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New Technology for Physical Therapy: The Serious Games

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PRESENTATION

This book is the result of the efforts of a research team working on the development and clinical applications of new technologies in the area of physical rehabilitation of elderly and neurological patients. Our interdisciplinary team includes researchers from the fields of health and technology.

An important part of the research conducted in recent years with emphasis on these special populations is shown in the chapters of this book that we are very pleased to present here.

The authors.

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SUMMARY

CHAPTER

1

1.1. INTRODUCTION

The use of digital games (DG) has been shown to be an efficient approach in neurological rehabilitation, as they increase the motivation to the therapy that helps the rehabilitation process (Lloréns et al., 2015; Darekar et al., 2015). Commercial digital games are interesting from a motivational point of view, but they are designed for the entertainment of healthy people and need to be adapted for therapeutic use. The main limitations of commercial digital games not focused on rehabilitation are: do not contemplate all aspects of the rehabilitation process (Staiano and Flynn, 2014); do not consider the patients limitations; do not generate data for analysis (Proffitt, 2014); there is no relation of the game score to the performance of the treatment activity (Goble et al., 2014; Anderson et al., 2015; Pastor et al., 2010); game visual design is not always adequate to the target population (Staiano and Flynn, 2014); typical commercial games may increase the risk in the therapeutic procedures (Pastor et al., 2010; Chao et al., 2014), and they not present gameplay adjustments for different degrees of patient's commitment (Anderson et al., 2015; Taylor et al., 2011).

Digital games developed for rehabilitation are safe for the treatment because it enables the setting of the exercises for each patient's individual conditions (Soares et al., 2016). Digital games for specific purposes, such as education and health, mixed with the playful aspect of entertainment, are called Serious Games (SG) (Alvarez and Djaouti, 2011). However, developing a SG for rehabilitation is not a trivial task. It should be done in a multidisciplinary way considering many aspects involved, such as physiological, psychological and technological (Rego et al., 2010). Unlike video games for entertainment, video games for rehabilitation should focus on treatment and consider aspects that make the game motivating for the patient.

Borghese et al. (2013) used classical principles and strategies of entertainment games adapted to the rehabilitation context. Some critical factors were considered, such as repeatability of exercises, executing time of tasks, and motor and cognitive limitations of the patients. However, repeatability of the exercises is an intrinsic characteristic of the rehabilitation processes, which may lead the patient to a boredom condition (Burdea, 2003). Thus, the key point is to minimize this unwanted condition by introducing elements of game variability.

Most rehabilitation process of neurological patients is long and tiring (Hackett and Pickles, 2014), which results in lack of motivation and abandonment of treatment programs. Depression is a factor found in these patients leading to a lower treatment adherence (Li et al., 2016). The use of SG minimizes these negative factors, generates increased attentional demand, motivation, and pleasure in the treatment. Thus, the patient becomes an active agent of his own rehabilitation process (Soares et al., 2016).

Particularly in relation to stroke, where about 75% of cases occur with people over 65 years of age (Lloyd Jones et al., 2009), it is necessary to consider the factors related to age, such as motor skills decline, sensory deficits and associated chronic diseases (Gerling et al., 2012). Gerling et al. (2012) suggest usability criteria in games for older people that include: reduction of steps for task completion, reduction of cognitive load, availability of immediate feedback and adaptation of digital systems to user goals (e.g. therapeutic). All these aspects are fundamental to keep patient motivation and engagement in the rehabilitation process. Motivation is often used as a determining factor for the rehabilitation outcomes (McLean et al., 2002).

Although it is not an easy concept to describe, motivation can be defined more simply as a psychological property that encourages a person's action toward a goal, causing and/or retaining the behavior to achieve the goal (Lohse et al., 2013).

According to Drummond et al. (2017), the combination of motivation for the learning activity itself (intrinsic motivation) with the motivation for a future outcome desirable (extrinsic motivation) is essential for SG to be motivating. In addition, there are four important cognitive factors associated with learning: attention, active learning, feedback and consolidation (Drummond et al., 2017). The integration of these neuropsychological aspects with the game design helps therapeutic dosage increases, which are recommended in the neurological rehabilitation (Lohse et al., 2013).

Based on the previous context, our research group has developed some biomedical serious game systems for training and evaluation of neurologic and geriatric patients. In this book will be presented three different applications of SG. The first, for training of muscle strength in lower limb post-stroke rehabilitation, the second, for balance training post-stroke, and the last, for physical rehabilitation of frail elderly. Will be presented the biomedical systems developed and their therapeutic efficacy, and the possible metric properties of the game scores.

CHAPTER

2

SERIOUS GAME FOR REHABILITATION OF THE LOWER LIMB OF HEMIPARETICS POST-STROKE

2.1. INTRODUCTION

Stroke is characterized by high morbidity, mortality and disability (Lou et al., 2020). Currently is the second major cause of death worldwide (Benjamin et al., 2017), and is responsible for a variety of clinical changes involving motor, sensory, cognitive, perceptive and language impairment (Gibson and Attwood, 2016).

The motor dysfunction is one of the most frequently encountered problems and is the most evident consequence after stroke (Dorsch et al., 2016). The main motor deficit is hemiparesis, a classic clinical condition of this disease (Gibson and Attwood, 2016). Studies indicate muscle weakness as the primary impairment and the most limiting factor of motor performance (Dorsch et al., 2016). Therefore, frequent muscle weakness of the lower limbs, especially in quadriceps femoris (QF) and hamstrings (HS), results in locomotor limitations, which are present in approximately 65% of these patients (Aaron et al., 2017).

Recovering gait capacity is the main goal in rehabilitating many of these patients. In this sense, conventional rehabilitation techniques have been shown to produce positive results over time (Winstein et al., 2016), especially muscle strengthening programs, which are able to reduce strength deficits (Billinger et al., 2014). However, such strategies present the monotony, boredom and repetitiveness of the exercises as limiting factors (Burdea, 2003), which often generate motivation problems and reduce adherence to the treatment program (Burke et al., 2009).

To overcome existing limitations, the use of new rehabilitation strategies has increased, among them the digital games (Lohse et al., 2014), which have been recommended for hemiparetic patients due to stroke. However, in most cases traditional commercial games are used (Deutsch et al., 2011) that are not developed for use in rehabilitation, but for the entertainment of healthy people, which limits its therapeutic application. An alternative to reduce these limitations is the use of Serious Games (SG) (Alvarez and Djaouti, 2011).

Serious Games are computer games created with specific goals, aiming to go beyond entertainment and provide the individual with distinct experiences, such as training, for example (Noveletto et al., 2018; Susi et al. 2007). In neurorehabilitation, these games can be considered as valuable tools because they are capable of improving conventional treatment (Cauraugh et al., 2000). This type of resource enables the individual to have active experiences that reduce the monotony of repeated movements, in addition to providing performance feedback, increasing motivation (Mubin et al., 2020). SG allow customization, enabling patient care according to their functional limitations.

Although there is evidence of positive results from the use of Serious Games in the rehabilitation of hemiparetic stroke patients, most research is directed towards the upper limb. There is still a gap related to the evidence of the effects of this type of intervention for the lower limbs in this population. In addition, studies comparing the effects of programs based on the use of SG with those from conventional rehabilitation are still scarce (Laver et al., 2017).

The present study aims to verify the therapeutic effects of an exercise program using an SG developed for evaluation and rehabilitation of hemiparetic stroke patients, in addition to comparing the effects of the proposed intervention with those resulting from conventional kinesiotherapy.

2.2. METHODOLOGY

This Non-Randomized Controlled Clinical Trial involved 24 hemiparetic stroke patients. The study was carried out at the Center of Research in Neurorehabilitation at Neurology Outpatient Clinic of the Guilherme Guimbala College, Joinville/SC, Brazil. The inclusion criteria were patients with subacute or chronic hemiparesis due to stroke (injury time ≥3 months), clinically stables, able to walk independently. The exclusion criteria were hemiparesis due to other diseases, symmetric bilateral motor impairment, severe visual and/or auditory impairment, uncooperative patients and/or with severe cognitive deficits, patients who were performing or who performed (in the last 3 months) any other type of rehabilitation for trunk and/or lower limbs. This study was approved by the Ethics Committee for Research with Humans (CAAE 56995816.6.0000.0118), by the Brazilian Registry of Clinical Trials (RBR-2MF595), and the procedures were in accordance with the Helsinki declaration.

The instruments used were chosen according to the International Classification of Functioning, Disability and Health (ICF) domains, developed by the World Health Organization (WHO) in 2004.

Domain Function/Body structure (ICF)

1) Anthropometric digital scale and stadiometer: to measure body mass and height, respectively.

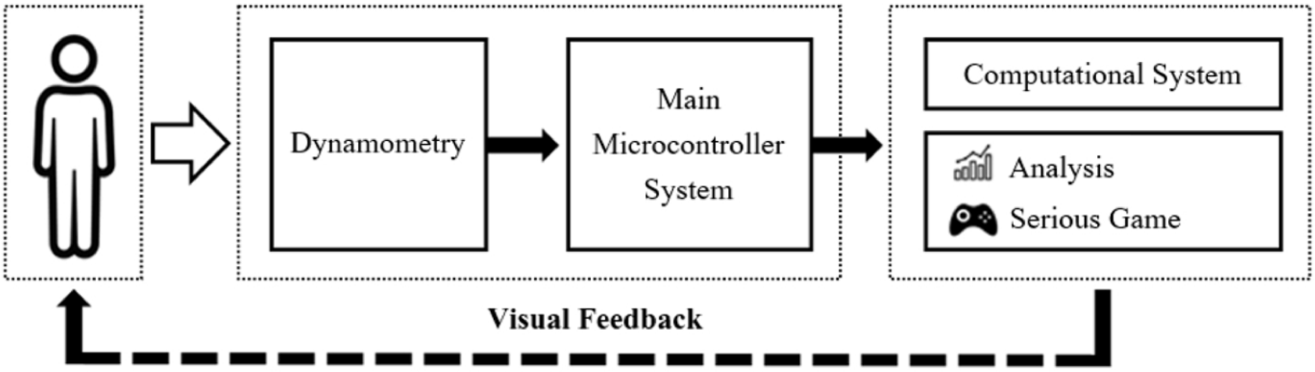
2) Fugl-Meyer Assessment Scale (FMAS): to measure the level of motor impairment of the patients before and after the intervention. Only the section for motor evaluation of the lower limb was used, which includes the analysis of reflex activity, synergic muscular action in flexion and extension, and movements with and without synergy. Classification according to degree of motor impairment in severe (0-7), marked (>7 to 14), moderate (>14 to 21) and slight (>21 to 28);

3) Modified Ashworth Scale (MAS): for assessment of spasticity. Only the QF muscle group was evaluated. Classification varies from 0 to 5, where 0 is considered normal, and 5 when there is an expressive increase of tonus that makes movement impossible, maintaining body segment rigid in flexion or extension;

4) Mini Mental State Examination (MMSE): to assess the cognitive level of patients. This instrument was used only for patient screening, following the cut-off points related to schooling, proposed by Bertolucci et al. in 1994;

5) Mim-Pong SG: for assessment and training of muscle strength (MS) of patients. This game operates by means of a system based on a compression load cell (capacity of 589 N). Two muscle groups of the lower limb were evaluated: QF and HS. For operation, specific software and hardware were developed. The hardware used the signal obtained with dynamometry (Figure 1).

