

FCT Fundação para a Ciência e a Tecnologia

MINISTÉRIO DA EDUCAÇÃO E CIÊNCIA



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Visão global da candidatura

Application overview

Referência do projeto

Project reference

EXPL/SAU-SER/0761/2021 (Lacrado a 10-03-2021 às 11:13)

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1. Identificação do projeto

1. Project description



Área científica principal

Main Area

Ciências da Saúde - Cuidados de Saúde e Serviços
Health Sciences - Health Care Sciences and Services

Área científica Secundária

Secondary area

Ciências da Saúde - Cuidados de Saúde e Serviços
Health Sciences - Health Care Sciences and Services

Painel de Avaliação

Evaluation Panel

Health and Sport Sciences Evaluation Panel – 2021

Acrónimo do projeto

Project's Acronym

LIFTT

Título do projeto (em português)

Project title (in portuguese)

Treino Intensivo de Quedas em Trampolim para Parkinson: Programa LIFTT

Título do projeto (em inglês)

Project title (in english)

Lisbon Intensive Falls Trampolines Training for Parkinson's: LIFTT Program

Financiamento solicitado

Requested funding

48.315,00€

Palavra-chave 1

treino em trampolins

Palavra-chave 2

treino equilíbrio

Palavra-chave 3

quedas

Palavra-chave 4

Doença de Parkinson

Data de início do projeto

Starting date

01-01-2022

Existem questões éticas identificadas neste projeto?

Are there Ethics Issues identified in this project?

Sim

Yes

Declaração(ões) de ética

Keyword 1

trampoline training

Keyword 2

balance training

Keyword 3

falls

Keyword 4

Parkinson disease

Duração do projeto em meses

Duration in months

18

Ethical declaration(s)

4 - Protection of personal data

2 - Humans

Fundamentação ética

Ethical justification

LIFTT enhances two major ethics areas such as Humans in general and the Protection of general personal data issues. Regarding the Protection of general personal data, LIFTT will follow all requirements of GDPR with a particular focus on Article 29 Workgroup conclusion on Anonymity and Informed Consent on their questionnaires and collected data. In general, the public impact/interest of LIFTT in Humans will allow the reduction of gaps in science, particularly in Parkinson's Disease rehabilitation and in patient's autonomy which leads to an improvement of patients quality of life. In this project, patients will be assessed and trained for motor skills with noninvasive techniques and also their functional status will be studied using standard metrics for Parkinson's Disease.

Objetivos de Desenvolvimento Sustentável das Nações Unidas – Agenda 2030

United Nations Sustainable Development Goals – 2030 Agenda

Objetivo 3 - Garantir o acesso à saúde de qualidade e promover o bem-estar para todos, em todas as idades

Goal 3 - Ensure healthy lives and promote well-being for all at all ages

Enquadramento da candidatura nos Objetivos de Desenvolvimento Sustentável

Framework of the application for the United Nations Sustainable Development Goals

The LIFTT project aims to explore a different solution for gait and balance using a trampoline specific training program. It can ultimately represent an effective alternative mode of physical activity training for improving balance, gait performance, endurance and functional outcomes in a very salient and safe manner in people with PD. It defines the first steps to identify the benefits people with PD most likely to have with such training, the type of exercises and ideal environments for balance programs. This will promote the appropriate use of non-pharmacological interventions in health care systems world-wide.

2. Instituições envolvidas

2. Institutions and their roles

Instituição Proponente

Principal Contractor

Egas Moniz - Cooperativa de Ensino Superior, CRL (CESEM)

Campus Universitário - Quinta da Granja

2829-511Monte de Caparica

Descrição da Instituição

Egas Moniz (EM) is the founding body of the Egas Moniz University (UEM) and the Egas Moniz School of Health (ESSEM), dedicated to the training of health professionals and provision of clinical care.

The headquarters of EM is located in the Campus Universitário, Monte da Caparica. Additionally, the Institution has other facilities in the peninsula of Setúbal where it develops teaching and health care activities, establishing itself as a reference at regional and national level.

EM develops scientific research and technological development activities in research laboratories, within the Interdisciplinary Research Centre Egas Moniz (CiiEM). It composed by more than 100 members, 43 of them are integrated members.

The research at the CiiEM is organized in 4 research biomedical and human science areas of strategic importance for Egas Moniz, aligned with national and international priority objectives. The action of the lines is complemented by external partnerships, focusing on subjects in which the institution has competencies to intervene with the community in its various aspects, including teaching, research and clinics.

In its assistance activities and interaction with the community, we highlight the EM Dental Clinic (in the Campus), the EM/Almada Clinic, the EM/Setúbal University Clinic and the Senior Residency EM/Sesimbra, which provide support to the community in the areas of Dentistry, Nursing, Physiotherapy, Nutrition, Speech Therapy, and Clinical and Forensic Psychology

Instituição Participante

Participating Institution

ASSOCIAÇÃO PORTUGUESA DE DOENTES DE PARKINSON

Bairro da Liberdade, Lote 11, Loja 17

1070-023Lisboa

Descrição da Instituição

Founded on 14th of April 1984 to advocate for the rights and needs of estimated 20.000 people with Parkinson's and their families in Portugal. In 1997, a small group of people with Parkinson's disease and caregivers prepared it to revive, but it was only in 1999 that it was officially recognised as an Institute of Social benefit and became a member of the European Parkinson's Disease Association. In 2010 there were 15 affiliated Branches of APDPk throughout Portugal. The aim of APDPk are

1: To Inform, educate and advise Parkinson's community across Portugal regarding up-to-date information, research and resources. The right amount of information at the right time.

2: To raise awareness among general community, health professionals and decision makers of the complexity and the impact of Parkinson's disease.

3: Engage and set useful collaborations and partnerships and develop solutions to unmet needs nationally and specific to each branch too.

4: To support research in the search for better understanding of the disease and better care models. Objective 5: To influence national and local healthcare models advocating that people with Parkinson's receive early and specialized treatment. To implement or help implement a National Parkinson Care strategy.

In this project we will have the APDPk collaborations to identify people with PD to participate in the study and also to disseminate the results to all Nacional Parkinson community.

Faculdade de Motricidade Humana (FMH/ULisboa)

Estrada da Costa

1499-002Cruz Quebrada

Descrição da Instituição

The Faculty of Human Kinetics (FMH - University of Lisbon) was founded in 1940 and is the oldest faculty of Sports Science in Portugal. From a historical perspective, its tradition in the field of Sports Science is well illustrated by important outcomes in the domain of Physical Education and Sports Pedagogy at the national level. Presently, FMH is open to a wide range of scientific areas focused on diverse sectors of society. It offers 5 undergraduate courses, 15 masters programmes and 2 doctoral degrees (Human Kinetics and Education). FMH has several partnerships with other universities (national and foreign institutions), together with public and private entities. Over the years, these synergies have extensively contributed to improving the scientific and pedagogical programs offered to all the students interested in pursuing a career in Sports Science. Finally, the organizational structure of FMH also includes the Centre for the Study of Human Performance (CIPER); a research unit sponsored by FCT. CIPER intends to establish a common conceptual framework between different disciplines by applying multidimensional models to analyze human functioning and performance in different contexts (i.e., sports, exercise and occupational context). It uses a non-invasive approach to create/design valid research tools aimed at exploring task performance in different populations across the lifespan. FMH give us technical and scientific support to the movement nonlinear analysis.

Hospital Garcia de Orta EPE (HGO)

Av. Prof. Torrado da Silva

2805-267Almada

Descrição da Instituição

The Garcia de Orta Hospital is a central hospital that provides differentiated health care to the population of the municipalities of Almada and Seixal with a total of approximately 380,000 citizens. HGO has more than 550 inpatient beds and 2700 health professionals distributed over a wide range of medical specialties, organized into services and functional units. Its clinical activities include Inpatient Wards, External Consultation, Day Hospitals, Outpatient Surgery and Outpatient Diagnostic and Therapeutic Means. HGO also develops research and training activities, pre- and post-graduate of health professionals coordinated by the Garcia de Orta Center (CGO) whose mission is to enhance the Hospital's scientific

knowledge production capacity, by promoting and coordinating health activities. Training, Teaching and Research, from HGO and annually awards the prestigious Garcia de Orta Prize. For this projet we will have the colaborations of the neurology department to identify, invite / recruit and screening the people with Parkinson Disease.

Unidade de Investigação

Research Unit

Centro Interdisciplinar de Investigação Egas Moniz (CiiEM)

Quinta da Granja
2825-516Caparica

Unidade de Investigação Adicional

Additional Research Unit

(Vazio)

(Void)

3. Componente Científica

3. Scientific Component



3.1. Sumário

3.1 Abstract

3.1.a (Em português)

3.1.a (In Portuguese)

As quedas frequentes em pessoas com Doença de Parkinson (DP) têm sido associadas a alterações dos reflexos posturais antecipatórios e dos recursos cognitivos (1). Como tal, as pessoas com DP beneficiam de programas de treino de equilíbrio com exercícios motores e cognitivos (2, 3). No entanto, existem preocupações sobre a segurança necessária para a implementação de tais programas uma vez que existem estudos que demonstram efeitos adversos significativos como a ocorrência de quedas (4, 5).

