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Virtual reality and serious game therapy for post-stroke individuals: A preliminary study with humanized rehabilitation approach protocol

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ABSTRACT

Objective: The current study proposed the development and preliminary validation of a humanized training approach for upper limb rehabilitation of chronic post-stroke individuals, using serious game (SG) and virtual reality (VR) technologies.
Materials and methods: Ten individuals with chronic stroke participated in the study. Accompanied by a health professional, 15 sessions of the SG were performed in a laboratory, in a humanized way, lasting between 30 and 45 min each. The assessments were made pre- and post-intervention with the SG, and the following parameters were evaluated (considering the elbow joint): Modified Ashworth Scale (MAS), range of movement (ROM) and tonic stretch reflex threshold (TSRT). Global measures such as quality of life (QOL) were also assessed by the Stroke-Specific Quality of Life Scale (SSQL), Brunnstrom Recovery Scale (BRS) and General Health Questionnaire (GHQ-28). The following tests were applied to verify statistically significant differences: Shapiro-Wilk test, *t*-test, and Wilcoxon-Mann-Whitney test.
Results: The parameters ROM, TSRT, BRS, and SSQL showed statistically significant differences between pre- and post-intervention ($p < 0.01$). The ROM increase was about 8%. The objective evaluation of spasticity (provided by the TRST) showed an increase of 28% over the average pre- and post-intervention values. Three participants showed decreased resistance to passive stretching according to the results of the MAS, and seven participants moved to the next stage of the BRS. For QOL, the scores indicated around 20% of post-intervention improvement.
Conclusion: The intervention had no adverse effects, showed a high degree of compliance, provided increased ROM, improved QOL, reduced spasticity and allowed these individuals the opportunity to test a promising technology for upper limb rehabilitation with emphasis in humanized aspects of therapy.

1. Introduction

Approximately 16 million individuals worldwide are victims to stroke every year, making this condition one of the leading causes of mortality and disability [1]. It is estimated that 80% of people affected by stroke do not regain proper arm function even six months after the event [2,3]. This condition limits or prohibits the performance of several activities of daily living, such as eating, getting dressed, taking care of

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personal hygiene, among others, negatively impacting the quality of life [4].

Several studies have reported the difficulty of rehabilitating the motor function of the upper limbs (UL), especially for those individuals in chronic phase. For those individuals, spontaneous neuroplasticity has almost disappeared, leading to the necessity of constant rehabilitation activities with adequate intensity and volume of practice, variety, specificity, motivation and biofeedback [5]. Due to the monotony of traditional methods and slow improvement in patients' conditions, some of these individuals end up stopping the rehabilitation process altogether or are discharged from treatment in hospitals and rehabilitation clinics when the therapeutic possibilities are exhausted and the chances of functional recovery are diminished [2,6].

In this context, the implementation of technologies such as serious games (SG) and virtual reality (VR) provide an alternative strategy for the treatment of UL of people with chronic post-stroke conditions. Studies have shown that therapy using such technologies can contribute significantly in maintaining quality of life (QOL) and enable neurological rehabilitation in these individuals. These methods also provide greater engagement and efficiency in rehabilitation treatments [7,8], with proven clinical benefits [9].

In order to propose more efficient ways of interaction with SG and VR, researchers have been trying to underline important characteristics that contribute to the increase of engagement of individuals in therapy, increasing the chances of success of the rehabilitation program [10]. A humanized approach can reduce the barriers to seek help and reduce the suffering of the patient and his family from the first contact with the team [11]. However, the focus of each of those studies is generally restricted to aspects related to the construction and development of the SG such as visuals, music and goals [11]. The implementation of technological devices and the automation of healthcare services can bring an aspect of dehumanization to the relationship between the health professional and the patient, making it extremely necessary to propose a humanized approach, in which the health professional is able to make the patient feel truly well and welcome [12].

No studies were found that focused on evaluating whether the presence, support and adoption of a humanized treatment for the health professional towards patients positively influenced the clinical outcomes of a SG and VR therapy. Therefore, this study proposed a preliminary humanized approach protocol of application and interaction with the SG, incorporating actions by which the humanization of care can be understood and applied, aimed at individuals with chronic post-stroke. In addiction, the health professional was not only an adjuvant during the therapy sessions, but rather actively participated in creating a hospitable environment for the participants and provided social support through positive feedback and instructions on how to use the game. Motor aspects and global measures were registered in order to verify the impact of this intervention on the UL, and consequently in the QOL of chronic post-stroke individuals.