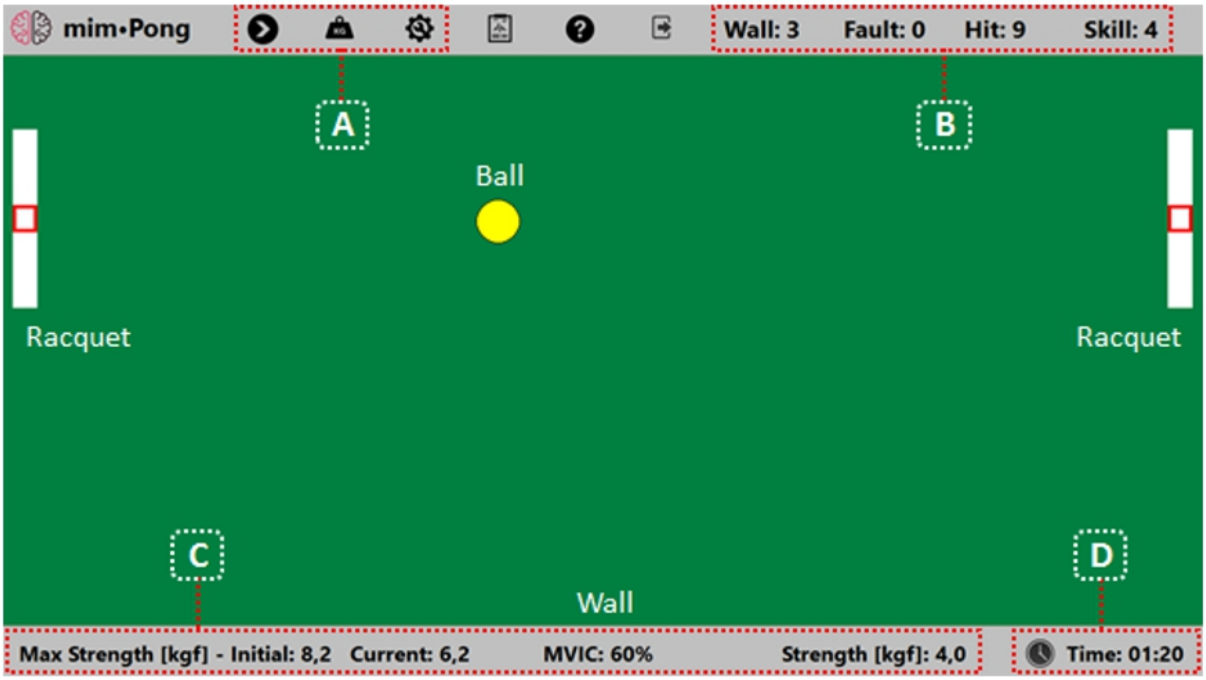
Figure 1. General diagram illustrating the basic units of the system used for evaluation and treatment of patients.



Source: The authors

For evaluation of muscular strength (MS), the load cell was coupled to a device that allows the adjustment and positioning of the region to be worked, acting as a handheld dynamometer for measuring strength in any muscle group (Noveletto et al., 2014). The software enables configuration of hardware-related parameters, calibration for acquisition initialization, real-time visualization of the captured signal and recording of acquisition data. This SG has simple visual aspects that focus the patient on hitting the ball. Racquets move simultaneously on the screen vertical sides based on the strength applied on the load cell, which can be calibrated individually with the evaluation of the maximal voluntary isometric contraction (MVIC) of each muscle group in each session. However, when no strength is applied, the racquets stay still at the bottom of the screen. The upper limit of the racquets (at the top of the screen) is based on the maximum strength of each subject. The horizontal walls bounce the ball back. Game parameters can be adjusted, for example, the racquet size, ball size, ball speed and duration of the match. The score for assessing the performance of the patient in the training considers the aspects related to the gameplay. Figure 2 shows the main screen of the SG used.

Figure 2. The *mim-Pong* SG main screen



Legend: A) Game control and settings; B) Game score components;
C) Muscular strength data; D) Game session elapsed time.
Source: The authors

Domain Activities (ICF)

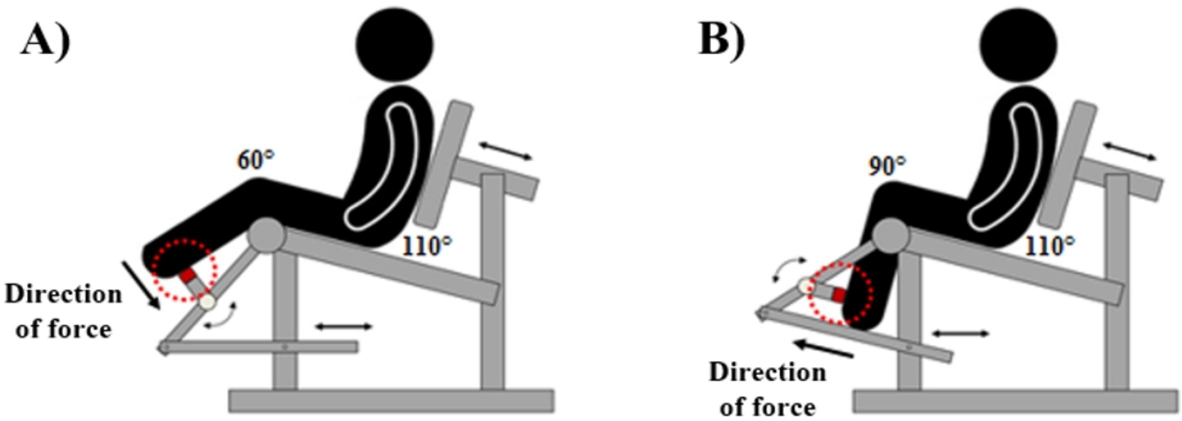
- Timed Up and Go Test (TUGT): to evaluate the functional mobility, which consists of measuring the executing time of a proposed task (Persson et al., 2014). This test has been widely used in individuals with stroke, which is considered the best predictor of ADL participation for post-stroke patients.

- Gait Speed Test (GST): to evaluate the gait speed, which measures the time for the individual to walk a 10-meter course. Three meters were added at the start and end of the course to eliminate the effects of acceleration and deceleration on the test. Patients were instructed to perform the test at the fastest possible speed.

The study participants were divided into two non-randomized groups: Experimental Group (EG 16 patients) and Control Group (CG 8 patients). Three evaluations were carried out before initiating the rehabilitation program (pre-intervention) and three evaluations at the end of the program (post-intervention).

For evaluation and training with the *mim-Pong* SG, a leg extensor apparatus was prepared and adapted with a load cell, which was coupled to the chair and allowed to assess bilaterally the strength of the muscle groups above-mentioned (QF and HS). Both patient and device position depend on the muscular group analyzed, as follows. For the QF, the patient sits in the chair with the trunk supported by the backrest, legs hanging, hip at 110º of flexion relative to the trunk and knees flexed at 90º (Cooper et al., 2011). The sensor is placed perpendicular to the distal third of the leg (just above the malleolar region), on the anterior face. For the HS test, the patient is positioned in the chair as in the QF test, but with knees flexed at 60º (Correa et al., 2011) and the sensor is placed perpendicular to the distal third of the leg, on the posterior face. Figure 3 illustrates the positioning of the patient and the sensor with the load cell during procedures.

Figure 3. Illustration of the positioning of the patient and the load cell for evaluation and training of the muscular groups



Legend: A) Control by dynamometry using the HS muscle group;
B) Control by dynamometry using the QF muscle group; The red color highlights the sensor with the load cell.
Source: The authors

For evaluation, three measures were performed bilaterally on each muscle group in MVIC for 5 seconds (Souza et al., 2014), with an interval of 1 minute between each measurement. All evaluations were on alternate days, with a minimum interval of 24 hours, and performed by the same examiners. The arithmetic mean resulting from the three evaluations was used as a reference. The patient was instructed to perform as much force as possible from a green signal projected on the screen, which indicated the beginning of the test, and this force should be maintained until the green color disappears, indicating the end of the test. After each MS measurement, the patient had a rest period of 2 minutes and then perform the evaluation protocol of the *mim-Pong* SG that generates a score related to the performance of the subject in the test.

A protocol was proposed to evaluate motor control (MC) of patients, which consists of a task in which the goal is to hit a ball at 5 different levels (from 1 to 5). These levels are associated with the MVIC obtained during the calibration. At level 1, the patient should produce a strength equivalent to 20% MVIC to hit the ball in the racquet center. Levels 2 to 5 represent the percentages of 40, 60, 80 and 100% MVIC, respectively. The rationale for these different levels of strength is that most tasks performed in daily life do not require the use of maximum strength for their performance (Cunha et al., 2016).

During the evaluation mode task, the ball moved in a straight line from the left side of the screen to the right side where the racket is located at the different levels, which represent the percentages of the MVIC. One ball leaves every 10 seconds, starting with the lower strength level (20% of the MVIC) up to the maximum level (100% of the MVIC). The maximum score in the evaluation mode is 100 and is used to measure the MC of the patient. After the evaluation phase, the patients of both groups were submitted to the same treatment period, 10 consecutive weeks, having 2 sessions a week on alternate days (total of 20 sessions).

The EG consisted of 16 patients, who received a rehabilitation program for the paretic lower limb based on exercises using the *mim-Pong* SG. This exercise program was divided into two phases with 10 sessions: Phase 1 (using 60% of the MVIC) and Phase 2 (using 80% of the MVIC). These percentage values full fill the guidelines of resistance exercises for post-stroke patients (Billinger et al., 2014). It was standardized for all patients with the same configuration of the game (racket size, ball size and ball speed). In each session, the passive mobilization of the paretic side was performed for 10 minutes, after which the training was started. A SG calibration was always performed by measuring the MVIC and, after obtaining this data, the exercise was started with the patient. A SG calibration was always performed by measuring the MVIC and, after obtaining this data, the exercise was started with the patient. Each session was composed of 3 sets of 2 minutes with 1 minute break between each one for rest, for each paretic muscle group (QF and HS). It always started with the strengthening of femoral quadriceps, and after that, the exercises for hamstrings were performed (Figure 4). The CG consisted of 8 patients, who received a rehabilitation program based on conventional kinesiotherapy (passive mobilization, stretching and active-assisted exercises). The sessions performed with this group lasted 30 minutes.

