UNIVERSIDADE DE LISBOA

FACULDADE DE MOTRICIDADE HUMANA

The PLE^{2}NO self-management and exercise program: effects on knee osteoarthritis symptoms, health behaviors, quality of life and physical fitness in elderlies

Tese elaborada com vista à obtenção do Grau de Doutor em Motricidade Humana na especialidade de Atividade Física e Saúde

Tese por compilação de artigos, realizada ao abrigo da alínea a) do nº2 do artº 31º do Decreto-Lei nº 230/2009

Orientadora: Professora Doutora Maria Margarida Marques Rebelo Espanha
Coorientadora: Professora Doutora Flávia Giovanetti Yázigi

Júri:

Presidente:
Reitor da Universidade de Lisboa

Vogais:
Doutor José António Pereira da Silva
Professor Catedrático
Faculdade de Medicina da Universidade de Coimbra

Doutor Pedro Jorge do Amaral de Melo Teixeira
Professor Catedrático
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Maria Margarida Marques Rebelo Espanha
Professora Associada
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Maria Helena Santa Clara Pombo Rodrigues
Professora Auxiliar
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Sandra Cristina Cozinheiro Fidalgo Rafael Gamboa Pais
Professora Adjunta
Escola Superior de Saúde de Faro da Universidade do Algarve

Priscila Ellen Pinto Marconcin
2016

UNIVERSIDADE DE LISBOA

FACULDADE DE MOTRICIDADE HUMANA

The PLE^{2}NO self-management and exercise program: effects on knee osteoarthritis symptoms, health behaviors, quality of life and physical fitness in elderlies

Tese elaborada com vista à obtenção do Grau de Doutor em Motricidade Humana na especialidade de Atividade Física e Saúde

Tese por compilação de artigos, realizada ao abrigo da alínea a) do nº2 do artº 31º do Decreto-Lei nº 230/2009

Orientador(a): Professora Doutora Maria Margarida Marques Rebelo Espanha
Coorientador(a): Professora Doutora Flávia Giovanetti Yázigi

Júri:

Presidente:
Reitor da Universidade de Lisboa

Vogais:
Doutor José António Pereira da Silva
Professor Catedrático
Faculdade de Medicina da Universidade de Coimbra

Doutor Pedro Jorge do Amaral de Melo Teixeira
Professor Catedrático
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Maria Margarida Marques Rebelo Espanha
Professora Associada
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Maria Helena Santa Clara Pombo Rodrigues
Professora Auxiliar
Faculdade de Motricidade Humana da Universidade de Lisboa

Doutora Sandra Cristina Cozinheiro Fidalgo Rafael Gamboa Pais
Professora Adjunta
Escola Superior de Saúde de Faro da Universidade do Algarve

Priscila Ellen Pinto Marconcin
2016

The work presented in this dissertation was supported by Ciências Sem Fronteiras Brazilian Scholarship Program (BEX:13212/13-3).

Declaração de Reprodução da Tese

Nome: Priscila Ellen Pinto Marconcin

Endereço eletrónico: pri_edf@hotmail.com Telefone: +351915356604

Número de passaporte: YB879885

Título: The PLE^{2}NO self-management and exercise program: effects on knee osteoarthritis symptoms, health behaviors, quality of life and physical fitness in elderlies

Orientadora: Professora Doutora Maria Margarida Marques Rebelo Espanha

Coorientadora: Professora Doutora Flávia Giovanetti Yázigi

Ano de conclusão: 2016

Doutoramento: Motricidade Humana na especialidade de Atividade Física e Saúde

Faculdade de Motricidade Humana – Universidade de Lisboa

Cruz Quebrada, 22/12/2016

Priscila Marconcin

“Educação não transforma o mundo. Educação muda as pessoas.
Pessoas transformam o mundo”.

Paulo Freire

A todos aqueles que já foram e que ainda serão meus alunos.

Acknowledgements / Agradecimentos

O percurso até aqui foi um caminho, muitas vezes, percorrido sozinha. Mas é certo que este percurso não culminaria em sucesso se não fosse a ajuda e apoio de muitos, que direta ou indiretamente me suportaram nesta trajetória.

Em primeiro lugar agradeço a Deus, nosso Senhor Jesus que me amparou nos momentos mais difíceis e está sempre ao meu lado.

À minha orientadora, Professora Margarida Espanha. O que aprendi consigo ultrapassa a barreira do científico e do académico, reforcei a minha crença nos valores da vida, na humildade, na solidariedade e no amor ao próximo. Obrigada por ter estado sempre do meu lado, em todos os momentos, por ter sempre acreditado em mim. O que aprendi consigo levarei comigo para toda a vida.

À minha coorientadora, Professora Flávia Yázigi, por todo o suporte dado a este trabalho, expandindo os meus conhecimentos e ajudando-me a tornar numa melhor investigadora. Agradeço cada sugestão e correção.

À Professora Júlia Teles por sua prontidão e disponibilidade em me ajudar neste trabalho, contribuindo com a sua sabedoria, especialmente nas análises estatísticas.

Ao meu amigo Pedro Campos, que esteve do meu lado durante todos os momentos e que foi o meu braço direito no desenvolvimento e execução do PLE^{2}NO. Além do suporte técnico, partilhou das minhas angústias e incertezas, foi um companheiro ao qual estarei sempre grata.

Aos Professores Pedro Teixeira e Helena Santa-Clara por pertencerem à minha Comissão de Acompanhamento de Tese e por me terem acompanhado e auxiliado no processo de desenvolvimento do meu projeto.

Aos Professores Adilson Marques, António Rosado, Marta Marques e Paulo Bento por terem participado em estudos desta tese, pelas suas contribuições que enriqueceram este trabalho.

Aos funcionários da Faculdade de Motricidade Humana, em especial à Cláudia Pinho, que foi sempre muito prestável e atenta às minhas requisições e procurou sempre atendê-las de forma muito amável.

Àos colegas que contribuíram nas avaliações do Programa PLE^{2}NO: Maria, Rita, Joana, Catarina, Eliana, Teresa, João e Daniela. Em especial à Maria, que contribuiu também nas sessões do programa PLE^{2}NO.

A todos os que fizeram ser possível a concretização do Programa PLE^{2}NO, aos coordenadores dos locais que nos receberam e principalmente a todos aqueles que foram nossos alunos. Vocês foram os responsáveis pelos melhores momentos desta trajetória, encheram-me de luz ao dividirem comigo as vossas experiências de vida e ao permitirem-se aprender algo mais.

Um agradecimento especial à minha família e aos meus amigos. Aos meus pais que sempre acreditaram em mim e me fizeram ver que tudo valeria a pena. À minha irmã, que para além de ter estado sempre ao meu lado na vida, exerceu um papel fundamental nesse percurso, não medindo esforços para me ajudar sempre que precisei, ser-lhe-ei eternamente grata. Às minhas amigas que mesmo do outro lado do oceano me ajudaram a ultrapassar todas as dificuldades, incentivando-me sempre, motivando-me e alegrando os meus dias. E aos novos amigos que fiz durante esta trajetória e que foram fundamentais para tornar os meus dias mais leves.

Ao Thiago, meu companheiro de vida, por ter sonhado junto comigo e ter dado todos os passos do meu lado na concretização deste sonho. Por me amar como eu sou, me ajudar a superar os obstáculos da vida e a ser uma pessoa melhor a cada dia. A minha filha, Maria Luísa, responsável pela minha alegria diária, sendo sempre a luz dos meus olhos. Chegámos até aqui juntos, percorremos todo esse caminho juntos, um apoiando o outro. Sempre acreditámos que este dia iria chegar. Soubemos aproveitar o percurso, as oportunidades e crescemos muito. Concretizamos nossas teses, cumprimos com os nossos objetivos, esta experiência deixou-nos mais fortes, sem dúvida alguma.

Institutional Acknowledgements / Agradecimentos Institucionais

É preciso salientar e agradecer todo o suporte institucional que este trabalho recebeu. Agradeço à Liga Portuguesa Contra as Doenças Reumáticas pelo apoio na divulgação do programa PLE^{2}NO e em algumas questões de secretariado, nomeadamente à Ana Ribeiro que sempre se mostrou disponível para ajudar. Ao Dr. Rui André por, de uma forma muito proativa e recetiva, ter feito a análise dos exames radiológicos dos participantes do PLE^{2}NO. Ao laboratório Pierre Fabre Médicament por ter dado apoio na elaboração do material de divulgação do programa PLE^{2}NO, na brochura entregue aos participantes do grupo de controlo e por ter fornecido o suplemento aos participantes do programa PLE^{2}NO. Aos locais que receberam o programa PLE^{2}NO, a Junta de Freguesia de Linda-a-Velha, Universidade Sénior de Carnaxide, Universidade Sénior Nova Atena e Igreja Evangélica Assembleia de Deus de Algés e seus respetivos coordenadores e responsáveis, que foram todos sempre muito disponíveis e abertos a ajudar-nos a concretizar este programa. À Faculdade de Motricidade Humana que auxiliou no financiamento da brochura entregue aos participantes do programa PLE^{2}NO. Por fim, ao Conselho Nacional de Desenvolvimento Científico e Tecnológico – CNPq, que através do programa Ciências Sem Fronteiras/Doutorado Pleno no Exterior, me forneceu a bolsa de estudo que tornou possível a realização deste trabalho.

Abstract

The main international guidelines recommend physical exercise and participation in self-management programs as a non-pharmacological treatment for Knee Osteoarthritis (KOA). This project was based on the non-pharmacological intervention for KOA, namely on exercise and education. Thus, the thesis is presented in five articles format. The first article is the protocol of PLE^{2}NO program (Free Education and Exercise Program for Osteoarthritis), was designed to investigate the efficacy of a combined self-management and exercise program in older adults with KOA. The following two articles are cross-sectional studies with analysis of the baseline data from PLE^{2}NO sample. The second article aimed to investigate which factors best predict the Timed "up-and-go" test. It concludes that functional lower limbs strength, ability to walk long distances, walking speed, perception of the impact of pathology in the tasks of daily life and the perception of health-related self-care and usual activities are predictors of the Timed "up-and-go" test. Thus, the test Timed "up-and-go" appears to be a good choice in the assessment of KOA elderly patients. The third article analyzes the use of coping strategies and the effect that sociodemographic variables, severity of disease, pain and other KOA symptoms have on the choice of coping strategies. It concludes that none of the variables investigated was decisive in the choice of coping strategies and the strategies most used by the sample are related in the literature with better outcome measures. It is an important contribution to the development of future educational programs. The last two articles focus on the main purpose of this thesis: to evaluate the effectiveness of a self-management and exercise program in elderly with KOA. The fourth article investigated the effect of the program on the variables: KOA symptoms, self-management behavior, health-related quality of life (VAS) and on health related physical fitness components (aerobic capacity, functional lower limb strength, flexibility and handgrip). It concludes that the PLE^{2}NO program had a significant effect on communication with the physician and physical variables: aerobic capacity, functional lower limb strength and upper limb flexibility. The fifth article investigated the effect of the program on the variables: self-efficacy, physical activity, health-related quality of life (index) and on skills related physical fitness components (agility, balance and gait speed). It concludes that the PLE^{2}NO program had a significant effect on self-efficacy, physical activity level, sedentary behavior and balance. Both articles contribute to reinforce international recommendations concerning exercise and self-management for KOA.

Keywords: Self-management, education, exercise program, knee osteoarthritis, elderly.

Resumo

As principais diretrizes internacionais recomendam a prática de exercício físico e a participação em programas de autogestão como alternativas não farmacológicas para o tratamento da osteoartrose do joelho (OAJ). Esta tese apresenta cinco artigos elaborado no âmbito do tratamento não farmacológico da OAJ, nomeadamente a participação em programas de educação e de exercício físico. O primeiro artigo é de cunho metodológico e apresenta o protocolo do programa PLE^{2}NO (Programa Livre de Educação e Exercício na Osteoartrose), desenvolvido para investigar a eficácia de um programa combinado de autogestão e exercício em idosos com OAJ. Os dois artigos seguintes são estudos transversais com análise feita a partir dos dados do baseline da amostra do programa PLE^{2}NO. O segundo artigo trata de investigar quais os fatores preditivos do teste Timed "up-and-go" e chega à conclusão de que a força funcional dos membros inferiores, a capacidade de caminhar longas distâncias, a velocidade da marcha, a perceção do impacto da patologia na realização das tarefas da vida diária e a perceção do estado de saúde relacionada com o autocuidado e as atividades usuais são fatores preditores do teste analisado. Assim, o teste Timed "up-and-go" configura-se como uma boa opção na avaliação de idosos com OAJ. O terceiro artigo procura analisar a utilização das estratégias de *coping* e o efeito que as variáveis sociodemográficas, o grau de severidade da patologia, a dor e outros sintomas da OAJ têm nessa escolha. Conclui que nenhuma das variáveis investigadas foi determinante na escolha das estratégias e que as estratégias mais utilizadas pela amostra estão relacionadas na literatura com melhores medidas de resultado. O que se configura num importante contributo para a elaboração de programas educacionais. Os dois últimos artigos que compõem esta dissertação procuram responder ao principal objetivo geral deste trabalho: avaliar a eficácia de um programa de autogestão e exercício em idosos com OAJ. O quarto artigo investigou o efeito do programa nas variáveis: sintomas da OAJ, comportamento de autogestão, qualidade de vida relacionada com a saúde (VAS) e nas componentes da aptidão física relacionadas com a saúde (capacidade aeróbia, força funcional dos membros inferiores, flexibilidade e força de preensão manual). Conclui que o programa PLE^{2}NO teve efeito significativo na comunicação com o médico e nas variáveis físicas: força funcional dos membros inferiores, capacidade aeróbia e flexibilidade dos membros superiores. O quinto artigo investigou o efeito do programa nas variáveis: autoeficácia, nível de atividade física, qualidade de vida relacionada com a saúde (índex) e nas componentes da aptidão física relacionadas com a habilidade (agilidade, equilíbrio e velocidade da marcha). Conclui que o programa PLE^{2}NO teve efeito significativo na autoeficácia, no nível de atividade física, na diminuição do comportamento sedentário e no equilíbrio. Ambos os artigos contribuem para reforçar as recomendações internacionais de tratamentos de educação e exercício para OAJ.

Palavras-chave: Autogestão, educação, programa de exercício, osteoartrose do joelho, idosos.

Abbreviation

6MWT - 6 Minutes Walking Test

ACL - Anterior Cruciate Ligament

ACMS - American College of Sport and Medicine

ACR - American College of Rheumatology

ADL - Activities of Daily Living

AGS - American Geriatric Society

ANCOVA - Univariate Analyses of Covariance

ASE - Arthritis Self-Efficacy

ASHC - Arthritis Self-Help Course

ASMP - Arthritis Self-Management Program

BMI - Body Mass Index

BST - Back Scratch Test

CBT - Cognitive Behavioral Therapy

CDSMP - Chronic Disease Self-Management Program

CS - Chondroitin Sulfate

CSM - Cognitive Symptoms Management

CSR - Chair Sit and Reach test

CWP - Communication With Physician

DMOADs - Disease-Modifying Osteoarthritis Drugs

EG - Educational Program

EULAR - European League Against Rheumatism

EuroQol -EQ-5D-5L - EuroQol Five Dimensions Five Level

FRSTST - Five-Repetition Sit to Stand Test

GlcN - Glucosamine Sulfate

HRQoL - Health-Related Quality of Live

IPAQ – International Physical Activity Questionnaire

KOA - Knee Osteoarthritis

KOOS - Knee Osteoarthritis Outcome Scales

MANOVA - Multivariate Analysis of Variance

NSAIDs - Nonsteroidal anti-inflammatory drugs

OA - Osteoarthritis

OAJ - Osteoartrose do joelho

OARSI - Osteoarthritis Research Society International

OMNI - RES - Omni-Perceived Exertion Scale for Resistance Exercise

PGIC - Patient's Global Impression of Change

PLE^{2}NO - Programa Livre de Educação e Exercício na Osteoartrose

QOL - knee related Quality of Life

RCT - Randomized Controlled Trial (RCT)

ROM - Range of Motion

SMEG - Self-Management and Exercise Group

SMP - Self-Management Program

Sport/rec - Function in sport and recreation

SPPB - Short Physical Performance Battery

SYSADOA - Symptomatic Slow Acting Drugs for Osteoarthritis

TUG - Timed "up-and-go"

VAS - Visual Analogue Scale

VIF - Variance Inflation Factor

VNP - Visual Numeric Pain Scale

Table of Contents

Tables and Figures

Tables

Figures

Chapter 1: Introduction

Introduction

Osteoarthritis (OA) affects millions of people worldwide, compromising the individual's life, from job performance to daily living activities. In Portugal, OA (knee and/or hip and/or hand) affects 19.1% (95% CI 17.1 to 21.1%) of the Portuguese population, where knee osteoarthritis (KOA) is responsible for 12.4% (95% CI 11.0% to 13.8%) [1].

OA is a common debilitating joint disorder, characterized by a progressive loss of articular cartilage, sclerosis of subchondral bone, marginal osteophytes, and variable synovial inflammation [2]. KOA diagnose can be done using clinical and laboratory criteria, clinical criteria alone or clinical combining with radiographic features. According with these features the grade of severity is classified in four stages [3]. The grade of severity does not have a linear and direct relation with symptoms.

Pain, the most important KOA symptom, is present in 31% of women between 40 and 55 years old without X-ray alterations [4]. Besides pain, other signs and symptoms are stiffness, crepitus with motion, joint effusions, joint deformity and muscle weakness [2]. Those symptoms lead to physical impairments affecting physiological and social parameters. Pain is associated with a worse physical function [5], consequently leading to poor quality of life [6]. Therefore, high economic and social costs are related to high prevalence of disability [7].

The international recommendations for KOA treatment are non-pharmacological, pharmacological and surgical [8]. Among non-pharmacological treatments, self-management educational programs and exercise interventions can be highlighted for their efficacy, already shown in different studies. Exercise is effective for pain relief and improves limitation in function [9], and self-management educational programs are effective to improve health status and self-management behaviors [10].

The present thesis, entitled "The PLE^{2}NO self-management and exercise program: effects on knee osteoarthritis symptoms, health behaviors, quality of life and physical fitness in the elderly" aims to investigate the efficacy of a combined self-management and exercise program in elderlies with knee osteoarthritis. In addition, analysis some KOA patients characteristics relating to physical test and coping strategies.

This thesis incorporates a literature review, methodology and a compilation of five articles. Thus, it is organized as follows:

1.1 Dissertation Structure

Chapter 2 includes a literature review of the topic about KOA (epidemiology, pathology and KOA diagnosis), KOA treatment (self-management programs, exercise and supplementation for OA) and assessments for KOA subjects. This section finishes by highlighting the main research goals of the thesis.

A brief methodology is presented on **Chapter 3**, with an overall indication of each article methodology. The study protocol of the PLE^{2}NO´s program, a randomized controlled trial, is described on **Chapter 4.** Apart from this, each paper has its methodology described.

Chapter 5 and **6** are both cross sectional studies with the baseline values of the PLE^{2}NO program. **Chapter 5** is about predictor factors of a specific test of PLE^{2}NO´s assessment, the Timed "up-and-go" test. **Chapter 6** is an analysis of the coping strategies and their relation to pain, other symptoms and some demographic characteristics.

Chapter 7 and **8** analyze the effects of PLE^{2}NO program. This analysis is divided into two articles. The first one, on **chapter 7,** focuses more on the impact of the intervention on pathology outcomes and in the health related physical fitness outcomes. The second article, on **chapter 8,** focuses on the impact of the intervention on general health, self-efficacy and skill-related physical fitness outcomes.

Chapter 9 corresponds to a general discussion that provides a summary and integrated discussion of the main findings obtained from the five articles of this thesis.

1.2 List of publications related to the dissertation

Peer-reviewed articles published, submitted or under review

Marconcin, P., Espanha, M., Yázigi, F. & Campos, P. The PLE^{2}NO self-management and exercise program for knee osteoarthritis: Study Protocol for a Randomized Controlled Trial. BMC Musculoskeletal Disorders, 2016. 17(1): p. 1-12.

Marconcin, P., Espanha, M., Yázigi, F., Teles, J. (2015). Predictors of Timed "up-and-go" Test in Elderly with Knee Osteoarthritis. In Cabri, J. J. & Pezarat, P. P. Proceedings of 3rd International Congress on Sport Sciences Research and Technology Support, Lisbon, Portugal, 2015 pp. 97 - 99. SCITEPRESS.

Marconcin, P., Espanha, M., Rosado, A., Marques, A., Campos, P. & Yázigi, F. O impacto da dor e outros sintomas nas estratégias de coping em idosos com osteoartrose do joelho. Revista Brasileira de Reumatologia (submitted).

Marconcin, P., Espanha, M., Teles, J., Bento, P., Campos, P., André, R., Yázigi, F. Responsiveness of KOA symptoms, self-management behavior and health related physical fitness outcomes after 3 months of the PLE^{2}NO Program. Clinical Rehabilitation (under review).

Marconcin, P., Espanha, M., Teles, J., Marques, M., Campos, P., Yázigi, F. Effects of PLE^{2}NO program on self-efficacy in the elderly with knee osteoarthritis: a randomized controlled trial. International Journal of Behavior Medicine (submitted).

Book

Espanha, M., Marconcin, P., Yázigi, F., Marques, A., Machado, M., Campos, P., & Carrão, L. (2015). Guia para viver em PLE^{2}NO: com menos dor e mais qualidade de vida. Lisboa: FMH-ULisboa.

Abstracts

Marconcin, P., Espanha, M., Yázigi, F., André, R., & Campos, P. (2015). Fatores Preditivos da Autoeficácia em Idosos com Osteoartrose do Joelho. In Miranda, L. C. Suplemento da Acta Reumatológica Portuguesa, XXIII Jornadas Internacionais do Instituto Português de Reumatologia, Lisboa, Portugal, 26-27 Novembro, Publicação, 40 (2), pp. 31.

Marconcin, P., Espanha, M., Yázigi, Santos, T., André, R., & Campos, P. (2016) Walking performance depends on body mass and functional strength but is not facilitate by self-efficacy in knee osteoarthritis patients. In Lohmander, S. Supplements of Osteoarthritis and Cartilage, 24 (1), Amsterdam, Netherlands, March 31 April 3, pp. 192-193.

Marconcin, P., Espanha, M., & Campos, P. (2016). Dor, Função Física e Nível de Atividade Física em Idosos com Osteoartrose do Joelho. In Revista Portuguesa de Ciências do Desporto, 2016/S2R[1], pp.118 ISSN:1645-0523.

Marconcin, P., Espanha, M., Yázigi, F. & Campos, P. (2016). Efeitos de um programa de educação e exercício em cinco parâmetros da qualidade de vida relacionada à saúde em uma população idosa com osteoartrose do joelho. In Silva, C. Suplemento da Acta Reumatológica Portuguesa, XXIV Jornadas Internacionais do Instituto Português de Reumatologia, Lisboa, Portugal, 24-25 Novembro, Publicação, 41, pp. 80.

Chapter 2: Literature Review

2.1 Epidemiology and socioeconomic impact of OA

Rheumatics diseases also called musculoskeletal diseases are the most common cause of severe long-term pain and physical disability [11]. Osteoarthritis (OA) is one of four major musculoskeletal conditions with rheumatoid arthritis, osteoporosis and low back pain. OA is not a fatal disease, but patients with OA have higher risk of death compared with the general population [12]. One reason is because OA, being an age-related pathology, is associated with a high level of comorbidity [13, 14], which determines high mortality [12, 15].

OA is a major public health issue and it is the most costly disease in economic terms [13, 16]. The cost of OA can be translated into direct, indirect and intangible costs. The direct cost includes non-pharmacological and pharmacological treatment, surgery, adverse effects of treatment, long-term care and health care provision. The indirect includes absenteeism, reduced employment, reduced productivity, caregiver time and premature mortality. The intangible cost involves pain, activity limitation, decrease of life quality, fatigue and reduction of social participation [17]. The total annual costs per patient with lower limb osteoarthritis varied from 0.7 to 12 k€/year, where direct costs per patients derived from 0.5 to 10.9k€/year and indirect from 0.2 to 12.3 k€/year, worldwide [18]. The costs of surgery comprise nearly half of the direct costs. However, one-third of the direct OA expenditures are allocated to medications, mostly pain relief medication. Hospitalization is not frequent in OA, approximately 5% of OA patients undergo knee or hip replacement surgery [17].

OA can occur in any joint, but it is most common in the hip, knee and in the joints of the hand, foot and spine [2, 11]. Knee osteoarthritis (KOA) mostly affects elderly and overweight individuals [19] and accounts for 89% of the total OA burden [20]. Nevertheless, it is also high in younger age groups, particularly in obese women [21]. Although the estimation of KOA prevalence and incidence varies across studies, there is general consensus that a substantial percentage of the world population is affected.

One of the most cited epidemiologic study, the Framingham Osteoarthritis Study exposes the age-associated increase of KOA, showing that the age-standardized prevalence of radiographic KOA was of 19% among adults aged 45 years and older, in

the USA. A more recent global age-standardized research showed that 3.8% (95% CI 3.6% to 4.1%) of the world population has radiographically confirmed symptomatic KOA [22]. This value didn´t present a discernible change from 1990 to 2010 [23].

Prevalence rates for KOA, based on population studies in the US, are comparable to those in Europe. A Sweden cohort study [24] with adults (age 56 – 84) evidenced that 25.4% (95% CI = 24.1, 26.1) of the population of Sweden showed radiographic KOA and 15.4% (95% CI= 14.2, 16.7) showed symptomatic KOA. Primary care health records on northeast Spain showed KOA incidence rates of 6.5(6.4, 6.6) per 1000 persons (99%CIs) [25]. In Germany, the prevalence of KOA in those aged 55 and above was 15.6% in men and 30.5% in women [26]. In Portuguese population the value is 12.4% of the global population [1].

2.2 Pathology

2.2.1 Etiology and risk factors

OA can be classified in relation to its causes, as primary or secondary. Primary OA, or idiopathic, can be developed without a known cause, purely because of joint degeneration, which is common on elderly subjects. Secondary OA, which is less frequent than primary OA, is a result of joint degeneration caused by injuries or a variety of hereditary, inflammatory, developmental, metabolic and/or neurologic disorders. Ankle, wrist, elbow, and shoulder are joints commonly associated with secondary OA, as a result from injury. In contrast, knee and hip are frequently primary OA [2], normally related with the aging process.

The pathophysiology of the joint degeneration that leads to KOA remains little understood, although some factors, such as advanced age and overweight, are known to increase the risk of degeneration in all joints. [2].

KOA has a multifactorial etiology. It is an interplay between systemic and biomechanical local factors. Age, genetic susceptibility, gender and race characteristics establish the foundation for cartilage properties. However, it is the local factors, such as elevated weight bearing on account of obesity, joint deformity, muscle weakness, joint laxity, mechanical forces and meniscal injuries that have crucial influence on the final

qualities of articular cartilage [21, 27]. Repetitive joint overuse, joint injury, posttraumatic joint incongruity, joint instability or malalignment and joint dysplasia, all can create mechanical demands that damage articular surfaces [2].

In old adults, the most consistent risk factors for KOA are obesity, previous knee injury, female gender, and the presence of hand OA. In addition, previous knee trauma increases the risk of KOA in 3.8 times [28]. Old age is the greatest risk factor for KOA. Firstly, joint tissues change with the aging process. The cells' senescence results in the development of senescent secretory phenotype and changes in the matrix, including formation of advanced glycation end-products, that affect the mechanical properties of joint tissues [29]. Hormonal changes affect cartilage metabolism. An age-associated reduction in growth factor signaling and an increase in oxidative stress may also play an important role in the relation age-OA [30]. In the ageing individual, alterations in the content or functions of growth factors locally in the joint, or brought to the joint through circulation, may affect the capacity of cartilage abrasions to heal or regulate new bone formation, and in individuals at risk, joint changes may progress to OA [31]. In addition with aging, individuals lose muscle and gain fat mass [32], which are related with others two risk factors: muscle weakness and obesity.

Quadriceps' weakness is another risk factor for KOA [33]. Loss of quadriceps muscle results in a loss of strength in the leg, and more difficulty to do some activities such as walking or rising to the standing position and is also often associated with knee pain [34]. A study with 3026 individuals (6052 knees) shows that thigh muscle strength seems to predict the incidence of symptomatic KOA [35]. In these cases, exercise is strongly recommended, with the goal of increasing muscle-strength, reducing pain and preserving the range of movement.

Obesity has a double role as a risk factor for KOA; contributing to the progress of the disease due to changes in joint loading and as a metabolic/inflammatory pathway [36]. A study with overweight and obese older adults indicates that a weight loss of 10% of body mass shows a significant reduction of knee joint load [37]. Data from the Netherlands Epidemiology of Obesity study (NEO) show that fat mass and fat percentage were positively associated with KOA in men and women, but more pronounced in women [38].

Previous knee injury is a major risk factor for KOA [39]. Anterior cruciate ligament (ACL) injury is a common cause of post-traumatic OA, developing in young adults as a result of sport injuries [29]. Patients with anterior cruciate ligament deficiency and reconstructed knees had altered synovial fluid biomarker levels, which are an indicative of KOA [40]. Meniscal tissue removed remains the strongest predictor of long-term onset of osteoarthritis. After meniscectomy, the risk factor to developed KOA increases 53.3% [41] Knee injury is also associated with accelerated KOA [42].

The life time risk of developing symptomatic KOA is more pronounced in women (47%) than men (40%) [43]. One possible explanation are sex hormones, primarily estrogen, which have long been considered a possible factor in the systemic predisposition to osteoarthritis, especially in women and mostly around menopause. The evidence suggests that post-menopausal estrogen replacement may be a protector factor against significant joint OA [44].

High bone density is another KOA risk factor referred in the literature [43]. The association of KOA with high bone density may reflect increased biomechanical stress on cartilage in women with high bone mass, due to greater estrogen exposure or could be due to a direct adverse effect of estrogen on cartilage [45].

Certain job occupations, specific physical activities or sportive practice are also an important KOA risk factor [46]. Activities that involve staying in the same position for a long time, or activities with extreme joint impact should be avoided. However, the relationship between physical activities and sport practice and the increasing of KOA incidence depends on others factors, such as previous injuries and additional risk factors. A review study revealed that intense physical activity didn't show a significant association with KOA in general population, and simply in cases of former joint injury, and in acquired and congenital joint defects an association was found with KOA [47].

It is impossible to avoid the natural degeneration on articular surface, but it is possible to prevent the start and progression of KOA. Obesity, muscle weakness, overload associated with job occupation, daily living activities or sports activities are some modifiable risk factors. In this sense, is crucial an educational intervention to warning individuals of this relationship, as a prevention strategy.

2.2.2 Physiopathology of KOA

KOA can be defined as a pathogenetic disease (mechanical and biological events), morphological disease (changes in articular cartilage and subchondral bone) and clinical disease (joint pain, stiffness, tenderness, limitation on movement, crepitus and inflammation) [48].

KOA is a common disorder of synovial joints characterized by deterioration and loss of articular cartilage. This deterioration has several possible consequences: new bone formation at the joint margins (osteophytosis), remodeling subchondral bone, sclerosis of the subchondral bone, variable degrees of synovitis and thickening of the joint capsule (figure 2.1) [2, 11, 27, 49]. In experimental models of KOA, before deterioration on cartilage surface, a decrease of the superficial proteoglycans concentration, increased water content and separation/disorganization of the superficial collagen fibril is expected [27]. In consequence, there is a loss of physical and/or biochemical functional integrity of the cartilage having consequences in the overall joint function [34].

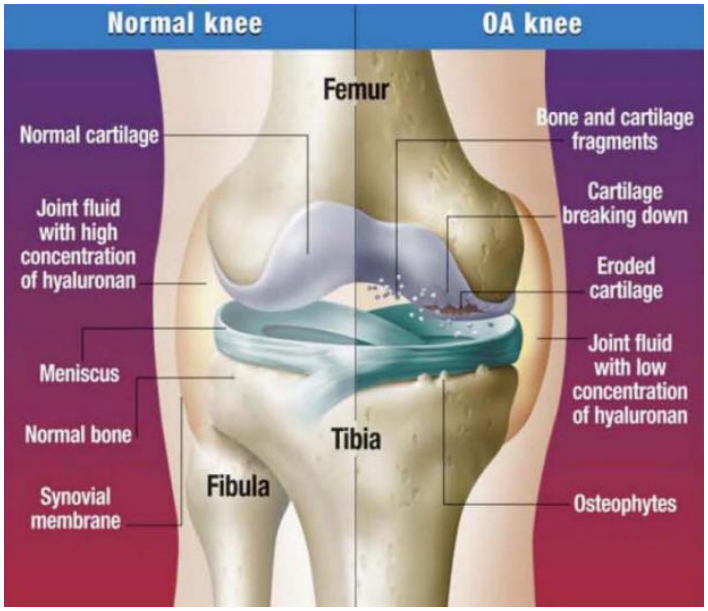


Figure 2.1 - Healthy joint and joint with OA (femoral-tibial compartments).

2.2.3 Signs and Symptoms: impact on health-related quality of life

Pain is the main symptom of KOA. The clinical syndrome of osteoarthritis depends on the presence of chronic joint pain. It is also the major complaint of KOA individuals

and has a profound effect on the quality of life, affecting both, physical function and psychological parameters [21]. The pain experienced by KOA patients is related to damage in the articular tissue, psychosocial factors [49, 50] and/or the pain pathway itself [51].

The source of pain is quite complex, the hyaline cartilage does not have pain receptors, they are present on subchondral bone, periosteum, synovium, ligaments, and the joint capsule. Those tissues are all richly innervated and contain nerve endings that could be the source of nociceptive stimuli in KOA. [34, 49]. Some of the pain experienced by patients appears to be sympathetic efferent nerve mediated pain, and/or a result of the convergence-projection concept of pain expression [52]. Knee pain can have several sources. Image studies show the correlation between pain and both, synovitis and subchondral bone changes, suggesting that these two tissues could be sources of KOA pain [53-55].

Other source is due to primary injury such as tear, stretch or contusion of the medial/lateral/collateral ligaments and stretch or contusion of anterior and posterior cruciate ligaments [34]. Additionally, peripheral pain sensitization (mediated by nerve growth factors or cytokines) and central pain sensitization at the spinal or cortical level can occur in KOA [56, 57]. Initially, hypersensitivity is only observed at the site affected, but, when pain becomes refractory, mechanisms for central and peripheral sensitization start to contribute towards maintaining painful conditions, independently of the peripheral process that originated the pain [58]. Mechanical factors can also trigger pain. Example of those are knee alignment, body size and strength, which facilitate degradation of tissues and influence the magnitude or manner of knee loading [51].

Knee pain is usually felt in the medial and lateral joint compartments, the retropatellar area, the upper tibia at the region of the anserine bursa, or in a combination of all of the above areas [34]. It is important to listen carefully to patients' reports, which frequently describe the pain as a deep aching that can be hard to localize, causing discomfort, which increases with changes in the weather, specially storms or drop in temperature [2]. They usually report pain while kneeling, squatting, or going up or down stairs. Activity associated pain typically begins immediately, or shortly after beginning of joint use and may persist for hours after cessation of the activity [2]. In more advanced

stages of KOA, patient can feel a constant pain, and sometimes even be woken up by pain.

Besides pain, other symptoms that patients usually report are stiffness during less than 30 minutes (commonly in the morning or following periods of inactivity), crepitus with motion, joint effusions and in more severe cases the physician observes joint deformities and subluxations [2]. Some patients may present sensory hypersensitivity of the surrounding skin, usually in the distribution of the medial or lateral saphenous nerves, associated with severe knee pain [34]. Crepitus or crunching sensations and cracking sound may be felt or heard in the knee due to cartilage erosion [34]. In addition, tenderness to palpation of involved joints may be evident in physical examination [21].

The first sign of KOA can be a decrease in the freedom of active joint movement, caused by different sources: incongruity or loss of articular cartilage, ligament and capsular contracture, muscle spasm and contracture, osteophytes or intraarticular fragments of cartilage, bone or meniscus [2].

In general, these symptoms result in a loss of function, leading to impaired performance in workplace or at home [5, 34].

Different studies already documented the associations of pain severity with the degree of functional limitation [5, 59, 60]. Pain, loss of balance, muscle weakness, stiffness and swelling have a significant influence on daily living disability [61, 62]. A global study showed that among 291 conditions, hip and knee OA was ranked as the 11^{th} highest contributor to global disability and 38^{th} highest in impairment of daily life activities [23].

Among symptomatic KOA patients, the most common limitation is walking long distances with faster decline on gait speed [63]. Besides walking, stair climbing and housekeeping are both difficult activities to do without help [64]. An UK study shows that one quarter of people over the age of 55 report a significant episode of knee pain in one year, and approximately half of these reports are associated with disability [65].

McDonough and Jette (2010) [66] clarify the relation between KOA and disability, showing that KOA does not incapacitate individuals by itself, but in a complex way. The

evidence provides support for the role of physical impairment along with other predisposing factors. Those factors can be individual (such as age, body mass index, obesity, lack of exercise, comorbid conditions or depression) and/or extra-individual (e.g. need for aid or assistance and lack of access to public/private transportation).

Physical disability compromises physical, psychological and social factors, impacting directly on Health-Related Quality of Live (HRQoL). This is understood, at the individual level, as physical and mental health perceptions and their correlates - including health risks and conditions, functional status, social support, and socioeconomic status [67]. Local factors, like laxity and proprioceptive inaccuracy, as well as age, BMI and knee pain intensity are the greatest risks to a poor function outcome. However, strength, psychosocial factors, mental health, self-efficacy, social support and the activity level are protecting factors against poor function [68]. KOA is significantly and independently associated with worst HRQoL in Italy population [69]. The same was observed in a Portuguese study [1].

2.3 KOA diagnosis

The KOA diagnosis can be done according to clinical and laboratory criteria, clinical and radiographic criteria or only clinical criteria. KOA was the first joint disease to have a clinical criteria definition by the American College of Rheumatology [70], which is summarized on table 2.1.

Table 2.1 - Criteria for classification of idiopathic KOA. From Altman et al. (1986) [70]

Clinical and laboratory	Clinical and radiographic	Clinical
Knee pain +	**Knee pain +**	**Knee pain +**
At least 5 of 9:	At least 1 of 3:	At least 3 of 6:
Age > 50 years	Age > 50 years	Age > 50 years
Stiffness < 30 minutes	Stiffness < 30 minutes	Stiffness < 30 minutes
Crepitus	Crepitus	Crepitus
Bony tenderness	+	Bony tenderness
Bony enlargement	Osteophytes	Bony enlargement
No palpable warmth		No palpable warmth
ESR< 40 mm/hour		
RF<1:40		
SF OA		
92% sensitive	91% sensitive	95% sensitive
75% specific	86% specific	69% specific

Abbreviations: ESR= erythrocyte sedimentation rate (Westergren); RF= rheumatoid factors, SF OA= synovial fluid signs of OA (clear, viscous or white blood cell count < 2000/mm^3).

The European League Against Rheumatism (EULAR) describes clinical KOA diagnosis based on the presence of three symptoms: persistent knee pain, morning stiffness and functional impairment; and three clinical signs: crepitus, restricted movement and bony enlargement [8].

To interpret and identify the natural history of osteoarthritis it is useful to access radiological imaging techniques [34]. Structural alterations can be seen in a plain radiography, when the disease is in an advanced stage, as a narrowing of joint space (due to cartilage loss), the presence of osteophytes, increased density of subchondral bone and subarticular bone cysts or geodes (figure 2.2) [2, 34, 71]. In general, these four radiographic events may occur together, but, sometimes, and in some joints only one or two of the four characteristics may be visible by radiography [2].

Figure 2.2 - Anteroposterior radiograph of knee joint with osteoarthritis. Note the greatly narrowing of joint space in lateral compartment (right knee and medial compartment (left knee) and marginal osteophyte formation.

Grading of the radiological KOA severity was first proposed by Kellgren and Lawrence (1957) [3]. It is based on a five-point scale: 0 indicates absence of any feature of osteoarthritis; 1 indicates a minute osteophyte of doubtful significance; 2 represents a definite osteophyte, but with normal joint space; 3 indicates a moderate diminution of joint space; 4 represents a greatly narrowed joint space and sclerosis of the subchondral bone.

The correlation between radiographic changes and clinical presentation of the disease varies considerably among patients [2, 21, 34], nevertheless for more severe

radiographic KOA, there is a correlation between the severity and the degree of the symptoms [72]. A study with women (40-55 years old) shows that 6% had an X-ray evidence of KOA with no pain [4].

2.4 KOA treatment

KOA, as a chronic and degenerative pathology, has currently no cure. Therefore, the aims of treatment are to reduce joint pain and stiffness, maintaining and improving joint mobility, reducing physical disability, improving health related quality of life, limiting the progression of joint damage, while aiming to minimize the toxicity of the pharmacological therapy whenever possible [73]. Additionally, KOA patients should be handled in the community and primary care [65].

The recommendations for KOA treatment includes non-pharmacological, pharmacological therapy and surgery. Figure 2.3 exposes a sequential, pyramidal approach to the management of KOA. In the first line of treatment, patients with KOA diagnosis should be engaged in an educational program, exercise and weight control. In some cases, the first line should be carried out together with the second line treatment, pharmacological and passive treatment (manual therapy, acupuncture, and other treatments given by a therapist and not requiring an active lifestyle change by the patient). Few patients will need a third line of treatment, which is surgery intervention [74]. It is important to comprehend that many elderly feel pain and stiffness and consider that this is a normal part of the aging process, rather than a disease [75], and consequently do not look for an appropriated treatment.

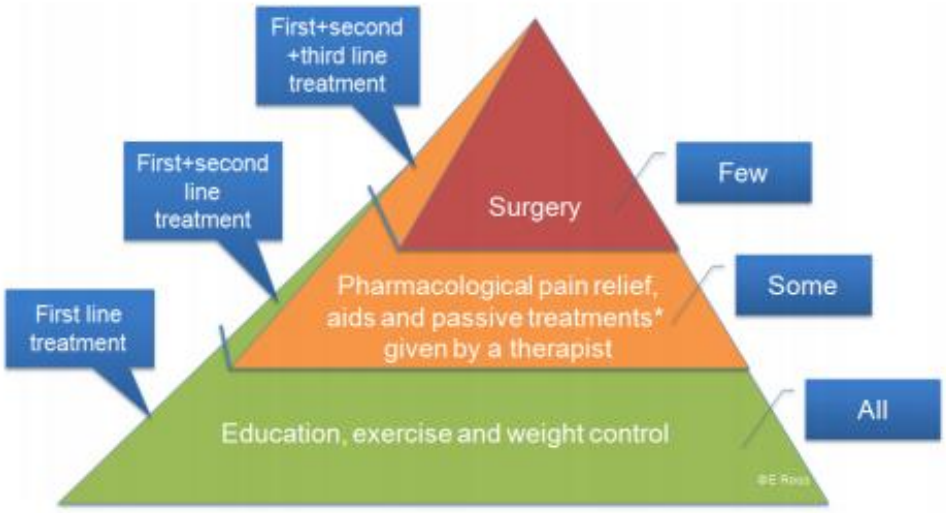


Figure 2.3 - Management of KOA: suggesting a sequential, pyramidal approach to disease management. From Ross and Juhl (2012) [74].

The Osteoarthritis Research Society International (OARSI), in 2014, proposed a non-surgical treatment for KOA (figure 2.4). It considers two important features: OA joint type (KOA only and multiple-joint OA) and the presence or not of co-morbidities. In the core treatment, for all individuals, it is recommended: land-based exercise, weight management, strength training, water based exercise, self-management, and educational programs. For pharmacological treatment they recommend acetaminophen (paracetamol) for individuals without relevant co-morbidities, capsaicin for individuals with only KOA without relevant co-morbidities, corticosteroids (intra-articular injection), duloxetine NSAIDs (oral COX-2 inhibitors) and NSAIDs (oral non-selective NSAIDs) for individuals without relevant co-morbidities, NSAIDs (topical) for individuals with only KOA. In addition, OARSI describe acupuncture, balneotherapy/spa therapy, biomechanical interventions, walking stick, electrotherapy/neuromuscular electrical stimulation, transcutaneous electrical nerve stimulation (TENS) and ultrasound, as other non-pharmacological treatments [76].

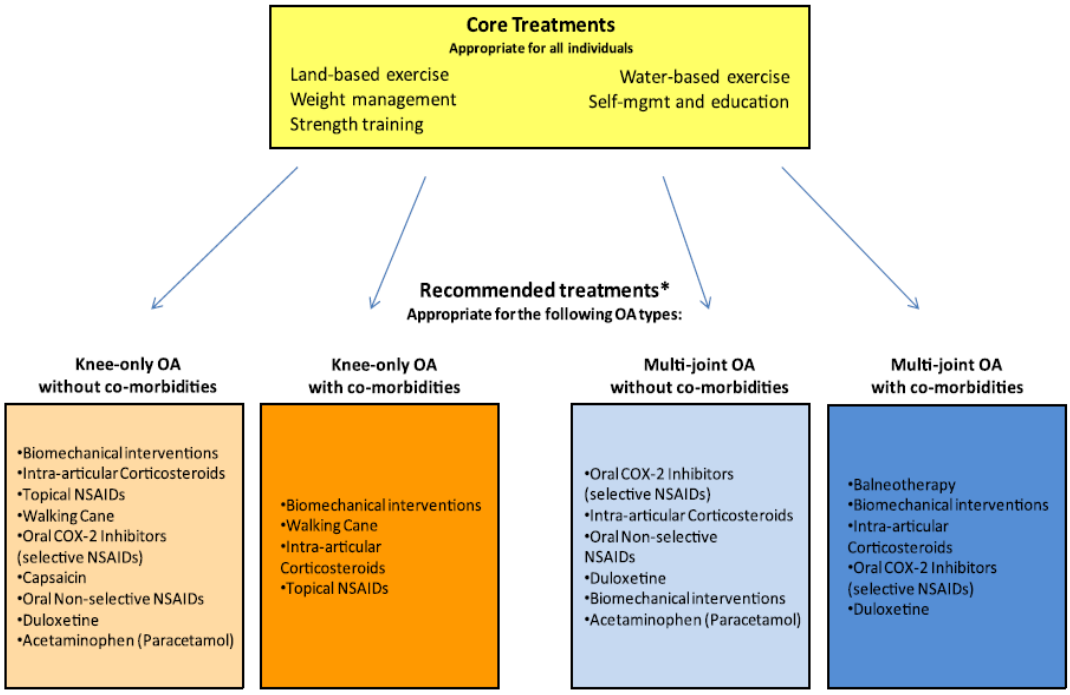


Figure 2.4 - OARSI guidelines for non-surgical management of KOA. From McAlindon et al. (2014) [76].

