VIRTUAL REALITY THERAPY IN THE TREATMENT OF HAM/TSP INDIVIDUALS

• *radomized clinical trial* •

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Abstract

Introdution: The myelopathy associated with HTLV-1 or tropical spastic paraparesis (HAM/TSP) is a chronic, progressive demyelination disease that predominantly affects the spinal cord. The balance and locomotion in affected individuals are compromised and require therapeutic alternatives for rehabilitation. Objective: To determine the effect on aspects of balance, pain and quality of life for the use of virtual reality as an additional therapeutic option in the treatment of patients with HAM / TSP. Methodology: Randomized double blind clinical trial was conducted with nine individuals with the diagnosis confirmed by WHO criteria, divided into a group that performed a protocol of therapeutic exercises and another added that the exercise protocol, four games to virtual reality. All participants underwent an evaluation of the balance by Berg scale, of pain by visual analogical scale (VAS) and quality of life by SF-36 before and after 10 sessions. Results: The group that performed exercises with virtual therapy showed improvements in balance (p=0.033), functional capacity (p=0.010) and emotional aspects (p=0.004) in the intragroup analysis and the emotional aspects on intergroup analysis (p=0.027). Conclusion: Virtual reality did not reduce pain intensity but demonstrated a positive impact on the emotional aspects of quality of life.

Keywords: HTLV-1; HAM/TSP; Therapeutic exercises; Virtual therapy; Balance.

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INTRODUCTION

HTLV-1 associated Myelopathy, or Tropical Spastic Paraparesis (HAM/TSP), is a chronic progressive demyelinating disease that predominantly affects the spinal cord.[1] About 5% of patients infected with HTLV-1, may developd HAM/TSP, usually in the fourth or fifth decade of life.[2-3] Although uncertain, the pathogenesis of HAM/TSP is characterized as a peri-vascular demyelination and axonal degeneration, with destruction of nerve cells and a consequent reduction in the sensoriomotor ability.[4]

The classic symptoms of HAM/TSP are a progressive weakness of the lower limbs, urinary urgency, spasticity, patellar hyperreflexia, Babinski sign, impairment of proprioceptive sensitivity of the limbs and chronic pain, especially lumbar.[5-6] Individuals with myelopathy can progress with impairment of locomotion, impaired balance and posture disorders.[7] Many of them will need to use assistive devices such as crutches, walkers and wheelchairs, which increase physical dependence and the risk of falls, and reduce social participation, quality of life and productive capacity.[6]

Different physiotherapeutic approaches have been shown to help treating people with sensorimotor deficits arising from central nervous system diseases, such stroke, cerebral palsy, head trauma and spinal cord injuries,[8] and some perspectives have been presented to individuals with HAM/TSP.[9] The evidence about the benefits of exercises evaluated through clinical trials with this population is still incipient. Protocols using functional exercises[10] and Pilates[11] showed positive results as regards to pain and balance, with a positive impact on quality of life.[11] However, the strong locomotion dysfunctions are limiting factor for the attendance of these individuals to health care facilities. For this reason, the search for alternatives to improve sensory-motor skills autonomously, in a domiciliary program, is an alternative to this population.

Virtual reality therapy using video games has been used to stimulate the function of the body movement and reduce sedentarism.[12] These resources have strong potential in assisting autonomy, motor learning, physical activity, social and cultural participation.[13-20] Virtual reality therapies involve the concept of augmented reality by combining elements of the real and virtual elements of the world to improve overall function.[12,13] As it may be helpful to treat neurological conditions, we hypothesized that it would be a complementary alternative to treat pain and balance in participants with HAM / TSP.

MATERIALS AND METHODS

STUDY DESIGN AND POPULATION

This study was a blind randomized clinical trial conducted with individuals of both gender, with a confirmed diagnosis of HAM/TSP according to criteria of the World Health Organization (WHO) and De Castro-Costa et al, 2006[12] All of them were regular patients of the Multidisciplinary Center for HTLV Care and Research of Bahian School of Medicine and Public Health (EBMSP).