Quando uma pessoa com DP divide a sua atenção entre 2 tarefas, a falta de recursos cognitivos atencionais resulta num impacto negativo numa ou em ambas as tarefas com aumento do risco de queda (1, 4). O benefício dos exercícios motores e cognitivos e a recomendação de incluir este treino em fisioterapia com DP (2), exige conhecimento específico sobre a doença e sobre o envolvimento de forma a garantir a segurança e a eficácia destas intervenções (6). A nossa equipa tem aplicado o treino motor-cognitivo com pessoas com DP desde 2004 (7-13). Recentemente, temos realizado este tipo de treino num ambiente seguro com trampolim (cama elástica), de modo a melhorar o equilíbrio em dupla tarefa enquanto garantimos a segurança, reduzimos o medo de cair, e inclusive treinar quedas sem risco de lesão.

Temos agora como objetivo realizar um ensaio clínico randomizado com os seguintes objetivos: a) avaliar a eficácia do programa de Treino Intensivo de Quedas em Trampolim para Parkinson (LIFTT) comparativamente às intervenções usuais relativamente ao equilíbrio, medo de cair, frequência e severidade das quedas, marcha, capacidade física, cognição e alterações clínicas em pessoas com DP leve ou moderada; e b) criar um protocolo de avaliação clinicamente adequado e metodologias válidas que respondam a este tipo de protocolo de intervenção em pessoas com DP.

Preveremos incluir 60 indivíduos com diagnóstico de DP idiopática, nas fases 2-4 da escala de Hoehn e Yahr, com história clínica de alterações da marcha e quedas (pelo menos 1 queda nos últimos 6 meses). Os participantes serão recrutados através na Associação Portuguesa de Doentes de Parkinson (APDPK) e no Hospital Garcia de Orta. Os participantes serão randomizados para um grupo de intervenção (GI=30) com exercícios motores-cognitivos em trampolim ou um grupo de controlo (GC=30) (cuidados standard).

O programa de treino para o GI consiste em 1h de exercícios, 3 vezes por semana durante 8 semanas, que incluirá exercícios de equilíbrio e marcha com a adição progressiva de desafios físicos e cognitivos realizados num trampolim (cama elástica) (figura 1). O grupo controlo irá receber tratamento habitual dos clínicos assistentes, serviços de saúde ou comunitários.

Todos os participantes serão submetidos a 3 momentos de avaliação motora e cognitiva: T0 antes do início do programa; T1 ao fim das 8 semanas de treino, e; T2 3 meses depois do final do programa de treino. A bateria de testes incluirá a avaliação de variáveis primárias: equilíbrio (Mini-BEST Test, análise não linear) e medo de cair (Escala de Eficácia de Quedas) e de variáveis secundárias: melhoria clínica (Escala Unificada da Doença de Parkinson); quedas (registro semanal); marcha (Timed-Up-Go Motor e Cognitivo; análise não linear); capacidade física (teste de marcha de 6 min); cognição (Avaliação Cognitiva de Montreal).

Com base nos nossos resultados preliminares (13), o programa LIFTT é bem aceite pelos participantes e demonstra ser seguro. Esperamos agora que se prove benéfico para a melhoria do equilíbrio, medo de cair, marcha, capacidade física, cognição e estado clínico geral.

O nosso projeto é inovador porque vai permitir validar o melhor contexto/ambiente para a realização de treino de equilíbrio com dupla tarefa em DP. Permitirá definir quais os instrumentos de avaliação que melhor se adequam à identificação de efeitos relacionados com este tipo de programas de treino. Paralelamente, permitirá identificar as pessoas que melhor respondem a este tipo de programas e o tipo de exercícios que preferem. Tudo isto proporcionará a utilização de intervenções não farmacológicas de uma forma segura, eficaz e adequada nos sistemas de saúde a nível mundial.

Proporcionar intervenções relevantes, seguras e progressivamente mais complexas é um empolgante avanço na gestão dos problemas de equilíbrio e alterações da marcha em DP. É urgente implementar estratégias de intervenção que respondam às lacunas na gestão da frequência e gravidade das quedas relacionadas com a interferência das funções motora e cognitiva.

Somos uma equipa multidisciplinar com o conhecimento e a experiência necessários para aplicar programas de treino com dupla tarefa (7-13), vários anos de experiência em DP, investigação clínica, avaliação funcional e análise de dados, pelo que, acreditamos ser este projeto uma mais-valia para o avanço conhecimento sobre como minimizar a sobrecarga relativa à gestão das quedas em pessoas com DP.

3.1.b (Em inglês)

3.1.b (In English)

Frequent falling in people with Parkinson's disease (PD) has been highly associated to impaired reactive postural adjustments and impairments in attentional resources (1). As such, increasing research suggest that people with PD benefit from combined balance motor and cognitive exercise (2, 3). However, uncertainties persist regarding the safety issues as some studies have shown benefit but with significant adverse events such as falls and injuries during training sessions (4, 5).

Importantly, when a person with PD is required to perform two tasks or divide attention between tasks, the lack of sufficient attentional resources results in the decrement in one or both concurrent tasks with risk of losing balance and falling (1, 4). Thus, despite the potential benefits of motor-cognitive exercise for people with PD and calls to include cognitive exercise as a component of comprehensive physiotherapy care (2), motor-cognitive programs will require specific knowledge in PD and safe environments to provide effective balance challenging exercises (6). Our team has applied this approach since 2004 (7-13). We recently applied a motor-cognitive training approach on a trampoline bed as a means to guarantee safety, reduced fear of falling, and training falling without injury (13).

We now have the intention to develop a randomized clinical trial that aims: a) to estimate the effectiveness of the Lisbon Intensive Falls Trampoline Training (LIFTT) program in addition to usual care on balance impairment, fear of falling, falls frequency and severity, gait, physical capacity, cognition and clinical impairments in people with mild or moderate PD; and b) to create a clinically adequate assessment protocol and valid methodologies that respond to this type of intervention in people with PD.

We will include 60 individuals diagnosed with idiopathic PD, in stage 2-4 Hoehn and Yahr, with clinical history of gait deficits, and a fall history (at least one fall in the last 6 months). Participants will be recruited from the Portuguese Parkinson Disease Association (APDPK) and Movement Disorders Out-patient Clinic from Hospital Garcia de Orta (MDOC-HGO).

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.

The intervention for the IG will consist of an 8-week training program with 1-hour sessions of individual training, 3-days a week, that will include a variety of balance and gait exercise on a trampoline bed (figure 1) with a progressive addition of motor and cognitive challenges. All participants will undergo to three assessments: T0 immediately before the program (baseline); T1 after training program, and; T2 3 months follow-up.

Primary outcome measures will be balance performance (assessed using the Mini-BEST Test and nonlinear analysis) and change in fear of falling (assessed using the Falls Efficacy Scale). Secondary outcomes will be change in clinical improvement (Movement Disorder Society Unified Parkinson's Disease Rating Scale), falls (Falls weekly registry), gait parameters (Motor and Cognitive Timed-Up-Go, nonlinear analysis), physical capacity (6-minute walk test), cognition (Montreal Cognitive Assessment).

Based on our preliminary results (13), the LIFTT program is safe and well received by the participants. It is now expected to have specific benefits over balance, fear of falling, gait, physical capacity, and cognitive and clinical outcomes.

This program is innovative because it will validate the benefits and ideal environment to perform balance motor-cognitive exercise programs in PD. It is also expected to define the outcome measures that best respond to such training protocol, alongside, identifying people with PD most likely to benefit and the type of exercises preferred. This will ultimately promote the safe, effective and appropriate use of non-pharmacological interventions in worldwide health care systems.

Care delivery in a salient, safe and progressively complex training mode is a promising and exciting step forward in managing balance and gait deficits in PD. Bottom line is, there is an urgent and critical need to implement care strategies to reduce the obvious pitfalls in managing frequency and severity of falls related to motor-cognitive interference in PD. Here we have a multidisciplinary team with the knowledge and necessary experience to apply balance training programs with dual tasks (7-13), several years of experience in PD, clinical

research, functional assessment and data analysis. So, we believe that this project will be an asset for the advancement of scientific knowledge in order to minimize the burden related to falls management in people with PD and their caregivers.