The European League Against Rheumatism (EULAR) published in 2013 recommendations for non-pharmacological treatment of hip and knee OA. Some important characteristics to highlight are: (1) the individualized character of the interventions according to the expectations of the individual, risk factors, level of pain and restriction of daily activities and societal participation; (2) the importance of exercise regimen that includes strengthening, aerobic activity and adjunctive range of movement/stretching exercises; (3) education should include every aspect of self-management [77].

Other recommendations are given by the ACR and englobe non-pharmacological and pharmacological therapies for KOA patients. As non-pharmacological approach, cardiovascular and/or resistance land-based exercise, aquatic exercise and loss weight are strongly recommended. In addition, self-management programs are conditionally recommended. As a pharmacological approach, the ACR conditionally recommend the use of acetaminophen, oral NSAIDs, topical NSAIDs, tramadol and intraarticular corticosteroid injections [78].

The Portuguese national recommendations described on the National Program Against Rheumatisms, *Programa Nacional contra as Doenças Reumáticas*, are in

accordance with the international recommendations and reaffirm the importance of patient education, rehabilitation and kinesiotherapy, together with the pharmacological treatment. In more severe cases, surgical treatment is recommended [79].

2.4.1 Self-management Programs

A self-management program is a kind of educational program that involves personal responsibility, and has been shown as an effective treatment for different chronic diseases [80-82]. There is no gold standard definition for the self-management concept, but Barlow refers to self-management as [83]: "the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and lifestyle changes inherent to living with chronic conditions. Efficient self-management involves the ability to monitor one's condition and to give the cognitive, behavioral and emotional responses necessary to maintain a satisfactory quality of life" (p. 547). Clark complements this idea by defining self-management as [84]: "day-to-day tasks an individual must undertake to control or reduce the impact of disease on physical health status. At-home management tasks and strategies are undertaken with the collaboration and guidance of the individual's physician and other health care providers" (p. 5). These two definitions have in common the importance of the role of patients, which must assume the control and management of their treatment.

A review of Chronic Disease Self-Management Programs [85] describes three main models of self-management program: the Flinders Model, the Expert Patient Program and the Stanford Model. The first one is based on the principles of Cognitive Behavioral Therapy (CBT). It is patient-centered and aims to enhance self-efficacy to deal with the pathology, emphasizing the role of physicians in the process [86]. The Expert Patient Program has the premise that patients are experts in managing their own disease, and with the engagement in program, patients could reduce the severity of symptoms and improve confidence, resourcefulness and self-efficacy [87]. Finally, the Stanford Model is based on Social Cognitive Theory and aims to develop self-management skills by using self-management tools. This program uses peer educators to develop self-efficacy. At least one of the peer must have some chronic condition to establish a better connection with the patient [88].

Therefore, self-management programs aim to empower individual to deal with the disease and have fewer restrictions in life. These programs are most often based on Social Cognitive Theory, by Albert Bandura [89]. Bandura affirms that the mainly determinants for adherence to health behaviors are: knowledge of risks and benefits that the practice can cause on health; expectations of benefits and expected costs of behavior; goals and aims; social and structural impediments and self-efficacy.

Self-efficacy assumes the main role on Social Cognitive Theory. It can be understood as the level of confidence that an individual has in his or her ability to succeed in dealing with their own chronic disease. To develop self-efficacy there are several tools described in literature. Examples of those are: problem solving strategy, monitoring their own condition, relapse prevention plans, group support (often peer-led) and shared decision making [85].

In the line of the Stanford Model there are several self-management programs. The first one created was the Arthritis Self-Management Program (ASMP), then, later appear the Diabetes Self-Management Program, Positive Self-Management Program, Cancer: Thriving and Surviving Program and Chronic Disease Self-Management Program (CDSMP) [90]. The focal point of these programs is to help patients to manage aspects of their chronic disease with their health care provider by empowering them with skills and confidence. This intervention is implemented around the world and shows good results in patients with different chronic conditions.

Tables 2.2 and 2.3 summarizes different self-management interventions (all with OA patients, mostly KOA) to highlight some common points that deserve attention. These programs are mostly applied for short time, and in a condensed mode. A timeline example are interventions that last 6 weeks, with one session per week for more than 2 hours each [91-93]. This aspect is important for maintaining patient's adherence, which is an important barrier to treatment. The contents of each program can vary, but self-efficacy and self-management skills appear to be important aims to be developed [91-95]. Assessments can vary from 2 month [92], 4 month [91, 94], 6 month [92-95], 9 month [96] and, less often, 12 months [91, 93]. The outcomes and results depend of each study, but most commonly the improvement on self-efficacy [91, 93, 94], self-management

behavior [91, 94], pain [92-94, 96] and self-reported physical function [92, 96] are highlighted.

In addition, a study of the Chronic Disease Self-Management Program in the United States with 1170 community-dwelling participants from 17 different states and involving 22 organizations, with three assessments: before intervention, after 6 months and after 12 months, shows significant reduction in emergency room visits (5%) at both 6-month and 12-month assessments, as well as a reduction in hospitalization (3%) at 6-month assessment. This corresponds to potential savings of $364 per participant and a national saving of $3.3 billion US dollars if 5% of adults with one or more chronic conditions were reached [97].

Table 2.2 - Self-management Programs, sample, study design, program details and main results.

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s name Program´s principles Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
Self-Management education for Persons with Arthritis: Managing Comorbidity and Eliminating Health Disparities **Goeppinger, et al. 2007** [94]	• N=416 (Arthritis patients) • Mean age=64yrs 2 groups: • Arthritis Self-Help Course (ASHC) • Chronic Disease Self-Management Program (CDSMP)	• RCT • ASHC and CDSMP • Self-management skills • 6 weeks, 2 times per week, 2h30min • 4 and 6-month follow-up	• Self-efficacy, Self-reported general health ASHC: + CDSMP: + • Disability, Pain ASHC: = CDSMP: + • Stretching, strengthening and aerobic exercise (minutes/week) ASHC: + CDSMP: = • Fatigue, Cognitive symptom management, Activity limitation, Health distress, Physician visits, Hospitalizations, Nights in hospital ASHC: = CDSMP: =
Effect of an education program for patients with osteoarthritis in primary care: a randomized controlled trial **Hansson, et al. (2010)** [95]	• N=114 (knee, hip or hand OA patients) • Means age=63yrs 2 groups: • Patient Education Program for Osteoarthritis (PEPOA) • CG (usual care)	• RCT (6-month follow-up) • PEPOA • Self-efficacy principles, • 5 weeks, once per week, 3hours • 6-month follow-up	• Health-related quality of life, balance: + • Pain, function and other symptoms, grip ability (Between groups analyses)
The effect of an educational program to improve health-related quality of life in patients with osteoarthritis on waiting list for total knee replacement: a randomized study **Nunez, et al. (2006)** [96]	• N=80 (KOA patients, waiting list for TKR) • Mean age=71yrs 2 groups: • Therapeutic Education and Functional Readaptation (TEFR) • CG (conventional treatment)	• RCT • TEFR • General education about disease and exercise. Table of exercise to practice at home • 3-month, 1st week and 3th month: 2 individual visit (30 min), 3th and 4 th week 2 group session (90 min). • 9-month follow-up	• Function (self-reported): + (between group analyses) • Physical function, physical role, bodily pain, general health, vitality, social, function, emotional role, mental health: = (between group analyses) • Pain, bodily pain and function: + TERFR (comparison with baseline)

Abbreviations: RCT=randomized controlled trial; CSM=cognitive symptoms manage; CWP=communication with physician; CG=control group.

Table 2.3 - Self-management Programs, sample, study design, program details and main results. (Continuation)

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s name Program´s principles Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
A randomized controlled trial of a self-management education program for osteoarthritis of the knee delivered by health care professionals **Coleman, et al. (2012)** [92]	• N=146 (KOA patients) • Mean age 65yrs 2 groups: • Osteoarthritis of the Knee Self-Management Program (OAK) • CG (usual care)	• RCT • OAK • Self-Management skills + printed information • 6 weeks, once week, 2,5 hours • 8 weeks, 6-month follow-up	• Pain, physical function, role physical, Body Pain, Vitality and Social Function, mobility: + (8 weeks, 6-month, between groups) • Hamstring strength, range of motion, knee flexion: = (8 weeks, 6-month, between groups)
The Internet-Based Arthritis Self-Management Program: A One-Year Randomized Trial for Patients with Arthritis or Fibromyalgia **Lorig, et al. (2008)** [93]	• N=855 (rheumatoid arthritis, OA, or fibromyalgia patients) • Mean age=52 years 2 groups: • Internet-based Arthritis Self-Management Program (ASMP) • CG (usual care)	• RCT • ASMP • Self-Management skills, self-efficacy theory and skills mastery • 6 weeks, (log on at least 3 times, total 2 hours/week) • 6 and 12-months follow-up	• Health distress, activity limitation, self-reported global health, pain, self-efficacy: + (6 and 12 month, between groups) • Health behaviors or health care utilization: = (6 and 12-month, between groups)
A randomized controlled study of the Arthritis Self-Management Programme in the UK **Barlow, et al. (2000)** [91]	• N=544 (Arthritis patients) • Mean age=58yrs 2 groups: • Arthritis Self-Management Program (ASMP) • CG (usual care)	• RCT • ASMP • Self-Management skills • 6 weeks, once week, 2 hours • 4, 12 months follow-up	• Pain and other symptoms (Arthritis Self-Efficacy), CSM, CWP, dietary habit, exercise and relaxation: + (4 and 12 month, between groups) • Physical functioning, pain and general physicians visits: = (4 and 12 month, between groups)

Abbreviations: RCT=randomized controlled trial; CSM=cognitive symptoms manage; CWP=communication with physician; CG=control group.

2.4.2 Exercise Programs

Even thou international guidelines strongly recommend exercise as the core of non-pharmacological treatment for KOA patients, exercises are not often endorsed by general practitioners [98, 99].

Evidence from systematic review and meta-analysis strongly recommend exercise to improve pain and physical function in KOA patients, in short and medium term [9, 100-103]. However, it continues to be a challenge to maintain exercise benefits for a longer time [104].

Patient´s adherence to exercise programs for a long time is challenging. The reason why people give up exercise practice involves complex factors. Social support from friends, relatives and physicians is rated as a significant motivator to join and continue with exercise [105]. Campbell [106] shows that reasons to continue compliance with a home-based exercise program for KOA patients involve: willingness and ability to accommodate exercises within everyday life, the perceived severity of the symptoms, attitudes towards arthritis and comorbidity and previous experiences of osteoarthritis. In addition, a necessary precondition to continue compliance is the perception that the exercise is effective in ameliorating unwanted symptoms.

Facilitators and barriers to exercise can be analyzed as interplay between internal and external factors, which can influence exercise behavior [107]. Internal factors can be analyzed as individual attribute and personal experience. Individual attributes include: motivation, personality, self-image, health attitude, exercise history and disease knowledge. On the other hand, personal experience includes: effect of pain, effects of stiffness and fatigue, finding suitable exercise, perceived benefits of exercise and quality of sleep. External factors can be divided into social or physical environment. Social environment involves: family support, physical therapy professional care, encouragement of physicians, training partners and socioeconomic status, while physical environment involves: effect of weather, availability of exercise classes, accessibility of facilities and transportation.

Pain is the major barrier to exercise adherence and maintenance [108], however the hope of decreasing the pain by exercising turns out to be a major facilitator to encourage regular exercise [107].

The belief that osteoarthritis is a common consequence of the aging process is another barrier that prevents exercise practice [108]. Several strategies can be used by clinicians, physiotherapists or health professionals to overcome barriers to exercise. A personalized exercise prescription is important, considering the clinical condition, goals and preferences of the subject. Also important is the availability of appropriate exercise equipment and facilities (like transportation) [99].

Land-based exercise, strength training and water based exercise are present in the core recommendation of OARSI [109]. Different types of land-based exercises have been reported on literature to be effective on KOA management, including: muscle strengthening/resistance training [110-112], stretching/range of motion [113], cardiovascular/aerobic conditioning [114], neuromuscular exercise [115] and Tai Chi [116]. A current systematic review supports a combined intervention of strengthening, flexibility, and aerobic exercise to improve limitation in function for lower limb osteoarthritis patients [100].

For strengthening exercise, the American Geriatric Society (AGS) suggests: (1) Isometric: low–moderate, 40–60% maximal voluntary contract, daily; and (2) Isotonic: low (40% 1 RM 10–15 reps), moderated (40–60% 1 RM 8–10 reps) and high (>60% 1 RM 6–8 reps), for 2–3 times per week [117]. Similar benefits are found with concentric and concentric-eccentric training [111], as well as with isokinetic, isotonic and isometric muscle-strengthening [112], and as weight-bearing and non-weight-bearing training [118]. A study with KOA elderly subjects found no difference between high-resistance exercise and low-resistance exercise for improvement of pain and physical function [119].

Aerobic exercise is effective to improve pain and physical function and to reduce depressive symptoms [120], as well as to improve self-efficacy for managing arthritis symptoms [113]. For aerobic training, the recommendation is low–moderate intensity (from 40–60% of VO2 max until 60–65% VO2 max), accumulation of 20–30 min/day, 2–5/week [117].

Reduced joint range is common in KOA patients due to reduced extensibility of nearby muscles and contracture of periarticular soft tissue [99]. For that matter, it is important that an exercise program for KOA aims to increase joint range of motion. Joint range of motion exercises are frequently integrated at the beginning and/or in the end of the exercise program sessions [113, 114]. The recommendation is to stretch until subjective sensation of resistance, once a day, and for a long term goal stretch to full range of motion, 3-5 times a week [117].

There is no clinical recommendation for balance exercises, but people with KOA have impaired balance, placing them at increased risk of falling [121]. For this reason, clinicians should assess this component and prescribe specific balance exercise [99]. Neuromuscular exercises aim to improve sensorimotor control and achieve compensatory functional stability, using functional and weight-bearing exercises. The level of training and progression is determined by the patient's neuromuscular function. The efficacy is little documented, because it is a new approach, but studies have shown improvement on pain and function in KOA patients [115, 122].

It is also important that KOA patients that are in an exercise program also increase their physical activity level in everyday life. Higher levels of spontaneous activity generate a better overall physical function [123]. A pedometer or accelerometer can facilitate the improvement on physical activity by providing additional motivation [99].

There are several ways to deliver exercise, including individual (one-on-one) treatments, class-based (group) programs and home-based programs. The evidence suggest that to improve pain and function, individual treatment shows the greatest benefits, but not statistically different in comparison with the remaining programs [124].

An important and difficult characteristic of exercise programs for KOA patients is to prescribe load, progression and intensity of exercise, especially concerning strength. The main challenge is to adequate ideal exercise intensity, without causing pain. Pain can be a signal that the individual is overtraining and should diminish intensity. For this matter, it is fundamental that the desired load intensity and pain level are taken together into consideration, when prescribing the exercise intensity. When the American College of Sport and Medicine (ACMS) [125] recommends exercise for arthritis patients, it

reinforces the idea that intensity, time and progression should be determined by the pain level, and suggests the Visual Numeric Pain Scale [126] to assess this outcome.

Besides intensity, dosage must be taken into account when prescribing exercise for KOA patients. Dosage is the combination of the total number of sessions within a program, the frequency, duration and volume. In tables 2.4, 2.5 and 2.6 some exercise programs are reviewed. It can be noted that programs often take the duration of 8 weeks and a periodicity of 3 times a week [110-112, 118, 119]. Less observed are programs with the duration of 12 weeks and periodicity of 2 times a week [113, 116, 127]. Programs' follow-ups vary from 3 months [110, 114, 116, 127], 6 months [114, 116] to 12 months [112, 116]. Assessments post-intervention, without follow-up, are also described in the same table [111, 112, 118, 119].

Interventions' results depend on the specificity of each program. For strength training, improvements on pain [110-112, 119], physical function [111, 118, 119], strength [111, 112, 118, 119], disability [112], Cross-Sectional Area of the quadriceps and hamstring [111], and waking capacity [118, 119] are observed. For multi-component land based exercises, improvements on pain and symptoms [113, 114, 116], self-reported function [114, 116], exercise self-efficacy [114, 116], disability [127], speed, aerobic endurance, and arm strength [113] are observed on post-intervention; and improvement on pain and fatigue [114, 116] are observed at 6-months follow-up.

Table 2.4 - Exercise Programs, sample, study design, program details and main results.

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s detail Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
Osteoarthritis of the Knee: Isokinetic quadriceps Exercise Versus an Educational Intervention **Maurer, et al. (1999)** [110]	• N=113 (KOA patients) • Mean age=65yrs 2 groups: • Isokinetic Exercise (IE) • Patient education (PE)	• RCT • IE: strength training of the knee extensor muscle group unilaterally with dynamometer • 3 x week, 8 weeks • PE: 4 discussion and lectures + Arthritis Foundation pamphlets • 12-weeks follow-up	• Isometric and 90º/sec extension torque: + both group, no difference between groups • Pain change and stairs pain: + IE (difference between groups) • ROM: - (both groups) • Extension torque at 120º/sec related to reduce pain, improved function, and overall outcome
A Randomized Controlled Trial of the People with Arthritis Can Exercise Program: Symptoms, Function, Physical Activity, and Psychosocial Outcomes **Callahan, et al. (2008)** [114]	• N=346 (Arthritis patients) • Mean age=70yrs 2 groups: • People with Arthritis Can Exercise (PACE) • Usual Care (CG)	• RCT • PACE: Land-base (Arthritis Foundation), Self-management through exercise • 8-week, twice weekly for 1 hour • 8 weeks, 3 and 6-months follow-up	• Symptoms (pain, fatigue and stiffness), function and arthritis self-efficacy: + (8 weeks, PACE) • Level of physical activity, exercise self-efficacy: = (8 weeks, PACE) • Pain, and fatigue: + (6-month, PACE) • Function, exercise self-efficacy: = (6-month, PACE)
Concentric Versus Combined Concentric-Eccentric Isokinetic Training: Effects on Functional Capacity and Symptoms in Patients with Osteoarthritis of the Knee **Gur, et al. (2002)** [111]	• N=23 (KOA grade 2 and 3) • Mean age=56yrs 3 groups: • Concentric (CON) • Concentric-eccentric (CON-ECC) • Non treatment (CG)	• Repeated measure • CON:12 concentric contractions of each knee extensor and flexor muscles; • CON-ECC: 6 concentric and 6 eccentric contractions of each knee muscle group. Both: using a spectrum of angular velocities ranging from 30°/s to 180°/s with 30°/s intervals, for both sides • 3 days a week for 8 weeks • Pre and post intervention	• Daily functions, functional capacity, pain for the selected daily life activities, pain during the functional tests, Cross-Sectional Area (CSA) of the quadriceps and hamstring, concentric and eccentric peak torque of hamstring: + (CON and CON-ECC) • Concentric peak torque of quadriceps: + (CON) = (CON-ECC) • Eccentric peak torque of quadriceps: + (CON-ECC) = (CON)

Abbreviations: RCT= randomized control trial; CG= control group; sec=seconds; ROM=range of motion; RM=maximum repetition; rep=repetition; ADL=activities of daily living; BMI=body mass index.

Table 2.5 - Exercise Programs, sample, study design, program details and main results. (Continuation)

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s name Program´s principles Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
Effects of Weight-Bearing Versus Non-Weight-Bearing Exercise on Function, Walking Speed, and Position Sense in Participants with Knee Osteoarthritis: A randomized Controlled Trial **Jan, et al. (2009)** [118]	• N=106 (KOA patients) • Mean age=62yrs 3 groups: • Weight-bearing (WB) exercise • Non-weight-bearing (NWB) exercise • CG	• RCT • WB: sitting position, EN-Dynamic resistance device, extend and flex the knee join (90°/2s) • NWB: sitting position, a pad (attached to the cable of the isotonic dynamometer) was placed on the foot extend and flex the knee join (90°/2s) • Both for 3 sessions a week, 4 sets, with 6 repetitions a set and 1 minute of rest, 8-week • Pre and post intervention	• WOMAC functional scale, walking time on 4 different terrains, knee extensors and flexors at the 3 velocities of muscle contraction: + WB and NWB • Reposition error, walking speed on the figure of 8 and spongy surface: + WB = NWB • Walking speed up and down stairs: + NWB = WB
Evaluation of a multi-component group exercise program for adults with arthritis: Fitness and exercise for People with Arthritis (FEPA) **Levy, et al. (2012)** [113]	• N=110 (Arthritis patients) 2 groups: • Middle-aged (55yrs) • Older (76yrs) • Fitness and Exercise for People with Arthritis (FEPA)	• Preliminary evaluation • FEPA: designed to increase strength, flexibility, balance, and cardiovascular health, with low-impact, safe, and joint-protective, and focus on teaching proper body mechanics • Twice weekly, one-hour for 3-month	• Mobility, upper body flexibility: + older, = middle-aged • Speed, aerobic endurance, arm strength and endurance, pain symptoms: + both group • Physical function (self-reported), self-efficacy for arthritis pain management: + middle-aged = older • Affect: = both group

Abbreviations: RCT= randomized control trial; CG= control group; sec=seconds; ROM=range of motion; RM=maximum repetition; rep=repetition; ADL=activities of daily living; BMI=body mass index.

Table 2.6 - Exercise Programs, sample, study design, program details and main results. (Continuation)

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s name Program´s principles Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
Physical Exercise and the Prevention of Disability in Activities of Daily Living in Older Persons with Osteoarthritis **Penninx, et al. (2001)** [127]	• N=250 (KOA patients) • Mean age=69yrs 3 groups: • Aerobic Exercise program (AE) • Resistance Exercise program (RE) • Attention CG	• RCT (3, 9 and 18-month follow-up) • AE: 3-month facility-based walking program and a 15-month home-based walking program • RE: 3-month RE and a 15-month home-based program • Control group: monthly education group session (3 months), bimonthly (months 4-6) or monthly (months 7-18) to maintain health updates and provide support	Aim to examines whether an exercise program can prevent ADL disability. • Incidence of ADL disability was lower in the exercise groups (37.1%) than in the attention control group (52.5%) • The relative risks were 0.60 for resistance exercise and 0.53 for aerobic exercise • The lowest ADL disability risks were found for participants with the highest compliance to exercise
Tai Chi Is Effective in Treating Knee Osteoarthritis: A Randomized Controlled Trial **Wang, et al. (2009)** [116]	• N=40 (KOA patients) • Mean age=65yrs 2 groups: • Tai Chi • Attention control	• RCT • Tai Chi: 10min self-massage and a review of Tai Chi principles, 30min Tai Chi movement, 10min breathing technique and 10min relaxation + printed teaching materials. Twice weekly, 60 min, for 12 weeks • Attention control: wellness education and stretching, 40 min didactic lessons + 20 min stretching exercises (held for 10-15sec) • Once a week, 60 min for 12 weeks • (3, 6, 12-months follow-up)	• Pain, physical function (self-reported), subjective self-report patient global assessment, objective physician global assessment: + (Tai Chi, 3 months, between group) • Self-efficacy and depression: + (Tai Chi, 3, 6 and 12 months, between group) • Pain, physical function (self-reported), subjective self-report patient global assessment, objective physician global assessment: = (6, 12 months, between group) • Stiffness, physical performance, BMI: = (3, 6, 12 months, between group)

Abbreviations: RCT= randomized control trial; CG= control group; sec=seconds; ROM=range of motion; RM=maximum repetition; rep=repetition; ADL=activities of daily living; BMI=body mass index.

2.4.3 Combined intervention: Education and Exercise

Several interventions combine an educational program, mostly self-management, with an exercise program. Tables 2.7 and 2.8 summarizes those programs where the sample is mostly KOA individuals and elderly.

In relation to program frequency, several possibilities can be observed: once per week [128, 129], twice per week [130, 131] and three times per week [132]. The duration also varies from 4 weeks [128], to 6 weeks [129], 5 weeks [130], 8 weeks [132] until 10 weeks [131].

The most interesting fact about those programs is that they usually assume one component (educational or exercise) as the main component, the other one having a complementary role. For example, in Kao´s study (2012) [128], more attention was given to the educational component (60 minutes), while exercise had a duration of only 20 minutes. Same occurs with Yip´s study [129] which added the exercise as a part of the educational program. Patients were encouraged to make their own action plans, (one of the main activities that are part of the educational program) as an exercise activity and to use a pedometer three times per week. In other studies [130, 132-135], more attention was given to the exercise component. Just one study gave the same importance to both components [131]. This program was performed 2 times per week with duration of 10 weeks, one hour for the educational component and one hour for the exercise component.

The exercise is often multi-component [128-130, 132, 133, 136]. There are two exceptions: the Mendelson´s study [131], which applied a warm water exercise and the Skou´s study [134], which used neuromuscular exercise.

The educational framework of the above programs is mostly based on the Behavior Change Theory [128-131, 136], Self-Efficacy principles [128, 129, 132, 133] and self-management skills [129-131]. McKnight´s study [133] emphasized coping strategies and had the purpose of providing more information about the pathology [134].

The results of the several studies (table 2.7 and 2.8) are consistent and show improvements on pain and other symptoms [129, 131-134, 136], physical function [132, 133, 136], self-management skills [129, 131], self-reported function [129, 136], self-

reported disability [131, 133], exercise health believe [130], coping techniques [131], self-efficacy [131, 132], exercise adherence [132], weight loss [136].

Table 2.7 - Combined Exercise and Educational Programs, sample, study design, program details and main results.

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s detail Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
The effectiveness of a self-management program on quality of life for knee osteoarthritis (OA) patients **Kao, et al. (2012)** [128]	• N=205 (KOA patients) • Mean age=67yrs 2 groups: • TOAP (Taiwan OA Program) • CG (routine care)	• Quasi-experimental • TOAP: Self-Efficacy and Behavior Change, 20 min education, 20 min stretching and strengthening exercise and 40 min discussion • 4 weeks, once per week, 1h20min • (post-intervention and 8-month follow-up)	• Health related Quality of life: physical component summary: = post intervention and follow-up • Mental component summary = post intervention and + follow-up; disability = post intervention and follow-up
Impact of an arthritis self-management program with an added exercise component for osteoarthritic knee sufferers on improving pain, functional outcomes, and use of health care services: An experimental study **Yip, et al. (2007)** [129]	• N=120 (KOA patients) • Mean age=65yrs 2 groups: • Arthritis Self-Management Program (ASMP) • CG (routine care)	• RCT • ASMP: self-efficacy and behavior change + action plain (stretching exercises, walking, and Tai Chi + pedometer 3 days/week) • 6 weeks, once week, 2 hours • Post-intervention and 16-weeks follow-up	• Pain, other symptoms (ASE), 3 in 5 self- management skills, ability to perform daily activities, arthritis pain: + • Disability health outcomes: = (16 weeks between groups analyses)
Long-term clinical benefits and costs of an integrated rehabilitation program compared with outpatient physiotherapy for chronic knee pain **Jessep, et al. (2009)** [130]	• N=64 (chronic knee pain) • Mean age=66yrs 2 groups: • Enabling Self-management and Coping with Arthritic Knee Pain through Exercise ESCAPE • Physiotherapy	• RCT • ESCAPE: 10-15 min behavior change, self-management skills, coping strategies + 40 min, 10 exercise individually tailored (quadriceps strength, dynamic control, balance, co-ordination and function). Booklet with exercise for follow-up and 1 visit at 4th month • 5 weeks, twice week • Post-intervention and 12-month follow-up	• Exercise health believe: + • Physical function, pain, anxiety, depression and HRQOL: = (12-month between group analyses) • Cost effectiveness: favorable to ESCAPE

Abbreviations: CG=control group, min=minutes; RCT=randomized control trial; ASE=Arthritis Self-Efficacy; HRQOL=Health related quality of life.

Table 2.8 - Combined Exercise and Educational Programs, sample, study design, program details and main results. (Continuation)

Study	**Sample** N (participants' characteristic) Mean age Intervention groups	**Study design and program details** Design Program´s detail Program´s duration and frequency Assessment time	**Results** **Outcomes** + significant improvement = no significant difference
Integrating self-management and exercise for people living with arthritis **Mendelson et al. (2011)** [131]	• N=347 (arthritis patients) • Mean age=70yrs • Arthritis Control through Education and Exercise, PACE-Ex	• Retrospective Review (9yrs) • PACE-Ex:1st hr group discussion: SM skills and lifestyle changes 2nd hr a warm water (34°C) exercise session • Twenty 2-hour group sessions, twice weekly, 10 weeks	• Self-efficacy to manage arthritis pain and stress, use relaxation and coping techniques, improve fitness without flare and contact the correct health care professional, self-reported health status and disability, pain, self-management behaviors: + • Keep list of medications: =
The efficacy of 12-weeks non-surgical treatment for patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up **Skou, et al. (2014)** [137]	• N=79 (knee, hip and both pain) • Mean age 62yrs 2 groups: • Good Life with Arthritis in Denmark (GLAD) • CG	• RCT • GLAD: three 1.5hr of education (about OA and its treatment) + 12 sessions, individualized exercise, Neuro Muscular Exercise Program (NEMEX). • 3 and 12-month follow-up	• Pain and HRQoL: + (3 and 12-month follow-up) • Change in self-efficacy, functional lower limb strength and self-efficacy at 3-month were predictors of 12-month pain improvements • Self-efficacy at 3 months was predictor of 12-mont quality of life improvements
Exercise and Dietary Weight Loss in Overweight and Obese Older Adults with Knee Osteoarthritis **Messier, et al. (2004)** [136]	• N=316 (BMI>28 kg/m2, KOA patients) • Mean age=69yrs 4 groups: • Exercise only (I) • Dietary weight loss only (II) • Dietary weight loss plus exercise (III) • Usual care healthy lifestyle (control)	• RCT (6 and 18-months follow-up) • I: aerobic and resistance, 3 days/week, facility based (4 month), transition facility and home (2 month) • II: goal weight loss of 5% during the 18-month, 3 phases: intensive (months 1–4), transition (months 5–6), and maintenance (months 7–18) • 16 weekly sessions • III= I+II • Control	• Physical function (self-reported), weight loss, 6-minute walk distance, stair-climb time, pain: + (III, 18 months, compared with control) • Physical function (self-reported): = (I, II, 18 months, compared with control) • Weight loss: + (II, 18 months, compared with control) • 6-minute walk distance: + (I, 18 months, compared with control) • Radiographic progression: = (I, III, III, 18 months, compared with control)

Abbreviations: CG=control group, min=minutes; RCT=randomized control trial; ASE=Arthritis Self-Efficacy; HRQoL=Health related quality of life.

2.4.4 Supplementation for osteoarthritis

The pharmacological recommendation for KOA patients to control symptoms involves mainly NSAIDs and analgesic [8]. Those drugs have been effective on pain relief and improvement of function, but account for relevant side effects, including peptic ulcer (less commonly) and hepatic or renal failure [138, 139]. For this reason, it is crucial to consider different possibilities that can bring a safer profile and as well good results to control symptoms, such as supplements treatment.

Approximately 30 percent of OA patients have already used supplements to treat their condition [140]. Physicians are increasingly preescribing the use of dietary and nutritional supplements for KOA patients [141]. The most recommended supplements are Chondroitin Sulfate (CS) and Glucosamine Sulfate (GlcN) [142]. Both are glycosaminoglycans considered as Symptomatic Slow Acting Drugs for Osteoarthritis (SYSADOA); besides controlling symptoms, these compounds demonstrate disease-modifying (DMOAD) potential, based on measurements of joint space narrowing on radiographs [143].

Others nutritional supplements commonly used by KOA patients are: S-**S**-Adenosyl-L-methionine, Harpagophytum procumbens (devil's claw), Curcuma longa (turmeric), and Zingiber officinale (ginger). However, there are insufficient reliable evidences regarding long-term safety or effectiveness of these substances[142]. Natural substances can be used to prevent the degradation or enhance the repair of joint cartilage. In the other hand, this is an intriguing field, with little scientific evidence [138].

CS and GlcN are considered chondroprotective agents, which can: (1) stimulate chondrocyte synthesis of collagen and proteoglycans, as well as hyaluronate production at synoviocytes level; (2) inhibit joint degradation and (3) prevent fibrin formation at the level of subchondral and synovial blood vessels [144]. CS is the predominant glycosaminoglycan in the joint cartilage, and besides the metabolic effect at the joint level, it has an inhibitory competitive action against the degradative enzymes on the matrix and synovial fluid [144, 145]. In other hand, GlcN participates as a substrate in the synthesis of glycosaminoglycans (GAGs), proteoglycans and joint cartilage hyaluronate [146]. In addition, GlcN inhibits the enzymatic degradation and reduces the fibrin thrombin in the periarticular microcirculation [144]. Its efficacy was tested on animal

models and in vitro studies, which showed normalization of articular metabolism during the healing of chondral lesions and a discreet anti-inflammatory action [147]. The combination of CS and GlcN is satisfactorily orally absorbed by saturation mechanism, which is important for clinical practice [148]. The supplement dose usually prescribed for KOA patients is 1500 mg of GlcN and 1200 mg of CS a day [146].

In 2012, the American College of Rheumatology [78] conditionally recommended that patients with KOA should not use those substances. Later, in 2014 the OARSI described as uncertain the use of GlcN and CS related to its efficacy on symptoms relief and as inappropriate for disease modification for KOA individuals [76].

A meta-analysis of double-blind, randomized, placebo-controlled trials with glucosamine and chondroitin sulfates, demonstrates moderate to large effects on reduction of pain and improvement on function. However, quality issues and probable publication bias suggest that these effects are exaggerated [149].

A study which reviews 8 meta-analysis and 5 RCT concluded that the use of CS and GlcN did not have clinical effects on knee and hip OA patients [146].

A systematic review concluded that even though international guidelines for KOA treatment do not recommend the use of CS and GlcN supplement, there is significant evidence in published literature, which supports the promising disease-modifying potential, based on measurement of joint space narrowing on radiographs, of GlcN and CS combined [143].

A current meta-analysis of placebo controlled trials with GlcN, shows that it moderately reduced pain, although a high level of between-trial inconsistencies were observed, mainly because of different supplement brands and overall risk of bias [150].

A multicenter, randomized, double-blind, non-inferiority trial concludes that combined chondroitin sulfate and glucosamine have comparable efficacy on celecoxib regarding symptoms, function, and joint swelling/effusion in patients with symptomatic KOA [151].

The evidence needs more clarification. Nevertheless, the international guidelines do not recommend these supplements mainly for economic reasons [143]. Even thou

experts consider as questionable the recommendation for CS and GlcN, they do recognize that those substances have a good quality of evidence, a very low risk score, a moderate to high effect size (up to 0.75 for CS) and a high benefit score [76].

The use of these supplements is an individual patient/physician decision, taking into consideration the scientific, medical and economic evidence.

2.5 Assessments for KOA patients

It is important to know the patient´s characteristics in a biopsychosocial approach, as there is interaction between them. Besides, before prescribing any treatment, it is essential to assess the effectiveness of a program. For this matter, it is important to address KOA assessment. The assessment should include both self-reported measures and physical fitness tests. Which are complementary and essential to clinical practice [152]. The self-reported measures reveal the self-perception of how a condition affects the individual´s life or what a person is able to accomplish, and have broad use in the health field [153, 154]. The main outcomes for KOA patients are symptoms, quality of life and physical function. Those outcomes can be assessed by specific and/or general instruments. The most used specific instruments are the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [155], the Lequesne Algofunctional Index [156] and the Knee Injury and Osteoarthritis Outcome Score (KOOS). The more frequent general instruments used as measures of health outcomes are: the Medical Outcomes Study – 36 item Short Form (SF-36) [157, 158], EuroQol (EQ-5D) [159] and the Health Assessment Questionnaire (HAQ) [160]. In addition, during clinical trials, pain should be assessed every day, in a pain diary, to provide individualized care. The ACSM recommends the use of the Visual Numeric Pain Scale [126].

Among the recommendations for performance-based tests, the OARSI suggests a set of five physical performance measurements for hip and knee OA: 30-s chair-stand test, 40 m fast paced walk test, stair-climb test, 6MWT and Timed “up-and-go” [161]. Those measures are representative regarding typical activities relevant to KOA patients. Another battery of tests, that is not specifically for KOA but can be used as an indicative of sarcopenia, is the Short Physical Performance Battery (SPPB) [162]. These tests

evaluate balance (individual's ability to stand with feet together side-by-side, semi-tandem and tandem positions), gait (walk 8 ft), strength and endurance (time to rise from a chair and return to the seated position five times) [163]. Therefore, when choosing assessment tests to be part of the assessment to characterize KOA subjects or analyze the effectiveness of an intervention, it is crucial to take into consideration the international recommendations [161], training specificity and the subjects' characteristics, in order to obtain an efficient assessment, but not painful or exhausting.

In the health educational field, when analyzing self-management programs, the assessment must be done according to the strategies used in each program. In addition, self-management education is focused on patient concerns and problems. Therefore, a detailed needs assessment must be done for each new topic and group of patients. Outcomes assessment should include several behaviors, such as exercise behaviors, medical care, self-efficacy for managing the disease, diet behavior and lifestyle [88]. The choice of an appropriated instrument should take into consideration a thorough examination. Regarding self-management interventions, it is common to assess the results on follow-up, because some behavior changes need time to be expressed; e.g. communication with physician, requires time to express the difference.

In clinical research, besides the statistical significance concerning the selected outcomes, it is important to assess clinically the participants perception of change; for this matter the Patient Global Impression of Change Scale (PGICS) is often used in clinical research, mostly in musculoskeletal studies, only after the intervention [164].

2.6 The aims of the dissertation

The present dissertation aims to investigate the efficacy of a self-management and exercise program in knee osteoarthritis symptoms, health behavior, quality of life and physical fitness in elderlies.

The thesis presents five articles conducted under a clinical trial of a self-management and exercise program for KOA elderly subjects.

Chapter 4 is a methodological study (**article 1**) with the purpose of designing a Self-Management and Exercise Program for elderly patients with KOA, named PLE^{2}NO. This was a 3-month Randomized Controlled Trial (RCT).

Articles 2 and 3 (chapters 5 and 6) are cross-sectional analyses with baseline values of the PLE^{2}NO sample. **Article 2** aims to explore which factors (symptoms, physical function and quality of life) best predict the performance of the Timed "up-and-go" test. **Article 3** aims to investigate the coping strategies utilized by the sample, and if any differences in relation to sociodemographic data, the severity of KOA, pain and other symptoms can be observed.

Furthermore, articles 4 and 5 (chapters 7 and 8) analyze the effects of PLE^{2}NO intervention. **Article 4** aims to assess the impact of the Self-Management and Exercise program in KOA symptoms, self-management behavior (communication with physician and cognitive symptoms management) and physical fitness outcomes (aerobic capacity, lower limb functional strength, handgrip strength and flexibility). A**rticle 5** aims to evaluate the effectiveness of the Self-Management and Exercise program on Health Related Quality of life (HRQoL index), physical activity, self-efficacy and skill related physical fitness components (agility, gait speed and balance).

Chapter 3: Methodology

3.1 Studies Overview

This chapter contains a brief description of the methodology involving the five articles of this thesis. The study protocol (Article 1) is described on Chapter 4 and contains details about the methodology of the clinical trial. In addition, further specific details will be provided in each article. The study protocol presented in this thesis was approved by the Faculty of Human Kinetics - University of Lisbon Ethics Committee and conducted in accordance with the Declaration of Helsinki. Articles 2 and 3 (chapter 5 and 6) result from a cross-sectional analysis, with data collected on the baseline assessment of PLE^{2}NO program. The PLE^{2}NO is a single-blinded, Randomized Controlled Trial (RCT) registered at the ClinicalTrials.gov (ID: NCT0256283) with a three-month duration and a six-month follow-up. Articles 4 and 5 (chapter 7 and 8) include the analysis of the effects of PLE^{2}NO program (table 3.3).

3.2 Participants

All articles concern the same sample: elderly individuals with KOA. The enrolment procedure, eligibility criteria and randomization process are described in detail on chapter 4. The participants' characteristics on baseline are presented on table 3.1 and 3.2.

Table 3.1 - Frequency analyses of demographic variables at baseline for Educational Group (EG), Self-Management Exercise Group (SEG) and total sample.

	Variables	EG (n=32) n (%)	SEG (n=35) n (%)	Total n (%)
Sex	Male	13(40.6)	7(20)	20(29.9)
	Female	19(59.4)	28(80)	47(70.1)
Age Groups (years)	60-70	26(81.3)	15(42.9)	41(61.2)
	70-80	4(12.5)	16(45.7)	20(29.9)
	80-90	2(6.3)	4(11.4)	6(9)
Educational Level	Primary School	9(28.1)	9(25.6)	18(26.9)
	Elementary school grade 6-9	5(15.6)	10(28.6)	15(22.4)
	High school	8(25)	8(22.9)	16(23.9)
	College or more	10(31.3)	8(22.9)	18(26.9)
BMI Classification	Normal	4(12.5)	2(5.7)	6(9)
	Overweight	12(37.5)	9(25.7)	21(31.3)
	Obesity grade 1	12(37.5)	14(40)	26(38.8)
	Obesity grade 2	2(6.3)	6(17.1)	8(11.9)
	Obesity grade 3	2(6.3)	4(11.4)	6(9)
KOA	Unilateral	2(6.3)	2(5.7)	4(6)
	Bilateral	30(93.8)	33(94.3)	63(94)
KOA grade	I and II, %	50.0	62.9	56.4
	III and IV, %	50.0	37.1	43.5
Retired	No	3(9.4)	3(8.6)	6(9)
	Yes	29(90.6)	32(91.4)	61(91)

Table 3.1- Frequency analyses of demographic variables at baseline for Educational Group (EG), Self-Management Exercise Group (SEG) and total sample. (Continuation)

Marital Status	Single	1(3.1)	3(8.6)	4(6)
	Married	23(71.9)	17(48.6)	40(59.7)
	Widower	2(6.3)	9(25.7)	11(16.4)
	Divorced	6(18.8)	6(17.1)	12(17.9)

Abbreviations: BMI=Body Mass Index.

Table 3.2 - Descriptive analyses, median and standard deviation, for demographic outcomes for Self-Management Exercise Group (SEG), Educational Group (EG) and for total sample.

Variables	CG (n=32)	SEG (n=35)	Total
Age	67,8(5,3)	70,3(6,1)	69,1(5,8)
Weight	79,3(15,4)	78,8(15)	79,1(15,1)
Height	1.62(.08)	1.56(.09)	1.59(.09)
BMI	30,1(5,3)	32,3(5)	31,2(5,2)

Abbreviations: *BMI=Body Mass Index*.

3.3 Intervention

Articles 4 and 5 include an intervention. The active treatment group was engaged in self-management and exercise (SMEG), and the control group was engaged in educational program (EG). The details of each intervention are described on chapter 4 (study protocol) and on articles 4 and 5 (chapter 7 and 8).

All intervention sessions of the Self-Management and Exercise Group, documented in articles 4 and 5, were conducted in four different places: two senior universities, one church and one community center. Intervention sessions of the Educational Group were done at the Faculty of Human Kinetics.

3.4 Assessments

All assessments were done at the Faculty of Human Kinetics. The only exception was the X-Ray screening for KOA diagnosis, which was done on a clinic.

Assessments were performed three times: one week prior to the start of the program (baseline), during the week following the final intervention (three months later), and at a 6-month follow-up. The study protocol (chapter 4) presents a detailed description of each variable and the test/questionnaire to measure them.

Table 3.3 summarizes the main methodological procedures of study.

Table 3.3 - Summary of the main procedures of study.

Design	Sample (N)	Statistical Analysis	Variables	
			Physical Fitness Test	Self-reported measures
			Article 1	
			Study Protocol	
			Article 2	
Cross-sectional	67 KOA	Multiple linear regression analysis	• Mobility • Aerobic capacity • Lower limb strength • Hand grip strength • Gait speed • Balance	• Pain, other symptoms, daily living activities, sports and recreations activities and quality of life (related with OA) • HRQoL • Physical activity behavior
			Article 3	
Cross-sectional	73 KOA	MANOVA		• Pain, other symptoms, coping strategies.
			Article 4	
RCT	67 KOA	ANCOVA	• Aerobic capacity • Flexibility (upper and lower limb) • Handgrip strength • Functional lower limb strength	• Pain, other symptoms, daily living activities, sports and recreations activities and quality of life (related with KOA) • Self-management behavior • HRQoL (VAS)
			Article 5	
RCT	67 KOA	ANCOVA	• Gait speed, • Mobility • Balance	• Self-efficacy • Physical activity behavior • HRQol (index)

Abbreviations: RCT=randomized controlled trial; KOA=knee osteoarthritis; HRQol=Health related quality of life; VAS= visual analogue scale.

3.5 Data analysis

The data were analyzed in a blinded manner. Descriptive statistics were used to describe subject characteristics and Kolmogorov-Smirnov test was used to assess normality.

