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EXERCISES WITH AND WITHOUT VIRTUAL REALITY IN THE CONTROL OF PAIN ASSOCIATED WITH PARKINSON'S DISEASE: A RANDOMIZED, CONTROLLED, SINGLE-BLIND TRIAL

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Introduction: PPain in individuals with Parkinson's Disease (PD) may result from many factors such as progressive Centrak Nervous System (CNS) and/or musculoskeletal dysfunction. Pain may also be associated with functional deficits such as balance and gait, which share some central processing pathways. There is no consensus with regard to the treatment of pain in this condition, and exercises associated with virtual reality (VR) may be an effective intervention. **Objective:** To evaluate the influence of an exercise program associated with virtual reality (VR) on pain intensity, correlating changes in this symptom with the functional performance of elders with Parkinson Disease (PD). **Design:** randomized comparative clinical trial. **Setting:** clinical facility from a school of physiotherapy in Brazil. **Participants:** 29 elders with PD. **Interventions:** exercises with VR and exercises without VR. **Main Outcome Measures:** pain, balance and gait, evaluated before and after 10 sessions, by Visual Analog Scale (VAS), Berg Balance Scale and 10 Meter Walk Test. **Results:** Reduction in pain intensity in the VR Group, and groups improved their balance and gait performance. Significant correlation was between the improvement in pain intensity and reduction in gait timing in the non VR Group *($r = 0.713$; $p < 0.005$)*. **Conclusion:** VR in elders with PD may be a tool for reducing pain intensity, and independently of the type, physical exercises had positive impact on their functional performance.

Keywords: Parkinson's disease. Pain. Balance. Gait. Virtual reality exposure therapy.

List of Abbreviations: PD (Parkinson Disease); VR (Virtual Reality); TFIC (Term of Free and Informed Consent); EG (Experimental Group); CG (Control Group); HY (Hoehn and Yahr); MoCA (Montreal Cognitive Assessment); VAS (Visual Analog Scale); BBS (Berg Balance Scale); 10MWT (10 Meter Walk Test); CNS (National Health Council)

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INTRODUCTION

Parkinson Disease (PD) is ranked as the second most frequent neurodegenerative disease in the elderly, after Alzheimer disease[1]. Its classical manifestations (bradykinesia, muscle rigidity, resting tremor and postural instability) interfere in activities such as transferences, balance and gait[2]. Associated with these manifestations, some non motor compromise may occur, with pain being one of the most frequent complaints reported by these individuals[3]. Therapeutic exercises may be considered an alternative for pain control in individuals with PD, but there is insufficient evidence with regard to their use.

Due to rapid technological advancement, resources used in rehabilitation by means of exercises have been developed exponentially. With specific regard to pain, Virtual Reality (VR) may be applied as a sensory feedback resource that creates illusory scenarios by manipulating and increasing the intensity of exercise practice. The lucid challenges of virtual games add extra motivation for the task and reduce the attention to the painful symptom[4].

Distinct groups of patients have been benefited by VR for reduction of the pain[5,6]. With specific regard to patients with neurological diseases, there is great scarcity of studies that endeavor to understand the interference of VR in the algic symptom, and up to now, the effect of the use of VR associated with exercises on pain control in elders with PD is unknown.

In parallel, there is little evidence about analgesic therapies for individuals with PD, so that the purpose of this study is to fill the gaps in these two areas and in their interaction. Therefore, the aim of this study was to evaluate the influence of an exercise program associated with VR on pain intensity, correlating changes in this symptom with the functional performance of elders with PD.

METHODS

Study Design and Participants

Randomized, comparative, single blind study, conducted in the clinical school facility in Brazil. The estimated sample was 26 individuals, considering a bicaudal test with an effect size of 0.5, alpha value of 5% study and power of 80%. The potential individuals were invited by a neurologist to voluntarily participate in the research.

