

Effects of exergames on the balance of older adults with type 2 Diabetes Mellitus: protocol of a randomized clinical trial

Efectos de los exergames en el equilibrio de los adultos mayores con Diabetes Mellitus tipo 2: protocolo de un ensayo clínico aleatorizado

Efeitos dos exergames no equilíbrio de idosos com Diabetes Mellitus tipo 2: protocolo de ensaio clínico randomizado

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ABSTRACT: This is a protocol study that aims to investigate the effects of Exergames on the body balance of elderly people with type 2 Diabetes Mellitus. The primary outcome will be body balance, followed by cognition, functional performance, manual muscle strength, confidence in balance and symptoms. depressive. The study has been registered in the Brazilian Registry of Clinical Trials (REBEC), RBR-67y6cz, since October 14, 2019.

Keywords: Exergame; Type 2 Diabetes Mellitus; Balance training.

RESUMEN: *Este es un estudio de protocolo que tiene como objetivo investigar los efectos de Exergames en el equilibrio corporal de personas mayores con Diabetes Mellitus tipo 2. El resultado principal será el equilibrio corporal, seguido de la cognición, el rendimiento funcional, la fuerza muscular manual, la confianza en el equilibrio y los síntomas depresivos. El estudio está inscrito en el Registro Brasileño de Ensayos Clínicos (REBEC), RBR-67y6cz, desde 14 de octubre de 2019.*

Palabras clave: *Exergame; Diabetes Mellitus tipo 2; Entrenamiento de equilibrio.*

RESUMO: *Trata-se de um estudo de protocolo que visa a investigar os efeitos dos Exergames no equilíbrio corporal de idosos com Diabetes Mellitus tipo 2. O desfecho primário será o equilíbrio corporal, seguido por cognição, desempenho funcional, força muscular manual, confiança no equilíbrio e sintomas depressivos. O estudo está inscrito no Registro Brasileiro de Ensaios Clínicos (REBEC), RBR-67y6cz, desde 14 de outubro de 2019.*

Palavras-chave: *Exergame; Diabetes Mellitus tipo 2; Treino de equilíbrio.*

Introduction

Type 2 Diabetes Mellitus (T2DM) is the most common form of diabetes, comprising 90% – 95% of all diabetes cases registered in Brazil (Sociedade Brasileira de Diabetes, SBD, 2015). One in four older adults (≥ 65 years) have T2DM, and the proportion increases with age (Ghouse, *et al.*, 2020). One of the most common complications of T2DM in the elderly is impaired balance, which is directly related to falls. Increased blood glucose reduces nerve perfusion, especially in the peripheral nerves, retina and vestibular system, causing peripheral neuropathy, diabetic retinopathy, vestibular impairment and postural problems (Dixon, *et al.*, 2017; Lu, Lin, & Kuo, 2009; Maurer, Burcham, & Cheng, 2005; Nozabieli, *et al.*, 2012; Oliveira, *et al.*, 2012; Schwartz, *et al.*, 2008).

Approximately 30.6% of elderly people with diabetes recur, and only 19.4% of elderly people without diabetes experience these events (D’Silva, *et al.*, 2016).

In addition, the limitations caused by the imbalance can affect even everyday activities. Thus, the association of T2DM with other chronic diseases may justify an 85% increase in the risk of falls in the elderly (Bianchi, & Volpato, 2016). The imbalance resulting from T2DM in the elderly is directly related to the increased risk of falls and all its consequences, such as fractures and serious injuries (Grewal, *et al.*, 2015; Mettelinge, *et al.*, 2013). Exercise is indicated to reduce and treat these complications.