3.1.c Resumo para publicação (em português)

3.1.c Abstract for publication(in Portuguese)

As quedas frequentes em pessoas com Doença de Parkinson (DP) têm sido associadas a alterações dos reflexos posturais antecipatórios e dos recursos cognitivos (1). Como tal, as pessoas com DP beneficiam de programas de treino de equilíbrio com exercícios motores e cognitivos. No entanto, existem preocupações sobre a segurança necessária para a implementação de tais programas uma vez que existem estudos que demonstram efeitos adversos significativos como a ocorrência de quedas. Quando uma pessoa com DP divide a sua atenção entre 2 tarefas, a falta de recursos cognitivos atencionais resulta num impacto negativo numa ou em ambas as tarefas com aumento do risco de queda. O benefício dos exercícios motores e cognitivos e a recomendação de incluir este treino em fisioterapia com DP, exige conhecimento específico sobre a doença e sobre o envolvimento de forma a garantir a segurança e a eficácia destas intervenções. A nossa equipa tem aplicado o treino motor-cognitivo com pessoas com DP desde 2004. Temos agora como objetivo realizar um ensaio clínico randomizado com os seguintes objetivos: a) avaliar a eficácia do programa de Treino Intensivo de Quedas em Trampolim para Parkinson (LIFTT) comparativamente às intervenções usuais relativamente ao equilíbrio, medo de cair, marcha, capacidade física, cognição e alterações clínicas em pessoas com DP leve ou moderada; e b) criar um protocolo de avaliação clinicamente adequado e metodologias válidas que respondam a este tipo de protocolo de intervenção em pessoas com DP. Prevemos incluir 60 indivíduos com diagnóstico de DP idiopática, nas fases 2-4 da escala de Hoehn e Yahr, com história clínica de alterações da marcha e quedas. Os participantes serão randomizados para um grupo de intervenção (GI=30) com exercícios motores-cognitivos em trampolim ou um grupo de controlo (GC=30) (cuidados standard). O programa de treino para o GI consiste em 1h de exercícios, 3 vezes por semana durante 8 semanas, que incluirá exercícios de equilíbrio e marcha com a adição progressiva de desafios físicos e cognitivos realizados num trampolim (cama elástica). O grupo controlo irá receber tratamento habitual dos clínicos assistentes, serviços de saúde ou comunitários. Todos os participantes serão submetidos a 3 momentos de avaliação motora e cognitiva: T0 antes do início do programa; T1 ao fim das 8 semanas de treino, e; T2 3 meses depois do final do programa de treino. Com base nos nossos resultados preliminares, o programa LIFTT é bem aceite pelos participantes e demonstra ser seguro. Esperamos agora que se prove benéfico para a melhoria do equilíbrio, medo de cair, marcha, capacidade física, cognição e estado clínico geral. O nosso projeto é inovador porque vai permitir validar o melhor contexto/ambiente para a realização de treino de equilíbrio com dupla tarefa em DP. Permitirá definir quais os instrumentos de avaliação que melhor se adequam à identificação de efeitos relacionados com este tipo de programas de treino. Paralelamente, permitirá identificar as pessoas que melhor respondem a este tipo de programas e o tipo de exercícios que preferem. Tudo isto proporcionará a utilização de intervenções não farmacológicas de uma forma segura, eficaz e adequada nos sistemas de saúde a nível mundial. Proporcionar intervenções relevantes, seguras e progressivamente mais complexas é um empolgante avanço na gestão dos problemas de equilíbrio e alterações da marcha em DP. É urgente implementar estratégias de intervenção que respondam às lacunas na gestão da frequência e gravidade das quedas relacionadas com a interferência das funções motora e cognitiva. Somos uma equipa multidisciplinar com o conhecimento e a experiência necessários para aplicar programas de treino com dupla tarefa, vários anos de experiência em DP, investigação clínica, avaliação funcional e análise de dados, pelo que, acreditamos ser este projeto uma mais-valia para o avanço do conhecimento sobre como minimizar a sobrecarga relativa à gestão das quedas em pessoas com DP.

3.1.d Resumo para publicação (em inglês)

3.1.d Abstract for publication(in English)

Frequent falling in people with Parkinson's disease (PD) has been highly associated to impaired reactive postural adjustments and impairments in attentional resources. As such, increasing research suggest that people with PD benefit from combined balance motor and cognitive exercise. However, uncertainties persist regarding the safety issues as some studies have shown benefit but with significant adverse events such as falls and injuries during training sessions. Importantly, when a person with PD is required to perform two tasks or divide attention between tasks, the lack of sufficient attentional resources results in the decrement in one or both concurrent tasks with risk of losing balance and falling. Thus, despite the potential benefits of motor-cognitive exercise for people with PD and calls to include cognitive exercise as a component of comprehensive physiotherapy care, motor-cognitive programs will require specific knowledge in PD and safe environments to provide effective balance challenging exercises. Our team has applied this approach since 2004. We now have the intention to develop a randomized clinical trial that aims: a) to estimate the effectiveness of the Lisbon Intensive Falls Trampoline Training (LIFTT) program in addition to usual care on balance impairment, fear of falling, gait, physical capacity, cognition and clinical impairments in people with mild or moderate PD; and b) to create a clinically adequate assessment protocol and valid methodologies that respond to this type of intervention in people with PD. We will include 60 individuals diagnosed with idiopathic PD, in stage 2-4 Hoehn and Yahr, with clinical history of gait deficits, and a fall history. 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. The intervention for the IG will consist of an 8-week training program with 1-hour sessions of individual training, 3-days a week, that will include balance and gait exercise on a trampoline bed with a progressive addition of motor and cognitive challenges. All participants will undergo to three assessments: T0 immediately before the program (baseline); T1 after training program, and; T2 3 months follow-up. Based on our preliminary results, the LIFTT program is safe and well received by the participants. It is now expected to have specific benefits over balance, fear of falling, gait, physical capacity, and cognitive and clinical outcomes. This program is innovative because it will validate the benefits and ideal environment to perform balance motor-cognitive exercise programs in PD. It is also expected to define the outcome measures that best respond to such training protocol, alongside, identifying people with PD most likely to benefit and the type of exercises preferred. This will ultimately promote the safe, effective and appropriate use of non-pharmacological interventions in worldwide health care systems. Care delivery in a salient, safe and progressively complex training mode is a promising and exciting step forward in managing balance and gait deficits in PD. Bottom line is, there is an urgent and critical need to implement care strategies to reduce the obvious pitfalls in managing frequency and severity of falls related to motor-cognitive interference in PD. Here we have a multidisciplinary team with the knowledge and necessary experience to apply balance training programs with dual tasks, several years of experience in PD, clinical research, functional assessment and data analysis. So, we believe that this project will be an asset for the advancement of scientific knowledge in order to minimize the burden related to falls management in people with PD and their caregivers.

3.2. Descrição Técnica

3.2 Technical Description

3.2.1. Revisão da Literatura

3.2.1. Literature Review

Parkinson's disease (PD) presents many challenges due to the significant functional disabilities affecting posture, gait, daily living activities and cognition. Frequent falling in people with PD has been highly associated to impaired reactive postural adjustments and impairments in attentional resources (1, 14). Increasing research suggests that non-pharmacological interventions, such as exercise/physiotherapy and cognitive training have shown to benefit people with PD in both physical and cognitive outcomes (2, 3, 15). Combining interventions may be a new potential method of treatment and comes in line with the growing evidence on the feasibility and potential benefits of motor-cognitive training programs in older adults and in PD (16-18). Initial research in this area concluded that 30 min once a week for 3 weeks of multiple-task gait training can be feasible in people with PD (16), and sustained benefits upon multiple-task walking velocity, levels of fatigue and anxiety. Later (2010) (19) showed that one 20 min dual-task training session increased step length in 20 patients during ambulation while simultaneously performing added tasks. Currently many uncertainties persist about: the best type of motor-cognitive exercises to use and when; which type of exercises people prefer and why; the accuracy and type of benefit they reflect; what outcomes to use; where can they be applied to guarantee the safety of participants, etc.

When people with PD are required to divide attention between tasks, the lack of sufficient attentional resources results in the decrement in one or both concurrent tasks with possible loss of balance and risk of falling (1). Supervised programs with a focus on challenging balance and driving motor-cognitive processes are recommended to prevent falls and maintain mobility in PD (20). Such programs will require specific knowledge in PD, in cognitive rehabilitation and the use of safe environments. Management is currently challenged as we see a proliferation of exercise programs with limited evidence and expertise, placing patients at risk and unnecessary procedures (6).

