Gait Re-education Program in Subjects With Parkinson´s Disease

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Brief Project Description (type of study, methodological design, samples or subjects, research variables):
This is a randomized controlled trial including participants diagnosed with mild to moderate stage Parkinson's Disease and exhibiting gait pattern alterations. Participants will be randomized using a simple randomization procedure. One group will receive an intervention based on a gait reeducation program called "TAPIZ FISIOR"—which combines motor control and learning with a conventional physiotherapy program. The other group will receive only the conventional physiotherapy program. Evaluators will be blinded to the treatment allocation of the patients.

The project will follow the guidelines of the Declaration of Helsinki. Subject confidentiality will be maintained in accordance with current regulations (Organic Law 15/1999 of December 13 on the Protection of Personal Data) and the law governing biomedical research (Law 14/2007 of July 3 on Biomedical Research).

Description of the intervention:
The control group will participate in a physiotherapy program commonly used for Parkinson's patients (including manual therapy on a treatment table; kinesitherapy; and exercises for: unilateral balance with support, postural control, gait, lower limb strength, and spatial-somatic coordination). Three sessions per week will be conducted for 12 weeks.

The experimental group will participate in the same physiotherapy program as the control group, with the addition of the gait reeducation program using a sequential square mat (including exercises for: anterior and lateral postural control, anterior and lateral balance overcoming obstacles, anterior and lateral gait sequencing, and lower limb strength).

An initial assessment will be conducted at the beginning of the study and another after three months. The following variables will be measured:

Variables and evaluation instruments:

- **For gait functional capacity, balance, and basic functional capacity:**
    - *Short Physical Performance Battery (SPPB, Guralnik et al., 1994)*: composed of three tests—balance (feet together, semi-tandem, tandem), 4-meter gait speed, and chair stand test (five times).
    - *Timed "Up and Go" Test (Mathias et al., 1986)*: designed to assess basic functional mobility in frail older adults. It measures the time taken to stand up from a chair without using arms, walk three meters, turn, return, and sit down again.
    - *Berg Balance Scale (Berg et al., 1992)*: evaluates postural balance through 14 different items analyzing static balance.
    - *MDS-UPDRS*: evaluates motor status, disability level, and disease progression.
- **For the quality of life variable:**
    - *Barthel Index*: assesses the individual's ability to perform ten basic

activities of daily living, yielding a quantitative estimate of the subject's level of dependence.

Sample/Subjects Characteristics:
Participants will be informed about the project and will be required to sign informed consent.

Sample size: calculation and/or reference:
The estimated sample size is 40 participants. This estimation is based on the results of the study by Valverde Guijarro et al. (2020), which investigated the effects of dance on balance and gait in subjects with Parkinson's Disease and reported statistically significant results.

Inclusion criteria:

- Aged over 50 years
- Diagnosed with Parkinson's Disease in stages 1 to 3 of the Hoehn & Yahr scale (1967), i.e., mild or moderate stage
- Not institutionalized
- Able to communicate and walk at least 10 meters
- Barthel Index score ≥ 60
- No cognitive impairment, or a score ≥ 24 on the Spanish-adapted and validated version of the Mini-Mental State Examination (MMSE) by Folstein, Folstein, and McHugh (1975)

Exclusion criteria:

- Medical contraindications to the treatment
- Severe cognitive or behavioral problems that may hinder participation in the training program

Statistical analysis plan

Frequencies and percentages were calculated for categorical variables, while means and standard deviations were computed for numerical variables, given their normal distribution according to the histogram.

For the bivariate analysis, the Student's t-test was used. Finally, linear regression models with robust variance were constructed to quantify the association between covariates according to the intervention group, considering changes in variable values before and after the intervention. Beta coefficients (β), standard errors, p-values, and 95% confidence intervals were estimated.All variables were included in the adjusted model because they were considered confounders according to the reviewed literature.. The absence of collinearity was verified using the VIF command.

All analyses were performed using Stata v.18.0 for Windows.

