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Impact of an immediate dental prosthetic functionalization protocol on the general functionality of patients with deficient removable dental prostheses: a randomized clinical trial protocol

Abstract

The ageing population has increased globally, leading to the prevalence of geriatric syndromes, including frailty. Frailty is associated with multiple physiological system impairments, increased vulnerability to stressors, and functional disabilities. Dental problems are common among older adults and can contribute to frailty by causing chewing difficulties and malnutrition. The objective of this randomized clinical trial is to evaluate the impact of an immediate prosthetic functionalization protocol on the general functionality of patients with deficient removable prostheses in the Chilean public health system.

This study protocol follows the Standard Protocol Items for Reporting in Trials (SPIRIT) guidelines. Patients aged 70 years or older, referred for prosthetic rehabilitation treatment, will be enrolled from the Eastern Metropolitan Health Service of Chile. The sample size calculation determined a sample universe of 120 individuals. The participants will be randomized into two groups: the control group will receive conventional prosthetic treatment, while the experimental group will undergo immediate prosthetic functionalization prior to conventional treatment.

Various measurements will be assessed at baseline, 15 days after baseline, and at patient discharge, including hand grip strength, Timed Up and Go test, and quality of life related to oral health. Statistical analysis will be performed to compare the outcomes between the two groups, considering age, gender, and comorbidities.

The findings from this trial will provide insights into the impact of immediate prosthetic functionalization on general functionality in patients with deficient removable prostheses. The results will contribute to improving the oral health and overall well-being of older adults, particularly those in the Chilean public health system. This study has received ethical approval and is registered in the U.S. National Library of Medicine Clinical Trials database (ClinicalTrials.gov Identifier: NCT05818436).

Keywords: prostheses, elders, treatment, teeth

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Introduction

In recent decades, life expectancy worldwide has increased, leading to the ageing of society, especially in developed countries.[1] As a result, geriatric syndromes have become increasingly relevant. These syndromes are a set of conditions that are usually caused by the combination of diseases with a high prevalence in the elderly, and they are often the source of functional or social disability in the population.[2] One of these syndromes is frailty, which is characterized by a decrease in the functioning of multiple physiological systems and an increase in vulnerability to stressors. Frailty is associated with an increased risk of mortality, cognitive decline, hospitalization, falls, and admission to long-term healthcare. It also has a significant individual burden, as it alters the quality of life and increases the risk of loneliness.[3,4]

Although there is no universal operational definition of frailty, it can be identified in an individual by unintentional weight loss, fatigue (exhaustion), muscle weakness, gait/sluggishness, and low levels of physical activity.[5] Frailty is also considered to be multidimensional and multisystemic, as it can affect the physical, cognitive, social, psychological, sensory, and nutritional domains.[6]

Several factors can contribute to an individual becoming frail, including medical, social, pharmacological, psychological, and environmental factors.[7] Among these factors, dental problems experienced by older people are common, as they often have poor oral health.[8,9] These dental problems can cause chewing difficulties, which can lead to changes in food selection, malnutrition, and ultimately, frailty and sarcopenia.[7] Sarcopenia is defined as the progressive decrease in muscle mass due to ageing, which decreases the functional capacity of the muscles.[10] Malnutrition is defined as a state of nutrition in which a deficiency of energy, protein, and other nutrients causes measurable adverse effects on tissue and body form and function.[11] Together with poor oral health, sarcopenia and malnutrition can form a triad (oral health-nutrition-sarcopenia), which can contribute to the development of frailty in older adults.[12]

In the last decade, the concept of "oral fragility" has emerged to refer to a series of phenomena and processes associated with ageing that generate a decrease in oral function and are accompanied by a decrease in interest in oral health, physical reserve, and mental capacity. This, in turn, leads to eating dysfunction and generates physical and mental deterioration.[13] Oral fragility may present specific signs or symptoms, including loss of masticatory functionality and chewing difficulty due to tooth loss. To restore oral function, it is necessary to provide dental treatment, including dental prostheses to replace missing teeth.[7]

In Chile, a significant percentage of older people who receive dental care in the public health system are referred from primary care to secondary care to access prosthetic treatment. However, a growing demand compared to an insufficient supply means that these people must wait years before they can access dental treatment. In the meantime, they live with impaired oral functionality due to tooth loss or the poor condition of older dental prostheses, which can have an impact on their general functionality that may not be quantified. It has been reported that decreased number of teeth and lack of posterior occlusal pairs may be risk factors for decreased gait speed and decreased total muscle mass, leading to an increased risk of falls and, in consequence, to a worse quality of life.[7,12,13]

The objective of this study is to evaluate the impact of an immediate prosthetic functionalization protocol on general functionality, in patients with deficient removable prostheses of the Chilean public health system.

