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ORIGINAL ARTICLE

Effects of the exercise mobile app and distance supervision on the functional performance of the older adults. Protocol of a clinical, randomized, controlled trial.

André Issao Kunitake*, Keoma Santos Dias, Henrique Pereira Vegh, Leticia Garcia Ramos, Victor Gonçalves Bossert, Hitanna dos Santos Bezerra, Maria Jucilane Soares Solai, Fernanda Ishida Corrêa
Laboratory of Neuromodulation, functionality, and analysis of human movement - LANFAM, Nove de Julho University. São Paulo, SP, Brazil.

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ABSTRACT

Objective: To check the effects of the exercise mobile app with face-to-face and distance supervision on the functional performance, postural balance, and lower limb strength of older adults.
Methods: This is a protocol of a controlled, randomized, and blind clinical trial in which we will recruit older adults of both genders, who will be randomized into two types of training: a control group (exercises using a mobile app with face-to-face monitoring by the therapist) and an experimental group (exercises with a mobile app without face-to-face monitoring by the therapist). The training will be carried out with the free app "Exercício para idosos", which should be installed on the participants' smartphones. The participants should do the proposed exercises three times a week for eight consecutive weeks. The evaluations will be conducted in person pre-training and after the 12th and 24th sessions. Functional performance, postural balance, and lower limb strength will be assessed. The data in each evaluation will be compared as well as the difference between the groups. It is believed that physical exercise apps for older people will benefit both groups by improving functional capacity, postural balance, and lower limbs strength of older adults.

*Corresponding author:
Universidade Nove de Julho
Addr.: Av. Vergueiro: 235/249, Liberdade. São Paulo, SP, Brazil | CEP: 01.504-001
Phone: +55 11 97148-4616
E-mail: issaokun@gmail.com (Kunitake AI)

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INTRODUCTION

The older population has grown globally, and it is estimated that by 2040 it will be larger than children and adolescents[1]. Aging demands an effective public health response to promote health and maintain the functional capacity of this population[2].

Physical activity is a recommendation to maintain or improve the functional capacity of older adults[3]. Some studies[4,5] observed that physical exercises could reverse frailty, reduce mobility deficits, improve gait, postural balance, lower limb strength, cognition, and emotional and social relationships in older adults[4,6]. However, a major challenge for health care professionals is to make the older population maintain their participation in supervised exercise programs[7].

Thus, the use of smartphone apps to improve physical activity performance in older people has been investigated[8,9], showing good adherence, easy applicability and viability, and displaying good results for quality of life and autonomy, and can be performed by participants in their homes[10,11]. The effectiveness of smartphones in stimulating physical activity practice and improving the functional capacity of older adults can be of great importance, especially in the current context of the COVID-19 pandemic. Older adults have been forced to stay at home, decreasing their routine activities and, in the worst-case scenario, having to recover sequela left by the disease[12]. Therefore, this resource can be an effective alternative to prevent further compromise if proven to be effective.

Given these considerations, this study aims to evaluate the functional capacity of older adults pre-and-post practice of physical activity performed using smartphone apps, with and without face-to-face therapeutic supervision. This study hypothesizes that older adults will improve their functional capacity/performance after physical activity practice using a smartphone exercise app; however, the results will be better for those under face-to-face supervision.

METHODS

Study design

This protocol is for a randomized, controlled, longitudinal, and blind (rater) clinical trial in older adults. This study was approved by the Human Research Ethics Committee of Universidade Nove de Julho (CAAE: 46199321.3.0000.5511, decision number 4.705.816) and was registered in the Brazilian Clinical Trials Registry (REBEC; RBR-22ctkjq), following Resolution 466/12 of the National Health Council of Brazil. All participants must sign an informed consent form approved by the ethics and research committee to participate in the study.

Participants

Participants will be recruited in the city of São Paulo, SP, Brazil, being residents of the region and participants previously enrolled in Universidade Nove de Julho's research and study activities. They will be contacted by telephone. They should be between 60 and 80 years old, of both genders, functionally or partially independent with a score ≤ 4 KATZ13, who are not participating in other physical activity programs such as bodybuilding, dance, or sports practice, and who are vaccinated and immunized against COVID-19. The participants who exhibit cognitive impairment as measured by the Mini-Mental State Examination (MMSE)14 and those with injuries, fractures, or lower limb amputations, neurological, vestibular, cardiovascular, and respiratory diseases that limit or contraindicate the performance of physical exercises will be excluded.

Intervention

The experimental design of the study is shown in Table 1.

The intervention of the control group and evaluations of all participants will be conducted in the Laboratory of Neuromodulation, Functionality, and Analysis of the Human Movement (LANFAM) located in the Memorial Campus of the Nove de Julho University, São Paulo, Brazil.

