Immersive virtual reality and antigravity treadmill training for gait rehabilitation in Parkinson's disease: a pilot and feasibility study

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Introduction. Treadmill training is considered an effective intervention to improve gait ability in patients with Parkinson's disease (PD). In parallel, virtual reality shows promising intervention with several applications in the inpatient medical setting.

Aim. To evaluate the feasibility and preliminary efficacy of mechanical gait assistance combined with immersive virtual reality in patients with PD.

Patients and methods. This pilot and feasibility study followed a pre-post study design. The intervention consisted of 12 sessions of 30 minutes, distributed regularly over four consecutive weeks. Participants walked on a treadmill with a body-weight support system set at approximately 20% of body weight and equipped with a virtual reality helmet controlled by a two-handed joystick. Feasibility and intervention outcomes were collected at baseline and after four weeks of intervention.

Results. Twelve participants of 60 patients were finally enrolled. Nine of them (75%) completed the treatment intervention with an adherence rate of 97%. Two participants left the study, one of them due to sickness associated with virtual reality and another because of a lack of motivation. There were significant differences associated with small-medium effect sizes when comparing the pre and post values for walk distance, walk speed, balance, and quality of life.

Conclusions. The present study provided preliminary evidence supporting the feasibility of the combination of antigravity treadmill and immersive virtual reality system for the rehabilitation of patients with PD.

Key words. Gait. Parkinson's disease. Physical therapy. Quality of life. Treadmill training. Virtual reality.

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Funding:
P.B.L. is supported by the Grant FPI 2018 (CPB09/18) from 'Gobierno de Aragón' and co-financed by 'Programa Operativo FSE Aragón 2014-2020'. Aldebran provided the equipment, and Cross4Health supported the project that led to the development of Motigravity (Grant Agreement 731391, Sub-Grant Agreement no. 2018/A05-4).

Acknowledgments:
Aragon Association of Parkinson.

Accepted:
30.10.20.

How to cite this paper:
Brandín-De la Cruz N, Secorro N, Calvo S, Benyoucef Y, Herrero P, Bellosta-López P. Immersive virtual reality and antigravity treadmill training for gait rehabilitation in Parkinson's disease: a pilot and feasibility study. Rev Neurol 2020; 71: 447-54. doi: 10.33588/rn.7112.2020352.

Versión española disponible en www.neurologia.com

Introduction

Neurological disorders are a common health problem affecting people of different ages and sexes all around the world. During the last decades, despite innovative treatments and early detection, both the prevalence and the number of disability-adjusted life-years of the population with neurological disorders continue to increase [1]. All of the neurological disorders which affect the central nervous system are associated with a decrease in quality of life, higher disability, and a loss of functional performance, such as gait difficulties [2].

Parkinson's disease (PD) is the most frequent neurological affectation in the elderly, along with dementia [2]. Prevalence in industrialized countries is estimated between 0.3-1% in subjects older than 60 years, and 3% in people over 80 years of age, with incidence rates of between 0.08 and 0.18 per 1,000 people/year [3]. PD is a progressive illness associated with the death of dopamine-producing cells, causing an imbalance between neurotransmitters due to an increase in acetylcholine and glutamate [4]. It mainly affects a person's movements, characterized by tremor, rigidity, and bradykinesia, causing muscle weakness and balance alteration [5,6]. This neurological disease affects gait with a gait pattern frequently altered, leading to difficulties in daily activities. Nowadays, the standard physiotherapy treatment consists of improving balance skills, strength, and coordination by teaching simple exercises [7], combining with robotic gait assistance when possible [8].

This study used a rehabilitation approach that combines immersive virtual reality with a treadmill providing mechanical body weight support thanks to a system of harnesses and pulleys. Treadmill training is considered an effective intervention to improve gait endurance [9] and gait parameters such as gait speed, stride length [9,10] in patients with PD, without additional risk compared to standard physiotherapy treatment [10]. In parallel, virtual reality

shows promising interventions with several applications in the inpatient medical setting [11]. Indeed, rehabilitation with virtual reality allows the person to work on locomotion disorders, gait, and balance, as well as any other diseases. Virtual reality is noted as a potential therapeutic tool to improve balance and gait ability [9,12,13] in patients with PD without any associated adverse effects [14]. The combination of both existing treatment procedures may provide innovation in neurologic rehabilitation, therefore becoming an alternative to the standard physiotherapy methods for gait rehabilitation. The innovative treatment resulting from joining mechanical, proprioceptive, and immersive visual stimuli could have more effect at the central level, and thus improve the autonomy and independence of individuals. Besides, there are no previous studies in patients with PD or other adult neurological populations which have considered this therapeutic combination. This study aimed to evaluate the feasibility and preliminary efficacy of mechanical gait assistance combined with immersive virtual reality in patients with PD.