In order to participate, they had to present the following eligibility criteria: a) minimum age of 60 years; b) proven clinical diagnosis of PD; c) score between 1 and 3 in the Hoehn and Yahr (HY) scale; d) capacity to understand the information provided by the researchers. Excluded from the study were those who: a) did not report pain; b) did not agree to sign the TFIC; c) were absent at a minimum of two sessions; d) presented dementia, according MoCA (Montreal Cognitive Assessment) test.

Randomization Criteria

29 composed the final sample, with 14 being randomized the VR Group and 15 to the non VR Group. This randomization was based on the scores of each patient, in accordance with the HY scale, which evaluates the development of PD and helps to classify the patients into one of five stages, according to motor symptoms. The patients were referred to a neurologist at the site of the research, together with a chart containing data such as name, age, gender and score of this scale.

A second researcher, who did not have access to the initial information about the evaluations and characterization of the subjects, was the only person responsible for carrying out the procedure of allocating the patients to groups, using a spreadsheet created by a computer program[7]. This spreadsheet, based on the scores obtained by the HY scale, randomly indicated the group to which the patient would be allocated. The spreadsheet contained a table with three columns: in the first, numbering from 1 to 29 in increasing order, from top to bottom; and in the second, the names of the two groups in a random manner. In the third column, the scores between 1 and 3, based on the HY scale, also distributed randomly. In possession of the referral chart, the researcher in charge of allocation verified the score presented by the patient and sent the individual to the group corresponding to the draw. After allocation, four researchers (two physical therapists and two physical therapy undergraduate students) previously trained and instructed, were responsible for the interventions. The CONSORT flow diagram can be followed in Figure 1.