Figure 4. Patient during a session with the mim-Pong SG, performing training for the hamstring muscle group on the paretic lower limb (left)

Source: The authors

Data analysis

Data were analyzed with software SPSS for Windows (IBM, version 20.0). Descriptive statistics (mean, median, standard deviation, and distribution of frequencies with absolute and percentage values) were used to characterize the participants. Shapiro-Wilk test (to verify if data are normally distributed); One Way ANOVA for repeated measurements and Friedman's test; paired Student’s t-test and Wilcoxon signed-rank test (comparison of variables in the pre- and post-intervention period, for parametric and non-parametric data, respectively). Effect Sizes (ES) were calculated to evaluate if differences observed corresponded to important clinical effects. For the parametric data, ES values <0.2, 0.8-0.2 and ≥0.8 were considered small, medium and large, respectively. For the nonparametric data, ES values are <0.1, 0.5-0.2 and ≥0.5 (Cohen, 1988). A significance level of 0.05 was always used.

2.3. RESULTS

Twenty-four hemiparetic stroke patients (12 male and 12 female; 57.8 ± 10.4 years old; mean time since the stroke of 16.8 ± 19.6 months) participated in this study. In both groups, a predominance of ischemic stroke was observed (EG = 80% and CG = 62.5%), and there was a prevalence of hemiparesis on the left side of the body. Table 1 presents the sociodemographic, clinical, and anthropometric characterization of the participants of the both groups.

Table 1. Sociodemographic, clinical, and anthropometric characterization of patients

Characteristics (n=24)	EG (n=16)		CG (n=8)	
	$\underline{x} \pm s$	f (%)	$\underline{x} \pm s$	f (%)
Sex				
Female	----	8 (50.0)	----	4 (50.0)
Male	----	8 (50.0)	----	4 (50.0)
Age [full years]	56.8 (10.8)	----	59.8 (9.8)	----
BMI [kg/m^2]	29.1 (7.8)	----	28.3 (5.8)	----
Self-reported laterality				
Right-handed	----	16 (100)	----	5 (62.5)
Left-handed	----	0 (0)	----	1 (12.5)
Ambidextrous	----	0 (0)	----	2 (25.0)
Hemiparesis				
Left	----	9 (56.3)	----	4 (50.0)
Right	----	7 (43.7)	----	4 (50.0)
Stroke time [months]	19.3 (23.1)		13.8 (12.3)	
Phase of the stroke				
Subacute	----	5 (31.3)	----	3 (37.5)
Chronic	----	11 (68.7)	----	5 (62.5)
Type of the stroke				
Ischemic	----	13 (81.3)	----	5 (62.5)
Hemorrhagic	----	3 (18.7)	----	3 (37.5)

BMI: body mass index; n: total sample; f: absolute frequency.

Comparison of sociodemographic, clinical, and anthropometric variables between the EG and the CG in the pre-intervention period revealed that there were no statistically significant differences between groups in any of the variables.

All of the following results are presented according to the ICF.

Domain Function/Body structure (ICF)

Table 2 shows the evaluation results (pre/post) of the variables muscle strength and MC of both muscle groups in the paretic and non-paretic limbs. It is noteworthy that only the EG showed significant gains in muscle strength in both muscle groups in the paretic limb, in addition to HS on the non-paretic side. Regarding the MC measured by the score provided by SG, important improvements were observed in both groups, bilaterally in the EG and only in the paretic member for the CG.

Table 2. Results referring to the variables MS and score of both muscle groups in the paretic and non-paretic limbs, compared in the pre- and post-intervention period.

Patients (n=24)	**Pre** ($\bar{x} \pm s$)	**Post** ($\bar{x} \pm s$)	***p*-value**	**ES**
EG (n=16)				
QFMS [kgf]	14.8 (6.6)	21.2 (11.6)	0.002	0.7
HSMS [kgf]	5.4 (3.0)	10.2 (4.3)	0.000	1.3
QFS	67.8 (18.7)	87.8 (12.8)	0.000	1.2
HSS	54.3 (21.8)	78.9 (16.6)	0.000	1.3
NP-QFMS [kgf]	24.3 (7.3)	27.5 (10.9)	0.081	0.3
NP-HSMS [kgf]	11.7 (4.2)	15.2 (5.2)	0.000	0.7
NP-QFS	78.8 (11.7)	87.6 (4.7)	0.007	1.0
NP-HSS	69.9 (14.2)	82.3 (12.6)	0.000	0.9
CG (n=8)				
QFMS [kgf]	14.7 (11.9)	15.4 (12.0)	0.185	0.1
HSMS [kgf]	7.1 (6.3)	8.1 (6.0)	0.072	0.2
QFS	52.4 (19.9)	65.0 (17.1)	0.003	0.7
HSS	51.3 (27.7)	64.8 (25.2)	0.006	0.5

Patients (n=24)	Pre ($\underline{x} \pm s$)	Post ($\underline{x} \pm s$)	*p*-value	ES
NP-QFMS [kgf]	23.9 (8.8)	24.2 (10.0)	0.761	0.0
NP-HSMS [kgf]	12.8 (7.0)	13.1 (4.4)	0.744	0.1
NP-QFS	65.6 (16.1)	74.3 (13.7)	0.142	0.6
NP-HSS	64.8 (20.9)	69.3 (13.4)	0.407	0.3

Significance level p<0,05; p-value: probability of significance obtained by the paired t-test; ES: effect size; EG: experimental group; CG: control group; QFMS: quadriceps femoris muscle strength; HSMS: hamstrings muscle strength; QFS: femoral quadriceps score; HSS: hamstrings score; NP: non-paretic; n: total sample.

Table 3 shows the patients' performance in the tests with the FMAS and the MAS in the pre- and post-intervention period. Significant improvements were observed in these variables only in the EG. However, the ES analysis showed very similar values in the CG.

Table 3. Patient performance in the evaluations with FMAS and MAS analyzed in the pre- and post-intervention period.

Patients (n=24)	Pre	Post	*p*-value	ES
EG (16)				
FMAS	20.5	24.5	0.001	0.6
MAS	1.00	0.00	0.006	0.5
CG (8)				
FMAS	25.0	25.5	0.068	0.5
MAS	0.50	0.00	0.066	0.5

Significance level p<0,05; p-value: probability of significance obtained by the Wilcoxon signed-rank test. Values expressed by median, because they are non-parametric data; ES: effect size; EG: experimental group; CG: control group; FMAS: Fugl-Meyer assessment scale; MAS: modified Ashworth scale; n: total sample.

Domain Activities (ICF)

Table 4 summarizes the results of the comparative tests between the pre- and post-intervention measures of the variables obtained with TUGT and GST, where statistically significant differences were found only in the EG.

Table 4. Patient performance on the TUGT and TVM,
analyzed pre and post-intervention

Patients (n=24)	Pre ($\underline{x} \pm s$)	Post ($\underline{x} \pm s$)	*p*-value	ES
EG (16)				
TUGT [s]	26.7 (14.3)	21.3 (13.1)	0.000	0.4
GST [m/s]	0.55 (0.31)	0.71 (0.42)	0.001	0.4
CG (8)				
TUGT [s]	33.3 (28.4)	28.9 (22.0)	0.247	0.2
GST [m/s]	0.66 (0.5)	0.70 (0.54)	0.204	0.1

Significance level p<0,05; p-value: probability of significance obtained by the paired t test. Values expressed by mean, because they are parametric data; ES: effect size; EG: experimental group; CG: control group; TUGT: timed up and go test; GST: gait speed test; n: total sample.

2.4. DISCUSSION

Three elements are considered fundamental for therapeutic strategies used in post-stroke rehabilitation: intensive training, repetitive exercises, and task-oriented training (Warland et al., 2018; Veerbeek et al., 2014). The muscular strengthening programs involve these elements, being able to modify the characteristic strength deficits of these patients, promoting improvements in functional mobility (Signal, 2014). Classical rehabilitation methods have already been shown to produce positive long-term results (Billinger et al., 2014), however, are usually characterized by monotony and repeatability (Burdea, 2003). Thus, problems of motivation and adherence to treatment appear (Burke et al., 2009), making it difficult to obtain positive results, or even resulting in the abandonment of treatment, in some cases (McGrane et al., 2015). In this sense, the use of virtual reality (VR) technologies and games for rehabilitation has increased in the last years, since they are viable alternatives, which contribute to reduction of the motivation caused by the monotonous repetition of movements (Lee et al., 2017; Winstein et al., 2016). In addition, they may result in improvements in other health-related aspects such as motor functions, energy expenditure, muscle strength and recovery time in stroke patients (Swanson and Whittinghill, 2015). Especially SG, which are developed with a specific goal, can associate physical training with motor rehabilitation, without losing the motivational focus (Brückheimer et al., 2012).

In this study, the exercise program with the *mim-Pong* SG resulted in significant improvements in all variables analyzed in the EG, including the non-paretic limb. The only exception was QF muscle strength in the non-paretic limb (p=0.081), which was not trained. In the group receiving conventional treatment, significant improvements were observed only in QF and HS scores in the paretic limb.

Muscle weakness consists of the primary impairment of stroke patients (Dorsch et al., 2016), which commonly affects the lower limbs (Aaron et al., 2017), especially the QF and HS (Hsiao Ching et al., 2017), directly influencing of the independence of the individual to perform daily life activities (Menezes et al., 2017). In general, the participants of this research had an important hemiparesis in both muscle groups, but more evident in HS. In the EG, a strength decreases of 39.3% in QF and 53.0% in HS was observed, comparing with the non-paretic side. In the CG, the observed decrease in QF was 38.5% and 44.5% in HS.

An important clinical result of this study was the MS gain. In the EG significant gains were obtained with a large ES for HS on the paretic side (p=0.000, ES=1.3), and moderate ES for QF on the paretic side (p=0.003, ES=0.7) and HS on the non-paretic side (p=0.001, ES=0.7). One hypothesis for the change observed in the non-paretic limb would be the increase in activities performed routinely by the patient from the moment that he presents an improvement of MS in the paretic limb. For example, there may be increases in gait frequency and distance, in activities such as sitting and lifting or go up and downstairs (Menezes et al., 2017). In the CG there were no significant improvements, and the ES was small for both muscle groups on the paretic and non-paretic side, which reinforces the hypotheses presented previously; that is, stimulation of new activities and specificity of SG. Veerbeek et al. (2014) analyzed in a systematic review 19 randomized clinical trials related to MS training in the paretic lower limb at different stages of post-stroke rehabilitation and concluded that progressive resistance exercise results in significant improvements in MS, as well muscle tone and gait. Although the training method adopted in the present study is different, performing isometric strengthening through a SG, the findings converge towards the same direction because the therapeutic objective is the same.