Exercise improves insulin sensitivity and glycemic control (Chiang, *et al.*, 2019). Kinesiotherapy improves balance, functional activities, confidence and cognition, and reduces falls and fear of falling (Hewston, & Deshpande, 2018; Podolski, *et al.*, 2017; Soares, & Sachelli, 2008). Diabetic patients can benefit from a kinesiotherapy exercise program to improve balance and gait quality (Timar, *et al.*, 2016). Older adults should exercise for at least 60 min per week, and exercises should include strengthening, stretching, flexibility and relaxation (Mendes, *et al.*, 2016); Mendes, *et al.*, 2017; Mora, & Valencia, 2018; There should also be attention to changes in positions/postures, direction of travel/walking, proper footwear, sensory obstacles and continuous progression (Nascimento, Patrizzi, & Oliveira, 2012). Therefore, many aerobic resistance exercises are recommended for this population. Its combined form was recommended by the European Society of Cardiology, American College of Sports Medicine, Belgian Physical Therapy Association and Exercise and Sports Science Australia (Pan, *et al.*, 2018). Aerobic training is recommended for diabetics, 2 to 3 times a week for 150 minutes a week, and resistance training is recommended 2 or 3 times a week (Colberg, *et al.*, 2010). These factors must be carefully analyzed to avoid training that could possibly not improve.

Exergames have been used as interactive video game-based exercises (Zheng, *et al.*, 2019). Exergames are well-suited for training and rehabilitation because of the virtual interaction, market availability, multisensory stimuli (vision, somatosensory, vestibular and hearing), immediate feedback, and because they can be fun and stimulating (Clark, *et al.*, 2010; Grewal, *et al.*, 2013; Meireles Lima, *et al.*, 2017; Pigford, & Andrews, 2010). This immediate feedback is important to promote motor learning, which is a basic principle of specific training. This provides rewards that increase performance (Schättin, *et al.*, 2016). The approach performed by games occurs with the movement of the participant's body and allows multisensory stimuli by adding a virtual interface in the user's training, causing training "gamification".

In addition, this modality improves the speed of cognitive processing (Ordnung, *et al.*, 2017) and the executive function of the brain (Adcock, *et al.*, 2020). Thus, exergames are significantly potential as physical exercise strategies for the elderly and improving body balance in this audience (Chen, *et al.*, 2018).

Playing exergames has been found to improve balance in several populations including in patients with hemiparesis (Henrique, Colussi, & Marchi, 2019), healthy older adults (Mussato, Brandalize, D., & Brandalize, M., 2012; Pina, *et al.*, 2016), pregnant women (Sousa, 2016), sedentary individuals (Santos, *et al.*, 2016), people with Parkinson's disease (Pompéu, 2012), chronic peripheral vestibulopathy (Doná, Santos, & Kasse, 2011), intradialytic chronic renal failure (Santos, 2016), Steinert muscular dystrophy (Vicente, Ferraz, & Jeremias, 2018) and frailty (Zheng, *et al.*, 2019).

A systematic review indicated positive outcomes of exergames on individuals with T2DM, but balance was not one of the outcomes measured (Höchstmann, Schupbah, & Schmidt-Truckass, 2016). Only one study investigated the effects of exergames on balance in older adults with diabetes (Lee, & Shin, 2013), and it was a randomized clinical trial with 55 elderly people in which the control group received guidance on the management of T2DM, and the experimental group conducted 20 virtual reality sessions of 50 min with PlaysTation 2. It was concluded that this training was effective in reducing the risk of falls in elderly patients with diabetes. Little is known about the effects of exergames on the balance of older adults with diabetes, and the effects of exergames have not been compared with the effects of traditional kinesiotherapy in older adults with diabetes.

The hypothesis of this study is that training with exergames associated with 12-week kinesiotherapy focusing on the body balance of elderly people with diabetes provides an effect superior to the exclusive kinesiotherapy training. Therefore, this study aims to compare the effects on balance of exergames and traditional kinesiotherapy in older adults with T2DM.

Methodology

This protocol was published in dx.doi.org/10.17504/protocols.io.bkcvksw6.

Type of study

This study is a single-blinded, randomized controlled trial, parallel, open, two-arm treatment and superiority relationship. designed according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) recommendations (Chan, *et al.*, 2013).

Study Location

Data collection will take place at the Laboratory of Technological Innovation in Health at the Advanced Nucleus of Research and Technological Innovation in Health at the Onofre Lopes University Hospital (HUOL) in the city of Natal, Rio Grande do Norte.

