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Research Article

The Effect of Vitamin D on Physical Performance and Activities of Daily Living in Independent Community-Dwelling Elderly: Study Protocol

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Abstract

Background: Despite the high incidence of sunlight, the prevalence of vitamin D deficiency is increasing, especially in the oldest old population. Although observational studies with community-dwelling older adults demonstrate an association between low serum levels of 25(OH)D (Vitamin D) and poor mobility, balance and strength, the results of its supplementation as a strategy to improve physical performance are controversial. The aim of this study is to evaluate the effect of vitamin D on physical performance and functional capacity in community-dwelling oldest old individuals. **Methods:** This is a longitudinal study with participants of the "Longevos Project" followed from 2010 to 2022. Physical performance was evaluated using the Brazilian version of the Short Physical Performance Battery. For the assessment of handgrip strength, we used a manual dynamometer, adopting the cutoff points of <26 kg for men and <16 kg for women. The assessment of functional capacity was performed using the Katz and Lawton scales adapted for Brazil. Serum vitamin D concentrations were determined via blood tests, with low levels defined as vitamin D <30 ng/mL. Multiple linear regression models will be used to evaluate the simultaneous effects of vitamin D with each variable of physical performance and functional capacity. A significant level of $p<0.05$ will be adopted. **Discussion:** The hypothesis of the present study is that low vitamin D levels are associated with worse physical performance and impairment of activities of daily living and that maintaining serum levels of 25(OH)D>30 ng/mL can improve functional capacity.

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Keywords: Vitamin D; Aged; Aged 80 and over; Physical functional performance; Aging

Introduction

Vitamin D deficiency affects more than one billion people in the world [1] and even in tropical countries, where there is an elevated ultraviolet radiation, such as Brazil, low levels of 25(OH)D (Vitamin D) are highly prevalent. Observational studies with elderly residents of São Paulo showed a prevalence of this hypovitaminosis, which is defined as serum levels of Vitamin D <30 ng/mL, between 42% and 63% [2,3].

Elderly population represents one of the main risk groups for the development of Vitamin D deficiency due to a decrease in the skin's capacity for pre-Vitamin D3 synthesis, reduced exposure to sunlight, increased adiposity, low consumption of food sources, reduced intestinal absorption capacity and presence of comorbidities that can affect its metabolism, such as chronic kidney disease [4,5].

Vitamin D deficiency seems to be related to increased oxidative stress with consequent skeletal muscle atrophy [12] compromising strength, balance and mobility [6-8]. The potential role of Vitamin D in skeletal muscle strength and function in community dwelling older adults have been suggested in recent epidemiological studies. Low levels of Vitamin D seem to be associated with poor results in tests of strength, gait speed, balance and mobility, mainly in populations at higher risk such as the elderly aged 80 years or more (oldest old) [9-13].

A study with 2225 independent community-dwelling older adults with mean age of 86.3±12.2 years showed an association between serum 25-hydroxyvitamin D deficiency and disability in Activities of Daily Living (ADL), mobility and physical functioning among the oldest-old in China [14].

Although Vitamin D supplementation is proposed as a potential strategy to prevent physical decline and ADL disability in older adults, results of clinical trials that evaluated the effects of the supplementation showed insufficient evidence to support the therapeutic use of vitamin D to improve or maintain muscle function, physical performance and independence in the elderly population [1,15-17].

A review of clinical trials published between January 2015 and June 2021, which evaluated the effect of Vitamin D supplementation on physical performance of community-dwelling older adults, showed that when combined with resistance exercise and other nutrients that are also important for muscle health, supplementation might result in beneficial effects. Nonetheless, the heterogeneity of the studies performed until now, with variability in assessment methods of physical performance, different designs, population, duration and dose of the supplement, make it difficult to understand the effect of vitamin D [18].

Therefore, with the hypothesis that the increase and maintenance of serum levels of 25(OH)D>30 ng/mL improves functional capacity, the aim of this research protocol is to evaluate the effect of vitamin D on physical performance and in the ADL in community-dwelling oldest old individuals. The data set collected by this survey will support a better understanding about the role of vitamin D to preserve independence and promote healthy aging.

Materials and Methods

Study design

This is a longitudinal study with participants of the "Longevos Project", a cohort of community-dwelling elderly aged 80 years or older carried out since 2010 by the Division of Geriatric and Gerontology of the Federal University of São Paulo.