Article 2 used multiple linear regression analysis. Pearson correlation coefficient (r) was used to evaluate the correlation between continuous variables, and Spearman correlation coefficient (rS) was used in the case of ordinal variables. Some rough guidelines were employed for designating the strength of correlation: if $|r| \geq 0.7$, the correlation is considered strong; if $0.3 < |r| < 0.7$, is classified as moderate; and if $|r| < 0.3$, the correlation is weak. These guidelines were also used to classify Spearman correlation coefficients. Residual analysis was conducted to ensure no violation of the assumptions of normality, homoscedasticity, linearity. Variance Inflation Factor (VIF) and Durbin-Watson statistics

were used to verify if multicollinearity was present and if errors were independent, respectively.

In article 3, MANOVA test was used. The test was applied after validation of the assumptions of normality and homogeneity of variance-covariance matrix, checked through the Box M test, with the trace of Pillai. In addition, an exploratory factor analysis (maximum likelihood method with Promax rotation) was done.

Articles 4 and 5 used the Univariate Analyses of Covariance (ANCOVA) in order to compare the effects of intervention, between groups (EG vs. SMEG), on primary and secondary outcomes, adjusted to the baseline value of each outcome. Mean differences within groups were calculated as Mom 1 (baseline) minus Mom 2 (after intervention program). In the analysis of ordinal variables, the nonparametric ANCOVA was used. Effect size was quantified using partial eta squared (η^2). The effect size was classified as small (partial $\eta^2<0.06$), medium ($0.06\leq$ partial $\eta^2<0.14$) and large (partial $\eta^2\geq0.14$)[165].

All statistical analyses were performed using IBM SPSS Statistics 22.0 and MedCalc Statistical Software (MedCalc Software, Mariakerke, Belgium). Significance was established at a level of 5%.

Chapter 4: The PLE²NO Self-management and Exercise Program for Knee Osteoarthritis: study protocol for a Randomized Controlled Trial[1]

[1] Marconcin, P., Espanha, M., Yázigi, F. & Campos, P. The PLE²NO self-management and exercise program for knee osteoarthritis: Study Protocol for a Randomized Controlled Trial. BMC Musculoskeletal Disorders, 2016. 17(1): p. 1-12.

Abstract

Background: International recommendations suggest exercise and self-management programs, including non-pharmacological treatments, for knee osteoarthritis (KOA) because they can benefit pain relief and improve function and exercise adherence. The implementation of a combined self-management and exercise program termed PLE^{2}NO may be a good method for controlling KOA symptoms because it encourages the development of self-efficacy to manage the pathology. This study will assess the effects of a self-management and exercise program in comparison to an educational intervention (control program) on symptoms, physical fitness, health-related quality of life, self-management behaviors, self-efficacy, physical activity level and coping strategies.
Methods/Design: This PLE^{2}NO study is a single-blinded, randomized controlled trial of elderly (aged above 60 yrs old) patients with clinical and radiographic KOA. The patients will be allocated into either an educational group (control) or a self-management and exercise group (experimental). All participants will receive a supplement of chondroitin and glucosamine sulfates. This paper describes the protocol that will be used in the PLE^{2}NO program.
Discussion: This program has many strengths. First, it involves a combination of self-management and exercise approaches, is available in close proximity to the patients and occurs over a short period of time. The latter two characteristics are crucial for maintaining participant adherence. Exercise components will be implemented using low-cost resources that permit their widespread application. Moreover, the program will provide guidance regarding the effectiveness of using a self-management and exercise program to control KOA symptoms and improve self-efficacy and health-related quality of life.
Trial registration: NCT02562833

Keywords: self-management, exercise, knee osteoarthritis, elderly.

Background

Osteoarthritis (OA) is the most common type of rheumatic disease [1]. OA is prevalent in elderly populations and has a substantial influence on the health care industry [2, 3]. In the USA, 27 million people, including 12.1% of the population aged 25–74 years old, are clinically defined as having OA [4].

OA is an active disease [5] that affects all articular tissues [6]. OA can be characterized by examining a person´s symptoms, especially pain [7], which influence the performance of daily living activities [8] and psychological parameters [3]. Among older adults, OA primarily affects weight bearing joints, such as the knee and hip, and is therefore a cause of lower extremity disability [9]. In Portugal, knee OA (KOA) is considered to be the third most prevalent rheumatic disease (affecting 12.4% of the population)[10].

Most types of interventions that are aimed at managing KOA involve community and primary care [5]. Hence, it is imperative to consider international recommendations that can assist individuals and that are feasible alternatives to health services. The Osteoarthritis Research Society International (OARSI) [11], the American College of Rheumatology (ACR) [12] and the European League Against Rheumatism (EULAR) [13] strongly recommend exercise (including land-based, such as strengthening and aerobic activity or water-based activities) and self-management programs as non-pharmacological treatments for KOA patients.

Self-management Programs

Patient education, information and self-management support are critical for patient cooperation during treatment. Besides OARSI international recommendations (11), several evidence-based studies of self-management programs have demonstrated that it is effective to empower patients to better manage their own chronic diseases [14-26].

Psychoeducational interventions are growing in popularity in the primary care field [24]. Among these efforts, self-management programs deserve special attention. The following three models of chronic disease self-management programs are the most widely used: the Expert Patient Programme [27], the Flinders Model [28], and the Stanford Model [29]. The Expert Patient Programme focuses on increasing patient knowledge to manage conditions, the Flinders Model emphasizes the role that physicians play in building patient self-efficacy, and the Stanford Model uses peer educators to build self-efficacy [30].

Two programs have followed the format of the Stanford Model. These include the Arthritis Self-Management Program (ASMP) and the Chronic Disease Self-Management Program (CDSMP) [31, 32]. The first of these, the ASMP, is a specific program for people with arthritis that was developed in the 1970s at the Stanford Patient Education Research Center [19]. Later, the same group developed a more generic proposal for patients with any chronic condition, the CDSMP. This program has now spread in popularity throughout the US [31, 32] and other countries [17, 18, 23, 25, 33].

A meta-analysis of the ASMP and the CDSMP [34] revealed that improvements were observed in several outcome measures in patients with chronic diseases at 4- and 12-month follow-ups.

Exercise Programs

Studies have demonstrated that exercise benefits patients with KOA [35-46]. The two most recognized approaches for KOA treatment with exercise are land-based [47-49] and aquatic programs [44, 50-53]. A recent systematic review and meta-analysis [54] provided evidence showing that land-based exercise is beneficial for people with KOA because it reduced joint pain and improved physical function and quality of life over the short-term and for at least two to six months after the cessation of treatment. Regarding the exercise mode, studies have demonstrated that there is no difference between the efficacies of strengthening, flexibility plus strengthening, flexibility plus strengthening plus aerobic exercise, aquatic strengthening, aquatic strengthening plus flexibility and a combined intervention that included strengthening, flexibility, and aerobic exercise when each was compared to a no exercise control, and there were no differences between the effect of the interventions on improving functional limitations in people with lower limb OA [55]. Additionally, no difference was observed in the effectiveness of providing pain relief between strengthening and aerobic exercises across eight studies that involved KOA patients [56].

Thus, combining aerobic and muscle strengthening exercises into a single program may produce even better outcomes in arthritis patients [57] than programs based on only one of these components. A program that combined aerobic and resistance exercises significantly improved physical function and daily living activities and reduced pain in older adults with arthritis [40], as well as decreased depression [36, 49, 58, 59]. Another program combined a variety of exercises focused on core strength and balance, flexibility, upper and lower body strength and aerobic conditioning and resulted in improvements in mobility, aerobic endurance, strength, flexibility, and self-reported pain perception [35].

Nutritional Supplements: Glucosamine and Chondroitin Sulfate

Although important, controlling symptoms is not the only target when treating OA patients. Indeed, an ideal treatment for OA should preserve joint structures, improve quality of life and for drug therapy or supplementation, have a good safety profile [60]. It is paramount that the administrator account for side effects that can result from the chronic use of OA pharmacological therapies, such as nonsteroidal anti-inflammatory drugs (NSAIDs) [61]. Therefore, glycosaminoglycans such as chondroitin sulfate (CS) and glucosamine

sulfate (GlcN-S) are two natural supplements that are considered to be symptomatic slow-acting drugs for osteoarthritis (SYSADOA) [60].

GlcN-S has been shown to exhibit structure-modifying effects, including small to moderate protective effects on minimum joint spaces after 3 years, in KOA patients [62]. This finding was in agreement with the results of a previous trial that indicated that GlcN-S prevents total knee replacement (TKR) [63].

CS has also been evaluated in different clinical trials that have sought to document both its symptomatic potential and its structure-modifying effects. A recent study [64] demonstrated the efficacy of CS for treating symptoms (i.e., pain and lower-limb function) and concluded that CS is an efficient and safe intervention. Interestingly, CS produced a significant reduction in joint swelling and effusion in a gait study [65].

A double-randomized placebo-controlled clinical trial with a 2-year follow-up of 605 patients with KOA demonstrated that after adjusting for factors associated with structural disease progression, a dietary supplement that consisted of a combination of GlcN-S and CS resulted in significantly less joint space narrowing than was observed with the placebo, whereas neither CS nor GlcN-S alone was effective [66]. A combination of GlcN-S-hyaluronic acid (500 mg) and CS (400 mg) was found to be efficient at providing pain relief and functional improvement in OA patients with moderate to severe knee pain [65]. These findings suggested that a combination of GlcN-S and CS may be more efficient than either CS or GlcN-S alone.

Although some interventions have combined patient self-management with an exercise component, we were unable to identify any study that combined these components with GlcN-S and CS supplementation.

Aim and hypothesis

The aim of this study is to design and implement a PLE²NO program (in Portuguese: Free Program of Education and Exercise for Osteoarthritis) for elderly patients with KOA for a duration of three months. The PLE²NO is based on applying the principle of self-efficacy to manage the pathology. When patients gain confidence in taking control of their disease, they are more comfortable exercising and managing OA symptoms and consequently make better decisions about treatment. This allows them to increase their

quality of life. To encourage participant´s adherence to and maintenance of the program and to contribute to pain control, all participants will receive a supplement containing CS and GlcN-S.

The following three hypotheses were therefore formulated. H1, self-reported KOA symptoms (i.e., pain and stiffness) and physical fitness will improve more in the self-management and exercise group than in the control group; H2, self-management skills and self-efficacy will improve more in the self-management and exercise group than in the control group; and H3, health-related quality of life, physical activity levels and coping strategies will improve more in the self-management and exercise group.

Methods and design

Study design

The PLE^{2}NO is a single-blinded, randomized controlled trial with a three-month duration and a six-month follow-up. The participants will be individually randomly assigned to one of two groups: (1) a self-management and exercise group or (2) an educational control group. Both groups will receive supplementation (CS and GlcN-S). Figure 4.1 provides a flowchart of the PLE^{2}NO design. It will not be possible to blind the participants because of the nature of the intervention. However, the assessors will be blinded to group allocation.

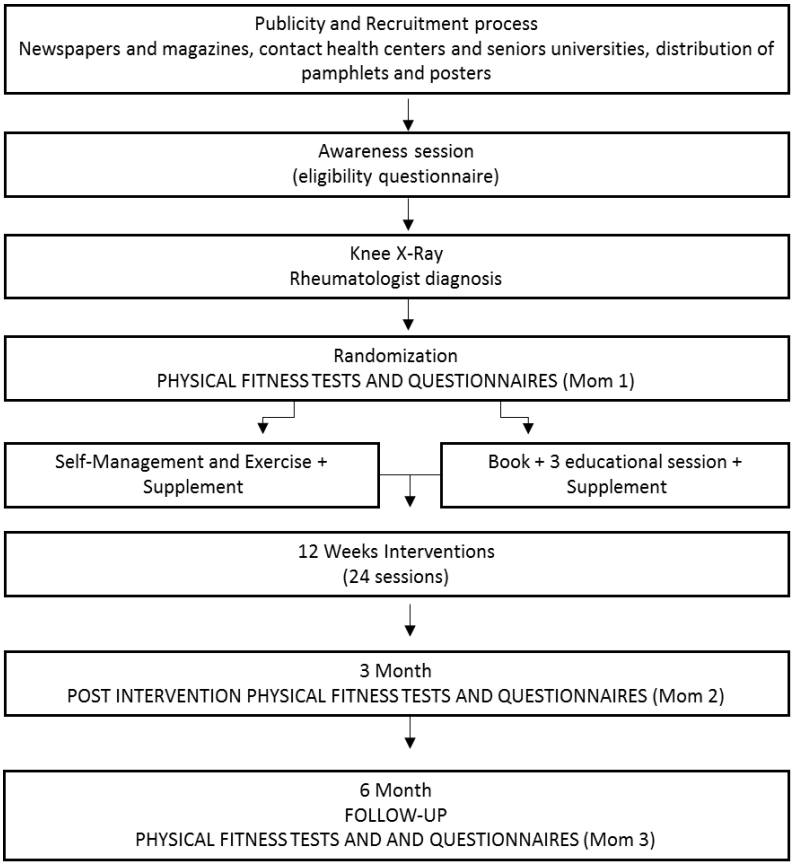


Figure 4.1 - The PLE²NO flowchart

Ethical Issues

All participants will be informed about the procedures and their potential risks, and written informed consent will be obtained from each participant. This study was approved as a clinical trial (U.S. National Institutes of Health, NCT02562833) and by The Ethical Committee of the Faculty of Human Kinetics of the University of Lisbon (N=43/2014).

Sample Size

The sample size was calculated based on the primary outcome (self-reported pain). Using the program GPower 3.1 [67], were selected a priori analysis with ANCOVA, selecting one covariate and two groups with 80% power at a 5% significance. According to McKight´s study, a combined strength training and a self-management program, we fixed the effect size on 0.35 and determined we needed a total sample size of 67. Considering a possible dropout of 20%, we aimed to recruit 80 subjects and allocated 40 subjects per group.

Participants and procedures

The recruitment and selection processes will be performed using the following eligibility criteria: (1) an age of 60 years old or older, (2) bilateral or unilateral KOA diagnosed according to the clinical and radiological criteria of the American College of Rheumatology (ACR) [69], and (3) participants who are independently mobile and literate. The exclusion criteria will be the following: (1) involvement in another intervention program (exercise, education or physical therapy), (2) the prior use of supplements (chondroitin and/or glucosamine sulfate) for at least three months, and (3) other pathologies (e.g., cardiovascular, respiratory, and musculoskeletal pathologies and cancer) that prevent the practice of physical exercise, (4) a mental/psychological state that hinders understanding the program, (5) surgery for knee replacement or a plan to undergo surgery to place a prosthesis within the next eight months, (6) an allergy to shellfish or another component of the supplements, and (7) administration (injections) of corticosteroids or hyaluronic acid in the last 6 months.

To avoid convenience sampling, the participants will be recruited from the Lisbon area, and different marketing strategies will be used to advertise and publicize the PLE²NO program. Social networks, newspapers, magazines, contacts with senior universities, health centers, churches and community centers, and the site of the Portuguese League Against Rheumatic Disease will be the main channels used for PLE²NO announcements.

All individuals interested in participating will be invited to an awareness session in which the details of the program will be explained, and the patients will complete an eligibility questionnaire, which is necessary to acquire more detailed information, including whether they have any allergies to components in the supplements. As many sessions as necessary will be performed until the expected sample size is attained. Anyone who is interested and fulfills the eligibility criteria will receive a request for an x-ray examination. The exam requests will be referred to a rheumatologist who will make the final diagnosis according to the ACR clinical and radiological criteria. This is a more specific diagnosis (86%) than a simple clinical diagnosis (69%) [70]. If the subject is found to be positive for KOA, he or she will be invited to a second interview during which consent will be obtained.

The randomization process will be performed on the baseline assessment day by the research team leader. The randomization sequence will be a 1:1 allocation to the two treatment arms.

Interventions

The active treatment group will engage in self-management and exercise (SMEG), and the control group will engage in patient education (EG) only. The SMEG patients will receive a combination program including self-management and exercise that will be delivered on the same days twice per week. Each session will last 90 minutes. The first 30 minutes will be allocated for self-management, and the remaining 60 minutes will be used for exercise. The program will be offered in a group format that encourages interaction and socialization, which can help to counteract feelings of depression and isolation. To avoid any conflict of interest and because we believe that it will help support the participants' adherence, maintenance and pain control, all participants will receive a supplement that consists of a combination of two main substances: 1500 mg of glucosamine sulfate and 1200 mg of chondroitin sulfate, in addition to two secondary substances: 100 mg of *Harpagophytum* extract and 10 mg of hyaluronic acid. The recommendation is to use two packets per day. The participants themselves will have to complete daily sheets that request information regarding pain levels that are assessed on a visual numeric pain scale [71] and a bi-daily supplementation diary. All participants will be covered by personal accident insurance.

Self-Management and Exercise Group (SMEG)

Self-management component

The self-management component is based on a program that was developed at Stanford University, the Chronic Disease Self-Management Program (CDSMP) [32], which aims to develop self-efficacy and emphasizes skills mastery. These are accomplished through the weekly performance of specific behaviors and the receipt of feedback (action plan and problem solving). The contents of the program will include the following: self-management principles, managing symptoms, exercise and physical activity, communication skills, healthy eating, and managing medicines. The program will be administered by a certified Master Trainer and Leader of the CDSMP at Stanford University.

Exercise Component

The exercise component is based on the Fit and Strong Program [72], Exercise for People with Arthritis (FEPA) [35] and the Taking Control with Exercise (Arthritis

Foundation) program. This exercise program contains health-related (muscular resistance/strength, and flexibility) and skill-related (balance) physical fitness components. Additionally, the program will include socialization games that help to decrease symptoms related to pain, stress, depression, and fatigue. In addition to improvements in physical fitness, the development of self-efficacy in exercise is another goal.

The exercise session type includes a warm up for the first 5 minutes, followed by 15 to 20 minutes of recreation activity and balance exercise, 30 to 40 minutes of the strengthening exercises, and 10 to 15 minutes of stretching and relaxation exercises at the end.

Specific strength exercises will be performed to recruit specific muscle groups in the lower limbs (quadriceps, hamstrings, hip adductors/abductors, gluteus, and gastrocnemius) and the upper limbs (pectoralis, trapezius, dorsal, deltoids, biceps and triceps). The strength exercises will use a combination of elastic bands (upper limbs) and cuff weights (lower limbs) or calisthenics, as previously used in other studies [73, 74] and replicated in the Fit and Strong program [72]. The resistance will be progressively increased throughout the program by adding weights in increments of 0.250 Kg to the cuff weights. The progressions in the numbers of repetitions and series are illustrated in table 4.1.

Table 4.1 - Training volume

Week 1-3 No additional load	Week 4-6 Load 1	Week 7-9 Load 2	Week 10-12 Load 3
1 x 12 rep	Week 4: 1 x 12 rep	Week 7: 1 x 12 rep	Week 10: 1 x 12 rep
2 x 8 rep	Week 5: 2 x 8 rep	Week 8: 2 x 8 rep	Week 11: 2 x 8 rep
2x12 rep	Week 6: 2x12 rep	Week 9: 2x12 rep	Week 12: 2x12 rep

The prescribed intensity and management of exercise resistance will be primarily guided by answers related to self-reported pain, which will be assessed using a visual numeric pain scale [71] before, during and after each session. At the beginning of each session, all participants will be required to present their pain diaries. If the pain level is above 5 points on the day before the last session, the load will not be increased, but if pain is below 5 points, they patients will receive increased loads. The intensity interval desired for strengthening exercises will be maintained at 4-6 (somewhat easy – somewhat hard) according the Omni-Perceived Exertion Scale for Resistance Exercise (OMINI-RES) [75].

This component will be overseen by a professional with a master's degree in Science of Physiotherapy and another individual who is an Exercise and Health master's student. Both will be from the Faculty of Human Kinetics.

To develop exercise self-efficacy and promote the maintenance of the exercise program before the end of the class, a chart with the main exercises for each physical fitness component (i.e., muscular resistance/strength, flexibility, and balance) will be given to the participants during the last two weeks of the intervention program. The participants will be encouraged to perform the exercises by themselves by following the chart during the last two weeks with supervision from the same professionals that conducted the exercise program. It is expected that they will develop the capacity to perform the exercises by themselves in their homes without supervision by the end of the intervention.

Education control Group (EG)

This group will receive a book [76] published by PLE^{2}NO´s scientific team. This book contains descriptions and tips for managing KOA in addition to educational and exercise information presented as images. Additionally, the participants will attend three monthly educational sessions that are one hour in length each regarding joint protection strategies, exercise, and self-management techniques. These sessions will be delivered by the coordinator of the PLE^{2}NO project, who is a PhD Professor in the Faculty of Human Kinetics, and an Exercise and Health master's student from the same institution. Telephone contacts will be established 15 days after each educational session to avoid withdrawals and to maintain closer monitoring.

Assessments and procedures

The assessments will be performed one week prior to the start of the program (baseline), during the week following the final intervention (three months later), and at a 6-month follow-up. Each assessment will use the same protocol, and the results will be evaluated by PLE^{2}NO team member(s) (all of whom are master's students in exercise and health specialties) who are blinded to group allocation. The assessments will be performed on the same day. To avoid overloading the participants, the physical tests and questionnaires will be performed alternately. Additionally, the physical tests involving load-bearing

activities will be alternated with those that are performed while seated. The order of those tests and questionnaires were determined previously, in accordance with the statements already mentioned. Each evaluator perform the same test to avoid inter-rater variability.

The main outcomes will be pain. The secondary outcomes will be: other KOA symptoms, KOA-specific health-related quality of life, self-efficacy, self-management behaviors, a healthier quality of life, a physically active lifestyle, coping strategies, aerobic capacity, functional strength, mobility, flexibility, gait speed, static balance and handgrip. All outcomes and instruments are illustrated in table 2 and will be assessed at baseline, post-intervention and a 6-month follow-up.

Eligibility Questionnaire: This questionnaire collects personal data (including name, phone contact, address, and email) and the inclusion and exclusion criteria for participation in the program. It will be available both online and on paper.

X-Ray: Bilateral, anterior-posterior knee radiographs will be used to identify OA in the tibiofemoral joint, and sunrise views will be used to identify OA in the patellofemoral compartment. The severity of OA in the tibiofemoral and patellofemoral joint will be measured by a rheumatologist using the K-L grading scale [77].

Socio-demographic information: A questionnaire will be created by the researchers that poses demographic questions, including date of birth, race, sex, marital status, current occupation, occupation before retiring and education level. Body mass index (BMI) will also be calculated as weight (measured in kilograms) over height squared (height measured in meters).

Use of medicine: A list containing the names of all medications being used and their doses and indications will be requested from the patients before and after the intervention (baseline and post-intervention).

Table 4.2 - Outcomes and instruments.

	Outcomes	Instruments
Questionnaires	KOA-specific health-related quality of life	Knee Injury and Osteoarthritis Outcome Score (KOOS)
	Self-efficacy	Self-efficacy for managing Chronic Disease 6-Item Scale
	Self-management behaviors	Cognitive Symptom Management and Communication with Physicians
	Health-related quality of life	Euroquol five dimensions five level (EuroQol -EQ-5D-5L)
	Physical activity	International Physical Activity Questionnaire (IPAQ)
	Coping strategies	Brief COPE
Physical fitness tests	Aerobic Capacity	Six-Minute Walking Test (6 MWT)
	Functional lower-limb strength	Five-Repetition Sit to Stand Test (FRSTST)
	Mobility	Timed "Up-and-Go" test
	Flexibility upper limb	Back Scratch Test (BST)
	Flexibility lower limb	Chair Sit and Reach (CRS)
	Gait speed	6-Meter Test
	Balance	Standing Balance
	Hand strength	Hand grip test

Questionnaires

Knee Injury and Osteoarthritis Outcome Score (KOOS). This questionnaire includes 5 dimensions to measure KOA-specific health-related quality of life (QOL), knee pain (Pain), other disease-specific symptoms (Other Symptoms), daily living activities (ADL), and sport/recreation functions (Sport/Rec). A score for each of the five dimensions is calculated as the sum of the items that are included, which is then converted to a 0-100 scale in which 0 represents extreme knee problems and 100 represents no knee problems. The KOOS has been validated for use in patients with knee injuries and patients with knee OA and is a reliable and responsive self-administered instrument for short-term follow-ups [78].

Self-efficacy for managing Chronic Disease 6-Item Scale. This 6-item scale contains items taken from several self-efficacy scales that were developed for the Chronic Disease Self-Management study. This is a one to ten scale that includes six questions. The scale was tested on 605 subjects with chronic diseases [31]. The observed range of outcomes was 1-10 with a mean of 5.17, a standard deviation of 2.22, and an internal consistency reliability of 0.9.

Cognitive Symptom Management. This scale comprises six questions and has an observed range of 0-5. The scale was tested on 1129 subjects with chronic disease, and 51 of these subjects who underwent a test-retest protocol [79]. The mean result was 1.33 with a

standard deviation of 0.91, an internal consistency reliability of 0.75 and a test-retest reliability of 0.83.

Communication with Physicians. This questionnaire includes three questions. The scale was tested on 1130 subjects with chronic disease, and 51 of these subjects underwent a test-retest protocol [79]. The results showed an observed range of 0-5, a mean of 3.08, a standard deviation of 1.20, an internal consistency reliability of 0.73 and a test-retest reliability of 0.89.

Perception of health and quality of life (EuroQol - EQ-5D-5L). The EQ-5D-5L is a generic instrument for measuring health-related quality of life (HRQoL) that allows the generation of an index that represents a status value of the health of an individual. This scale is based on a classification system that describes health along the following five dimensions: mobility, personal care, usual activities, pain/discomfort, and anxiety/depression. Each of these dimensions has five levels of severity. This instrument employs psychometric techniques similar to those of the EQ-5D [80].

International Physical Activity Questionnaire (IPAQ). The short form of the IPAQ was chosen because it is easy to apply. Its reliability has been verified in many countries and in different populations [81, 82].

Brief COPE. The first version of the COPE inventory by Carver, Scheier and Weintraub [83] was subsequently abbreviated by Carver [84]. The abridged version (brief COPE) contains only 28 items that are answered on a Likert 4-point scale (ranging from 1 = never use this strategy to 4 = I often use this strategy) and divided into the following 14 sub-scales (two items per scale): active coping, denial, substance use, emotional support, instrumental support, behavioral divestment, ventilation, revaluation, planning, mood, acceptance, religion, and self-blame. Data from a study of survivors of Hurricane Andrew indicate that the brief COPE scales have an adequate internal reliability [84].

Physical fitness tests

Six-Minute Walk Test (6 MWT). This test is a valid measure of aerobic capacity in older adults [85], and it has been used in studies of KOA [86, 87].

Five-Repetition Sit to Stand Test (FRSTST). This measure is a widely used measure of functional strength. The ICC values for this test reveal good to high test-retest reliability for adults and subjects with osteoarthritis [86, 88, 89].

Timed "up-and-go". This is a test of strength, agility and dynamic balance that incorporates multiple activity themes. The time (seconds) taken to rise from a chair, walk 3 m (9 ft, 10 inches), turn, walk back to the chair and then sit down wearing regular footwear (while using a walking aid if required) is assessed [90].

Chair Sit and Reach test (CSR). The CSR test is a safe and socially acceptable alternative to traditional floor sit-and-reach tests and is a reasonably accurate and stable measure of hamstring flexibility [91]. The subjects are allowed three attempts for each limb, and the best of these scores is recorded to the nearest centimeter.

The Back Scratch Test (BST). The BST is a measure of overall shoulder range of motion. This test involves measuring the distance, using a ruler, between (or overlap in) the middle fingers when they are placed behind the back [92]. After a practice trial, this test is assessed twice, alternating between both hands, and the best value is registered for each.

Six-meter test. This test measures linear walking ability, excluding acceleration and deceleration [93]. This variable is also used as a primary outcome in an algorithm for sarcopenia in older individuals [94].

Standing Balance Test. This test will be performed bilaterally. While near a wall, the subject crosses theirs arms over their chest, lifts the preferred leg off the floor without touching the other leg, and holds this position with their eyes open as long as possible. Contact between the legs, the support touching the ground, touching the wall and withdrawing the arms from the chest are considered errors. The evaluator stops recording the time upon the occurrence of any error. The participants will perform two repetitions of the test, and the best result will be recorded [95].

Hand Grip Test (HGT). This test evaluates the maximal isometric force exerted by the muscles of the hand and forearm using a dynamometer. Although this study will not examine hand OA, this test has been used in the elderly as an indicator of sarcopenia and/or disability [96, 97]. Prior to the test, the grip dynamometer will be adjusted to the size of the hands of each subject. The subjects will stand with their arms along their bodies without contact with their trunk and with their elbows slightly bent at a 20º angle. Testing will first be conducted

using the dominant hand and subsequently using the non-dominant hand. Strength will be evaluated during the expiratory phase to avoid the Valsalva maneuver. The best of three repetitions will be chosen for further analysis.

Other measures

Patient´s Global Impression of Change (PGIC). This scale is often used in clinical research, particularly in musculoskeletal studies [98]. The changes will be classified on dichotomous scales, and the classifications that will be used will include perceived change (5-7), an experience reflecting significant changes (1-4) and a lack of experience reflecting significant changes [98].

Visual Numeric Pain Scale (VNS). This scale is used to self-report pain. It combines strong visual cues with an 11-point numeric rating scale. The VNS is highly correlated with the visual analogue scale (VAS, r = 0.85), is sensitive to changes in pain, and has been demonstrated to be a valid measure [71].

OMNI resistance exercise scale. This scale is a perceived exertion scale used with resistance exercise, and its high level of construct validity indicates that the OMNI-RES measures the same properties related to exertion as the Borg RPE scale [99] during resistance exercise [75].

Data analysis

The data will be analyzed in a blinded manner. Descriptive statistics will be used to describe subject characteristics. The intervention and control groups will be examined for baseline comparability with respect to demographic and other factors. Kolmogorov-Smirnov tests will be used to test for normality. Univariate analyses of covariance (ANCOVA) will be conducted to compare changes between groups (i.e., the self-management and exercise group compared to the educational group) with adjustments for baseline values. The mean difference within groups will be calculated as Mom 1 (baseline) minus Mom 2 (after intervention program). The effect sizes will be verified using partial eta squared statistics. Repeated measures analyses using linear mixed models will be used to assess the constancy of any effects in the self-management and exercise group over time. Missing data will be assumed to be missing at random. All statistical analyses will be performed using IBM SPSS

Statistics 22.0 and MedCalc Statistical Software (MedCalc Software, Mariakerke, Belgium), and significance will be established at a level of 5%.

Discussion

It is essential to identify the best approach to treating patients with KOA. Such an approach should consider the individuals' quality of life, international recommendations for treatment and the availability of health services. Therefore, the combined use of self-management, exercise and supplements (glucosamine and chondroitin sulfate) appears to be a feasible and effective option for treating elderly patients with KOA.

There are several strengths to the design and implementation of this study protocol. First and foremost, this program combines the recommendations of international organizations (OARSI, EULAR and ACR) with a combination of exercise and educational (self-management) programs. The study design is extremely current, ambitious and grounded.

Second, the program will be administered in close proximity to the patients. To achieve this goal, the program will take place at four different locations: two senior universities, one church, and one community center. This is necessary because when we consider the age and pathological conditions that we expect to find in the study patients, locomotion may be a barrier. Therefore, if a patient will not be able attend for financial reasons, a van from a church or a team member's car will provide transportation services. These efforts will minimize the problem of access to the classes.

Third, the methodology of the program, in terms of both self-management and exercise, has been planned in extreme detail using simple resources, including paper roles for the self-management component and elastic bands, ankle weights and chairs for the exercise components. Thus, the program can be feasibly disseminated (e.g., it uses minimal, low-cost equipment and has few storage requirements). The exercise program will be administered by highly qualified exercise instructors, two of whom have master's degrees in Sport Science and the Science of Physiotherapy, and one other instructor who is an Exercise and Health master's student from the Faculty of Human Kinetics. All of these instructors specialize in exercise, health and fitness group skills. Furthermore, a certified leader of the

Chronic Disease Self-Management Program (CDSMP) at Stanford University will administer the self-management program.

The program will also have a self-efficacy component for exercise, with a goal that following the end of the program, the patients will continue doing exercises, and they will receive support in this endeavor, including access to the materials that were used in the program, a chart with a description of all of the exercises that they performed in class and a brief explanation about how these exercises should be performed.

With the exception of the knee radiographs for the OA diagnoses, all measurements will be obtained at the same place at baseline immediately after the end of the program and at the 6-month follow-up. Therefore, to support the project, the staff team includes one secretary who is responsible for the administrative work and four health professionals who will conduct the tests and questionnaires. To avoid inter-rater error, the same health professionals will lead the applications of the three assessments, i.e., the baseline, post-intervention and follow-up assessments.

Participant adherence to the exercise program is one of the main challenges, mainly because the participants are elderly and susceptible to other health problems. Therefore, motivational cues, intragroup social interactions, frequent telephone calls and the quality of the professors are the main strategies that have been selected to prevent the occurrence of dropouts.

One possible constraint to the success of the program is the extensive exclusion criteria, but these criteria are required to maintain the quality of the study. In this study, all adverse events will be documented and reported from screening until study completion.

Our study is based on the premise that elderly patients with KOA need an appropriate treatment regimen that is accessible and achievable, given their condition. Therefore, the study treatment regimen was designed to develop their self-efficacy to manage their own condition. The concepts of autonomy, self-management and self-efficacy are therefore essential. Moreover, once the program ends, the participants are expected to continue the treatment using self-management skills and by performing the exercises on their own, which should consequently assist them in coping better with pain and KOA symptoms.

The findings of this study will contribute to clinical trial reference data for elderly individuals with KOA by adding information regarding the effectiveness of combining a self-management strategy with an exercise program.

The format of the sessions, the study duration and the weekly frequency of the program are organized in a manner that ensures that this proposal is executable not only for this project but also for future implementations by communities.

Conclusion

This study is a randomized controlled trial (RCT) that uses a self-management and exercise intervention strategy along with glucosamine and chondroitin sulfate supplementation. The protocol was specially designed according to a carefully controlled methodology. The projected results will enable the implementation of a new combination treatment for elderly patients with KOA.

References

1. Lawrence RC, Felson DT, Helmick CG, Arnold LM, Choi H, Deyo RA et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part II. Arthritis & Rheumatism. 2008;58(1):26-35. doi:10.1002/art.23176.

2. Sangha O. Epidemiology of rheumatic diseases. Rheumatology. 2000;39(suppl 2):3-12. doi:10.1093/rheumatology/39.suppl_2.3.

3. Heidari B. Knee osteoarthritis prevalence, risk factors, pathogenesis and features: Part I. Caspian Journal of Internal Medicine. 2011;2(2):205-12.

4. Helmick CG, Felson DT, Lawrence RC, Gabriel S, Hirsch R, Kwoh CK et al. Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part I. Arthritis & Rheumatism. 2008;58(1):15-25. doi:10.1002/art.23177.

5. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. Annals of the Rheumatic Diseases. 2001;60(2):91-7. doi:10.1136/ard.60.2.91.

6. Bruyère O, Cooper C, Arden N, Branco J, Brandi M, Herrero-Beaumont G et al. Can We Identify Patients with High Risk of Osteoarthritis Progression Who Will Respond to Treatment? A Focus on Epidemiology and Phenotype of Osteoarthritis. Drugs Aging. 2015;32(3):179-87. doi:10.1007/s40266-015-0243-3.

7. Lane NE, Brandt K, Hawker G, Peeva E, Schreyer E, Tsuji W et al. OARSI-FDA initiative: defining the disease state of osteoarthritis. Osteoarthritis and Cartilage. 2011;19(5):478-82. doi:http://dx.doi.org/10.1016/j.joca.2010.09.013.

8. Tanimura C, Morimoto M, Hiramatsu K, Hagino H. Difficulties in the daily life of patients with osteoarthritis of the knee: scale development and descriptive study. Journal of Clinical Nursing. 2011;20(5-6):743-53. doi:10.1111/j.1365-2702.2010.03536.x.

9. Johnson VL, Hunter DJ. The epidemiology of osteoarthritis. Best Practice & Research Clinical Rheumatology. 2014;28(1):5-15. doi:http://dx.doi.org/10.1016/j.berh.2014.01.004.

10. Branco JC, Rodrigues AM, Gouveia N, Eusébio M, Ramiro S, Machado PM et al. Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt– a national health survey. RMD Open. 2016;2(1). doi:10.1136/rmdopen-2015-000166.

11. McAlindon TE, Bannuru RR, Sullivan MC, Arden NK, Berenbaum F, Bierma-Zeinstra SM et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and Cartilage. 2014;22(3):363-88. doi:http://dx.doi.org/10.1016/j.joca.2014.01.003.

12. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care & Research. 2012;64(4):465-74. doi:10.1002/acr.21596.

13. Fernandes L, Hagen KB, Bijlsma JWJ, Andreassen O, Christensen P, Conaghan PG et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Annals of the Rheumatic Diseases. 2013. doi:10.1136/annrheumdis-2012-202745.

14. Goeppinger J, Armstrong B, Schwartz T, Ensley D, Brady TJ. Self-management education for persons with arthritis: Managing comorbidity and eliminating health disparities. Arthritis Care & Research. 2007;57(6):1081-8. doi:10.1002/art.22896.

15. Goeppinger J, Lorig KR, Ritter PL, Mutatkar S, Villa F, Gizlice Z. Mail-delivered arthritis self-management tool kit: A randomized trial and longitudinal followup. Arthritis Care & Research. 2009;61(7):867-75. doi:10.1002/art.24587.

16. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial. BMC Musculoskelet Disord. 2010;11:244. doi:10.1186/1471-2474-11-244.

17. Kao M-J, Wu M-P, Tsai M-W, Chang W-W, Wu S-F. The effectiveness of a self-management program on quality of life for knee osteoarthritis (OA) patients. Archives of Gerontology and Geriatrics. 2012;54(2):317-24. doi:http://dx.doi.org/10.1016/j.archger.2011.05.018.

18. Wu S-FV, Kao M-J, Wu M-P, Tsai M-W, Chang W-W. Effects of an osteoarthritis self-management programme. Journal of Advanced Nursing. 2011;67(7):1491-501. doi:10.1111/j.1365-2648.2010.05603.x.

19. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. ann behav med. 2003;26(1):1-7. doi:10.1207/S15324796ABM2601_01.

20. Lorig KR, Ritter PL, Laurent DD, Plant K. The internet-based arthritis self-management program: A one-year randomized trial for patients with arthritis or fibromyalgia. Arthritis Care & Research. 2008;59(7):1009-17. doi:10.1002/art.23817.

21. Nuñez M, Nuñez E, Segur JM, Macule F, Quinto L, Hernandez MV et al. The effect of an educational program to improve health-related quality of life in patients with osteoarthritis on waiting list for total knee replacement: a randomized study. Osteoarthritis and Cartilage. 2006;14(3):279-85. doi:http://dx.doi.org/10.1016/j.joca.2005.10.002.

22. Osborne RH, Buchbinder R, Ackerman IN. Can a disease-specific education program augment self-management skills and improve Health-Related Quality of Life in people with hip or knee osteoarthritis? BMC Musculoskeletal Disorders. 2006;7:1-10. doi:10.1186/1471-2474-7-90.

23. Yip YB, Sit JWH, Fung KKY, Wong DYS, Chong SYC, Chung LH et al. Effects of a self-management arthritis programme with an added exercise component for osteoarthritic knee: randomized controlled trial. Journal of Advanced Nursing. 2007;59(1):20-8. doi:10.1111/j.1365-2648.2007.04292.x.

24. Barlow JH, Turner AP, Wright CC. A randomized controlled study of the Arthritis Self-Management Programme in the UK. Health education research. 2000;15(6):665-80.

25. Coleman S, Briffa K, Conroy H, Prince R, Carroll G, McQuade J. Short and medium-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: A quality assurance study. BMC Musculoskeletal Disorders. 2008;9:1-8. doi:10.1186/1471-2474-9-117.

26. Coleman S, McQuade J, Rose J, Inderjeeth C, Carroll G, Briffa NK. Self-management for osteoarthritis of the knee: Does mode of delivery influence outcome? BMC Musculoskeletal Disorders. 2010;11:56-61. doi:10.1186/1471-2474-11-56.

27. Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. Clinical medicine (London, England). 2002;2(3):227-9.

28. Lawn SBM. Capabilities for supporting prevention and chronic condition self-management: A resource for educators of primary health care professionals. Flinders University, Adelaide: Australian Government Department of Health and Ageing.; 2009.

29. Lorig KR, Sobel DS, Stewart AL, Brown BW, Jr., Bandura A, Ritter P et al. Evidence suggesting that a chronic disease self-management program can improve health status while reducing hospitalization: a randomized trial. Med Care. 1999;37(1):5-14.

30. Jonhston SL, Clare; Ives, Sarah Mae; Soto, Enrique. <Literature Review on Chronic Disease Self-Management The Champlain Local Health Integration Network. 2008.

31. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. Effective clinical practice : ECP. 2001;4(6):256-62.

32. Lorig KR, Mazonson PD, Holman HR. Evidence suggesting that health education for self-management in patients with chronic arthritis has sustained health benefits while reducing health care costs. Arthritis and rheumatism. 1993;36(4):439-46.

33. Yip YB, Sit JWH, Wong DYS. A quasi-experimental study on improving arthritis self-management for residents of an aged people's home in Hong Kong. Psychology, Health & Medicine. 2004;9(2):235-46.

34. Brady T, Murphy, L., Beauchesne, D., Bhalakia, A., Chervin, D., Daniels, B., Greenberg, M., House, M., O'Colmain, B. . Executive Summary of ASMP/CDSMP Meta-Analyses. Centers for Disease Control and Prevention 2011.

35. Levy SS, Macera CA, Hootman JM, Coleman KJ, Lopez R, Nichols JF et al. Evaluation of a multi-component group exercise program for adults with arthritis: Fitness and Exercise for People with Arthritis (FEPA). Disability and health journal. 2012;5(4):305-11. doi:10.1016/j.dhjo.2012.07.003.

36. Callahan LF, Mielenz T, Freburger J, Shreffler J, Hootman J, Brady T et al. A randomized controlled trial of the people with arthritis can exercise program: symptoms, function, physical activity, and psychosocial outcomes. Arthritis and rheumatism. 2008;59(1):92-101. doi:10.1002/art.23239.

37. Callahan LF. Evaluation of Group and Self-Directed Formats of the Arthritis Foundation's Walk With Ease Program. Arthritis Care & Research. 2011;63(8):pp 1098–107.

38. Jan M, Lin J, Liau J, Lin Y, Lin D. Investigation of clinical effects of high- and low-resistance training for patients with knee osteoarthritis: a randomized controlled trial. Phys Ther 2008;88:427–36.

39. Salli A, Sahin N, Baskent A, Ugurlu H. The effect of two exercise programs on various functional outcome measures in patients with osteoarthritis of the knee: A randomized controlled clinical trial. Isokinetics & Exercise Science. 2010;18(4):201-9.

40. Ettinger WH, Jr., Burns R, Messier SP, Applegate W, Rejeski WJ, Morgan T et al. A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis. The Fitness Arthritis and Seniors Trial (FAST). Jama. 1997;277(1):25-31.

41. Maurer BT, Stern AG, Kinossian B, Cook KD, Schumacher Jr HR. Osteoarthritis of the knee: Isokinetic quadriceps exercise versus an educational intervention. Archives of Physical Medicine and Rehabilitation. 1999;80(10):1293-9. doi:http://dx.doi.org/10.1016/S0003-9993(99)90032-1.

42. Penninx B, Messier, S., Rejeski, W., Williamson, J., DiBari, M., Cavazzini, C. et. al. Physical Exercise and the Prevention of Disability in Activities of Daily Living in Older Persons With Osteoarthritis. American Journal of Health Promotion. 2003;17(3):217.

43. Topp R, Woolley S, Hornyak Iii J, Khuder S, Kahaleh B. The effect of dynamic versus isometric resistance training on pain and functioning among adults with osteoarthritis of the knee. Archives of Physical Medicine and Rehabilitation. 2002;83(9):1187-95. doi:http://dx.doi.org/10.1053/apmr.2002.33988.

44. Wang T-J, Belza B, Elaine Thompson F, Whitney JD, Bennett K. Effects of aquatic exercise on flexibility, strength and aerobic fitness in adults with osteoarthritis of the hip or knee. Journal of Advanced Nursing. 2007;57(2):141-52. doi:10.1111/j.1365-2648.2006.04102.x.

45. Huang M-H, Lin Y-S, Yang R-C, Lee C-L. A comparison of various therapeutic exercises on the functional status of patients with knee osteoarthritis. Seminars in Arthritis and Rheumatism. 2003;32(6):398-406. doi:http://dx.doi.org/10.1053/sarh.2003.50021.

46. Yázigi F, Espanha, M. & Messier, S. P. . Knee Osteoarthritis and Obesity: Effectiveness of PICO Aquatic Exercise Program on Symptoms, Physical Fitness and Quality of Life. Oeiras, Portuga: Universidade de Lisboa; 2014.

47. Messier SP, Loeser RF, Miller GD, Morgan TM, Rejeski WJ, Sevick MA et al. Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: The arthritis, diet, and activity promotion trial. Arthritis & Rheumatism. 2004;50(5):1501-10. doi:10.1002/art.20256.

48. van Baar ME, Dekker J, Oostendorp R, Bijl D, Voorn T, Bijlsma J. Effectiveness of exercise in patients with osteoarthritis of hip or knee: nine months' follow up. Annals of the Rheumatic Diseases. 2001;60(12):1123-30. doi:10.1136/ard.60.12.1123.

49. Gyurcsik NC, Brittain DR. Partial Examination of the Public Health Impact of the People with Arthritis Can Exercise (PACE®) Program: Reach, Adoption, and Maintenance. Public Health Nursing. 2006;23(6):516-22. doi:10.1111/j.1525-1446.2006.00591.x.