Population and Sample

The subjects will be older adults with T2DM. They will be recruited from the HUOL geriatric and/or endocrinology departments. The strategy to reach the desired sample will be as follows: the elderly individuals seen in the aforementioned outpatient clinics will be invited to participate in this research by the doctor responsible for the sector till sample calculation.

Sample Size

The sample size calculation was performed using the website www.openepi.com (Dean, Sullivan, & Soe, 2013). The sample size was calculated for the primary outcome of the study (total balance score on the Mini Balance Evaluation Systems Test - Mini BESTest). The minimum detectable balance score difference between groups of older adults is 3.5 points on the Mini BESTest (Godi, *et al.*, 2013; Anson, *et al.*, 2019). This value was used as the effect size, and we used the standard deviations from a similar clinical trial (4.0 for the experimental group and 0.1 for the control group) (Gomes, 2019). Considering these values, a minimum of 28 participants would be required for a power of 90% with an alpha error of 5%. Anticipating 20% attrition/dropout rate, 34 participants (17 per group) will be recruited.

The analysis of the sample calculation was based on the pre-intervention period for post-intervention data, equivalent to the period from T1 to T2 in the present study. Statistical tests will be based on these findings in the same way.

Eligibility Criteria

Inclusion criteria were as follows: (1) age between 65 and 79 years; (2) diagnosis of T2DM according to the criteria of the American Diabetes Association guidelines (Gross, *et al.*, 2002); (3) self-reported balance impairment and/or dizziness (Simoceli, *et al.*, 2003); (4) high risk of falling indicated by a score of 19 or less on the Dynamic Gait Index (Shumway-Cook, & Woollacott, 1995); (5) no cognitive impairment based on the Mini-Mental State Examination adjusted by educational level (≥ 19 for illiterate, ≥ 24 for literate) (Brucki, *et al.*, 2003); (6) mild to moderate peripheral neuropathy based on the Neuropathic Symptom Score (Moreira, *et al.*, 2005); and (7) good visual acuity assessed by the Snellen Table (Jannuzzi, *et al.*, 2014). The exclusion criteria were as follows: (1) currently following balance rehabilitation or done so in the past six months (Balducci, *et al.*, 2017); (2) clinical diagnosis of carpal tunnel syndrome.

Randomization and Blinding

Randomization was carried out online (randomization.org) in 3 blocks of 12, 12 and 10 participants. The participants were equally divided into 2 distinct groups. This moment was performed by a researcher external to the study, who placed the numerical sequence in opaque envelopes that were sealed and divided into white and black, corresponding to the groups. When starting the training, the contents of the envelope will be revealed by the therapists responsible for the intervention. The same therapists will implement the protocols for both groups. The principal investigator will be blinded to the intervention groups. Another researcher will perform the statistical analysis by treating the groups only by colors. At the end of this stage, each group will match a specific color. The principal investigator will have access to the data at the end of his analysis and will decide to end the study. All data will be confidential before, during and after the end of the project.

The study follows the SPIRIT recommendations as shown in Figure 1 and Annex 1.

Figure 1. SPIRIT recommendations for preparing a protocol study, 2020

	STUDY PERIOD			
	Screening	Baseline (T1)	Twelve weeks (T2)	Follow up assessment (T3)
TIMEPOINT	Week -1	Week 0	Week 1 – Week 12	Week 13 and Week 24
ENROLMENT				
Eligibility screen	X			
Informed consent	X			
Allocation		X		
INTERVENTIONS				
Control Group			◆————◆	
Experimental Group			◆————◆	
ASSESSMENT				
Postural balance		X	X	X
Cognitive screening		X	X	X
Functional performance		X	X	X
Functional capacity		X	X	X
Palmar muscle strength		X	X	X
Balance confidence		X	X	X
Depressive symptoms		X	X	X
Adverse events				X

SOURCE: Chan, *et al.* (2013)

Measures

Sample characterization measures

A structured questionnaire will be completed including data on sex, age, marital status, race, education, income, occupation, housing situation, social support and falls within six months. Clinical data will include comorbidities, time since T2DM diagnosis, medication(s), history of alcoholism and/or smoking, body mass index (Cervi, Francerchini, & Priore, 2005; Lipschitz, 1994), general health self-perception, musculoskeletal pain and intensity in the lower limbs using the Visual Analog Scale (VAS) (Wewers, & Lowe, 1990), glycated hemoglobin and glycemia in the last six months, orthostatic hypotension (Wanergarten, Serro-Azul, & Maciel, 2007) and skin (Toledo, & Barela, 2010), vibratory and proprioceptive sensitivities (Speciali, 1996).