2. Materials and Methods

This research was approved by the Committee of Ethics in Research. Participants were advised of the research procedures prior to participation and had consented for publishing collected data.

The eligibility criteria for participation were: (i) ischemic or hemorrhagic stroke with impairment in the right and/or left cerebral hemispheres, documented by computed tomography (CT) or magnetic resonance (MR) with medical reports; (ii) clinical signs of hemiparesis with UL impairment; (iii) spasticity of elbow flexors (Modified Ashworth Scale or MAS $1 \leq x \leq 3$); (iv) being in stages III or IV of BRS; (v) ability to understand and execute the game; (vi) no severe visual and/or hearing impairments; (vii) no associated musculoskeletal or neurodegenerative diseases; (viii) no cognitive or psychomotor deficit; (ix) no presence of drugs that influence muscle tone and/or waking state any time over the last six months; (x) be clinically stable; and (xi) have signed the clarified consent form.

2.1. Participants

All participants included were previously assessed by a clinical physiologist with extensive experience in the field of rehabilitation post-stroke, with emphasis in spasticity rehabilitation. Ten individuals were included in this study, and the general characteristics of the participants are shown in Table 1.

2.2. Study design and Harpy Game

This study is a longitudinal experimental study. Clinical assessments were performed before the intervention and at the end of each session. There was a total of 15 sessions of therapy using SG for each of the participants, with the total time for each session lasting between 30 and 45 min. The sessions were executed in a controlled environment.

The serious game used for the current research was the Harpy Game [13]. To control the flight of the harpy, participants are required to perform eight different movements of the UL. For the elbow, the game detected movements of flexion/extension; as for the shoulder, the movements detected were abduction/adduction, internal/external rotation and flexion/extension. To provide interaction with the system, the Inertial Measurement Unit (IMU) of Myo [14] armband was used.

The game also offers customization options, where the healthcare professional is able to register and configure the specific parameters of therapy, respecting the limitations and development of each individual. The configurable parameters were:

- Time: maximum number of minutes in which the stage must be completed.
- Object size: large, medium, or small objects, where large objects are easier to reach, requiring less accuracy to complete the task.
- Speed: determines the velocity of the harpy in the virtual environment.
- Objects to capture: more objects in the scenario requires increased effort from the user.
- Damage recovery: determines if the harpy loses health or not.
- Accuracy: refers to the sensitivity of rotation of the harpy on each axis.
- Health recovery: determines whether or not the harpy recovers health.

Harpy Game has a tutorial stage, followed by three other stages with different challenges, as shown in Fig. 1 [13]. During the tutorial (Fig. 1a), users must move their arm in the direction indicated by the red arrow; when the user reaches the goal, the arrow turns green. For the first stage (Fig. 1b), users must fly through rings. In the second stage (Fig. 1c), users are required to catch five fishes, and during the third stage (Fig. 1d), users must hunt for meat spread throughout the game environment.

2.3. Humanized approach

According to Borbasi et al., 2013 [15], to humanize the care, there are eight dimensions that must be understood and applied: insiderness; agency; uniqueness; togetherness; sense making; personal journey; and

Table 1
General characteristics of participants.

Subjects	Sex (M/F)	Type of stroke (H/I)	Side of stroke (L/R)	Dominant side (L/R)	Age (Years)	Years since stroke
10	8 M/2F	3H/7I	6L/4R	10R	59.7 (±9.07)	3 (±1.73)