Post-stroke muscle dysfunction is a multifactorial phenomenon (Hunnicutt and Gregory, 2017), so there is already evidence that hemiparesis involves factors that go beyond muscle strength deficit (Chang et al., 2013). Thus, therapeutic modalities that provide improvements in MC, in addition to muscle strength, are extremely important. The exercise program using the *mim-Pong* SG is an example of an intervention that has this purpose. In this SG the score of the game evaluates the MC, where the closer to the center of the racket the patient hits the ball, the higher the score. In this way, the SG provides increased MS using different muscle activation strategies.

After the experimental treatment, there were important improvements in the MC of the patients of both groups. In the EG, a significant improvement with a large ES was observed in the QF and HS in the paretic limb (p=0.000, ES=1.3 / p=0.001, ES=1.3), and in the non-paretic limb (p=0.008, ES=1.3 / p=0.001, ES=0.9). The CG showed significant improvements only in the paretic limb, but with a moderate ES (p=0.003, ES=0.7 / p=0.006, ES=0.5). In the non-paretic limb, although there were no significant improvements, moderate ES was found in both muscle groups (p=0.142, ES=0.6 / p=0.407, ES=0.3). The comparison of these findings is hampered by the fact that there were no studies that analyzed this variable in a similar way. However, hypotheses can be raised to justify the improvements that occurred in the variable MC, evaluated by the score provided by the SG. For the paretic limb, which received training, improvements can be attributed to the different treatment modalities used, where a superiority of the intervention with the serious game is evidenced, that demands different levels of muscle contraction from the patient. However, improvements also occurred in the non-trained limb. A justification for this is related to learning, where the individual presents a greater facility in performing activities that already have some experience (Lundy Ekman, 2017). Another factor that may have resulted in improved MC in the non-paretic limb is the so-called "cross-effect" of training. From the neurological point of view, this can be explained, since there are not only intrahemispheric communication pathways, but also interhemispheric pathways. The main communication structure between the cerebral hemispheres is the corpus callosum, which consists of the largest set of nerve fibers that perform this function (Ocklenburg et al., 2016), causing the transcortical flow of information and playing an important role in the control of movement (Stewart et al., 2017). However, studies suggest that the integrity of the sensorimotor regions of the corpus callosum correlates with motor function after stroke (Li et al., 2015). A study (Dragert and Zehr, 2013) investigating the effects of non-paretic limb training for improvements in the paretic limb of chronic stroke patients has found that this type of intervention can result in gains related to MS and muscle activation.

Regarding the variable functional mobility, in a longitudinal study (Persson et al., 2014), the performance of 91 patients in the TUGT was evaluated in the first week, in the third, in the sixth and in the twelfth month post-stroke. There was a significant improvement in the performance of the test only in the first 3 months (acute phase). These findings differ from the present study, since all patients were subacute or chronic, and had significant improvements with a moderate ES in the functional mobility assessed with TUGT in the EG in relation to the CG (EG p=0.000, ES=0.4 vs CG p=0.247, ES=0.2). In a double-blind randomized clinical trial (Cho and Lee, 2013), the efficacy of a training program with VR technology on functional mobility in chronic hemiparetic stroke patients was investigated. 14 patients were divided into two groups (EG and CG), both received conventional physiotherapy and the EG had VR treatment, additionally. Both groups showed significant improvements in the TUGT, which were higher in the EG. The present study diverges from these findings since it was found significant improvement only in the EG.

Gait speed is a very reliable, valid, sensitive, and specific measure related to functional capacity, and for these reasons, considered by some studies as the "sixth vital sign" (Fritz and Lusardi, 2009). This research indicated significant improvements with a moderate ES in this variable after intervention using the exercise program based on SG in the EG (p=0.001, ES=0.4). In the CG, which received treatment based on conventional kinesiotherapy, the improvements were not significant, and the ES was small (p=0.204, ES=0.1). In general, these patients had moderate to severe gait impairment (GE 0.56±0.32 and GC 0.66±0.53), this information deserves attention (Winstein et al., 2016; Salbach et al., 2015; Fritz and Lusardi, 2009). Some studies with a good level of evidence and higher degree of recommendation (Cho and Lee, 2013) have used VR technologies to improve lower limb motor functions in hemiparetic stroke patients, especially related to gait. In general, the results of these studies corroborate with those obtained in the present study, evidencing improvements in the various gait parameters, including speed.

Regarding the variables motor impairment and spasticity, significant improvements were also observed, with moderate ES in the EG (FMAS p=0.001, ES=0.6 / MAS p=0.010, ES=0.5). In the CG, no significant improvements were obtained in these variables, but the ES was moderate, suggesting that in a larger population, that is, in research with greater power, these results could become significant (Lindenau and Guimarães, 2012).

The present study involved two groups of patients with similar general characteristics, for example: gender, age (EG 57.3±10.9 and CG 59.8±9.8), BMI (EG 29.2±8.1 and CG 28.3±5.8), laterality, hemiparesis, stroke time (EG 19.3±23.1 and CG 13.8±12.3) and phase of stroke. This allows a more reliable comparison between the effects of the different treatment proposals used with the groups. It is important to emphasize that the majority of the participants of both groups were in the chronic phase of the disease (EG 19.3±23.1 and CG 13.8±12.3 months), a period characterized by greater difficulty in obtaining improvement, when compared to the phase subacute (Langhorne et al., 2011). These characteristics of the participants make the results even more valuable, since they indicate that the intervention using the *mim-Pong* SG can result in important improvements even in chronic patients, who are often already disillusioned with rehabilitation. Flansbjer et al. (2012) affirm that MS training promotes improvements and maintenance of this valence for up to 4 years post-stroke. The present research corroborates with these authors about the existence of improvements in the chronic phase. However, significant improvements were also observed in patients with lesions eight years ago, approximately. This finding may justify the functional improvements that are often achieved with rehabilitation after many years of the event (Veerbeek et al., 2014).

CHAPTER

3

SERIOUS GAME FOR BALANCE REHABILITATION OF HEMIPARETIC STROKE PATIENTS

3.1. INTRODUCTION

The stroke has high rates of incidence and prevalence worldwide. It represents the second largest cause of death and the first one of physical and mental incapacity in adults (Rist et al., 2016; Daneshfard et al., 2015). It is a global public health problem and currently is one the main causes of functional dependency (Campos et al., 2017). The hemiparesis is a classical clinical consequence of stroke. It is characterized by an impairment of the body side contralateral to the brain injury side. There is an inability to transfer the weight to the impaired of a body side, which indicates disturbances related to the regulation of the balance (Barcala et al., 2011).

The balance requires integration of the somatosensory, visual, and vestibular systems. They generate information to the central nervous system, which interprets the messages and returns as a motor response for an adequate regulation (Horak, 2006). However, these systems do not interact correctly because of the stroke, which results in inadequate postural responses (Horak, 2006). The balance change in hemiparetic patients is mainly due to muscle weakness, sensorial loss, uncontrolled reflex, and visuospatial distortion. The muscular dyssynergy and motor control impairment affect the individual's ability to produce and to control the motor settings to maintain balance (Horak, 2006; Corrêa et al., 2005). Therefore, shortcomings in the integration processes of the different systems involved, resulting from stroke, can directly affect the balance (Oliveria et al., 2008). That compromises daily life activities generating greater fatigue (Houdijk et al., 2010) and increasing the risk of falls of these individuals (Giriko et al., 2010).

A systematic review and meta-analysis conducted by Duijnhoven et al. (2016) has shown that balance capacity can be improved by exercise therapy in the chronic phase after stroke. However, they highlighted the need to use new types of training in order to sustain improvements. This includes approaches such as dynamic and challenging balance training by using balance perturbation, dual task and/or gait adaptability exercises. In this sense, strategies for the balance rehabilitation have been researched for the recovery of these patients. The use of virtual reality and digital games has been shown to be an efficient approach in neurological rehabilitation, as they increase the motivation to the therapy that helps the rehabilitation process (Lloréns et al., 2015; Darekar et al., 2015). Commercial digital games are interesting from a motivational point of view, but they are designed for the entertainment of healthy people and need to be adapted for therapeutic use. The main limitations of commercial digital games not focused on rehabilitation are: do not contemplate all aspects of the rehabilitation process (Staiano and Flynn, 2014); do not consider the patients limitations do not generate data for analysis (Proffitt, 2014); there is no relation of the game score to the performance of the treatment activity (Goble et al., 2014; Anderson et al., 2015; Pastor et al., 2010); game visual design is not always adequate to the target population (Staiano and Flynn, 2014); typical commercial games may increase the risk in the therapeutic procedures (Chao et al., 2014; Taylor et al., 2011), and they not present gameplay adjustments for different degrees of patient's commitment (Anderson et al., 2015; Soares et al., 2016).

Digital games developed for rehabilitation are safe for the treatment because it enables the setting of the exercises for each patient's individual conditions (Soares et al., 2016). Digital games for specific purposes, such as education and health, mixed with the playful aspect of entertainment, are called Serious Games (SG) (Alvarez and Djaouti, 2011). However, developing a SG for rehabilitation is not a trivial task. It should be done in a multidisciplinary way considering many aspects involved, such as physiological, psychological, and technological (Rego et al., 2010). Unlike videogames for entertainment, videogames for rehabilitation should focus on treatment and consider aspects that make the game motivating for the patient.

Borghese et al. (2013) used classical principles and strategies of entertainment games adapted to the rehabilitation context. Some critical factors were considered, such as repeatability of exercises, executing time of tasks, and motor and cognitive limitations of the patients. However, repeatability of the exercises is an intrinsic characteristic of the rehabilitation processes which may lead the patient to a boredom condition (Burdea, 2003). Thus, the key point is to minimize this unwanted condition by introducing elements of game variability.

Most rehabilitation process of neurological patients is long and tiring (Hackett and Pickles, 2014), which results in lack of motivation and abandonment of treatment programs. Depression is a factor found in these patients leading to a lower treatment adherence (Li et al., 2016). The use of SG minimizes these negative factors, generates increased attentional demand, motivation, and pleasure in the treatment. Thus, the patient becomes an active agent of his own rehabilitation process (Soares et al., 2016).

Particularly in relation to stroke, where about 75% of cases occur with people over 65 years of age (Lloyd Jones et al., 2013), it is necessary to consider the factors related to age, such as motor skills decline, sensory deficits and associated chronic diseases (Gerling et al., 2012). Gerling et al. (2012) suggest usability criteria in games for older people that include reduction of steps for task completion, reduction of cognitive load, availability of immediate feedback and adaptation of digital systems to user goals (e.g. therapeutic). All these aspects are fundamental to keep patient motivation and engagement in the rehabilitation process. Motivation is often used as a determining factor for the rehabilitation outcomes (McLean et al., 2002). Although it is a not easy concept to describe, motivation can be defined more simply as a psychological property that encourages a person's action toward a goal, causing and/or retaining the behavior to achieve the goal (Lohse et al., 2014). According to Drummond et al. (2017), the combination of motivation for the learning activity itself (intrinsic motivation) with the motivation for a future outcome desirable (extrinsic motivation) is essential for SG to be motivating. In addition, there are four important cognitive factors associated with learning: attention, active learning, feedback, and consolidation (Drummond et al., 2017). The integration of these neuropsychological aspects with the game design helps therapeutic dosage increases, which are recommended in the neurological rehabilitation (Lohse et al., 2014).