The following factors will be evaluated to assess dizziness: topographic diagnosis (peripheral, central, or mixed), time since symptom onset, type of dizziness (rotatory, non-rotatory, or mixed), duration (days, hours, minutes, or seconds), frequency (sporadic, monthly, weekly, or daily), associated symptoms (tinnitus, nausea/vomiting, aural

fullness, sweating/tachycardia, oscillopsia, hearing loss and fear of falling) and VAS for intensity. This stage is expected to last 5 minutes.

Outcome Measures

Primary outcome

Balance

The Mini BEST will be used to assess balance (Horak, Wrisley, & Frank, 2009). It is a questionnaire formed by 14 tests, with a total of 36 items divided into four sections: 1. Anticipatory postural transitions and adjustments; 2. Postural responses to disturbance; 3. Sensory orientation, and 4. Walking stability. Each item is scored on an ordinal scale of three points ranging from zero (worst performance) to two (best performance) (Maia, 2012; Padgett, Jacobs, & Kasser, 2012). The test has been translated and adapted to Portuguese (Maia, 2012). The scores were found to be reliable and valid for older adults with balance deficits and falls (Horak, Wrisley, & Frank, 2009). The test results are measured out of a total of 28 points, or in percentage (0-100%) (Yingyongyudha, *et al.*, 2016). This test is expected to be applied for 8 min.

Secondary outcomes

Cognitive screening

Cognitive screening will be evaluated using the Leganès Cognitive Test, a scale whose final score is not affected by the subject's level of education and is easy to use (Zunzunegui, *et al.*, 2000). The test has 32 questions, grouped into 07 categories: temporal orientation (3 points), spatial orientation (2 points), personal information (3 points), appointment test (6 points), immediate memory (6 points), late memory (6 points) and logical memory (3 points). The domains covered by the categories are memory and orientation. The total score ranges from 0 to 32 points; 0 to 8 in the orientation domain and 0 to 24 points in the memory domain.

The higher the score, the better the performance. The cutoff point for cognitive deficit is 22 points. It has been translated, adapted and validated for older Brazilians and is measured out of a total of 22 points (Caldas, 2011). This test is expected to be applied for 5 min.

Functional performance

Functional performance will be evaluated using the Short Physical Performance Battery, which consists of three tests that evaluate in sequence, the static balance in standing, the gait speed in usual steps measured twice in a certain round-trip path and indirectly, the muscular strength of the lower limbs through the movement to get up from the chair and sit on it five times in a row and without the aid of the upper limbs (Guralnik, *et al.*, 1989; Ferrucci, *et al.*, 2000). It has been validated for older Brazilians (Nakano, 2007). The total SPPB score is obtained by adding the scores of each test, ranging from zero (worst performance) to 12 points (best performance). The result can be graded as follows: 0 to 3 points (disability or very poor performance), 4 to 6 points (low performance), 7 to 9 points (moderate performance) and 10 to 12 points (good performance) (Ferrucci, *et al.*, 2000; Guralnik, *et al.*, 1989;). This test is expected to be applied for 5 min.

Functional capacity

Functional capacity will be evaluated using the two-minute stationary gait test, which has been validated for older Brazilians with chronic diseases. The participants will be encouraged to perform a stationary walk for 2 minutes and the number of steps taken will be counted. The greater the quantity, the greater the functional capacity. This test has good reliability and sensitivity for elderly people with chronic conditions. It requires at least 69 single-limb elevations (Guedes, *et al.*, 2015). This test is expected to be applied for 2 min.