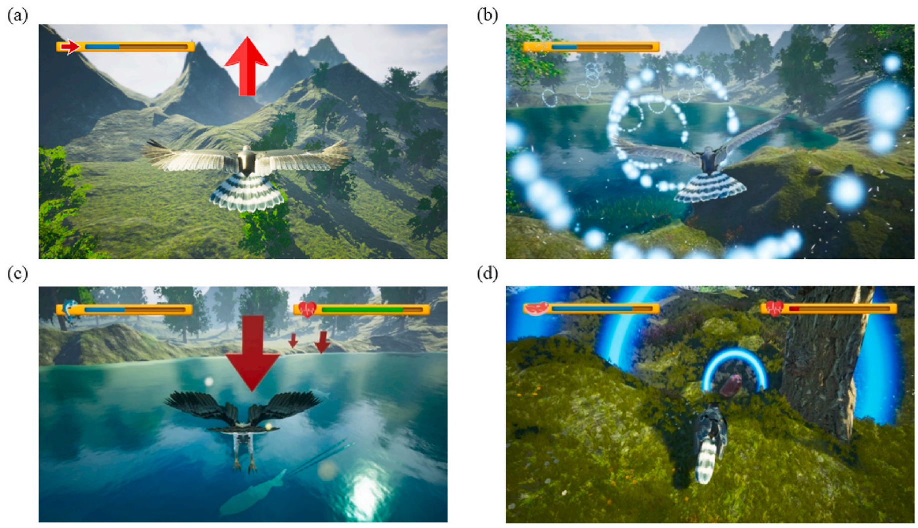

Fig. 1. (a) Training interface; (b) First gaming stage; (c) Second stage; (d) Third stage.

sense of place. That is, when dealing with a humanized protocol, parameters such as respect for the patient's dignity, uniqueness, individuality and humanity, empathy, respect for the patient's autonomy and involvement must be respected, in addition, the professional must treat the patient with impartiality/equity. To incorporate these dimensions into the study, the researchers adopted specific actions that started at the reception of the volunteers and ended only after they left:

(i) Volunteers' reception: Upon arrival at the site where the experiments were conducted, participants and their respective caregivers were welcomed by the healthcare professional. Initially, the professional interacted with the post-stroke individuals for approximately 10 min, promoting a pleasant and hospitable environment. The focus at that moment was to show how much he was expected that the time was just his and that the treatment would be personalized according to his needs, focusing on the patient as a person with individual history, giving them sense of place.

(ii) Preparation for interaction with the SG: Participants were then prepared to interact with the SG. They were instructed to sit comfortably in a chair placed approximately 2 m away from a television displaying the Harpy Game (Fig. 2), and the Myo armband was placed on the participant's paretic forearm and synchronized with the serious game. While this, the interaction of the volunteer with the health professional on various subjects, for example aspects related of daily life, was encouraged. This moment was important for there to be trust and intimacy between the parties; moreover, the health professional showed that he cared about what was going on in the volunteer's life, giving the volunteer a sense of intimacy, uniqueness, and togetherness.

(iii) User-centered therapeutic plan: Since it was possible to configure the settings of the SG, parameters such as the speed of the harpy or amount of objectives included in the scenario were adjusted by the health professional on a case-by-case basis, that is, the therapy was completely focused on the skills of the volunteers. This method was applied with the intention that the abilities could be touched and noticed throughout the rehabilitation process, giving the volunteer the sense making and personal journey. That resulted in the creation of a difficulty progression protocol for Harpy Game therapy, which ranged from D1 to D8, with D1 (easiest level) being the difficulty level initiated by all research participants (Table 2).

To increase the level of difficulty of the Harpy Game, the healthcare professional observed two major aspects:

1. If the participants accomplished all the game objectives in time.
2. If they were feeling well after therapy, without displaying excessive fatigue.

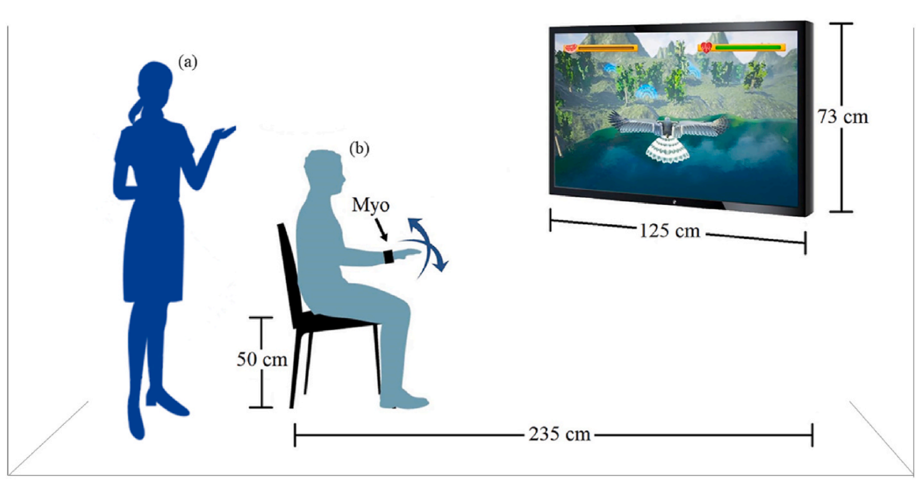

Fig. 2. Schematic of the experimental scenario (lateral view): (a) Healthcare professional; (b) Participant.