In the LIFTT program, we will explore a unique solution focused on improving gait and balance under dual task interference with reduced risks (safe environment with trampoline beds with clinical supervision). Trampoline training is a nontraditional form of exercise that incorporates weight shifting, dynamic changes in balance, aerobic training, strength, and reduce risk of injury if a fall should happen. It has been shown to be feasibility and efficient in different populations such as, older adults (21), individuals with intellectual disabilities and people who suffered a stroke (22). The study by Aragão (2011) (21), showed that a 14-week program training on a trampoline improved the ability of older adults to recover balance during forward falls due to higher rate of hip moment generation. A 2-week trampoline exercise intervention program was an effective intervention for improve motor and balance ability of school aged children with intellectual disability (23). Hahn (2015) (22), also showed that a both the trampoline and the control group had significant improvements in balance, gait, and falls self-efficacy compared to before the 6-week intervention (30 min sessions, 3 times a week) after stroke.

In PD, we identified one study that compared the effect of 8-week rebound therapy-based exercise program over range of motion, proprioception, and quality of life in 20 people with PD (24). In 2019, our team published preliminary results (13) of the acceptability of novel trampoline training in 13 people with PD. Participants were "very satisfied" or "satisfied" with the program. Adverse effects were mild ("feeling tired", excessive sweating). Transportation, physical disability and dependency on others were the main barriers for participation. Caregiver support, easy transportation, perceiving the benefits and flexibility in schedules were main facilitators. Participants had favorable perceived benefit (80% very useful; 20% moderately useful) and all referred that they were willing to continue in the program and recommend it to others. Our preliminary results suggest that training on a trampoline combining balance and cognition was well received and safe for people with DP.

In this project we will use a large size trampoline beds (a differentiating factor) that allows participants to train not only the balance exercises more freely, but also allows for true gait training (under uni and dual task conditions) and practice safe falling strategies (figure 1). We know that more significant transfer effects will occur in the conditions that are trained, so the closer the activity is to how it happens in real life, the greater our chances of improving it outside the clinic. In our project we want to objectively improve the participant's capacity to dual task in real life by mimicking activities in daily-life that the individuals do under dual task conditions.

Our project tackles the complex nature of falls in PD. It will validate the use of trampoline beds as a safer environment to train dual task gait deficits in PD. Trampoline exercises with motor-cognitive challenges may ultimately represent an effective, innovative and salient mode of motor-cognitive training with significant impact on balance, fear of falling, frequency and severity of falls, gait, and overall improvements in cognitive function. It will also allow us to apply a novel approach of teaching older adults the movement strategies to fall safely. Identifying effective outcome measures that are responsive to such interventions is also needed to improve the ability to design future clinical studies with such programs. Results will also contribute to the urgent knowledge needed to define clear dual motor-cognitive task guidelines for PD to allow minimize the burden related to falls management.

3.2.2. Plano e Métodos

3.2.2. Plan and Methods

An innovative, effective, and safe training protocol such as motor-cognitive exercises on a large trampoline beds (figure 1) can be the efficient solution to achieve the benefits of motor-cognitive trainings while bypassing safety issues and falling with injury. It will also allow for training of safe fall landing strategies, a novel approach to reduce the risk of injury in accidental falls that will lead to a greater confidence in everyday activities, with improve autonomy and quality of life.

Our solution will be:

- 1- To perform a randomized controlled trial to estimate the effectiveness of the LIFFT program in addition to usual care on: balance impairment; fear of falling; falls frequency and severity; clinical impairments; gait; physical capacity, and cognition in people with mild or moderate PD.
- 2- To create a clinically adequate assessment protocol and valid methodologies that respond to this type of intervention protocol in people with PD.

Study Procedures

Planning (task 1):

Firstly, we will focus on the elaboration of all documents and necessary procedures for the ethical approval and study implementation. The study will be submitted to the National Data Protection Commission and to the ethical committee of all partner's institutions evolved, to ensure all requirements for the legal protection of participant's data. We also will deal with logistical procedures to rent the training place (Bounce Inc. Lisbon), already previously contacted and available for this partnership.

Participant recruitment (task 2a):

People with 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 (JD) and the Neurologist (MG), respectively.

Participants will be invited to voluntarily participate in the study if they fulfill the inclusion criteria:

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

Participants will be excluded if they have:

- a) Severe postural instability assessed by MDS-UDPRS Part III item 3.12;
- b) Severe cognitive difficulties and significant active psychiatric problems that aggravate when exercising.

Screening (task 2a)

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 research's.

Participants Assessments (task 2b)

Assessments will take place in a private room of the Bounce, Inc. (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 (CG, JF, ACR, JV) will be blind for group intervention (task 3).

All participants will be assessed in ON medication phase with the following specific clinical scales and tests that will have their order randomized:

Primary outcomes:

- a) Balance (Mini-BEST Test) (2);
- b) Fear of falling (Falls Efficacy Scale - FES-I) (2).

Secondary outcomes:

- c) Clinical impairments (The Movement Disorder Society Unified Parkinson Disease Rating Scale - MDS-UPDRS) (25);
- d) Frequency and severity of falls (falls weekly registry) (2);
- e) Gait (Motor and Cognitive Timed Up Go - TUG) (2);
- f) Physical capacity (6 min walking distance test - 6MWD) (2), and;
- g) Cognition (Montreal Cognitive Assessment - MoCA) (26);

Nonlinear gait and balance analysis:

For 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 quite for 2 min, so sufficient amount of data will be collected for nonlinear features extraction.

In the end of T0 assessment an online software will be used to generate the randomization plan to task 3.

Training sessions (task 3)

For the 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 international recognized educator of motor and cognitive rehabilitation programs (JD). 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. See complete description in task 3 below.

The 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 (Bounce, Inc.) in Lisbon and 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 withdrawal 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 (task 4)

We will perform descriptive statistics of data collected at T0, T1 and T2, to identify differences between the four 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.

Why this plan?

Because motor-cognitive training programs are being applied but participants are being placed at risk of falling! Our team has experience in creating, applying and researching such programs since 2004 (7-13) and have now the know-how and the opportunity to explore a methodology that we believe to be innovative and efficient as it will guarantee safety and falling without injury while improving clinical outcomes in PD.

With the LIFTT program we expect benefits in balance, gait, physical capacity, cognitive performance and utilization of safe fall landing strategies with decreased fear of falling. We will also gain knowledge on the best outcome measures to assess such programs. This will add to the therapeutic options in PD and promote the appropriate use of non-pharmacological interventions in health care systems.

Team role:

The PI and task 1 leader (C. Godinho) with AC. Ramos and J. Fernandes will be responsible for all procedures associated to data protection and ethical approvals of the project, as well as ensuring compliance with all the specifications legally required for the development of scientific projects.

The MDOC-HGO neurologist (M. Grunho) and the physical therapist specialized in PD and APDPk Health National Coordinator (J. Domingos) will be responsible for recruitment and screening (task 2a). Assessments (task 2b) will be led by J. Fernandes. The J. Vaz (physiotherapist) will ensure specialized nonlinear data analysis of the participants' motor function. The cognitive assessment will be carried out by AC. Ramos (clinical psychologist).

The implementation of the LIFTT program will be ensured by co-PI (task 3 leader) with assistance of MSc Student fellow.

L. Proença with AC. Ramos (task 4 leaders) are responsible for all statistical analysis.

All team members are responsible for results dissemination actions through participation on scientific meetings and for design, writing and review the scientific articles foreseen for the project.

3.2.3. Tarefas

3.2.3. Tasks

Lista de tarefas (4)

Task list (4)

Designação da tarefa

Task denomination

Planning

Data de início

Start date

01-01-2022

Data de fim

End date

28-02-2022

Duração

Duration

2

Pessoas * mês

Person * months

1,6

Descrição da tarefa e Resultados Esperados

Task description and Expected results

The planning phase will include a variety of tasks, namely: Writing Research, Plan Protocol, Solicitation and wait for Ethics permission of Proposed Research, Create evaluation protocol (CRF), Information Letter to the Participant, Informed Consent Form for the Participant, Confidentiality Agreement for Research Personnel, Logistic organization of research site.

The information will be confidentially handled in order to prevent subject names or other directly identifiable information appear on any reports, publications, or other disclosures of clinical study outcomes. All data will be anonymized through the application of codes, using the alphanumeric system through the code P, relative to participant, followed by the Arabic numbering, according to the order of data collection. The data will be introduced by the investigators on a database to perform statistical analysis.

Record maintenance and retention.

Essential documents will be archived in a way that ensures that they are readily available, upon request, to the competent authorities.

CRFs will be used as source documents for collecting data. All paper copies will be stored in a locked file as well as all electronic data. Data will be maintained for 5 years in a restricted access locked file cabinet at Egas Moniz University. After that, they will be destroyed. All data will be confidentially locked and all subject information will remain anonymous.

The informed consent form (CRF) will contain comprehensive information about contents, objectives, duration, procedures, voluntariness and possible risks of study participation. It will be emphasized that the participant is at liberty to withdraw their consent to participate at any time, without penalty or loss of benefits to which the participant is otherwise entitled. Participants who refuse to give, or withdraw, written informed consent will not be included or continued in this study, but this will not impact on their subsequent care. During the screening visit, an explanation of the objective and compliance needed for the study will be given to the participants and caregivers. Any kind of questions will be considered and answered. In case of agreement to voluntarily participate in the study, the participant has to sign 2 copies of the informed consent form; one will be given to the participant, the other form will be retained at the local study center.