50. Bartels EM, Lund H, Hagen KB, Dagfinrud H, Christensen R, Danneskiold-Samsoe B. Aquatic exercise for the treatment of knee and hip osteoarthritis. The Cochrane database of systematic reviews. 2007(4):Cd005523. doi:10.1002/14651858.CD005523.pub2.

51. Lim J-Y, Tchai E, Jang S-N. Effectiveness of Aquatic Exercise for Obese Patients with Knee Osteoarthritis: A Randomized Controlled Trial. PM&R. 2010;2(8):723-31. doi:http://dx.doi.org/10.1016/j.pmrj.2010.04.004.

52. Lu M, Su Y, Zhang Y, Zhang Z, Wang W, He Z et al. Effectiveness of aquatic exercise for treatment of knee osteoarthritis : Systematic review and meta-analysis. Zeitschrift fur Rheumatologie. 2015;74(6):543-52. doi:10.1007/s00393-014-1559-9.

53. Yazigi F, Espanha M, Vieira F, Messier SP, Monteiro C, Veloso AP. The PICO project: aquatic exercise for knee osteoarthritis in overweight and obese individuals. BMC musculoskeletal disorders. 2013;14(1):320. doi:10.1186/1471-2474-14-320.

54. Fransen M, McConnell S, R. HA, Van der Esch M, Simic M, Bennell K. Exercise for osteoarthritis of the knee. Cochrane Database Systematic Reviews. 2015;4:Cd004376. doi:CD004376.

55. Uthman OA, van der Windt DA, Jordan JL, Dziedzic KS, Healey EL, Peat GM et al. Exercise for lower limb osteoarthritis: systematic review incorporating trial sequential analysis and network meta-analysis. BMJ. 2013;347. doi:10.1136/bmj.f5555.

56. Tanaka R, Ozawa J, Kito N, Moriyama H. Efficacy of strengthening or aerobic exercise on pain relief in people with knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials. Clinical Rehabilitation. 2013;27(12):1059-71.

57. Bennell KL, Hinman RS. A review of the clinical evidence for exercise in osteoarthritis of the hip and knee. Journal of Science and Medicine in Sport. 2011;14(1):4-9. doi:http://dx.doi.org/10.1016/j.jsams.2010.08.002.

58. Boutaugh ML. Arthritis Foundation community-based physical activity programs: Effectiveness and implementation issues. Arthritis Care & Research. 2003;49(3):463-70. doi:10.1002/art.11050.

59. Callahan LF, Schoster B, Meier A, Mielenz T, DiMartino L. The People with Arthritis Can Exercise (PACE) Program: A Qualitative Evaluation of Participant Satisfaction. Preventing Chronic Disease. 2005;2(3):A11.

60. Henrotin Y, Marty M, Mobasheri A. What is the current status of chondroitin sulfate and glucosamine for the treatment of knee osteoarthritis? Maturitas. 2014;79(4):487. doi:10.1016/j.maturitas.2014.04.015.

61. Wieland HA, Michaelis M, Kirschbaum BJ, Rudolphi KA. Osteoarthritis - an untreatable disease? Nature reviews Drug discovery. 2005;4(4):331-44. doi:10.1038/nrd1693.

62. Lee Y, Woo J-H, Choi S, Ji J, Song G. Effect of glucosamine or chondroitin sulfate on the osteoarthritis progression: a meta-analysis. Rheumatol Int. 2010;30(3):357-63. doi:10.1007/s00296-009-0969-5.

63. Bruyere O, Pavelka K, Rovati LC, Gatterová J, Giacovelli G, Olejarová M et al. Total joint replacement after glucosamine sulphate treatment in knee osteoarthritis: results of a mean 8-year observation of patients from two previous 3-year, randomised, placebo-controlled trials. Osteoarthritis and Cartilage. 2008;16(2):254-60. doi:http://dx.doi.org/10.1016/j.joca.2007.06.011.

64. Zegels B, Crozes P, Uebelhart D, Bruyère O, Reginster JY. Equivalence of a single dose (1200 mg) compared to a three-time a day dose (400 mg) of chondroitin 4&6 sulfate in patients with knee osteoarthritis. Results of a randomized double blind placebo controlled study. Osteoarthritis and Cartilage. 2013;21(1):22-7. doi:http://dx.doi.org/10.1016/j.joca.2012.09.017.

65. Clegg DO, Reda DJ, Harris CL, Klein MA, O'Dell JR, Hooper MM et al. Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis. New England Journal of Medicine. 2006;354(8):795-808. doi:doi:10.1056/NEJMoa052771.

66. Fransen M, Agaliotis M. Glucosamine and chondroitin for knee osteoarthritis: a double-blind randomised placebo-controlled clinical trial evaluating single and combination regimens. 2015;74(5):851-8. doi:10.1136/annrheumdis-2013-203954.

67. Faul F, Erdfelder E, Lang AG, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behavior research methods. 2007;39(2):175-91.

68. Cohen J. Statistical power analysis for the behavioral sciences. . Hillsdale, NJ: Lawrence Erlbaum Associates; 1998.

69. Altman R, Asch E, Bloch D, Bole G, Borenstein D, Brandt K et al. Development of criteria for the classification and reporting of osteoarthritis. Classification of osteoarthritis of the knee. Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association. Arthritis and rheumatism. 1986;29(8):1039-49.

70. Altman R, Asch E, Bloch D, Bole G, Borenstein D, Brandt K et al. Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee. Arthritis & Rheumatism. 1986;29(8):1039-49. doi:10.1002/art.1780290816.

71. Ritter PL, Gonzalez VM, Laurent DD, Lorig KR. Measurement of pain using the visual numeric scale. J Rheumatol. 2006;33(3):574-80.

72. Hughes SL, Seymour RB, Campbell R, Pollak N, Huber G, Sharma L. Impact of the fit and strong intervention on older adults with osteoarthritis. The Gerontologist. 2004;44(2):217-28.

73. Fiatarone MA, O'Neill EF, Ryan ND, Clements KM, Solares GR, Nelson ME et al. Exercise training and nutritional supplementation for physical frailty in very elderly people. The New England journal of medicine. 1994;330(25):1769-75. doi:10.1056/nejm199406233302501.

74. Fisher NM, Pendergast DR, Gresham GE, Calkins E. Muscle rehabilitation: its effect on muscular and functional performance of patients with knee osteoarthritis. Arch Phys Med Rehabil. 1991;72(6):367-74.

75. Lagally KM, Robertson RJ. Construct validity of the OMNI resistance exercise scale. Journal of strength and conditioning research / National Strength & Conditioning Association. 2006;20(2):252-6. doi:10.1519/r-17224.1.

76. Espanha M, Priscila M, Yázigi F, Marques A, Machado M, Campos P et al. Guia para viver em PLENO: com menos dor e mais qualidade de vida. Lisboa: FMH-Ulisboa; 2015.

77. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Ann Rheum Dis. 1957;16(4):494-502.

78. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health and Quality of Life Outcomes. 2003;1:64-. doi:10.1186/1477-7525-1-64.

79. Lorig KR, Stewart A, Ritter PL, González V, Laurent D, Lynch J. Outcome Measures for Health Education and Other Health Care Interventions. Thousand Oaks CA: Sage Publications; 1996.

80. Pickard AS, Kohlmann T, Janssen MF, Bonsel G, Rosenbloom S, Cella D. Evaluating Equivalency Between Response Systems: Application of the Rasch Model to a 3-Level and 5-Level EQ-5D. Medical Care. 2007;45(9):812-9. doi:10.1097/MLR.0b013e31805371aa.

81. Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE et al. International physical activity questionnaire: 12-country reliability and validity. Medicine and science in sports and exercise. 2003;35(8):1381-95. doi:10.1249/01.mss.0000078924.61453.fb.

82. Rutten A, Abu-Omar K. Prevalence of physical activity in the European Union. Sozial- und Praventivmedizin. 2004;49(4):281-9.

83. Carver CS, Scheier MF, Weintraub JK. Assessing coping strategies: a theoretically based approach. Journal of personality and social psychology. 1989;56(2):267-83.

84. Carver CS. You want to measure coping but your protocol's too long: consider the brief COPE. International journal of behavioral medicine. 1997;4(1):92-100. doi:10.1207/s15327558ijbm0401_6.

85. Rikli REJ, C. J. . The reliability and validity of a 6-minute walk test as a measure of physical endurance in older adults. Journal of Aging and Physical Activity,. 1998;6: 363–75.

86. Schlenk EA, Lias JL, Sereika SM, Dunbar-Jacob J, Kwoh CK. Improving Physical Activity and Function in Overweight and Obese Older Adults with Osteoarthritis of the Knee: A Feasibility Study. Rehabilitation Nursing. 2011;36(1):32-42. doi:10.1002/j.2048-7940.2011.tb00063.x.

87. Escalante Y, García-Hermoso A, Saavedra JM. Effects of exercise on functional aerobic capacity in lower limb osteoarthritis: A systematic review. Journal of Science and Medicine in Sport. 2011;14(3):190-8. doi:http://dx.doi.org/10.1016/j.jsams.2010.10.004.

88. Bohannon RW. Sit-to-stand test for measuring performance of lower extremity muscles. Perceptual and motor skills. 1995;80(1):163-6. doi:10.2466/pms.1995.80.1.163.

89. Bohannon RW. Test-retest reliability of the five-repetition sit-to-stand test: a systematic review of the literature involving adults. Journal of strength and conditioning research / National Strength & Conditioning Association. 2011;25(11):3205-7. doi:10.1519/JSC.0b013e318234e59f.

90. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American Geriatrics Society. 1991;39(2):142-8.

91. Jones CJ, Rikli RE, Max J, Noffal G. The reliability and validity of a chair sit-and-reach test as a measure of hamstring flexibility in older adults. Research quarterly for exercise and sport. 1998;69(4):338-43. doi:10.1080/02701367.1998.10607708.

92. Rikli RE, Jones CJ. The development and validation of a functional fitness test for community-residing older adults. Journal of Aging and Psysical Activity. 1999;7:129-61.

93. Cesari M, Kritchevsky SB, Newman AB, Simonsick EM, Harris TB, Penninx BW et al. Added Value of Physical Performance Measures in Predicting Adverse Health-Related Events: Results from the Health, Aging, and Body Composition Study. Journal of the American Geriatrics Society. 2009;57(2):251-9. doi:10.1111/j.1532-5415.2008.02126.x.

94. Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F et al. Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People. Age and ageing. 2010;39(4):412-23. doi:10.1093/ageing/afq034.

95. Rose DJ. A Comprehensive Balance and Mobility Training Program. Champaign: Human Kinectics; 2003.

96. Giampaoli S, Ferrucci L, Cecchi F, Lo Noce C, Poce A, Dima F et al. Hand-grip strength predicts incident disability in non-disabled older men. Age and ageing. 1999;28(3):283-8.

97. Alley DE, Shardell MD, Peters KW, McLean RR, Dam TT, Kenny AM et al. Grip strength cutpoints for the identification of clinically relevant weakness. The journals of gerontology Series A, Biological sciences and medical sciences. 2014;69(5):559-66. doi:10.1093/gerona/glu011.

98. Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. Journal of manipulative and physiological therapeutics. 2004;27(1):26-35. doi:10.1016/j.jmpt.2003.11.003.

99. Borg G. Borg´s Perceived Exertion and Pain Scale. Champaign (IL): Human Kinetics; 1998.

Chapter 5: Predictors of Timed “up-and-go” Test in Elderly with Knee Osteoarthritis[2]

[2] Marconcin, P., Espanha, M., Yázigi, F., Teles, J. (2015). Predictors of Timed “up-and-go” Test in Elderly with Knee Osteoarthritis. In Cabri, J. J. & Pezarat, P. P. Proceedings of 3rd International Congress on Sport Sciences Research and Technology Support, Lisbon, Portugal, 2015 pp. 97 - 99. SCITEPRESS.

Abstract

Objective: To investigate which factors best predict the performance of the Timed "up-and-go" test in the elderly people with Knee Osteoarthritis (KOA).
Design: Cross-sectional study.
Setting: Community-dwelling elderly from Lisbon area.
Participants: A query yielded a total of 224 patients and a 67 followed the **e**ligibility criteria: age ≥ 60 years and uni or bilateral KOA, diagnosed according clinical and radiological criteria of the American College of Rheumatology (ACR).
Interventions: Not applicable.
Main Outcome Measure(s): Subject performed physical tests [Timed "up-and-go" (TUG), Six Minutes Waking Test (6MWT), Five Repetition Sit-to-Stand Test (FRSTST)], Handgrip, 6 meters gait speed, Standing Balance], and filled self-reported questionnaires [Knee Injury and Osteoarthritis Outcome Score (KOOS), Euroquol five-dimensions five-level (EQ-5D-5L) and International Physical Activity Questionnaire (IPAQ)].
Results: Two models can explain TUG test. The best model (explained 80.7% of variance) included FRSTST, 6MWT, Gait Speed, KOOS daily living activities dimension and EQ-5D-5L Self-Care dimension.
Conclusions: Functional strength, aerobic capacity, gait speed, perceived limitation in activities of daily living and self-care influenced the TUG performance.

Keywords: Osteoarthritis, Knee, Aged, Outcome Assessment.

Introduction

Knee Osteoarthritis (KOA) is a joint disease that most often affects middle-age to elderly individuals, and a leading cause of lower extremity disability and loss of functionality in this population [1].

The burden of KOA can be measured in terms of its signs and symptoms. Pain is the main symptom that incapacitates the individual to perform daily activities [2], which directly affects physical function. Several studies have shown the relationship between symptomatic KOA with physical disabilities [3-5]. Furthermore, a 3-years cohort study with hip and KOA patients [6] refereed pain, reduced range of motion (ROM) and decreased muscle strength as good predictors of self-reported limitation in daily activities.

It is essential to assess the physical function in people with KOA to evaluate the best treatment and to monitor the impact of the disease on patient´s life. This can be done by self-report methods or performance-based tests, and a combination of both is recommended to provide additional information [7].

A big concern with physical assessment in KOA patients is to avoid overload that can exacerbate pain, which can be a damaging factor in the performance of tests. In this sense is important to choose the best tests that can be a good indicatives of patient´s functional status, and don´t intensify the symptoms.

A battery that can be used in KOA patients is the Short Physical Performance Battery (SPPB), that evaluates balance (side-by-side stand, tandem and semi-tandem position), gait speed (8 ft walk) and lower strength (time to rise from a chair and return to the seated position five times) [8]. This battery also can be used as an indicative of sarcopenia [9], which is associated with KOA[10].

Furthermore, the Osteoarthritis Research Society International (OARSI), through an expert advisory group, recommended a set of five physical performance measures for hip and KOA: 30-s chair-stand test, 40 m fast paced walk test, a stair-climb test, 6MWT and Timed “up-and-go”, which was the most feasible of the performance-based tests [11].

Timed “up-and-go” test quantifying functional mobility and is used for daily mobility skills assessment in elderly [12]. This test were widely used in assessment of KOA patients [13-15].

Thus, the aim of this study was to investigate which factors best predict the performance of elderly individuals with symptomatic KOA in the Timed “up-and-go” test.

Methods

The study was conducted with Ethical Committee of the Faculty of Human Kinetics of the University of Lisbon approval (N=43/2014).

Sample

The recruitment and sample selection were done in the Lisbon area and, to avoid convenience sampling, different strategies for announcement by communication channels were use: social networks, newspapers, magazines, contacts with senior universities, health centers, churches and community centers.

Community-dwelling elderly with persistent knee pain, age over than or equal to 60 years, with KOA diagnosed according clinical and radiological criteria of the American

College of Rheumatology (ACR) [16], independently mobile and literate were selected to participate in the study. The exclusion criteria were: (1) having undergone surgery for knee replacement; or go to perform surgery to place knee(s) prosthesis in the next eight months; (2) have made applications (injections) of corticosteroids or hyaluronic acid in the last 6 months. The eligible subjects, according to the aforementioned eligibility criteria, were invited to an interview for explanation of the study and gave their written informed consent.

Measures and instruments

The measures and instruments used were: (1) socio demographic questionnaire [sex, age, educational level, body index mass (BMI) and marital status]; (2) performance-based tests (physical mobility, aerobic capacity, lower limb strength, hand grip strength, gait speed and balance); (3) specific self-reported measures related with KOA (pain, other symptoms, daily living activities, sports and recreations activities and quality of life), general health-related quality of life (QoL) (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and (4) level of physical activity.

Physical mobility was assessed by Timed “up-and-go”, a test that incorporates multiple activities including sit-to-stand, walking short distance, changing direction during walking, and transitions between them, allowing evaluation of strength, agility and dynamic balance [12].

Aerobic capacity was measured by the Six Minutes Walk Test (6MWT), that was a valid measure for older adults [17], and it has been used in studies with KOA [18, 19].

Lower limb strength was measured by the Five Repetitions Sit to Stand Test (FRSTST) that is a widely used measure of functional strength. ICC values demonstrated from good to high test-retest reliability for adults and subjects with osteoarthritis [18, 20, 21].

For hand grip strength a dynamometer was used to evaluate maximal isometric force of the hand and forearm muscles. This test has been used in elderly as an indicator of sarcopenia and/or disability [22, 23].

Gait speed was assessed with a 6 meters test, measuring the ability of linear walking since acceleration and deceleration were excluded [24].

Balance was assessed by Standing Balance Test [25], and both most painful and least painful leg were assessed. For analysis, only the most painful one was used.

Pain and other symptoms, function in daily living (ADL), sports and recreations activities and quality of life, related with the pathology, were evaluated by the Knee Injury and Osteoarthritis Outcome Score (KOOS). This questionnaire includes five dimensions, a score in each of the five dimensions is calculated as the sum of the items included and then converted to a 0-100 scale, with 0 representing extreme knee problems and 100 representing no knee problems. The KOOS is validated for patients with knee injury or with knee OA and is a reliable and responsive self-administered instrument for short-term follow-up [26]. The Portuguese validation was done by Gonçalves, Cabri, Pinheiro & Ferreira [27].

The EQ-5D-5L is a generic instrument for measuring health-related quality of life in five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each of these dimensions has five levels of severity (no, light, moderate and severe problems, and unable). This instrument has similar psychometric techniques as the EQ-5D [28] and is validated to the Portuguese population [29].

Level of physical activity was measured by short form of the International Physical Activity Questionnaire (IPAQ). Its reliability was verified in many countries and with different populations [30, 31].

Statistical analysis

Prior to performing multiple linear regression analysis to identify the significant predictors of TUG, correlation analyses and independent samples *t*-test were conducted to gain a better understanding of how predictors are associated with TUG.

Pearson correlation coefficient (r) was used to evaluate the correlation between continuous variables, and Spearman correlation coefficient (r_S) was used in the case of ordinal variables. Some rough guidelines were employed for designating the strength of correlation: if $|r| \geq 0.7$, the correlation is considered strong; if $0.3 \leq |r| < 0.7$, is classified as moderate; and if $|r| < 0.3$, the correlation is weak. These guidelines were also used to classify Spearman correlation coefficients [32].

Independent samples *t*-test was used to test if there were significant differences in the mean values of TUG between males and females. The candidate predictors that were

considered for the linear regression model were the following: (i) age, sex, BMI a risk or related factors; (ii) health related physical fitness measures (aerobic capacity, lower limb strength, hand grip strength); (iii) skill related physical fitness measures (gait speed and balance); (iv) general and specific self-reported health-related QoL measures, and (v) physical activity. Multiple regression analysis, using the backward elimination stepwise method, was done to identify the significant predictors of Timed "up-and-go" test. Residual analysis was conducted to ensure no violation of the assumptions of normality, homoscedasticity, linearity; Variance Inflation Factor (VIF) and Durbin-Watson statistics was used to verify if multicollinearity is present and if errors were independent, respectively. All statistical analyses were performed with the software SPSS v.22 and a significance level of 5% was considered.

Results

Study sample included 67 participants, 47 female and 20 male, with mean (SD) age of 69.1 (5.8) years, Body Mass Index (BMI) of 31.2 (5.2) Kg/m^2, with 38.8% having obesity grade 1 and 94.0% having bilateral KOA. The participants were mostly retired (91.0%) and married (59.7%).

Independent samples *t*-test revealed that there were significant differences in the mean values of TUG between males and females (males: $M = 6.19$, $SD = 1.29$; females: $M = 7.19$, $SD = 1.84$; $t(65) = 2.193$, $p = .032$). Among the other socio-demographic variables, Timed "up-and-go" was positively correlated with age ($r = .285$, $p = .020$; weak correlation) and BMI ($r = .379$, $p = .002$; moderate correlation), and negatively correlated with education level ($r_S = –.331$, $p = .006$; moderate association). Relatively to performance-based tests, Timed "up-and-go" was strongly negatively correlated with 6MWT test ($r = –.709$, $p < .001$) and gait speed ($r = –.734$, $p < .001$); FRSTST showed a moderate positive correlation with Timed "up-and-go" ($r = .635$, $p < .001$); Balance showed a moderate negative correlation with Timed "up-and-go" ($r_S = –.347$, $p = .004$). Concerning KOOS dimensions, all of them showed moderate negative correlations with Timed "up-and-go" (Pain: $r = –.504$, $p < .001$; Symptom: $r = –.451$, $p < .001$; ADL: $r = –.663$, $p < .001$; Sport/Rec: $r = –.562$, $p < .001$; QoL: $r = –.521$, $p < .001$). Among EQ-5D-5L dimensions, Timed "up-and-go" had moderate positive correlations with Mobility ($r_S = .481$, $p < .001$), Self-care ($r_S = .566$, $p < .001$), Usual

activities (r_S = .651, p < .001), and Pain/Discomfort (r_S = .311, p = .010). Timed "up-and-go" showed no significant correlations with the level of physical activity (IPAQ).

Multiple regression analysis, using the backward elimination stepwise method, allowed identifying two models to predict Timed "up-and-go". The variables FRSTST, 6MWT, Gait Speed, and KOOS ADL were included in both models. The Model 1 contained also the variable EQ-5D-5F Self Care and the Model 2, EQ-5D-5F Usual Activities instead of EQ-5D-5F Self Care. The results indicated that in Model 1 the five predictors explained 80.7% of the variance of Timed "up-and-go" (R^2 = .807, *adj*. R^2 = .787, F(6,60) = 41.719, p < .001) and 78.7% of the variance (R^2 = .787, *adj*. R^2 = .766, F(6,60) = 37.057, p < .001) in case of Model 2. The regression coefficients and standard error estimates for both models are presented in Table 5.1.

Table 5.1 - Predictor´s variables of Timed "up-and-go".

Predictors - Model 1	*B (SE)*	*t*	*p*	*Contribution to R^2 (%)*
Intercept	11.400 (0.921)	12.376	<.001	
FRSTST (s)	0.145 (0.037)	3.940	<.001	16.9
6MWT	–0.006 (0.002)	–3.443	.001	20.6
Gait Speed	–1.027 (0.359)	–2.862	.006	17.7
KOOS ADL	–0.016 (0.006)	–2.487	.016	12.5
EQ-5D-5F Self Care(1)[a]	–0.930 (0.330)	–2.816	.007	12.9
EQ-5D-5F Self Care(2)[a]	–1.181 (0.314)	–3.755	<.001	
Predictors - Model 2	***B (SE)***	***t***	***p***	
Intercept	10.767 (0.958)	11.241	<.001	
FRSTST (s)	0.151 (0.038)	4.003	<.001	17.6
6MWT	–0.005 (0.002)	–2.826	.006	17.1
Gait Speed	–1.119 (0.373)	–3.001	.004	19.3
KOOS ADL	–0.017 (0.007)	–2.448	.017	13.1
EQ-5D-5F Usual Act(1)[a]	–0.795 (0.323)	–2.462	.007	11.6
EQ-5D-5F Usual Act (2)[a]	–0.706 (0.290)	–2.437	.018	

[a] *The reference level for the predictors EQ-5D-5L Usual Act and EQ-5D-5L Self Care was "At least moderate problems", and (1) represents "No problem" and (2) represents "Slight problems".*

Discussion

Performance measure and self-reported measure are complementary, since they not measure the same construct: self-report tests can show disability which is the social side of the functional limitation [33], therefore, they cannot substitute each other. Moreover, as this

study involved older adults that may underestimate or overestimate their functional status, the use of these two types of measures is advocate.

The Timed “up-and-go” test is one of the most widely used tests of functional mobility, being similar to many daily activities. In this study, involving elderly individuals with KOA, the predictors of this test, identified by multiple linear regression analysis, were the following: FRSTST, 6MWT, Gait Speed, KOOS ADL and EQ-5D-5F self-care and usual activities dimensions. Besides that, were founded that Timed “up-and-go” was significantly associated with pain and other OA symptoms, balance and subjective general and specific health-related quality of life factors.

It is understandable that FRSTST and gait speed were predictors, as they are parts of the Timed “up-and-go” test [34]. Although 6MWT is not incorporated in the Timed “up-and-go” test, it reflects overall physical functional performance and mobility [17], being strongly associated with others functional tests like Timed “up-and-go”.

Considering the self-reported measures, only the EQ-5D-5L (self-care and usual activity dimension), and KOOS ADL were included in the regression models. Both questionnaires assess similar domains, but in different ways, as EQ-5D-5L includes 5 levels of severity, that only one should be reported, in each of the dimensions, and in the KOOS ADL subscale a final score is obtained from seventeen daily activities performed in the previous week, assessing therefore a wider range of activities.

It has previously been found in others studies that health status (self-reported) is a predictor of functional tests, namely the FRSTST [35] and 6MWT [36].

In a related study, involving subjects with knee and hip osteoarthritis, all dimensions/subscales of KOOS and WOMAC had a moderate and inverse relationship with Timed “up-and-go” [13, 37], as occurred in this study. However, it is important to highlight that all KOOS’s subscales were correlated with each other, therefore in the final multiple regression models only ADL dimension was included, because this dimension had the strongest correlates with Timed “up-and-go” variable.

In a study with 163 KOA patients, self-reported measure of function (SF-36) was more influenced by pain (WOMAC pain) than a performance-based physical functioning test [38], and in a similar study, pain severity, obesity and helplessness were the most important determinants of physical function [39]. Interestingly, in the present study Time

“up-and-go” performance was more associated with limitation on daily living activities, than by self-reported pain and other symptoms. One possible explanation is because the test involves a quick activity [mean (SD), 6.9s (0.2)] and therefore stimulus duration was not sufficient to cause mechanical pain. It seems that only when knee pain is severe, is significantly associated with limited mobility [40].

It is challenging select the best physical function tests, especially in people with KOA that might complain of mechanical pain if exposed to overloading due to performance of several tests. Thus, for this population, the Timed “up-and-go” test may be most suitable than 6 meters test, FRSTST and 6MWT.

Conclusions

In conclusion, the findings of this study indicate that in older individuals with KOA, Timed “up-and-go” performance is influenced by lower limb strength, gait speed, mobility, and the perceived limitation in performing activities of daily living.

In a further study will be interesting to investigate which physical fitness component the Timed “up-and-go” test can predict.

References

1. Johnson, V.L. and D.J. Hunter, *The epidemiology of osteoarthritis*. Best Practice & Research Clinical Rheumatology, 2014. **28**(1): p. 5-15.
2. Tanimura, C., et al., *Difficulties in the daily life of patients with osteoarthritis of the knee: scale development and descriptive study*. Journal of Clinical Nursing, 2011. **20**(5-6): p. 743-753.
3. Machado, G.P., M.A. Gignac, and E.M. Badley, *Participation restrictions among older adults with osteoarthritis: a mediated model of physical symptoms, activity limitations, and depression*. Arthritis Rheum, 2008. **59**(1): p. 129-35.
4. Wood, L., et al., *Associations between physical examination and self-reported physical function in older community-dwelling adults with knee pain*. Phys Ther, 2008. **88**(1): p. 33-42.
5. Davis, M.A., et al., *Knee osteoarthritis and physical functioning: evidence from the NHANES I Epidemiologic Followup Study*. J Rheumatol, 1991. **18**(4): p. 591-8.
6. van Dijk, G.M., et al., *Prognosis of limitations in activities in osteoarthritis of the hip or knee: a 3-year cohort study*. Arch Phys Med Rehabil, 2010. **91**(1): p. 58-66.
7. Stratford, P.W. and D.M. Kennedy, *Performance measures were necessary to obtain a complete picture of osteoarthritic patients*. J Clin Epidemiol, 2006. **59**(2): p. 160-7.
8. Guralnik, J.M., et al., *A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission*. J Gerontol, 1994. **49**(2): p. M85-94.

9. Cruz-Jentoft, A.J., et al., *Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People*. Age Ageing, 2010. **39**(4): p. 412-23.

10. De Ceuninck, F., A. Fradin, and P. Pastoureau, *Bearing arms against osteoarthritis and sarcopenia: when cartilage and skeletal muscle find common interest in talking together*. Drug Discov Today, 2014. **19**(3): p. 305-11.

11. Dobson, F., et al., *OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis*. Osteoarthritis Cartilage, 2013. **21**(8): p. 1042-52.

12. Podsiadlo, D. and S. Richardson, *The timed "Up & Go": a test of basic functional mobility for frail elderly persons*. Journal of the American Geriatrics Society, 1991. **39**(2): p. 142-148.

13. Sabirli, F., N. Paker, and D. Bugdayci, *The relationship between Knee Injury and Osteoarthritis Outcome Score (KOOS) and Timed Up and Go test in patients with symptomatic knee osteoarthritis*. Rheumatology International, 2013. **33**(10): p. 2691-2694.

14. Oliveira, A.M., et al., *Impact of exercise on the functional capacity and pain of patients with knee osteoarthritis: a randomized clinical trial*. Rev Bras Reumatol, 2012. **52**(6): p. 876-82.

15. Wright, A.A., et al., *Relationship between the Western Ontario and McMaster Universities Osteoarthritis Index Physical Function Subscale and physical performance measures in patients with hip osteoarthritis*. Arch Phys Med Rehabil, 2010. **91**(10): p. 1558-64.

16. Altman, R., et al., *Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee*. Arthritis & Rheumatism, 1986. **29**(8): p. 1039-1049.

17. Rikli, R.E.J., C. J. , *The reliability and validity of a 6-minute walk test as a measure of physical endurance in older adults*. Journal of Aging and Physical Activity,, 1998. **6**: p. 363–375.

18. Schlenk, E.A., et al., *Improving Physical Activity and Function in Overweight and Obese Older Adults with Osteoarthritis of the Knee: A Feasibility Study*. Rehabilitation Nursing, 2011. **36**(1): p. 32-42.

19. Escalante, Y., A. García-Hermoso, and J.M. Saavedra, *Effects of exercise on functional aerobic capacity in lower limb osteoarthritis: A systematic review*. Journal of Science and Medicine in Sport, 2011. **14**(3): p. 190-198.

20. Bohannon, R.W., *Sit-to-stand test for measuring performance of lower extremity muscles*. Percept Mot Skills, 1995. **80**(1): p. 163-6.

21. Bohannon, R.W., *Test-retest reliability of the five-repetition sit-to-stand test: a systematic review of the literature involving adults*. J Strength Cond Res, 2011. **25**(11): p. 3205-7.

22. Alley, D.E., et al., *Grip strength cutpoints for the identification of clinically relevant weakness*. J Gerontol A Biol Sci Med Sci, 2014. **69**(5): p. 559-66.

23. Giampaoli, S., et al., *Hand-grip strength predicts incident disability in non-disabled older men*. Age Ageing, 1999. **28**(3): p. 283-8.

24. Cesari, M., et al., *Added Value of Physical Performance Measures in Predicting Adverse Health-Related Events: Results from the Health, Aging, and Body Composition Study*. Journal of the American Geriatrics Society, 2009. **57**(2): p. 251-259.

25. Rose, D.J., *A Comprehensive Balance and Mobility Training Program*. 2003, Champaign: Human Kinectics.

26. Roos, E.M. and L.S. Lohmander, *The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis*. Health and Quality of Life Outcomes, 2003. **1**: p. 64-64.

27. Goncalves, R.S., et al., *Cross-cultural adaptation and validation of the Portuguese version of the Knee injury and Osteoarthritis Outcome Score (KOOS)*. Osteoarthritis Cartilage, 2009. **17**(9): p. 1156-62.

28. Pickard, A.S., et al., *Evaluating Equivalency Between Response Systems: Application of the Rasch Model to a 3-Level and 5-Level EQ-5D*. Medical Care, 2007. **45**(9): p. 812-819.

29. Ferreira, P.L., L.N. Ferreira, and L.N. Pereira, *Contribution for the Validation of the Portuguese Version of EQ-5D*. Acta Médica Portuguesa; Vol 26, No 6 (2013): November-December, 2013.

30. Craig, C.L., et al., *International physical activity questionnaire: 12-country reliability and validity*. Med Sci Sports Exerc, 2003. **35**(8): p. 1381-95.

31. Rutten, A. and K. Abu-Omar, *Prevalence of physical activity in the European Union*. Soz Praventivmed, 2004. **49**(4): p. 281-9.

32. Sheskin, D.J., *Handbook of Parametric and Nonparametric Statistical Procedures* ed. t. ed. 2007, Boca Raton, Florida.: Chapman and Hall/CRC.

33. Hoeymans, N., et al., *Measuring functional status: Cross-sectional and longitudinal associations between performance and self-report (Zutphen Elderly Study 1990–1993)*. Journal of Clinical Epidemiology, 1996. **49**(10): p. 1103-1110.

34. Reid, K.F. and R.A. Fielding, *Skeletal muscle power: a critical determinant of physical functioning in older adults*. Exerc Sport Sci Rev, 2012. **40**(1): p. 4-12.

35. Lord, S.R., et al., *Sit-to-Stand Performance Depends on Sensation, Speed, Balance, and Psychological Status in Addition to Strength in Older People*. The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 2002. **57**(8): p. M539-M543.

36. Lord, S.R. and H.B. Menz, *Physiologic, psychologic, and health predictors of 6-minute walk performance in older people*. Arch Phys Med Rehabil, 2002. **83**(7): p. 907-11.

37. Juhakoski, R., et al., *Factors affecting self-reported pain and physical function in patients with hip osteoarthritis*. Arch Phys Med Rehabil, 2008. **89**(6): p. 1066-73.

38. Terwee, C.B., et al., *Self-reported physical functioning was more influenced by pain than performance-based physical functioning in knee-osteoarthritis patients*. J Clin Epidemiol, 2006. **59**(7): p. 724-31.

39. Creamer, P., M. Lethbridge-Cejku, and M.C. Hochberg, *Factors associated with functional impairment in symptomatic knee osteoarthritis*. Rheumatology, 2000. **39**(5): p. 490-496.

40. Lamb, S., et al., *Factors that modify the association between knee pain and mobility limitation in older women: the Women's Health and Aging Study*. Annals of the Rheumatic Diseases, 2000. **59**(5): p. 331-337.

Chapter 6: O impacto da dor e outros sintomas nas estratégias de *coping* em idoso com osteoartrose do joelho[3]

[3] Marconcin, P., Espanha, M., Rosado, A., Marques, A., Campos, P. & Yázigi, F. O impacto da dor e outros sintomas nas estratégias de coping em idosos com osteoartrose do joelho. Revista Brasileira de Reumatologia (submitted).

Resumo

O objetivo do presente estudo foi investigar quais as estratégias de *coping* mais utilizadas por idosos com osteoartrose do joelho (OAJ) e se existem diferenças na utilização das estratégias isoladas, ou agrupadas em categorias, conforme as características sócio demográficas, o grau de severidade da osteoartrose, a dor e outros sintomas da OAJ. A amostra foi constituída por 73 indivíduos com 69±5.9 anos e diagnóstico clínico e radiológico de OAJ. Os instrumentos utilizados foram os questionários *Knee Injury and Osteoarthritis Outcome Score (KOOS)* e o *Brief* COPE. O tratamento estatístico dos dados foi feito com base na análise de variância multivariada (MANOVA). A ausência de resultados estatisticamente significativos indicam que as estratégias de *coping*, isoladas ou agrupadas, não foram influenciadas pelas variáveis testadas. Assim, é possível concluir que enfrentar as adversidades da OAJ independe do género, do nível acadêmico, da severidade da patologia e do nível de percepção da dor. Os achados podem contribuir na idealização de programas educacionais com o propósito de trabalhar as estratégias de *coping* em idosos com OAJ.

Palavras-chave: Estratégias de enfrentamento, Osteoartrose do joelho, Idosos.

Introdução

A osteoartrose (OA) é a mais prevalente dentre as doenças reumáticas [1] e é mais frequente na articulação do joelho [2], sendo considerada a principal causa de incapacidade dos membros inferiores [3]. A incidência da osteoartrose do joelho (OAJ) é maior na população idosa [4], causando um grande impacto econômico nos serviços de saúde [5]. É uma patologia em que o principal sintoma é a dor de caráter persistente, causando considerável incômodo [6] com comprometimento direto da funcionalidade e da capacidade de realizar as tarefas da vida diária [7]. Outros sintomas igualmente presentes são a rigidez e a disfunção da articulação [8], que também impactam diretamente na vida do indivíduo, tornando-se uma experiência frustrante e estressante. Saber gerir a dor e os outros sintomas da OAJ é uma condição imprescindível para o paciente viver com melhor qualidade de vida e funcionalidade.

Nesse sentido, a forma de enfrentar essa realidade pode ser decisiva no impacto que a mesma trará para o bem-estar do indivíduo [9]. Assim, Lazarus (1992) [10] enfatiza a importância das estratégias de *coping* para pacientes com doenças crônicas. Essas estratégias podem ser compreendidas como o conjunto de esforços comportamentais e cognitivos [11] para prevenir ou diminuir o dano, a perda ou o estresse associado a um

evento desgastante [12, 13]. É um conceito amplo e o seu campo de classificação em sistemas de categorias é extenso [14]. Um dos primeiros sistemas de classificação foi proposto por Lazarus e Folkman em 1984 [11] que desenvolveram um modelo que diferencia o *coping* em dois tipos: (1) resposta focada no problema e (2) resposta focada na emoção. O primeiro envolve esforços para alterar a fonte do estresse ou fazer algo para enfrentá-lo e o segundo envolve esforços para reduzir ou controlar o estresse emocional provocado pelo agente estressor. Contudo, ambos estão interligados e podem ser vistos como complementares [15]. Outra classificação adotada considera as estratégias de *coping* como ativas ou passivas, em que a primeira ocorre quando o indivíduo tem a intenção de enfrentar, de alguma forma, o estressor e a segunda, quando o indivíduo nega, deixa de se esforçar para enfrentar o estressor ou busca refúgio em comportamentos adversos [16].

É importante ressaltar que não existem estratégias melhores ou piores, isso depende de quem as usa, sob quais circunstâncias e a que situação pretende adaptar-se [17]. O *coping* é influenciado por fatores contextuais, recursos sociais, por características da personalidade e pela avaliação das características do contexto de stress, incluindo o seu controle [18, 19].

A literatura acerca das estratégias de *coping* na OA é relativamente escassa [9, 20-22]. Idosos com OA que tem a percepção de que sua patologia é muito grave, utilizam principalmente estratégias de *coping* passivas e aqueles que percebem a patologia como pouco grave fazem uso de estratégias ativas, que envolvem esforços para manter a funcionalidade ou para distrair-se da dor [21]. Pacientes com OA do quadril e OAJ, aumentam a utilização de estratégias passivas com o aumento da duração da patologia, sendo superior a utilização dessas estratégias em pacientes com maior percepção da dor, mais velhos, com sobrepeso, que não praticam atividade física, aposentados e solteiros [22]. As estratégias de *coping* podem ser consideradas estáveis ao longo do tempo, sendo que a utilização de estratégias de reorientação está associada ao aumento da perceção da dor e o uso das estratégias focadas na emoção mostra-se associado a uma maior incapacidade [9].

As investigações acerca da OA e a utilização das estratégias de *coping* apontam na direção de que estratégias tidas como ativas resultam em resultados mais positivos, ao

contrário de estratégias consideradas como passivas. Contudo, até o presente momento, não foram encontrados estudos que procurassem compreender a utilização das estratégias de *coping* consideradas individualmente na população com OAJ. Também é escassa a informação acerca da variabilidade da utilização dessas estratégias em função de um conjunto de variáveis preditoras, nomeadamente variáveis demográficas, o grau de severidade da patologia, intensidade da dor e outros sintomas.

Assim, o objetivo da presente pesquisa é investigar quais as estratégias de *coping* mais utilizadas por idosos com OAJ e se existem diferenças na utilização das estratégias isoladas, ou agrupadas em categorias, conforme as características sócio demográficas (gênero, escolaridade), o grau radiológico de severidade da patologia e quatro diferentes níveis de perceção da dor e de outros sintomas (rigidez, inchaço, crepitação e limitação do movimento) da OAJ.

Material e métodos

Participantes

O recrutamento da amostra foi feito na região de Lisboa (Portugal) e foram utilizados diferentes canais de divulgação: jornais, revistas, contatos com universidades seniores, igrejas, hospitais, centros de saúde e o site e a lista de contatos da Liga Portuguesa Contra as Doenças Reumáticas (LPCDR).

Como critérios de inclusão, os participantes deveriam ter mais de 60 anos, diagnóstico clínico e radiológico da OAJ de acordo com o *American College of Rheumatology (ACR)* [8], e compreensão da língua portuguesa para preenchimento do questionário. Demonstraram interesse em participar no estudo 224 indivíduos, tendo sido excluídos 136 porque não cumpriram os critérios de elegibilidade e 15 desistiram de participar do estudo por questões pessoais, ficando um total de 73 idosos com OAJ.

Instrumentos

Os dados sociodemográficos foram coletados por meio de um questionário específico com itens referentes a idade, género, escolaridade, entre outras informações.

O grau de severidade da patologia foi feito pela classificação de Kellgren e Lawrence [23], através da análise do raio-x das articulações tibiofemoral e patelo femoral, realizado por um reumatologista.

A Dor e os Outros Sintomas (rigidez, inchaço, crepitação, limitação do movimento) foram avaliados através das dimensões do questionário *Knee Injury and Osteoarthritis Outcome Score* (KOOS). O KOOS é um instrumento auto-administrado validado para população com OAJ [24] e a validação portuguesa possui confiabilidade aceitável, com um coeficiente alfa de Cronbach entre 0.77 e 0.95, e ICC variando de 0.82 a 0.94 para as subescalas do questionário [24]. A pontuação de cada dimensão é calculada pela soma de todos os itens que a compõem e depois convertida para uma escala de 0 a 100, em que 0 representa problemas extremos e 100 nenhum problema relacionado a OAJ.

As estratégias de *coping* foram obtidas pelo questionário Brief COPE [25], que possui validação para o português [26]. O questionário contém 28 itens, agrupados em 14 subescalas, redigidos em termos da ação que as pessoas implementam, sendo a resposta dada numa escala ordinal com quatro alternativas entre "nunca faço isso" (1) até "faço sempre isso" (4). Os itens estão apresentadas na tabela 6.1.

Table 6.1 - Estatística descritiva, características sociodemográficas, presença de OAJ uni ou bilateral (ACR), grau de severidade da OAJ, níveis de dor e outros sintomas.

Escala	Definição
1. *Coping* ativo	Iniciar uma ação ou fazer esforços para remover ou circunscrever o estressor
2. Planejar	Pensar sobre o modo de se confrontar com o estressor, planejar esforços de *coping* ativo.
3. Utilizar suporte instrumental	Procurar ajuda, informações, ou conselhos acerca do que fazer.
4. Utilizar suporte social e emocional	Conseguir simpatia ou suporte emocional de alguém.
5. Religião	Aumento de participação em atividades religiosas.
6. Reinterpretação positiva	Fazer o melhor da situação crescendo a partir dela, ou vendo-a de um modo mais favorável.
7. Auto-culpabilização	Culpabilizar-se e criticar-se a si próprio pelo que aconteceu.
8. Aceitação	Aceitar o fato que o evento estressante ocorreu e é real
9. Expressão de sentimentos	Aumento da consciência do estresse emocional pessoal e a tendência concomitante para exprimir ou descarregar esses sentimentos.
10. Negação	Tentativa de rejeitar a realidade do acontecimento estressante.
11. Autodistração	Desinvestimento mental do objetivo com que o estressor está a interferir, através do sonho acordado, dormir, ou auto distração.

12. Desinvestimento comportamental	Desistir, ou deixar de se esforçar da tentativa para alcançar o objetivo com o qual o estressor está a interferir.
13. Uso de substâncias (medicamentos/álcool)	Virar-se para o uso do álcool ou outras drogas (medicamentos) como um meio de desinvestir do estressor.
14. Humor	Fazer piadas acerca do estressor

Análise estatística

A análise dos dados foi feita por meio de estatística descritiva (média, desvio padrão e análise de frequências), com o objetivos de traçar o perfil sócio-demográfico, a presença da OAJ uni ou bilateral e o grau de severidade da mesma, a Dor e Outros sintomas e as estratégias de *coping*. A sensibilidade das provas foi avaliada através do teste de normalidade Kolmogorov-Smirnov e por recurso aos rácios críticos dos coeficientes de assimetria e de achatamento.

A significância dos fatores gênero, escolaridade, severidade da patologia e perceção da dor e outros sintomas da OAJ em relação as estratégias de *coping*, foi avaliada através da MANOVA depois de validados os pressupostos de normalidade e de homogeneidade da matriz de variância-covariância, verificados através do teste M de Box, com o traço de Pillai. Procedeu-se, ainda, a uma análise factorial exploratória (método da máxima verossimilhança com rotação promax) de modo a estruturar as estratégias de *coping* em fatores. A decisão de quantos fatores reter, um componente crítico da análise exploratória, baseou-se na Análise Paralela, um dos mais precisos métodos de retenção de fatores [27]. Calcularam-se, ainda, os valores destes dois fatores e procedeu-se à sua inclusão na análise Manova. A análise estatística foi feita com o software SPSS Statistics 22 (IBM SPSS, Chicago, IL). Considerou-se um nível de significância $p<0.05$.