Table 2
Protocol for increasing the difficulty level of the Harpy Game.

Variables	Difficulty Levels							
	D1	D2	D3	D4	D5	D6	D7	D8
Time (minutes)	30	40	45	45	45	45	45	45
Object size (L/M/S)	L	L	L	L	M	M	M	M
Speed (5/10/15/20/25)	10	15	20	25	10	15	20	25
Objects to capture	32	43	54	54	54	54	54	54
Damage recovery (Y/N)	Y	Y	Y	Y	Y	Y	Y	Y
Accuracy (9–1)	9	8	7	6	9	8	7	6
Health recovery (Y/N)	Y	Y	N	N	N	N	N	N

(iv) Support during interaction with the SG: Stroke can reduce the patient's perception of dignity due to loss of functionality and reduced control over their body and daily activities. In this sense, it is necessary for the health professional to promote the participant's dignity, developing an understanding and recognizing how the conditions affect the patient's life and, at the same time, trying to emphasize the characteristics less affected by the disease. This type of approach is closely linked to greater patient satisfaction and adherence to therapy. Taking this into account, the health professional remained by the participant's side during the entire session, providing social and affective support to help overcome their limitations and finish the objectives of the SG, through positive feedback and providing instructions about the game.

(v) Questions and notes: At the end of the session, the health professional conversed with the volunteers to understand how the session had been in their perception and accompanied them as they left the data collection site. Following the volunteers' departure, main aspects of the sessions and information about the participants were noted in the diary collection.

2.4. Data acquiring

The pre- and post-treatment evaluations were performed at the same time of day to avoid oscillations caused by external factors such as medication and climatic alterations. To ensure no bias in the assessment after the intervention, the data concerning the assessment made before the experiment was concealed from the health professional. The variables evaluated for the elbow joint were: resistance to passive stretching (MAS) [16]; range of movement (ROM); spasticity through tonic stretch reflex threshold (TSRT) [17]. Global measures were assessed using the following: QOL by Stroke-Specific Quality of Life Scale (SSQL) [18] and stages of neurological recovery proposed by Brunnstrom Recovery Stage (BRS) [19]. To assess the effect of psychosocial intervention on well-being, the GHQ-28 was chosen as the primary outcome because it is an appropriate tool for capturing emotional stress. The minimum score for version 28 is 0 and the maximum is 84, higher scores for the GHQ-28 indicate higher levels of distress.

The quantitative assessment of spasticity by TSRT was measured using the Spasticity Evaluation System (SpES) device [20]. This equipment was installed in the Assistive Technology Lab from the Federal University of Uberlândia and consists of a two-channel electromyography and an electrogoniometer [21]. The software then extracts the aforementioned biological signals and, after some processing techniques, is able to estimate the value of TSRT in real-time with visual feedback for the healthcare professionals. For the experiment proposed, the protocol suggested by Marques was used [17], with the results obtained expressed in degrees.

Other relevant data such as the number of absences, self-related opinions and discomfort displayed during and after the intervention were recorded as well, which is currently in possession of the corresponding author. All dataset is available from the corresponding author upon reasonable request.

2.5. Data analysis

Both data description and presentation were determined using descriptive statistics as suggested in the R Project for Statistical Computing [22]. The Shapiro-Wilk test was used to identify if samples have a normal distribution. For normal data ($p \geq 0.05$), the *t*-test (ROM) was used, and for non-normal data ($p < 0.05$), the non-parametric Wilcoxon-Mann-Whitney test was used (TSRT, MAS, BRS, QOL).

3. Results

Considering that the purpose of the serious game was also to provide therapy with customizable parameters, the health professional was able to identify changes in the participants' behaviors in relation to the levels of difficulty adopted in the protocol for increasing the difficulty level of the Harpy Game (Table 2), as shown in Fig. 3. As previously stated, all participants started the protocol on difficulty level D1.

