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Lisbon intensive falls trampoline training for Parkinson's: The LIFTT Program

Submission date
09/02/2022

Recruitment status
No longer recruiting

Registration date
23/02/2022

Overall study status
Completed

Last Edited
18/01/2024

Condition category
Nervous System Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Background and study aims
Parkinson's disease (PD) is a condition in which parts of the brain become progressively damaged over many years. The 3 main symptoms of Parkinson's disease are: involuntary shaking of particular parts of the body (tremor); slow movement; stiff and inflexible muscles.
People with Parkinson’s disease are twice as likely to fall as the healthy older population, leading to debilitating effects on fear of future falls, balance confidence, activity levels and quality of life.
Research suggests that people with PD benefit from combined balance and mental exercise. We will develop a randomized clinical trial that aims to estimate the effectiveness of the Lisbon Intensive Falls Trampoline Training (LIFTT) program in addition to usual care on symptoms of PD and daily life.

Who can participate?
Adults over 18 years, diagnosed with Parkinson’s disease, who can walk independently and currently able to tolerate a minimum of 1 hour of exercise

What does the study involve?
Participants will be randomly allocated to an intervention group (IG) (30 participants) receiving balance motor-cognitive trampoline training or a control group (CG) (30 participants) whose participants will continue to receive their usual care from their medical physician and/or the community services Controls will be offered the intervention after ending their participation.

What are the possible benefits and risks of participating?
Participants will benefit in overall health from participating in an exercise based intervention. The LIFTT program was considered to be safe and well received by the participants in pilot studies, so no severe risks are anticipated due to high supervision via clinical experts.

Where is the study run from?
Egas Moniz – Cooperativa de Ensino Superior, CRL (Portugal)

When is the study starting and how long is it expected to run for?
January 2022 to December 2023

Who is funding the study?
Egas Moniz – Cooperativa de Ensino Superior, CRL (Portugal)

Who is the main contact?
Prof. Catarina Godinho, cgcgodinho@gmail.com

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
EXPL/SAU-SER/0761/2021

Study information

Scientific Title
Lisbon Intensive Trampoline Training for people with Parkinson's for balance and Falls Prevention: LIFTT Program

Acronym
LIFTT

Study objectives
1. The LIFT program protocol is feasible to people with Parkinson Disease.
2. The LIFFT program is effective for improving balance, reducing fear of falling, falls frequency and severity and also to improve clinical impairments, gait, physical capacity, and cognition in people with mild or moderate Parkinson Disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/01/2022, Ethics Committee of Egas Moniz - Cooperativa de Ensino Superior, C.R.L. (Campus Universitário, Quinta da Granja, Monte de Caparica, 2829 - 511 Caparica, Portugal; no telephone number provided; iuem@egasmoniz.edu.pt), ref: 1052/2022

Primary study design
Interventional

Study design
Multicenter interventional randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Parkinson's disease

Interventions
Participant recruitment:
People with Parkinson's Disease (PD) will be recruited from the Portuguese Parkinson Disease Association (APDPK) and from the Movement Disorders Outpatient Clinic, Department of Neurology, from Hospital Garcia de Orta (MDOC-HGO) by the Senior Physiotherapist Specialist and the Neurologist, respectively.

Screening:
Informed consent will be obtained from participants before any study related proceedings. The participants will have a general information intake where data on demographics, clinical manifestations and disease management, comorbidities and past medical conditions, and usage of healthcare resources will be obtained using a structured questionnaire. A brief clinical assessment of postural instability and risk of falling (MDS-UDPRS Part III item 3.12) will also be performed by the recruiting researchers.

Participants Assessments
Assessments will take place in a private room of the community trampolines place in Lisbon in the week before (T0), after 8 weeks training protocol (T1) and 3 months after the ending of the program (T2), with the same protocol. The researchers who will perform these assessments will be blind for group intervention.
All participants will be assessed in ON medication phase with the following specific clinical scales and tests that will have their order randomized:
a) Balance (Mini-BEST Test);
b) Fear of falling (Falls Efficacy Scale - FES-I).
c) Clinical impairments (The Movement Disorder Society Unified Parkinson Disease Rating Scale - MDS-UPDRS);
d) Frequency and severity of falls (falls weekly registry);
e) Gait (Motor and Cognitive Timed Up Go - TUG);
f) Physical capacity (6 min walking distance test - 6MWD);
g) Cognition (Montreal Cognitive Assessment - MoCA), and;
h) Quality of life (Parkinson Disease Questionnaire – PDQ8);
i) Nonlinear gait and balance analysis: Participants will be asked to walk on a treadmill for 10 min at their preferred walking speed. Stride intervals will be determined from an accelerometer placed at their ankles, and nonlinear features will be extracted from the signals as measures of

adaptability of the locomotor system. Moreover, their static balance will be tested in both eyes opened and closed conditions. They will be asked to remain quiet for 2 min, so a sufficient amount of data will be collected for nonlinear features extraction.
At the end of T0 assessment, an online software will be used to generate the randomization plan for the intervention group (IG) or control group (CG).