Based on the previous context, a biomedical serious game system for balance assessment and balance training of hemiparetic stroke patients was developed. The objective of this study is to present the system and its therapeutic efficacy for training balance.

3.2. METHODOLOGY

This project was approved by the Human Research Ethics Committee of Santa Catarina State University, register number 45881615.9.0000.0118 (CAAE). We selected 20 participants for the study. Twelve patients were included in the experimental group (EG), 6 males and 6 females, aged 59.9±10.2 years. Eight patients were included in the control group (CG), 5 males and 3 females, aged 60.3±8.3 years. Inclusion criteria for both groups were chronic hemiparesis for stroke (injury time ≥ 6 months); over 18 years old; able to independent walking, even using walking aid. As exclusion criteria were defined: hemiplegic patients; hemiparesis due to other pathologies; patients with severe visual and/or auditory impairment, sensory aphasia, and cognitive deficit.

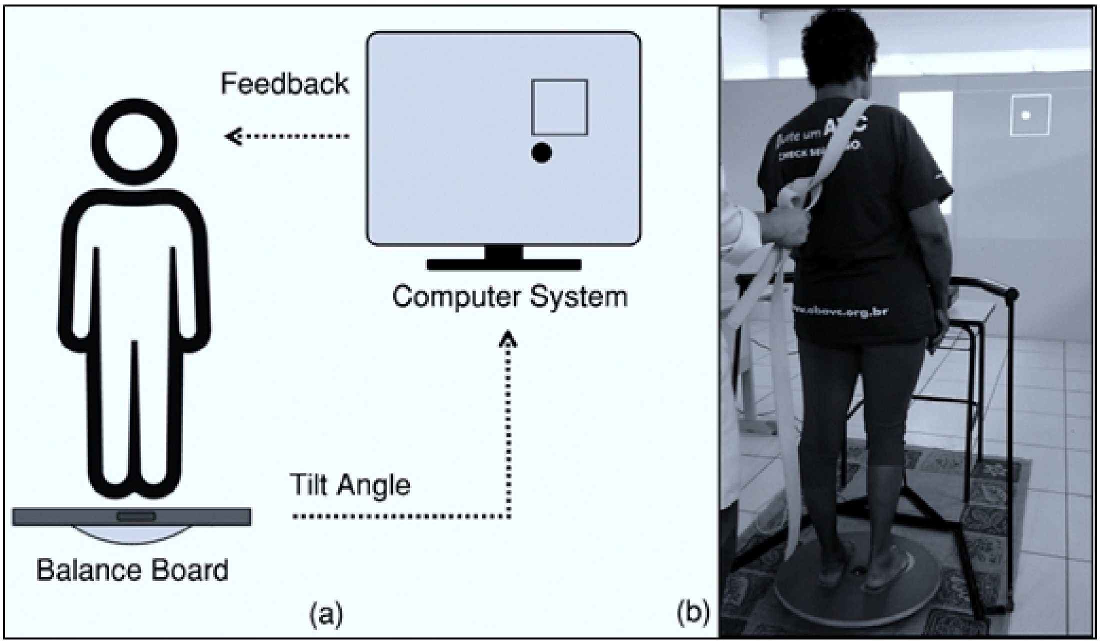
All participants were submitted to protocols of balance evaluation, functional mobility and quality of life perception. The Berg Balance Scale (BBS) was used to evaluate the balance. This scale involves performing tasks related to the individual's daily life (Tyson and Souza, 2004). The Timed Up and Go Test (TUGT) was used to evaluate the functional mobility, based on the time that the individual performs a particular task (Hafsteinsdóttir et al., 2014). The Nottingham Health Profile (NHP) questionnaire was used to evaluate the patient's quality of life perception. The NHP is a self-administered questionnaire that provides a simple measure of the individual's physical, social, and emotional health (Teixeira Salmela et al., 2004).

After the evaluation period, the rehabilitation program was started. Both groups were submitted to the treatment for 10 weeks, having 2 weekly sessions on alternative days (total of 20 sessions). All clinical studies (evaluation and treatment) were performed in a controlled environment (lighting and temperature), always by the same researchers. The experimental group was submitted to the treatment with the SG, while the control group received conventional physical therapy treatment.

A software and hardware were developed for balance evaluation and rehabilitation. It consists of a balance board with inertial sensors, a micro controlled board and a computer system that runs the SG (Noveletto et al., 2015). Figure 1 shows an overview of the whole system and the experimental settings.

EG participants did not undergo any other rehabilitation therapy that could influence the evaluation of the balance during the clinical study.

Figure 1. Balance training and evaluation system diagram and experimental setup.



Source: The authors

Balance Board

The balance board is composed of a circular wooden board coupled to a semi-sphere of epoxy resin. The wooden board is 50 cm in diameter and 15 mm thick. The semi-sphere has an arrow of 5 cm and is build based on a sphere with 40 cm radius. The maximum tilt angle of the board is 10 degrees. These specifications were based on a study (Almeida et al., 2006) where ankle, knee and hip balance strategies were evaluated on balance boards of different dimensions. Mediolateral (ML) and anteroposterior (AP) angles are obtained by an Inertial Measurement Unit (Invensense MPU-6050) coupled to the center of the board. Data of the board tilt angles are processed by a microcontrollersystem (Arduino Due 32-bit ARM) and sent to the computer to control the SG.

Serious Game (SG)

The SG is called myBalance and was developed in Delphi language, compatible with Microsoft Windows Operating System. Its visual aspects are designed so that the patient would focus only on the task of positioning a ball within a target. The ball movement is based on the board tilt angles. In this case, the time between the action (tilt of the board) and viewing the ball positioning on the computer screen should be fast enough for the user to have a real-time experience. Human visual reaction time, without motor or cognitive limitations and in a state of concentration, is about 200 ms (Kosinski, 2013). In this developed biomedical system, the time between tilt signal capture and ball positioning on the screen is about 15 ms. In addition, the game provides fast visual feedback that shows the task status. Target in green color indicates that the ball is on-target and target in red color, indicates that the ball is off-target. The system provides a quick and simple biofeedback, allowing interaction that requires an increase in the patient's attention demand, something crucial in the rehabilitation process (Uriarte et al, 2015).

The game dynamic is based on the flow theory (Csikszentmihalyi, 1991). This theory establishes a relationship between the challenge level and the player skill level. The goal is to keep the game at a level not too easy, which would lead the patient to boredom but not too hard, that would lead the patient to frustration. According to this theory, the challenge level must increase when the player's skill level increases, leading the player to enter a high level of flow.

In games for rehabilitation a higher level of flow makes the patient focus only on the challenge which engages him in longer sessions and longer periods of treatment. The flow condition in the My Balance can be maintained by changing the game settings. Based on the therapeutic objective, it is possible for the therapist to change the configuration of the following game parameters: target size, on-target stay time, target moving mode and session time.

Procedures using the SG

To perform the tests and rehabilitation sessions, the balance board was positioned in front of a multimedia projection at 3 m, with the subject standing barefoot on the board, looking at the projection positioned at the eyes' level. The feet were far apart in a natural and comfortable position but no more than shoulder width (Duarte and Freitas, 2010).

The rehabilitation program consists of 2 tasks with 3 minutes duration each, where each task is repeated 2 times. The first task is the SDS. In the second task, called Random Dynamic Stabilometry (RDS), the target moving mode is set to random mode and the target moves randomly by positions 0 to 8. In both tasks the target stays for 5 s in each position. From the second half of the rehabilitation program, the task time was increased to 5 minutes. Based on the patient performance evolution, some settings can be changed to increase the challenge level, such as: target size reduction, increase the on-target stay time, increase the time that target stays on each position and session time increase.

Data Analysis

Data were analyzed with Minitab Statistical Software - Release 17. Descriptive statistics (mean, median, standard deviation, and distribution of frequencies with absolute and percentage values) were used to characterize the participants. Shapiro-Wilk test (to verify if data are normally distributed); paired Student's t-test and Wilcoxon signed-rank test (comparison of variables in the pre- and post-intervention period, for parametric and non-parametric data, respectively). Effect Sizes (ES) were calculated to evaluate if differences observed corresponded to important clinical effects. For the parametric data, ES values <0.2, 0.8-0.2 and ≥0.8 were considered small, medium, and large, respectively. For the nonparametric data, ES values are <0.1, 0.5-0.2 and ≥0.5 (Cohen, 1988). A significance level of 0.05 was always used.

3.3. RESULTS

Twenty chronic hemiparetic stroke patients (11 males and 9 females; 60.1 ± 9.3 years old; mean time since stroke of 33.3 ± 28.1 months) participated in this study. In EG, there was a prevalence of hemiparesis on the right side of the body, while in the CG there was a predominance of the left side. In both groups everyone was right-handed. Table 1 presents the sociodemographic, clinical, and anthropometric characterization of the participants of the EG and CG.

Table 1. Sociodemographic, clinical and anthropometric characterization of patients

Characteristics (n=20)	EG (n=12)		CG (n=8)	
	$\underline{x} \pm s$	f (%)	$\underline{x} \pm s$	f (%)
Sex				
Female	- - - -	6 (50.0)	- - - -	3 (37.5)
Male	- - - -	6 (50.0)	- - - -	5 (62.5)
Age [full years]	59.9 (10.2)	- - - -	60.3 (8.3)	- - - -
Hemiparesis				
Left	- - - -	3 (25.0)	- - - -	6 (75.0)
Right	- - - -	9 (75.0)	- - - -	2 (25.0)
Stroke time [months]	37.3 (32.9)		27.1 (19.2)	

n: total sample; f: absolute frequency.

Comparison of sociodemographic, clinical, and anthropometric variables between the EG and the CG in the pre-intervention period revealed that there were no statistically significant differences between groups in any of the variables.

Table 2 shows the patients' performance in the tests with the TUGT, the BBS and NHP in the pre- and post-intervention period. Significant improvements were observed in all variables in the EG and only in the BBS in the CG.

Table 2. Patient performance in the evaluations with BBS, TUGT and NHP analyzed in the pre- and post-intervention period.

Patients (n=20)	Pre	Post	*p*-value	ES
EG (12)				
BBS	43.5 (6.5)	49.9 (4.5)	0.001	0.9
TUGT	26.1 (12.9)	22.5 (11.2)	0.001	0.8
NHP	15 (4.3-22.8)	6 (1.3-13.0)	0.007	0.5
CG (8)				
BBS	42.6 (7.8)	49.5 (6.1)	0.008	0.9
TUGT	28.1 (15.1)	25.2 (15.0)	0.237	0.4
NHP	11.5 (8.8-24.8)	10.0 (4.0-24.5)	0.078	0.5

Significance level p<0,05; p-value: [a] probability of significance obtained by the Wilcoxon signed-rank test and values expressed by median; [b] probability of significance obtained by the paired t test and values expressed by mean; ES: effect size; EG: experimental group; CG: control group; BBS: Berg balance scale; TUGT: timed up and go test; NHP: Nottingham health profile; n: total sample.

