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Original Article

Device or not device...what is the APA program the best for patients with neurological disability? Pilot study.

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Abstract:
The aim of this study was to compare effectiveness of two programs of APA in patients with neurological disability in order to reduce the risk of fall and to improve state of global health. Forty-six patients with MS, PD and Stroke, divided in APA group (adapted physical exercises) and APA-D group (with devices). Each group participated in two 60-minute weekly sessions for 2 months, they were tested at T0, T1 and at follow-up 6 months about: FIM, Tinetti, Berg Balance, TUG, 6MWT, Hads, EuroQol, Cop, Walking Analysis. Both groups, in the T1 phase, showed an increase level of performance and health status, though the APA_D group presented a more pronounced decrease in the risk of fear of fall for balance variable (T0_T1:Tinetti: 30%; Berg: 30%; Tug: 18,3%; Cop: 52,1%). Results demonstrate fall risks relationship with "functional tests" currently used to measure dynamic balance, and its accuracy in predicting falls in neurologic subjects.
Key words: APA, functional tests, fear of fall, neurological disability, training program.

Introduction

Falls, particularly common in older people, are a leading cause of death, disability, and health care costs (Tinetti & Kumar, 2010). Prevalence rates of fear of falling varies greatly depending on different factors such as assessment methods and sample selection (range: 12–65% in people without history of falls), with the highest rates documented in fallers (range: 29%–92%) and frail population (Jorstad, Hauer, Becker & Lamb, 2005; Hauer et al.,2011). Falls and fall-induced injuries are a leading cause of morbidity and mortality among older and frail neurological disability people worldwide and preventing them is an international priority (Guirguis-Blake, Michael, Perdue, Coppola & Beil, 2018; Sherrington et al., 2017). As falls rates increase with age, functional impairment also increases the costs of falls and associate injuries are of global concern, estimated at 1.5% of health care costs in European countries, both directly from the fall-related injuries and indirectly through loss of mobility, confidence and functional independence (World Health Organization [WHO], 2007;Ambrose, Paul & Hausdorff, 2013). Bladder incontinence, osteoarthritis, Parkinson's disease, cardiovascular accidents, and conditions associated with cardiovascular disease, such as hypertension can have a significant effect on fall rates in older adults. Additionally, deficits in the somatosensory and vestibular systems can also contribute to falls because they are associated with an increase in postural sway, a strong indicator of standing balance. Locomotor disturbance is among the early signs of Parkinson's disease (PD). Cardinal indicators include hand tremors, rigidity, bradykinesia and postural instability. These symptoms effect locomotion and, as the disease progresses, can lead to an increased risk of falling. Nearly 70% of people with Parkinson's experience a fall, and 15% of those falls result in a fracture (Leavy, Kwak, Hagströmer & Franzén, 2017; Conran J, Leavy, Mattsson, Falk & Franzén, 2018).

Multiply Sclerosis (MS), demyelinating disease of central nervous system, is characterized with neurodegeneration, inflammation, axonal demyelination and transaction (Pilutti, Platta, Motl & Latimer-Cheung, 2014; Swank, Thompso & Medley, 2013; Motl & Sandroff, 2015). The chronic course of MS can result in significant mental and physical symptoms and irreversible neurologic deficits (Sa, 2014). Motor dysfunctions in MS patients are frequently due to muscle weakness, abnormal walking mechanics, balance problems, spasticity and fatigue (White, 2004; Gutierrez et al., 2005) .

Chronic stroke survivors are exposed to long-term disability and physical deconditioning, effects that may impact their independence and quality of life (Lamberti, 2017). Experimental evidence suggests that different types of exercise training in older age and in disabilities patients has the potential to favorably affect physical function and prevent disability (Halabchi, Alizadeh, Sahraian & Abolhasani, 2017; Conran et al., 2018). Indeed, WHO, in 2015, recommends the elderly to perform at least 150 min a week of moderate-intensity aerobic activity or 75–150 min a week of vigorous activity and exercises at least 3 days a week to improve balance and prevent falls .