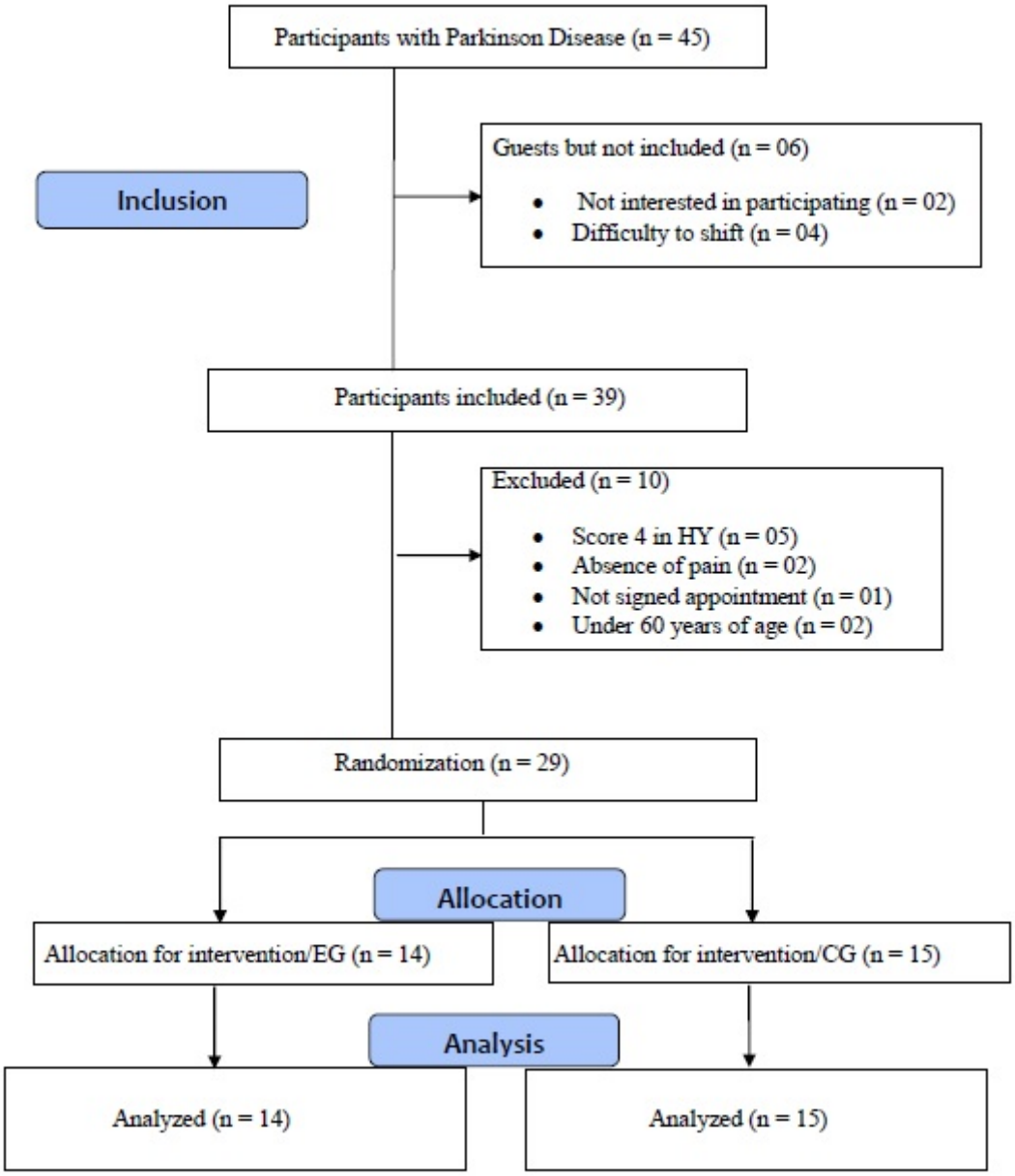

Figure 1: CONSORT Flow Diagram for Randomized Controlled Trials.

Evaluation

All the participants were submitted to 12 meetings with the researchers: a) an initial meeting, characterized as a pre-test, for sociodemographic description, with investigation about the time of disease, appearance of pain, and possible previous contacts with some VR resource, in addition to verification of the cognitive level, pain intensity and functional performance (balance and gait); b) 10 meetings with a duration of 35 minutes for the intervention sessions; c) a meeting for re-evaluation. These meetings were held on interspersed days, with Mondays, Wednesdays and Fridays being selected, in the afternoon period, for one month. The final evaluation was always on Mondays, Wednesdays or Fridays, after the last intervention's day.

Clinical Measures

To determine the patients' level of understanding of the commands given, the MoCA, a brief cognitive screening tool for mild cognitive impairment, was applied. This is a scale developed as a screening instrument for slight deficits in cognition, involving evaluation of functions such as naming, memory, attention, language, abstraction, orientation, late evocation, visual spatial execution and function. Its application time is short, an average of 10 minutes, during which the individual may attain 30 points, with

scores below 26 indicating some cognitive deficit. The Brazilian version was validated by Memória et al.[8], using individuals with clinical diagnosis of Alzheimer's Disease, slight cognitive dysfunction and with normal cognitive function.

Pain was evaluated by means of a Visual Analog Scale (VAS), an unidimensional instrument for quantification of pain severity[9]. During the course of the initial evaluations, it was not possible to state whether all patients were in the on or off period with regard to the use of medication, because some did not report control of the time of administration of their medications. This information was duly corrected for the interventions, in which each participant was advised to use dopaminergic medication between 40 minutes and one hour before the start of each session, causing all sessions to be performed during the ON period of dopaminergic medication.

The functional performance of these elders was evaluated by means of the Berg Balance Scale (BBS) and 10 Meter Walk Test (10MWT). The first evaluate the balance and the risk of falls in 14 activities, that has a repercussion on variables such as strength and flexibility[10], while the second is an instrument used in clinical evaluations as a measurable and comparative parameter during rehabilitations programs and scientific researches[11], with the objective of evaluating gait speed.

Intervention Protocols

As regards the procedures themselves, two stages of the intervention process were common to the two groups. Before and after each session, the participants were submitted to an exercise protocol that served to prepare the body for the activities that were developed, with duration of five minutes for each day of session. The protocol consisted of the following movements, with the patient seated: 1) active mobilization of the cervical spine at all anatomical plans (one minute); 2) active mobilization of shoulders, forward and backward (one minute); 3) Stretching of the upper limbs principal muscle groups (one minute); 4) active mobilization of the upper trunk (30 seconds); 5) Stretching spine muscles (40 seconds); 6) anteroposterior mobilization of the spine (20 seconds); 7) active mobilization of ankles (30 seconds).