3.4. DISCUSSION

Balance deficits are common motor dysfunctions in hemiparetic stroke patients and impact the ability to stand and walk, consequently increasing the risk of falls (Schinkel Ivy et al., 2020). Therefore, training to regain balance function is crucial in the rehabilitation of these patients (Zhang et al., 2020). Even in the chronic phase, the specific balance training in hemiparetic post-stroke patients seems to result in significant plastic changes in the central nervous system (Scalzo et al., 2011).

In the present study, both groups showed significant improvements and a large ES on balance (ES=0.9). This indicates that specific balance training can be beneficial to this population. These effects have been demonstrated in similar studies in hemiparetic subjects and elderly (Santos et al., 2015; Lubetzky Vilnai and Kartin, 2010; Soares et al., 2009).

In a systematic review with meta-analysis (Iruthayarajah et al., 2017) involving 20 clinical trials, the effectiveness of the use of virtual reality interventions in the rehabilitation of hemiparetic stroke patients was analyzed. Significant improvements were found in balance assessed by the BBS and in functional mobility assessed by the TUGT, evidencing the potential of this type of intervention for the treatment of post-stroke patients. In addition, the systematic review of Lubetzky-Vilnai and Kartin (2010) analyzed the effect of balance training on balance performance in individuals poststroke. Authors concluded that balance training in post-stroke individuals was beneficial, but the optimal dose of training is not known. Most of the studies used training programs of 8 to 9 weeks, twice a week, similar to the one used in our study (10 weeks).

Some studies (Lloréns et al., 2014; Barcala et al., 2013) compared the therapeutic efficacy between approaches with digital games and conventional therapy. The results showed that both approaches were beneficial to patients. However, no significant differences were found (mean difference = 5.3±3.1) (Hiengkaew et al., 2012) - 4.7 points is a Minimal Detectable Change.

In a study by Barcala et al. (2011), 12 post-stroke hemiparetic patients were submitted to a balance training program using the *Wii Fit* game together *with Wii Balance Board* (WBB). The WBB is like a force platform but is a lower cost device. The CG was treated with conventional physiotherapy, twice a week, lasting 60 minutes. In addition to conventional physiotherapy, the EG also was submitted to a balance training with the *Wii Fit* interactive program. Sessions lasted 30 minutes of conventional physiotherapy and 30 minutes of exercise with the game was performed, twice a week for five weeks. The balance evaluation was performed by a pressure plate (Stabilometry) and BBS. Results for the gain of the balance control were significant in both groups. Authors also pointed out that using the game is a more interactive and playful approach. Despite software-based metrics being not so reliable for balance evaluation, *Wii Fit* has been accepted as neurorehabilitation tool for balance training (Goble et al., 2014). In this sense, some attempts have been done using the WBB as a low-cost device for balance assessment by using customized software applications (Bower et al., 2014; Verma et al., 2017). Results of the present study indicate that the use of *My Balance* SG altogether with the developed balance board was valid to train the balance of all subjects. Similarly, to the *Wii Fit*, our system is a low cost too (about $100).

As already pointed out, there are significant differences between SG and the commercial digital games, as for example: the objective and the target audience. In SG there is a clear specific objective beyond entertainment. A specific objective is the rehabilitation of subjects with functional limitations. On the other hand, commercial digital games are created for the purpose of entertainment and for healthy people (Soares et al., 2016). These differences limit comparisons of the results obtained in the present study with other studies that use commercial games. This suggests that the use of SG in neurological rehabilitation helps the motivational factor to the treatment. In fact, clinicians have already stated that a motivated patient affect the treatment results (McLean et al., 2000). However, the *My Balance* SG has an improved evaluation module and new training options that helps to improve the balance of patients.

Motor dysfunctions are the most evident post-stroke consequences. For example, muscle strength deficits impact gait and balance, compromising patients' mobility and functional independence. Thus, the Timed Up and Go Test is considered important resource for evaluation of the hemiparetic stroke patients, being widely used (Hafsteinsdóttir et al., 2014).

An important clinical result of this study was the functional mobility gain, which was higher in the EG. The EG obtained significant improvements and with large ES (p=0.001 and ES=0.8) in this variable evaluated with the TUGT. In the CG, which received treatment based on conventional kinesiotherapy, the improvements were not significant, and the ES was moderate (p=0.237, ES=0.4).

In a meta-analysis (Dominguez Tellez et al., 2019) involving 14 clinical trials, it was concluded that virtual reality interventions have potential benefits in restoring balance and gait after stroke. Similar findings were found in a double-blind randomized clinical trial (Cho and Lee, 2013), which investigated the efficacy of a training program with VR technology on functional mobility in 14 chronic hemiparetic stroke patients. The patients were divided into two groups (EG and CG), both received conventional physiotherapy and the EG had VR treatment, additionally. Both groups showed significant improvements in the TUGT, which were higher in the EG. The present study diverges from these findings since it was found significant improvement only in the EG. Related studies found in the literature (Soares et al., 2016; Saposnik and Levin, 2011) indicate that the associate between SG and rehabilitation is positive, pointing to a new paradigm in the rehabilitation area.

In a randomized clinical trial (Taesung et al., 2016) involving 25 chronic hemiparetic patients it was investigated whether the use of a virtual reality rehabilitation program associated with conventional physical therapy produces positive results. The authors concluded that the association of conventional rehabilitation with virtual reality in these chronic patients may be more beneficial than just the use of isolated conventional rehabilitation.

Among the main goals in post-stroke rehabilitation is to improve the quality of life of patients (Tastekin, 2015; Billinger et al., 2014). One of the most used instruments to assess this variable is the NHP, considered as a simple measure of the individual's physical, social and emotional health (Teixeira Salmela, 1999), which indicates the subject's perception of their quality of life (Lima et al., 2014). After the treatment period, significant improvements were obtained in this variable only in the EG (p=0.007). However, the ES analysis revealed a large ES for both groups (ES=0.5). These findings suggest that the EG showed a perception of improvement in quality of life higher than the CG, however the improvement in the group that received conventional treatment should not be underestimated, as although not significant, it had a large ES (Lindenau and Guimarães, 2012). It is important and valid to highlight that quality of life is a multifactorial variable, which can be influenced by several different elements (Tastekin, 2015; Lima et al., 2014). Certainly, the motivation for treatment can have a significant impact on patients' quality of life (Grahn et al., 2004).

The use of video games extends the range of therapeutic resources. Physiotherapists already consider commercial games device such as *Nintendo Wii easy* to operate and safe to use for upper limb rehabilitation in stroke patients (Thomson et a., 2014). However, it is important to consider the risks of a home rehabilitation program, mainly in balance exercises. The system used in our study is not recommended for home use without the supervision of a physiotherapist. The balance board is an unstable platform and there is the risk of fall.

Unlike the commercial digital games, the proposed system is focused on rehabilitation and was designed by a specialist team. The specialists were the heads for the design requirements and may involve experts from many science fields related to health and technology. Health care experts define based on the function that it wants to rehab, the therapy to be applied to the patient (considering the patients limitations) and the metrics of interest for evaluation. From the requirements stated by the health experts, the experts of the technology area, such as engineering and computing, define the technology of the biomedical device for patient interaction, and the serious game design. A strong interaction between the experts is a key point to the success of the rehabilitation process (Kato, 2012). These aspects allow contemplating all rehabilitation processes and are present in our system. As a result, training protocol proposed by the specialists seem adequate to balance training.

CHAPTER

4

A SERIOUS GAME DEVELOPED FOR PHYSICAL REHABILITATION OF FRAIL ELDERLY

4.1. INTRODUCTION

The frailty syndrome (FS) is common in older people and characterized by several alterations as sarcopenia, dynapenia, loss of balance, mobility, and decrease in the level of physical activity (Manini and Clark, 2012; Soares et al., 2003; Fried et al., 2001). The FS predisposes the older people not only to recurrent falls, but also traumas, hospitalizations and even death (Gillespie et al., 2009; Fried et al., 2001). Recent studies have considered that physical activity programs are an appropriate and a valid strategy to prevent or minimize the harmful effects of the FS (Duque et al., 2013; Franco et al., 2013; Rendon et al., 2012).

One technique used to increase the level of physical activity in older people, improving muscle strength and balance, is the Virtual Reality (VR). Recent researches have gradually integrated this technique as a valuable therapeutic tool in the rehabilitation of older people (Duque et al., 2013; Singh et al., 2012; Agmon et al., 2011; Szturm et al., 2011). Indeed, VR, especially in the form of Serious Games (SG), combines therapeutic and recreational challenges (Bleakley et al., 2015). This implicit interactive strategy prevents boredom, making the therapy less tiring and dispiriting. SG can motivate patients to do the sessions with pleasure and thus, improving adherence to treatment (Rendon et al., 2012; Saposnik et al., 2010; Lucca, 2009). Furthermore, this interaction can be expanded in terms of intensity, time and space (Correa et al., 2011; Holden, 2005). This ludic and challenging environment is the main aspect that differentiates the VR to the traditional physical rehabilitation programs.

However, most studies using VR are based on commercially available games designed for the entertainment of healthy people (Bleakley et al., 2015). Studies have shown different VR systems with specific interfaces, graphics, sceneries, principles of gameplay, and presentation of scores. The non-adaptation of these commercial games may cause a risk in procedures when applicable to older people with FS. Indeed, commercial games do not consider neither the level of disability nor the appropriate play options for an individual setup, which may induce dangerous movements (e.g, fast and high range of motions).

To improve the physical activity practice and its benefits through VR of the specific population of older people with FS, it is crucial to develop rehabilitation games considering the security and the customization of these games. Thus, this study proposed to evaluate the therapeutic effects of an exercise program using a SG developed for rehabilitation of older people with FS.

4.2. METHODOLOGY

This quasi-experimental study was conducted at Bethesda Institution, in Joinville, Brazil. The researchers presented a lecture about the FS and its treatment possibilities to the residents. Then the invitation was made to potential participants.

Both men and women aged from more than 65 years old and diagnosed with a FS according to the Fried et al. criteria were included in the study (Fried et al., 2001). The exclusion criteria were dementia; stroke; severe heart disease; visual, vestibular and hearing impairments; and disabling orthopedic and rheumatic diseases.

Study participants included 24 older people (8 men and 16 women) distributed into 2 groups matched by gender. The experimental group was composed by persons who wish to participate in the SG program. As the SG was a "new" physical exercise program, some residents reported that they did not feel confidence to start the program but accepted to do the clinical and functional evaluations of this study. These persons composed our control group. The persons in this control group who showed interest late to participate in the SG program were met after the completion of this project, but their results were not analyzed. This study was approved by the Ethics Committee on Human Research of the Bom Jesus/IELUSC Lutheran Educational Association (n. 393.274) and all participants signed an informed consent form.

