Dentaid SL, Cerdanyola, Spain). Finally, periapical radiographs (Dürr Dental AG, Bietigheim-Bissingen, Germany) of all implants will be taken using a paralleling cone technique and a film-holder (7mA- 60kV/20ms).

The same calibrated examiner (E.R) will record clinical variables of mPI, BOP, PPD, MR and clinical attachment level (CAL).

Oral hygiene instructions.

Individualized instructions in proper oral hygiene measures will be given to all patients (E.R) enrolled in the study. Patients will be instructed to brush their teeth and implants twice daily to remove bacterial plaque with

a low-abrasive dentifrice and to use specific cylindrical or conical brushes in the interproximal area. Patients will be indicated to brush under, around, and in the peri-implant crevice circumferentially. In those cases with no access for the interdental brush, patients will be instructed to use a floss threader or a specialized floss that has a built-in threader (Super Floss®, OralB®, Procter & Gamble, Cincinnati, OH, USA) and to wrap in a circle and move into the peri-implant crevice.

Randomization and study groups

Once oral hygiene instructions were provided, patients will be randomly assigned to the Test or Control groups. Allocation of patients will be decided following randomization tables with permuted blocks of four while the information will be concealed by using opaque envelopes, which will be labelled with the patient study number and only be revealed after oral hygiene instructions are provided.

Debridement

All the supragingival debridement will be performed by the residents of the Master's Program in Periodontology at CUO – UIC (Sant Cugat del Vallès). Subjects will receive a session of full-mouth professional prophylaxis with:

- Control group: an ultrasonic device (DTE-D5, Woodpecker®, Guilin, China) with a plastic tip (Hu-Friedy®, Rockwell St, Chicago, IL, USA) and scaling with plastic curettes (Hu-Friedy®, Rockwell St, Chicago, IL, USA) around dental implants and a conventional metal tip for teeth will be used.

- Test group: an erythritol based air-polishing powder (Air-Flow, EMS, Nyon, CH) during 5 seconds on each site (Schwarz et al., 2015).

In those cases where implant-supported restorations do not facilitate oral hygiene access, the modification of the implant prosthesis in order to facilitate oral hygiene access will be performed using the protocol described in de Tapia et al., 2019.

VAS

After finishing the supragingival debridement around teeth, another calibrated examiner (T.R.A) will give the patients graded pain intensity on a visual analogue scale (VAS) (0 = no pain and 10 = extreme, unbearable pain), and then perform supragingival debridement around the dental implants and give VAS again. Patients will be instructed to point at the VAS.

Follow-up visits

Patients enrolled in the study will be called for supportive periodontal therapy considering their SPT program and supragingival debridement will be performed accordingly to their group (control or test). All clinical variables will be re-examined by the same blinded examiner (C.V.) after the first SPT visit, at 1 year and 2

years of follow-up. Additionally, a periapical radiograph of all implants involved in the study will be taken at 1 year and 2 years of follow-up. Individual compliance will be registered as well in the CRF.

Patients will be further motivated with respect to oral hygiene habits during the entire period of the study.

2.5 Clinical and VAS examination

A guidebook will be prepared to standardize procedures throughout the protocol, step by step, for all questionnaires and evidence collection. The data will be transferred to a computerized database.

The study variables will be recorded in a case report form (CRF) specially designed for the study. Each study patient will be assigned a numerical code comprising a 3-digit patient code (assigned correlatively as they are included in the study). Only the study investigator will be able to identify the patient by their code.

Anthropometric and socio-demographic data

An initial questionnaire will be conducted to obtain information regarding age, race, gender, medical history, medication, and health behavior (smoking habits). Smoking behavior will be specified as 3 categories: never smoker, former smoker, or current smoker (light smokers: < 10 cigarettes/day). Patients will be asked about their tobacco smoke exposure in terms of consumption (i.e. the number of cigarettes consumed per day); duration (i.e. the number of years of smoking); and lifetime exposure (i.e. the accumulated exposure as formed by the product of consumption and duration: cigarette-years). In case of former smokers, patients will be asked about the smoke-free time following cessation.