Patients and methods

Study design

This pilot and feasibility study followed a pre-post study design [15], approved by the Ethics Committee of Aragon (CEICA) with registration number C.P.-C.I. PI18/386 and registered in ClinicalTrials.gov with the identifier NCT04117737.

Patients

Each patient was informed about the nature of the study, objectives, and voluntary participation, as well as possible adverse effects that may occur during its implementation, such as muscle fatigue, sickness, or nausea. Each participant signed informed consent before participating in the study.

Inclusion criteria were: diagnosis of PD by a neurological doctor; an alteration of the gait but being able to walk independently for a distance of at least 10 meters; a height higher than 150 cm; being more than 18 years old. Exclusion criteria were: being blind; having medical contraindications for walking; being an amputee; a history of intake of alcohol-drugs; presenting other diseases that impede the intervention. Withdrawal criteria were: experiencing pain during walking that changed the gait pattern; refusal to continue; missing more than two interventions or one assessment.

Procedure

The study was executed in the Aragon Association of Parkinson (Zaragoza, Spain) for patients with PD. The association informed all their members of the possibility of participating through internal communication methods. Those patients who reported their willingness to participate in the study were codified with a consecutive number. Participants were consecutively assessed for eligibility according to a randomized list. Participants who fulfilled the inclusion criteria were enrolled in the intervention group. Every participant was assessed for all intervention outcomes at baseline (hereafter called 'pre') and after 4-weeks (hereafter called 'post'), precisely three days after the end of the intervention program. The intervention began just after the baseline assessment was completed.

Intervention

The intervention consisted of 12 sessions of 30 minutes, distributed regularly over four consecutive weeks (3 sessions per week) [16-19]. Sessions consisted of walking at a self-selected comfortable walking speed on a treadmill with a body-weight support system set at approximately 20% of body weight and equipped with a virtual reality helmet controlled by a two-handed joystick (Motigravity, manufactured by Aldebran; Curno, Italy) (Fig. 1). Before and after each training session, participants performed warm-up and cool-down exercises of 5-minutes each. The body-weight support discharge was selected, taking into account previous studies [18-21]. The virtual environment consisted of a Martian landscape with dunes, rocks, and buildings, allowing slope changes, obstacles, and barriers, respectively (Fig. 2). The virtual reality system was controlled via the two-handed joystick device and was independent of the treadmill speed. The joysticks offered the ability to use both hands, further enhancing virtual reality interaction and dual-task rehabilitation. The patient was told to explore the landscape and move forward by pushing both joysticks simultaneously in the forward direction. At the same time, the patient was instructed to push both joysticks simultaneously to the right or the left to change the direction and overcome obstacles. The patient's representation in the virtual reality system was designed to stop when there was no interaction with the joysticks, although the treadmill follows running. Each patient was asked to select their comfortable speed during the warm-up. Nevertheless, the physiotherapist responsible for the

intervention adjusted the velocity during each session, depending on the patient's perception and fatigue.

Measures

Sociodemographic and clinical variables

Patient's sociodemographic data (gender, age, height, weight) and clinical data (modified Hoehn and Yahr staging scale [22], number of hours walking by day, number of falls during the last week) were collected at baseline.

Feasibility of recruitment and protocol adherence

Rates of recruitment, eligibility, and adherence to the intervention were registered. One week after the end of the intervention program, an independent evaluator, blinded to the intervention and the assessment, conducted a short interview regarding the participants' satisfaction and acceptability of assessment and intervention procedures. Participants rated their level of satisfaction with the intervention in a 5-points Likert scale (0: 'very dissatisfied'; 1: 'quite dissatisfied'; 2: 'neither satisfied nor dissatisfied'; 3: 'quite satisfied'; 4: 'very satisfied').

Intervention outcomes for investigating preliminary efficacy

All outcome measures, at Pre and Post assessments, were evaluated by a single physiotherapist trained in the protocol. All evaluations were performed when participants were in the 'on' medication state, approximately one hour after the intake of their regular medication [23].