SAMPLING AND ELIGIBILITY CRITERIA

We included in the study only participants with confirmed diagnosis of HAM/TSP, made by a neurologist, and confirmed by positive ELISA, Western Blot, liquor, and neurological imaging. The exclusion criteria involved orthopedic disorders, cardiovascular and other associated neurological diseases (sequelae of stroke, Polio, Tumors, Plate Motor Diseases), inadequate visual acuity without correction (especially nystagmus), absence of independent walking and absence on three or more treatment sessions. The sample was composed of six individuals per group, assuming a standard deviation of seven points and an estimated difference between groups of 10 points in the Berg scale (primary outcome).

INSTRUMENTS AND PROCEDURES

The volunteers were divided into two groups by a randomization performed using a table of random numbers by a technician, who had no contact with patients. The control group (CG) consisted of participants who performed exercises without virtual reality, while the test group underwent exercises associated with virtual reality (VR) (Figure 1).

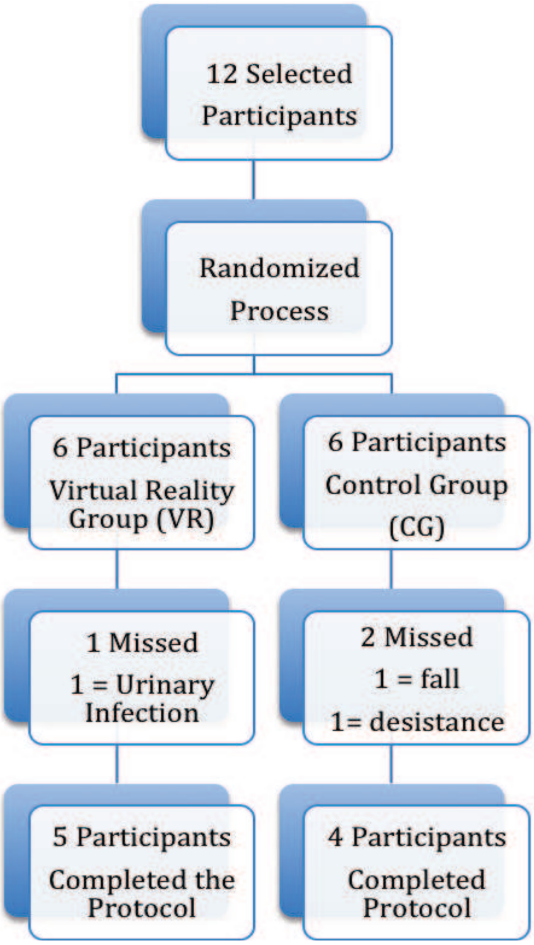

Figure 1 - Sample Flowchart

All participants answered a questionnaire on quality of life (SF-36), were evaluated for pain intensity by visual analogue scale of pain (VAS) and were assessed for balance by the Berg Scale. Those instruments were applied in the first and after the last session by an experienced examiner, blinded to the participants allocation. The interventions took place twice a week, with an average duration of 30 minutes for eight weeks. The exercise protocol was undergone in a private room and was instructed by a physiotherapist. The virtual reality protocol was also performed in a private room by another physiotherapist who did not perform any kind of guidance during exercises, only guarantee the comprehensive implementation of the protocol and controlled the time.

The VR protocol involved four Wii® mini games: Boxe®, Plataform®, Bajo Fishing Cero® and Footing Plus®. The group that performed exercises without virtual reality underwent a functional activities training protocol encompassing step workout, squats with the Swiss ball, and strengthening for the sural triceps, hip adductors and abductors, ranging from two series of eight repetitions to three of 15 repetitions.[10] The materials used in the protocol was a complete virtual reality of Wii® Nintendo device.

ETHICAL ASPECTS

The study followed the guidelines on human research of the Declaration of Helsinki and the Resolution 196/96 of the Brazilian National Health Council. All subjects received detailed information about the study objectives, as well as the risks and benefits to which they were submitted, and after signed the consent form. The study was approved by the ethics committee of the Health Secretary of the state of Bahia (CAAE: 04193012.3.0000.0052).