Materials and methods

The present randomized clinical trial protocol is described according to the Standard Protocol Items for Reporting in Trials (SPIRIT) (Figure 1).

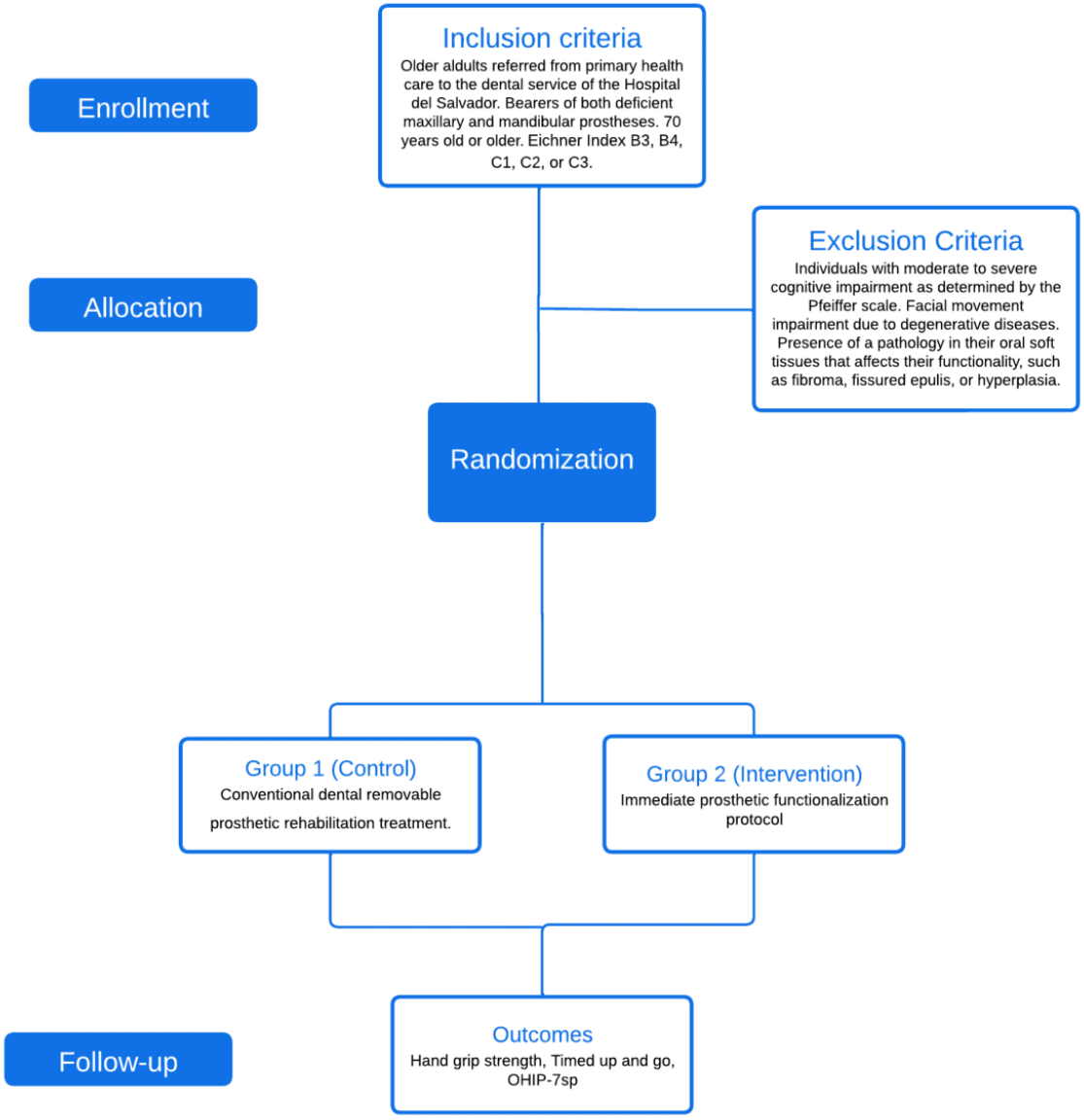

Figure 1 Flowchart of the randomized clinical trial protocol to evaluate the impact of an immediate prosthetic functionalization protocol on the functionality of patients with deficient removable prostheses.

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Ethical issues

The Eastern Metropolitan Health Service Ethics Committee has approved the clinical trial (Approval Number: 722023) and was registered with the U.S. National Library of Medicine Clinical Trials database (ClinicalTrials.gov Identifier: NCT05818436). Each patient will sign an informed consent form that explains their health condition, diagnosis, available treatments, intervention, possible risks, and discomforts resulting from it, and their right to withdraw from the study at any time. They will also receive verbal and written information with the contact details of the project directors to address any questions they may have during or after the study.

Regarding the risk-benefit assessment, the research involves minimal harm to the patients since the clinical actions involved in the intervention protocol and the materials used are similar to those used in conventional prosthetic treatment. The intervention's benefit in masticatory function can be immediately perceived by the individuals in the experimental group thanks to the recovery of oral functions through their previously deficient removable prosthetic appliances. Participating in the study will not incur any additional costs beyond the conventional dental treatment plan, and participants will also receive brushes for cleaning their removable dental prosthesis. If patients refuse to participate in the study, they will receive the conventional treatment for which they were referred to the service.

Study design

This study is a randomized, single-blind, controlled clinical trial with a two-group parallel design. The participants will be patients enrolled in the Chilean Public Health System, particularly the Eastern Metropolitan Health Service of Chile, referred for prosthetic rehabilitation treatment to the Hospital del Salvador in Providencia, Santiago.

Sample calculation