The primary outcome for investigating preliminary efficacy was gait distance, in meters, by using the 6 Minute Walk Test (6MWT). This test consists of measuring the maximum distance that the subject can walk a flat surface for 6 minutes [24].

Secondary outcomes for investigating preliminary efficacy were gait speed, balance, and quality of life.

Gait speed, in meters per second, was assessed by using the 10 Meter Walk Test (10MWT). This test consists of asking the subject to walk at a comfortable speed a 14-meters distance on a flat surface and measuring the time spent from meter 2 to meter 12 (to remove the increase and decrease velocity phases) [25].

The balance level was estimated by using the Tinetti scale. The Tinetti test is a simple and reproducible scale which is composed of two subscales, the balance and gait sections. The balance section is performed in sitting and standing positions and covers a maximum of 16 points, while the gait section is performed by walking and represents a maximum of 12 points. Total scores over 24 points indicate a low risk of falls, while scores under 18 points indicate a high risk of falls [26].

Quality of life was assessed by using the 36-Item Short-Form Health Survey (SF-36) [27]. SF-36 assesses eight physical and mental health domains: limitations in physical activities because of health problems (physical functioning); limitations in social activities because of physical or emotional problems (social functioning); limitations in usual role activities because of physical health problems (role physical); bodily pain (bodily pain); psycho-

Figure 1. Experimental image of a patient walking on the Motigravity system. a) Posterior view; b) Anterior view.

Figure 2. Representative images of the virtual environment. The environment consisted of a Martian landscape with rocks and buildings (a) or dunes (b).

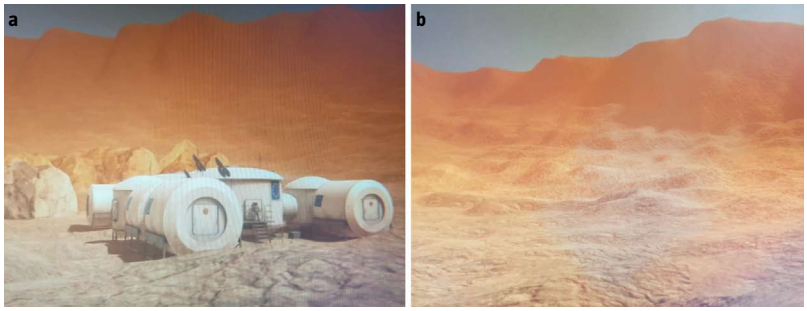
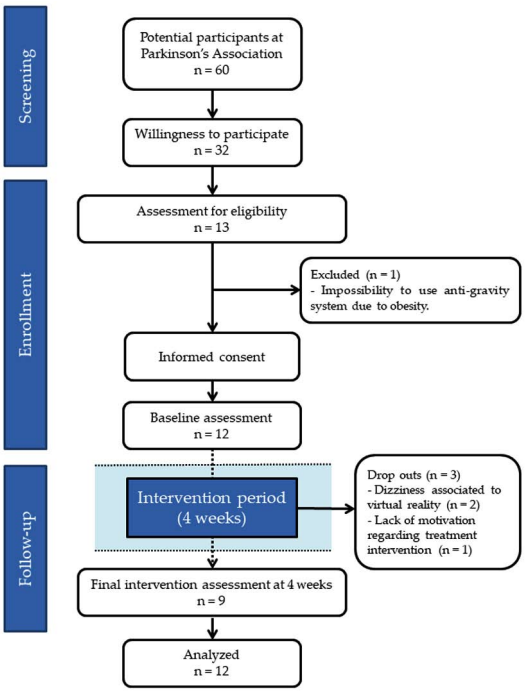


Figure 3. Flow chart.



logical distress and well-being (mental health); limitations in usual role activities because of emotional problems (role emotional); energy and fatigue (vitality); and general health perceptions (general health). For each scale, item scores are coded, summed, and transformed, with final values expressed as a percentage ranging from 0 (worst health) to 100 (best health).

Sample size

An estimated pilot study sample size was conducted using G*Power v. 3.1.9.2 software, taking into account previous data of minimal detectable change for the 6MWT in the population with PD [24]. A total sample of 12 participants was required expecting an improvement considered as large effect size (Cohen's d = 0.8), with a significance level of 0.05 and a power of 80%.