The participants are selected through advertisement at local neighborhood newspapers, radio media and personal contact. The inclusion criteria for the "Longevos Project" are: being 80 full years or over; being independent at ADLs and being able to wander aid-free (canes can be used); having compensated chronic illnesses, but no cognitive compromises or serious illnesses such as neoplasm, acute cardiovascular events, chemotherapy or dialytic treatment. Elders who fit these criteria are assigned to annual check-ups by trained geriatricians, nutritionists and physiotherapists in addition to the collection of biochemical tests.

Throughout the process, participants that present cognitive compromise, neoplasm (except skin cancer), cardiovascular events and dependency or sensory compromise (visual or auditory) that impede their comprehension or engagement in the tests are no longer subjected to them, but are only removed from the project upon death. The long-lived elders that remain in evaluation are independent from a physical and cognitive standpoint, representing elders from the community.

The "Longevos Project" is in conformity to the Declaration of Helsinki (2000) and approved by the Comitê de Ética Médica da Universidade Federal de São Paulo - Escola Paulista de Medicina - report 87015/12. Only the elders or their legal representatives who signed the Term of Free and Informed Consent Form are included.

This study will include elderly followed from 2010 to 2022 in the "Longevos Project". For this project the exclusion criteria are: diagnosis of clinical conditions that may affect vitamin D levels such as chronic kidney disease and liver disease; use of medications that influence 25(OH)D serum levels such as carbamazepine; osteoarticular limitations that prevent the accomplishment of the physical performance assessment tests. In addition, participants without information on serum concentrations of vitamin D, results

of physical performance tests, ADLs and control variables will be excluded.

Any individual who meets the inclusion and does not meet the exclusion criteria is eligible. We expect to collect data from more than 400 elderly living in the community in the southern region of São Paulo, Brazil.

This new protocol study was approved by the Research Ethics Committee of the Federal University of São Paulo and of the "Hospital São Paulo" (protocol number: 0764/2022).

Data Collection

Trained geriatricians, nutritionists and physiotherapists will review the medical records for data collection.

Physical performance

Physical performance is assessed in accordance with the Brazilian version of the Short Physical Performance Battery (SPPB), which is composed of three subtests that assess balance, gait speed and lower limb strength and power [19].

For gait speed, the participant is required to walk at their usual pace a distance of four meters twice. The shorter time of the two is used to assign the score. For those who fail to perform the test the score is zero, those who complete in more than 8.7 seconds receive one point, between 6.21 and 8.7 seconds two points, between 4.82 and 6.2 three points and if the best time is less than 4.82 seconds the score is four.

Balance is assessed by the ability to stand upright looking ahead for 10 seconds in each position: feet together, semi-tandem (the ankle of one foot behind the joint of the other foot) and tandem (ankle of one foot directly behind the other foot and touching it). The participants who maintained balance for the required time in the first two positions receive one point for each. At the tandem position those who remain for 10 seconds receive two points, from 3 to 9.99 seconds one point and those who maintain less than 3 seconds or cannot perform the task are awarded with no points. The balance test's score is calculated by the sum of the points gained in each of the three positions.

The chair stand test evaluates the participants' lower-limb strength. They are asked to stand up and sit down on a chair five times in a row as quickly as possible with arms crossed over the chest. Those who are unable to perform the test safely, fail to get up and sit five times or complete in more than 60 seconds do not receive a score. If the time to complete is 16.7 seconds or more the score is one, between 13.7 and 16.69 seconds two, between 11.2 and 13.69 seconds three and if the time to complete is less than 11.19 seconds the score is four. This test is only performed after the elderly demonstrate the ability to stand without using their arms.

A total SPPB score is obtained through the sum of the results in the three tests and ranges from 0 (worst performance) to 12 (best performance) with the following classification: 0 to 3 points: disability/very poor performance; 4 to 6 points: poor performance; 7 to 9 points: moderate performance and 10 to 12 points: good performance.

Grip Strength

Hand grip strength is evaluated using a "Jamar" manual dynamometer with scale from 0 to 100 kg. Before the test, the participant is seated on an armless chair with their dominant arm's elbow in 90 degree flexion and with forearm and wrist in a neutral position. With the dynamometer adjusted to the size of each participant's hand, they are asked to do as much strength as they can. Motivation stimulus is performed by the investigator to encourage the patient to make its maximum grip effort.