Due to the organizational capacity and large research experience of this multidisciplinary team, we expect the fulfillment of the necessary procedures to obtain a favorable ethical opinion as quickly as possible.

Prior to the ethical approval of the study, the recruitment of participants cannot be initiated, which limits any other study procedure.

Membros da equipa de investigação nesta tarefa

Members of the research team in this task

Ana Catarina Marques Barge Ramos; Catarina Afonso Godinho; júlio alexandre belo andrade fernandes;

Designação da tarefa

Task denomination

Recruitment, Screening and Assessments

Data de início

Start date

01-03-2022

Data de fim

End date

31-03-2023

Duração

Duration

13

Pessoas * mês

Person * months

18,3

Descrição da tarefa e Resultados Esperados

Task description and Expected results

-Task 2a Recruitment and screening:

A senior physiotherapist specialist (JD) and the neurologist (MG) will be responsible for recruiting 60 patients' from APDPk and MDOC-HGO accordingly to the above cited inclusion/exclusion criteria. This phase will include: recruitment, patient clinical evaluation (screening), enrollment in the study and obtaining written informed consents.

-Task 2b Assessments (Bounce Inc.):

Assessments will be conducted by 4 researchers (CG, JF, ACR, JV) blinded for the group intervention, through a battery of tests, equal for both IG and CG group, prior to (T0) and immediately after the 8-week intervention (T1) and at 3 months' follow-up (T2). All assessments will be done during the ON phase of patient's levodopa medication and at the same time of day to minimize the impact of medication fluctuations. Additionally, the order of the objective and clinical tests will be randomized for every participant to avoid systematic bias and in the end of this task all participants are also randomly allocated to the IG and CG. An online software will be used to generate the randomization plan, using a random block sizes method. Besides, proper randomization ensures no prior knowledge of group allocation, which is following the single-blind assessment process described above.

Clinical test and Scales (CG, JF, ACR): all these clinical tests and scales have validated protocols so we will follow the specific recommendations for the application of each one.

a) Balance (Mini-BEST Test) (2);

b) Fear of falling (Falls Efficacy Scale - FES-I) (2).

c) Clinical impairments (The Movement Disorder Society Unified Parkinson Disease Rating Scale - MDS-UPDRS) (25);

d) Frequency and severity of falls (falls weekly registry) (2);

e) Gait (Motor and Cognitive Timed Up Go - TUG) (2);

f) Physical capacity (6 min walking distance test - 6MWD) (2); and;

g) Cognition (Montreal Cognitive Assessment - MoCA) (26).

Nonlinear assessments (JV):

GAIT: To assess the gait treadmill walking trial, we will first determine the preferred walking speed (PWS). The PWS will be determined by first starting the treadmill running at 1km/h. Then, we will increase the treadmill's speed by 0.1km/h until the participant feels it is going too fast to be comfortable. At this point, we will decrease the speed by 0.1km/h until the participant refers it is going too slow to be comfortable. This procedure will be done three times and the mean of the six values will be used as PWS. Once the PWS is completed, we will place the Accelerometers (Plux Biosignals, Portugal) while the participant rests for about 10mins. Then, a 10mins long walking trial will be conducted at the PWS.

BALANCE: The participants will be asked to perform 2mins long double-leg standing trials with eyes-opened and eyes-closed. Measures will take place on a forceplate (Plux, Portugal) and collected at 1kHz.

- T0: Application of baseline assessment protocol - 2 h p/ participant
- T1: Application of post-training (LIFTT or usual care) assessment protocol - 2h p/ participant
- T2: Application of follow-up assessment protocol - 2h p/ participant

The tasks explained above are carried out in sequence. Task 2 will only start after the completion of task1. Task 2a is expected to identify and qualify 60 patients according to the established selection criteria. These patients are expected to agree to participate in the study by providing their informed consent. Only after documenting this consent, will task 2b proceed, in which the assessments described above will apply.

The 3 evaluation moments will allow to analyze the effects of the program on the participants. The 3 month-term follow-up will allow us to address important questions concerning potential maintenance of effects of and limitations of transfer of this individualized trampoline balance training.

Membros da equipa de investigação nesta tarefa

Members of the research team in this task

(B) Bolsa 1; Ana Catarina Marques Barge Ramos; Catarina Afonso Godinho; João Pedro Casaca de Rocha Vaz; Josefa Maria Malta Domingos; júlio alexandre belo andrade fernandes; Miguel Dias Grunho;

| Designação da tarefa | Data de início | Data de fim | Duração | Pessoas * mês |
|-------------------------------|----------------|-------------|----------|-----------------|
| Task denomination | Start date | End date | Duration | Person * months |
| Delivery of the LIFTT Program | 01-04-2022 | 31-12-2022 | 9 | 11 |

Descrição da tarefa e Resultados Esperados

Task description and Expected results

This is a randomized controlled trial comparing an innovated trampoline motor-cognitive exercise intervention to best practice usual care.

In this task we aim to:

- Organize training site and equipment;
- Deliver of the intervention program – three times a week for 8 weeks (24 days per participant, 1 hour per day/per participant);
- Creating ongoing positive, rewarding training environments.

The intervention will consist of an 8-week individual training regime (1-hour individual training, three times per week), which will be performed by two professionals (JD and MSc student fellow) to ensure training progression and safety. Sessions will be led by a physiotherapist specialized in Parkinson for more than 15 years and international recognized educator of motor and cognitive rehabilitation programs.

Each session will start with a warmup outside of the trampolines, comprising a varied of body movements and walking tasks focusing on the cardiovascular system, (lasting for 10 min). After the sessions will consist of exercising on the trampolines using motor and cognitive exercises. Motor exercises will include an array of frequently recommend movements that directly enhance functional activities of daily living, and relevant to PD such as sit and standing; stepping in place; unexpected balance challenges, walking; reaching; turning and running or getting up from the floor (28). All physical exercises will focus upon high-amplitude, multidirectional movements with increasing speed and complexity. Cognitive exercises will target the 4 main cognitive domains particularly affected in PD: attention, working memory, executive function, and visual exploration. During the sessions, modifications to the exercises will include adjustments to type of physical activities, length, use of verbal feedback, time for learning, and additional cognitive exercises. The utilization of safe fall landing strategies will be taught and reinforced throughout the sessions. There is emerging evidence to suggest that these landing strategies can be safe and effective for a geriatric population (29); however, this intervention has not been examined in a clinical physical therapy practice setting in PD. This will be an additional novelty of our program.

Our study will be the first to show that the combination of motor and cognitive interventions on a trampoline will significantly improve balance and fear of falling in PD, alongside improvements in clinical status, physical capacity, gait and cognition. This new training approaches such as trampoline exercises can help health professionals to better train motor and cognitive performance while guaranteeing safety and falling without injury.

Therapist will ask about falling outside the program at the end of each week and register in study log. Feedback from each session will be used to adapt the program to the personal needs of each participant.

We will enhance translation of this research intervention into the clinical setting by allowing the therapists conducting the training to adapt the program to the patient, without a restrictive standardized protocol.

We also expect that this randomized controlled trial has the potential to stimulate other groups to study similar protocols, provide new knowledge in the fall's arena and a paradigm shift in balance interventions in PD.

Guidance for exercise in PD was underpinned by clinical experience from the team and evidence from the European Physiotherapy Guidelines for PD (27).

Task 3 will only start after the development of tasks 1 and 2. As we contemplated 2 phases for the assessment of participants', after finishing the task 3, all participants will be immediately assessed, and the follow-up will be carried out 3 months after, thus making it possible to finish task 2b and give start task 4 (data analysis and results dissemination).

Membros da equipa de investigação nesta tarefa

Members of the research team in this task

(B) Bolsa 1; Josefa Maria Malta Domingos;

| Designação da tarefa | Data de início | Data de fim | Duração | Pessoas * mês |
|---|----------------|-------------|----------|-----------------|
| Task denomination | Start date | End date | Duration | Person * months |
| Data analysis and results dissemination | 01-05-2022 | 30-06-2023 | 14 | 12,56 |

Descrição da tarefa e Resultados Esperados

Task description and Expected results

In this task we will proceed to the data analysis with results extraction, interpretation, dissemination.

For the first group of assessments the data will be extract directly from the scales and test scores (see task 2).

For the data extraction related to nonlinear assessment procedures are:

BALANCE: First, the signals will be downsampled to 50Hz. Linear measures of balance will be calculated for both anterior-posterior and medial-lateral components from the centre of pressure (COP): range, sway, displacement, velocity, frequency. Additionally, sample entropy will be used to calculate the regularity of the COP as a metric of complexity. Input parameters of $m=2$, $r=0.2$ and $N=6000$ (120secx50Hz).

