



Effects of physical training with the Nintendo Wii Fit Plus[®] and protein supplementation on musculoskeletal function and the risk of falls in pre-frail older women: Protocol for a randomized controlled clinical trial (the WiiProtein study)

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ABSTRACT

Background: Frailty is one of the key geriatric syndromes and is related to the loss of functional independence. However, the practice of physical training (PT) combined with protein supplementation (PS) may improve musculoskeletal function (MF).

Objective: To verify the effect of PT using 'exergames' with or without PS on MF, nutritional status, and risk of falls in pre-frail older women.

Method: The protocol is for a randomized controlled clinical trial with a sample of pre-frail older women, divided into 5 groups: control group; PT using exergames; PS; PT using exergames combined with PS; PT using exergames combined with isoenergetic supplementation. The primary outcomes will be: the strength and power of the lower limbs, assessed by isokinetic dynamometer and the sit-and-stand test carried out 5 times; muscle architecture, assessed by ultrasound; body composition, assessed by anthropometric measurements, bioelectrical impedance and dual energy X-ray absorptiometry; and functional mobility and risk of falls, assessed using the Timed-Up and Go test. The secondary outcomes will be: centre of pressure (CoP), assessed using a force plate; and fear of falling, assessed using the Falls Efficacy Scale – International, Brazil. PT using exergames with a gradual increase in the mass weighted vest will be carried out twice a week for 50 min over 3 months. The supplements will be ingested 5 days a week for 3 months. All outcomes will be assessed before and after 3 months.

Discussion: The WiiProtein study will be the first clinical trial to examine the effects of PT using exergames with progressive resistance, which may or may not be combined with PS, on MF, nutritional status, and risk of falls in pre-frail older women.

1. Introduction

Frailty is a geriatric syndrome characterized by decreasing muscle strength, endurance and physiological function that may occur as the result of a variety of diseases and clinical conditions, such as the post-fall and fracture syndrome, resulting in increased vulnerability of an individual with respect to dependence and/or mortality after exposure

to a stressor [1]. The prevalence of frail older people in Brazil is 9.1% [2] while the rate for pre-frail is even greater (51.8%), both affecting more women than men [2].

According to the consensus for the management of physical frailty, physical exercise and caloric-protein support are recommended. However, the 'dose' of these therapies and their effects on musculoskeletal function have not yet been fully elucidated [1]. Decreases in

Abbreviations: PT, physical training; PS, protein supplementation; MF, musculoskeletal function; CG, control group; EPTG, exergames physical training group; PSG, protein supplementation group; EPTSG, exergames physical training combined with protein supplementation; EPTIG, exergames physical training combined with isoenergetic supplementation group; BP, blood pressure; HR, heart rate

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frailty state among older women (> 75 years) and improvements in their muscle mass and functional mobility after performing multi-component physical exercises in groups have been reported in the literature [3]. One study reported a reduction in frailty and an improvement in the functional mobility of pre-frail and frail older adults who carried out multicomponent exercises twice a week for 12 weeks, including progressive resistance exercises. The intervention included education on nutrition, with an emphasis a better quality of diet and an adequate intake of protein. However, the sample was not stratified according to sex, limiting the conclusions [4].

Physical frailty in older people may decrease their functional mobility and thereby increase the risk of falls [1,5]. Thus, exercise programmes that include balance training could be of benefit [6,7]. When compared with conventional balance training, the use of the Nintendo Wii Fit Plus by institutionalized frail older people for 6 weeks significantly improved their balance and reduced the risk of falls. The group that undertook this video game physical training ('exergaming') experienced greater improvements than the group that received conventional training [7].

The effects of exercise for frail and/or pre-frail older people has been assessed in recent systematic reviews, but these have reported a lack of consensus and so failed to recommend specific types of exercise for pre-frail individuals. Nonetheless, multicomponent progressive and resistance exercises are recommended for the treatment and/or reversal of frailty and pre-frailty [1,8]. Even so, there is limited evidence regarding the 'dose' of each type of exercise, in particular regarding the gradual increase in load [3,4].

Moreover, no parameters have yet been established for the prescription of exergames, with the goal of improving musculoskeletal function in pre-frail older people [6]. There are also no published studies that have combined progressive resistance physical training (PT) using exergames with protein intake and/or supplementation (PS) in pre-frail older people [9].