Three trials are performed with a one-minute interval between them. The highest value achieved on the dominant hand will be considered in the analyses. The cut-off points to define low handgrip strength are <26 kg for men and <16 kg for women [20].

Functional capacity

Functional status is evaluated using multidimensional instruments that are based on the individual self-reported capacity to perform basic (ABDL) and instrumental (AIDL) activities of daily living [22].

The Brazilian version of the Katz Index is used to assess ABDL [21]. This scale evaluates the dependence of six self-care activities: bathing, dressing, going to the toilet, transference, continence and feeding. For each activity there are three options of response: without help, with partial help and with total help. At the end, the elderly are classified with a score from 0 to 6, in which 0 represents independence for all activities and 6 dependence for all activities [22].

The Lawton Scale is one of the most widely used instruments for IADL assessment in the elderly population. The Brazilian validated and adapted version consists of nine items that measure the difficulties of housekeeping, doing laundry, preparing meals, using transportation, shopping, using the telephone, handling finances, and managing medications. There are standardized answers for each question and the participant should choose the one that represents the best of your ability. The final score ranges from 7 to 21 points with the higher the score, the greater the person's abilities [23].

Laboratory evaluation

Blood samples were collected during the morning after a 12-h fast. Serum concentration of 25(OH)D was determined by

chemiluminescence using the LIAISON® 25OHvitaminD-310600 (DiaSorin Inc., USA) assay. The following cutoff points will be considered: 25(OH)D <30 ng/mL deficiency and between 30-40 ng/mL vitamin D sufficiency [5].

Covariates

The covariates selected are based on associations between the physical performance, ADLs and serum 25(OH)D concentrations reported in previous studies. These factors are: age, sex, medical diagnosis, Fitzpatrick skin typing test, sun exposure, Body Mass Index (BMI), daily intake of vitamin D, season of the year in which the blood test was performed, pain, level of physical activity, calf and waist circumference, polypharmacy, falls in the last 12 months and depression.

The concentration of melanin characterized by the type of skin color can influence vitamin D levels, as the more melanin the less vitamin will be produced with the same amount of exposure to sunlight. To classify the skin type the Fitzpatrick Questionnaire will be used. It allows six different classifications according to the skin phototype and its reaction to sunlight [24].

Depressive symptoms were investigated using the Geriatric Depression Scale (GDS) of 15 items. The final score of zero to four is considered to be within the normal, five to six indicates a possible depression and seven or more a probable depression [25]. The diagnosis of depression will be based on the DSM-V criteria [26]. The consumption of five or more medications per day will be considered as polypharmacy [27].

Weight was measured using a portable electronic Tanita UM-080 Body Fat Scales model with a capacity of up to 150 kg with graduations from 100 to 100 grams. A single measurement was recorded in kilograms with the participants standing fully upright on the scale platform, arms freely alongside the body without shoes and wearing light clothes.

For the height measured, individuals were positioned in the stadiometer, without shoes, maintaining the head in the Frankfurt plane with hands facing the body and with their heels, calves, hips and the back of the head touching the back support the maximum as possible. The BMI was calculated from the following equations: BMI: body weight/height^2 (kg/m^2). For comparison purposes, the classifications proposed by the Pan American Health Organization (PAHO) [28] and by Lipschitz [29] will be used, according to the cutoff points below (Table 1):

Nutrition Status	PAHO	Lipschitz
Underweight	≤23kg/m²	<22 kg/m²
Normal weight	>23 e <28 kg/m²	≥22 e ≤27 kg/m²
Overweight	≥28 e <30 kg/m²	>27 kg/m²
Obesity	≥30 kg/m²	

Table 1: Nutritional Status by the Pan American Health Organization (PAHO) [28] and Lipschitz [29] classification according to the BMI.

Waist circumference was defined, as recommended by the International Diabetes Federation, as the midpoint between the lowest rib and the iliac crest and was obtained by inelastic tape with accuracy of 0.1 cm, directly on the skin. The cut-off points proposed by the World Health Organization (WHO) [30] and the International Diabetes Federation (IDF) [31] will be used to classify abdominal obesity (Table 2):

	OMS	IDF
Men	>102 cm	≥90 cm
Women	>88 cm	≥80 cm

Table 2: Cut-off points by World Health Organization (WHO) [30] and the International Diabetes Federation (IDF) [31] to classify abdominal obesity.