Clinical Parameters

The following clinical parameters will be evaluated by the same examiner (T.R.A) using a manual periodontal probe PCP-UNC 15 (HuFriedy®, Rockwell St, Chicago, IL):

1. Full mouth plaque index (FMPI) will be assessed dichotomously at four sites per tooth (mesial, buccal, distal and lingual). Presence or absence will be recorded after staining with an erythrosine disclosing dye (Plac-Control®, Dentaid SL, Cerdanyola, Spain). Presence of plaque will be scored if an area of clearly stained material is present along the gingival margin and if this material can be removed with the side of the probe. The percentage of surfaces with plaque out of the total number of examined tooth surfaces will be calculated (O'Leary et al., 1972).
2. Full mouth bleeding index (FMBI) will be assessed dichotomously as presence or absence of bleeding after 30 seconds of gently probing. The proportion of bleeding surfaces out of the total number of examined surfaces will be calculated (Ainamo and Bay, 1975).
3. Full mouth PPD measured at six aspects around tooth.
4. Gingival Recession (GR) will be recorded at six aspects per implant: mb, b, db, ml, l and dl.
5. mPI (Mombelli et al., 1987) will be measured at six aspects around implants:

Score 0 - no detection of plaque.

Score 1 - plaque only recognized by running a probe across the smooth marginal surface of the implant.

Score 2 - plaque can be seen by the naked eye.

Score 3 - abundance of soft matter.

6. mBI (Mombelli et al., 1987) will be assessed 30 seconds after 0.15 N force probing.

   Score 0 - no bleeding.

   Score 1 - isolated bleeding spots visible.

   Score 2 - blood forms a confluent red line on margin.

   Score 3 - heavy or profuse bleeding. This variable will be dichotomized in presence/absence of bleeding and will serve as the main variable.

7. SOP evaluated after assessing dichotomously the presence of suppuration within 30 seconds after gentle probing.
8. Implant PPD, measured from the mucosal margin to the bottom of the probable pocket, determined at six aspects per implant: mb, b, db, ml, l and dl with a resin splint.
9. MR at the implant will be recorded at six aspects per implant: mb, b, db, ml, l and dl.

Outcomes of the study

Main outcome;

- Patient Pain/Discomfort (VAS) reported after decontamination during SPT.

Secondary outcome;

- *Changes in the following clinical variables: FMPI, FMBI, PPD, GR, mPI, mBI, SOP, Implants PPD and MR after decontamination during SPT.*
- Compliance to SPT reported after decontamination during SPT.

Intra-examiner reproducibility

Reproducibility of clinical examinations will be conducted by the examiner (T.R.A), evaluating the Implant PPD and mBI in 5 patients, not involved in the study, on two separate occasions, 1 week apart. The intra-class correlation coefficient and the kappa index will be calculated. Calibration will be accepted when

measurements at baseline and at one-week evaluation will be within a difference of 0.5 mm >90% of the time.

Withdrawal of consent

The Patient Information Sheet will clearly state that the patient can withdraw from the study at any time without prejudice or explanation. Such withdrawal will be documented in the medical record file. Losses to follow-up are taken into account in the sample size calculations (12%).

Statistical analysis

Descriptive analysis

Descriptive statistical methods (percentage and numbers on total) will be used to analyze the evaluated parameter

Inferential analysis

Data will be calculated at patient level and implant/tooth level. VAS score will be considered as the main outcome (quantitative).
If the distribution is normal, the following tests will be used:
- Binary categorical variables: T-Student / Fisher's exact test;
- Categorical variables with > 2 categories: ANOVA;
- Quantitative variables: Simple linear regression / Pearson correlation coefficient.

If it doesn't follow normality:
- Binary categorical variables: U of Mann-Whitney;
- Categorical variables> 2 categories: H of Kruskal-Wallis;
- Quantitative variables: Spearman's correlation coefficient.