Este estudo enquadra-se no Programa PLE^{2}NO, Clinical Trial NCT02562833, cujo protocolo detalhado foi previamente publicado. E recebeu aprovação do comitê de ética da Faculdade de Motricidade Humana, Universidade de Lisboa (N=43/2014). Todos os voluntários concordaram em participar do estudo e assinaram o termo de consentimento livre e esclarecido.

Resultados

Participaram do estudo 73 idosos com OAJ, cujas características estão descritas na tabela 6.2, que apresenta os dados sociodemográficos, a presença da OAJ uni ou bilateral, a severidade da patologia e os valores da Dor e dos Outros sintomas, bem como a distribuição dos indivíduos em quartis para estas duas últimas variáveis.

Table 6.29 - Estatística descritiva, características sociodemográficas, presença de OAJ uni ou bilateral (ACR), grau de severidade da OAJ, níveis de dor e outros sintomas.

Variáveis	**Amostra total (N=73) N (%) ou M±DP**
Gênero	
Mulheres	52 (71.2)
Homens	21 (28.8)
Idade	69±5.9
Nível educacional	
1º ciclo	19 (26,0)
2º e 3º ciclos	17 (23,3)
Secundário	18 (24,7)
Ensino Superior	19 (26,0)
Aposentadoria	
Sim	67 (91.8)
Não	6 (8.2)
Presença de OA	
Unilateral	7 (9.6)
Bilateral	66 (90.4)
Severidade	
Grau I e II	33 (45.2)
Grau III e IV	40 (54.8)
Dor	55.7±19.6
1º quartil (0 – 41.6)	21 (28.8)
2º quartil (41.7 – 54.1)	16 (21.9)
3º quartil (54.2 – 69.4)	19 (26.0)
4º quartil (69.5 – 100)	17 (23.3)
Outros sintomas	60.5±22.1
1º quartil (0 – 42.8)	18 (24.7)
2º quartil (42.9 – 64.3)	22 (30.1)
3º quartil (64.4 – 78.6)	17 (23.3)
4º quartil (78.7 – 100)	16 (21.9)

Em relação a utilização das estratégias de *coping*, como pode observar-se na tabela 6.3, as estratégias mais utilizadas foram a aceitação seguida do *coping* ativo e do planejar,

enquanto que a negação, o desinvestimento comportamental e o uso de substâncias (medicamentos/álcool) foram as estratégias menos utilizadas.

Table 6.3 - Resultados da utilização das estratégias de coping (N=73)

Estratégias	**M±DP**
Aceitação	6.45±1.41
Coping ativo	6.37±1.38
Planejar	6.30±1.53
Reinterpretação positiva	5.92±1.77
Humor	5.34±1.82
Religião	5.18±2.34
Auto-distração	5.08±2.02
Uso de suporte instrumental	4.97±1.73
Expressão de sentimentos	4.85±1.62
Auto-culpabilização	4.84±1.78
Uso de suporte social e emocional	4.74±1.90
Negação	3.88±1.73
Desinvestimento comportamental	3.60±1.80
Uso de substâncias (medicamentos/álcool)	2.26±0.83

Num segundo momento procedemos ao agrupamento destas estratégias por via da análise fatorial tendo-se obtido dois fatores, um primeiro fator constituído pelas estratégias: *coping* ativo, planejar, utilizar suporte instrumental, utilizar suporte social e emocional, reinterpretação positiva, aceitação, auto-distração e humor ($\alpha = 0.83$); e um segundo fator contituido pelas estratégias: auto-culpabilização, expressão de sentimentos, desinvestimento comportamental, negação e uso de substâncias ($\alpha = 0.65$). A variância total explicada pelo modelo foi de 43.80%.

O primeiro fator recebeu a denominação de estratégias ativas e o segundo de estratégias passivas, pela característica de cada uma das estratégias identificadas em cada agrupamento e pelo suporte teórico [16]. Sendo assim, dois fatores foram integrados na MANOVA, sendo a análise foi feita quer com as estratégias individuais quer com as estratégias individuais agrupadas nesses dois fatores.

A MANOVA revelou que nenhuma das variáveis independentes teve efeito significativo sob as estratégias de *coping*, isoladas ou agrupadas nos fatores obtidos (tabela 6.4).

Table 6.4 - Análise de variância multivariada das variáveis, dor, sintomas, grau de severidade da OAJ, gênero e nível educacional em relação as estratégias de coping, isoladas ou agrupadas.

	Manova Pillai´s Trace			
Variáveis	F	p	η^2_p	Potência
Gênero	1.215	.290	0.227	0.656
Nível educacional	0.882	.678	0.175	0.863
Severidade da AO	1.326	.108	0.246	0.982
Dor	1.094	.336	0.209	0.944
Sintomas	1.024	.441	0.198	0.924

Discussão

O presente estudo teve como objetivo identificar quais as estratégias de *coping* mais utilizadas por idosos com OAJ e perceber o impacto da Dor e Outros sintomas (rigidez, inchaço, crepitação, limitação do movimento), do grau de severidade da patologia, bem como de algumas características sociodemográficas, nomeadamente o gênero e o nível educacional, na utilização das estratégias de *coping*, isoladas e agrupadas. Os resultados mostraram que, na amostra investigada, as principais estratégias utilizadas para lidar com as situações estressantes causadas pela patologia, são a aceitação, o *coping* ativo e o planejar, e as estratégias menos utilizadas são a negação, o desinvestimento comportamental e o uso de substâncias. É preciso esclarecer que em relação a esta última estratégia foi questionado somente medicamentos além dos utilizados habitualmente para o tratamento da patologia ou de comorbidades e o uso de álcool.

De notar em particular, que a estratégia religião, foi a sexta estratégia mais utilizada, mas após a análise fatorial, não foi integrada nem no fator *coping* ativo, nem no fator *coping* passivo, apresentando uma correlação não significativa com estes dois fatores. Na análise fatorial exploratória, a religiosidade corresponderia a um 3º fator que não reuniu as condições para permanecer na análise (seria constituído, apenas, por esta variável). A investigação do papel do *coping* religioso requer abordagens mais complexas do que tentar atribuí-lo a um fator de ordem superior, como o *coping* ativo ou passivo,

uma vez que se tende a diferenciar destes. As questões do *coping* centrado na religiosidade merecem investigação futura já que a função do enfrentamento religioso pode ser eventualmente devido à variabilidade na religiosidade da amostra. Os níveis de religiosidade podem afetar as diversas estratégias de *coping* em uso, pelo que a religiosidade deve ser analisada não só como uma estratégia de *coping* mas como um determinante das mesmas.

É preciso ressaltar que para lidar com os eventos estressantes causados pela patologia, dor e outros sintomas, os indivíduos não utilizam somente uma dada estratégia, pois elas não são mutuamente exclusivas [10], mas as várias possibilidades, ainda que algumas possam receber maior atenção que outras. O que ficou explícito no presente estudo, em que houveram estratégias utilizadas mais frequentemente, mas todas as estratégias foram mencionadas.

E em relação ao impacto das variáveis independentes, nenhuma das variáveis consideradas pode ser um preditor significativo das estratégias de *coping*, isoladas ou agrupadas em dois fatores, a serem adoptadas, nem da intensidade da sua utilização, consideradas individualmente. As estratégias de *coping* não parecem, assim, ser influenciadas pelo gênero e nível educacional, mas também não são influenciadas pela severidade da doença ou pela percepção de dor tal como as medimos. Nossos achados podem ser analisados em concordância aos resultados apresentados no estudo de Vivan e Argimon [28] em que não foram encontradas diferenças entre a utilização das estratégias de *coping* e o gênero e o nível educacional, em idosos institucionalizados, contraditoriamente a outros estudos que encontraram relações significativas entre o gênero e a escolha das estratégias de *coping* [29-32], e ao nível educacional e a escolha das estratégias [21, 28, 31, 33].

Em relação a severidade da patologia, da forma com que foi avaliada, refere-se a progressão das alterações estruturais da mesma, ainda que possa ter um impacto emocional e psicológico ao indivíduo [21], muitas vezes não tem correspondência direta com a dor e outros sintomas, e para a presente amostra, não mostrou-se determinante também na escolha das estratégias de *coping*.

Se observarmos a média da autoavaliação da dor e dos sintomas percebemos que os valores estão acima da média da escala, indicando resultados mais próximos ao "não ter dor e sintomas nenhum" do que ao "pior dor e sintomas imagináveis". Estes níveis de dor e sintomas percebidos pode explicar o facto de estas variáveis não explicarem a variabilidade nas estratégias de *coping* adoptadas.

A investigação tem referenciado estudos que evidenciaram uma relação positiva entre a utilização de estratégias ativas, e dentre elas, a aceitação, o *coping* ativo e o planejar, com medidas de resultado mais positivas, como menor perceção da dor e melhor funcionalidade, enquanto as estratégias tidas como passivas, como a negação, o desinvestimento comportamental e o uso de substâncias, foram relacionadas com medidas de resultado negativas como a depressão e baixa autoeficácia (compreendida como a crença que se tem sobre a capacidade de realizar as ações necessárias para cumprir com as exigências de uma situação específica) [20, 21, 34].

Com os resultados encontrados é possível que a escolha das estratégias de *coping* e a intensidade da sua utilização serão, eventualmente determinadas por outros fatores, a incluir num futuro modelo, mais alargado, de explicação dos fatores determinantes do *coping* para pessoas com o diagnóstico da OAJ.

Conforme afirmam os estudiosos [35, 36], se algumas estratégias de *coping* apresentam um comportamento relativamente estável ao longo do tempo e sob situações de estresse muitas outras dependem, também, significativamente, de um processo de suporte social e de transação com os contextos, como, por exemplo, ao defrontar-se com uma doença crônica [9, 37]. Sendo assim, outras variáveis psicossociais relevantes na adoção de estratégias de *coping* (como tipos de personalidade, locus de controle, auto-confiança, otimismo, resiliência, sentido de controle, resistência mental, rede social de apoio, etc.) devem ser incorporadas na investigação futura.

Lidar com a osteoartrose do joelho envolve fatores que são independentes da idade, do nível educacional, da severidade e do nível de percepção da dor. Programas de intervenção direcionados à esta população devem estar atento a isto, não necessitando distinguir os participantes de acordo com as características supracitadas, e devem assim, promover por exemplo, o autocontrolo, a assertividade e a gestão de stress.

Na realidade, as pessoas podem aprender a identificar os métodos de *coping* que melhor ajustem-se a sua realidade e aprender a utilizá-los. Essa formação deve orientar-se para a diversidade dos fatores que facilitam o lidar com o stress que a doença introduz, promovendo os diversos recursos que facilitam, de forma integrada, lidar com a doença. Isso deve ser feito através de programas estruturados, realizados por especialistas, com uma componente psicoeducacional para a maioria das pessoas ou psicoterapêutico em situações mais avançadas de desajustamento.

O presente estudo possui algumas limitações no que se refere primeiramente ao tamanho da amostra, que por ter seguido um critério de elegibilidade rígido em relação ao diagnóstico da osteoartrose (clínico e radiológico) foi reduzida. Outra questão relevante é que os dados foram todos recolhidos por meio de questionários e a amostra foi constituída por pessoas idosas que podem apresentar alguma dificuldade na leitura e/ou compreensão dos mesmos. Para minimizar esse problema o questionário foi preenchido ao lado de um pessoa da equipe de investigadores, que estava disponível para ajudar sempre que fosse preciso. Contudo, e apesar das limitações, este estudo traz uma mais-valia quando contribui para a investigação específica da escolha das estratégias de *coping* para população idosa com osteoartrose do joelho, e fornece uma ferramente teórica de suporte à programas educacionais que pretendam atuar no propósito de auxiliar pacientes com OAJ na escolha das estratégias de *coping*. Para estudos futuros sobre esta patologia sugere-se a análise da eficácia relativa das diversas estratégias de *coping* e a inclusão de outras variáveis que possam ter maior poder explicativo na escolha das estratégias de *coping*.

Referências

1. Lawrence, R.C., et al., *Estimates of the prevalence of arthritis and other rheumatic conditions in the United States: Part II*. Arthritis & Rheumatism, 2008. **58**(1): p. 26-35.
2. Valderrabano, V. and C. Steiger, *Treatment and Prevention of Osteoarthritis through Exercise and Sports*. J Aging Res, 2011. **2011**: p. 374653.
3. Johnson, V.L. and D.J. Hunter, *The epidemiology of osteoarthritis*. Best Practice & Research Clinical Rheumatology, 2014. **28**(1): p. 5-15.
4. Heidari, B., *Knee osteoarthritis prevalence, risk factors, pathogenesis and features: Part I*. Caspian Journal of Internal Medicine, 2011. **2**(2): p. 205-212.

5. Sangha, O., *Epidemiology of rheumatic diseases*. Rheumatology, 2000. **39**(suppl 2): p. 3-12.
6. Dieppe, P.A. and L.S. Lohmander, *Pathogenesis and management of pain in osteoarthritis*. The Lancet, 2005. **365**(9463): p. 965-973.
7. Tanimura, C., et al., *Difficulties in the daily life of patients with osteoarthritis of the knee: scale development and descriptive study*. Journal of Clinical Nursing, 2011. **20**(5-6): p. 743-753.
8. Altman, R., et al., *Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee*. Arthritis & Rheumatism, 1986. **29**(8): p. 1039-1049.
9. Regier, N.G. and P.A. Parmelee, *The stability of coping strategies in older adults with osteoarthritis and the ability of these strategies to predict changes in depression, disability, and pain*. Aging Ment Health, 2015: p. 1-10.
10. Lazarus, R.S., *Coping with the stress of illness*. WHO Reg Publ Eur Ser, 1992. **44**: p. 11-31.
11. Lazarus, R.S.F., S. , *Stress, appraisal and coping* 1984, New York: Springer.
12. Carver, C.S. and J. Connor-Smith, *Personality and coping*. Annu Rev Psychol, 2010. **61**: p. 679-704.
13. Gelder, M., Gath, D., Mayou, R., Cowen, P. , *Orford Textbook of Psychiatry*, ed. r. ed. 1996, Oxford: Oxford University Press.
14. Skinner, E.A., et al., *Searching for the structure of coping: A review and critique of category systems for classifying ways of coping*. Psychological Bulletin, 2003. **129**(2): p. 216-269.
15. Lazarus, R.S., *Emotions and interpersonal relationships: toward a person-centered conceptualization of emotions and coping*. J Pers, 2006. **74**(1): p. 9-46.
16. Langens, T.A. and S. Mörth, *Repressive coping and the use of passive and active coping strategies*. Personality and Individual Differences, 2003. **35**(2): p. 461-473.
17. Carver, C.S., M.F. Scheier, and J.K. Weintraub, *Assessing coping strategies: a theoretically based approach*. J Pers Soc Psychol, 1989. **56**(2): p. 267-83.
18. Holahan, C.J. and R.H. Moos, *Personal and contextual determinants of coping strategies*. J Pers Soc Psychol, 1987. **52**(5): p. 946-55.
19. Folkman, S. and J.T. Moskowitz, *Positive affect and the other side of coping*. Am Psychol, 2000. **55**(6): p. 647-54.
20. Rosenberger, P.H., et al., *Physical recovery in Arthroscopic knee surgery: unique contributions of coping behaviors to clinical outcomes and stress reactivity*. Psychology & Health, 2004. **19**(3): p. 307-320.
21. Hampson, S.E., R.E. Glasgow, and A.M. Zeiss, *Coping with osteoarthritis by older adults*. Arthritis Care Res, 1996. **9**(2): p. 133-41.
22. Perrot, S., et al., *Active or passive pain coping strategies in hip and knee osteoarthritis? Results of a national survey of 4,719 patients in a primary care setting*. Arthritis Rheum, 2008. **59**(11): p. 1555-62.
23. Kellgren, J.H. and J.S. Lawrence, *Radiological assessment of osteo-arthrosis*. Ann Rheum Dis, 1957. **16**(4): p. 494-502.
24. Roos, E.M. and L.S. Lohmander, *The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis*. Health and Quality of Life Outcomes, 2003. **1**: p. 64-64.
25. Carver, C.S., *You want to measure coping but your protocol's too long: consider the brief COPE*. Int J Behav Med, 1997. **4**(1): p. 92-100.
26. Pais Ribeiro, J.L.R., A. P. , *Questões acerca do coping: a propósito do estudo de adaptação do Brief COPE*. Pscicologia, Saúde e Doenças, 2004. **5**(1): p. 3-15.

27. Hayton, J.C., Allen, D. G. & Scarpello, V., *Factor retention decisions in exploratory factor analysis: a tutorial on parallel analysis*. Organizational Research Methods, 2004. **7**: p. 191-205.

28. Vivan, A.d.S.A., Irani Iracema de Lima *Estratégias de enfrentamento, dificuldades funcionais e fatores associados em idosos institucionalizados*. Caderno Saúde Pública, 2009. **25**(2): p. 436-444.

29. Parkes, K.R., *Coping, negative affectivity, and the work environment: additive and interactive predictors of mental health*. J Appl Psychol, 1990. **75**(4): p. 399-409.

30. Kelly, M.M., et al., *Sex differences in the use of coping strategies: predictors of anxiety and depressive symptoms*. Depress Anxiety, 2008. **25**(10): p. 839-46.

31. Matos, A.S.S., *Ansiedade, Depressão e Coping na Dor Crónica*, in *Universidade Fernando Pessoa, Faculdade de Ciências Humanas e Sociais*. 2012, Universidade Fernando Pessoa: Porto

32. Hart, S., et al., *the relationship between pain and coping styles among hiv-positive men and women*. Psychology & Health, 2000. **15**(6): p. 869-879.

33. Souza, J.N.C., E. C.; Caramelli, P. , *Coping em Idosos com doença de Alzheimer*. Revista Latino Americana de Enfermagem, 2007. **15**(1).

34. Brown, G.K. and P.M. Nicassio, *Development of a questionnaire for the assessment of active and passive coping strategies in chronic pain patients*. Pain, 1987. **31**(1): p. 53-64.

35. Moos, R.H. and C.J. Holahan, *Dispositional and contextual perspectives on coping: toward an integrative framework*. J Clin Psychol, 2003. **59**(12): p. 1387-403.

36. Powers, D.V., D. Gallagher-Thompson, and H.C. Kraemer, *Coping and depression in Alzheimer's caregivers: longitudinal evidence of stability*. J Gerontol B Psychol Sci Soc Sci, 2002. **57**(3): p. P205-11.

37. Endler, N.S., et al., *Coping with chronic pain*. Personality and Individual Differences, 2003. **34**(2): p. 323-346.

Chapter 7: Responsiveness of KOA symptoms, self-management behavior and health related physical fitness outcomes after 3 months of the PLE^{2}NO Program[4]

[4] Marconcin, P., Espanha, M., Teles, J., Bento, P., Campos, P., André, R., Yázigi, F. Responsiveness of KOA symptoms, self-management behavior and health related physical fitness outcomes after 3 months of the PLE^{2}NO Program. Clinical Rehabilitation (under review).

Abstract

Objective: This study aimed to assess the effectiveness of a 12-week randomized controlled trial (the PLE^{2}NO program) in elderly individuals with knee osteoarthritis (KOA).
Design: Randomised controlled trial.
Setting: Four different community setting (two senior universities, one community center and one church).
Subjects: Sixty-seven participants, mean age 69.1 (5.8) years, with clinical and radiographic KOA.
Intervention: A combined Self-management and Exercise intervention.
Main Measures: The primary outcomes were pain and other KOA symptoms (assessed by the KOOS questionnaire), self-management behaviors, which were assessed by communication with the physician (CWP), cognitive symptoms management (CSM) and functional lower limb strength (FRSTST). Secondary outcomes were aerobic capacity (6MWT), lower and upper limb flexibility (CSR and BST), handgrip (dynamometer), KOA-specific health-related quality of life, activities of daily living and sport/recreation function (assessed by the KOOS questionnaire), self-perceived health (assessed by the EQ-5D-5L).
Results: A significant group effect favorable to the SMEG was observed in the communication with the physicians (p = .048), walking long distance (p = .035), functional lower limb strength (p = .015) and upper right limb flexibility (p < .001) results. A clinical improvement in pain and KOA symptoms was found. This study supports the importance of a combined self-management and exercise intervention that is easily reproduced in the community.
ClinicalTrial.gov identifier: NCT02562833

Keywords: Self-management, Exercise, Knee osteoarthritis, Elderlies.

Introduction

The prevalence of osteoarthritis is a burden on public health, especially as the incidence continues rising [1] and the aging population and obesity increase [2, 3]. In the elderly, the knee and hip are the most affected joints and are the major cause of lower extremity disability [2]. Such disability represents a burden in economic terms. In Europe, the annual cost is approximately 934 euros (directly) and 1236 euros (indirectly) per patient [4]. In Portugal, knee osteoarthritis (KOA) affects 12.4% of the population [5].

Exercise and education are universally recommended by clinical guidelines for KOA management [6-8], irrespective of patient age, joint involvement, radiographic disease severity, pain intensity, functional levels or comorbidities [9].

The benefits of land-based exercise on KOA management, consistently mentioned in the literature, are physical function improvement and pain relief [10-12]. Regarding exercise type, a combined intervention for KOA management should consider strengthening, flexibility, and aerobic exercise [12].

Although the effectiveness of exercise is undeniable in the short and medium terms, the long-term results decline as expected due to a detraining effect [13-18]. Thus, for benefit maintenance, participants' lifestyle should change. Therefore, it is essential to improve self-management behavior to address symptoms, be more physically active and engage in a regular exercise program. Patient education and self-management programs are committed to educating patients about exercise and activity planning, enhancing self-efficacy to manage the common symptoms of the pathology, and teaching pain coping strategies and ways to overcome barriers to exercise [19]. The current literature confirms the benefits of self-management programs on health status, self-management behaviors, pain relief and improved function in chronic diseases and arthritis [20-24].

The difficulty of making lifestyle changes is often due to the continued presence of pain, which incapacitates the subject to perform physical activity/daily living activities. Therefore, it is essential to think about other resources that can help control the pain and improve physical function. Chondroitin sulfate (CS) and glucosamine sulfate (GlcN-S) are two natural supplements that are considered to be symptomatic slow-acting drugs in osteoarthritis [25], which can help to minimize pain. Although there is no current recommendation on the widespread use of such supplements, a recent double-blind randomized clinical trial compared the efficacy of using chondroitin sulfate plus glucosamine with celecoxib and has found the same efficacy on symptoms, physical function and joint swelling, with a better safety profile, in a sample with symptomatic KOA during a 6 month period [26].

In addition to the combined intervention, supplementation seems to reinforce KOA management. Thus, the aim of the present study is to investigate the effectiveness of the PLE^{2}NO combined self-management and exercise program [27] on knee symptoms, KOA specific health-related quality of life, self-perceived health, self-management behaviors and health-related physical fitness components compared with the effectiveness of an educational program in elderly with KOA. In accordance with the

current evidence, both groups received supplementation with glucosamine and chondroitin sulfates.

Methods

This study was a 12-week single-blinded randomized controlled trial in which participants were allocated into two groups: (1) the self-management and exercise group (SMEG) and (2) the educational group (EG). The study was conducted as a clinical registered trial (U.S. National Institutes of Health, NCT02562833) and was approved by the Ethical Committee of the Faculty of Human Kinetics of the University of Lisbon (N=43/2014). A detailed methodology of the PLE^{2}NO program can be found in the study protocol, previously published [27].

All the participants gave written informed consent prior to randomization.

Participants. Recruitment was conducted in the community using various marketing strategies (figure 1). After staff telephone screening, all the subjects were invited to an awareness session and completed an eligibility questionnaire. Those who met the eligibility criteria were referred for bilateral knee radiographs (anterior-posterior, lateral and skyline views). Eligibility criteria were as follows: KOA (Clinical and radiological criteria according ACR) [28], age $\geq$ 60 years, being functionally independent and fully Portuguese language proficient. Subjects involved in other intervention programs (exercise, education or physical therapy), with other pathologies (e.g., cardiovascular, respiratory, musculoskeletal, cancer) that are unable to the practice physical exercise, with a mental/psychological/cognitive state hindering the understanding of the program, that had undergone a knee replacement surgery or were going to have a replacement surgery in the next eight months, who had received corticosteroid or hyaluronic acid treatments in the last 6 months, and who used supplements (chondroitin and/or glucosamine sulfate) for at least three months and had allergies to shellfish or other components of the supplements were excluded. Knee OA classification severity was determined by a rheumatologist [29], and patients from 1 to 4 K-L grades were included.

The randomization sequence was conducted with a 1:1 allocation to the two treatment groups. The study was performed in the Lisbon region, Portugal, in four

different locations (two senior universities, one community center and one church) in the community. All the assessments, except the X-ray, were conducted at the Faculty of Human Kinetics.

The final sample included sixty-seven community-dwelling subjects previously diagnosed with KOA, who volunteered and participated in the present study. The flowchart of the study design is shown in figure 7.1.

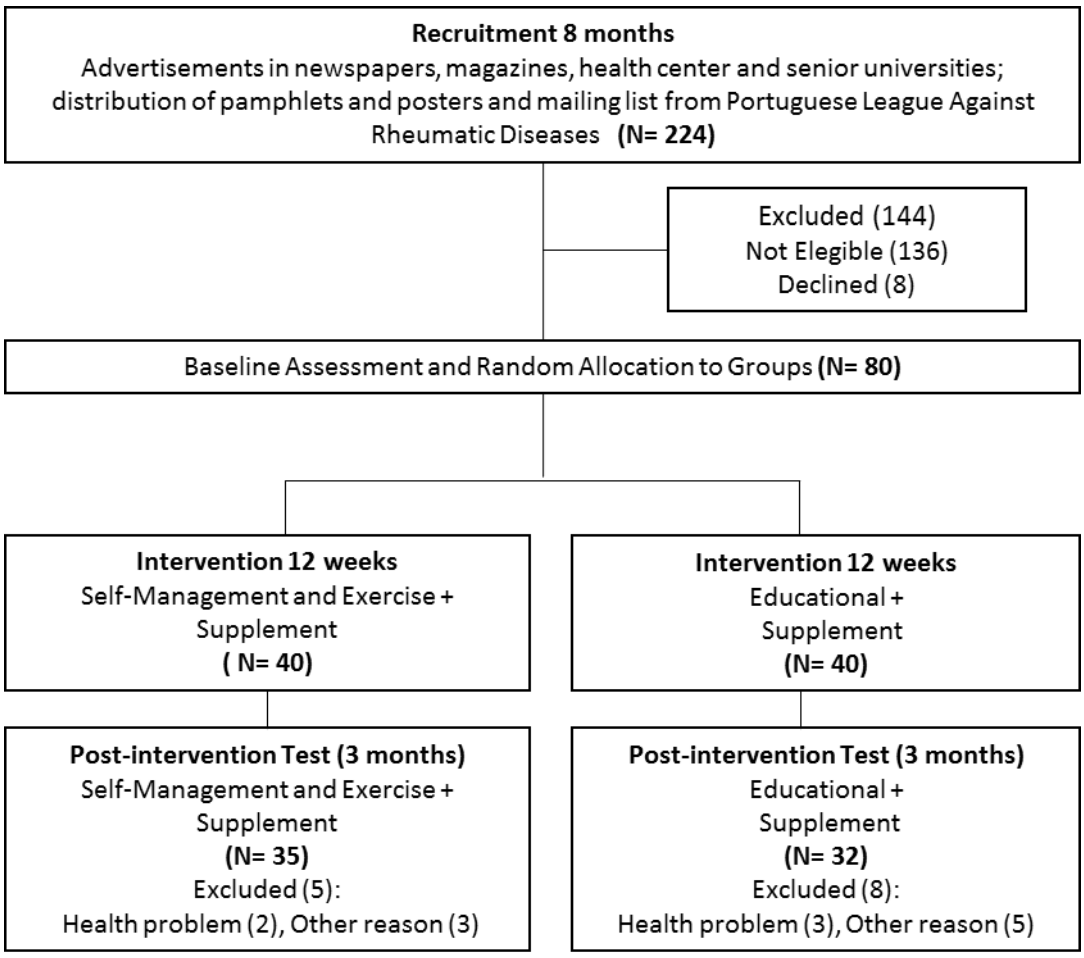


Figure 7.1 - PLE²NO flowchart of study design

Interventions. The Self-Management and Exercise Group (SMEG), the active treatment group, performed a 90-min intervention twice a week for 12 weeks. The maximum number of participants in each class was 15. The session was led by two professionals, one leader of the Chronic Disease Self-Management Program (CDSMP), who was responsible for the self-management component, and a master in sciences of physiotherapy, who was responsible for the exercise component. The program was

carried out in a room with limited space and with tables and chairs, which is a characteristic allowing easy reproduction in the community.

The first 30 minutes of each session were for self-management programs, and several topics were discussed, such as self-management principles, understanding and managing common symptoms, using the mind to manage symptoms, exercise and physical activity, communication skills, healthy eating, managing medicines and making treatment decisions. This component was based on the Chronic Disease Self-Management Program (CDSMP), which was developed at the Stanford Patient Education Research Center by Kate Lorig [30, 31]. The CDSMP follows the Social Cognitive Theory [32] and aims to improve self-management skills, such as cognitive symptom management and communication with physicians.

The remaining 60 minutes were for exercise. The exercise program aimed to improve physical function by addressing muscular resistance/strength, flexibility and balance. The class was structured to begin with a warm-up activity, which comprised range of motion exercises (5 minutes). Then, a recreation activity and balance exercises (15-20 minutes), strengthening exercises (the core of the program) (30-40 minutes), and a cool down activity with stretching and relaxation exercises (10-15 minutes) were performed. Although this was a group class, a personalized exercise approach was accomplished by adapting exercise conditions according to pain intensity and other knee OA symptoms (e.g., joint swelling). Therefore, according to participant condition, they either could do the exercises standing or seated in a chair.

The strength exercises were performed with elastic bands (upper limbs) and cuff weights (lower limbs). During the first three weeks, subjects adapted themselves to the strength exercises without a load. Then, the intensity prescription of strength exercises was evaluated using a repetition to failure test. A load was selected that the subjects could lift it for 10 repetitions or less. If they were able to perform more than 10 repetitions, they stopped and rested for 3 minutes [33]. Then, depending on the subject´s perceived level of pain and exertion, the load was increased by 250 g, and the test was repeated until the adequate load was reached. The load increments progressed three times every three weeks for 12 weeks.

The management of exercise intensity was primarily guided according to the self-reported pain, which was assessed with a visual numeric pain scale [34]. If pain values

were above 5 [35], before the session started, the intensity interval desired for strengthening exercises was not modified, and if necessary, the subject would perform the exercise with only the limb weight. Adjustments in positioning and even in movement type were made to perform a painless movement. If the level of pain was tolerated, below or equal to 5, the intensity would be controlled according to the Omni-Perceived Exertion Scale for Resistance Exercise (OMINI-RES) [36].

In the last two weeks of the PLE^{2}NO intervention, the participants received a flyer with the core exercises of a typical session with drawings and explanations to maintain exercise practice at home after the end of the PLE^{2}NO intervention. In the first week, participants performed the exercises with minor supervision looking at the flyer. In the second week, participants were encouraged to do the exercises without supervision. They were advised to acquire the necessary materials (elastic bands and cuff weights) for exercise by themselves at home.

The educational group (EG), the control group, received a book [37] with information about knee osteoarthritis, types of exercise and self-management skills, and participated in three educational sessions, one per month, one hour each, about joint protection strategies, exercise that can be performed at home and the action plan (a self-management tool). Telephone calls were made 15 days after each educational session to make sure that they were taking the supplement as prescribed and registering pain in a diary.

Both groups, SMEG and EG, also received a supplement of glucosamine (1500 mg) and chondroitin (1200 mg) sulfates, harpagophytum extract (100 mg) and hyaluronic acid (10 mg), and the recommendation was to use two sachets per day.

Outcomes and Instruments

All measures were collected at baseline and post-intervention. Outcome assessors were blinded to participants' allocation.

The primary outcomes were self-reported pain and other symptoms (swelling, crepitus, limitation of movement, stiffness), assessed by pain and the Other Symptom dimension of the Knee Injury and Osteoarthritis Outcome Score (KOOS) [38]; self-management behavior, assessed by the Cognitive Symptom Management (CSM) and the

Communication with Physician scales (CWP) [39]; and functional lower limb strength, assessed by the Five Repetition Sit To Stand Test (FRSTST) [40-43]. Secondary outcomes were KOA-specific health-related quality of life, activities of daily living and sport/recreation function, assessed by the KOOS questionnaire [38]; self-perceived health, assessed by the Visual Analogue Scale of EuroQol (EQ-5D-5L-VAS) [44]; aerobic capacity, assessed by the 6 Minute Walking Test (6MWT) [45]; lower body flexibility, assessed by the Chair Sit and Reach test (CSR); overall shoulder flexibility, assessed by the Back Scratch Test (BST) [46, 47]; and handgrip, measured by a handheld dynamometer [48].

Sample Size

The sample size was determined using the program GPower 3.1 [49], selecting a priori analysis with ANCOVA, one covariate and two groups, with 80% power at a 5% significance level. A priori analysis [50] showed that a 67 patient sample would be sufficient to detect a large effect size on pain dimension between the intervention and the control group. Considering a possible dropout of 20%, recruiting 80 subjects and allocating 40 subjects per group was the goal.

Statistical Analyses

Chi-squared tests of homogeneity, Mann-Whitney test or independent sample *t*-tests were used to compare the EG and SMEG groups in terms of demographic variables, such as age, sex, educational level, retired status, uni- or bilateral OA, body mass index (BMI), OA specific measures and health-related physical fitness assessment, at baseline.

Univariate analyses of covariance (ANCOVA) were conducted to compare the effects of the intervention, between groups (EG vs. SMEG), on primary and secondary outcomes, adjusting to the baseline value of each outcome. Mean differences within groups were calculated as Mom 1 (baseline) minus Mom 2 (after intervention program). In the analysis of ordinal variables, the nonparametric ANCOVA was used. Effect size was quantified using partial eta squared (η^2). The effect size was classified as small (partial $\eta^2<0.06$), medium ($0.06\leq$ partial $\eta^2<0.14$) and large (partial $\eta^2\geq0.14$) [51]. All

statistical analyses were performed with the software SPSS v.22, and a significance level of 5% was used.

Results

As shown in the flowchart (Figure 7.1), 224 subjects were screened for eligibility. Of this group, 80 met the inclusion criteria and were enrolled in the study, and 144 were excluded (of these, 133 were ineligible and 11 were eligible but refused to participate). Of the 80 participants who began the PLE²NO program, 67 completed the post-intervention assessment (35 in the SMEG and 32 in the EG) and were included in the main data analysis. Of the 13 participants that did not complete the post-intervention assessment, five dropped out due to health conditions not related to the knee osteoarthritis and eight due to other personal reasons.

Participants' baseline characteristics are shown in Table 7.1. Overall, participants had a mean age of 69.1 (5.8) years, 70.1% were females and 49.0% had at least a high school degree. There were no significant differences between groups on demographic characteristics and on body composition between the EG and SMEG.

Table 7.1 - Participants' baseline results. Values are in percentage, except for age, weight, height and BMI, mean and standard deviation.

	Outcomes	EG (n=32)	SMEG (n=35)	Total Sample	Test Statistic	*p* value
Demographic	Age in years	67.8(5.3)	70.3(6.1)	69.1(5.8)	1.78 [b]	.080
	Female sex, %	59.4	80.0	70.1	3.39 [a]	.108
	Educational Level				0.74 [a]	.466
	Primary school, %	28.1	25.6	26.8		
	Elementary school grade 6 - 9, %	15.6	28.6	22.4		
	High school, %	25.0	22.9	23.9		
	College or more, %	31.3	22.9	26.9		
	Retired, %	90.6	91.4	91.0	0.01 [a]	1.00
	Bilateral KOA, %	93.8	94.3	94.0	0.00 [a]	1.00
	Kellgren/Lawrence grade				2.43 [a]	.486
	I and II, %	50.0	62.9	56.4		
	III and IV, %	50.0	37.1	43.5		
Body composition	Weight	79.2(15.3)	78.8(15.0)	79.0(15.0)	-0.12 [b]	.898
	Height	1.62(.08)	1.56(.09)	1.59(.09)	-2.64 [b]	.010 *
	BMI Kg/m²	30.1(5.3)	32.3(5.0)	31.2(5.2)	1.73 [b]	.088

*Abbreviations: BMI = Body Mass Index; [a] Chi-square test of homogeneity; [b] Independent Samples t-test; * p < .05*

Mean differences within groups and results of ANCOVA to compare variables between groups are shown in table 2.

*Self-reported outcomes***.** For all KOOS dimensions, only other symptoms had a marginally significant group effect after adjusting for baseline values. Regarding the other KOOS dimensions, no group effect was found. However, a significant clinical improvement was found for all KOOS dimensions on self-management and exercise group [52].

Regarding the Communication with Physician scale (CWP), scores changed from 2.5(1.2) to 2.3(1.3) in the EG and from 2.3(1.2) to 2.7(1.4) in the SMEG. This difference represents a significant group effect [$F(2,64) = 4.06$, $p = .048$], with a small effect size (.058). The EG did not show any improvement in cognitive symptom management, with an average score of 1.5(0.9) at baseline and post-intervention. In the SMEG, the average score changed from 1.7(0.9) to 2.0 (1.0), but no group effect was observed [$F(2,64) = 3.25$, $p = .076$].

The average score on the visual analogue scale of the EuroQol improved from baseline in both groups (11% for SMEG, $t(34) = –2.21$, $p = .034$ and 6% for EG $t(31) = -2.10$, $p = .044$), but there was no significant group effect.

Health-related physical fitness. A significant group effect was found on 6MWT ($p = .035$), FRSTST ($p = .015$) and right limb BST ($p < .001$) (table 7.2). There were no group effects in BST left limb and CSR (both knees).

Table 7.2 - Group effect analysis for all variables. ANCOVA adjusted for values at baseline.

	EG (n=32)			**SMEG (n=35)**			**ANCOVA**	
	Mom 1 Mean (SD)	Mom 2 Mean (SD)	Changes Mean (SD)	Mom 1 Mean (SD)	Mom 2 Mean (SD)	Changes Mean (SD)	Group Effect *F*	*p*
Pain	61.4(20.4)	67.4(18.2)	-6.0(16.2)	52.1(18.9)	68.2(17.4)	-16.0(17.8)	2.41	.125
Symptoms	66.4(22.7)	71.6(21.3)	-5.2(15.9)	55.3(21.0)	72.1(17.5)	-16.8(17.2)	3.94	.051
ADL	64.9(19.7)	73.6(18.5)	-8.7(13.6)	49.7(18.5)	65.7(18.8)	-16.0(16.7)	0.33	.569
Sports/rec	38.1(27.5)	42.9(29.6)	-4.8(21.0)	22.3(17.5)	35.3(28.3)	-13.0(26.8)	0.44	.511
QOL	46.9(27.4)	55.0(24.5)	-8.2(18.0)	35.2(20.0)	48.9(22.8)	-13.7(19.5)	0.17	.684
EQ-5D-5F VAS	75.5(13.3)	80.0(13.2)	-4.5(12.2)	71.1(19.5)	79.0(14.9)	-7.9(21.2)	0.01	.894
6MWT (m)	470.5(86.0)	466.6(91.7)	3.9(59.6)	423.6(68.2)	455.9(68.1)	-32.3(42.9)	4.64	.035*

Table 7.2 - Group effect analysis for all variables. ANCOVA adjusted for values at baseline (Continuation).

CSR $_{MPK}$ (cm)	-7.1(12.0)	-5.6(12.8)	-1.5(9.6)	-13.6(16.5)	-6.6(14.4)	-7.0(10.9)	2.17	.145
CSR $_{LPK}$ (cm)	-6.6(9.9)	-6.5(11.53)	-0.1(9.5)	-11.8(14.9)	-7.6(14.1)	-4.2(8.9)	1.62	.208
BST $_{right}$ (cm)	-13.4(11.4)	-14.2(11.4)	0.8(4.3)	-14.3(13.4)	-11.5(11.9)	-2.9(3.7)	15.09	<.001***
BST $_{left}$ (cm)	-18.9(11.8)	-16.8(12.3)	-2.2(4.2)	-19.2(12.3)	-16.1(11.4)	-3.1(6.1)	0.49	.484
Handgrip test (kg)	30.04(8.9)	30.07(8.1)	-0.03(2.3)	27.98(8.6)	28.65(9.5)	-.67(2.7)	0.88	.351
FRSTST (s)	11.6(2.9)	12.6(4.3)	-0.9(3.3)	12.4(3.4)	11.0(3.2)	-1.4(3.8)	6.29	.015*

Abbreviations: *ADL= Activity of daily living; Sports/rec= Sports and recreation; EQ-5D-5L VAS= Euroquol five dimension five level Visual Analogue Scale; 6MWT= Six Minute Walking Test; CSR= Chair Sit and Reach; MPK= Most Painful Knee; LPK= Less Painful Knee; BST= Back Scratch Test; FRSTST= Five Repetition Sit to Stand Test*.
** $p < .05$*

A large effect size was found on the Back Scratch Test of the right arm (0.191), and a medium effect size was found on the 6MWT (0.068) and FRSTST (0.090) tests.

Discussion

This study had high compliance in both groups; 12.5% dropped out in the SMEG and 20% dropped out in the EG. The location of the PLE²NO intervention was close to the participants, and it was conducted in four different places, which helped participants adhere to and maintain the intervention. Classes were small, with a maximum of 15 participants per class, which allowed more individualized attention. Additionally, supplementation worked as a motivational tool to promote adherence to and maintenance of the program as the participants recognized the effort to provide an expensive treatment.

Among the sample characteristics, an important factor was the diverse educational level, which was a challenge for the self-management program, as the participants' needs, questions and involvement differed. Furthermore, participants were predominantly classified as obese, which requires extra attention in exercise performance. Additionally, most of them presented bilateral KOA, which is common among the elderly but requires extra caution in exercise classes.

Regarding self-reported pain, an improvement was expected between group analyses, particularly in the self-management and exercise groups, although it did not occur. Nevertheless, it is important to highlight that the difference found on the KOOS

pain subscale was considered clinically relevant [38] and was larger than 10 points in the intervention group (-16), whereas the control group (-6) did not achieve this clinical difference. Moreover, the average KOOS score in the SMEG improved by 31% ($p < .001$), whereas the average score in the EG improved by 10% ($p = .042$) after the intervention. The lack of a group effect is in contrast with other studies with integrated educational and exercise programs [53-55, 19]. A possible explanation is that the initial level reported at baseline by participants in both groups was above the scale average (56.5±20), indicating that the PLE^{2}NO sample was relatively adapted to pain. Compared with Yázigi´s study (KOOS pain = 47.7±16, mean age = 55 years and BMI = 35 Kg/m^2) [56], Ageberg´s study (KOOS pain = 43±12, mean age = 69 years and BMI = 30 Kg/m^2) [57] and Skou´s study (KOOS pain = 52±14, mean age = 66 years and BMI = 30 Kg/m^2) [55], the PLE^{2}NO sample had the highest score. Another possible explanation is the supplementation (CS and GlsN-S) intake, which is controversial in the literature [58-62]. Hence, the participants of the various groups (SMEG and EG) may have responded positively to the supplemental treatment; thus, the similarity between the groups may be, in part, explained by this factor.

KOOS Other Symptoms (swelling, crepitus, limitation of movement, stiffness) has shown a marginal significant group effect (p=.051). The average score in the SMEG improved by 30% compared with 8% in the EG after the intervention, which is also considered clinically relevant [38]. This improvement on Other Symptoms could represent better overall physical function [63, 64]. No group effect was observed in the other KOOS dimensions (ADL, Sport/rec, QOL). If no significant group effect was observed regarding pain and Other Symptoms, these factors might compromise the ability to perform daily life activities and recreational and sport activities and have a negative impact on quality of life. However, all dimensions presented clinically relevant improvements in the intervention group [38]. Those improvements should not be overlooked, as a small change could represent a substantial difference in the way subjects live [65].

Self-management behaviors, which were the main construct of the Self-management Program, showed a significant group effect on the Communication with Physician scale (CWP) and no group effect on the Cognitive Symptoms Manage scale (CSM). These findings can be compared with three studies from McKnight, Barlow and

Elzen. McKnight´s study [50], which applied a combined self-management and exercise program in adults with KOA, found a significant group effect on CSM and CWP. Barlow´s study [66], which compared the Arthritis Self-Management Program with a control group in UK, had similar results and found a significant group effect for both the CWP and CSM. In contrast, in a study [67] on the Chronic Disease Self-Management Program, a general self-management program, conducted in the Netherlands, no group effect was found for either the CWP or CSM. The sample was composed of individuals with diverse health conditions. The first two studies, which found a significant group effect for both variables, CSM and CWP, applied a specific program targeted to the investigated disease. In contrast, Elzen´s study [67], which did not find a significant group effect, applied a general program for chronic disease. These results show that the program structure, its specifications and participant characteristics may determine the intervention's effectiveness. Thus, it is mandatory to consider these characteristics when developing a self-management intervention. Additionally, the PLE^{2}NO sample in terms of educational level was diverse (EG: 56.3% of participants had a higher than high school degree; SMEG: 45.8% of participants had a higher than high school degree). Perhaps some participants in the EG with higher educational levels might have been using some of the cognitive strategies to control symptoms (e.g., practice visualization or guided imagery, such as picturing yourself somewhere else). In the SMEG, the educational level was very diverse, creating difficulties in the development of the educational program, especially regarding the skills necessary for action plan and problem solving techniques, both of which are important in enhancing cognitive symptom management. However, the Communication with Physician scale is an easier scale to understand.