INFORMED CONSENT:

PATIENT INFORMATION SHEET AND INFORMED CONSENT

PATIENT INFORMATION SHEET

STUDY TITLE: EFFECTIVENESS OF A GAIT RETRAINING PROGRAM ON A SEQUENTIAL SQUARES MAT IN SUBJECTS WITH PARKINSON'S DISEASE

Dear Sir/Madam,

Your physician has invited you to participate in this study. In compliance with Law 41/2002 of November 14th, "Basic Law regulating patient autonomy and rights and obligations regarding information and clinical documentation," we now reiterate in writing the verbal explanation already provided, in order to request your authorization to include you in this study.

Before deciding whether to participate, it is important that you understand why this study is being conducted and what your involvement would entail if you choose to participate.

Please read the following information carefully. If there is anything unclear or if you would like more information, do not hesitate to ask. You may request further details from the principal investigator or any of their collaborators, or from your attending physician. We will allow you as much time as needed to make your decision.

STUDY IDENTIFICATION AND DESCRIPTION

This is a randomized controlled trial involving participants diagnosed with mild to moderate stage Parkinson's disease who present gait pattern alterations. Participants will be randomly assigned using a simple randomization procedure. One group will receive an intervention based on a gait retraining program called "TAPIZ FISIOR," which involves motor control learning in addition to a conventional physiotherapy program. The other group will receive only the conventional physiotherapy program. The evaluators will be blinded to the participants' treatment group.

STUDY OBJECTIVES

The main aim of this study is to demonstrate the effectiveness of a structured motor control training sequence using a square mat to improve key gait parameters and functional capacity in individuals diagnosed with Parkinson's disease.

Specific objectives:

- To demonstrate the effectiveness of a structured motor control training sequence on a square mat to improve gait functionality and balance in people diagnosed with Parkinson's disease.

- To demonstrate the effectiveness of this intervention in improving basic functional capacity in people with Parkinson's disease.

- To demonstrate the effectiveness of the square mat motor control training sequence in enhancing activities of daily living in this population.

Participation is entirely voluntary. You are under no obligation to participate, and if you choose to do so, you may withdraw at any time. All aspects of this study, including results, will be handled with strict confidentiality.

WHY HAVE YOU BEEN SELECTED?

You have been selected because you meet the following criteria:

- Being over 50 years of age.
- Being diagnosed with Parkinson's Disease in stages 1 to 3 of the Hoehn & Yahr scale (1967), corresponding to mild or moderate stages.
- Not being institutionalized.
- Being able to communicate and walk at least 10 meters. A score of ≥ 60 on the Barthel Index.

- Not presenting cognitive impairment, or scoring ≥ 24 on the Spanish-adapted and validated version of the Mini-Mental State Examination (MMSE) by Folstein, Folstein, and McHugh (1975), known in Spain as the Mini Examen Cognoscitivo (MEC).

CONFIDENTIALITY:

Your right to privacy and the confidentiality of all health-related data is guaranteed, including both the data obtained during the research and the data recorded in your medical history. This is in accordance with Law 3/2018 on Personal Data Protection and guarantee of digital rights, and Law 41/2002 regulating patient autonomy and rights and obligations regarding clinical information and documentation.

For the purposes of this study, you will be identified by a code, and your personal information will not be shared or disclosed to third parties without your prior written consent. You will not be personally identified in any written publications or seminars in which the results of this study may be presented.

Monitors, auditors, the Research Ethics Committee (CEIC), and competent authorities will have direct access to the subject's original medical records to verify the procedures and/or data of the study/clinical trial, without violating subject confidentiality, as permitted by applicable regulations. By signing the informed consent form, the subject or their legal representative authorizes access to this data.

ETHICAL CONSIDERATIONS:

This study will be conducted in accordance with the principles of good clinical practice and is solely intended to demonstrate the effectiveness of a non-invasive, low-cost, and easy-to-implement intervention aimed at improving the functional abilities of individuals with Parkinson's Disease. This means that by participating in the study, you will not be subjected to any unnecessary procedures, nor will you be denied necessary care for your condition should you choose not to participate.