Based on the National Health Survey, 37% of people over 65 use dental removable prostheses in the maxilla and mandible simultaneously, with a mean of seven remaining teeth.[9] Data was collected at the Dental Service of the Hospital Del Salvador to calculate the sample size, which receives referrals from primary healthcare centres in the eastern area of the Metropolitan Region of Chile. In 2019, the dental service rehabilitated 342 patients aged 70 or older. Considering similar prosthetic care in 2019 and projecting that 35% of those receiving prosthetic treatment in 2020 will wear them at the beginning of recruitment, and will be 70 years old or older, the sample universe was defined as 120 people.

Estimating a confidence level of 95% and an error of 3%, using a Z value of 1.96, a p value of 0.5, and q=0.5, with a defined universe, the sample size calculation formula was applied, and the value obtained was 108 people aged 70 and over. However, given the morbidity characteristics of the group, an estimate of eventual losses of 10% was calculated, resulting in the sample being defined as 118 individuals, divided into 59 people in the experimental group and 59 people in the control group.

Selection of patients

Patients will be eligible for inclusion if they meet the following criteria:

a) They have been referred from primary health care and will start treatment in the prosthesis dental service of the Hospital del Salvador.

b) They are bearers of both deficient maxillary and mandibular prostheses.

c) They are 70 years old or older.

d) Their masticatory functionality is classified according to the Eichner Index (Nakatsuka, 2010) as B3, B4, C1, C2, or C3. Group B3 has upper and lower remaining teeth, but only one contact of masticatory opponent pairs exists in the premolar or molar area. Group B4 has upper and lower teeth but no contact between the premolars and opposing molars. Categories C1, C2, and C3 refer to edentulous patients without any occlusal contact.

Exclusion Criteria

Patients will be excluded from the study if they meet any of the following criteria:

a) They have moderate to severe cognitive impairment as determined by the Pfeiffer scale.

b) They have facial movement impairment due to degenerative diseases.

c) They present with a pathology in their oral soft tissues that affects their functionality, such as fibroma, fissured epulis, or hyperplasia.