The intervention protocol in the VR group was divided into two parts. The first part, performed between the first and fifth sessions, involved three games: 1) Free Step® (10 minutes); 2) Hula Hoop® (eight minutes); 3) Boxing® (eight to nine minutes). The second part, performed between the sixth and tenth sessions, involved four games; 4) Half Moon® (time corresponding to two rounds); 5) Penguin Slide® (time corresponding to four rounds); 6) Togo Twist® (time corresponding to two rounds); 7) Table Tilt® (10 minutes). The choice of these games was based on a study of Pompeu et al.[12], who used the Nintendo® Wii to verify their effects on balance and cognition in PD patients.

The intervention protocol in the non VR group (control group) was also divided into two parts, with exercises similar to those performed in the VR group. The first part, performed between the first and fifth sessions, involved three activities: 1) training of climbing up and down a stair; 2) Activity of lateral displacement of the body, while seated on a ball; 3) Balance training associated with the movement of reaching. The second part, between the sixth and tenth sessions, involved four activities: 4) Lateral displacement on an unstable surface, however, controlled by the examiner; 5) Lateral displacement on an unstable surface; 6) Trunk rotation movements with the use of a staff; 7) Balance training on an unstable surface, with the individual needing to keep a small ball in movement, making movements through 360°. The times were similar in both groups. The elaboration of this protocol was based on the observation of the movements realized in the protocol of the group that used the virtual reality, not being a validated protocol, but possessing movements exactly similar to the group with VR, without the participation of an audiovisual resource.

The procedures developed in this study were analyzed and approved by the Research Ethics Committee of the State University of Santa Cruz, Ilheus, Bahia, Brazil, on January 11, 2012, at extraordinary meeting No. E-44, Protocol No. 473/2011, in accordance with Resolution No. 196/96 of the National Health Council (CNS), which regulates researches involving human beings. Participation in the research was voluntary and occurred by means of signing the TFIC, after volunteers had been informed about the objectives, evaluation and intervention protocols and possible risks of the study.

Statistical Analysis

The results of the sociodemographic profile were described by means and standard deviation or absolute frequency. The groups were compared with each other before and after the intervention, by means of the Student's t-test for independent sample, and in a paired manner, by means of the paired Student's t-test, considering the Alpha value of 5%. The analysis were performed using the statistical software package SPSS 20.0.

To test the correlation between the changes in pain intensity with functional performance, the pre-intervention values were subtracted from the post-intervention values. In the case of VAS and the 10MWT, negative values indicated a reduction in the magnitude of pain and execution time of the test. Whereas for BBS, positive values indicated improvement in balance.

RESULTS

There was no loss of follow-up during the course of the interventions. Of the participants, 17 were of the male sex, aged between 60 and 80 years. The sociodemographic information, data about PD and the HY and MoCA scales, are presented in Table 1. Of all participants, 22 had mild cognitive impairment, according MoCA scale. For exploratory analysis of the data, descriptive and frequency statistical tests were used. For inferential analysis, the Student's t-test was used to compare the means of the general scores.

Table 1: Socioepidemiological characterization of individuals who composed the sample.

	Wii (n = 14)	Control (n = 15)	
Sex (n)			P* 0.113
M (17)	6 (20.70%)	11 (37.93%)	
F (12)	8 (27.58%)	4 (13.79%)	
Age (in years)			***P* 0.031***
Between 60 and 70	4 (13 .79%)	9 (31.03%)	
Between 71 and 80	10 (34.48%)	6 (20.70%)	
Educational level			P* 0.988
Eighth year completed	4 (13.79%)	4 (13.79%)	
11th year completed	7 (24.14%)	7 (24.14%)	
College education completed	3 (10.35%)	4 (13.79%)	
Time of diagnosis			P* 0.815
Up to 1 year	4 (13.79%)	4 (13.79%)	
Between 1 and 5 years	5 (17.24%)	6 (20.70%)	
Over 5 years	5 (17.24%)	5 (17.24%)	
Time of symptoms			P* 0.815
< 1 year	4 (13.79%)	4 (13.79%)	
Between 1 and 5 years	5 (17.24%)	6 (20.70%)	
>5 years	5 (17.24%)	5 (17.24%)	
HY	2.14 (1.03)	2.33 (1.11)	P* 0.636
MoCA	23.71 (2.79)	23.47 (3.07)	P* 0.822