EXPECTED DURATION OF YOUR PARTICIPATION IN THE STUDY:

The study will last 12 weeks.

APPROXIMATE NUMBER AND CHARACTERISTICS OF PARTICIPANTS EXPECTED TO BE INCLUDED IN THE STUDY:

50 participants will be selected.

QUESTIONS THAT MAY ARISE DURING AND AFTER YOUR PARTICIPATION IN THE STUDY:

If you have any questions about the study at any time, you can contact: (Principal Investigator's contact information)

FINANCIAL COMPENSATION:

There is no financial compensation for participation in this study.

PATIENT INFORMED CONSENT

I have read and understood the Patient Information Sheet. I have had the opportunity to discuss any issues related to this information. My questions and concerns have been answered satisfactorily.
I understand that my participation is voluntary and that I am free to withdraw from the study at any time without affecting my legal rights.
I understand that anonymized data may be used in other documents, excluding personal data, and will be handled with due discretion and confidentiality.
I give authorization for my medical reports to be accessed without disclosing personal information. I agree that information related to my participation in this study may be shared with my specialist and general practitioner if requested.
I have read the above information and I agree to participate in the study.

PARTICIPANT

Full name: .....

Signature: _____ Date: _____

LEGAL REPRESENTATIVE

Full name: .....

Signature of parent, guardian, or legal representative: _____
Date: _____

INVESTIGATOR

Full name: JOSÉ ALEGRE TAMARIZ / ALBERTO BERMEJO FRANCO

Signature: _____ Date: _____

WITHDRAWAL OF PATIENT INFORMED CONSENT

Mr./Ms.: ....., aged ....., residing at
(Full name of the patient) ..... and holder of ID number .....

I HEREBY WITHDRAW the consent granted on the date ....., and I request the deletion or anonymization of all personal data and any stored samples, without this resulting in any harm or loss of healthcare benefits to which I am entitled. I understand that this deletion will not apply to data derived from consented research studies that have already been carried out.

In Las Palmas de Gran Canaria, on the ..... day of ....., ...

INFORMATION SHEET AND PERSONAL DATA CONSENT FORM

In compliance with the provisions of Article 5 of Organic Law 3/2018 on the Protection of Personal Data and the Guarantee of Digital Rights, which regulates the right to information in the collection of data, we inform you that the personal data provided in this form will be included in and treated with confidentiality and security in files under the responsibility of THE GENERAL MANAGEMENT OF ……., the purpose of which is to carry out A RESEARCH STUDY making use of new technologies.

The recipient of the data is THE RESEARCH TEAM OF THE SERVICE (indicate name of the Service), WITH THE PRINCIPAL INVESTIGATOR (indicate name(s) of the principal investigator(s)) BEING RESPONSIBLE, and there is no intention to transfer data to third parties other than those provided for by law or those expressly authorized by you or your legal representative. Likewise, the Collaborating Investigators (indicate name(s) of the collaborating investigator(s)) shall also assume this responsibility.

The data provided must be truthful, accurate, complete, and up to date. The participant will be responsible for any direct or indirect damage or harm resulting from failure to comply with this obligation.

In compliance with the principle of data quality, the GENERAL MANAGEMENT OF ……. will retain the information recorded for the purpose described. If you wish to modify your data, you must contact the principal investigator.

The participant may exercise the rights of access, rectification, cancellation, and opposition under the terms established in the aforementioned Organic Law 3/2018 and related regulations before the GENERAL MANAGEMENT OF ....., located at .....

You may revoke the consent granted, without retroactive effect, by submitting a written request to the GENERAL REGISTRY of ……, expressly mentioning “Data Protection”, or by email to the following address (email of the principal investigator(s); either provide a corporate email address or create one exclusively for the study), or by ordinary mail to the above-mentioned address, enclosing a copy of your National ID Card (DNI).

PARTICIPANT

Full Name: .....

Signature: _____ Date: _____

LEGAL REPRESENTATIVE

Full Name: .....

Signature of parent/guardian: _____ Date: _____

INVESTIGATOR

Full Name: .....

Signature: _____ Date: _____