The Brazilian OARS Multidimensional Functional Assessment Questionnaire (BOMFAQ) assesses functional capacity over the difficulty of performing 15 activities of daily living (ADL), with eight physical activities of daily living (AFVD) and seven instrumental activities of daily living (IADL). In the questionnaire, when there is

difficulty in performing any task, it is categorized as “too much” or “little” (Ramos, *et al.*, 1993). Quantification of the number of ADLs referred to as “difficult” to perform is carried out, which will be equal to the total of committed activities (Ramos, *et al.*, 1993). This test has good reliability and sensitivity for elderly Brazilians (Blay, Ramos & Mari, 1988). This test is expected to be applied for 2 min.

Grip strength

Grip strength was measured using the Palmar Grip Test. The Palmar Grip Dynamometer will be used according to the manufacturer’s guidelines and adjusted according to gender and body mass index (Marucci, & Barbosa, 2003). The patient will be seated in a comfortable chair, with no inclination, feet resting on the floor, forming an angle of 90° in relation to the leg, and the dynamometer will be held by the patient using his dominant hand. Thus, the arm of the dominant hand must be neutral, the forearm flexed at 90° and the wrist in a neutral position. The result will be in Kg and the average will be obtained in 3 attempts (absolute value of the patient). The period of 1 min between attempts will be respected (Costa, & Neri, 2011). Its measures have been found to be valid, reliable and comparable to the measures of other dynamometers (Reis, & Arantes, 2011).

Confidence in balance

Confidence in balance will be assessed using the Activity-Specific Balance Confidence Scale, which assesses confidence during a set of everyday activities. It consists of assessing balance in a set of daily activities associated with certain difficulties. It consists of 16 activities, in which the evaluator asks the individual about their confidence in the balance to perform the activities of the questions on an ordinal scale that varies between “without confidence - 0%” and “total confidence 100%”. The scale has been translated, validated and the measures has been found to be reliable (Branco, 2010; Marques, *et al.*, 2013).

Depressive symptoms

Depressive symptoms were evaluated using the 15-item Geriatric Depression Scale. This reduced version is composed of 15 questions different from each other, in which the values from 0 to 4 points indicate patients without depressive symptoms, 5 to 10 points show signs of mild or moderate depression and from 11 to 15 points, evidence of severe depression. It has been validated for older adults in an outpatient setting (Paradela, Lourenço, & Veras, 2005; Bretanha, *et al.*, 2015). Those with high depressive symptoms will be referred to HUOL's Psychiatry and Psychology department.

Adverse events

During the follow-up assessment, participants will be asked about adverse events, hospitalizations, out-of-routine medical consultations, changes in medication, new diagnoses and any negative events.

Evaluation Procedures

All researchers will be trained beforehand to perform evaluations in order to maintain reliability. During routine consultations at the endocrinology and geriatrics departments at HUOL, patients diagnosed with T2DM will be referred to the appointment scheduling department for screening. If the patient meets all inclusion criteria, they will be directed to the Laboratory of Technological Innovation in Health on a scheduled date and time for evaluation. The interventions will begin subsequently.

First, the participants will be asked about their clinical status and will undergo physical tests alternated with sitting tests to avoid fatigue. Then, the participants will stand up to perform the Mini BESTest, with 2 min of rest at the end. After this step, the participants will complete the Leganès Cognitive Test. After that, the participants will perform the Short Physical Performance Battery and the Two-Minute Stationary Gait Test. At the end, they will be given 2 more minutes of rest and will then sit down to perform the BOMFAQ, the Palmar Grip Test, the Activity-Specific Balance Confidence Scale, and the Geriatric Depression Scale to screen for symptoms of depression.

After the baseline assessment, the participants will start their exercise program (kinesiotherapy or exergames multi-component). At the end of the intervention period, the patient will be reassessed, and they will be assessed one last time three months later (follow-up). The initial assessment will be called T1, the post-intervention assessment will be called T2 and the follow-up assessment will be called T3.

Intervention groups

Interventions will be carried out individually by each participant in full supervision of a therapist throughout the session.