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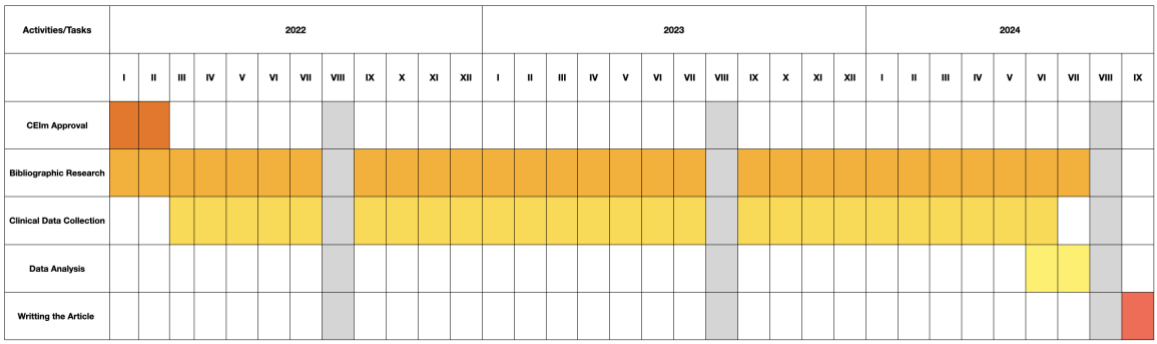
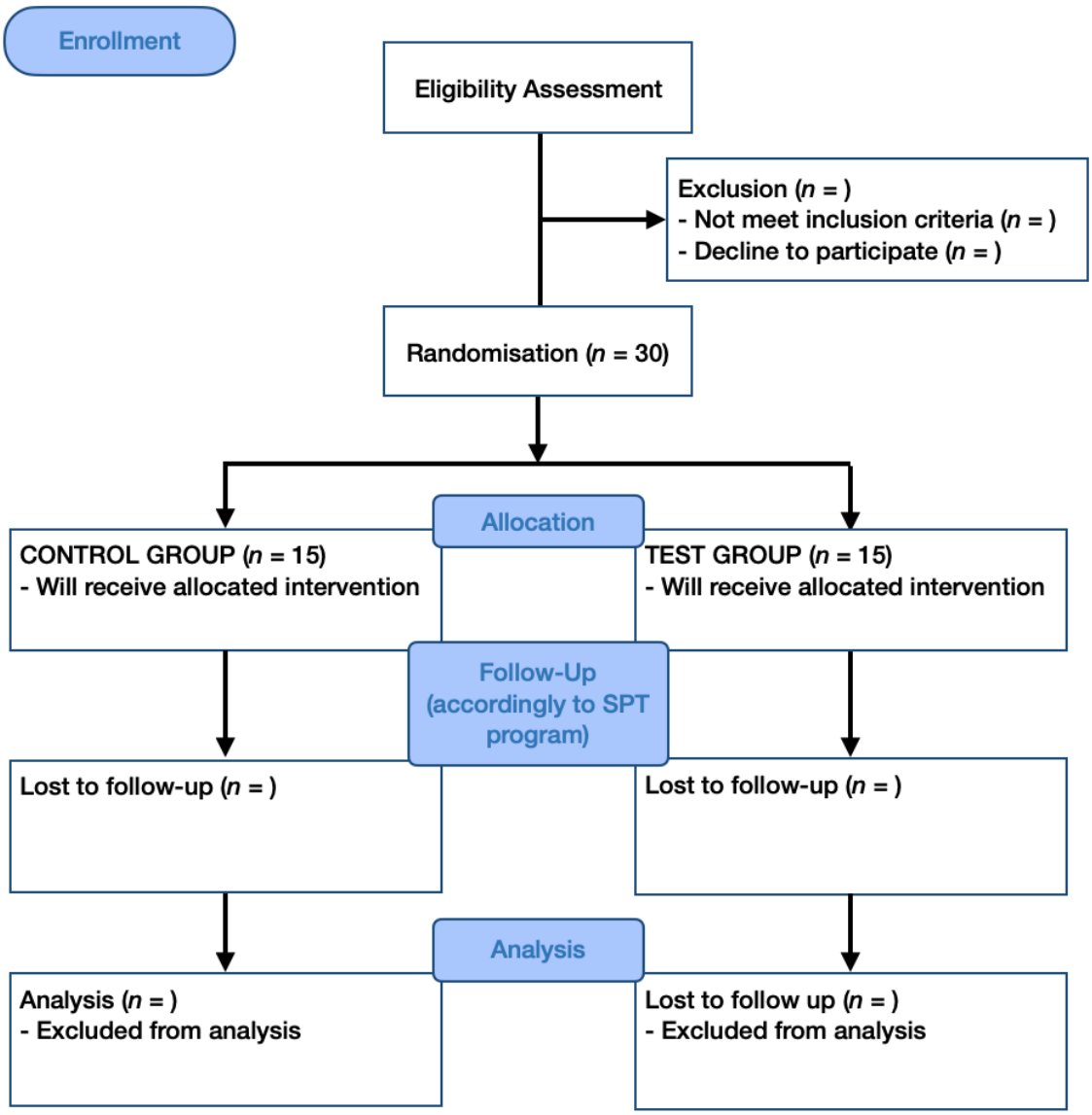
a. Cronograma del estudio (se debe considerar claramente las etapas de reclutamiento y seguimiento. Por su sencillez, se sugiere el uso de un diagrama de Gantt).



b. Diagrama de flujo que cuente con una línea de tiempo de los sujetos del estudio (acorde a los grupos estudiados)



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Investigador/a Principal

Fdo: Dr./Dra.