Abbreviations: HY (Hoehn and Yahr Scale); MoCA (Montreal Cognitive Assessment). Values presented in absolute numbers and relative frequencies, and in means and standard deviation. * Student's-*t* test

Figure 2 shows the results of the evaluations before and after the intervention protocols in the two groups, showing the primary outcome (pain) and the secondary outcomes (balance and gait speed) separately. The groups studied were similar at baseline, as regards pain intensity (VAS) and scales that evaluated functional performance. After the interventions, there was reduction in pain intensity (Figure 2A) in the VR group ($p = 0.0186$). Both groups presented improvement in functional performance by means of BBS (Figure 2B; VR group, $p = 0.003$; non VR group, $p = 0.006$) and 10MWT (Figure 2C; VR group, $p = 0.005$; non VR group, $p = 0.008$).

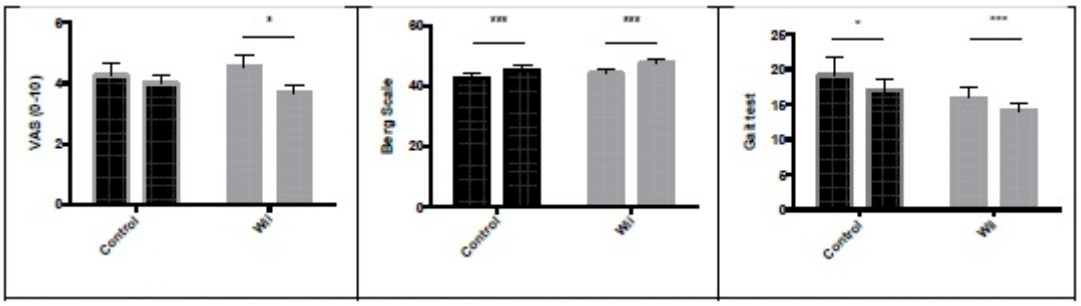

Figure 2. The figure present the pain intensity values (VAS), balance (BBS) and gait speed (10mWT), measured at baseline and on conclusion of the interventions. A reduction in pain intensity was noted only in the group submitted to VR (2A). The two groups presented improvements in both balance (2B) and gait speed (2C).

Correlations between the primary outcome and the secondary outcomes are shown in Figure 3, using the Pearson correlation coefficient. The only significant correlation was between the improvement in pain intensity and reduction in time of execution of 10MWT in the non VR group (Figure 3B; $r = 0.713$, $p < 0.005$). The first figure (Figure 3A) shows the correlation between pain reduction and balance improvement in the group that did not use VR ($r = -0.450$; $p = 0.092$). In the group that used virtual reality as a resource, no statistically significant correlation was verified, either between reduction in pain intensity and improvement of balance (Figure 3C; $r = -0.302$; $p = 0.293$), or between reduction of pain and increase in walking speed (Figure 3D; $r = 0.178$; $p = 0.541$).