Common to both groups

Exercise protocols in both groups will be performed individually twice a week for 12 weeks (a total of 24 sessions) (Allet, *et al.*, 2010; Ribeiro, 2015; Yang, *et al.*, 2014). Before the beginning of the interventions, the groups will receive 10 min of general T2DM care education based on the Brazilian Diabetes Society guidelines (SBD, 2015), including information on healthy eating, the importance of physical activity and correct use of medications. In addition, both groups will perform 10 minutes of lower limb strengthening (Table 1) at the beginning of each session (Allet, *et al.*, 2010; Ribeiro, 2015; Soares, & Sacchelli, 2008).

Table 1. Lower limb strengthening exercises

Exercise	Progression	Materials Used
1. Get up and sit on a chair	Floor change	1 or 2 sleeping mattress
2. Go up and down steps	Increased step height	Bigger steps
3. Fortification of the hip extensors	Increased weight	Shin guard of 1 kg and 2 kg
4. Stand on tiptoes	Increased weight	Shin guard of 1 kg and 2 kg

SOURCE: adapted from Allet, *et al.* (2010)

Each exercise will be performed according to the patient's level, prioritizing uninterrupted training of two sets for 60 s, with a rest of 30 s between them. There will be two progressions for each exercise in sessions 8 and 16. Both groups will perform lower limb muscle strengthening because older people with diabetes have reduced

strength and mobility in the ankle, leading to significant gait deficits (Allet, *et al.*, 2010). Lower limb muscle weakness has been associated with spatiotemporal gait changes in older patients with diabetes (Allet, *et al.*, 2009). Decreased lower limb muscle strength is an important risk factor for falls in older adults (Barnett, *et al.*, 2003).

All participants will be told to maintain their activities and continue their usual medical treatment (consultations and maintenance). They will be instructed not to engage in any other physical activity for body balance during the study period. The participants will be contacted by telephone to confirm and remind them of the assessments and training sessions. To increase adherence, the following modifications may be made to reduce difficulty, decrease pain, avoid hemodynamic instability, cramps and/or fatigue: I) adaptation of time or amount of exercises per session; II) increased rest period and III) adjustment of weights and the amount of mats.

Control Group (Kinesiotherapy protocol)

The kinesiotherapy sessions will last 40 min, including lower limb strengthening exercises described and balance training. The kinesiotherapy protocol was based on previous studies that included balance training in older adults (Allet, *et al.*, 2010; Nascimento, Patrizzi, & Oliveira, 2012; Pompéu, 2012; Ribeiro, 2015; Soares, & Sacshelli, 2008). Exercises that involved stimuli similar to those of the experimental group were selected to create similar sensorimotor demands. The sequence of the protocol is described in Table 2.

Table 2. Exercises for the kinesiotherapy protocol

Exercise	Evolution	Materials Used
1. Gait training on a stable floor	Gait training on an unstable floor; change in the direction of gait	A pair of 1 kg shin pads added
2. Lateral weight transfer and discharge	One sleeping mat added	Two sleeping mats added
3. Anteroposterior weight transfer and discharge	One sleeping mat added	Two sleeping mats added
4. Laterolateral cephalic movement with eyes open	Same movement with eyes closed	One sleeping mat added
5. Anteroposterior cephalic movement with eyes open	Same movement with eyes closed	One sleeping mat added
6. Dissociation of scapular and pelvic girdles	One sleeping mat added	Two sleeping mats added

SOURCE: Adapted from Allet, *et al.* (2010), Nascimento, Patrizzi, & Oliveira (2012), Ribeiro (2015), Soares, & Sachelli (2008).

Exercise 1 will be performed in two sets of three minutes; exercises 2-5 will be performed in three sets of one minute; and exercise 6 will be performed in three sets of two minutes. After each series is performed, the participant will have 30 s of rest. Exercise progression will occur during sessions 8 and 16.

Experimental Group (Exergame multi-component group)

The experimental group will participate in the previously mentioned lower limb strengthening protocol plus a seven-game virtual reality protocol using the Nintendo Wii® and the Wii® Fit Plus game storage consoles. This equipment generates an interaction between the individual and an interface in which the game is played on the Wii® Balance Board using the Wii® Remote Controller (Corrêa, *et al.*, 2011; Meldrum, *et al.*, 2012; Lima, *et al.*, 2017). The games focus on balance and involve stimuli similar to the kinesiotherapy protocol. This group will also exercise for a total of 40 min, divided into 10 min of lower limb strengthening and 30 min of exergames multi-component. The individuals in this group will have an initial meeting in order to adapt to the games. They will have access to all the games, and it will be explained how each one works. At this time, a demonstration will also be done so that they understand the scores and movements involved.