No significant group effect was observed on global self-perceived health based on the EQ-5D-5L VAS scale. However, in analyzing each group, an improvement of 11% (7.9 points) was found in the SMEG (p = .034) and 6% (4.5 points) in the EG (p = .044). The intervention group showed greater improvement (even with no group effect) compared with Hansson´s study [21], with a 6-week educational program, and the average score improved 5.6 points in the experimental group and 1.18 points in the control group. Another interesting point is that the PLE^{2}NO baseline values were higher compared with the other studies [66, 21], indicating that subjects had a positive evaluation of their global health. Consequently, they would not have much to improve.

In relation to the physical fitness component, the OARSI recommends the 6MWT as one of the main outcome dimensions that should be evaluated in studies focusing on physical function [68]. This test reveals not only aerobic endurance but also the capacity to walk long distances, which is important to overall functional ability. A significant group effect was observed in the self-management and exercise group, corresponding to an increase of 7.6% after intervention, equivalent to 32.3 meters, which was not clinically significant [69] but represents better ability to walk. This finding is similar to the findings of other studies involving elderly individuals affected by KOA that also showed a significant improvement in 6MWT [70, 71]. Additionally, a complementary analysis in which pain was recorded before and after the 6MWT revealed a significant improvement after the intervention ($t(34) = 2.19$; $p = .018$) on pain perception during the 6MWT (measured by visual analogue pain scale) in the SMEG. The same finding was not found in the EG ($t(31) = 0.32$; $p = .373$). These findings indicate that although participants could walk more, they walked with less pain, which is extremely important in KOA subjects who usually consider pain as an important barrier to practice any activity. Additionally, the exercise component of the PLE^{2}NO program did not include aerobic training; therefore, it would have been difficult to improve this outcome.

With respect to flexibility, although it was not the main physical outcome of this study, there was a significant group effect and a large effect size of the right upper limb. The same did not occur with the left limb. This improvement can be explained mainly due to performing stretching activities at the end of every class. Furthermore, upper limb strength exercises were applied using elastic bands, and many exercises needed a good shoulder range of motion to be performed correctly. Thus, shoulder flexibility was also worked during the strength training. In comparison, Levy (2012) [72] found an improvement in flexibility, measured by a back strength test, after a multi-component exercise intervention. However, after the PLE^{2}NO intervention, no significant group effect was found regarding lower body flexibility, which was assessed by CSR. The same occurred in Maurer's study [73]. This result could be associated with the fact that the PLE^{2}NO sample was mostly obese, and even if the abdominal circumference was not assessed, this factor would be an obstacle in performing the test before and after the intervention. Moreover, the PLE^{2}NO sample showed a small improvement in pain and

other symptoms, which might have hindered the performance of lower limb flexibility exercises.

Regarding strength, two measures were adopted: lower limb functional strength and upper limb handgrip strength. As the PLE^{2}NO sample was composed of the elderly, handgrip strength was measured. Although it is not a specific test for KOA assessment, it is an indicator of sarcopenia and disability [74, 75]. Both are important outcomes in aged people affected by KOA. Values in both groups at baseline and post intervention were considered within an intermediate stage (not weak) by Alley´s study [75], and no group effect was found. This result was expected because the upper limb exercises were performed with elastic bands and not with dumbbells, which hinder improvement in hand grip. This result could reflect the performance on the functional lower limb strength test, which had a significant group effect with a moderate effect size. This finding may be explained by the use of a rigorous methodology in strength training planning (personalized load progression), which was designed to allow for a 0.250 g load increase each time and minimal load control. This better exercise intensity control permitted avoiding or minimizing pain after exercise. This improvement is crucial in considering that symptomatic KOA is related to muscle strength, especially quadricep weakness [76, 77, 63]. Progress on functional lower limb strength could lead to symptom relief in the PLE^{2}NO sample. A similar pattern was found with an 8-week strengthening exercise [78], 12 weeks of a Thai Chi intervention [79], 6 weeks of a Walk With Ease program [80] and an 8-week strengthening exercise with elastic bands [81].

The improvements found in the performance-based test can reflect positively on daily living activities and have a substantial impact on quality of life. Analyzing performance-based tests is important in considering the functional ability framework [82] that highlights the relationship among physical impairment, performance functional limitation and physical disability/dependence. It is important to assess parameters that can reflect directly on daily living activities. Yet, the relationship is not linear. The results can underestimate physical performance and reflect a significant difference in patient life. Furthermore, a small improvement in physical parameters can represent a large enhancement in daily living activities, greatly impacting quality of life.

This study has some limitations. First, it was not possible to blind the participants with respect to the group allocation. Therefore, some self-reported measures can reflect

respondents' bias. Second, the assessment was performed in a single day to ensure that participants did not have to travel twice. Concomitantly, an extensive test battery was applied, which might have implied more fatigue and less capacity to concentrate, giving rise to additional bias in the results. However, to minimize this issue, physical tests and questionnaires were performed alternately, and the physical tests involving load-bearing activities were alternated with those that were performed while seated. Third, the control group (EG) received, in addition to the regular treatment, three educational sessions and the PLE^{2}NO book [83] and were encouraged to practice exercise at home, which possibly triggered improvement, making the group effect analysis more difficult. In future studies, in looking for group effects, it may be better to provide the control group with regular treatment only.

Conclusion

In conclusion, the findings suggest that the PLE^{2}NO self-management and exercise intervention had a significant group effect in favor of the intervention group on self-management behavior (communication with physician) and on health related physical fitness outcomes (capacity to walk long distances, upper limb flexibility and functional lower limb strength). A clinical improvement in pain and other KOA symptoms was observed. Healthcare providers may confidently recommend a self-management and exercise program to their elderly patients affected by KOA, who may be constrained by availability, cost, burden or preference. Finally, the PLE^{2}NO features, including a simple setup with chairs, low cost materials and a published protocol, enable easy dissemination in the community.

References

1. Neogi T and Zhang Y. Epidemiology of osteoarthritis. *Rheumatic Diseases Clinics of North America* 2013 ;39(1):1-19. doi:10.1016/j.rdc.2012.10.004.

2. Johnson V and Hunter DJ. The epidemiology of osteoarthritis. *Best Practice & Research Clinical Rheumatology* 2014; 28(1):5-15. doi:http://dx.doi.org/10.1016/j.berh.2014.01.004.

3. Losina E, Weinstein AM, Reichmann WM, et al. Lifetime risk and age at diagnosis of symptomatic knee osteoarthritis in the US. *Arthritis Care Research (Hoboken)* 2013; 65(5):703-11. doi:10.1002/acr.21898.

4. Leardini G, Salaffi F, Caporali R, et al. Direct and indirect costs of osteoarthritis of the knee. *Clinical and Experimental Rheumatology* 2004; 22(6):699-706.

5. Branco JC, Rodrigues AM, Gouveia N, et al. Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt– a national health survey. *RMD Open* 2016;2(1). doi:10.1136/rmdopen-2015-000166.

6. McAlindon TE, Bannuru RR, Sullivan MC, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. *Osteoarthritis and Cartilage* 2014; 22(3):363-88. doi:http://dx.doi.org/10.1016/j.joca.2014.01.003.

7. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. *Arthritis Care & Research* 2012; 64(4):465-74. doi:10.1002/acr.21596.

8. Fernandes L, Hagen KB, Bijlsma JWJ, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. *Annals of the Rheumatic Diseases* 2013. doi:10.1136/annrheumdis-2012-202745.

9. Bennell KL, Dobson F and Hinman RS. Exercise in osteoarthritis: moving from prescription to adherence. *Best Practice & Research Clinical Rheumatology* 2014; 28(1):93-117. doi:10.1016/j.berh.2014.01.009.

10. Fransen M, McConnell S, R. HA, et al. Exercise for osteoarthritis of the knee. *Cochrane Database Systematic Reviews* 2015; 4:Cd004376. doi:CD004376.

11. Tanaka R, Ozawa J, Kito N, et al. Efficacy of strengthening or aerobic exercise on pain relief in people with knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials. *Clinical Rehabilitation* 2013; 27(12):1059-71.

12. Uthman OA, van der Windt DA, Jordan JL, et al. Exercise for lower limb osteoarthritis: systematic review incorporating trial sequential analysis and network meta-analysis. *BMJ* 2013; 347.

13. Callahan LF, Mielenz T, Freburger J, et al. A randomized controlled trial of the people with arthritis can exercise program: symptoms, function, physical activity, and psychosocial outcomes. *Arthritis and Rheumatism* 2008; 59(1):92-101. doi:10.1002/art.23239.

14. Ettinger WHea. A randomized trial comparing aerobic exercise and resistance exercise with a health education program in older adults with knee osteoarthritis *JAMA* 1997 ;277(1):25-31.

15. Salli A SN, Baskent A and Ugurlu H. . The effect of two exercise programs on various functional outcome measures in patients with osteoarthritis of the knee: A randomized controlled clinical trial. I*sokinetics and Exercise Science* 2010; 18:201–9. doi:10.3233/ies-2010-0385.

16. Tak PS, P.; Van Hespen, a.; Hopman-Rock, M. The effects of an exercise program for older adults with osteoarthritis of the hip. *The Journal of Rheumatology* 2005; 32(6).

17. Penninx B, Messier, S., Rejeski, W., et al. Physical Exercise and the Prevention of Disability in Activities of Daily Living in Older Persons With Osteoarthritis. *American Journal of Health Promotion* 2003; 17(3):217.

18. Pisters MF, Veenhof C, van Meeteren NL, et al. Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a systematic review. *Arthritis and Rheumatism* 2007; 57(7):1245-53. doi:10.1002/art.23009.

19. Walsh NE, Mitchell HL, Reeves BC, Hurley MV. Integrated exercise and self-management programmes in osteoarthritis of the hip and knee: a systematic review of effectiveness. *Physical Therapy Reviews* 2006; 11(4):289-97. doi:10.1179/108331906X163432.

20. Brady TJ, Murphy L, O'Colmain BJ, et al. A Meta-Analysis of Health Status, Health Behaviors, and Health Care Utilization Outcomes of the Chronic Disease Self-Management Program. *Preventing Chronic Disease* 2013; 10:E07. doi:10.5888/pcd10.120112.

21. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial. *BMC Musculoskelet Disorders* 2010; 11:244. doi:10.1186/1471-2474-11-244.

22. Warsi A, LaValley MP, Wang PS, et al. Arthritis self-management education programs: A meta-analysis of the effect on pain and disability. *Arthritis & Rheumatism* 2003; 48(8):2207-13. doi:10.1002/art.11210.

23. Osborne RH, Buchbinder R, Ackerman IN. Can a disease-specific education program augment self-management skills and improve Health-Related Quality of Life in people with hip or knee osteoarthritis? *BMC Musculoskeletal Disorders* 2006; 7:1-10. doi:10.1186/1471-2474-7-90.

24. Coleman S, Briffa K, Conroy H, et al. Short and medium-term effects of an education self-management program for individuals with osteoarthritis of the knee, designed and delivered by health professionals: A quality assurance study. *BMC Musculoskeletal Disorders* 2008; 9:1-8. doi:10.1186/1471-2474-9-117.

25. Henrotin Y, Marty M and Mobasheri A. What is the current status of chondroitin sulfate and glucosamine for the treatment of knee osteoarthritis? *Maturitas* 2014; 79(4):487. doi:10.1016/j.maturitas.2014.04.015.

26. Hochberg MC, Martel-Pelletier J, Monfort J, et al. Combined chondroitin sulfate and glucosamine for painful knee osteoarthritis: a multicentre, randomised, double-blind, non-inferiority trial versus celecoxib. *Annals of the Rheumatic Diseases* 2016; 75(1):37-44. doi:10.1136/annrheumdis-2014-206792.

27. Marconcin P, Espanha M, Yázigi F, Campos P. The PLE2NO self-management and exercise program for knee osteoarthritis: Study Protocol for a Randomized Controlled Trial. *BMC Musculoskeletal Disorders* 2016; 17(1):1-12. doi:10.1186/s12891-016-1115-7.

28. Altman R, Asch E, Bloch D, et al. Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee. *Arthritis and Rheumatism* 1986; 29. doi:10.1002/art.1780290816.

29. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. *Annals of the Rheumatic Diseases* 1957; 16(4):494-502.

30. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. *Annals of Behavioral Medicine* 2003; 26(1):1-7. doi:10.1207/S15324796ABM2601_01.

31. Lorig K, Fries JF. The Arthritis Helpbook: A Tested Self-management Program for Coping with Arthritis and Fibromyalgia. Da Capo Lifelong; 2006.

32. Bandura A. Social learning theory. NJ: Prentice Hall: Englewood Cliffs; 1977.

33. Medicine ACoSa. ACSM´s Guidelines for Exercise Testing and Prescription. 2013;ninth edition.

34. Ritter PL, Gonzalez VM, Laurent DD, et al. Measurement of pain using the visual numeric scale. *The Journal of Rheumatology* 2006; 33(3):574-80.

35. Skou ST, Odgaard A, Rasmussen JO, et al. Group education and exercise is feasible in knee and hip osteoarthritis. *Danish Medical Journal* 2012; 59(12):A4554.

36. Lagally KM and Robertson RJ. Construct validity of the OMNI resistance exercise scale. *Journal of Strength and Conditioning Research / National Strength & Conditioning Association* 2006; 20(2):252-6. doi:10.1519/r-17224.1.

37. Espanha M, Priscila M, Yázigi F, et al. *Guia para viver em PLENO: com menos dor e mais qualidade de vida*. Lisboa: FMH-Ulisboa; 2015.

38. Roos EM and Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health and Quality of Life Outcomes* 2003; 1:64-. doi:10.1186/1477-7525-1-64.

39. Lorig KR, Stewart A, Ritter PL, et al. *Outcome Measures for Health Education and Other Health Care Interventions*. Thousand Oaks CA: Sage Publications; 1996.

40. Schlenk EA, Lias JL, Sereika SM, et al. Improving Physical Activity and Function in Overweight and Obese Older Adults with Osteoarthritis of the Knee: A Feasibility Study. *Rehabilitation Nursing* 2011; 36(1):32-42. doi:10.1002/j.2048-7940.2011.tb00063.x.

41. Bohannon RW. Sit-to-stand test for measuring performance of lower extremity muscles. *Perceptual and Motor Skills* 1995;80(1):163-6. doi:10.2466/pms.1995.80.1.163.

42. Bohannon RW. Test-retest reliability of the five-repetition sit-to-stand test: a systematic review of the literature involving adults. *Journal of Strength and Conditioning Research / National Strength & Conditioning Association* 2011; 25(11):3205-7. doi:10.1519/JSC.0b013e318234e59f.

43. Lin YC, Davey RC, Cochrane T. Tests for physical function of the elderly with knee and hip osteoarthritis. *Scandinavian Journal of Medicine & Science in Sports* 2001; 11(5):280-6.

44. EuroQol. EuroQol--a new facility for the measurement of health-related quality of life. *Health policy (Amsterdam, Netherlands)* 1990; 16(3):199-208.

45. Rikli REJ, C. J. . The reliability and validity of a 6-minute walk test as a measure of physical endurance in older adults. *Journal of Aging and Physical Activity* 1998; 6: 363–75.

46. Jones CJ, Rikli RE, Max J, et al. The reliability and validity of a chair sit-and-reach test as a measure of hamstring flexibility in older adults. *Research Quarterly for Exercise and Sport* 1998; 69(4):338-43. doi:10.1080/02701367.1998.10607708.

47. Rikli RE and Jones CJ. The development and validation of a functional fitness test for community-residing older adults. *Journal of Aging and Psysical Activity* 1999; 7:129-61.

48. Roberts HC, Denison HJ, Martin HJ, et al. A review of the measurement of grip strength in clinical and epidemiological studies: towards a standardised approach. *Age and Ageing* 2011; 40(4):423-9. doi:10.1093/ageing/afr051.

49. Faul F, Erdfelder E, Lang AG, et al. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. *Behavior Research Methods* 2007; 39(2):175-91.

50. McKnight PE, Kasle S, Going S, et al. A comparison of strength training, self-management, and the combination for early osteoarthritis of the knee. *Arthritis Care Research (Hoboken)* 2010; 62(1):45-53. doi:10.1002/acr.20013.

51. Cohen J. *Statistical power analysis for the behavioral sciences*. . Hillsdale, NJ: Lawrence Erlbaum Associates; 1998.

52. Roos EM and Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes* 2003; 1. doi:10.1186/1477-7525-1-64.

53. McKnight PE, Kasle S, Going S, et al. A comparison of strength training, self-management, and the combination for early osteoarthritis of the knee. *Arthritis Care Research (Hoboken)* 2010; 62. doi:10.1002/acr.20013.

54. Mendelson AD, McCullough, C and Chan, A. Integrating self-management and exercise for people living with arthritis. *Health Education Research* 2011; 26(1):167-77.

55. Skou ST, Rasmussen S, Laursen MB, et al. The efficacy of 12 weeks non-surgical treatment for patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up. *Osteoarthritis and Cartilage* 2015; 23:1465-75. doi:10.1016/j.joca.2015.04.021.

56. Yázigi F, Espanha, M. and Messier, S. P . *Knee Osteoarthritis and Obesity: Effectiveness of PICO Aquatic Exercise Program on Symptoms, Physical Fitness and Quality of Life*. PhD Thesis, Universidade de Lisboa, Oeiras, Portugal:2014.

57. Ageberg E, Nilsdotter A, Kosek E, et al.. Effects of neuromuscular training (NEMEX-TJR) on patient-reported outcomes and physical function in severe primary hip or knee osteoarthritis: a controlled before-and-after study. *BMC Musculoskelet Disord*ers 2013; 14:232. doi:10.1186/1471-2474-14-232.

58. Clegg DO, Reda DJ, Harris CL, et al. Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis. *New England Journal of Medicine* 2006; 354(8):795-808. doi:doi:10.1056/NEJMoa052771.

59. Sharma L. Osteoarthritis year in review 2015: clinical. *Osteoarthritis and Cartilage*. 2016; 24(1):36-48. doi:http://dx.doi.org/10.1016/j.joca.2015.07.026.

60. Irsay L, Borda MI, Nitu AD, et al. Effectiveness of Glucosamine and Chondroitin Sulfate Combination in Patients with Primary Osteoarthritis. *Applied Medical Informatics* 2010; 27(4):47-54.

61. Clegg DO, Reda DJ, Harris CL, et al. Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis. *The New England Journal of Medicine* 2006; 354. doi:10.1056/NEJMoa052771.

62. Erhan B, GÜNdÜZ B, ÜStÜNel SH, et al. The Efficacy of Topical Glucosamine Sulfate-Chondroitin Sulfate in Knee Osteoarthritis Treated With Physical Therapy: A Randomized, Double-Blind, Placebo-Controlled Study. / Fizik Tedavi Uygulanan Diz Osteoartritli Hastalarda Topikal Glukozamin Sülfat-Kondroitin Sülfatın Etkinliği: Randomize Çift Kör Plasebo Kontrollü Bir Çalışma. *Turkish Journal of Physical Medicine & Rehabilitation / Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi* 2012; 58:194-8.

63. Salli A, Sahin N, Baskent A, et al. The effect of two exercise programs on various functional outcome measures in patients with osteoarthritis of the knee: A randomized controlled clinical trial. *Isokinetics and Exercise Science* 2010; 18.

64. Jan M-H, Lin C-H, Lin Y-F, et al. Effects of Weight-Bearing Versus Nonweight-Bearing Exercise on Function, Walking Speed, and Position Sense in Participants With Knee Osteoarthritis: A Randomized Controlled Trial. *Archives of Physical Medicine and Rehabilitation* 2009; 90(6):897-904. doi:http://dx.doi.org/10.1016/j.apmr.2008.11.018.

65. Wilkie R, Peat G, Thomas E, et al. Factors associated with restricted mobility outside the home in community-dwelling adults ages fifty years and older with knee pain: An example of use of the International Classification of Functioning to investigate participation restriction. *Arthritis Care & Research* 2007; 57(8):1381-9. doi:10.1002/art.23083.

66. Barlow JH, Turner AP and Wright CC. A randomized controlled study of the Arthritis Self-Management Programme in the UK. *Health Education Research* 2000; 15(6):665-80.

67. Elzen H, Slaets JP, Snijders TA, et al. Evaluation of the chronic disease self-management program (CDSMP) among chronically ill older people in the Netherlands. *Social Science & Medicine* 2007; 64(9):1832-41. doi:10.1016/j.socscimed.2007.02.008.

68. Dobson F, Hinman RS, Roos EM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. *Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society* 2013;21(8):1042-52. doi:10.1016/j.joca.2013.05.002.

69. Naylor JM, Hayen A, Davidson E, et al. Minimal detectable change for mobility and patient-reported tools in people with osteoarthritis awaiting arthroplasty. *BMC Musculoskeletal Disorders* 2014; 15(1):1-9. doi:10.1186/1471-2474-15-235.

70. Hughes SL, Seymour RB, Campbell R, et al. Impact of the fit and strong intervention on older adults with osteoarthritis. *The Gerontologist* 2004; 44(2):217-28.

71. French HP, Fitzpatrick M and FitzGerald O. Responsiveness of physical function outcomes following physiotherapy intervention for osteoarthritis of the knee: an outcome comparison study. *Physiotherapy* 2011; 97(4):302-8. doi:10.1016/j.physio.2010.03.002.

72. Levy SS, Macera CA, Hootman JM, et al. Evaluation of a multi-component group exercise program for adults with arthritis: Fitness and Exercise for People with Arthritis (FEPA). *Disability and Health Journal* 2012; 5(4):305-11. doi:10.1016/j.dhjo.2012.07.003.

73. Maurer BT, Stern AG, Kinossian B, et al. Osteoarthritis of the knee: Isokinetic quadriceps exercise versus an educational intervention. *Archives of Physical Medicine and Rehabilitation* 1999; 80. doi:10.1016/s0003-9993(99)90032-1.

74. Giampaoli S, Ferrucci L, Cecchi F, et al. Hand-grip strength predicts incident disability in non-disabled older men. *Age and Ageing* 1999; 28(3):283-8.

75. Alley DE, Shardell MD, Peters KW, et al. Grip strength cutpoints for the identification of clinically relevant weakness. *The journals of Gerontology Series A, Biological Sciences and Medical Sciences* 2014; 69(5):559-66. doi:10.1093/gerona/glu011.

76. Segal NA, Torner JC, Felson D, et al. Effect of thigh strength on incident radiographic and symptomatic knee osteoarthritis in a longitudinal cohort. *Arthritis Care & Research* 2009; 61(9):1210-7. doi:10.1002/art.24541.

77. Mikesky AE, Mazzuca SA, Brandt KD, et al. Effects of strength training on the incidence and progression of knee osteoarthritis. *Arthritis Care & Research* 2006; 55(5):690-9. doi:10.1002/art.22245.

78. Gür H, Çakın N, Akova B, et al. Concentric versus combined concentric-eccentric isokinetic training: Effects on functional capacity and symptoms in patients with osteoarthrosis of the knee. *Archives of Physical Medicine and Rehabilitation* 2002; 83(3):308-16. doi:http://dx.doi.org/10.1053/apmr.2002.30620.

79. Wang C, Schmid CH, Hibberd PL, et al. Tai Chi is effective in treating knee osteoarthritis: A randomized controlled trial. *Arthritis Care & Research* 2009; 61(11):1545-53. doi:10.1002/art.24832.

80. Callahan LF, Shrefler J. H , Aalpetter M , et al. Evaluation of Group and Self-Directed Formats of the Arthritis Foundation's Walk With Ease Program. *Arthritis Care & Research* 2011; 63(8):pp 1098–107.

81. Chang TF, Liou TH, Chen CH, et al. Effects of elastic-band exercise on lower-extremity function among female patients with osteoarthritis of the knee. *Disability and Rehabilitation* 2012; 34(20):1727-35. doi:10.3109/09638288.2012.660598.

82. Rikli RE, Jones CJ. Assessing Physical Performance in indepentend Older Adults: Issues and Guidelines. *Journal of Aging and Physical Activity* 1997; 5:244-61.

83. Espanha M, Priscila M, Yázigi F, et al. *Guia para viver em PLENO: com menos dor e mais qualidade de vida*. Lisboa: FMH-Ulisboa; 2015.

Chapter 8: Effects of PLE^{2}NO program on self-efficacy in the elderly with knee osteoarthritis: a randomized controlled trial[5]

[5] Marconcin, P., Espanha, M., Teles, J., Marques, M., Campos, P., Yázigi, F. Effects of PLE2NO program on self-efficacy in the elderly with knee osteoarthritis: a randomized controlled trial. International Journal of Behavior Medicine (submitted).

Introduction

Live with knee osteoarthritis is an individual skill which can be learned. Self-management programs could attend this purpose by helping participants to change their health behavior, using the role of self-efficacy as a mediator in this process [1]. According to Bandura, self-efficacy is define as someone's belief in his own ability to succeed in specific situations or to accomplish a task. Perception of high self-efficacy increased the likelihood of consideration, adoption and maintenance of self-management skills [2]. Therefore, self-efficacy has been empirically associated with positive outcomes in the health field [3-5].

There are four main sources of self-efficacy belief: mastery experience, vicarious experience, social persuasion and interpretations of somatic state [6]. Mastery experience is the most influential source of efficacy information, because it provides the most authentic evidence of whether one can muster what it takes to succeed. Self-management programs resort to this specific source to develop tasks to improve self-management skill, (e.g., action plan). In addition, generally, self-management programs use a group format to explore the vicarious experience, as people must often appraise their capabilities in relation to the attainments of others [2]. Therefore, self-efficacy is an important mediator of disease-related outcomes, providing a linking mechanism between psychosocial factors and functional status [1].

Besides involvement in self-management programs, the core of the main international recommendations reinforce the importance of participation in an exercise program as a non-pharmacological treatment for KOA subjects [7]. The benefits of exercise in KOA subjects are exhaustively documented for pain relief and improving limitation in function [8-11]. Physical function is related to the ability to perform daily activities, and is generally considered one of the most important outcomes for KOA subjects, especially in elderly patients [12]. The performance of daily activities is mostly associated with skill-related physical fitness outcomes, such as mobility, balance and gait speed. Several exercise programs show good results in those parameters [13-15]. However, long-term patient adherence to a regular exercise program is a major challenge [16]. For this matter, evidence suggests that an integrated self-management program with

exercise could help to solve this issue by developing self-efficacy, and showing good results in short, medium and long term [17].

Therefore, a Self-Management and Exercise program (PLE^{2}NO) was implemented for elderly people with KOA. Together, self-management and exercise were hypothesized to improve self-efficacy, physical activity, health-related quality of life and skill-related physical fitness components.

Methods

The study protocol of PLE^{2}NO´s intervention is already published [18]. It is a 12-weeks randomized controlled trial, single-blind, conducted in Portugal (Lisbon region). Participants were equal randomly assigned (1:1) to one of two groups: the intervention condition - Self-Management and Exercise Group (SMEG) - or the control condition - Educational Group (EG). Whereas participants allocated to the intervention group were aware of the allocated arm, outcome assessors and data analysts were kept blinded to the allocation.

Eligible participants were all diagnosed with KOA, according to clinical and radiological criteria of the American College of Rheumatology (ACR) [19]; aged 60 years or over and fully understanding and speaking in Portuguese language.

Interventions

Self-Management and Exercise Group (SMEG). The program was twice a week with 90 minutes of duration each session, the first 30 minutes for the self-management component and the last 60 minutes for exercise. The self-management component aimed to improve self-efficacy to deal with symptoms and other KOA consequences. The exercise component aimed to improve muscular resistance/strength, flexibility and balance.

Educational Group (EG) (Control). This group of participants received three 1-hour educational sessions, one per month and a book [20] with KOA information. They also received a telephone call, once a month, to guarantee the attendance.

Outcomes

Data collection occurred at baseline and at 3 months (post-intervention). All the assessments were done at Faculty of Human Kinetics.

Demographic data: age, education, job status, medical condition and other demographic information were obtained by a questionnaire done especially for this purpose.

Self-efficacy was assessed by the Self-efficacy for managing Chronic Disease 6-Item Scale [5]. The amount of physical activity per week was assessed by The short form of the International Physical Activity Questionnaire (IPAQ). [21, 22]. Health-related quality of life (HRQol) was assessed by the EuroQol (EQ-5D-5L) [23]. The patient´s impression of change was verified by the Patient´s Global Impression of Change (PGIC), recommended for clinical research, especially in musculoskeletal area [24].

Skill related physical fitness components for this study comprised agility, gait speed and balance. Agility was assessed by Timed "up-and-go" test, which measured the time (seconds) taken to rise from a chair, to walk 3 m (9 ft, 10 inches), turn, walk back to the chair and then sit down, wearing regular footwear and using a walking aid if required [25]. Gait speed was assessed by Six-meter test, which measured linear walking ability; participants were invited to walk as fast as they could in a 10-meter space, excluding the first and the last two meters. Balance was evaluated by a Standing Balance Test (SBT), participants performed two repetitions of the test, bi-lateral, and the best result was counted (if failure occurred in the first test) [26].

Sample Size

To detect a large effect size on pain, which is in agreement with the study of Mcknight [27], a sample size total of 80 participants was necessary, given an anticipated dropout rate of 20%. One-sided 5% significance level and a power of 80% were established.

Statistical analysis

All analyses were performed using the software Statistical Package for Social Sciences, version 22 (SPSS Inc., Chicago, Il, USA) and a significance level of 5% was considered. Descriptive analyses were done for all variables investigated. Differences between SMEG and EG on baseline were performed using independent Samples t-test (for continuous variables), Mann-Whitney-Wilcoxon test (for ordinal variables) and chi-square test of homogeneity (for dichotomous variables). Intervention effects were examined using mixed model repeated measure analysis of covariance (ANCOVA), controlling the baseline values of each variable tested. Group effect size (ES) in the analysis of covariance was evaluated using Partial Eta Squared (ηp2). The effect size was classified as small (ηp2<0.06), medium (0.06<= ηp2<0.14) and large (ηp2>=0.14)[28].

Results

Participants had a mean age of 69.1 (5.8) years, 70.1% were female, 50.8% had at least a high school degree, 94% had bilateral KOA and mean BMI of 31.2(5.2) Kg/m^2. No differences between groups were founded regarding those cited variables.

Variable values at baseline are described on table 8.1 Differences between groups were founded for sitting time, health-related quality of life and gait speed.

Table 8.1 - Baseline characteristics of the study participants, values are mean and standard deviation.

	Outcomes	EG (n=32)	SMEG (n=35)	Total Sample	Test Statistic	*p* value
Self-Efficacy	Self-Efficacy	6.8(1.9)	6.9(1.7)	6.9(1.8)	0.18 [a]	.861
IPAQ	Physical activity (MET/week)	522(834)	423(432)	470(652)	-0.62 [a]	.536
	Sitting time (min/week)	693(276)	570(294)	629(247)	-2.06 [a]	.043*
EQ-5D-5L	Index	0.77(0.17)	0.62(0.23)	0.69(0.21)	-2.84 [a]	.006*
Skill-related physical fitness measure	TUG	6.5(1.6)	7.2(1.8)	6.8(1.7)	1.74 [a]	.087
	Balance $_{MPK}$	2.8(1.4)	2.2(1.5)	2.4(1.4)	418.5 [b]	.063
	Balance $_{LPK}$	2.4(1.5)	2.0(1.3)	2.2(1.3)	475.0 [b]	.279
	Gait speed	1.7(0.4)	1.5(0.4)	1.6(0.4)	-2.50 [b]	.015*

Abbreviations: *MPK = Most Painful Knee; LPK = Less Painful Knee; IPAQ = International Physical Activity; Questionnaire. EQ-5D-5L = Euroqol five dimensions five level, TUG= Timed "up-and-go".*
[a] *Independent Samples t-test*
[b] *Wilcoxon-Mann-Whitney test*
** p<.05*

The values of studied variables at baseline (T 1) and post-intervention (T 2), the difference between the values in the two moments and the results of parametric and non-parametric ANCOVA between groups are shown in tables 8.2 and 8.3, respectively. A significant group effect was noted for self-efficacy [$F(2,64)=9.2$, $p=.003$], physical activity [$F(2,)=43.6$, $p<.001$] and siting time [$F(2,64)=8.2$, $p=.005$]. All with a medium effect size, .127, .138, .115, respectively. In relation to EQ-5D-5L Index, no significant effect of intervention was observed.

Relatively to skill-related physical fitness component, just balance exhibited a significant group effect for both: most painful knee [$F(2,64)=4.87$, $p=.031$] and less painful knee [$F(2,64)=6.94$, $p=.010$], with medium effect size .070 and .096, respectively. Agility and gait speed did not reveal a significant group effect.

Table 8.2 - Group effect analysis for all variables. Parametric ANCOVA adjusted for values on baseline.

	EG (n=32)			**SMEG (n=35)**			ANCOVA Group Effect	
	T1	T2	Change	T 1	T 2	Changes		
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	*F*	*p*
Self-Efficacy	6.8(1.9)	6.8(1.8)	0.03(1.3)	6.9(1.7)	7.8(1.5)	-0.8(1.5)	9.2	.003*
Physical activity (MET/week)	522(834)	417(455)	-105(863)	423(432)	843(.658)	420(701)	10.2	.002*
Siting time (min/week)	693(276)	738(265)	44(246)	570(294)	518(227)	-51(211)	8.2	.005*
EQ-5D-5L Index	0.77(0.17)	.75(0.20)	0.01(0.18)	0.62(0.23)	0.77(.18)	-0.14(0.27)	1.4	.240
TUG (s)	6.50(1.6)	6.71(2.3)	-0.21(1.9)	7.23(1.7)	7.01(1.6)	0.22(1.2)	0.3	.573
Gait Sped (m/s)	1.77(0.4)	1.80(0.42)	-0.03(0.4)	1.53(0.4)	1.67(0.3)	-0.14(0.18)	0.1	.707

Abbreviations: *EQ-5D-5L = Euroqol five dimensions five level,* TUG= Timed "up-and-go",

Table 8.3 - Group effect analysis for ordinal variables. Non-parametric ANCOVA adjusted for values on baseline.

	EG (n=32)		**SMEG (n=35)**		**ANCOVA**	
	T 1	T 2	T 1	T 2	***F***	**p**
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)		
Balance MPK	2.17(1.46)	2.31(1.49)	2.81(1.40)	2.22(1.40)	4.87	.031*
Balance LPK	2.03(1.29)	2.49(1.38)	2.41(1.47)	1.91(1.55)	6.94	.010*

Abbreviations: MPK = most painful knee; LPK = less painful knee; CWP = communication with physicians; CSM = cognitive symptoms management.

Discussion

This study analyzed the efficacy of a 12-week self-management and exercise program (PLE^{2}NO). At post-treatment, participants in the self-management and exercise group had significantly better outcomes, than participants in educational group with respect to self-efficacy, physical activity, siting time and balance.

Analyses revealed that the intervention group experienced a statistically significant group effect regarding self-efficacy. Self-efficacy was the key construct of PLE^{2}NO´s self-management component, because it is closely related to the adoption of self-management skills [29] . This construct was evaluated specifically in relation to the symptoms control. Numerous techniques, such as progressive relaxation, guided imagery, breathing technics, were used in the program to achieve the symptoms control by participants. In addition, the action plan involved activities that would help in controlling symptoms, such as exercise practice. Same results, improvement on self-efficacy to control symptoms, were found in Lorig's study [5], in an evaluation of CDSMP with 489 patients in 1-year follow-up. It was difficult to find other studies with similar characteristics of PLE^{2}NO´s sample, i.e., using the same scale (6-itens self-efficacy scale) to assess self-efficacy. Other findings showed a significant improvement on Self-Efficacy (assessed by ASE- Arthritis Self-Efficacy scale), after self-management interventions [17, 30-33]. In addition, McKnight´s study [34] also found an improvement on self-efficacy in various domains in arthritis patients, after a combined self-management and exercise program. On the other hand, Hughes´s study [35] did not found significant differences between groups in self-efficacy for disease management, but found them on self-efficacy to overcome barriers to adherence on exercise program, because Hughes´s intervention was designed to enhance self-efficacy related to exercise practice. Suggesting that self-efficacy is not a general construct, it should be developed specifically for each outcome intended. An increase in the level of perceived self-efficacy may result in more investment of effort by sufferers in self-management skills, such as regular exercise [36].

PLE^{2}NO´s sample showed a significant group effect in relation to self-reported physical activity level and sedentary behavior variables. Besides the 480 METs/week, corresponding of the PLE^{2}NO´s exercise session, the participants added more 420

METs/week relating to other activities, mainly walking, and diminish 51 min/week of sitting time (sedentary behavior). Previous studies with self-management program exhibited positive effect on enhanced exercise practice [36-39].

In respect to HRQoL, no group effect was found. The same occurred in other studies [31, 40] which did not find a significant improvement after educational interventions relating to HRQoL. A possible explanation for this finding is that the instrument analyzes the general health and PLE²NO2´s program was developed specifically for KOA, so even a general health benefit was expected. In addition, the instrument includes five different dimensions, and the analysis was for an index of all dimensions together. Maybe it will be interesting, in a further investigation, to analyze each dimension alone beyond an index, to understand how each dimension is affected by intervention. However, on PLE²NO´s sample, the SMEG had a significant improvement (p=.003) corresponding to 24.2%, but EG had a worsening of 2.6%, (p=.702).

In relation to performance-based measures, participants in the current study displayed significant group effect in the static balance variable and did not show a significant group effect on mobility and gait speed variables. KOA individuals have impaired static and dynamic balance that may result in falls [41]. PLE²NO´s intervention worked exhaustively the static balance outcome, in every session, before the strength component a series of static balance exercises were done. These findings can be analyzed in comparison with other interventions, like walking programs [42] and education programs [40] that had improvements on static balance in KOA patients, contrary to the Tai Chi intervention that did not have significant improvements [43]. Regarding Timed "up-and-go" test, it was observed a lack of treatment effect. On the other hand, a previous report [13, 34] showed an improvement face to a combined intervention exercise and self-management on KOA adults. However, when comparing PLE²NO´s baseline values with their baseline values, PLE²NO´s sample had better values, even though the participants were older in age. Therefore, it would be more difficult to have an improvement. By the way, the test Timed "up-and-go" assess besides agility, dynamic balance and PLE²NO´s intervention worked out with statistic balance. Further studies should give more attention to dynamic balance on their interventions.

Walking speed did not have a significant group effect, although single analyses revealed a significant improvement on SMEG (p<.001), but the same did not occur on EG (p=.307). Factors related to the training intervention may also partly explain this limited effect. PLE²NO´s exercise component highlighted the strength and static balance exercises. In addition, sessions occurred in a small place, to achieve the purpose of developing an intervention close to the participant, which allowed a broad distribution on community; for this reason, PLE²NO´s exercise intervention did not had space to work out with walking speed. Even so, it is important to assess walking speed, because this represents an important outcome for KOA patients. In addition, the strength exercise could help to achieve this propose, as it was observed on Chang´s study [15], which shows a significant effect on walking speed after strength exercise in KOA females. A theme for further study is to elucidate whether an exercise program focused on strength training could represent better results on walking speed.

Complementary analyses, analyzing the Patient's Global Impression of Change scale (PGIC) showed that 77% of the participants in SMEG and 47% in the EG had significant and positive changes face to intervention. It means that PLE²NO program was well accepted and caused significant changes in participants' life.

Additionally, there was a decrease in medication use in both groups, 31.4% in SMEG and 31.3% in EG, and no participant increased the use of medication. This could be explained as a result of the self-management program that helps participants to use other resources for symptoms relief and not just medication. Nunez' study [44] found a significant reduction on medicine use face to an educational intervention on KOA elderly subjects.

Limitation

A limitation of this study was that the control group also received an educational intervention (once a month with one-hour duration and the PLE²NO´s book), which can underestimate the analysis of the program effect. In addition, the participants were not blind to intervention type, so some self-reported measures can reflect the gratitude for having participated in an intervention.

Conclusion

In conclusion, the findings suggest that the PLE²NO´s combined self-management and exercise program, with 3 months duration, had a positive effect in enhancing self-efficacy, physical activity behavior and balance for KOA elderly subjects, in 12 weeks. PLE²NO´s findings add to the evidence of applying self-management programs focused on participants' self-efficacy with an exercise component in the treatment of KOA patients.

References

1. Lorig, K.R., et al., *Outcome Measures for Health Education and Other Health Care Interventions*. 1996, Thousand Oaks CA: Sage Publications. pp.24,40.
2. Bandura, A., *Self-Efficacy: The Exercise of Control*. 1997, New York: W.H. Freeman.
3. Sharma, L., et al., *Physical functioning over three years in knee osteoarthritis: role of psychosocial, local mechanical, and neuromuscular factors*. Arthritis Rheum, 2003. **48**(12): p. 3359-70.
4. van Dijk, G.M., et al., *Course of functional status and pain in osteoarthritis of the hip or knee: a systematic review of the literature*. Arthritis Rheum, 2006. **55**(5): p. 779-85.
5. Lorig, K.R., et al., *Effect of a self-management program on patients with chronic disease*. Eff Clin Pract, 2001. **4**(6): p. 256-62.
6. Bandura, A., *Self-efficacy*, in *Encyclopedia of human behavio*, V.S. Ramachaudran, Editor. 1994, Academic Press: New York. p. 71-81.
7. McAlindon, T.E., et al., *OARSI guidelines for the non-surgical management of knee osteoarthritis*. Osteoarthr Cartil, 2014. **22**.
8. Fransen, M., et al., *Exercise for osteoarthritis of the knee*. Cochrane Database Systematic Reviews, 2015. **4**: p. Cd004376.
9. Tanaka, R., et al., *Efficacy of strengthening or aerobic exercise on pain relief in people with knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials*. Clinical Rehabilitation, 2013. **27**(12): p. 1059-1071.
10. Uthman, O.A., et al., *Exercise for lower limb osteoarthritis: systematic review incorporating trial sequential analysis and network meta-analysis*. Br J Sports Med, 2014. **48**(21): p. 1579.
11. Roddy, E., W. Zhang, and M. Doherty, *Aerobic walking or strengthening exercise for osteoarthritis of the knee? A systematic review*. Ann Rheum Dis, 2005. **64**(4): p. 544-8.
12. Terwee, C.B., et al., *Performance-based methods for measuring the physical function of patients with osteoarthritis of the hip or knee: a systematic review of measurement properties*. Rheumatology, 2006. **45**.
13. da Silva, F.S., et al., *Efficacy of simple integrated group rehabilitation program for patients with knee osteoarthritis: Single-blind randomized controlled trial*. J Rehabil Res Dev, 2015. **52**(3): p. 309-22.
14. Callahan, L.F., et al., *A randomized controlled trial of the people with arthritis can exercise program: symptoms, function, physical activity, and psychosocial outcomes*. Arthritis Rheum, 2008. **59**.
15. Chang, T.F., et al., *Effects of elastic-band exercise on lower-extremity function among female patients with osteoarthritis of the knee*. Disabil Rehabil, 2012. **34**(20): p. 1727-35.
16. Bennell, K.L., F. Dobson, and R.S. Hinman, *Exercise in osteoarthritis: moving from prescription to adherence*. Best Pract Res Clin Rheumatol, 2014. **28**(1): p. 93-117.
17. Hughes, S.L., et al., *Impact of the fit and strong intervention on older adults with osteoarthritis*. Gerontologist, 2004. **44**(2): p. 217-28.

18. Marconcin, P., et al., *The PLE2NO self-management and exercise program for knee osteoarthritis: Study Protocol for a Randomized Controlled Trial*. BMC Musculoskeletal Disorders, 2016. **17**(1): p. 1-12.
19. Altman, R., et al., *Development of criteria for the classification and reporting of osteoarthritis: Classification of osteoarthritis of the knee*. Arthritis & Rheumatism, 1986. **29**(8): p. 1039-1049.
20. Espanha, M., et al., *Guia para viver em PLENO: com menos dor e mais qualidade de vida*. Vol. 1. 2015, Lisboa: FMH-Ulisboa.
21. Craig, C.L., et al., *International physical activity questionnaire: 12-country reliability and validity*. Med Sci Sports Exerc, 2003. **35**(8): p. 1381-95.
22. Rutten, A. and K. Abu-Omar, *Prevalence of physical activity in the European Union*. Soz Praventivmed, 2004. **49**(4): p. 281-9.
23. Herdman, M., et al., *Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L)*. Qual Life Res, 2011. **20**(10): p. 1727-36.
24. Hurst, H. and J. Bolton, *Assessing the clinical significance of change scores recorded on subjective outcome measures*. J Manipulative Physiol Ther, 2004. **27**(1): p. 26-35.
25. Podsiadlo, D. and S. Richardson, *The timed "Up & Go": a test of basic functional mobility for frail elderly persons*. Journal of the American Geriatrics Society, 1991. **39**(2): p. 142-148.
26. Rose, D.J., *A Comprehensive Balance and Mobility Training Program*. 2003, Champaign: Human Kinectics.
27. McKnight, P.E., et al., *A comparison of strength training, self-management, and the combination for early osteoarthritis of the knee*. Arthritis Care Res (Hoboken), 2010. **62**.
28. Cohen, J., *Statistical power analysis for the behavioral sciences*. . Vol. 2nd edn. 1998, Hillsdale, NJ: Lawrence Erlbaum Associates.
29. Bandura, A., *Self-efficacy: Toward a unifying theory of behavioral change*. Psychological Review, 1977. **Vol 84(2)**: p. 191-215.
30. Yip, Y.B., et al., *Effects of a self-management arthritis programme with an added exercise component for osteoarthritic knee: randomized controlled trial*. Journal of Advanced Nursing, 2007. **59**(1): p. 20-28.
31. Barlow, J.H., A.P. Turner, and C.C. Wright, *A randomized controlled study of the Arthritis Self-Management Programme in the UK*. Health Educ Res, 2000. **15**(6): p. 665-80.
32. Levy, S.S., et al., *Evaluation of a multi-component group exercise program for adults with arthritis: Fitness and Exercise for People with Arthritis (FEPA)*. Disabil Health J, 2012. **5**(4): p. 305-11.
33. Goeppinger, J., et al., *Self-management education for persons with arthritis: Managing comorbidity and eliminating health disparities*. Arthritis Care & Research, 2007. **57**(6): p. 1081-1088.
34. McKnight, P.E., et al., *A comparison of strength training, self-management, and the combination for early osteoarthritis of the knee*. Arthritis Care Res (Hoboken), 2010. **62**(1): p. 45-53.
35. Hughes, S.L., et al., *Impact of the fit and strong intervention on older adults with osteoarthritis*. The Gerontologist, 2004. **44**.
36. Yip, Y.B., et al., *Effects of a self-management arthritis programme with an added exercise component for osteoarthritic knee: randomized controlled trial*. J Adv Nurs, 2007. **59**.
37. Talbot, L.A., et al., *A Home-Based Pedometer-Driven Walking Program to Increase Physical Activity in Older Adults with Osteoarthritis of the Knee: A Preliminary Study*. Journal of the American Geriatrics Society, 2003. **51**(3): p. 387-392.
38. Goeppinger, J., et al., *Self-management education for persons with arthritis: Managing comorbidity and eliminating health disparities*. Arthritis Care Res, 2007. **57**.
39. Barlow, J.H., A.P. Turner, and C.C. Wright, *A randomized controlled study of the Arthritis Self-Management Programme in the UK*. Health Educ Res, 2000. **15**.
40. Hansson, E.E., et al., *Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial*. BMC Musculoskelet Disord, 2010. **11**: p. 244.
41. Hurley, M., et al., *Sensorimotor changes and functional performance in patients with knee osteoarthritis*. Annals of the Rheumatic Diseases, 1997. **56**(11): p. 641-648.
42. Callahan, L.F., Shrefler,J. H., Aalpetter, M., Schoster, B., Hootman, J., Houenou, L. O., Martim, K. R., Schwartz, C. H. , *Evaluation of Group and Self-Directed Formats of the Arthritis Foundation's Walk With Ease Program*. Arthritis Care & Research, 2011. **63**(8): p. pp 1098–1107.