Statistical analysis

Descriptive statistics were used to report data on the feasibility of recruitment and protocol adherence. Variables were described in mean and standard deviation or median and interquartile range. An intention to treat analysis was made by carrying forward the last value. The Shapiro-Wilk test of normality showed that intervention variables did not follow a normal distribution. Therefore, the Wilcoxon signed-rank test was used to determine any difference between pre and post assessment scores for all intervention outcomes. The significance level was set at $p < 0.05$. Cohen's d was calculated by the standardized difference between pre and post means (small effect: 0.2; medium effect: 0.5; large effect: 0.8) in those patients who completed the intervention. The statistical analysis was performed with SPSS Statistics v. 25 software.

Results

The participants' flow diagram is presented in figure 3. Recruitment commenced in September 2019 and was completed by November 2019. Of the 60 potential participants who were invited to participate at Parkinson Aragon, 32 (54%) reported their willingness to participate. Potential participants were numbered and randomly allocated to reach the a priori sample size estimation. Thirteen patients were assessed for eligibility, and one of them was excluded because the participant was not able to wear the harness due to obesity. In total, nine participants (75%) completed the treatment intervention and were assessed at the 4-week follow-up. The adherence rate, calculated as the ratio between the sessions performed and the sessions scheduled (12 sessions), was 97%. Dropouts across the study were due to sickness associated with virtual reality after two sessions of intervention (n = 2) and because of lack of motivation after three sessions of intervention (n = 1). The three dropouts were male and had a score of 2-2.5 on the modified Hoehn and Yahr staging scale. Amongst the nine participants who completed the intervention, seven of them reported being 'very satisfied' with the intervention, while two were 'quite satisfied'. Participants favorably highlighted the security sensation of the body weight support at the same time they had to perform the dual-task consisting of walking over the treadmill and controlling the virtual reality system with the joystick devices. In contrast, the main suggestion of improvement concerned the Martian landscape, which sometimes was considered monotonous.

Participants had a mean age of 68.8 ± 7.7 years, and 58% were male. The mean weight was 70.2 ± 15.2 kg, and the mean height was 162.6 ± 8,2 cm. According to the modified Hoehn and Yahr staging

scale, there were four participants (33%) at stage 2, three participants at stage 2.5 (25%), four participants (33%) at stage 3, and one participant (8%) at stage 4. They reported a mean of 7.5 ± 4.9 hours of walking per week and a median of 0 falls per week (interquartile range: 0-1).

Table shows median scores for intervention outcomes at both time points. Significant differences were observed when comparing the pre and post values for distance (p = 0.005; effect size: 0.3) at 6MWT, for speed (p = 0.047; effect size: 0.2) at 10MWT, for balance (p = 0.044; effect size: 0.6) at the Tinetti scale, and for physical functioning (p = 0.027; effect size: 0.4), role physical (p = 0.049; effect size: 0.6) and bodily pain (p = 0.018; effect size: 0.5) at SF-36. Figure 4 shows individual changes in the 6MWT, 10MWT, and Tinetti scale for participants who fulfilled the treatment intervention.

Table. Median scores and interquartile range for study variables at pre and post-assessments.

	Pre (n = 12)	Post (n = 12)	p	ES
6MWT (m)	326 (181-379)	374 (201-394)	0.005 [a]	0.3
Tinetti: total (0-28)	24 (20.8-25.8)	26 (23.5-27.8)	0.044 [a]	0.6
Tinetti: gait section (0-12)	11 (9.3-12)	12 (11-12)	0.123	0.6
Tinetti: balance section (0-16)	13.5 (11.3-14)	14.0 (12.3-15.8)	0.066	0.5
10MWT (m/s)	1.38 (0.85-1.64)	1.39 (0.90-1.65)	0.047 [a]	0.2
Physical functioning (SF-36, 0-100)	48 (21-68)	60 (41-83)	0.027 [a]	0.4
Social functioning (SF-36, 0-100)	63 (50-72)	69 (41-85)	0.263	0.4
Role physical (SF-36, 0-100)	41 (9-74)	63 (31-75)	0.049 [a]	0.6
Bodily pain (SF-36, 0-100)	46 (24-65)	63 (27-82)	0.018 [a]	0.5
Mental health (SF-36, 0-100)	48 (41-56)	52 (45-64)	0.212	0.4
Role emotional (SF-36, 0-100)	67 (35-98)	67 (50-100)	0.246	0.4
Vitality (SF-36, 0-100)	38 (19-45)	43 (35-50)	0.065	0.6
General health (SF-36, 0-100)	38 (30-56)	45 (35-54)	0.234	0.3

6MWT: 6 Minute Walk Test; 10MWT: 10 Meter Walk Test; ES: effect size; SF-36: 36-Item Short-Form Health Survey. [a] Significant differences between pre and post after Wilcoxon signed-rank test (p < 0.05).