Therefore, the aim of this randomized controlled clinical trial is to verify the effects of a PT programme using exergames with a gradual increase in load, combined or not with PS, on musculoskeletal function, nutritional status and the risk of falls in pre-frail older women. The hypothesis of the study is that supervised PT using exergames with a gradual increase in load, carried out twice a week, when combined with PS five times per week for 12 weeks, is sufficient to reverse the state of pre-frailty and/or reduce the prevalence of frailty. It could also increase muscle strength and power, skeletal muscle mass and architecture, and nutritional status, and, consequently, improve balance and functional mobility and so reduce both the fear of falling and the risk of falls.

2. Method

2.1. Trial design

This is a protocol for a randomized controlled clinical trial, with five parallel groups, the participants being individually randomized to one of the five groups in a 1:1 allocation.

The WiiProtein study protocol was developed based on the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines [10]. The project was approved by the Research Ethics Committee of the Hospital de Clínicas (University General Hospital) of the Federal University of Paraná, Brazil (UFPR) (CAAE: 58865916.8.0000.0096) (protocol approved: version 2, 1 November 2016), and the study adheres to the CONSORT guidelines [11]. All the items from the WHO Trial Registration Data Set were registered in the publicly accessible Brazilian Registry of Clinical Trials (RBR-73c67m) database.¹

The assessments of the enrolled women will be carried out at

baseline, that is, prior to randomization, and after three months.

Any change made to the protocol will be reported to the Research Ethics Committee and will be modified in the Brazilian Registry of Clinical Trials.

2.2. Study setting

The study will be carried out in the city of Curitiba, Paraná, Brazil. The state of Paraná has a higher aging index compared with the national value for Brazil (41.73 and 36, respectively; the aging index is the number of adults aged 60 or more per 100 persons under 15 years of age), and it is estimated that by the year 2030 a further 15.12% of the population of Paraná will be above the age of 65 [12]. Moreover, according to the Paraná Secretary of State for Health 14% of the older population living in the state of Paraná are classified as being at risk of frailty, while 20% are classified as being at risk of pre-frailty [12]. The decision to enrol only older women was mainly because, globally, pre-frailty affects more women (9.6%) than men (5.2%) [1]. Furthermore, a higher prevalence of older women has been observed, both globally and in the state of Paraná, Brazil, and this increases with advancing age, justifying specific interventions for these individuals [13,14].

2.3. Participants

Women aged 65 years or more, living in the city of Curitiba, Paraná, Brazil and its metropolitan region, will be invited to take part in the study. The WiiProtein study will be advertised in the press, and in places more likely to be attended by older people, such as the Open University for Mature Students of the Federal University of Paraná, the outpatient clinic of the Hospital de Clínicas of the Federal University of Paraná, and by way of digital media.

Those considered eligible for inclusion in the WiiProtein study will be women aged 65 years or more, categorized as 'pre-frail' according to the criteria for frailty proposed by Fried et al. [5], that is, presenting at least one but no more than two of the following: unintentional weight loss; exhaustion/fatigue when carrying out activities; slow gait; muscle weakness; low energy expenditure; and 'moderate' kidney function (i.e. a glomerular filtration rate (GFR) of 30–60 ml/min/1.73m²) as estimated by the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation. If the woman has type II diabetes, this should be compensated (< 8% glycated haemoglobin) and she must not have a visual deficit as assessed by the Snellen card (20/70 unilateral).

The exclusion criteria are: having an acute or terminal illness; metabolic instability or decompensated cardiovascular disease; cognitive deficits as determined by the Mini-Mental State Examination, relative to school education [15]; neurological disorders and/or traumatic-orthopaedic conditions that prevent the participant from carrying out the evaluations and/or the proposed exercises; type I diabetes; taking medication that might affect muscle metabolism (corticoids) or postural balance (anticholinergics, antihistamines, benzodiazepines, calcium channel antagonists or dopamine receptor antagonists); being intolerant/allergic to milk protein; an auditory deficit that prevents understanding of verbal instructions; and any serious deficiency recorded in the medical records, such as cardiac, respiratory or hepatic deficiency and/or decompensated arterial hypertension (BP ≥ 140/90 mmHg).

2.4. Intervention groups

After randomization, the participants will be allocated to one of the five study groups: control group (CG); exergames physical training group (EPTG); protein supplementation group (PSG); exergames physical training combined with protein supplementation group (EPTSG); and exergames physical training combined with isoenergetic supplementation group (EPTIG).

The project team is multidisciplinary, composed of physiotherapists, nutritionists, physical education professionals and geriatricians. The

¹ <http://www.ensaiosclinicos.gov.br/rg/RBR-73c67m/>.

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