The participants will be randomized into two groups: a Control Group (which will perform the app training in a research laboratory, with the therapist's physical supervision) and an Experimental Group (which will perform the app training at their home, without the therapist's physical supervision). Both groups will perform the assessments in a research laboratory, in the physical presence of the therapist; on this day, everyone will receive the training instructions with the app. However, the experimental group will receive remote assistance (by phone or message) from the therapist when training begins, only for questions. The training will be carried out at the previously established times for both groups, three times a week, for eight weeks, totaling 24 sessions.

The functional capacity, upper and lower limb muscle strength, and postural balance will be determined at the beginning and repeated after the 12th and 24th sessions.

On the first day, the participants in both groups will receive instructions from the therapist on how to handle the exercise app. They will perform the exercises in the following days according to the randomized group, either with the therapist in the lab or at their respective homes.

Exercise with an exercise app on smartphones

The exercises will be carried out with the "Exercício para Idoso app", free and available for Android and iOS platforms for Brazilians, installed on the participants' smartphones. The choice of the application was due to its gratuity only, with no conflict of interest on the part of the authors. The selected exercise category will be "improve your strength and balance", consisting of warm-up exercises, followed by lower limb strength, abdominal, and balance exercises. The app has

a guide that explains each exercise to guide all the participants to perform. To ensure the correct execution of the app's exercises, an instruction manual was printed with all exercises in Portuguese (Supplementary File 1). The rest time between each exercise will be 60 s. The exercise program should be executed thrice a week, lasting eight weeks, totaling 24 sessions.

To avoid potential risks with the exercises, it will be suggested that the participants wear tennis shoes and comfortable clothes for practice. Before starting the activities, blood pressure (BP) and heart rate (HR) should be measured. In case of discomfort caused by pain, dyspnea, or tachycardia-induced exercise, the participant should remain at rest until the symptoms cease. If the symptoms persist, the participant will be asked to suspend the exercises and seek specialized help.

The participants who perform the activities in their homes will be oriented weekly via telephone calls to ask questions. They must report their difficulties and whether they have adequately performed the exercises. If the participant has a companion, they will only be asked to assist them in the exercises and not help them perform them

Outcomes

To characterize the participant, on the first day, the Beck Depression Inventory (BDI) questionnaire[15] will be applied to track clinical signs of depression, and the Pittsburgh Sleep Quality Index questionnaire (PSQI) to assess sleep quality[16]. Demographic data and information about the routine of the physical activity practice and medication use will be collected by applying a questionnaire prepared by the author (Supplementary File 2). Functional capacity, balance, and lower limb muscle strength will be assessed before physical training and repeated after the 12th and 24th sessions.

Functional Capacity evaluation

Functional capacity will be evaluated using the Glittre-ADL test[17], an instrument composed of a standardized set of movements that resemble the activities of daily living (ADL) and with good reproducibility (ICC = 0.91) in older adults from the community[18].

The test consists of getting up from a chair and walking 10 meters, in which, halfway through the course (5 m), participants will be instructed to go up and down a ladder with two steps and then walk the remaining distance to a bookshelf with three steps shelves. Participants must transfer three objects from the top shelf to the middle shelf and then to the bottom shelf closest to the floor, returning the objects to the middle shelf and ending up on the top shelf. The object weighs 1 kg each. After completing this step, participants must return to the 10-meter course, go up and down the two-step platform, and sit in the chair where they started the test. The course will be repeated five times, where each lap will be timed, and the total time spent. This test can be performed up to three times, being considered the best test execution time (Figure 2).

Functional balance evaluation

The functional balance will be evaluated using the Mini Balance Evaluation Systems Test (Mini BESTest), which consists of functional tests of static balance (standing on tiptoes with eyes closed and single-leg stance (SLS)) and dynamic balance (walking, sitting, and getting up from a chair during a dual-task). The score varies from 0 to 28, and, for each test, up to three attempts can be made, using the best performance. A point should be deducted from the test if adaptation or assistance is required during any task. This is a reliable instrument with an intraclass correlation of 0.84[19].

Lower limb muscle strength evaluation

The Sit-to-Stand (STS) test will be used to assess the strength of the lower limbs, which consists of the time it takes an individual to perform the sitting and rising movement five times from a chair with a backrest and without arm support. It is an easy applicability instrument, which does not require training and can be applied to older adults[20].

Table 1 — Study enrollment schedule, interventions, and assessments. t1: First day of training; t2: 12th day of training; t3: 24th day of training.