A multimedia projector will be used (EPSON, model: V11H856024, 1,024,000 pixels [1280 × 800] × 3, Native resolution: WXGA, Dimensions [WxDxH]: 30.2 × 24.9 × 8.7 cm (without feet), environment without external lighting), and the Wii® Balance Board will be positioned 1.50 m away from the games' projection on the wall. For each session, a trained evaluator will be positioned behind and to the side of the subjects to prevent potential falls. The scores obtained in each game by the participant will be recorded in order to provide temporal feedback of their evolution at the end of the therapy. Furthermore, this data can provide a future analysis on which game the scores did not evolve as desired, allowing us to infer that it represents the game with the greatest difficulty in execution. The seven-game sequence was selected for balance-based motor demands such as saccadic, cephalic visual-vestibular, and proprioceptive stimulation, dynamic balance training, static gait, ankle and hip strategies, fine pressure center control, optokinetic stimulus, double task (motor) and motor coordination (Mendes, *et al.*, 2016; Pompéu, 2012; Agmon, *et al.*, 2011; Silva, 2012; Tahmosybayat, *et al.*, 2018).

The stimuli used in each game are described below in Table 3. These games are the most commonly used for balance training in older adults. Each game will last for 3 min followed by a 1-min rest.

Table 3. Exercises for the exergame multimodal protocol

Free run	Control of patient pocket and “marching” on a firm surface.	Saccadic, visuo-vestibular stimulus with cephalic movement, proprioceptive stimulus, dynamic balance training and static gait.
Soccer heading	Over the scale, perform anteroposterior and laterolateral weight transfers to virtually “hit” the ball with their head, with 80 attempts in 180 sec.	Ankle and hip strategies, saccadic stimuli, head movement and dynamic balance training.
Penguin slide	On the scale, perform lateral-lateral weight transfers in order to “catch” the largest number of fish, with three attempts in 60 sec.	Saccadic stimulus, fine control of the pressure center, dynamic balance training.
Island cycling	On the scale, with the control in hand to “guide” the bike virtually; marching over the platform and using the control to perform the movement, with three 60 sec courses.	Optokinetic, saccadic stimulation, dual task, motor coordination and static gait.
Tilt table	On the scale, make small laterolateral and anteroposterior dislocations with a simulation of an unstable board to put the balls into holes, with three initial 30 sec attempts and to gain 20 sec every 1 level reached so that it does not exceed the 180 sec limit.	Ankle strategy, fine adjustment of the pressure center and motor coordination.
Free steps	Rising and falling of the scale, alternating feet with eyes open, with rising and falling of a medium density foam on the platform with eyes open for 180 sec.	Dynamic postural balance and motor coordination.
Balance bubble	On the scale, perform lateral-lateral and anteroposterior body displacements to avoid the bubble touching the banks of the virtual river with three attempts.	Motor coordination and fine adjustment of the pressure center.

SOURCE: Mendes, *et al.* (2016); Pompéu (2012); Agmon, *et al.* (2011); Silva (2012); Tahmosybayat, *et al.* (2018).

These games will be adapted in sessions 8 and 16 with the addition of 1 and 2 mats, respectively, except for the free step game where the adaptation will be the addition of shin pads weighing 1 and 2 kg, respectively. Absence, adverse symptoms, imbalance and/or falls will be recorded.

Statistical analyses

Data analysis will be performed by an evaluator blinded to the group allocation. The Statistical Package for Social Sciences software (version 20.0, IBM, New York, USA) will be used with a significance level of 5% for the statistical tests. Descriptive statistics (arithmetic mean, standard deviation, median, minimum and maximum values, and 95% confidence intervals [CI]) will be calculated. Nominal variables will be presented as absolute (n) and relative (percentage) frequencies. The Shapiro-Wilk test will be used to analyze the distribution of the data. The T-test or Mann-Whitney test will be used to compare means. The ANCOVA adjustment will be used to assess baseline values. The effect size (F) and 95% CI will also be calculated.