4.2.1 Evaluation

A registration form with a brief medical history was used to collect information about the associated diseases and pharmacological and non-pharmacological treatments. Also the Mini Mental State Examination (MMSE) (Brucki et al., 2003) and Geriatric Depression Scale (GDS) (Valim Rogatto et al., 2011) were included as screening instruments. Afterward, the follow tests were used as outcome measures of the SG intervention.

- **Functional mobility:** The Timed Up & Go test (TUG) was used to assess functional mobility (Schoene et al., 2013). This test has a good intra- inter-examiner reliability (ICC = 0.95 and 0.98 respectively) (Piva et al., 2004).
- **Balance:** The Functional Reach Test was used to assess balance (Kage et al., 2009). It is a fast and a convenient test that showed a good inter-examiner reliability (ICC = 0.81) (Figueiredo et al., 2007).
- **The level of physical activity**: The International Physical Activity Questionnaire–Short Form (IPAQ) (Craig et al., 2003) was used to assess the global level of physical activity of participants. The IPAQ presents a strong reproducibility (rs = 0.95) (Benedetti et al., 2007).
- **Muscle mass**: To evaluate muscle mass, the equation of Lee et al. (2011) was used, establishing the Total Muscle Mass Index (TMM) ranging from 5.9 to 9.5 kg.m-2. The TMM was calculated using the formula below:

$$\text{Total Muscle Mass (TMM)} = 0.244 \times BW + 7.8 \times H1 - 0.098 \times A + 6.6 \times S + Et - 3.3$$

Where: BW, body weight (kg); H1, height (meters); A, age (years); S, sex (female, 0 and male, 1); and Et, ethnicity (Caucasian, 0; Asian, -1.2; African descent, 1.4).

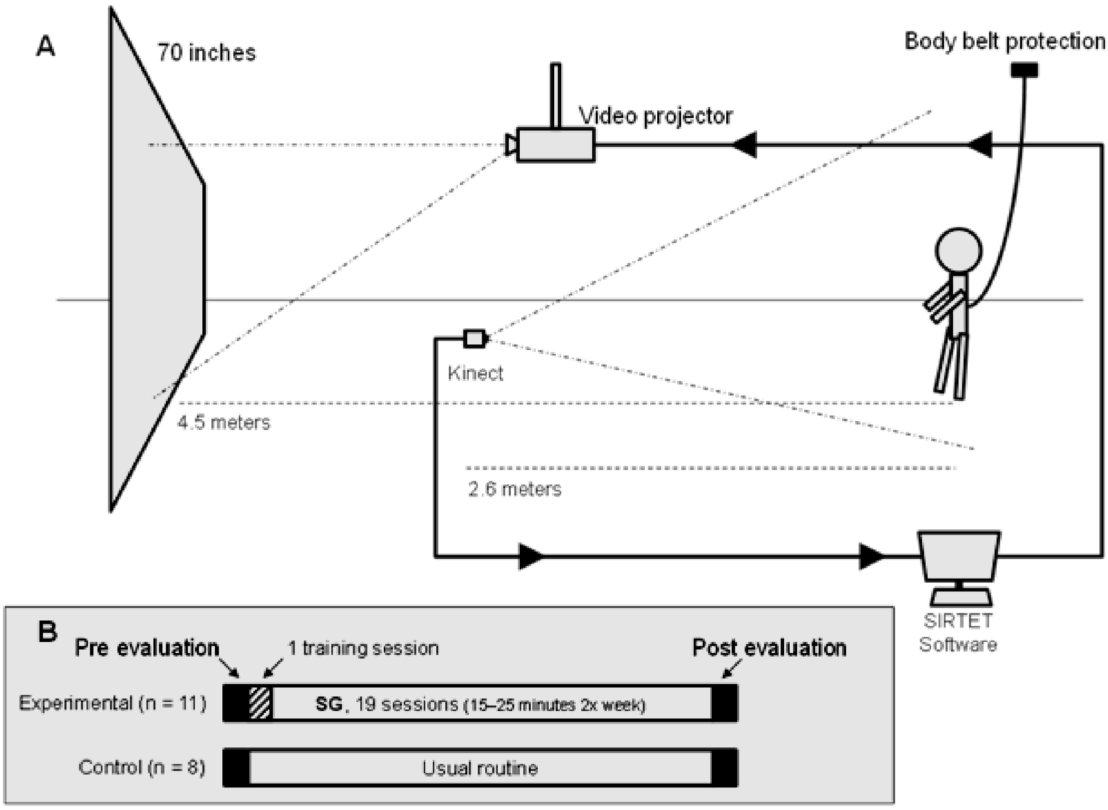
- **Muscle strength:** The muscle strength was evaluated with dynamometers which were calibrated prior to data collection. The left- and right-hand grip strengths were evaluated with a Takei manual dynamometer (Takei Scientific Instruments, Japan) according to the recommendations of the American Society of Hand Therapists (Fess, 1992). The strength of major muscle groups of the upper and lower limbs (i.e., shoulder flexors, elbow flexors, hip flexors, knee extensors and ankle dorsiflexors) was evaluated with a Chatillon dynamometer (Ametek, USA) according to the protocol proposed by Andrews et al. (1996). After taking two measurements of the maximum isometric contraction for approximately 3 to 5 seconds per muscle group, the best measurement was recorded. Then, the arithmetic means of both sides for upper and lower limbs and the arithmetic mean for upper and lower limbs (appendicular muscle strength) muscle strengths were calculated. To take in consideration the muscle size, the isometric strength of the upper and lower limb muscle groups were normalized by body weight ($N.kg^{-1}$) (Woods et al., 2011).

Serious Game SIRTET (SG SIRTET)

The SG was developed by the Laboratory of Research on Visual Applications of the University of the Santa Catarina State, Brazil. The guidelines that oriented the creation and the application of the SG in this study, were based on the recommendations of Bleakley et al. According to that study, the main objectives to promote SG in older people are the increase the level of physical activity, balance and the strength (Bleakley et al., 2015). The SG is composed of a Kinect camera, a video projector, a computer, and the SG SIRTET software (Figure 1-A) (Rossito et al., 2016). To maximize safety while training, the participants used a large body belt protection attached to the ceiling of the room. First of all, for the calibration process, the participant remained standing in front of the Kinect camera where his/her image was detected by anteroposterior movement of the body. In this phase, both avatar and scenery were set from the anthropometric characteristics of the user, thus creating a customized game.

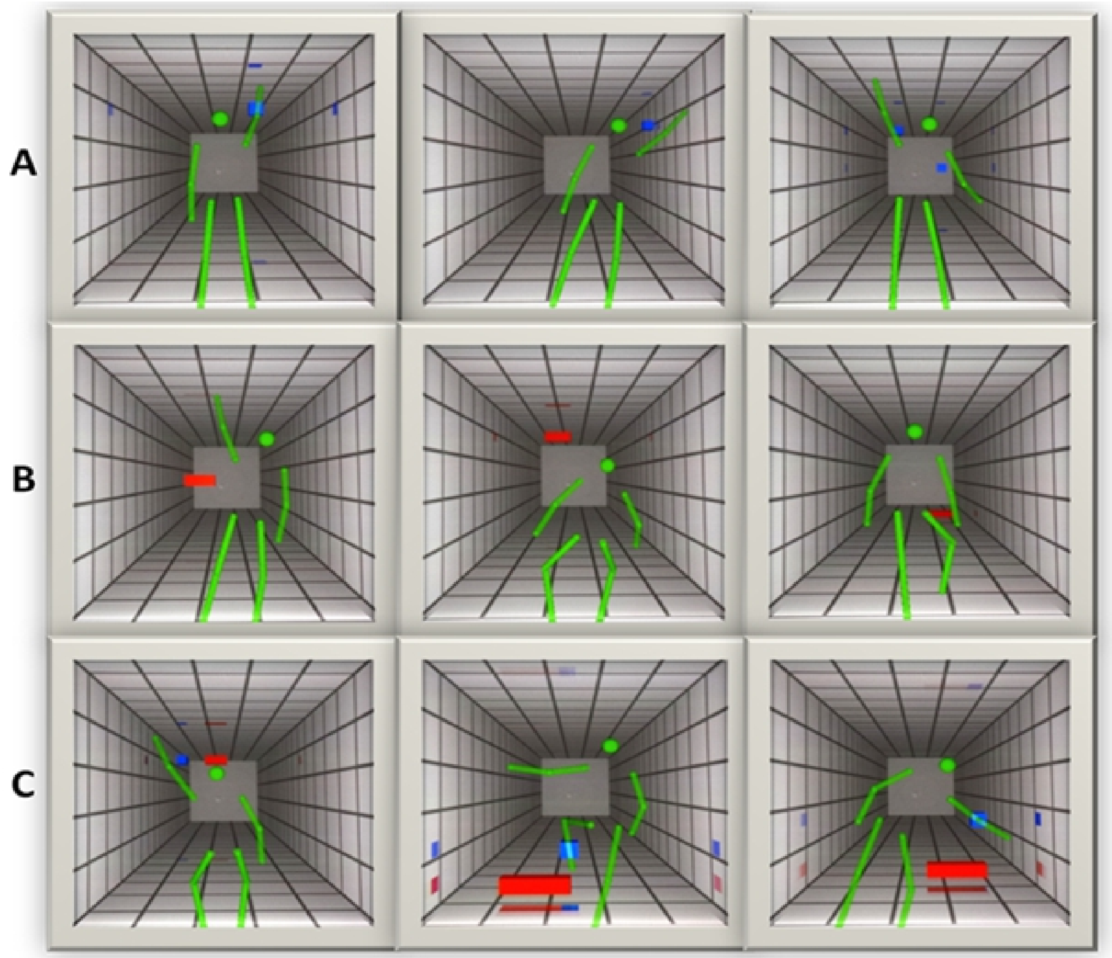
After the calibration phase, the user interacted by guiding the avatar in the virtual scenery (Figure 2). The graphical elements arise in a random order from the perspective of a checkered tunnel. The 3 main tasks which users must do consisted in (i) hit the targets (blue blocks), (ii) avoid the obstacles (red blocks), and (iii) and simultaneously hit and avoid tasks (Figure 2). During the game, participants were instructed to use any motor strategy to fulfill the tasks. With each target hit or obstacle avoided, the participant increases his/her score which s/he could observe in the projection. Moreover, an audio sound reinforced the correct motor behavior. The SG had 3 difficulty levels which were set based on previous experiments of the research group (Soares et al., 2014). Throughout the session, continuous visual and audible feedbacks were offered by the SG.