Discussion

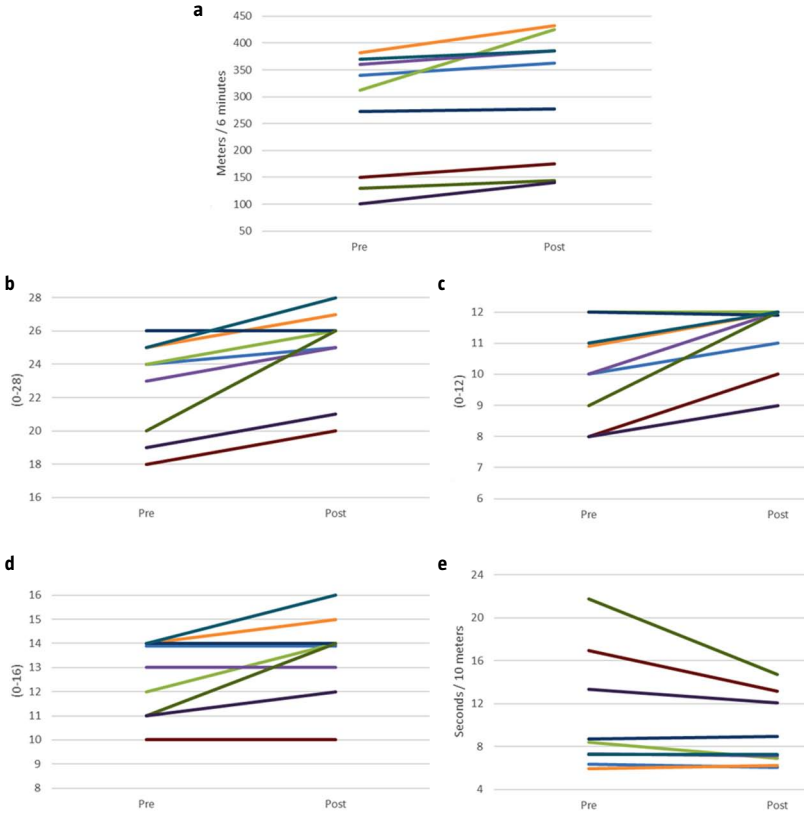
This study evaluated the feasibility and preliminary efficacy of an antigravity treadmill combined with immersive virtual reality for gait rehabilitation in patients with PD. The main findings suggested that 12 sessions of 30 minutes, over four weeks, were acceptable and feasible to deliver in persons with PD. Participants presented excellent adherence to the interventions and reported high levels of satisfaction with the intervention. The study also provides preliminary evidence to suggest that the intervention may have a positive impact on gait distance, gait speed, and quality of life.

Similar protocols of 3 sessions per week of 30-45 minutes treadmill training during four weeks revealed improvements in gait ability [17-19], motor function, balance [16,28], cognitive parameters, and depression [17] in patients with PD. Other studies found similar results to ours for the 6MWT, such as Picelli et al. [17] that reported an improvement of 36 meters during four consecutive weeks of treadmill training, Nadeau et al [29] that showed an increase between 34 to 40 meters and 29 to 44 meters in a period of 12-weeks and 24-weeks, respectively. In this line, de Melo et al [30] obtained an improvement of approximately 52 to 87 meters after a 3-weekly session during 4-weeks of treadmill training or intervention of immersive virtual reality compared to a control group. However, they did not explore the effect of combined interventions.

Concerning our secondary outcomes, post-treatment speeds in the 10MWT were similar to previous studies that implemented either treadmill [17,18,21, 28] or virtual reality [31] independently. Nevertheless, improvements were inferior because our baseline values were already high. The high baseline scores could indicate a ceiling effect that made it difficult to find differences in the pre and post values. Something similar may have occurred concerning the Tinetti scale, as initial scores were higher than baseline values reached in previous studies in PD [20,26].