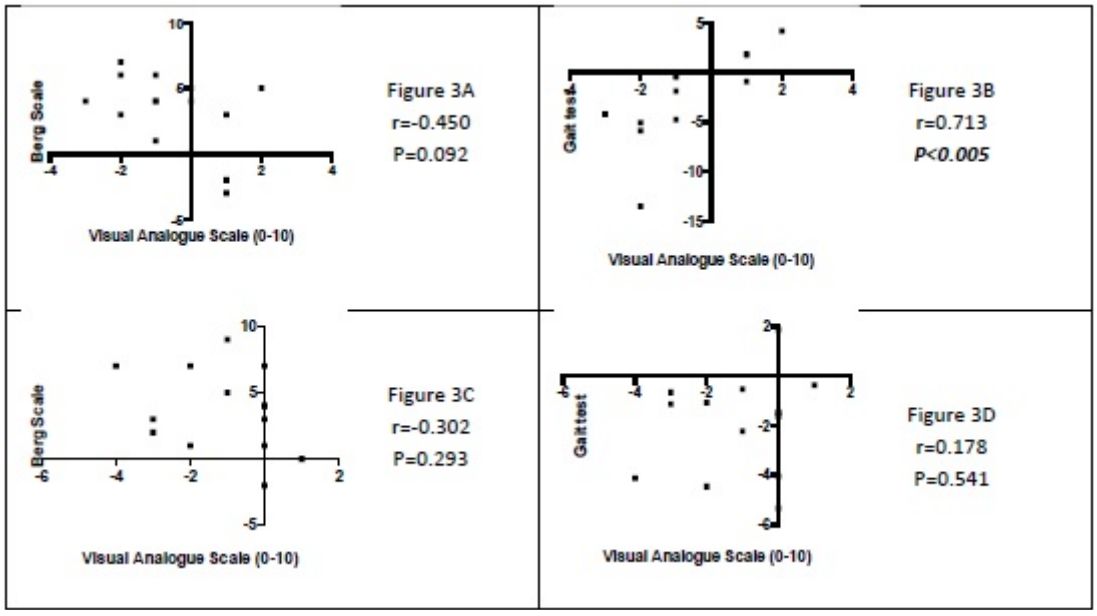

Figure 3. Figure shows the Person correlations between the variations in pain intensy (VAS) and balance (BBS) and with gait speed (10MWT), after the interventions. To obtain theses indices, the values obtained after the interventions were subtracted from the baseline values. The improvement is expressed by negative values in VAS and in 10MWT, an positive values in BBS. The only significant correlation occurred bertween pain intensy and gait speed in the control group (Figure 3B)

DISCUSSION

The aim of this study was to evaluate the influence of an exercise program associated with VR on the pain intensity and correlate this with the functional performance of elders with PD, comparing their findings with the results of an exercise program without the use of VR. Analysis of the data demonstrated that there was reduction in pain intensity only in the VR group, and improvement in functional performance in both groups.

The level of cognitive compromise must be considered when one evaluates subjects with PD, especially when an eminently subjective symptom such as pain is investigated. In the present study, 76.86% of the patients, irrespective of the group they were in, presented scores below 26 points. This study is, however, similar to others and individuals with PD who present some alteration in cognitive function have frequently been found[13]. As the primary outcome of our study was pain intensity analyzed by means of VAS, a simple scale, but one whose applicability can be difficult for children and elderly persons to understand, it's possible that rather imprecise reports may have influenced the responses given by individuals, due to the subjective nature of describing an algic symptom.

The participants that composed the sample of this research reported moderate levels of pain, which appears to be common in PD. Although the presence of neuropathic pain wasn't identified in this study, it may be a factor that contributes to increasing pain intensity. Muscle pain is the most frequent type of non dystonia pain associated with PD, and may be related not only to peripheral factors, but also to a system of abnormal nociceptive information processing in the Central Nervous System[14].

As a secondary symptom, pain may occur as a result of musculoskeletal dysfunctions observed in individuals with PD, such as camptocormia[15] (abnormal posture of the thoracolumbar spine region and of the knees in flexion), hypomobility and limitation in the amplitude of movement. These alterations commonly cause muscle weakening, and programs with a view to stimulating active mobility have been used with satisfactory responses. There are evidences that demonstrate positive results with the use of virtual reality in trunk mobility of patients with PD[16]. This may be a factor in pain reduction in specific groups of patients, and future studies should investigate the effect of exercises on different sub-groups of individuals with PD.