Figure 1. Experimental set (A) and procedures (B)



Source: The authors

Figure 2 The avatar in the virtual scenery



Legend: Some examples of tasks require in the SG. In ***A*** hit the targets (blue blocks), in ***B*** avoid the obstacles (red blocks), and in ***C*** and simultaneously hit and avoid tasks.
Source: The authors

Procedures using the SG

After the initial evaluations, the experimental group participated in the SG program. Participants were subjected to 20 individual sessions with the game, lasting between 15 and 25 minutes twice a week. The first session was dedicated to participant's familiarization. During the game the participants' perceived level of exertion, heart rate and blood pressure were monitored and used to interrupt sessions, if necessary. The participants in the control group did not undergo any treatment and were instructed to maintain their usual routine (Figure 1-B).

Data Analysis

The statistical analyses were performed with GraphPad Prism version 6 (GraphPad Software, Inc. USA). All parameters were presented in terms of mean and standard deviation (SD). After checked the normality of parameters, for each group, the differences between the pretest and posttest were conducted with a paired Student's t-test with a significance level set at 0.05. Finally, effect sizes (d) were calculated to evaluate if differences observed corresponded to important clinical effects (Cohen, 1988). Effect sizes of 0.2, 0.5 and 0.8 were regarded as *small, medium* and *large degrees* of differences, respectively.

4.3. RESULTS

Five participants did not complete the experiments: one woman in the experimental group due to hip fracture. One man and 3 women in the control group: two deaths, the man with pancreatitis and a woman for stroke; the other two women left the institution.

The main characteristics of the participants are presented in Table 1. No significant difference was found between experimental and control groups at baseline in terms of clinical and functional parameters. No participant showed significant depressive traits and all reported low levels of physical activity.

Table 1. Mean and (SD) of participants' clinical profile

Groups	Experimental (n = 11)	Control (n = 8)	*p*
Age (years)	83 (6.8)	80 (4.5)	*N.S*
Gender (male / female)	4 / 7	3 / 5	*N.S*
Associated diseases (nb)	4 (1.9)	4.1 (0.8)	*N.S*
MMSE (0-30)	28.4 (1.7)	27.8 (3.1)	*N.S*
BMI ($kg.m^{-2}$)	25.3 (4)	27.9 (4.3)	*N.S*
TUG (s)	15.4 (4)	13.3 (2.7)	*N.S*
Functional reach test (m)	1.73 (0.52)	1.91 (0.72)	*N.S*
Total muscle mass I ($kg.m^{-2}$)	7.4 (1.5)	8.1 (2.1)	*N.S*
Apendicular strength ($N.kg^{-1}$)	13.7 (4.3)	14.5 (4.7)	*N.S*

MMSE: mini mental state examination; BMI: body mass index; TUG: timed up and go test; I: Index; N.S: not significant; n: total sample.

While the control group did not significantly differ for any outcome, the experimental group showed large significant improvements, for functional mobility evaluated with the TUG (d = -1.3, p = 10^{-3}); for balance evaluated with the Functional Reach Test (d = 1.2, p = 10^{-2}); and small to moderate significant improvements for upper limb strength (d = 0.2, p = 0.04), appendicular strength (d = 0.4, p = 10^{-2}) and lower limb strength (d = 0.6, p = 0.02) (Table 2). For the performance in the SG, the experimental group had a significant increase in computed scores between the first and the last session (d = 3.1, p = 10^{-4}) (Table 2).

Table 2. Results for both experimental and control groups.

Groups	Experimental (n = 11)				Control (n = 8)			
	Pre	Post	*d*	*p*	Pre	Post	*d*	*p*
MMSE (0-30)	28.4 (1.7)	28.7 (1.7)	0.2	0.221	27.8 (3.1)	28.1 (3)	0.1	0.351
BMI (kg.m^{-2})	25.3 (3.9)	25.5 (3.6)	0.1	0.400	27.9 (4.3)	28.4 (4.5)	0.1	0.113
TUG (s)	15.4 (4)	11 (2.6)	**-1.3**	**0.000**	13.3 (2.7)	11.5 (3.2)	-0.6	0.112
Functional reach test (cm)	1.73 (0.52)	2.28 (0.38)	**1.2**	**0.003**	1.91 (0.72)	2.09 (0.5)	0.3	0.286
Total muscle mass Index (kg.m^{-2})	7.4 (1.5)	7.4 (1.6)	0	0.900	8.1 (2.1)	8.2 (2.2)	0	0.084
Right hand grip strength (N)	252.1 (95.2)	260 (90.3)	0.1	0.362	230.5 (104)	234.5 (105)	0.1	0.617
Left hand grip strength (N)	224.6 (75.5)	230.5 (62.8)	0.1	0.440	219.7 (86.3)	223.7 (93.2)	0	0.639
Upper limb strength (N.kg^{-1})	15 (5.3)	16.1 (5.1)	**0.2**	**0.043**	15.1 (5.5)	15 (5.4)	0	0.766
Lower limb strength (N.kg^{-1})	12.3 (3.9)	14.7 (4.3)	**0.6**	**0.022**	13.9 (4.4)	12.8 (3.4)	-0.3	0.147
Apendicular strength (N.kg^{-1})	13.7 (4.3)	15.4 (4.7)	**0.4**	**0.018**	14.5 (4.7)	13.9 (4.3)	-0.1	0.260
SG score	30.1 (12)	74.5 (16.2)	**3.1**	**0.000**	NA			

Pre, pretest; Post, posttest; MMSE, Mini Mental State Examination; BMI, Body Mass Index; TUG, Timed Up and Go test; I, Index; SG, Serious Game; NA, Not Applicable.

After experiments no significant changes were observed in the MMSE, Body Mass Index, TMM or grip strength (Table 2) for both groups. As somewhat expected, these outcomes were not related to the specificity of the implemented SG training.

All older people in the experimental group were evaluated after three months from the end of treatment. Positive results were maintained showing a good retention effect.

4.4. DISCUSSION

This study aimed to evaluate the therapeutic effects of a SG developed for the physical rehabilitation of older people with FS. Few studies have focused on the physical rehabilitation in this specific population, which in most cases, is institutionalized and has a physical and mental impairments greater than those peers not institutionalized. Moreover, this population is vulnerable to falls, traumas, physical limitations, and requires a permanent professional assistance (Soares et al., 2014; Woods et al., 2011).

This study showed that the exercise program with the SIRTET SG resulted in significant improvements of functional mobility and balance with the magnitudes of differences about 1.25 SDs. In the control group those magnitudes represented about 0.45 SD. In despite of the differences in older people characteristics (e.g., non-fallers, fallers outpatient, retirement communities), the VR games used (e.g., commercial or specific) and experiments (e.g., sample size, number and frequency of sessions), our results are in line with previous studies demonstrating the positive effect of VR when comparing the balance and functional mobility with the non-practice of any physical activity (Rendon et al., 2012; Young et al., 2011; Agmon et al., 2011; Studenski et al., 2010; Suárez et al., 2006) or its equivalence with conventional balance training (Singh et al., 2012; Hagedorn and Holm, 2010).

The second improvement in terms of magnitude found for this SG was the muscle strength. These strength improvements were especially for the lower limb muscles (d = 0.6), whereas in the control group values tended to reduce (d = -0.3). The better improvement of the lower limb strength is probably related with the specificity of the SG as the tasks were realized in a standing position and do not soliciting specific hand grip function for example. Although we could not find normative values for comparison with the data obtained in this study, our results suggest that SG could diminish the strength lost progression in older people. It is important to point out, that although sarcopenia is related to disability, functional decline, and mortality, dynapenia has been considered as the more crippling phenomenon and the strongest predictor of disability and death in the older people with FS than the loss of muscle mass alone (Fielding et al., 2011; Mitchell et al., 2011; Newman et al., 2006). Studies addressing this issue have average rates of muscle loss in the older people between 65 and 75 years old of 0.47% per year in men and 0.37% per year in women. Above 75 years, the loss rate increased from 0.80% to 0.98% per year in men and from 0.64% to 0.70% in women. These studies report a reduction in strength that is two to five times faster when compared to the loss of muscle mass.

Finally, some research emphasizes the need to develop new SG with greater specificity to the older people, improving exercise program planning and allowing customization of the game to users' condition. These features, as proposed by our SG, probably allow the training to be safer and more effective (Bleakley et al., 2015; Szturm et al., 2011). In this study the interventional group had an improvement of 3 SDs in the specific score of SG. This is in line with previous study which found that *computer feedback training* can improvement up to 400% in the training specific performance (Hagedorn and Holm, 2010). These results confirm the potentiality and the necessity to well design the SG in accordance with which clinical or functional aspects therapists would like to improve.

Although the results found in our quasi-experimental study are encouraging, this study presents several limitations and further work is warranted in order to confirm the benefits of SG. First, despite of the representativeness of our participants with equivalent clinical and demographic values (Gobbo et al., 2012; Cervi et al., 2005), our study was conducted in a relatively small sample size increasing the type 2 error; Secondly, the assignment to the groups were not randomize, despite no significant difference were found for clinical and functional parameters choose in this study at baseline. To finish, although a great satisfaction was reported by participants during the treatment period no significant changes were found for cognition and mood domains. This is probably associated with the specificity of the SIRTET SG in promoting motor skills. Other associated or independent SGs should be developed to improve cognition and mood domains, as they have been considered as the main symptoms related with FS.

CHAPTER

5

FINAL CONSIDERATIONS

About the SG showed in this book, some aspects are important for future research in this area: consider the possibility of using it in other special populations with the necessary modifications or adjustments, the expansion of the number of participants in the studies and improve the investigation of the potential metric properties of the SG.

Certainly, the development of SG must be stimulated, especially those more practical and low-cost systems, particularly for those emerging or developing countries, because the high technology resources are expensive and of difficult access.

This book brought three different applications of the use of Serious Games to use in the neurologic and geriatric rehabilitation. In fact, it seems very promising to consider this technology as an adjuvant therapeutic resource in the neurorehabilitation process, not only in post-stroke hemiparetic and frail elderly, but for many other applications in this area. The motivational characteristics, the repeatability of the movement, the induction of the movement directed to a goal, allow the patient a diversity of situations and stimuli, continuously challenging him to perform the tasks in a therapeutic context. This is because the game stimulates the patient in a spontaneous and natural way to move using different motor strategies for each challenge requested in the game, motivating the patient to join the treatment with enjoyment. Thus, the greater variability of movements in a therapeutic context and the increase of attentional demand and motivation are continuously required.

It is very important that researchers and physiotherapists are willing to test new therapeutic strategies for neurological and geriatric patients, especially for those in the chronic phase who have a limited prognosis, and more, the long periods required in rehabilitation make this process tiring and tedious. Then, the Serious Games emerge as a useful and promising tool to be allied to conventional techniques used to functionally recover patients and improve their quality of life.

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New Technology for Physical Therapy:

The Serious Games

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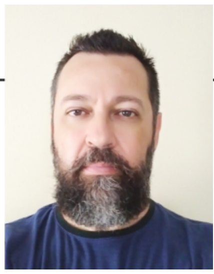

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