For sample losses, the data will be imputed considering the last recorded data of the individual. All analyses will consider the principle of intention-to-treat.

This study has a low risk of selection bias due to the randomization and concealment of the allocation of participants; there is also a low risk of detection bias, as the outcome evaluator will be blinded; it has a high risk of performance bias, justified because the subjects will not be blinded to the proposed therapies; and finally, reporting bias and attrition are not applicable as this is a protocol study.

Ethics approval and consent to participate

This research was submitted to the Research Ethics Committee of the Federal University of Rio Grande do Norte, under protocol number 3.084.420 and registered as a clinical trial in the Brazilian Registry of Clinical Trials (ReBEC) (registration number RBR-67y6cz, October 14, 2019). When recruited, all participants will be duly informed about the research and will sign a clear and informed consent form according to Resolution 510/16 of the National Health Council and in accordance with the Declaration of Helsinki.

Discussion

Exergames are effective for improving the balance of elderly diabetics (Lee & Shin, 2013). However, there are not many studies of virtual reality and balance in elderly diabetics that demonstrate the need for new research. With the knowledge derived from this study, the most effective therapy can be determined through satisfactory results in the health of elderly diabetics. The emphasis on the management of elderly diabetics in clinical practice should include reducing the risk of falls, improving gait, and focusing on strategies to maintain body balance and necessary body adjustments.

Most current studies on exergames used in diabetic individuals assess cardiorespiratory outcomes (Höchstmann, Schupbach & Schmidt-Trucksass, 2016; Höchstmann, Zurcher, Stamm, & Schmidt-Trucksass, 2016), or target a population of children and adolescents (Staiano, Abraham & Calvert, 2013; Staiano, Abraham & Calvert, 2012; Feltz, Irwin, & Kerr, 2012). Other studies related to the elderly, address exergames performance at home (Höchstmann, *et al.*, 2017) or do not include a control group to evaluate comparative effects (Senior, Henwood, & Mitchell, 2015).

A study performed in 2017 (Brinkmann, 2017) had a sample of elderly diabetics; however, one of the inclusion criteria was overweight. In addition to this difference, the control group of the mentioned study did not perform any physical activity, contrary to the proposal of this study. Based on these findings and the low methodological quality of current studies (Höchstmann, Zurcher, Stamm & Schmidt-Trucksass, 2016); Christensen, *et al.*, 2016) of elderly diabetics, it is necessary to include studies with greater methodological rigor.

For this reason, the present protocol involves the performance of exercises for 40 minutes a day, two days a week, for 12 weeks, as mentioned. In this context, the protocol is performed in a supervised manner, reducing the training execution bias. The primary outcome of the research is balance, but this study addresses other characteristics that may be associated with comorbidities of T2DM, such as functional performance, cognition and symptoms of depression as secondary outcomes.

In addition, the follow-up will provide information on the durability of the training and its effects, increasing the rigor of the research methodology.

After providing scientific evidence for the effectiveness of this protocol, both clinical and research fields will benefit from a new therapeutic modality that can be used

in diabetic care centers. In addition, it is intended to expand the scientific arsenal of research of the diabetic elderly and to generate support for the development of future research on the subject. With this, new protocols can be generated and new levels of research can be achieved.

If participants experience any negative effects from performing the protocol, they will receive any and all necessary physical assistance. All study results will be emailed to participants, collaborating health professionals and researchers and to scientific production products.

The limitations of this study include a short follow-up time of three months, which allows only short-term results. Future investigations need to be conducted to observe the late effects of these exercises. Another limitation is the fact that the data in this study may not be applicable to multiethnic populations because it was restricted to the Brazilian elderly (Kuwata, *et al.*, 2017). Another limitation is the fact that the diet will not be evaluated and this data is important for adherence to self-care for the elderly diabetic (Freeman-Hildreth, *et al.*, 2019).

Trial status

Currently, this study is in the subject recruitment phase.

Data Availability Statement

Data collected during the study will be made fully available without restriction upon study completion.

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