GAIT: We will first run our already developed custom Matlab code to determine heel strike and toe-off events. We will carefully visual inspect this event detection which often needs adjustments given the different treadmill's speed that participants will walk at.

Once the events detection is finalized, we will crop the time-series by removing the first 15sec to avoid any familiarization with the treadmill. Then, the time between the temporal events will be calculated for the 10mins period, resulting in a time-series of inter-stride-intervals. Each data point will represent a stride interval. Lastly, we will use Detrended Fluctuation Analysis to determine the fractal properties of gait - a well-known feature of adaptability of the locomotor system. We will use the range of window from 16 to $N/8$, where N stands for the number of stride intervals.

A set of descriptive and inferential statistical methodologies will be applied, for data characterization and group comparison. In order to evaluate the effect of the intervention and simultaneously account for time-related intra-individual correlation, a multivariate analysis approach based on Linear Mixed Models will be applied, allowing both fixed and random effects to be considered.

We expect to show that LIFTT program that incorporates progressive complexity with motor and cognitive activities will improve a battery of outcomes.

Dissemination plan

The overall results from previous tasks undergo a translational dissemination action to health professional community and for physiotherapeutic, clinical exercise and neurological Societies at International, National and Regional level.

At an international level, we will collaborate with the European Parkinson Disease Association (EPDA) to disseminate the project results to all institutional members of the EPDA in more than 20 European countries.

At a national level, we will have the collaboration of the Portuguese Medical Society for Movement Disorders (SPDMov) aiding in the dissemination of the project results through its partners and patients and in the annual national meeting that brings together over 300 neurologists and health professionals in PD and on SPDMov website. Our institutional collaboration protocol with the Associação Portuguesa de doentes de Parkinson (APDPk) will disseminate the results on their website and educational and scientific events, namely at the World Parkinson Day Commemoration events.

At a regional level, we have the support and collaboration of Hospital Garcia de Orta (HGO) and their health professionals and community.

According to the social responsibility mission of Egas Moniz and its partner institutions, the actions promoted by this task will allow transferring knowledge from scientific research to

the general public.

L, Proença and A.C. Ramos will be responsible for all data analysis. The license for Windows, Microsoft office, SPSS and AMOS used for writing papers and data analyses will be provided by the Egas Moniz University with a collective license that already exists.

All team will be responsible for writing and reviewing scientific articles and actively participating in the dissemination of the results through participation in national and international scientific congresses and meetings.

Membros da equipa de investigação nesta tarefa

Members of the research team in this task

(B) Bolsa 1; Ana Catarina Marques Barge Ramos; Catarina Afonso Godinho; João Pedro Casaca de Rocha Vaz; Josefa Maria Malta Domingos; júlio alexandre belo andrade fernandes; Luis Francisco Alexandrino Proença; Miguel Dias Grunho;

3.2.4. Calendarização e Gestão do Projeto

3.2.4. Project Timeline and Management

3.2.4.a Descrição da Estrutura de Gestão

3.2.4.a Description of the Management Structure

The LIFTT project assembles a highly motivated team of researchers with complementary expertise. The multidisciplinary team consist of C. Godinho, Exercise Physiologist and Professor from Egas Moniz University (EM) with expertise in Exercise prescription, training and in clinical research coordination functions, a senior investigator linked to several projects involving PD patients, an active member in Portuguese and European PD associations PI and responsible for TASK 1.

J. Domingos a Senior physiotherapist specialist in PD, co-PI and Investigator with expertise in clinical research in movement disorders, and PhD student of EM University, works in PD community care since 2004, is health coordinator in APDPk and board member of EPDA, is responsible for TASK 3.

J. Fernandes, Nurse Specialist in Rehabilitation, Professor in EM, and researcher with expertise in fall prevention and risk assessment, will be co-responsible for TASK 2 with J. Vaz an experienced physiotherapist and expert in nonlinear gait and balance analysis (30) from Faculdade de Motricidade Humana (FMH).

A.C. Ramos, phycologist, senior investigator and Professor in EM with expertise in data analysis and clinical research with L. Proença, senior investigator, Professor in EM and expertise in data analysis will be responsible for TASK 4.

In addition, the team includes a fellow MSc student recruited after approval of the project.

The PI will be responsible for all contractual deliverables to FCT. Execution of each task will be supervised by the PI in close articulation with all team. Together, they will supervise the development of the work involved for each task and will be responsible for the progression of the work, according to the milestones.

The research data and methodologies developed will be reported to FCT. Scientific results will be published in international and national journals and presented in conferences and meetings in Portugal and abroad. FCT support will be acknowledged. The EM administrative support will contribute to the project fund management and correspondence with FCT, in strict compliance with the legally required deadlines. All EU Directives will be followed and this project will not collide with the social, ethical and environmental laws or principles applicable in Portugal and in the European Union.

A monthly remote meeting with all team will take place to exchange ideas, resolution of eventual issues and work on FCT reports.

3.2.4.b Lista de Milestones

3.2.4.b Milestone List

| Data | Designação da milestone |
|---|--|
| Date | Milestone denomination |
| 01-03-2022 | Ethical Committees Approvals |
| Descrição | |
| Description | |
| Prepare documents for the Ethics Committees including informed consent, CRFs and build databases with all criteria evaluated by the LIFTT Project. | |
| Data | Designação da milestone |
| Date | Milestone denomination |
| 31-10-2022 | Completion enrolment of participants and baseline assessment |
| Descrição | |
| Description | |
| That all participants will be assessed in terms of inclusion and exclusion criteria, motor and cognition function (T0 baseline). | |
| Data | Designação da milestone |
| Date | Milestone denomination |
| 31-12-2022 | Completion of LIFTT program |
| Descrição | |
| Description | |
| Completion of LIFTT program. | |
| Objective: That all participants complete LIFTT program and T1 assessment. | |
| Data | Designação da milestone |
| Date | Milestone denomination |
| 30-04-2023 | Completion of follow-up assessments and data analysis. |
| Descrição | |
| Description | |
| To assess all participants 3 months after intervention (T2), and preform data analysis. | |
| Data | Designação da milestone |
| Date | Milestone denomination |
| 30-06-2023 | Results dissemination |
| Descrição | |
| Description | |
| Preparation of several articles with peer review in renowned journals from various health fields such as Neurology, Physiotherapy, Psychology. The dissemination of the results will also include the presentation of oral and poster communications in National and International Conferences. | |

3.2.4.c Cronograma

3.2.4.c Timeline

Ficheiro tipificado como "Cronograma", no 9. Ficheiros Anexos, desta Visão Global (caso exista).

File with "Timeline" type at 9. Attachments (if exists).