The use of exercises to control pain in individuals with PD has demonstrated that irrespective of the type of exercise performed, the intensity of the algic symptom in these individuals tends to diminish[17]. Our findings confirmed this hypothesis, although the effect sizes were small and without correlation with balance and gait in the VR group. Thus they can't be considered clinically conclusive and significant, since there was no reduction greater than 30% in pain intensity. In spite of VR involving higher degrees of distraction, which may diminish the focus on pain and maximize performance of the movements, apparently the exercises are also an important factor in control of the symptoms. This effect may have been the cause of a positive correlation between the improvement in gait with pain intensity in the non VR group, however the intensity of VR may be an important factor to consider in future studies involving subjects with PD.

It has been reported that individuals with posture and balance disturbances, associated with aging and neurodegenerative pathologies, who develop an inadequate postural response to an extrinsic disturbance, may be more susceptible to a condition of pain aggravation or more predisposed to falling[18]. Previous studies have also shown that one of the main factors that influence the appearance of lumbar pain is segmental instability, and that sudden changes in load are circumstances commonly incur an episode of lumbar pain[19]. Pain, as an etiologic factor of functional alterations, especially in individuals with PD at advanced stages, is exacerbated, leading to the occurrence of abnormal postures and changes in gait[20]. No matter to what extent the mechanisms that lead to these alterations in postural control remain obscure, it's possible that there may be a correlation between altered posture and the modifications in the sensorial and motor systems, since pain is an important factor for mechanical and neural alterations to occur[21,22].

Studies that have correlated the use of VR with balance in elders with PD have demonstrated positive impacts on this outcome variable. In one study[23] that compared the balance of elders in two distinct groups (exercises with and without VR), the

improvement in balance and postural stability was greater in the group submitted to a protocol of exercises with the use of VR. These findings possibly indicated that the individual's interaction with the games improves the performance of the exercises. It has also been suggested that dual-task exercises, either associated with VR, or not, have greater effect on motor behavior[24], which could help with pain reduction in these individuals, and improve functionality.

A positive and significant correlation was observed between pain reduction and gait improvement in the non VR group. The effects of a speed controller in the adaptation of cinematic gait analysis were investigated, proving that the use of VR associated with training on a treadmill could, among other benefits, provide an increase in cognitive engagement for the rehabilitation of gait, improving the strategic stability in its control[25]. The results of this study about performance in gait speed in elders with PD submitted to exercise programs were consistent, and the use of VR technologies may improve the performance and motor learning in individuals after neurological disturbances, including improvements in gait patterns and, consequently, in reducing pain intensity.

CONCLUSION

Based on the results found, it was concluded that the use of VR in elders with PD may be a tool for reducing pain intensity, and that irrespective of the type, physical exercises had a positive impact on functional performance in these individuals. There is growing and expanding interest in knowing about a technological resource used by various rehabilitation professionals, which leads us to think about the possibility of including games or entertaining resources in clinical practice and the rehabilitation process, providing greater sensorimotor and cognitive integration with the procedures performed.

It is noteworthy, as a limitation of the study, that it was not possible to control the period in which all subjects administered their dopaminergic replacement medications for the initial evaluations. Furthermore, it is necessary to control the use of medication by patients in all moments. It is important to emphasize that VAS, in its original format, without numbers or other forms of making, has not been shown to be a reliable instrument when applied to elderly individuals with cognitive alterations, because we have in terms of pain a symptom of merely subjective characteristics.

Given the reduced sample size and sample heterogeneity, it is necessary to carry out more studies about the relationship between pain, PD and VR, with a more homogeneous sample, with a greater number of patients and with the differentiation of the types of pain present in each individual.

AUTHOR CONTRIBUTIONS

d'Alencar MS participated in the elaboration of the project, the evaluations of the participants of the research, the interpretation of the data and the writing of the scientific article. Ribeiro JAM participated in the data collection of the research. Cruz RVS participated in the survey data collection. Sá KN contributed to the drafting of the scientific article. Pinto EBC contributed to the drafting of the scientific article. Baptista AF participated in the design, design, statistical analysis of the data and writing of the scientific article.

COMPETING INTERESTS

No financial, legal or political competing interests with third parties (government, commercial, private foundation, etc.) were disclosed for any aspect of the submitted work (including but not limited to grants, data monitoring board, study design, manuscript preparation, statistical analysis, etc.).

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