43. Wang, C., et al., *Tai Chi is effective in treating knee osteoarthritis: A randomized controlled trial*. Arthritis Care & Research, 2009. **61**(11): p. 1545-1553.
44. Nuñez, M., et al., *The effect of an educational program to improve health-related quality of life in patients with osteoarthritis on waiting list for total knee replacement: a randomized study*. Osteoarthr Cartil, 2006. **14**.

Chapter 9: General Discussion

8.1 Overview

Assessing the effectiveness of a self-management and exercise program constitutes an important contribution in KOA non-pharmacological treatment field. International guidelines, such as OARSI, EULAR and ACR, are constantly updating their recommendations. For this matter, a structured clinical trial can reinforce or contest those recommendations. The literature review section is organized as follows: firstly, the KOA field is described (epidemiology, etiology and risk factors, physiopathology of KOA, signs and symptoms and KOA diagnosis); subsequently, the KOA treatment is emphasized and the importance of a self-management and an exercise intervention is reinforced as a non-pharmacological management of KOA. In addition, the statements about chondroitin and glucosamine sulfates as a supplementation used on KOA treatment are reviewed. Lastly, the assessment used in clinical trials to evaluate their effectiveness is discussed. With this framework, the aim of this thesis was proposed.

Afterwards, the methodology of the five articles herewith presented were briefly described.

Then, follows article 1 (a study protocol of PLE^{2}NO intervention). After that, two cross sectional articles and two articles with the findings of PLE^{2}NO´s intervention are described.

Each article presented includes a specific discussion, and this chapter adds an integrated analysis of them, firstly the main findings, then baseline and finally the interventions' findings. Furthermore, this chapter also describes the limitations of this thesis and introduces a contribution for practical applications in clinical practices and future research.

8.2 Main research findings

The PLE^{2}NO program was designed to investigate the efficacy of a self-management and exercise program in different outcomes concerning elderly subjects with KOA. The study protocol previewed a follow-up at 6 months. The sample size calculated before the recruitment, considered that 67 individuals were necessary to have a power of 80%. Considering 20% of dropout, the aim was to recruit 80 individuals. However, at 6

months, the sample was reduced to 52 individuals (23% of dropout), and consequently the power reduced to 69%. For this reason, we opted to not analyze the follow-up data.

The PLE2NO´s program had several strengths. Three of them deserve more attention. First, the program was in accordance with the currently international recommendation of a combined self-management and exercise intervention for non-pharmacological treatment of KOA patients [109, 166, 167]. Second, the program was applied in four different places, to be close to the participants, diminishing the difficult to access and guarantee more adherence. Third, the program used minimal and low cost equipment and had a detail methodology already published [168], which allowed easy and broad delivery among the community.

The most important findings of this thesis are related to the effectiveness of PLE^{2}NO´s program, a self-management and exercise program designed for KOA participants. After 12 weeks of intervention, a significant improvement on self-efficacy, self-management behavior related to communication with physician, physical activity level and on physical fitness outcomes (lower limb functional strength, aerobic capacity, flexibility right upper limb and balance) were observed. Clinical improvement was observed on pain and other symptoms, daily living activities, sport/recreation activities and quality of life related with KOA [169]. In addition, by the analyses of the Patients Global Impression of Change 77% of the participants in the Self-Management and Exercise group and 47% in the Educational group experience significantly changes (scores 5-7) after intervention. These findings could represent an expressive change on participants' life, also contributing to reinforce the field of non-pharmacological clinical recommendation for KOA subjects [77, 109, 167].

To have a better understanding of PLE^{2}NO´s effectiveness, it is, first of all, important to analyze the variables on baseline assessment. Such analyzes are presented in two cross sectional articles.

8.2.1 Baseline findings

The second article aims to analyze the predictor factors of the Timed "up-and-go" test, a test that was used on PLE^{2}NO´s assessment. It is justified because in the baseline assessment it was observed that the physical tests were quite exhaustive and for some individuals even tiring and painful. Hence, this second article provided a better

understanding of how tests and questionnaires are related and, consequently, can reduce the assessment for future studies. For this purpose, a multiple regression analyzes, using stepwise methods was conducted. The variable mobility, analyzed by Timed "up-and-go" test was chosen as an independent variable. This test was selected since it is recommended by OARSI as a minimum set of performance-based measure of physical function in people with KOA [161]. In addition, it is a fast test, less painful and widely used for KOA patients' assessment [170-172]. The test analyzes three important tasks for KOA subjects: rising from a chair, walking speed and change direction while walking [173]. The results of this study indicates that the physical fitness variables (lower limb functional strength, aerobic capacity, gait speed) and the self-reported variables (daily living activities and self-care) are responsible for 80% of variance on Timed "up-and-go" test, highlighting that perception of physical function had an impact on real performance.

Regarding physical fitness assessment, it is understandable that lower limb functional strength and gait speed appear on the final model, since these actions are present on those tests: standing up from a chair and walking fast. An unexpected finding of the final model was the presence of the physical variable aerobic capacity, assessed by 6 MWT, since it is not an outcome necessary on Timed "up-and-go" test. Probably, as the literature supports, the 6MWT reveals an overall physical condition and this can be correlated with other physical tests [161, 174]. Anyway, further investigation is necessary to confirm this assumption.

Concerning the self-reported predictor variables included in the model calculated in article 2, two variables were identified: (1) the impact of KOA on daily living activity and (2) self-care and usual activity related with general health. Together they represent 25% of 80% variation on Timed "up-and-go" test. Pain and other symptoms were not present on this final model, but both were moderately and negatively correlated with Timed "up-and-go" test. This could indicate an indirect relation, since pain and other symptoms can affect directly daily living activities and self-care. In addition, pain and other symptoms were above the average level of the scale and also above, compared with other studies [134, 175, 176]. Apparently, the participants were adapted to pain and other symptoms. This is possible the reason why pain and other symptoms did not predict the performance of Timed "up-and-go" test. Nevertheless, the following article adds another important finding concerning pain and other symptoms.

The third article was important to give a better explanation of how PLE^{2}NO´s sample deals with KOA symptoms. This article aimed to analyze if pain and other symptoms (swelling, crepitus, limitation of movement and stiffness), KOA severity, and social demographic characteristics (sex and educational level) were determinant for coping strategies. Pain and other symptoms were not relevant to determine coping strategies in PLE^{2}NO´s sample, unlike other tested variables. As aforesaid, pain and other KOA symptoms had high values, which can be a possible explanation.

The most used coping strategies were: acceptance, active coping, planning and positive reframing. PLE^{2}NO´s sample did not change after intervention, the chosen strategies continued the same. This characteristic, being constant, is supported by literature [177, 178]. Also, those choosing most used strategies were related with positive outcomes (less pain and better physical function) in other studies [179-181]. Therefore, PLE^{2}NO´s participants were probably adapted to pain and other symptoms, because they resort to adequate coping strategies.

This result could help other educational interventions with samples with similar characteristics to PLE^{2}NO´s sample. In the sense that subjects choose coping strategies, independently of gender, educational level, KOA severity or level of pain and other symptoms. This reinforces that the heterogeneous character of a sample did not interfere with coping strategies.

8.2.2 Intervention findings

The program effectiveness was divided into two articles. The first article analyzed the impact of the intervention on pain, other symptoms, daily living activities, quality of life related with KOA, health behavior related with pathology (communication with physician and cognitive symptoms management) and one general health outcome, which was the health related quality of life (EQ-5D-5L VAS). In addition, health-related physical fitness outcomes (aerobic capacity, lower limb functional strength, handgrip strength and flexibility). The second article focused on the impact of intervention in self-efficacy, physical fitness level, health related quality of life (EQ-5D-5L index), and skill-related physical fitness outcomes (balance, mobility and gait speed).

The core of PLE^{2}NO´s program was the self-efficacy construct. According to literature, if subjects with chronic condition improve self-efficacy, they can have a better

control of their pathology and improve important outcomes such as pain and other symptoms, self-management behaviors, health-related quality of life and physical activity [68, 182, 183].

After PLE^{2}NO´s program, a significant group effect was found in the intervention group on self-efficacy, communication with physician (self-management behavior), physical activity level and physical fitness outcomes. However, improvement on pain and other symptoms, cognitive symptoms management (self-management behavior) and on health-related quality of life were not observed. The significant improvement on self-efficacy was described in other studies of self-management interventions [91, 94, 113, 129, 132].

The significant group effect observed on physical activity level and sedentary behavior (assessed by IPAQ questionnaire) was another important finding on PLE^{2}NO´s intervention. This means that PLE^{2}NO´s self-management program was efficient to help subjects change their behavior in relation to physical activity. In addition, the exercise component was efficient to improve functional lower limb strength. Therefore, this improvement could allow a better capacity to do physical activity and, consequently, a less sedentary behavior. The improvement on self-efficacy to control symptoms and consequences of KOA, could impact on the improvement at the physical activity level, in the sense that when participants feel more confident to control KOA, they feel more inclined to do physical activity. Nevertheless, this is only an assumption, since an analysis with self-efficacy as a mediator of program effect was not conducted.

Two possible explanations for the lack of group effect on pain and other symptoms were previously mentioned. One is the lower pain intensity on baseline assessment; second the use of coping strategies to deal with pain, which possibly provided good adaptability. An additional explanation is the use of the supplement for all participants. The supplement does not have a consensual description of its effect on literature [144, 184-187]. Thus, subjects could reflect in different ways the supplement effect. Participants on the control group could respond better to supplementation than participants of the intervention group. Nevertheless, this is only an assumption, since supplement administration was provided to both groups

To better comprehend the lack of significant results expected on cognitive symptoms management, it is necessary to analyze the questionnaire used on the

assessment. This questionnaire incorporated six strategies that are present on the PLE^{2}NO´s self-management component, however did not incorporate questions about exercise or other physical activities to manage symptom. Moreover, as already mentioned, the intervention group improved the physical activity level, so they could use this as a strategy to manage symptom, rather than strategies present on the Cognitive Symptoms Management questionnaire. However, only if this was present on the assessment questionnaire, could this conjecture be confirmed.

Another point to be considered is the heterogeneous educational level on PLE^{2}NO´s sample. Many participants had difficulty to understand the self-management skills developed on the program, especially the action plan tool. The cognitive symptoms management variable depends on the acquisition of self-management skills, needing time to be expressed by the participants. Besides, we assumed that some of the tools (guided imagery, play mental games, etc.) needed a minimum level of cognition, which was not assessed. However, communication with physician had a significant group effect. Participants showed much interest to discuss this point during the self-management class. The relation with a physician was a big concern for participants. Thus, this issue was strongly addressed during the intervention. Furthermore, the questionnaire had only 3 questions and was easier to comprehend, compared with the cognitive symptoms management scale.

In contradiction to other studies after PLE^{2}NO´s program, no group effect was founded on health related quality of life [93, 94, 188]. This variable refers to the way that chronic diseases and psychological parameters affect quality of life. PLE^{2}NO´s assessment did not control if participants had any other diseases (although the core recommendation of OARSI is equal for people with or without co-morbidities) and their psychological status (e.g. depression fillings). If so, these other parameters could affect the evaluation. However, PLE^{2}NO´s self-management component was based on a general program for chronic condition (the CDSMP from Stanford University); in this way, the self-management skills could help any chronic condition besides KOA. Yet, the variable that could help to solve this issue was the cognitive symptoms management, where no significant improvement was observed. The questionnaire used for health related quality of life assessment is a standardized instrument that comprehends five dimensions (EQ-5D), providing a single index value for health status. Thus, an individual analysis of each

dimension is not possible. If it was, this could provide a better understanding of the impact in each dimension.

In relation to physical fitness variables, a significant group effect on functional lower limb strength, aerobic capacity, flexibility upper limb and balance were observed. On the other hand, positive results on gait speed, mobility, handgrip strength and lower limb flexibility were not found. These results are in accordance with the characteristics of PLE^{2}NO´s exercise intervention, as mentioned before.

The main finding regarding physical fitness variables was the positive effect found on lower limb functional strength. A possible explanation is related with the nature of PLE^{2}NO´s intervention. The core of the exercise component was lower limb strength. Load prescription and progress were done carefully and individualized, primarily determined in accordance with the pain level and respecting it. To reduce pain caused by excessive body load, the exercises were mostly done in sitting position. In addition, the cuff weight used allowed small increases of 250g. Therefore, an improvement with group effect on lower limb functional strength was expected.

The improvement on the performance of 6 MWT represents a better capacity to walk, but did not represent a clinical improvement [189]. The literature reinforces the importance of aerobic activity for KOA patient [100, 124, 190]. Nevertheless, the PLE^{2}NO´s exercise component did not have the purpose to improve aerobic capacity; the main purpose was to develop functional lower limb strength. Consequently, the improvement on performance of 6 MWT is related with PLE^{2}NO´s self-management component, which encouraged subjects to do more physical activity and exercise during the days that they did not have classes; this effect was observed previously [191, 192]. One of the tools used on the self-management program was the action plan. All participants on the intervention group should do one individualized action plan for a week, and most of them chose the walking activity. It is the easiest activity to do without accompaniment; it is cheaper and has no necessity of any special material, this way it is the first option when people are encouraged to do more physical activity. In addition, a significant improvement on the physical activity level, mainly in walking activity (assessed by the questionnaire IPAQ) on the intervention group was observed. Therefore, this improvement on physical activity level might explain the improvement on the performance of 6MWT, as showed on Chmelo´s study [123].

The improvement achieved on the balance variable was important, since KOA individuals have impaired static and dynamic balance that may result in falls, and elderly had more predisposition to fall due to sarcopenia [193]. PLE^{2}NO´s intervention worked exhaustively the static balance outcome, on every session, before the strength component.

It is important to emphasize that an improvement on flexibility of the lower limb did not occur. A possible explanation is that flexibility exercises were always done at end of the session, and participants demonstrated tiredness; thus, the performance was not as expected. For future studies, we advise to alternate the order between balance exercise and flexibility exercise. In addition, the PLE^{2}NO´s sample was obese (32 Kg/m^2) and even the abdominal circumference that was not assessed, could compromise trunk flexion and interfere with the test performance.

No improvement was found on the performance of 6 meters test and Timed "up-and-go" test, probably because participants, even with pain, wanted to show that they were capable of it, therefore bearing pain for a short period of time (6m=1.6±0.4s; TUG=6.8±1.7s). Additionally, because the PLE^{2}NO´s exercise intervention did not focus on gait speed and agility, due to the small area where the sessions took place. Both are important physical function components for KOA subjects. In addition, gait speed can be used as an algorithm to sarcopenia assessment, which is a feature of KOA elderlies.

8.3 Limitation

This thesis has some limitations that must be mentioned for a better understanding of all the findings and to help future studies.

First, an instrument to assess the mental and cognitive condition was not used (such as the Mini Mental Exam). This fact would have helped to get a better understanding of PLE^{2}NO´s sample and to provide personalized strategies of assistance, especially on the self-management component.

Second, PLE^{2}NO`s control group also received an intervention, three educational meetings, three telephone calls and a book. This book contained exercise illustrations and participants were encouraged to do the exercises at home. This fact could prejudice the analysis of group effect, especially in several physical tests where no difference between groups were found.

Third, in the screening was not controlled the stages of behavior change concerning exercise practice. Participants could had different options regarding each stage and this could interfere in the exercise adherence (e.g. in a precontemplation stage individuals should not start with practice, but should receive first counselling for exercise).

8.4 Practical implications and future directions

In this section, the practical findings derived from all research articles are summarized.

The PLE^{2}NO´s self-management and exercise program provides a good contribution to the non-pharmacological KOA management field (regarding self-management and exercise approaches). It is a program designed in accordance with international recommendations. In addition, it uses inexpensive materials, it is close to the participants, allowing broad distribution in community settings. As demonstrated, this intervention increases self-efficacy, self-management behaviors and physical activity levels. Furthermore, it is an effective intervention to improve physical fitness outcomes (lower limb functional strength, aerobic capacity, flexibility and balance). An important contribution to this success is that the exercise intervention is combined with a self-management component. Both can guarantee better outcomes for KOA elderly subjects.

Self-efficacy is a key construct on health behavior change, and PLE^{2}NO´s program was effective to increase this variable. It is important to reinforce that the self-management program should be based on self-efficacy theory.

In this sense, we suggest that future studies:

- Assess the barriers to exercise adherence;
- Include a cognitive assessment in the screening;
- Include in the assessment a question concerning the use of exercise/physical activity as a tool to manage symptom;
- Include an assessment for exercise self-efficacy;
- Give more time for the self-management component (45 minutes), taking more time to explain the self-management skills and tools;
- To reproduce this study with a larger sample, in health centers and with a longer follow-up (12 month);

- Analyze the effect of self-efficacy as a mediator for other evaluated outcomes.

References

1. Branco JC, Rodrigues AM, Gouveia N, Eusébio M, Ramiro S, Machado PM, et al. Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt– a national health survey. Rheumatic & Musculoskeletal Diseases Open. 2016; 2(1): e000166.

2. Buckwalter JA, Martin JA. Osteoarthritis. Advanced Drug Delivery Reviews. 2006; 58(2):150-167.

3. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Annals of the Rheumatic Diseases. 1957; 16(4):494-502.

4. Lachance L, Sowers M, Jamadar D, Jannausch M, Hochberg M, Crutchfield M. The experience of pain and emergent osteoarthritis of the knee. Osteoarthritis and Cartilage. 2001; 9(6):527-32.

5. Morone NE, Abebe KZ, Morrow LA, Weiner DK. Pain and Decreased Cognitive Function Negatively Impact Physical Functioning in Older Adults with Knee Osteoarthritis. Pain Medicine. 2014; 15(9):1481-7.

6. Alkan BM, Fidan F, Tosun A, Ardicoglu O. Quality of life and self-reported disability in patients with knee osteoarthritis. Modern Rheumatology/The Japan Rheumatism Association. 2014; 24(1):166-71.

7. Dunlop DD, Manheim LM, Yelin EH, Song J, Chang RW. The costs of arthritis. Arthritis Care & Research. 2003; 49(1):101-13.

8. Zhang W, Nuki G, Moskowitz RW, Abramson S, Altman RD, Arden NK, et al. OARSI recommendations for the management of hip and knee osteoarthritis: Part III: changes in evidence following systematic cumulative update of research published through January 2009. Osteoarthritis and Cartilage. 2010; 18(4):476-99.

9. Fransen M, McConnell S, Harmer AR, Esch M, Simic M, Bennell KL. Exercise for osteoarthritis of the knee. The Cochrane database of systematic reviews. British Journal of Sports Medicine. 2015; 49(24):1554–7.

10. Brady TJ, Murphy L, O'Colmain BJ, Beauchesne D, Daniels B, Greenberg M. A Meta-Analysis of Health Status, Health Behaviors, and Health Care Utilization Outcomes of the Chronic Disease Self-Management Program. Preventing Chronic Disease. 2013; 10:E07.

11. Woolf AD, Pfleger B. Burden of major musculoskeletal conditions. Bulletin of the World Health Organization. 2003; 81(9):646-56.

12. Nuesch E, Dieppe P, Reichenbach S, Williams S, Iff S, Juni P. All cause and disease specific mortality in patients with knee or hip osteoarthritis: population based cohort study. British Medical Journal. 2011; 342:d1165.

13. Mendel OI, Luchihina LV, Mendel W. Aging and osteoarthritis. Chronic nonspecific inflammation as a link between aging and osteoarthritis (a review). Advances in Gerontology. 2015; 28(2):274-83.

14. Saltman DC, Sayer GP, Whicker SD. Co-morbidity in general practice. Postgraduate Medical Journal. 2005; 81(957):474-80.

15. Hochberg MC. Mortality in osteoarthritis. Clinical and Experimental Rheumatology. 2008; 26(5 Suppl 51):S120-4.

16. Bitton R. The economic burden of osteoarthritis. The American Journal of Managed Care. 2009; 15(8 Suppl):S230-5.

17. Hunter DJ, Schofield D, Callander E. The individual and socioeconomic impact of osteoarthritis. Nature Reviews Rheumatology. 2014; 10(7):437-41.

18. Salmon JH, Rat AC, Sellam J, Michel M, Eschard JP, Guillemin F, et al. Economic impact of lower-limb osteoarthritis worldwide: a systematic review of cost-of-illness studies. Osteoarthritis and Cartilage. 2016; in press:1-9.

19. Neogi T, Zhang Y. Epidemiology of osteoarthritis. Rheumatic Diseases Clinics of North America. 2013; 39(1):1-19.

20. Murray CJ, Vos T, Lozano R, Naghavi M, Flaxman AD, Michaud C, et al. Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. Lancet. 2012; 380(9859):2197-223.

21. Heidari B. Knee osteoarthritis prevalence, risk factors, pathogenesis and features: Part I. Caspian Journal of Internal Medicine. 2011; 2(2):205-12.

22. Felson DT, Naimark A, Anderson J, Kazis L, Castelli W, Meenan RF. The prevalence of knee osteoarthritis in the elderly. The Framingham Osteoarthritis Study. Arthritis and Rheumatism. 1987; 30(8):914-8.

23. Cross M, Smith E, Hoy D, Nolte S, Ackerman I, Fransen M, et al. The global burden of hip and knee osteoarthritis: estimates from the Global Burden of Disease 2010 study. Annals of the Rheumatic Diseases. 2014; 73(7):1323-30.

24. Turkiewicz A, Gerhardsson VM, Engstrom G, Nilsson PM, Mellstrom C, Lohmander LS, et al. Prevalence of knee pain and knee OA in southern Sweden and the proportion that seeks medical care. Rheumatology (Oxford, England). 2015; 54(5):827-35.

25. Prieto-Alhambra D, Judge A, Javaid MK, Cooper C, Diez-Perez A, Arden NK. Incidence and risk factors for clinically diagnosed knee, hip and hand osteoarthritis: influences of age, gender and osteoarthritis affecting other joints. Annals of the Rheumatic Diseases. 2014; 73(9):1659-64.

26. Bijlsma JW, Knahr K. Strategies for the prevention and management of osteoarthritis of the hip and knee. Best Practice & Research Clinical Rheumatology. 2007; 21(1):59-76.

27. Arokoski JP, Jurvelin JS, Väätäinen U, Helminen HJ. Normal and pathological adaptations of articular cartilage to joint loading. Scandinavian Journal of Medicine & Science in Sports. 2000; 10(4):186-98.

28. Blagojevic M, Jinks C, Jeffery A, Jordan KP. Risk factors for onset of osteoarthritis of the knee in older adults: a systematic review and meta-analysis. Osteoarthritis and Cartilage. 2010; 18(1):24-33.

29. Anderson AS, Loeser RF. Why is Osteoarthritis an Age-Related Disease? Best practice & Research Clinical Rheumatology. 2010; 24(1):15.

30. Loeser RF, Jr. Aging cartilage and osteoarthritis--what's the link? Science of Aging Knowledge Environment. 2004; 2004(29):pe31.

31. Hamerman D. Clinical implications of osteoarthritis and ageing. Annals of the Rheumatic Diseases. 1995; 54(2):82-5.

32. Delmonico MJ, Harris TB, Visser M, Park SW, Conroy MB, Velasquez-Mieyer P, et al. Longitudinal study of muscle strength, quality, and adipose tissue infiltration. The American Journal of Clinical Nutrition. 2009; 90(6):1579-85.

33. Slemenda C, Brandt KD. Quadriceps Weakness and Osteoarthritis of the Knee. Annals of Internal Medicine. 1997; 127(2):97-104.

34. Kean WF, Kean R, Buchanan WW. Osteoarthritis: symptoms, signs and source of pain. Inflammopharmacology. 2004; 12(1):3-31.

35. Segal NA, Torner JC, Felson D, Niu J, Sharma L, Lewis CE, et al. Effect of thigh strength on incident radiographic and symptomatic knee osteoarthritis in a longitudinal cohort. Arthritis Care & Research. 2009; 61(9):1210-7.

36. Murphy L, Schwartz TA, Helmick CG, Renner JB, Tudor G, Koch G, et al. Lifetime risk of symptomatic knee osteoarthritis. Arthritis and Rheumatism. 2008; 59(9):1207-13.

37. Messier SP, Legault C, Loeser RF, Van Arsdale SJ, Davis C, Ettinger WH, et al. Does high weight loss in older adults with knee osteoarthritis affect bone-on-bone joint loads and muscle forces during walking? Osteoarthritis and Cartilage. 2011; 19(3):272-80.

38. Visser AW, de Mutsert R, Loef M, le Cessie S, den Heijer M, Bloem JL, et al. The role of fat mass and skeletal muscle mass in knee osteoarthritis is different for men and women: the NEO study. Osteoarthritis and Cartilage. 2014; 22(2):197-202.

39. Allen KD, Golightly YM. Epidemiology of osteoarthritis: state of the evidence. Current Opinion in Rheumatology. 2015; 27(3):276-83.

40. Harkey MS, Luc BA, Golightly YM, Thomas AC, Driban JB, Hackney AC, et al. Osteoarthritis-related biomarkers following anterior cruciate ligament injury and reconstruction: a systematic review. Osteoarthritis and cartilage. 2015; 23(1):1-12.

41. Papalia R, Del Buono A, Osti L, Denaro V, Maffulli N. Meniscectomy as a risk factor for knee osteoarthritis: a systematic review. British Medical Bulletin. 2011; 99:89-106.

42. Driban JB, Eaton CB, Lo GH, Ward RJ, Lu B, McAlindon TE. Association of knee injuries with accelerated knee osteoarthritis progression: data from the Osteoarthritis Initiative. Arthritis Care Res (Hoboken). 2014; 66(11):1673-9.

43. Johnson VL, Hunter DJ. The epidemiology of osteoarthritis. Best Practice & Research Clinical Rheumatology. 2014; 28(1):5-15.

44. Nevitt MC, Felson DT. Sex hormones and the risk of osteoarthritis in women: epidemiological evidence. Annals of the Rheumatic Diseases. 1996; 55(9):673-6.

45. Spector TD, Campion GD. Generalised osteoarthritis: a hormonally mediated disease. Annals of the Rheumatic Diseases. 1989;48(6):523-7.

46. Cooper C. Occupational activity and the risk of osteoarthritis. The Journal of Rheumatology Supplement. 1995; 43:10-2.

47. Zeller L, Sukenik S. The association between sports activity and knee osteoarthritis. Harefuah. 2008; 147(4):315-9, 74.

48. Hinton R, Moody RL, Davis AW, Thomas SF. Osteoarthritis: diagnosis and therapeutic considerations. American Family Physician. 2002; 65(5):841-8.

49. Dieppe PA, Lohmander LS. Pathogenesis and management of pain in osteoarthritis. The Lancet. 2005; 365(9463):965-73.

50. Brandt KD, Dieppe P, Radin E. Etiopathogenesis of osteoarthritis. The Medical Clinics of North America. 2009; 93(1):1-24.

51. Maly MR, Costigan PA, Olney SJ. Mechanical factors relate to pain in knee osteoarthritis. Clinical Biomechanics (Bristol). 2008; 23(6):796-805.

52. Fink WA, Jr. The pathophysiology of acute pain. Emergency Medicine Clinics of North America. 2005; 23(2):277-84.

53. Felson DT, McLaughlin S, Goggins J, LaValley MP, Gale ME, Totterman S, et al. Bone marrow edema and its relation to progression of knee osteoarthritis. Annals of Internal Medicine. 2003; 139(5 Pt 1):330-6.

54. McCrae F, Shouls J, Dieppe P, Watt I. Scintigraphic assessment of osteoarthritis of the knee joint. Annals of the Rheumatic Diseases. 1992; 51(8):938-42.

55. Creamer P, Hunt M, Dieppe P. Pain mechanisms in osteoarthritis of the knee: effect of intraarticular anesthetic. The Journal of Rheumatology. 1996; 23(6):1031-6.

56. Kidd BL, Inglis JJ, Vetsika K, Hood VC, De Felipe C, Bester H, et al. Inhibition of inflammation and hyperalgesia in NK-1 receptor knock-out mice. NeuroReport. 2003; 14(17):2189-92.

57. Melzack R, Coderre TJ, Katz J, Vaccarino AL. Central neuroplasticity and pathological pain. Annals of the New York Academy of Sciences. 2001; 933:157-74.

58. Camanho GL, Imamura M, Arendt-Nielsen L. Genesis of pain in arthrosis. Revista Brasileira de Ortopedia. 2011; 46(1):14-7.

59. Creamer P, Lethbridge-Cejku M, Hochberg MC. Factors associated with functional impairment in symptomatic knee osteoarthritis. Rheumatology. 2000; 39(5):490-6.

60. Scott D, Blizzard L, Fell J, Jones G. Prospective study of self-reported pain, radiographic osteoarthritis, sarcopenia progression, and falls risk in community-dwelling older adults. Arthritis Care & Research. 2012; 64(1):30-7.

61. Tanimura C, Morimoto M, Hiramatsu K, Hagino H. Difficulties in the daily life of patients with osteoarthritis of the knee: scale development and descriptive study. Journal of Clinical Nursing. 2011; 20(5-6):743-53.

62. Neogi T. The epidemiology and impact of pain in osteoarthritis. Osteoarthritis and Cartilage. 2013; 21(9):1145-53.

63. White DK, Niu J, Zhang Y. Is symptomatic knee osteoarthritis a risk factor for a trajectory of fast decline in gait speed? Results from a longitudinal cohort study. Arthritis Care & Research (Hoboken). 2013; 65(2):187-94.

64. Guccione AA, Felson DT, Anderson JJ. Defining arthritis and measuring functional status in elders: methodological issues in the study of disease and physical disability. American Journal of Public Health. 1990; 80(8):945-9.

65. Peat G, McCarney R, Croft P. Knee pain and osteoarthritis in older adults: a review of community burden and current use of primary health care. Annals of the Rheumatic Diseases. 2001; 60(2):91-7.

66. McDonough CM, Jette AM. The contribution of osteoarthritis to functional limitations and disability. Clinics in Geriatric Medicine. 2010; 26(3):387-99.

67. McHorney CA. Health status assessment methods for adults: past accomplishments and future challenges. Annual Review of Public Health. 1999; 20:309-35.

68. Sharma L, Cahue S, Song J, Hayes K, Pai YC, Dunlop D. Physical functioning over three years in knee osteoarthritis: role of psychosocial, local mechanical, and neuromuscular factors. Arthritis and Rheumatism. 2003; 48(12):3359-70.

69. Salaffi F, Carotti M, Stancati A, Grassi W. Health-related quality of life in older adults with symptomatic hip and knee osteoarthritis: a comparison with matched healthy controls. Aging Clinical and Experimental Research. 2005; 17(4):255-63.

70. Altman R, Asch E, Bloch D, Bole G, Borenstein D, Brandt K, et al. Development of criteria for the classification and reporting of osteoarthritis. Classification of osteoarthritis of the knee. Diagnostic and Therapeutic Criteria Committee of the American Rheumatism Association. Arthritis and Rheumatism. 1986; 29(8):1039-49.

71. Watt I DM. Plain radiographic features of osteoarthritis. In: Brandt K DM, Lohmander LS, editor. Osteoarthritis. 2nd. Oxford: Oxford University Press; 2003. p. 211–25.

72. Petersson IF, Jacobsson LT. Osteoarthritis of the peripheral joints. Best Practice & Research Clinical Rheumatology. 2002; 16(5):741-60.

73. Zhang W, Moskowitz RW, Nuki G, Abramson S, Altman RD, Arden N, et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis and Cartilage. 2008; 16(2):137-62.

74. Roos EM, Juhl CB. Osteoarthritis 2012 year in review: rehabilitation and outcomes. Osteoarthritis and cartilage. 2012; 20(12):1477-83.

75. Sanders C, Donovan JL, Dieppe PA. Unmet need for joint replacement: a qualitative investigation of barriers to treatment among individuals with severe pain and disability of the hip and knee. Rheumatology (Oxford, England). 2004; 43(3):353-7.

76. McAlindon TE, Bannuru RR, Sullivan MC, Arden NK, Berenbaum F, Bierma-Zeinstra SM, et al. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and Cartilage. 2014; 22(3):363-88.

77. Fernandes L, Hagen KB, Bijlsma JWJ, Andreassen O, Christensen P, Conaghan PG, et al. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Annals of the Rheumatic Diseases. 2013; 72(7):1125-1135.

78. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care & Research. 2012; 64(4):465-74.

79. Marques A, Branco JC, Costa JT, Miranda LC, Almeida M, Reis P, et al. Programa Nacional Contra as Doenças Reumáticas. Direção Geral de Saúde ed2005.

80. Nie L, Xie B, Yang Y, Shan YM. Characteristics of Chinese m-Health Applications for Diabetes Self-Management. Telemedicine and e-Health. 2016.

81. Aaron M, Nelson BW, Kaltsas E, Brown RW, Thomas LJ, Patel MR. Impact of Goal Setting and Goal Attainment Methods on Asthma Outcomes: Findings From an Asthma Self-Management Intervention for African American Women. Health education & behavior : the official publication of the Society for Public Health Education. 2016.

82. Miller M, Zrim S, Lawn S, Woodman R, Leggett S, Jones L, et al. A Pilot Study of Self-Management-based Nutrition and Physical Activity Intervention in Cancer Survivors. Nutrition and cancer. 2016:1-10.

83. Barlow J. How to use education as an intervention in osteoarthritis. Best practice & Research Clinical Rheumatology. 2001; 15(4):545-58.

84. Clark NM, Becker MH, Janz NK, Lorig K, Rakowski W, Anderson L. Self-Management of Chronic Disease by Older Adults: A Review and Questions for Research. Journal of Aging and Health. 1991; 3(1):3-27.

85. Jonhston SL, Clare; Ives, Sarah Mae; Soto, Enrique. Literature Review on Chronic Disease Self-Management. The Champlain Local Health Integration Network. 2008.

86. Lawn SBM. Capabilities for supporting prevention and chronic condition self-management: A resource for educators of primary health care professionals. Flinders University, Adelaide: Australian Government Department of Health and Ageing; 2009.

87. Tattersall RL. The expert patient: a new approach to chronic disease management for the twenty-first century. Clinical Medicine (London, England). 2002; 2(3):227-9.

88. Lorig K, Holman H. Self-management education: History, definition, outcomes, and mechanisms. Annals of Behavioral Medicine. 2003; 26(1):1-7.

89. Bandura A, Walters RH. Social learning theory. NJ: Prentice Hall: Englewood Cliffs; 1977.

90. Lorig K, Fries JF. The Arthritis Helpbook: A Tested Self-management Program for Coping with Arthritis and Fibromyalgia: Da Capo Lifelong; 2009.

91. Barlow JH, Turner AP, Wright CC. A randomized controlled study of the Arthritis Self-Management Programme in the UK. Health Education Research. 2000; 15(6):665-80.

92. Coleman S, Briffa NK, Carroll G, Inderjeeth C, Cook N, McQuade J. A randomised controlled trial of a self-management education program for osteoarthritis of the knee delivered by health care professionals. Arthritis Research & Therapy. 2012; 14(1):R21.

93. Lorig KR, Ritter PL, Laurent DD, Plant K. The internet-based arthritis self-management program: A one-year randomized trial for patients with arthritis or fibromyalgia. Arthritis Care & Research. 2008; 59(7):1009-17.

94. Goeppinger J, Armstrong B, Schwartz T, Ensley D, Brady TJ. Self-management education for persons with arthritis: Managing comorbidity and eliminating health disparities. Arthritis Care & Research. 2007; 57(6):1081-8.

95. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care--a randomized controlled trial. BMC Musculoskelet Disord. 2010;11:244.

96. Nuñez M, Nuñez E, Segur JM, Macule F, Quinto L, Hernandez MV, et al. The effect of an educational program to improve health-related quality of life in patients with osteoarthritis on waiting list for total knee replacement: a randomized study. Osteoarthritis and Cartilage. 2006; 14(3):279-85.

97. Ahn S, Basu R, Smith ML, Jiang L, Lorig K, Whitelaw N, et al. The impact of chronic disease self-management programs: healthcare savings through a community-based intervention. BMC Public Health. 2013; 13(1):1-6.

98. Cottrell E, Roddy E, Foster NE. The attitudes, beliefs and behaviours of GPs regarding exercise for chronic knee pain: a systematic review. BMC Family Practice. 2010; 11(1):1-9.

99. Bennell KL, Dobson F, Hinman RS. Exercise in osteoarthritis: moving from prescription to adherence. Best Practice & Research Clinical Rheumatology. 2014; 28(1):93-117.

100. Uthman OA, van der Windt DA, Jordan JL, Dziedzic KS, Healey EL, Peat GM, et al. Exercise for lower limb osteoarthritis: systematic review incorporating trial sequential analysis and network meta-analysis. 2013; 347:f5555.

101. Fransen M, McConnell S. Land-based Exercise for Osteoarthritis of the Knee: A Metaanalysis of Randomized Controlled Trials. The Journal of Rheumatology. 2009; 36(6):1109-17.

102. Brosseau L, Pelland L, Wells G, Macleay L, Lamothe C, Michaud G, et al. Efficacy of Aerobic Exercises For Osteoarthritis (Part II): A Meta-analysis. Physical Therapy Reviews. 2004; 9(3):125-45.

103. Pelland L, Brosseau L, Wells G, Macleay L, Lambert J, Lamothe C, et al. Efficacy of strengthening exercises for osteoarthritis (Part I): A meta-analysis. Physical Therapy Reviews. 2004; 9(2):77-108.

104. Pisters MF, Veenhof C, van Meeteren NL, Ostelo RW, de Bakker DH, Schellevis FG, et al. Long-term effectiveness of exercise therapy in patients with osteoarthritis of the hip or knee: a systematic review. Arthritis and Rheumatism. 2007; 57(7):1245-53.

105. Damush TM, Perkins SM, Mikesky AE, Roberts M, O'Dea J. Motivational factors influencing older adults diagnosed with knee osteoarthritis to join and maintain an exercise program. Journal of Aging and Physical Aactivity. 2005; 13(1):45-60.

106. Campbell R, Evans M, Tucker M, Quilty B, Dieppe P, Donovan JL. Why don't patients do their exercises? Understanding non-compliance with physiotherapy in patients with osteoarthritis of the knee. Journal of Epidemiology & Community Health. 2001; 55(2):132-8.

107. Petursdottir U, Arnadottir SA, Halldorsdottir S. Facilitators and barriers to exercising among people with osteoarthritis: a phenomenological study. Physical Therapy. 2010; 90(7):1014-25.

108. Hendry M, Williams NH, Markland D, Wilkinson C, Maddison P. Why should we exercise when our knees hurt? A qualitative study of primary care patients with osteoarthritis of the knee. Family Practice. 2006; 23(5):558-67.

109. McAlindon TE, Bannuru RR, Sullivan MC, Arden NK, Berenbaum F, Bierma-Zeinstra SM. OARSI guidelines for the non-surgical management of knee osteoarthritis. Osteoarthritis and Cartilage. 2014; 22(3):363-388.

110. Maurer BT, Stern AG, Kinossian B, Cook KD, Schumacher Jr HR. Osteoarthritis of the knee: Isokinetic quadriceps exercise versus an educational intervention. Archives of Physical Medicine and Rehabilitation. 1999; 80(10):1293-9.

111. Gür H, Çakın N, Akova B, Okay E, Küçükoğlu S. Concentric versus combined concentric-eccentric isokinetic training: Effects on functional capacity and symptoms in patients with osteoarthrosis of the knee. Archives of Physical Medicine and Rehabilitation. 2002; 83(3):308-16.

112. Huang M-H, Lin Y-S, Yang R-C, Lee C-L. A comparison of various therapeutic exercises on the functional status of patients with knee osteoarthritis. Seminars in Arthritis and Rheumatism. 2003; 32(6):398-406.

113. Levy SS, Macera CA, Hootman JM, Coleman KJ, Lopez R, Nichols JF, et al. Evaluation of a multi-component group exercise program for adults with arthritis: Fitness and Exercise for People with Arthritis (FEPA). Disability and Health Journal. 2012; 5(4):305-11.

114. Callahan LF, Mielenz T, Freburger J, Shreffler J, Hootman J, Brady T, et al. A randomized controlled trial of the people with arthritis can exercise program: symptoms, function, physical activity, and psychosocial outcomes. Arthritis and Rheumatism. 2008; 59(1):92-101.

115. Ageberg E, Link A, Roos EM. Feasibility of neuromuscular training in patients with severe hip or knee OA: The individualized goal-based NEMEX-TJR training program. BMC Musculoskeletal Disorders. 2010; 11(1):1-7.

116. Wang C, Schmid CH, Hibberd PL, Kalish R, Roubenoff R, Rones R, et al. Tai Chi is effective in treating knee osteoarthritis: A randomized controlled trial. Arthritis Care & Research. 2009; 61(11):1545-53.

117. Society AG. Exercise prescription for older adults with osteoarthritis pain: consensus practice recommendations. A supplement to the AGS Clinical Practice Guidelines on the management of chronic pain in older adults. Journal of the American Geriatrics Society 2001; 49(6):808-23.

118. Jan M-H, Lin C-H, Lin Y-F, Lin J-J, Lin D-H. Effects of Weight-Bearing Versus Nonweight-Bearing Exercise on Function, Walking Speed, and Position Sense in Participants With Knee Osteoarthritis: A Randomized Controlled Trial. Archives of Physical Medicine and Rehabilitation. 2009; 90(6):897-904.

119. Jan M, Lin J, Liau J, Lin Y, Lin D. Investigation of clinical effects of high- and low-resistance training for patients with knee osteoarthritis: a randomized controlled trial. Physical Therapy 2008; 88:427–436.

120. Bridle C, Spanjers K, Patel S, Atherton NM, Lamb SE. Effect of exercise on depression severity in older people: systematic review and meta-analysis of randomised controlled trials. The British Journal of Psychiatry. 2012; 201(3):180-185.

121. Arnold CM, Gyurcsik NC. Risk factors for falls in older adults with lower extremity arthritis: a conceptual framework of current knowledge and future directions. Physiotherapy Canada Physiotherapie Canada. 2012; 64(3):302-314.

122. Fitzgerald GK, Piva SR, Gil AB, Wisniewski SR, Oddis CV, Irrgang JJ. Agility and perturbation training techniques in exercise therapy for reducing pain and improving function in people with knee osteoarthritis: a randomized clinical trial. Physical Therapy. 2011;91(4): 452-69.

123. Chmelo E, Nicklas B, Davis C, Miller GD, Legault C, Messier S. Physical Activity and Physical Function in Older Adults With Knee Osteoarthritis. Journal of Physical Activity & Health. 2013; 10(6):777-83.

124. Fransen M, McConnell S, R. HA, Van der Esch M, Simic M, Bennell K. Exercise for osteoarthritis of the knee. Cochrane Database Systematic Reviews. 2015; 4:Cd004376.

125. American College of Sports Medicine. ACSM´s Guidelines for Exercise Testing and Prescription. Lippincott Williams & Wilkins. Ninth edition; 2013.

126. Ritter PL, Gonzalez VM, Laurent DD, Lorig KR. Measurement of pain using the visual numeric scale. Journal of Rheumatology. 2006; 33(3):574-80.

127. Penninx B, Messier, S., Rejeski, W., Williamson, J., DiBari, M., Cavazzini, C. et. al. Physical Exercise and the Prevention of Disability in Activities of Daily Living in Older Persons With Osteoarthritis. American Journal of Health Promotion. 2003; 17(3):217.

128. Kao M-J, Wu M-P, Tsai M-W, Chang W-W, Wu S-F. The effectiveness of a self-management program on quality of life for knee osteoarthritis (OA) patients. Archives of Gerontology and Geriatrics. 2012; 54(2):317-24.

129. Yip YB, Sit JWH, Fung KKY, Wong DYS, Chong SYC, Chung LH, et al. Effects of a self-management arthritis programme with an added exercise component for osteoarthritic knee: randomized controlled trial. Journal of Advanced Nursing. 2007; 59(1):20-8.