Clinical examinations

Three dentists will clinically evaluate the participants according to the eligibility criteria and define the list that will enter randomization. The dentists will be calibrated with the Kappa test, with values between 0.7 and 1.

Randomization

Three dentists will clinically evaluate the participants according to the eligibility criteria and define the list that will enter randomization. The dentists will be calibrated with the Kappa test, with values between 0.7 and 1. Participants will be stratified by Eichner index, educational level, age, and sex, which will be recorded at the first visit of the patients after signing the informed consent. The allocation will be made using the minimization randomization methodology, according to the protocol described by Pocock-Simon[14] using the MinimPy software, with an arm equity weight of 1.0, marginal balance distance method, and a weight identical for each stratification variable of 1.0.

The randomization sequence will be generated by an independent assessor, stored in a secure location, and kept hidden from other investigators, including the trial director and statistician. Patients will be assigned to either the experimental or control group according to randomization.

The assignment status will not be concealed from the participant, but allocation status will be concealed from the data manager, trial statistician, and director until the blinded interpretation report is finalized.

Study groups

Participants will be randomly divided into two groups:

Group 1 (control): will receive only conventional dental removable prosthetic rehabilitation treatment. The control group will not receive the immediate prosthetic functionalization protocol.

Group 2 (experimental): In the experimental group, prior to the initiation of conventional dental removable prosthetic rehabilitation treatment, patients' prosthesis functionality will be restored by

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repairing and relining them to recover their support, retention, and stability. This will be achieved by using self-curing acrylic or permanent prosthetic conditioning material. Additionally, molar and premolar occlusal contacts will be restored by replacing missing teeth with prefabricated acrylic teeth, and the vertical dimension of badly worn teeth will be restored using self-curing acrylic. These procedures will be completed in a single clinical session by one qualified clinician dentist specializing in removable prosthetic treatments who will be blind to patient identification data, geriatric profile, and measurement values of variables under study. Subsequently, participants of experimental group will receive dental rehabilitation treatments, including new removable prostheses, according to the hospital's protocol in six clinical sessions, administered by dentists from the hospital dental service.

Data collection

An independent electronic file will be created for each patient attended, where demographic data, medical history (systemic pathologies, surgical history, drugs), and clinical characteristics derived from the dental clinical examination (number and distribution of teeth, soft tissue characteristics) will be recorded. These records will be unified in a database stored in a cloud safe haven.

Follow-up

Measurement parameters will be assessed at three different time points: baseline, 15 days after baseline, and at patient discharge from dental treatment. The measurements will be carried out by three calibrated researchers (Kappa >0.7).

Results

The main outcomes of this study will be:

a) Hand grip strength of the dominant hand: It will be evaluated in patients with their prostheses in their mouth while sitting in two oral positions: without occlusal contact and in occlusion. The measurement will be made with a hydraulic hand dynamometer (Jamar^{MR}) for 2 to 3 seconds. Grip strength levels ≤30 kg in men and ≤20 kg in older women indicate a risk of sarcopenia.[15]

b) Timed Up and Go test: This test evaluates the risk of falls. The time taken by the participant to get up from a chair, walk to a mark located three meters away, turn around, and walk back to the chair to sit down will be measured with a stopwatch. The patient will use their usual support element (cane, walker). The fall risk classification is determined by the score of the time spent walking: Normal <10 seconds; Slight fall risk: 11 to 20 seconds; High risk of falling >20 seconds.[16]

c) Quality of Life related to oral health: The reduced "Oral Health Impact Profile" questionnaire (OHIP-7sp) will be used. This questionnaire inquiry about pain and functional and psychological alterations derived from oral conditions. It consists of seven questions, with definite answers: "never", "rarely", "sometimes", "frequently", and "always", to which a value of 0 to 4 points is assigned, respectively. The total score is obtained by the direct sum of the seven responses and varies from 0 points (good quality of life) to 28 points (poor quality of life).[17]

Statistical analysis

Sample Characterization: The sample characterization will enable the integral analysis of data by evaluating the differences between groups according to age and gender. This will differentiate the results of the intervention between these groups. In addition, the medical history will evaluate the presence of polypharmacy and the frequency of comorbidities. Descriptive statistics will be applied through frequency registration and contingency tables for this purpose.