3.3. Referências Bibliográficas

3.3. Bibliographic References

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| | | | |
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| 6 | (6) | 2018 | Domingos J, Dean J, Godinho C, Melo F. Proliferation of community exercise programs with limited evidence and expertise: Safety implications. <i>Mov Disord</i> . 2018 Aug;33(8):1365-1366. doi: 10.1002/mds.27373. Epub 2018 Aug 25. PMID: 30145814. |
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| 13 | (13) | 2019 | Domingos, J.; Godinho, Catarina; John Dean; Katarzyna Smilowska; Melo, Filipe. "Acceptability of a novel trampoline intervention in rehabilitation for Parkinson's disease. Perceived barriers and facilitators". <i>Journal of Parkinson's Disease</i> 9 s1 (2019): 134. In <i>Abstract Book of the 5th World Parkinson Congress, Kyoto, Japan, June 4–7, 2019</i> . 1 Jan. 1 – 278. |
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| 15 | (15) | 2015 | Petrelli A, Kaesberg S, Barbe MT, Timmermann L, Rosen JB, Fink GR, Kessler J, Kalbe E. Cognitive training in Parkinson's disease reduces cognitive decline in the long term. <i>Eur J Neurol</i> . 2015 Apr;22(4):640-7. doi: 10.1111/ene.12621. Epub 2014 Dec 22. PMID: 25534579. |
| 16 | (16) | 2008 | Canning CG, Ada L, Woodhouse E. Multiple-task walking training in people with mild to moderate Parkinson's disease: a pilot study. <i>Clin Rehabil</i> . 2008 Mar;22(3):226-33. doi: 10.1177/0269215507082341. PMID: 18285432. |
| 17 | (17) | 2015 | Fernandes Â, Rocha N, Santos R, Tavares JM. Effects of dual-task training on balance and executive functions in Parkinson's disease: A pilot study. <i>Somatosens Mot Res</i> . 2015;32(2):122-7. doi: 10.3109/08990220.2014.1002605. Epub 2015 Apr 15. PMID: 25874637. |
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| 20 | (20) | 2017 | Fasano A, Canning CG, Hausdorff JM, Lord S, Rochester L. Falls in Parkinson's disease: A complex and evolving picture. <i>Mov Disord</i> . 2017 Nov;32(11):1524-1536. doi: 10.1002/mds.27195. Epub 2017 Oct 25. PMID: 29067726. |
| 21 | (21) | 2011 | Aragão FA, Karamanidis K, Vaz MA, Arampatzis A. Mini-trampoline exercise related to mechanisms of dynamic stability improves the ability to regain balance in elderly. <i>J Electromyogr Kinesiol</i> . 2011 Jun;21(3):512-8. doi: 10.1016/j.jelekin.2011.01.003. Epub 2011 Feb 8. PMID: 21306917. |
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| | | | |
|----|------|------|---|
| | | | Lees A, Leurgans S, LeWitt PA, Nyenhuis D, Olanow CW, Rascol O, Schrag A, Teresi JA, van Hilten JJ, LaPelle N; Movement Disorder Society UPDRS Revision Task Force. Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS): scale presentation and clinimetric testing results. Mov Disord. 2008 Nov 15;23(15):2129-70. doi: 10.1002/mds.22340. PMID: 19025984. |
| 26 | (26) | 2008 | Simões, M. R., Freitas, S., Santana, I., Firmino, H., Martins, C., Nasreddine, Z., & Vilar, M. (2008). Montreal Cognitive Assessment (MoCA): Manual - Versão final portuguesa [MoCA: Manual – final version]. Coimbra: Serviço de Avaliação Psicológica, Faculdade de Psicologia e de Ciências da Educação da Universidade de Coimbra. |
| 27 | (27) | 2018 | Marques-Vieira, C. M. A., Sousa, L. M. M., Sousa, L. M. R., & Berenguer, S. M. A. C. (2018). Validação da Falls Efficacy Scale International numa amostra de idosos portugueses. Revista Brasileira de Enfermagem, 71(Suppl. 2), 747-754. |
| 28 | (28) | 2014 | Keus, S. H. J., Munneke, M., Graziano, M., Paltamaa, J., Pelosin, E., Domingos, J., Bloem, B. R. (2014). European Physiotherapy Guideline for Parkinson's disease. KNGF/ParkinsonNet, the Netherlands. |
| 29 | (29) | 2021 | S G Kinney, PT, DPT, J D Kiesel, PT, DPT, Utilization of Safe Fall Landing Strategies in Physical Therapist Management of Geriatric Populations: A Case Report, Physical Therapy, Volume 101, Issue 3, March 2021, pzaa226, https://doi.org/10.1093/ptj/pzaa226 |
| 30 | (30) | 2020 | Vaz JR, Knarr BA, Stergiou N. Gait complexity is acutely restored in older adults when walking to a fractal-like visual stimulus. Hum Mov Sci. 2020 Dec;74:102677. doi: 10.1016/j.humov.2020.102677. Epub 2020 Oct 15. PMID: 33069099. |

3.4. Publicações Anteriores

3.4. Past Publications

| Nº de Ordem | Referência | Ano | Publicação |
|-------------|------------|------|---|
| Order No. | Reference | Year | Publication |
| 1 | (2) | 2015 | Capato TTC, Domingos JMM, Almeida LRS para a Versão em Português da Diretriz Europeia de Fisioterapia para a Doença de Parkinson, 2015. https://www.parkinsonnet.nl/app/uploads/sites/3/2019/11/diretriz_dp_brasil_versao_final_publicada.pdf |
| 2 | (3) | 2020 | Radder DLM, Lígia Silva de Lima A, Domingos J, Keus SHJ, van Nimwegen M, Bloem BR, de Vries NM. Physiotherapy in Parkinson's Disease: A Meta-Analysis of Present Treatment Modalities. Neurorehabil Neural Repair. 2020 Oct;34(10):871-880. doi: 10.1177/1545968320952799. Epub 2020 Sep 11. PMID: 32917125; PMCID: PMC7564288. |
| 3 | (4) | 2015 | Domingos, J. M., Godinho, C., Dean, J., Coelho, M., Pinto, A., Bloem, B. R., & Ferreira, J. J. (2015). Cognitive Impairment in Fall-Related Studies in Parkinson's Disease. Journal of Parkinson's disease, 5(3), 453–469. https://doi.org/10.3233/JPD-150590 |
| 4 | (6) | 2018 | Domingos J, Dean J, Godinho C, Melo F. Proliferation of community exercise programs with limited evidence and expertise: Safety implications. Mov Disord. 2018 Aug;33(8):1365-1366. doi: 10.1002/mds.27373. Epub 2018 Aug 25. PMID: 30145814. |
| 5 | 30 | 2020 | Vaz JR, Knarr BA, Stergiou N. Gait complexity is acutely restored in older adults when walking to a fractal-like visual stimulus. Hum Mov Sci. 2020 Dec;74:102677. doi: 10.1016/j.humov.2020.102677. Epub 2020 Oct 15. PMID: 33069099. |

4. Equipa de investigação

4. Research team



4.1 Lista de membros

4.1. Members list

| Nome | Função | Grau | Custos (€) | % de dedicação | CV nuclear | CV |
|------------------|-----------------------------|--------|------------|-----------------|------------|--------------|
| Name | Role | Degree | Costs (€) | % of commitment | Core CV | |
| Catarina Godinho | Inv. Responsável | - | 0,00 | 35 | ✓ | CIÊNCIAVITAE |
| Josefa Domingos | Co-investigador Responsável | - | 0,00 | 25 | ✓ | CIÊNCIAVITAE |
| Ana Ramos | Investigador | - | 0,00 | 15 | ✓ | CIÊNCIAVITAE |
| João Vaz | Investigador | - | 0,00 | 10 | ✓ | CIÊNCIAVITAE |
| Júlio Fernandes | Investigador | - | 0,00 | 15 | X | CIÊNCIAVITAE |
| Luis Proença | Investigador | - | 0,00 | 10 | X | CIÊNCIAVITAE |
| Miguel Grunho | Investigador | - | 0,00 | 10 | X | CIÊNCIAVITAE |

(O curriculum vitae de cada membro da equipa está disponível clicando no nome correspondente)

(Curriculum vitae for each research team member is available by clicking on the corresponding name)

Total: 7

4.2. Lista de membros a contratar durante a execução do projeto

4.2. Members list to hire during project's execution

| Membro da equipa | Função | Duração | %tempo |
|------------------|----------|----------|--------|
| Team member | Role | Duration | %time |
| (B) Bolsa 1 | Bolseiro | 12 | 100 |

Total: 1

5. Outros projetos

5. Other projects



5.1. Projetos financiados

5.1. Funded projects

(Sem projetos financiados)

(No funded projects)

5.2. Candidaturas similares

5.2. Similar applications

(Sem Candidaturas Similares)

(No Similar applications)

6. Indicadores previstos

6. Expected indicators

Indicadores de realização previstos para o projeto

Expected output indicators

| Descrição | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
|--|------|------|------|------|------|-------|
| Description | | | | | | |
| A - Publicações | | | | | | |
| Publications | | | | | | |
| Livros | 0 | 0 | 1 | 0 | 0 | 1 |
| Books | | | | | | |
| Artigos em revistas internacionais | 0 | 1 | 3 | 0 | 0 | 4 |
| Papers in international journals | | | | | | |
| Artigos em revistas nacionais | 0 | 0 | 1 | 0 | 0 | 1 |
| Papers in national journals | | | | | | |
| B - Comunicações | | | | | | |
| Communications | | | | | | |
| Comunicações em encontros científicos internacionais | 0 | 2 | 2 | 0 | 0 | 4 |
| Communications in international meetings | | | | | | |
| Comunicações em encontros científicos nacionais | 0 | 2 | 2 | 0 | 0 | 4 |
| Communications in national meetings | | | | | | |
| C - Relatórios | | | | | | |
| Reports | 0 | 1 | 1 | 0 | 0 | 2 |
| D - Organização de seminários e conferências | | | | | | |
| Organization of seminars and conferences | 0 | 0 | 1 | 0 | 0 | 1 |
| E - Formação avançada | | | | | | |
| Advanced training | | | | | | |
| Teses de Doutoramento | 0 | 0 | 0 | 0 | 0 | 0 |
| PhD theses | | | | | | |
| Teses de Mestrado | 0 | 0 | 1 | 0 | 0 | 1 |
| Master theses | | | | | | |
| Outras | 0 | 0 | 0 | 0 | 0 | 0 |
| Others | | | | | | |
| F - Modelos | | | | | | |
| Models | 0 | 0 | 0 | 0 | 0 | 0 |
| G - Aplicações computacionais | | | | | | |
| Software | 0 | 0 | 0 | 0 | 0 | 0 |
| H - Instalações piloto | | | | | | |
| Pilot plants | 0 | 0 | 0 | 0 | 0 | 0 |
| I - Protótipos laboratoriais | | | | | | |
| Prototypes | 0 | 0 | 0 | 0 | 0 | 0 |
| J - Patentes | | | | | | |
| Patents | 0 | 0 | 0 | 0 | 0 | 0 |
| L - Outros | | | | | | |
| Other | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 |
| | 0 | 0 | 0 | 0 | 0 | 0 |

Acções de divulgação da actividade científica

Scientific activity spreading actions

In the 3 main strategies of LIFTT project dissemination, the communication contents and channels will be tailored to different target groups:

a) Traditional scientific presentations and manuscripts will be presented in scientific conferences and journals;

b) Promotion of project activities through social networks;

c) the LIFTT project will produce a guideBook for practitioners to disseminate recommendations on the prevention of falls based on the outcomes of the project for the stakeholders including the European Parkinson's Disease Association (EPDA), the Portuguese Parkinson disease Association (APDPk) and the Portuguese Society of Movement Disorders (SPDMov), and National public and private Hospitals.