DATA ANALYSIS

SPSS version 14.0 for Windows was used for descriptive and inferential analyzes. The predictor variable was the use of the Wii® protocol, and the dependent variables were the Berg scale scores, the VAS and the eight domains of the SF-36. The paired and unpaired t test were used, adopting a significance level of 5% and a power of 80%.

RESULTS

The sample was initially composed of 12 subjects, which after randomization were grouped into two groups of six participants. However, three participants could not be included as part of the study due to absence of three sessions because of infections in the period, generating a total of nine participants, five in the test group and four in the control group (Figure 1).

Table 1 displays the characteristics of the sample according to gender distribution, age and education. Comparing the scores in each group separately, a significant pre-post difference was found only in the Berg Scale ($p = 0.033$) in VR group. Regarding quality of life, the VR group showed improvement in functional capacity ($p = 0.010$) and emotional aspects ($p = 0.004$) after training with virtual therapy (Table 2). Pain intensity decreased by 50% after intervention in VR group, while the CG reduced by 17% following treatment, despite not having been able to verified statistical significance ($p = 0.123$). No differences were found between the groups after the protocol, except for the emotional aspects of quality of life ($p = 0.027$), which improved in the VR group.

Table 1 - Sample Description of individuals with HAM/TSP from a Reference Centre for Assistance and Research in HTLV-1, EBMSP, 2013.

	Test Group (Wii) n(%) or M±DP	Control Group n(%) or M±DP
Gender		
Female	6 (100.00%)	2 (33.30%)
Age (years)	60.33 ffl7.42	55.83 ffl6.73
School Level		
Low	4 (66.70%)	2 (33.30%)
Meadle	1 (16.70%)	2 (33.30%)
High	1 (16.70%)	2 (33.30%)

Table 2 - Average scores of Berg Scale, VAS and SF-36 in test and control groups

	Test Group (n=5)			Control Group (n=4)		
	Before	After	p value	Before	After	p value
Berg Scale (Range 0-56)	33.60 ffl13.22	43.60 ffl9.83	**0.033**	33.25ffl14.29	36.25ffl16.91	0.114
VAS (Range 0-10)	6.60 ffl3.97	3.00 ffl4.47	0.109	3.00ffl3.55	2.50ffl5.00	0.664
Pain	22.40 ffl22.21	58.00ffl33.34	0.103	64.00ffl33.34	63.75ffl29.17	0.977
Vitality	31.00ffl26.78	55.00ffl31.81	0.203	46.25ffl25.29	48.75ffl33.75	0.769
Funtcional Capacity	10.00 ffl15.41	44.00ffl16.35	**0.010**	17.50ffl17.55	30.00ffl21.21	0.063
Physical Limitation	0	45.00ffl51.23	0.121	0	18.75ffl23.93	0.215
General Health State	36.80 ffl27.09	61.00ffl11.40	0.094	43.50ffl21.04	54.50ffl10.40	0.154
Social Aspects	32.50 ffl25.92	72.50ffl37.91	0.094	71.87ffl21.34	78.12ffl35.90	0.703
Emotional Aspects	6.66 ffl14.90	86.66ffl29.81	0.004	25.00ffl50.00	16.66ffl19.24	0.809
Mental Health	40.00ffl26.98	76.80ffl21.05	0.057	73.00ffl21.50	82.00ffl9.52	0.266

Paired Test *T;* Average ± Standard Deviation; VAS – Visual Analogic Scale

DISCUSSION

The use of virtual therapy as a complementary resource to the treatment of patients with HAM/TSP showed positive impacts on the balance and quality of life in the participants of this study, and has been shown to be a motivating and fun tool, which favored adherence to program proposed. The missed in this sample were related to common health problems in this population during the study period and 11 of 12 participants completed the program, but three had to be excluded for exceeding the number of acceptable faults.

Regarding painful aspect, there was no difference in intra or inter analyzes or groups, which is different from what has been seen in previous studies. [10-11] Although it may have been low the influence of these exercises on pain perception in the pain domain of the SF-36 and VAS, the RV group declined by more than 50% pain intensity, whereas the control group decreased by only 17%, which may clinically indicate that VR can be an important resource for symptom relief since the pain is a major complaint of this population.[5] Why not conclusive our findings, further studies should be conducted to evaluate the influence on pain of exercise protocols.