Regarding the TSRT parameter, there was an increase of 28% over the average pre- and post-intervention values, with a statistically significant difference ($p = 0.0019$). The ROM increase was about 8%, with a statistically significant difference ($p = 0.001$).

Three participants showed decreased resistance to passive stretching as indicated in the MAS, while seven participants moved to the next recovery stage for the BRS. For these parameters, p values were 0.162 and 0.010, respectively.

For the QOL parameter, participants' scores showed about 20% post-intervention improvement. There was a statistically significant difference between pre- and post-intervention average values ($p = 0.0019$).

The GHQ-28 results can be seen in Table 4. It was also calculated the average of the answers based in each parameter: somatization, anxiety, social dysfunction and depression.

The values of TSRT, MAS, BRS, and QOL obtained for each patient in the pre- and post-intervention period are shown in Table 3.

The GHQ-28 results can be seen in Table 4. It was also calculated the average of the answers based in each parameter: somatization, anxiety, social dysfunction and depression …"

The scores show that the aspect most affected by the research participants was social dysfunction. Remarkably, there were no adverse effects due to the use of the therapy. There was 100% adherence, as no participants missed any sessions; moreover, they demonstrated willingness to continue the therapy after the 15 experimental sessions.

4. Discussion

While the effect of active participation of the health professional in motivating and providing support to the research participant was the focus of the current research, several other topics were also analyzed during the study, namely: (i) the application of a serious game with excellent results in usability tests [13]; (ii) customizable and individualized training protocol, which contributes to participant involvement and motivation [23,24]; and (iii) hands-free activities, allowing the therapy to be applied to any patient regardless of the severity of the sequela [13,24], as several training movements can contribute positively to the improvement of motor function [19].

Considering the significant number of stroke victims worldwide and the impact left by residual sequelae, it is essential to ensure that new treatment protocols for the recovery of compromised limbs are engaging and efficient. Rehabilitation techniques using SG and VR are very common and have shown successful outcomes, which is ideal for chronic stage patients [23,25]. Those individuals displayed lower levels of adherence to traditional rehabilitation techniques for reasons such as lack of visible improvement, or for being outright discharged from rehabilitation clinics, given limitations in the physical space and low chance of recovery [6].

A brief review of the literature shows several studies whose aim is to adapt, develop, and apply serious games and VR for the treatment of UL

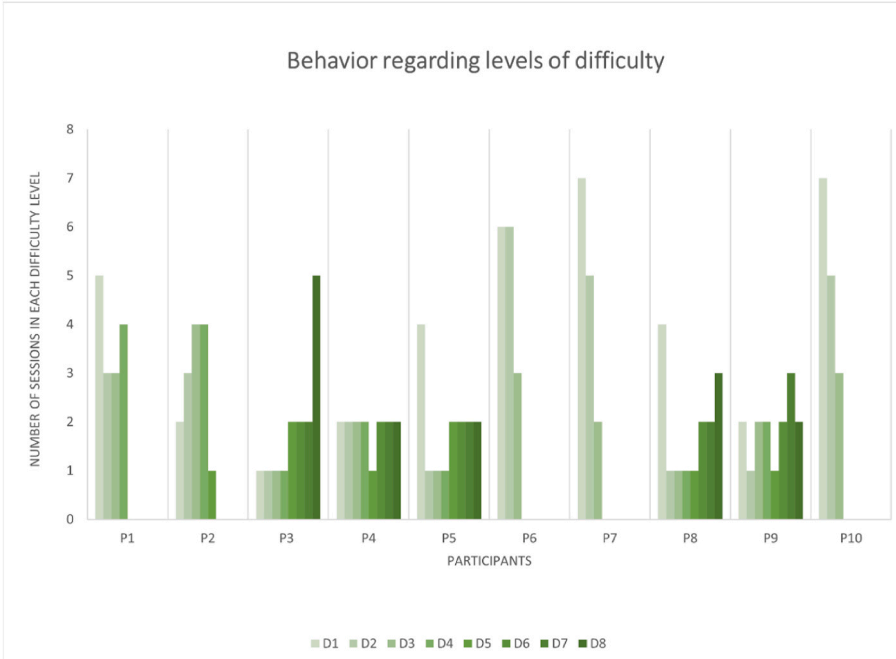

Fig. 3. Difficulty level achieved by participants.