The main dissemination task of the scientists in this team project is to transfer of research findings and knowledge to the scientific community. Dissemination of the research carried out will be through publication and presentation at scientific conferences as well as in scientific journals.

The following scientific conferences and journals will be targeted:

Potential events: World Parkinson Congress; International congress of Parkinson and movement disorders; Annual Meeting of Portuguese Movement Disorders Association, Ageing Congress; international rehabilitation nursing congress 2023

Potential journals: Movement Disorder (MDJ); Journal of Parkinson´s Disease (JPD); Journal of Parkinsonism and Related Disorders; Neurorehabilitation and Neural Repair; Journal of Physiotherapy; Physical Therapy; Clinical Rehabilitation; BMC Sports Science, Medicine and Rehabilitation.

FCT support is ever present as a standard academic good practice concerning citation. Websites and social media are the main communication tool and the interface for general audience.

7. Orçamento

7. Budget

Instituição Proponente

Principal Contractor

Egas Moniz - Cooperativa de Ensino Superior, CRL

| Descrição Description | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
|---|------|-----------|-----------|------|------|-----------|
| Recursos Humanos Human resources | 0,00 | 9.710,00 | 1.942,00 | 0,00 | 0,00 | 11.652,00 |
| Missões Missions | 0,00 | 2.000,00 | 3.000,00 | 0,00 | 0,00 | 5.000,00 |
| Subcontratos Subcontract | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Registo de patentes Patent registration | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Demonstração, Promoção e Divulgação Demonstration, Promotion and Publication | 0,00 | 3.000,00 | 5.000,00 | 0,00 | 0,00 | 8.000,00 |
| Adaptação de edifícios e instalações Adaptation of buildings and facilities | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Aquisição de Bens e Serviços Service procurement and acquisitions | 0,00 | 10.500,00 | 3.500,00 | 0,00 | 0,00 | 14.000,00 |
| Gastos gerais Overheads | 0,00 | 6.302,50 | 3.360,50 | 0,00 | 0,00 | 9.663,00 |
| TOTAL DESPESAS CORRENTES TOTAL CURRENT EXPENSES | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |
| Instrumentos e equipamento científico e técnico Instruments and scientific and technical equipment | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Total | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |

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| Orçamento Global | | | | | | |
|---|------|-----------|-----------|------|------|-----------|
| Global budget | | | | | | |
| Descrição Description | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
| Recursos Humanos Human resources | 0,00 | 9.710,00 | 1.942,00 | 0,00 | 0,00 | 11.652,00 |
| Missões Missions | 0,00 | 2.000,00 | 3.000,00 | 0,00 | 0,00 | 5.000,00 |
| Subcontratos Subcontract | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Registo de patentes Patent registration | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Demonstração, Promoção e Divulgação Demonstration, Promotion and Publication | 0,00 | 3.000,00 | 5.000,00 | 0,00 | 0,00 | 8.000,00 |
| Adaptação de edifícios e instalações Adaptation of buildings and facilities | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Aquisição de Bens e Serviços Service procurement and acquisitions | 0,00 | 10.500,00 | 3.500,00 | 0,00 | 0,00 | 14.000,00 |
| Gastos gerais Overheads | 0,00 | 6.302,50 | 3.360,50 | 0,00 | 0,00 | 9.663,00 |
| TOTAL DESPESAS CORRENTES TOTAL CURRENT EXPENSES | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |
| Instrumentos e equipamento científico e técnico Instruments and scientific and technical equipment | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Total | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |

=====

| Plano de financiamento | | | | | | |
|--|------|-----------|-----------|------|------|-----------|
| Finance plan | | | | | | |
| Descrição Description | 2021 | 2022 | 2023 | 2024 | 2025 | Total |
| Financiamento solicitado à FCT Requested funding | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |
| Financiamento próprio Own funding | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Outro financiamento público Other public-sector funding | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Outro financiamento privado Other private funding | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 | 0,00 |
| Total do Projecto Total of the project | 0,00 | 31.512,50 | 16.802,50 | 0,00 | 0,00 | 48.315,00 |

8. Justificação do orçamento

8. Budget rationale

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| 8.1. Justificação dos recursos humanos | | |
|---|---|--------------------------------------|
| 8.1. Human resources rationale | | |
| ===== | | |
| Tipo Type | Nº de pessoas No. of persons | |
| (B) Bolsa | 1 | |
| Duração (em meses) Duration (in months) | Custo envolvido (€) (calculado) Total cost (€) (estimated) | Outros custos (€) Other costs (€) |
| 12 | 11.652,00 | 0,00 |
| Justificação do financiamento solicitado | | |
| Rationale for requested funding | | |
| It is intended to open a grant for a graduate (BI Licenciado) with the objective that a Master's student can develop his/her dissertation relating physiotherapy and community care | | |

with the people with Parkinson's, thus promoting the link between academia and society, solving societal challenges.

8.2. Justificação de missões

8.2. Missions rationale

| | |
|---|--|
| Designação Designation Congresses | Custo envolvido (€) Cost (€) 5.000,00 |
| Justificação do financiamento solicitado Rationale for requested funding For the various institutions where researchers need to travel to participate in workshops and seminars/international conferences. | |

8.3. Justificação de aquisição de bens e serviços

8.3. Service procurement and acquisitions

| | |
|---|--|
| Tipo Type Transport of Study Participants (Patients) | Custo (€) Cost (€) 8.000,00 |
| Justificação do financiamento solicitado Rationale for requested funding It is intended to pay participants in the study for the travel they will have to make, and not to burden them with this expense. The project plan requires that participants have to travel 3 times a week to the training sessions. Additionally in 3 distinct phases of the project, to carry out the planned evaluations. We know from previous experiences that the expenses associated with there participation are one of the main barriers and dropout reason. We calculated this amount taking into account that we intend to include 60 participants and that each trip has an average cost of € 10. | |

| | |
|---|--|
| Tipo Type Rental trampoline site | Custo (€) Cost (€) 6.000,00 |
| Justificação do financiamento solicitado Rationale for requested funding Rental contract for the trampoline training site (Bounce, Inc.) in Lisbon for 12 months (500 € / month), provided for the duration of the training intervention and assessment of the participants. | |

8.4. Justificação do Equipamento

8.4. Equipment rationale

8.4.1. Equipamento já disponível para a execução do projecto

8.4.1 Available equipment

| | |
|---|----------------------------|
| Tipo de equipamento Equipment type Tri-axial Accelerometers (4 Units), Bioplux Research, Plux Biosignals | Ano Year 2020 |
| Tipo de equipamento Equipment type Forceplate (3 Units), Plux Biosignals | Ano Year 2017 |

8.4.2. Discriminação do equipamento a adquirir

8.4.2. New equipment requested

(Vazio)
(Void)

8.5. Justificação de registo de patentes

8.5. Patent registration

(Vazio)
(Void)

8.6. Justificação de adaptação de edifícios e instalações

8.6. Adaptation of buildings and facilities

(Vazio)
(Void)

8.7. Justificação Subcontratos

8.7. Subcontract

(Vazio)
(Void)

8.8. Justificação Demonstração, Promoção e Divulgação

8.8. Demonstration, Promotion and Publication

| | |
|---|--|
| Tipo Type Journals, book and seminars | Custo (€) Cost (€) 8.000,00 |
| Justificação do financiamento solicitado Rationale for requested funding In this project we intend to follow the open access policy, whenever possible, which is why we have budgeted for fees to be paid to journals. These will also be used for develop the workshops/seminars and guide book previously mentioned. | |

9. Ficheiros Anexos

9. Attachments



| | | |
|---|---|--|
| Nome Name Timeline.pdf Trampoline_bed.jpg | Tipo Type Cronograma Timeline Outros Others | Tamanho Size 329KB 223KB |
| 10-03-2021 11:13:54 | | |