The balance was extremely affected this population from the baseline, indicating that this impairment can significantly affect the functionality and increase the risk of falls in this population, as shown by Berg scale score that is below the cutoff described for fall risk in elderly people and after stroke.[22-25] This finding reinforces the signs of dysfunction of the spine in patients with HAM/TSP. The inability to keep up against gravity, found in patients in the present study may be related to the reduction of sensorimotor ability of the lower limbs, disturbances in muscle coordination, balance deficit and inefficient transfer of weight, resulting in reduced mobility.[7,24] Spinal cord injuries often affect sensorimotor involved in postural control system, causing changes in gait and prone conditions to fall. [26]

In chronic conditions, spinal cord injury can cause a progressive decline in muscle function deterioration with the viscoelastic and contractile tissue and this decreased ability to generate movements properties, making them weaker and more susceptible to muscle fatigue.[27] This particular group of patients has demonstrated significant disturbances of posture, balance and gait in preceding studies, with a negative impact on quality of life.[7,28] The low score on the scale of Berg observed in this study confirms the need for therapeutic programs that include proprioceptive exercises and workout balance.[26] Games Virtual tools can be indicated in this case, for guiding perform tasks without direct voluntary attention to standard movement.[13] This model results in a more effective performance during acquisition and transfer, surpassing the strategy conscience.[14] By focusing on the effects of the movement rather than the movement itself a learning motor skills in the real world occur.[23-24]

Functional exercises improved all parameters in both groups, despite the fact that the group that used the virtual training demonstrated better results. This phenomenon may be consequential to the dynamic process of the tool that combines different attentional demands,[23] dual task[28] and balance training.[29] In particular, the double task is essential to the life of any individual, because most daily activities require performing more than one task at a tempo.[30] Improved motor performance and functional exercises combined has been above conventional exercises in different therapeutic protocols.[10,11,24]

Because this is a population of low socioeconomic status and difficulties with ambulation that impacts the low frequency to outpatient care, stimulating leisure activities that assist in the rehabilitation of functional status may be relevant as a complementary strategy. The tool has been extensively used in rehabilitation centers with exercises supervised by a qualified physiotherapist, which is much safer and precise.[14-20] However, in order to provide an alternative to the use of virtual reality at home independently, the therapist did not affect the virtual therapy session, allowing each participant to experience their exclusive use as a leisure activity. Being a handy resource for buying and low cost, virtual games can easily be purchased for home use, as these patients not are able to go to rehabilitation centers for specialized and supervised or be applied in parallel to conventional programs.

The greatest impacts of the resource occurred on the emotional aspect of quality of life improved in both intra-group analysis as between groups. The association has been observed between depressive states and changes in the balance of asymmetries core activity vestibular.[31,32] On the other hand, it is possible to have a chronic progressive disease, this population, which usually attends health centers for prolonged treatment, becomes disheartened too repetitive and monotonous general protocols. Thus, virtual reality is a playful and relaxed alternative, the classic routine care, provides a moment of pleasure.[33] Stimulating leisure activities have been identified as necessary in the treatment of emotional problems.[32]

The sample size may have influenced the results since the dispersions compared to the averages were very high and do not allow definitive conclusions about the impact of the proposed protocol. Despite efforts to avoid loss to follow up, because it is very subject to infections population, it is almost impossible to ensure the participation in long protocols. Another factor that lowers the sample is completely tolerable for the diagnosis according to the parameters establish by the WHO. It is suggested, therefore, the extension of the protocol tested with inclusion of multicenter clinical trials.

The study makes feasible to visualize future prospects in the field of virtual reality therapy in patients with HAM/TSP. It is suggested that other parameters are incorporated in the pre and post test involving the gait assessment and development of a randomized virtual clinical trial home use trial therapy. The care of the security in the present study led to the decision to perform the protocol at the center of care.

CONCLUSION

In summary, virtual reality has not reduced the intensity of pain and did not improve the balance, but demonstrated positive impact on the emotional aspects of quality of life.

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