Table 3
Results of all patients for the evaluation of clinical variables.

Participant	*Pre* TSRT°	*Post* TSRT°	*Pre* ROM°	*Post* ROM°	*Pre* MAS	*Post* MAS	*Pre* BRS	*Post* BRS	*Pre* QOL	*Post* QOL
1	37.9	29.8	75	127	2	2	3	3	139	204
2	15.1	12.7	132	135	1	1	4	5	185	190
3	14.7	8.8	115	142	1	1	4	5	197	209
4	97.8	57.9	140	145	1	1	4	4	166	177
5	12.3	6.2	135	140	1	1	4	5	184	214
6	23.5	13.0	125	145	1	1	4	5	104	159
7	25.1	16.55	95	130	2	1	3	4	154	173
8	70.1	69.8	130	130	1.5	1	3	3	137	177
9	41.6	32.7	145	150	1.5	1	3	4	153	198
10	13.5	3.6	110	122	1	1	4	5	127	163
Mean	35.2 (±28.3)	25.1 (±22.2)	127.5 (±21.8)	137.5 (±9.1)	–	–	–	–	153.5 (±29.0)	183.5 (±19.4)
Median	–	–	–	–	1 (±0.46)	1 (±0.32)	4 (±0.52)	4.5 (±0.82)	–	–

Table 4
Results of all patients for the psychosocial assessment (GHQ-28).

GHQ-28 parameters scores					
Participant	Somatization	Anxiety	Social Dysfunction	Depression	Total Score
1	5	5	10	5	25
2	9	8	8	9	34
3	3	1	10	1	15
4	2	4	8	1	15
5	6	4	11	3	24
6	7	7	6	5	25
7	8	1	7	1	17
8	3	3	6	3	15
9	3	1	9	1	14
10	7	4	8	4	23
Mean (SD)	5.3 (±2.45)	3.8 (±2.44)	8.3 (±1.70)	3.3 (±2.58)	20.7 (±6.54)

of post-stroke individuals. That is generally done through adaptation of commercially available games [24]. In those studies, results indicated that the condition of affected members remained unchanged after the intervention [26], reinforcing the importance of developing new SG specific to rehabilitation of those sequelae.

Software developers are constantly searching for contributing factors to increase dedication, motivation and engagement in serious games. Combined with other psychological aspects of rehabilitation, it can lead to increased levels of engagement and adherence to VR therapy [10,27]. However, it is necessary to underline that the environment in which the SG is used and the relationships between health professionals and patients are also critical factors in creating an engaging and motivating serious game.

As previously stated by Lovato [12], intensive use of technological tools in healthcare can cause the relationship between health professionals and patients to be more impersonal (less humanized), negatively influencing the response to therapy. According to the study, feeling welcome by the healthcare professional team is an important factor for the patient and caregiver. McDonald and collaborators [28] reported the importance of an enriched environment where, aside from providing rehabilitation, there is meaningful social interaction to enable a better response to post-stroke therapies. Studies performed in laboratory with rats indicated that socialization positively impacted learning outcomes and motor recovery, as it involved multiple potentially beneficial mechanisms. The studies mentioned above indicate that the participation, involvement, and hospitality of the health professional during therapy is fundamental for better results to be achieved.

In addition, the results obtained by the psychosocial evaluation questionnaire corroborate this information, since it can be observed in Table 4 that social dysfunction was the aspect that obtained the highest score, indicating a higher level of anguish of the respondents in this item. Such information highlights the necessity to carry out humanized therapies, because when applying the eight dimensions of humanized care it is possible to give these people a sense of place and importance as participants in society, which can amplify the effects of therapy with serious games for the reinsertion of these people in society. Nevertheless, this aspect is yet to be studied in the context of SG for post-stroke rehabilitation.

The sole observation of the performance of the participants in accordance to the levels of difficulty (Fig. 3) has shown high degree of variation in behavior for each of the participants. However, analyzing the results obtained for all the parameters evaluated (Table 3) leads to the conclusion that the procedures adopted in this study were effective for all the participants, both in clinical and global aspects.