130. Jessep SA, Walsh NE, Ratcliffe J, Hurley MV. Long-term clinical benefits and costs of an integrated rehabilitation programme compared with outpatient physiotherapy for chronic knee pain. Physiotherapy. 2009; 95(2):94-102.

131. Mendelson AD, McCullough, C., Chan, A. Integrating self-management and exercise for people living with arthritis. Health education research. 2011; 26(1):167-77.

132. Hughes SL, Seymour RB, Campbell R, Pollak N, Huber G, Sharma L. Impact of the fit and strong intervention on older adults with osteoarthritis. The Gerontologist. 2004; 44(2):217-28.

133. McKnight PE, Kasle S, Going S, Villanueva I, Cornett M, Farr J, et al. A comparison of strength training, self-management, and the combination for early osteoarthritis of the knee. Arthritis Care & Research (Hoboken). 2010; 62(1):45-53.

134. Skou ST, Rasmussen S, Laursen MB, Rathleff MS, Arendt-Nielsen L, Simonsen O, et al. The efficacy of 12 weeks non-surgical treatment for patients not eligible for total knee replacement: a randomized controlled trial with 1-year follow-up. Osteoarthritis and Cartilage. 2015; 23:1465-75.

135. Messier SP, Loeser RF, Miller GD, Morgan TM, Rejeski WJ, Sevick MA, et al. Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: the Arthritis, Diet, and Activity Promotion Trial. Arthritis and Rheumatism. 2004; 50(5):1501-10.

136. Messier SP, Loeser RF, Miller GD, Morgan TM, Rejeski WJ, Sevick MA, et al. Exercise and dietary weight loss in overweight and obese older adults with knee osteoarthritis: The arthritis, diet, and activity promotion trial. Arthritis & Rheumatism. 2004; 50(5):1501-10.

137. Skou ST, Simonsen ME, Odgaard A, Roos EM. Predictors of long-term effect from education and exercise in patients with knee and hip pain. Danish Medical Journal. 2014; 61(7):A4867.

138. Gaby AR. Natural treatments for osteoarthritis. Alternative Medicine Review. 1999; 4(5):330-41.

139. Towheed TE. Published meta-analyses of pharmacological therapies for osteoarthritis. Osteoarthritis and cartilage. 2002; 10(11):836-7.

140. Herman CJ, Allen P, Hunt WC, Prasad A, Brady TJ. Use of complementary therapies among primary care clinic patients with arthritis. Preventing Chronic Disease. 2004; 1(4):A12.

141. Berman BM, Bausell RB, Lee WL. Use and referral patterns for 22 complementary and alternative medical therapies by members of the American College of Rheumatology: results of a national survey. Archives of Internal Medicine. 2002; 162(7):766-70.

142. Gregory PJ, Sperry M, Wilson AF. Dietary supplements for osteoarthritis. American Family Physician. 2008; 77(2):177-84.

143. Henrotin Y, Marty M, Mobasheri A. What is the current status of chondroitin sulfate and glucosamine for the treatment of knee osteoarthritis? Maturitas. 2014; 79(4):487.

144. Irsay L, Borda MI, Nitu AD, Ciortea V, Onac I, Ungur R. Effectiveness of Glucosamine and Chondroitin Sulfate Combination in Patients with Primary Osteoarthritis. Applied Medical Informatics. 2010; 27(4):47-54.

145. Verbruggen G. Chondroprotective drugs in degenerative joint diseases. Rheumatology (Oxford, England). 2006; 45(2):129-38.

146. Lopes Júnior OV, Inácio eAM. Uso de glucosamina e condroitina no tratamento da osteoartrose: uma revisão da literatura. Revista Brasileira de Ortopedia. 2013; 48(4):300-6.

147. McCarty MF. The neglect of glucosamine as a treatment for osteoarthritis--a personal perspective. Medical Hypotheses. 1994; 42(5):323-7.

148. Toffoletto O, Tavares A, Casarini DE, Redublo BM, Ribeiro AB. Farmacocinética da associação de glucosamina e sulfato de condroitina em humanos sadios do sexo masculino. Acta Ortopédica Brasileira. 2005; 13:235-7.

149. McAlindon TE, LaValley MP, Gulin JP, Felson DT. Glucosamine and chondroitin for treatment of osteoarthritis: a systematic quality assessment and meta-analysis. JAMA Internal Medicine 2000; 283(11):1469-75.

150. Eriksen P, Bartels EM, Altman RD, Bliddal H, Juhl C, Christensen R. Risk of bias and brand explain the observed inconsistency in trials on glucosamine for symptomatic relief of

osteoarthritis: a meta-analysis of placebo-controlled trials. Arthritis Care & Research (Hoboken). 2014; 66(12):1844-55.

151. Hochberg MC, Martel-Pelletier J, Monfort J, Moller I, Castillo JR, Arden N, et al. Combined chondroitin sulfate and glucosamine for painful knee osteoarthritis: a multicentre, randomised, double-blind, non-inferiority trial versus celecoxib. Annals of the Rheumatic Diseases. 2016; 75(1):37-44.

152. Stratford PW, Kennedy DM. Performance measures were necessary to obtain a complete picture of osteoarthritic patients. J Clin Epidemiol. 2006; 59(2):160-7.

153. Fitzpatrick R, Davey C, Buxton MJ, Jones DR. Evaluating patient-based outcome measures for use in clinical trials. Health Technology Assessment. 1998; 2(14):i-iv, 1-74.

154. Beaton DE, Schemitsch E. Measures of health-related quality of life and physical function. Clinical Orthopaedics and Related Research. 2003; (413):90-105.

155. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. The Journal of Rheumatology. 1988; 15(12), 1833-1840.

156. Lequesne MG, Mery C, Samson M, Gerard P. Indexes of severity for osteoarthritis of the hip and knee. Validation value in comparison with other assessment tests. Scandinavian Journal of Rheumatology Supplement. 1987; 65:85-9.

157. Ware JE, Sherbourne CD. The MOS-item short-form health survey (SF-36):I. Conceptual framework and item selection. Medical Care. 1992; 30: 473-483.

158. McHorney CA, Ware JE, Jr., Raczek AE. The MOS 36-Item Short-Form Health Survey (SF-36): II. Psychometric and clinical tests of validity in measuring physical and mental health constructs. Medical Care. 1993; 31(3):247-63.

159. EuroQol. EuroQol--a new facility for the measurement of health-related quality of life. Health Policy. 1990; 16(3):199-208.

160. Bruce B, Fries JF. The Stanford health assessment questionnaire (HAQ): a review of its history, issues, progress, and documentation. Jounal of Rheumatologt. 2003; 30(1):167-178.

161. Dobson F, Hinman RS, Roos EM, Abbott JH, Stratford P, Davis AM, et al. OARSI recommended performance-based tests to assess physical function in people diagnosed with hip or knee osteoarthritis. Osteoarthritis and cartilage / OARS, Osteoarthritis Research Society. 2013;21(8):1042-52.

162. Cruz-Jentoft AJ, Baeyens JP, Bauer JM, Boirie Y, Cederholm T, Landi F, et al. Sarcopenia: European consensus on definition and diagnosis: Report of the European Working Group on Sarcopenia in Older People. Age and Ageing. 2010; 39(4):412-23.

163. Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, et al. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. Journal of Gerontology. 1994; 49(2):M85-94.

164. Hurst H, Bolton J. Assessing the clinical significance of change scores recorded on subjective outcome measures. Journal of Manipulative and Physiological Therapeutics. 2004; 27(1):26-35.

165. Cohen J. Statistical power analysis for the behavioral sciences. Hillsdale, NJ: Lawrence Erlbaum Associates; 1998.

166. Fernandes L, Hagen KB, Bijlsma JWJ, Andreassen O, Christensen P, Conaghan PG. EULAR recommendations for the non-pharmacological core management of hip and knee osteoarthritis. Annals of the Rheumatic Diseases. 2013; 72(7): 1125-1135.

167. Hochberg MC, Altman RD, April KT, Benkhalti M, Guyatt G, McGowan J. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care and Research. 2012; 64(4): 465-474.

168. Marconcin P, Espanha M, Yázigi F, Campos P. The PLE2NO self-management and exercise program for knee osteoarthritis: Study Protocol for a Randomized Controlled Trial. BMC Musculoskeletal Disorders. 2016; 17(1):1-12.

169. Roos EM, Lohmander LS. The Knee injury and Osteoarthritis Outcome Score (KOOS): from joint injury to osteoarthritis. Health Qual Life Outcomes. 2003; 1(1):1

170. Sabirli F, Paker N, Bugdayci D. The relationship between Knee Injury and Osteoarthritis Outcome Score (KOOS) and Timed Up and Go test in patients with symptomatic knee osteoarthritis. Rheumatology International. 2013; 33(10):2691-4.

171. Oliveira AM, Peccin MS, Silva KN, Teixeira LE, Trevisani VF. Impact of exercise on the functional capacity and pain of patients with knee osteoarthritis: a randomized clinical trial. Revista Brasileira de Reumatologia. 2012; 52(6):876-82.

172. Wright AA, Cook CE, Baxter GD, Garcia J, Abbott JH. Relationship between the Western Ontario and McMaster Universities Osteoarthritis Index Physical Function Subscale and physical performance measures in patients with hip osteoarthritis. Archives of Physical Medicine and Rehabilitation 2010; 91(10):1558-64.

173. Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. Journal of the American Geriatrics Society. 1991; 39(2):142-148.

174. Rikli RE, Jones CJ. The reliability and validity of a 6-minute walk test as a measure of physical endurance in older adults. Journal of Aging and Physical Activity. 1998; 6:363-375

175. Yázigi F, Espanha M, Messier S. P. Knee Osteoarthritis and Obesity: Effectiveness of PICO Aquatic Exercise Program on Symptoms, Physical Fitness and Quality of Life. Oeiras: Universidade de Lisboa; 2014.

176. Ageberg E, Nilsdotter A, Kosek E, Roos EM. Effects of neuromuscular training (NEMEX-TJR) on patient-reported outcomes and physical function in severe primary hip or knee osteoarthritis: a controlled before-and-after study. BMC Musculoskelet Disorders. 2013; 14(1).

177. Moos RH, Holahan CJ. Dispositional and contextual perspectives on coping: toward an integrative framework. Journal of Clinical Psychology. 2003; 59(12):1387-403.

178. Powers DV, Gallagher-Thompson D, Kraemer HC. Coping and depression in Alzheimer's caregivers: longitudinal evidence of stability. The Journals of Gerontology Series B, Psychological sciences and social sciences. 2002;57(3):205-11.

179. Rosenberger PH, Ickovics JR, Epel ES, D'Entremont D, Jokl P. Physical recovery in Arthroscopic knee surgery: unique contributions of coping behaviors to clinical outcomes and stress reactivity. Psychology & Health. 2004; 19(3):307-20.

180. Hampson SE, Glasgow RE, Zeiss AM. Coping with osteoarthritis by older adults. Arthritis Care and Research. 1996; 9(2):133-41.

181. Brown GK, Nicassio PM. Development of a questionnaire for the assessment of active and passive coping strategies in chronic pain patients. Pain. 1987; 31(1):53-64.

182. van Dijk GM, Dekker J, Veenhof C, van den Ende CH. Course of functional status and pain in osteoarthritis of the hip or knee: a systematic review of the literature. Arthritis and Rheumatism. 2006; 55(5):779-85.

183. Lorig KR, Sobel DS, Ritter PL, Laurent D, Hobbs M. Effect of a self-management program on patients with chronic disease. Effective Clinical Practice. 2001; 4(6):256-62.

184. Clegg DO, Reda DJ, Harris CL, Klein MA, O'Dell JR, Hooper MM, et al. Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis. New England Journal of Medicine. 2006; 354(8):795-808.

185. Sharma L. Osteoarthritis year in review 2015: clinical. Osteoarthritis and Cartilage. 2016; 24(1):36-48.

186. Clegg DO, Reda DJ, Harris CL, Klein MA, O'Dell JR, Hooper MM. Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis. The New England Journal of Medicine. 2006; 354(8), 795-808.

187. Erhan B, Gündüz B, Üstünel SH, Bardak AN, SavaŞ F, Iska G, et al. The Efficacy of Topical Glucosamine Sulfate-Chondroitin Sulfate in Knee Osteoarthritis Treated With Physical Therapy: A Randomized, Double-Blind, Placebo-Controlled Study. Turkish Journal of Physical Medicine & Rehabilitation. 2012; 58:194-8.

188. Hansson EE, Jonsson-Lundgren M, Ronnheden AM, Sorensson E, Bjarnung A, Dahlberg LE. Effect of an education programme for patients with osteoarthritis in primary care: a randomized controlled trial. BMC Musculoskelet Disord. 2010;11(1).

189. Naylor JM, Hayen A, Davidson E, Hackett D, Harris IA, Kamalasena G, et al. Minimal detectable change for mobility and patient-reported tools in people with osteoarthritis awaiting arthroplasty. BMC Musculoskeletal Disorders. 2014; 15(1):1-9.

190. Tanaka R, Ozawa J, Kito N, Moriyama H. Efficacy of strengthening or aerobic exercise on pain relief in people with knee osteoarthritis: a systematic review and meta-analysis of randomized controlled trials. Clinical Rehabilitation. 2013; 27(12):1059-71.

191. Goeppinger J, Armstrong B, Schwartz T, Ensley D, Brady TJ. Self-management education for persons with arthritis: Managing comorbidity and eliminating health disparities. Arthritis Care and Research. 2007;57(6):1081-88.

192. Barlow JH, Turner AP, Wright CC. A randomized controlled study of the Arthritis Self-Management Programme in the UK. Health Education Research. 2000; 15(6):665-680.

193. Hurley M, Scott D, Rees J, Newham D. Sensorimotor changes and functional performance in patients with knee osteoarthritis. Annals of the Rheumatic Diseases. 1997; 56(11):641-8.

Appendices

Appendix 1: Assessment List of the PLE^{2}NO program

Assessment/Tests	Pre-screening	Baseline	3 month	6 month
Radiology				
Knee X-ray	X			
Questionnaires				
PLENO´s eligibility questionnaire	X			
Knee Injury and Osteoarthritis Outcome Score (KOOS)		X	X	X
Self-efficacy for managing Chronic Disease 6-Item Scale		X	X	X
Cognitive Symptom Management and Communication with Physicians		X	X	X
Euroquol five dimensions five level (EuroQol -EQ-5D-5L)		X	X	X
International Physical Activity Questionnaire (IPAQ)		X	X	X
Brief COPE		X	X	X
Patient's Global Impression of Change (PGIC)			X	X
Physical Function				
Six-Minute Walking Test (6 MWT)		X	X	X
Five-Repetition Sit to Stand Test (FRSTST)		X	X	X
Timed "Up-and-Go" test (TUG)		X	X	X
Back Scratch Test (BST)		X	X	X
Chair Sit and Reach (CRS)		X	X	X
6-Meter Test		X	X	X
Standing Balance		X	X	X
Hand grip test		X	X	X

Appendix 2: Informed consent

INFORMAÇÃO E CONSENTIMENTO INFORMADO

Está a ser convidado (a) a participar num projecto de investigação que pretende estudar os efeitos de um programa de intervenção na Osteoartrose do Joelho. A seleção para a participação baseia-se nos critérios de elegibilidade do estudo (idade acima de 60 anos, OA unilateral ou bi do joelho diagnosticada por médicos reumatologistas, de acordo com os critérios clínicos e radiológicos do Colégio Americano de Reumatologia, não estar envolvido em outro programa de intervenção (exercício, educacional ou fisioterapia), ter locomoção independente, não fazer uso de suplementação sulfato de condroitina e/ou glucosamina nos últimos 3 meses, não ter feito aplicações (injecções) de corticóides ou ácido hialurónico nos últimos 6 meses.

No caso de confirmação de diagnóstico, o participante compromete-se através deste documento a continuar a sua participação no estudo. A aceitação na participação deste projecto implica um compromisso mútuo no cumprimento dos seguintes aspectos:

1. Como participante será integrado aleatoriamente num dos dois grupos:

    - Grupo 1: será submetido a um programa de Educação e de Exercício durante três meses, duas vezes por semana, num dos locais: Universidade Sénior de Carnaxide, Junta de Freguesia de Linda a Velha, Universidade Sénior Nova Atena e Assembleia de Deus de Algés. Poderá escolher o local consoante a sua conveniência. E receberá o suplemento de Sulfato de Condroitina e Glucosamina para tomar duas vezes ao dia.
    - Grupo 2: Receberá uma brochura com recomendações educacionais e de Exercício para serem seguidas individualmente, e ainda, o suplemento de Sulfato de Condroitina e Glucosamina para tomar duas vezes ao dia.

2. Todos os participantes terão de realizar testes de aptidão física e do estado de saúde em geral, em três momentos distintos, antes do início do programa (Janeiro), no final do programa (Abril), e três meses após o final (Julho). As avaliações serão sempre na Faculdade de Motricidade Humana e a deslocação será da responsabilidade do participante. Todos os testes serão realizados por profissionais especializados e de acordo com as normas científicas.

3. Os custos do programa, dos testes e do seguro de acidentes pessoais serão suportados pelo projecto.

4. O programa não possui riscos associados, além dos já conhecidos riscos de qualquer prática de exercício físico, contudo é provável que após a atividade possa sentir um aumento da dor, sendo considerado aceitável um aumento da dor até o nível 5 numa escala numérica da dor (0 = sem dor, 10 = dor insuportável).
   O uso da suplementação deverá ser feito somente se não possuir alergia a qualquer um dos componentes constituintes, nomeadamente a glucosamina, a condroitina, o ácido

hialurónico, e o extracto de *harpagophytum*. Não deve-se ultrapassar as quantidades diárias recomendadas. Este suplemento alimentar não deve ser utilizado como substituto de um regime alimentar variado e equilibrado. Recomenda-se precaução no caso da toma de varfarina ou no caso de doenças gastrintestinais (úlcera gástrica ou duodenal). Não está recomendado no caso de hipersensibilidade ou alergia a crustáceos. No caso de alguma reacção adversa deverá suspender a toma do suplemento e contactar o responsável do programa.

5. A informação obtida neste estudo é confidencial e não será revelada a pessoa alguma sem o seu consentimento prévio, excepto à equipa responsável e pelo estudo.

6. A equipa do PLENO compromete-se a entregar a cada participante um relatório geral com a informação da aptidão física antes e após o período de intervenção.

   Em caso de dúvida ou de necessidade de informação adicionais poderá contactar a equipa do Projecto PLENO a partir do telefone 915356604.

   A sua colaboração é imprescindível para o aprofundamento do conhecimento nesta área.

   Obrigada pela disponibilidade.

Assinatura do Consentimento Informado, Livre e Esclarecido

Li (ou alguém leu para mim) o presente documento e estou consciente do que esperar quanto à minha participação no estudo. Tive a oportunidade de colocar todas as questões e as respostas esclareceram todas as minhas dúvidas. Assim, aceito voluntariamente participar neste estudo.

_____

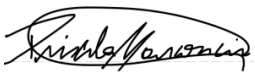
Nome do participante

_____ _____

Assinatura **Data**

Investigador/Equipa de Investigação

Os aspectos mais importantes deste estudo foram explicados ao participante ou ao seu representante, antes de solicitar a sua assinatura. Ser-lhe-á entregue uma cópia deste documento



Priscila Ellen Pinto Marconcin (Responsável do estudo)

Appendix 3: PLE^{2}NO´s eligibility questionnaire

Local:_____ Código EL_____ Código Final _____

CRITÉRIOS DE ELEGIBILIDADE

Nome Completo:	
E-mail:	Telefone:
Morada:	
Localidade:	Código Postal:
Sexo:	Idade:
Data de Nascimento:	

Assinale com um "X" a resposta "Sim", "Não" ou "Não Sei":	Sim	Não	Não Sei
1. Algum médico já lhe diagnosticou Osteoartrose no(s) joelho(s)?			
2. Costuma ter dor num ou nos dois joelhos?			
3. Se sim, a sua dor é pior de noite?			
4. Sentiu no último mês, rigidez no(s) joelho(s) de manhã ao acordar com duração inferior a 30 min? (Rigidez é uma sensação de dificuldade em iniciar o movimento (sensação de articulação presa).			
5. Costuma ouvir o(s) joelho(s) ranger, crepitar ou a fazer estalos quando se movimenta?			
6. Costuma ter o(s) joelho(s) inchado(s)?			
7. Acha que tem o(s) joelho(s) deformados?			
8. Está a frequentar algum programa supervisionado de exercícios ou sessões de fisioterapia?			
9. Consegue andar de forma independente? (Andar sem usar bengala ou canidianas (muletas))			
10. Possui outra doença (cardiovascular, respiratória, músculo-esquelética/reumática, cancro, hepática ou gastrointestinal) **que o(a) impeça de realizar atividade física?** Se sim, quais:			
11. Teve alguma lesão ou realizou alguma cirurgia ao joelho?			
12.Tomou algum medicamento com sulfato de condroitina e/ou sulfato de glucosamina nos últimos 3 meses?			
13. Tomou injeções de corticoides (IM ou intra ou periarticular) ou ácido hialurónico (intraarticular=viscosuplementação) nos últimos 6 meses?			
14. Tem alergia a crustáceos? (Exemplos de crustáceos também designados "marisco": camarões, caranguejos, lagostins, etc.)			
15. Tem radiografia(s) do(s) joelho(s)?			
16.Tem disponibilidade e interesse em participar num programa educacional e/ou de exercício físico para a OA do joelho(s)?			
17. Sabe ler, escrever e compreende o que lê?			

Caso venha participar do programa, quais os melhores dias e horários para si?

_____

Appendix 4: Exercise Program, strength progression

	Sem 1	Sem 2	Sem 3	Sem 4	Sem 5	Sem 6	Sem 7	Sem 8	Sem 9	Sem 10	Sem 11	Sem 12
Agachamento	1x 8-12 rep sentando c apoio	2x8 rep Sentando c apoio	2X8 rep Sentando c apoio	1x 8-12 rep sentando braço cruzado	2 x 8 rep Sentando braço cruzado	2X 12 rep Sentand braço cruzado	1X 12rep Sentando braço cruzado	2X 8 rep sem sentar braço cruzado	2x 12rep sem sentar braço cruzado	1x12 rep sem sentar braço cruzado	2x8 rep sem sentar braço cruzado	2x12 rep sem sentar braço cruzado
Crucifixo	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Extensão da perna (Elevação)	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Abdução da Anca	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Flexão da perna	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Elevação lateral	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Gêmeos	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Rosca (Bíceps)	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Extensão dos Tríceps	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3
Adução da anca	1x8 rep s/c	2x 8 rep s/c	2x12 rep s/c	1x12 rep C1	2 x 8 rep C1	2x12 rep C 1	1x12 rep C2	2x 8 rep C2	2x 12 rep C2	1x12 rep C3	2x 8 rep C3	2x12 rep C3

Appendix 5: Knee Injury and Osteoarthritis Outcome Score (KOOS)

QUESTIONÁRIO KOOS SOBRE O JOELHO

Data: _____/_____/_____ Código: _____

Nome: _____

INSTRUÇÕES: Este questionário pretende saber como vê o seu joelho. Esta informação dar-nos-á dados sobre como se sente em relação ao joelho e até que ponto é que é capaz de desempenhar as suas actividades normais.
Responda a cada uma das perguntas marcando o quadrado adequado, apenas um quadrado para cada pergunta. Se não tiver a certeza sobre a resposta a escolher, por favor escolha a que achar melhor.

Sintomas

Estas perguntas devem ser respondidas tendo em conta os sintomas no seu joelho durante a **última semana**.

S1. Tem tido o joelho inchado?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S2. Tem sentido ranger, ouvido um estalo ou qualquer outro som quando mexe o joelho?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S3. Tem sentido o joelho preso ou bloqueado quando se mexe?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S4. Tem conseguido esticar o joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

S5. Tem conseguido dobrar o joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

Rigidez

As perguntas que se seguem dizem respeito ao grau de rigidez no joelho que teve na **última semana**. Rigidez é uma sensação de dificuldade ou lentidão a mexer o seu joelho.

S6. Até que ponto sente rigidez no joelho logo após acordar de manhã?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

S7. Até que ponto sente rigidez no joelho depois de se sentar, deitar ou descansar **ao fim do dia**?

Nada	Pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

Dor

P1. Com que frequência tem dores no joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Sempre
☐	☐	☐	☐	☐

Que intensidade de dor no joelho é que teve durante a **última semana** nas seguintes actividades?

P2. Rodar/virar-se/torcer sobre o joelho

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P3. Esticar o joelho completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P4. Dobrar o joelho completamente

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P5. Andar sobre uma superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P6. Subir ou descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P7. À noite, na cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P8. Estar sentado/a ou deitado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

P9. Estar de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Actividades da vida diária

As perguntas que se seguem dizem respeito à sua função física. Por função física referimo-nos à sua capacidade de se deslocar e de cuidar de si. Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa do seu joelho.

A1. Descer escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A2. Subir escadas

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Para cada uma das seguintes actividades indique, por favor, o grau de dificuldade que teve na **última semana** devido ao seu joelho.

A3. Levantar-se a partir da posição de sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A4. Manter-se de pé

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A5. Dobrar-se para baixo/apanhar um objecto

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A6. Andar numa superfície plana

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A7. Entrar ou sair do carro

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A8. Ir às compras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A9. Calçar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A10. Levantar-se da cama

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A11. Descalçar meias/collants

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A12. Estar deitado/a na cama (virar-se, manter a posição do joelho)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A13. Entrar/sair da banheira

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A14. Estar sentado/a

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A15. Sentar-se ou levantar-se da sanita

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Para cada uma das actividades seguintes, indique o grau de dificuldade que sentiu na **última semana** por causa do seu joelho.

A16. Tarefas domésticas pesadas (ex.: pegar em caixas pesadas, esfregar o chão, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

A17. Tarefas domésticas leves (ex.: cozinhar, limpar o pó, etc.)

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Actividades desportivas e de lazer

As perguntas que se seguem dizem respeito à sua função física, estando activo/a a um nível mais elevado. As perguntas devem ser respondidas tendo em conta o grau de dificuldade que teve durante a **última semana** por causa do seu joelho.

SP1. Pôr-se de cócoras

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP2. Correr

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP3. Saltar

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP4. Rodar/virar-se/torcer sobre o joelho afectado

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

SP5. Ajoelhar

Nenhuma	Pouca	Moderada	Muita	Muitíssima
☐	☐	☐	☐	☐

Qualidade de Vida

Q1. Com que frequência é que tem consciência do problema que tem no joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Constantemente
☐	☐	☐	☐	☐

Q2. Modificou o seu estilo de vida para evitar actividades que poderiam afectar o joelho?

De modo algum	Um pouco	Moderadamente	Muito	Completamente
☐	☐	☐	☐	☐

Q3. Até que ponto é que a falta de confiança no joelho o/a incomoda?

Nada	Um pouco	Moderadamente	Muito	Muitíssimo
☐	☐	☐	☐	☐

Q4. Em geral, o joelho causa-lhe muitos problemas?

Nenhuns	Poucos	Alguns	Muitos	Muitíssimos
☐	☐	☐	☐	☐

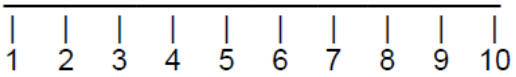
Obrigado por ter respondido a todas as perguntas do questionário.

Appendix 6: Self-efficacy for Managing Chronic Disease 6-Item Scale

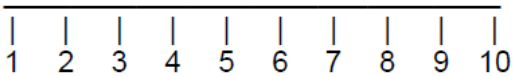
Escala de 6-itens de Autoeficácia na Gestão de Doenças Crónicas

Gostaríamos de saber quão confiante está em realizar certas atividades. Para cada uma das seguintes perguntas, por favor, escolha o número que corresponde ao nível de confiança com que consegue fazer as tarefas regularmente, no presente momento.

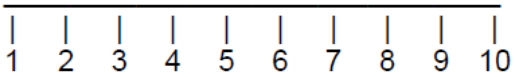
1. Quão confiante está em conseguir que o cansaço causado pela sua doença não interfira nas coisas que quer fazer?

Nada confiante  ***Totalmente confiante***

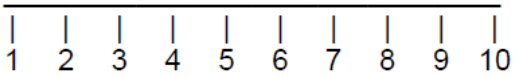
2. Quão confiante está em conseguir que o desconforto físico ou a dor da sua doença não interfiram nas coisas que quer fazer?

Nada confiante  ***Totalmente confiante***

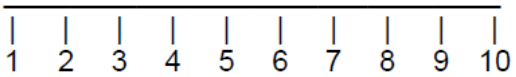
3. Quão confiante está em conseguir que o sofrimento emocional causado pela sua doença não interfira nas coisas que quer fazer?

Nada confiante  ***Totalmente confiante***

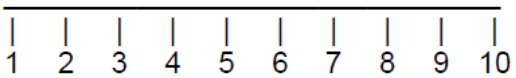
4. Quão confiante está em conseguir que quaisquer outros sintomas ou problemas de saúde não interfiram nas coisas que quer fazer?

Nada confiante  ***Totalmente confiante***

5.Quão confiante está em conseguir fazer as diferentes tarefas e atividades necessárias para gerir o seu problema de saúde, de forma a diminuir a necessidade de ir ao médico?

Nada confiante  ***Totalmente confiante***

6.Quão confiante está em fazer outras coisas, além de tomar a medicação, para diminuir a forma como a doença afeta o seu dia-a-dia?

Nada confiante  ***Totalmente confiante***

CHRONIC DISEASE SELF-MANAGEMENT PROGRAM - QUESTIONNAIRE CODE BOOK, STANDFORD UNIVERSITY (2007)

Appendix 7: Cognitive Symptom Management and Communication with Physicians

Comportamento de Auto-Gestão

Comunicação com o médico

Quando vai ao médico, quantas vezes (por favor, coloque um círculo à volta do número, para cada questão):

	Nunca	*Quase nunca*	*Algumas vezes*	*Frequentemente*	*Quase sempre*	*Sempre*
1. Prepara uma lista de perguntas para o seu médico.....	*0*	*1*	*2*	*3*	*4*	*5*
2. Coloca perguntas sobre algo que quer saber ou não entende sobre seu tratamento.....	*0*	*1*	*2*	*3*	*4*	*5*
3. Conversa sobre algum problema pessoal que possa estar relacionado com a sua doença.....	*0*	*1*	*2*	*3*	*4*	*5*

Gestão Cognitiva de Sintomas

Quando se sente em baixo, com dor ou com sintomas desagradáveis, quantas vezes: (por favor, coloque um círculo à volta do número para cada questão):

	Nunca	*Raramente*	*Por vezes*	*Frequentemente*	*Quase sempre*	*Sempre*
1. Tenta afastar-se do desconforto e fingir que este não faz parte do seu corpo.....	*0*	*1*	*2*	*3*	*4*	*5*
2. Não pensa nisso como desconforto, mas como outra sensação, tal como calor, dormência.....	*0*	*1*	*2*	*3*	*4*	*5*
3. Faz jogos mentais ou canta para manter o desconforto fora do seu pensamento.....	*0*	*1*	*2*	*3*	*4*	*5*
4. Pratica relaxação muscular progressiva.....	*0*	*1*	*2*	*3*	*4*	*5*

CHRONIC DISEASE SELF-MANAGEMENT PROGRAM - QUESTIONNAIRE CODE BOOK, STANDFORD UNIVERSITY (2007)

Appendix 8: Euroquol five dimensions five level (EuroQol -EQ-5D-5L)

Código ID: _____

EQ-5D-5L

Questionário de saúde
Versão Portuguesa para Portugal

Por baixo de cada título, assinale o quadrado que descreve melhor como a sua saúde está **HOJE**.

MOBILIDADE

Não tenho problemas em andar	❑
Tenho problemas ligeiros em andar	❑
Tenho problemas moderados em andar	❑
Tenho problemas graves em andar	❑
Sou incapaz de andar	❑

CUIDADOS PESSOAIS

Não tenho problemas em me lavar ou vestir	❑
Tenho problemas ligeiros em me lavar ou vestir	❑
Tenho problemas moderados em me lavar ou vestir	❑
Tenho problemas graves em me lavar ou vestir	❑
Sou incapaz de me lavar ou vestir sozinho/a	❑

ATIVIDADES HABITUAIS *(ex. trabalho, estudos, atividades domésticas, atividades em família ou de lazer)*

Não tenho problemas em desempenhar as minhas atividades habituais	❑
Tenho problemas ligeiros em desempenhar as minhas atividades habituais	❑
Tenho problemas moderados em desempenhar as minhas atividades habituais	❑
Tenho problemas graves em desempenhar as minhas atividades habituais	❑
Sou incapaz de desempenhar as minhas atividades habituais	❑

DOR/MAL-ESTAR

Não tenho dores ou mal-estar	❑
Tenho dores ou mal-estar ligeiros	❑
Tenho dores ou mal-estar moderados	❑
Tenho dores ou mal-estar graves	❑
Tenho dores ou mal-estar extremos	❑

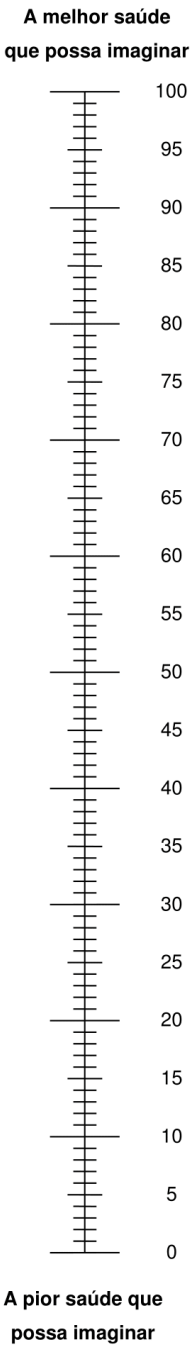
ANSIEDADE/DEPRESSÃO

Não estou ansioso/a ou deprimido/a	❑
Estou ligeiramente ansioso/a ou deprimido/a	❑
Estou moderadamente ansioso/a ou deprimido/a	❑
Estou gravemente ansioso/a ou deprimido/a	❑
Estou extremamente ansioso/a ou deprimido/a	❑

Código ID: _____

- Gostaríamos de saber o quanto a sua saúde está boa ou má HOJE.
- A escala está numerada de 0 a 100.
- 100 significa a melhor saúde que possa imaginar.
  0 significa a pior saúde que possa imaginar.
- Coloque um X na escala de forma a demonstrar como a sua saúde se encontra HOJE.
- Agora, por favor escreva o número que assinalou na escala no quadrado abaixo.

A SUA SAÚDE HOJE = ☐



Appendix 9: International Physical Activity Questionnaire (IPAQ)

IPAQ QUESTIONÁRIO INTERNACIONAL DE AVALIAÇÃO DA ACTIVIDADE FÍSICA - Versão Portuguesa Curta

Este questionário inclui questões sobre a actividade física que realiza habitualmente para se deslocar de um lado para outro, no trabalho, nas actividades domésticas (femininas ou masculinas), na jardinagem e nas actividades que efectua no seu tempo livre para entretenimento, exercício ou desporto. As questões referem-se à actividade física que realiza numa ***semana normal*****,** e ***não em dias excepcionais*****,** como por exemplo, no dia em que fez a mudança da casa.
Por favor responda a todas as questões mesmo que não se considere uma pessoa activa.

Ao responder às *seguintes questões considere o seguinte:*
Actividade física vigorosa *refere-se* a *actividades que requerem muito esforço físico* e a *respiração fica muito mais intensa que o normal.*
Actividade física moderada *refere-se* a *actividades que requerem esforço físico moderado* e a *respiração fica* um *pouco mais intensa que o normal.*
Ao responder às *questões considere apenas* as *actividades físicas que realize durante pelo menos 10 minutos seguidos.*

1a Durante a última semana, quantos ***dias*** fez actividade física ***vigorosa*** como levantar e/ou transportar objectos pesados, cavar, realizar ginástica aeróbica, correr, nadar, jogar futebol ou andar de bicicleta a uma velocidade acelerada?
_____ dias por semana
_____ Nenhum (passe para a questão **2a**)
1b Quanto ***tempo***, no total, despendeu num desses dias, a realizar actividade física ***vigorosa***?
_____ horas _____ minutos

2a Durante a última semana, quantos ***dias*** fez actividade física ***moderada*** como levantar e/ou transportar objectos leves, andar de bicicleta a uma velocidade moderada, actividades domésticas (ex: esfregar, aspirar), cuidar do jardim, fazer trabalhos de carpintaria, jogar ténis de mesa? Não inclua o andar/caminhar.
_____ dias por semana
_____ Nenhum (passe para a questão **3a**)
2b Quanto ***tempo***, no total, despendeu num desses dias, a realizar actividade física moderada?
_____ horas _____ minutos

3a Durante a última semana, quantos dias ***andou/caminhou*** durante pelo menos 10 minutos seguidos? Inclua caminhadas para o trabalho e para casa, para se deslocar de um lado para outro e qualquer outra caminhada que possa fazer somente para recreação, desporto ou lazer.
_____ dias por semana
_____ Nenhum (passe para a questão **4a**)
3b Quanto ***tempo***, no total, despendeu num desses dias a andar/caminhar?
_____ horas _____ minutos
3c A que ***ritmo*** costuma caminhar?
_____**Vigoroso,** que toma a sua respiração muito mais intensa que o normal;
_____ **Moderado,** que toma a sua respiração um pouco mais intensa que o normal;
_____ **Lento,** que não causa qualquer alteração na sua respiração.

As últimas questões referem-se ao tempo que está sentado diariamente no trabalho, em casa, no percurso para o trabalho e durante os tempos livres. Estas questões incluem por exemplo **o tempo** *em que está* **sentado à mesa ou à secretária***, a* **visitar amigos***,* a **ler ou sentado/deitado** *a* **ver televisão***.*

4a Quanto ***tempo***, no total, passou sentado(a) durante um dos dias de semana (segunda-feira a sexta-feira)? _____ horas _____ minutos
4b Quanto ***tempo***, no total, passou sentado(a) durante um dos dias de fim-de-semana (sábado ou domingo)? _____ horas _____ minutos

IPAQ – VERSÃO PORTUGUESA (CURTA) – ADAPTADO DE MIL-HOMENS, J (2004)

Appendix 10: Brief COPE

Brief COPE	**Nunca faço isso**	**Raramente faço isso**	**Faço isso algumas vezes**	**Faço sempre isso**
1.1. Concentro os meus esforços para fazer alguma coisa que me permita enfrentar a situação	☐	☐	☐	☐
1.2. Tomo medidas para tentar melhorar a minha situação (desempenho)	☐	☐	☐	☐
2.1. Tento encontrar uma estratégia que me ajude no que tenho que fazer	☐	☐	☐	☐
2.2. Penso muito sobre a melhor forma de lidar com a situação	☐	☐	☐	☐
3.1. Peço conselhos e ajuda a outras pessoas para enfrentar melhor a situação	☐	☐	☐	☐
3.2. Peço conselhos e ajuda a pessoas que passaram pelo mesmo	☐	☐	☐	☐
4.1. Procuro apoio emocional de alguém (família, amigos)	☐	☐	☐	☐
4.2. Procuro o conforto e compreensão de alguém	☐	☐	☐	☐
5.1. Tento encontrar conforto na minha religião ou crença espiritual	☐	☐	☐	☐
5.2. Rezo ou medito	☐	☐	☐	☐
6.1. Tento analisar a situação de maneira diferente, de forma a torná-la mais positiva	☐	☐	☐	☐
6.2. Procuro algo positivo em tudo o que está a acontecer	☐	☐	☐	☐
7.1. Faço críticas a mim próprio	☐	☐	☐	☐
7.2. Culpo-me pelo que está a acontecer	☐	☐	☐	☐
8.1. Tento aceitar as coisas tal como estão a acontecer	☐	☐	☐	☐
8.2. Tento aprender a viver com a situação	☐	☐	☐	☐
9.1. Fico aborrecido e expresso os meus sentimentos (emoções)	☐	☐	☐	☐
9.2. Sinto e expresso os meus sentimentos de aborrecimento	☐	☐	☐	☐
10.1. Tenho dito para mim próprio(a): “isto não é verdade”	☐	☐	☐	☐
10.2. Recuso-me a acreditar que isto esteja a acontecer desta forma comigo	☐	☐	☐	☐
11.1. Refugio-me noutras actividades para me abstrair da situação	☐	☐	☐	☐
11.2. Faço outras coisas para pensar menos na situação, tal como ir ao cinema, ver TV, ler, sonhar, ou ir às compras	☐	☐	☐	☐
12.1. Desisto de me esforçar para obter o que quero	☐	☐	☐	☐
12.2. Simplesmente desisto de tentar atingir o meu objectivo	☐	☐	☐	☐
13.1. Refugio-me no álcool ou noutras drogas (comprimidos, etc.) para me sentir melhor	☐	☐	☐	☐
13.2. Uso álcool ou outras drogas (comprimidos) para me ajudar a ultrapassar os problemas	☐	☐	☐	☐
14.1. Enfrento a situação levando-a para a brincadeira	☐	☐	☐	☐
14.2. Enfrento a situação com sentido de humor	☐	☐	☐	☐

Pais Ribeiro, 2004

Appendix 11: Patient's Global Impression of Change (PGIC)

Escala de Percepção Global de Mudança (PGIC versão Portuguesa)

Nome: _____ ID: _____

Desde o início do tratamento nesta instituição, como é que descreve a mudança (se houve) nas LIMITAÇÕES DE ACTIVIDADES, SINTOMAS, EMOÇÕES E QUALIDADE DE VIDA no seu global, em relação à sua dor (seleccione UMA opção):

Sem alterações (ou a condição piorou)	☐ 1
Quase na mesma, sem qualquer alteração visível	☐ 2
Ligeiramente melhor, mas, sem mudanças consideráveis	☐ 3
Com algumas melhorias, mas a mudança não representou qualquer diferença real	☐ 4
Moderadamente melhor, com mudança ligeira mas significativa	☐ 5
Melhor, e com melhorias que fizeram uma diferença real e útil	☐ 6
Muito melhor, e com uma melhoria considerável que fez toda a diferença	☐ 7

Adaptado e Validado por: Domingues, L. & Cruz, E. (2011)

Appendix 12: PLE2NO´s sample individual physical report

Relatório Individual da Aptidão Física

Nome: **Idade:**
Data:

Como está:	☺ Normal ou acima do normal	☹ Abaixo do normal

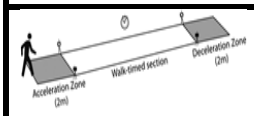
Índice de Massa Corporal
(Peso/estatura²)

Como está:

Avaliação **0** kg/m²

Baixo Peso *<19*	**Peso Normal** *19 a 24,9*	**Pré-obesidade** *25,0 a 29,9*
Obesidade		
Grau I *30,0 a 34,9*	**Grau II** *35,0 a 39,9*	**Grau III** *>40*

6 Metros marcha - Avalia a velocidade da marcha



Avaliação

m/s

Como está: ☺ ☹

Valores de referência

Normal ou acima: Mais que 1 m/s

Ir e vir 3 metros - Avalia a agilidade e o equilíbrio dinâmico

Avaliação

Inicial **s**

Como está: ☺ ☹

Valores de referência

Faixa etária	60-69	70-79	80-99
Homens	8,1	9,2	11,3
Mulheres	8,1	9,2	11,3

Senta e alcança - Avalia a flexibilidade dos membros inferiores

Avaliação Inicial

Membro		**Como está:**
Menos dor	**cm**	☺ ☹
Mais dor	**cm**	☺ ☹

Valores de referência

Faixa etária	Homens	Mulheres
60-74	≥ 0	≥ 0
75-84	≥ 0	≥ 0
+85	≥ 0	≥ 0

Alcançar atrás das costas - Avalia a flexibilidade dos membros superiores

Avaliação Inicial

Membro		Como está:
Direito	**cm**	☺ ☹
Esquerdo	**cm**	☺ ☹

Valores de referência

Faixa etária	Homens	Mulheres
60-74	≥ 0	≥ 0
75-84	≥ 0	≥ 0
+85	≥ 0	≥ 0

6 Minutos marcha – Avalia capacidade aeróbia

Avaliação

		Como está:
Inicial	**549 m**	☺ ☹

Valores de referência

Faixa etária	Homens	Mulheres
60-69	572	538
70-79	527	471
80-89	417	392

Preensão manual - Avalia a força da mão

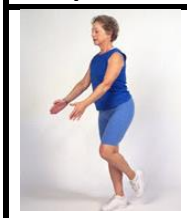
Avaliação	Como está:	Valores de referência	
33 kg	☺ ☹	Homens	≥ 30
		Mulheres	≥ 25

Valores inferiores aos de referência são indicativos de ***sarcopénia*** (perda de força e massa muscular).

Levantar e sentar da cadeira (5x) – Avalia a força dos membros inferiores

Avaliação	Como está:	Valores de referência	
13,02 s	☺ ☹	Homens	Entre 9 e 16,5 segundos
		Mulheres	Entre 9 e 16,5 segundos

Equilíbrio sobre um pé - Avalia a capacidade para manter o equilíbrio sobre um apoio



Avaliação

Membro		Como está:
Direito	**4**	☺ ☹
Esquerdo	**4**	☺ ☹

Valores de referência

☹ **0** – Incapaz de manter a posição, ou necessita de ajuda para prevenir a queda.
☹ **1** – Capaz de elevar o membro inferior sem ajuda, mas incapaz de manter a posição mais de 5 segundos.
☺ **2** – Capaz de elevar o membro inferior sem ajuda e de manter a posição mais de 5 mas menos de 12 segundos.
☺ **3** – Capaz de elevar o membro inferior sem ajuda e de manter a posição mais de 12 mas menos de 20 segundos.
☺ **4** – Capaz de elevar o membro inferior sem ajuda e de manter a posição durante 20 segundos.