Calf circumference was measured at the point of greatest circumference on the non-dominant leg, with the elderly sitting with the knee bent at a 90o angle and feet resting on the floor. The values proposed for the Brazilian population of <33 cm for women and <34 cm for men [32] and the classification proposed by the World Health Organization of <31 cm for men and women will be used as the cutoff point for low lean mass [33].

The level of physical activity will be evaluated through the type, frequency, duration and intensity, according to the guidelines of the World Health Organization [34]. Information on daily intake of vitamin D, number of medications, sun exposure and use of sunscreen, falls in the last 12 months, medical diagnosis and pain are self-reported at the annual appointments.

Demographic and lifestyle variables such as completed years of formal study, marital status (single, divorced, married, widowed), alcohol consumption (never drank, stopped over 1 year ago, often, occasionally), smoking (currently smoking or up to 1 year ago, past smoking, stopped over 1 year ago, never

smoked), nationality, ethnicity (Caucasian, African, Oriental, brown and Indigenous) are self-reported and will be considered to characterize the sample.

Statistical analysis

Data will be analyzed descriptively by absolute and relative frequencies for the categorical variables and mean and standard deviation for numerical ones. Continuous variables will be tested using the Kolmogorov-Smirnov test to verify whether the data have a normal distribution. Parametric tests will be conducted for those with normal distribution and non-parametric tests for the others with non-normal distribution.

Categorical variables will be compared using the Chi-square test or Fisher's exact test. Multiple linear regression will be used to evaluate the simultaneous effects of vitamin D with each variable of physical performance and functional capacity. A significance level of 5% will be used for all statistical tests.

Discussion

The global population aging represents an important challenge to public health. To preserve the independence and autonomy of the elderly, strategies that allow early screening of functional decline and physical performance are of extreme importance and need to be developed. In Brazil, in addition to the intense population aging, a fast increase of life expectancy is also observed, resulting in an increase in the number of oldest-old individuals [35].

Low serum levels of 25(OH)D may be associated with changes in muscle fiber metabolism due to reduced Ca^{2+} uptake by myocytes, which negatively impacts muscle contraction kinetics. Furthermore, vitamin D deficiency has been shown to influence the myogenesis and the expression of genes associated with myoblasts proliferation and differentiation [36,37].

A study with 3205 participants aged 50 or older of the English Longitudinal Study (ELSA) analyzed whether serum 25(OH) D deficiency and insufficiency were risk factors for the incidence of low grip strength (<26 kg for men and <16 kg for women). At baseline all participants had strength values above the cutoff point, nonetheless over the four years of follow-up, Vitamin D deficiency (25(OH)D <30 nmol/L) increased the risk of low handgrip strength incidence by 70% [38].

Functional limitations are related with greater dependence to perform ADLs and with increased mortality and health care costs [11-13]. Thus, this study aims to shed light and increase awareness of the importance of understanding the association between vitamin D, physical performance and ADLs among the oldest-old as its supplementation corresponds to a potential economic and safe adjuvant therapy to maintain and promote the elderly's independence and autonomy [18].

The hypothesis of this protocol study is that for the oldest old community dwelling, low levels of vitamin D lead to worse physical performance and impairment of activities of daily living and that maintaining serum levels of 25(OH)D >30 ng/mL can improve functional capacity.

Disclosure

Author Contributions

Conceptualization, R.C.P.C. and M.S.C.; methodology, R.C.P.C. and M.S.C.; validation, R.C.P.C. and M.S.C.; formal analysis, R.C.P.C. and M.S.C.; investigation, R.C.P.C., E.C.S., R.A.S.A, V.A.C. and M.S.C.; resources, M.S.C.; data curation, R.C.P.C. and M.S.C.; writing-original draft preparation, R.C.P.C.; writing-review and editing, R.C.P.C. and M.S.C.; supervision, M.S.C. All authors contributed significantly and are in agreement with the content of the manuscript.

Ethics Approval and Consent to Participate

The "Longevos Project" is carried out in conformity to the Declaration of Helsinki (2000), Resolution CFM 196/96 and is approved by the Research Ethics Committee of the Federal University of São Paulo (87015/12). Only the elders or their legal representatives who signed the Term of Free and Informed Consent Form were included. This new protocol study was approved by the Research Ethics Committee of the Federal University of São Paulo and of the "Hospital São Paulo" (protocol number: 0764/2022).

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