The ROM data obtained showed improvement, with a significant increase in the range of movement of the elbow joint between the pre- and post-intervention periods. An improvement of this parameter generally indicates greater flexibility, which results in increased physical fitness and improvement in motor performance, with a positive influence on the performance of movements related to daily activities [29]. This parameter has been tested in other SG and VG studies [30,31], whose results also showed improvement, corroborating the findings of the current research.

Although spasticity is one of the most debilitating conditions to UL performance [32], it has been assessed in very few studies [33], and only through use of the MAS. Two types of evaluation were performed to verify the influence of intervention on spasticity on the elbow joint: MAS [16] (subjective method) and TSRT (objective method) [17]. In the MAS evaluation, no statistically significant differences were found, in accordance with results found in other studies [23,34].

There were, however, statistically significant differences in the assessment of the TSRT between the periods pre- and post-intervention, resulting in reduction of spasticity ($p = 0.0019$). These results challenge the findings of articles presented in a systematic review of Hatem and collaborators [23]. In that review, the authors conclude that while VR therapy is effective in the motor return of UL, it does not interfere in the degree of spasticity. This statement was possibly due to a lack of humanized SG methodology and absence of objective instruments for this type of evaluation.

The presence of spasticity can also influence the results of BRS. Its presence is quite evident in stages III and IV of BRS, and voluntary movements have broad participation of synergistic muscles. In this context, providing freedom of movement and activities consistent with each stage also helped the participants. This was observed in 70% of the participants with a statistically significant difference ($p = 0.01073$) for this parameter in periods of pre- and post-intervention, which suggests positive motor recovery [35]. In a study performed by Yavuzer and collaborators [36], there was no statistically significant difference in pre- and post-intervention for the BRS parameter after using games with hands-free sensors. This may have occurred due to the use of pre-existing games, which they tried to adapt according to the participants' needs, and the type of environment and approach in which the therapy was proposed. The results may suggest the necessity of alternative forms for providing effective therapies for chronic post-stroke individuals.

Some authors have argued that motor impairment assessments alone are not able to provide sufficient information on the full impact of stroke [37]. Therefore, the perception of individuals to their QOL was verified using the SSQL scale. The results showed that intervention promoted an improvement in QOL ($p = 0.0019$). A point of interest is that in several studies involving the use of SG and VR, very few authors included the assessments of the impact of the technologies on the QOL of the participants. Assessments of QOL can cover global aspects concerning the lives of post-stroke individuals that may contribute to the overall recovery of these individuals.

This study investigates the feasibility of a humanized training approach, involving Serious Game and Virtual Reality of chronic post-stroke individuals. Although the results presented are promising and provide initial evidence on the effect of this approach of rehabilitation this study is limited by the sample size and the lack of a control group. Another limitation was the lack of a quantitative measure of the emotion of these participants during the activities. In this sense, this humanized training approach will have to be further explored in a larger-scale randomized controlled trial, where other parameters will be analyzed, including information related to the emotional aspects of these individuals.

5. Conclusions

This study presented a humanized approach protocol based on serious game and virtual reality for the upper limb rehabilitation of chronic post-stroke individuals. The humanized protocol was well received by the participants, showing high compliance rate and no adverse reactions. While the sample was obtained from participants with distinct characteristics (mainly regarding age difference), all participants showed improvement in their clinical and global measure parameters. After the intervention, participants displayed reduced biceps brachii muscle spasticity, increased elbow joint ROM, and improved QOL. Future works intend to include the presence of a control group (without intervention), increased number of participants, and comparison of results by single-blind or double-blind peer reviews.

Author statement

Isabela Alves Marques contributed in conceptualization of the study, validation, formal analysis, investigation, resources, and writing and reviewing the first draft of the manuscript. Camille Marques Alves and Andressa Rastrelo Rezende contributed in software, validation, and on writing the first draft and reviewing the final version. Thiago Sá de Paiva contributed on the protocol and writing the first draft of the manuscript. Gabriel Fernandes Cyrino and Júlia Tannús de Souza contributed on software. Marco Aurélio Maia Silva contributed in data analysis, visualization of data and reviewing the final version. Luciane Aparecida Pascucci Sande de Souza contributed in conceptualization and reviewing the final version. Eduardo Lázaro Martins Naves contributed supervision, resources, conceptualization and reviewing the final version.

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Financial benefits to the authors

The authors would like to declare the absence of financial benefits for themselves.

Conflicts of interest

The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.

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