Previous studies have shown the effectiveness of virtual reality training in gait [23,30-32], balance [31,32], and cognitive function [33], but without the integration of an antigravity mechanical support system. According to the authors' knowledge, there are no previous studies that combined an antigravity treadmill with immersive virtual reality in patients with PD. In this context, Mirelman et al [34] found that an intervention of 3-weekly sessions over six weeks, based on non-immersive virtual reality combined with a medical treadmill, reduced the risk of falls in older adults in the long term, including a sub-group of patients with PD. One year later, Peruzzi et al [35] compared the same treat-

Figure 4. Individual changes in participants who fulfilled the treatment intervention (*n* = 9). a) 6 Minute Walk Test; b) Tinetti scale: total; c) Tinetti scale: gait section; d) Tinetti scale: balance section; e) 10 Meter Walk Test.



ment against a treadmill-only based intervention in patients with multiple sclerosis and found that the dual-task intervention was effective in improving balance and spatiotemporal parameters of gait.

On the one hand, the improvement of patients in this study may be due to the benefits of treadmill training, which simulate the task of walking, improving motor learning, and strength of the lower extremities. On the other hand, dual-task with the virtual reality system could have contributed to improving motor function as well as the self-perception of the patients with PD [36].

Our pilot study followed a pre-post study design, which has the strength of temporality to be able to suggest that the outcome is impacted by the intervention [15]. However, a randomized controlled trial design would have been a better alternative due to pre-post studies not having control over other elements that are also changing at the same time as the intervention is implemented. Nevertheless, chronic diseases, such as PD, with extended periods of stability of clinical signs and symptoms, provide certainty that outcomes improvements are attributed to the specific intervention rather than the natural evolution of the disease [15]. Also, cognitive parameters should have been considered [37]; thus, cognitive impairment may have a substantial contribution to the manifestation in different parameters of gait in PD [38].

The present pilot study suggested that an intervention of 12 sessions over four weeks of antigravity treadmill combined with an immersive virtual reality system was feasible to deliver and acceptable for the rehabilitation of patients with PD. Preliminary evidence suggested that the proposed intervention has a positive effect on increasing gait distance, gait speed, balance, and quality of life. Future studies should evaluate the impact in the long term, with a randomized control trial design, considering both physical functioning and cognitive variables.

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Entrenamiento antigravitatorio e inmersivo de realidad virtual para la rehabilitación de la marcha en la enfermedad de Parkinson: estudio piloto y de viabilidad

Introducción. El entrenamiento en tapiz rodante se considera una intervención eficaz para mejorar la capacidad de la marcha en pacientes con enfermedad de Parkinson (EP). Paralelamente, la realidad virtual se muestra como una intervención prometedora con diversas aplicaciones en el entorno médico hospitalario.

Objetivo. Evaluar la viabilidad y la eficacia preliminar de la asistencia mecánica para la marcha combinada con la realidad virtual inmersiva en pacientes con EP.

Pacientes y métodos. Este estudio piloto y de viabilidad siguió un diseño pre-post. La intervención consistió en 12 sesiones de 30 minutos, distribuidas regularmente durante cuatro semanas consecutivas. Los participantes deambularon sobre un tapiz rodante con un sistema de descarga del peso corporal establecido aproximadamente en el 20% del peso corporal y equipados con un casco de realidad virtual controlado por un *joystick* para cada mano. Las mediciones de viabilidad y tratamiento se recopilaron al inicio del estudio y después de cuatro semanas de intervención.

Resultados. De un total de 60 pacientes, se reclutó finalmente a 12 participantes. Nueve de ellos (75%) completaron el tratamiento, con una tasa de adhesión del 97%. Dos participantes abandonaron el estudio, uno debido a náuseas asociadas con la realidad virtual y otro por falta de motivación. Hubo diferencias significativas asociadas con un tamaño del efecto pequeño-mediano al comparar los valores pre y post para la distancia recorrida, velocidad de la marcha, equilibrio y calidad de vida.

Conclusiones. El estudio proporcionó evidencia preliminar que apoya la viabilidad de la combinación de un tapiz rodante antigravitatorio y un sistema de realidad virtual inmersivo para la rehabilitación de pacientes con EP.

Palabras clave. Calidad de vida. Enfermedad de Parkinson. Entrenamiento en tapiz rodante. Fisioterapia. Marcha. Realidad virtual.