Intervention - Training sessions
For the Intervention Group (IG) the LIFTT program will consist of an 8-week program (1-hour individual sessions 3 times a week). Sessions will be led by a physiotherapist specialized in PD and internationally recognized educator of motor and cognitive rehabilitation programs. Support will be given by a MSc student fellow for additional safety.
The program will include motor and cognitive challenges performed on a trampoline bed.
The Control Group (CG) will receive usual care from their medical practitioner and/or the community services. They will be allowed to participate in their usual ongoing rehabilitation programs. After the LIFTT program, the control group will be offered the same balance program.

Setting
The site where the program will be delivered in a stress-free environment, a community trampoline fun house (Jumpyard, Inc.) in Lisbon, will show that the program can be easily incorporated into the normal routine and structure of a community setting. Safety vertical belts or suspension support equipment will be used for participants with more severe risks.

Withdrawal of participants
Participants will be able to withdraw from the study at any time. No more data will be collected and taken into consideration for statistical purposes regarding the withdrawal subjects.

Statistical methods and data analysis
We will perform descriptive statistics of data collected at T0, T1 and T2, to identify differences between the groups (CG and IG), and to evaluate which of these groups will have better results from T0 to T1 and T2.
Descriptive analyses, the assessment of the reliability and the correlational analysis of all variables, will also be conducted.
For achieving the objective mentioned above, we will use a two-way repeated measures ANOVA with an independent variable and a repeated measures factor, i.e., ANOVA, with 2 factors: One within factor (time, pre-post intervention, follow-up) and one between factor (treatment, two groups). The Latent Growth Modelling will be conducted to prove the effectiveness of individual intervention on growth of primary outcomes during the period between T0 and T2.
The sample size for this study was determined based on previous related interventional trials with people with PD. Considering a 0.7 effect size (e.g. for the FES-I outcome), for 80%power and an alpha level of 5%, a sample size of 26 subjects per group will be required. With a dropout rate set at 15%, a final sample of 60 (n=30 per group) was considered as optimal.

Intervention Type
Behavioural

Primary outcome(s)
1. Change in the Balance Evaluation Systems Test (Mini-BEST Test) at baseline (T0) after 8 weeks training protocol (T1) and 3 months after the ending of the program (T2).
2. Change in the Falls Efficacy Scale (FES-I) at baseline (T0) after 8 weeks training protocol (T1) and 3 months after the ending of the program (T2).

Key secondary outcome(s)

1. Clinical impairments measured using the Movement Disorder Society Unified Parkinson Disease Rating Scale (MDS-UPDRS) at baseline (T0) after 8 weeks training protocol (T1) and 3 months after the ending of the program (T2).
2. Frequency and severity of falls measured using a falls weekly registry at T0, T1 and T2.
3. Gait measured using Motor and Cognitive Timed Up Go Test (TUG) at T0, T1 and T2.
4. Physical capacity measured using the 6 min walking distance test (6MWD) at T0, T1 and T2.
5. Cognition measured using the Montreal Cognitive Assessment (MoCA) at T0, T1 and T2.
6. Quality of life measured using the short version of Parkinson Disease Questionnaire (PDQ8) at T0, T1 and T2.
7. Nonlinear gait and balance analysis: For dynamic parameters, participants will walk on a treadmill for 10 min. Stride intervals will be determined from an accelerometer placed at their ankles. The static balance parameters will be tested in both eyes opened and closed conditions. They will be asked to remain quiet for 2 min. These two tests will be applied at T0, T1 and T2.

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Diagnosis of idiopathic Parkinson’s disease (Movement Disorder Society Parkinson’s Disease criteria)
2. Hoehn and Yahr stages II-IV
3. Age above 18 years
4. Able to walk independently and currently able to tolerate a minimum 1 hour of exercise
5. Able to communicate with the investigator, to understand and comply the study procedures
6. Willing and able to provide written informed consent to participate and understand the right to withdraw his/her consent at any time without prejudice to future medical care

Participant type(s)
Patient, Other

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Total final enrolment
52

Key exclusion criteria
1. Severe postural instability assessed by MDS-UDPRS Part III item 3.12
2. Severe cognitive difficulties and significant active psychiatric problems that aggravate when exercising

Date of first enrolment

01/02/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Portugal

Study participating centre
Associação Portuguesa de Doentes de Parkinson (APDPk)
Rua C ao Bairro da Liberdade loja 21.
Lisbon
Portugal
1070-023 Lisboa

Study participating centre
Hospital Garcia de Orta
Av. Torrado da Silva
Almada
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Sponsor information

Organisation
Fundação para a Ciência e Tecnologia

ROR
https://ror.org/00snfqn58

Funder(s)

Funder type
University/education

Funder Name
Egas Moniz – Cooperativa de Ensino Superior, CRL

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication and available on request (cgcgodinho@gmail.com)

IPD sharing plan summary

Available on request, Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		08/02/2023	10/02/2023	Yes	No
Protocol file	in Portuguese	10/03/2021	10/02/2022	No	No