	STUDY PERIOD					
	Enrolment	Allocation	Post-allocation			Close-out
TIMEPOINT	-t1	0	t1	t2	t3	t3
ENROLMENT	X					
Eligibility screen	X					
Informed consent	X					
Ethics committee approval	X					
Trial registration	X					
Allocation		X				
INTERVENTIONS						
Exercises face-to-face supervision			◆—	—	—◆	
Exercises without face-to-face supervision			◆—	—	—◆	
ASSESSMENTS						
Functional capacity		X		X	X	X
Functional balance		X		X	X	X
Lower limb muscle strength		X		X	X	X

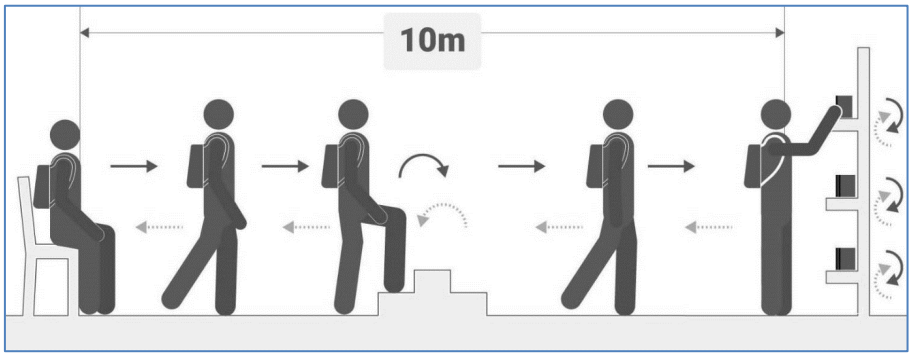

Figure 2 — Activities of Daily Living (Glittre ADL). Own Source.

Sample composition

The sample size for this protocol was calculated using the G*Power program performed with a pilot study (N = 10), considering α = 0.05 (significance), β = 0.2 (80% power), and effect size (f) of 0.55 (calculated from the mean and standard deviation of the Glittre-ADL). Considering possible dropouts and ensuring a sample size that will demonstrate the effect of the intervention, the sample will be expanded by 20%, resulting in 17 individuals in each group, thus totaling 34 participants.

Blinding and Randomization

To ensure blinding, the evaluators will be randomized to perform the three evaluations (before and after the 12thand 24th session of app training) for both groups so that the same evaluator will never be repeated for each participant.

Randomization will be performed using the program obtained from www.randomizer.org, in which 34 participants (based on sample size calculation) will be allocated to the control or experimental group. In case of absence or withdrawal, new numbers will be randomized until completing the study sample.

Statistical analysis

The software SPSS (Statistical Package for Social Sciences) will be used for data analysis. The normality of the data will be performed by Shapiro-Wilk, considering the significance level defined as a value of $\alpha \leq 0.05$. The parametric data will be expressed as a mean ± standard deviation (SD) and the nonparametric as a median and interquartile IQ25-75%. The categorical data will be described as absolute values and percentages of the total sample.

The data analysis to verify if there was an improvement in the training for the control and experimental groups will be performed by the unpaired t-test (parametric data) or the Mann-Whitney (nonparametric data) whereas comparison between groups by paired t-test (parametric data) or the Wilcoxon (nonparametric data) test. The Pearson (parametric data) or the Spearman correlations (nonparametric) will be applied to verify a relationship between functional capacity, lower limb muscle strength, postural control, and quality of life.

DISCUSSION

Physical activity is essential for promoting physical and mental well-being and quality of life. Additionally, it can help prevent or delay the progression of chronic diseases such as hypertension and diabetes[21].

However, many older people find it challenging to perform the exercises alone, as they need supervision, guidance, or instructions to avoid getting hurt[22,23]. Unfortunately, some older adults do not have the financial resources to hire a professional to advise them on performing exercises. Thus, a more affordable option is the use of smartphone exercise apps.

Currently, the smartphone is a resource widely used by people of all ages, including older adults, to encourage healthy habits such as physical activity[9,11]. The physical exercise apps for smartphones showed good adhesion[8], easy applicability, and feasibility[10], and can be performed by participants at their homes.

This device becomes even more critical faced with a scenario such as the one we are currently experiencing: a post-pandemic by COVID-19 as it is a highly contagious disease, which has caused many deaths in the last three years, and older adults were forced to remain in social isolation and reduce the practice of physical activity[24].

Thus, knowing the importance of physical activity for the maintenance of the physical capacity of older adults, physical exercise programs that allow its execution in the home environment can be an effective alternative for them to have an active life, in addition to reducing the risk of contamination by diseases, as happened during the COVID-19 pandemic.

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