Pre and Post-Intervention Statistics: The comparison between the experimental and control groups regarding hand grip strength, risk of falls, and quality of life will be made on the three measurement moments. Pearson's correlation will be used to compare hand grip strength between the pre- and post-intervention groups. The t-test for two related samples will be applied to compare the risk of pre- and post-falls in related groups. Chi2 will be used to compare the quality of life before and after the intervention. One-way ANOVA will be applied for related samples to compare the changes in hand grip strength, risk of falls, and quality of life between the different groups according to the Eichner index.

In case of losses or dropouts during the clinical trial, the analysis will be carried out with the intention to treat the best and worst-case scenarios.

Discussion

The aging population has led to an increased prevalence of geriatric syndromes, including frailty, which is associated with various adverse health outcomes and reduced quality of life. Dental problems, such as tooth loss and poor oral health, are common among older adults and can contribute to the development of frailty, malnutrition, and sarcopenia.[7] To restore oral function, dental prostheses are often provided, but the availability and waiting times for prosthetic treatment in public health systems can be significant challenges.[9]

This study protocol aims to evaluate the impact of an immediate prosthetic functionalization protocol on the general functionality of patients with deficient removable prostheses in the Chilean public health system. The study design is a randomized, single-blind, controlled clinical trial with a two-group parallel design. The participants will be elderly patients referred for prosthetic rehabilitation treatment, and they will be randomly assigned to either the control group, which will receive conventional dental removable prosthetic treatment, or the experimental group, which will undergo the immediate prosthetic functionalization protocol.

The study will assess several outcome measures to evaluate the impact of the intervention on functionality. Hand grip strength, a measure of muscle strength and a predictor of sarcopenia, will be evaluated in both groups with and without occlusal contact. The Timed Up and Go test will be used to assess the risk of falls, a common consequence of frailty. The quality of life related to oral health will be assessed using the reduced "Oral Health Impact Profile" questionnaire (OHIP-7sp).

This study has several strengths. Firstly, it addresses an important gap in the literature by evaluating the impact of an immediate prosthetic functionalization protocol on the functionality of patients with deficient removable prostheses. Secondly, it utilizes a randomized controlled trial design, which is considered the gold standard for assessing the effectiveness of interventions. The protocol also includes ethical considerations, ensuring patient consent, and minimizing harm.

However, there are some limitations to consider. The study is conducted in a specific context, the Chilean public health system, which may limit the generalizability of the findings to other settings. Efforts have been made to minimize potential biases through randomization and blinding, but it is challenging to completely eliminate bias in clinical trials. Blinding the patients to their group assignment (control

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or intervention) is not possible. Due to the recruitment system, we cannot control whether the groups and subgroups to be compared are similar in the number of individuals composing them, which may limit the validity of comparisons, especially for significant variables such as the type of edentulousness (assessed according to the Eichner Index), which will be randomly distributed.

Conclusion

This study protocol outlines a randomized controlled trial aimed at evaluating the impact of an immediate prosthetic functionalization protocol on the functionality of patients with deficient removable prostheses in the Chilean public health system. The findings from this study have the potential to contribute to improved oral health and overall functionality among older adults, particularly those with limited access to dental treatment. Further research in this area is crucial to address the needs of the aging population and promote healthy aging and improved quality of life.

Ethics approval

The Eastern Metropolitan Health Service Ethics Committee has approved the clinical trial (Approval Number: 722023) and was registered with the U.S. National Library of Medicine Clinical Trials database (ClinicalTrials.gov Identifier: NCT05818436).

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Authors' contributions

Barahona P conceived the idea. Celis A, Chavez B, Godoy J, Santibañez B, Michea M, Saa D, Saiz M and Fasce G participated in protocol design development. Barahona P, Celis A and Cisterna C participated in the literature review and lead the manuscript drafting. All authors contributed in manuscript drafting and approved the final version of the manuscript.

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Conflicts of interest

The authors declare that there are no conflicts of interest.

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