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Aim of the study is to compare effectiveness of two specific programs of adapted physical activity (APA) in patients with neurological disability in order to reduce the risk of fall and to improve the autonomy in the ADLs and the state of global health. Specifically, a specific exercise program based on the principles of the APA has been structured, whose mission is to promote full participation in physical activity through improvement of strength, aerobic ability, resistance, coordination and equilibrium, verifying the level of feasibility and effectiveness in patients with neurological disability.

Material & methods

Participants

After it was obtained the approval by the local Ethics Committee and signed the informed consent, 58 participants were recruited in the Physical Medicine and Rehabilitative Unit of University of Catanzaro.

Inclusion criteria were: subjects affected by neurological diseases (Multiple Sclerosis, Stroke and Parkinson), ability to be standing with or without aids, ability to control trunk / head.

Exclusion criteria: bedridden or wheelchair-bound, hospitalization in the last 3 months, use of any walking aid, amputation of the lower limbs, severe psychiatric illness, severe visual impairment or taking medication for balance, combined with other treatments kinetic in progress. Fortysix patients out of 58 were involved in the study (19 man and 27 women, 60,5± 1,3 yrs) : Multiple Sclerosis (16 pz, 6 man - 10 women; 54±0,6 yrs); Stroke (10 pz, 4 man-6 women,76±0,8 yrs); Parkinson's Disease (20pz, 9 man-11women, 67±2,4 yrs).

Study design

Before the start of the training program (T0), participants provided personal information and completed some psychological questionnaires and performed physical tests, to measure the variables of interest in this study. All participants have been submitted to anamnesis and clinical evaluation with the following evaluation scales and test: Functional Independence Measure (FIM), Tinetti, Berg Balance Staircases, Time Up and Go Test, 6MWT, Hospital Anxiety and Depression Scale (Hads), European Quality of Life Scale (EuroQol). All have performed functional evaluations by diagnostic tools: Barapodometric Analysis s-EMG, Balance Sistem Analysis, Walking Analysis (Tab 1).

Table1. Study design

	n		**APA** ***walking program***	**APA-D** ***walking program***
Participants	8	**MS**	Aerobic, strength, balance, coordination, and flexibility exercises	Treadmill Gait Trainer and Balance System
	23 tot 10	**PD**		
test T0			All subjects were tested	All subjects were tested
test T1			All subjects were tested	All subjects were tested
follow-up (6 months)	5	**S**	All subjects were tested	All subjects were tested

The activities had been planned by a team of experts: physicians, physiotherapists and kinesiologists, with the aim to prevent physical and functional decay, and to promote healthy status. Participants were randomly divided into two groups, using the minimization, a stratified sampling method: APA group, consisting of group sessions of adapted physical exercises, APA-D group, consisting of adapted physical activity with devices. Each group consisted of 23 individuals (8 with MS, 10 with PD, 5 with S), who participated in two 60-minute weekly sessions for 2 months. Each session was run by two physiotherapists and one kinesiologist. The APA group carried out moderate physical activity which included aerobic, strength, balance, coordination, and flexibility exercises, with the use of sticks, elastic bands, balance platforms, soft carpets, and rehabilitative balls. The APA-D group program consisted in a training with Treadmill Gait Trainer and Balance System (Tab.2).

Table 2. APA program and APA-D program

		training 1		training 2	
	dose	type	level/repetition	type	level/repetition
APA program	(2 x 1 h session/week x 8 weeks)	Aerobic exercise (walking) Fexibility exercise Strength Balance Coordination	1 series x 5 rep	Aerobic exercise (walking with obstacle) Flexibility exercise Strength Balance Coordination	2 series x 5 rep
APA-D	(2 x 1 h	Treadmil gait trainer 3	0.5 km/h x 7 min	Treadmil gait trainer	0.5

program	session/week x 8 weeks)	biodex Balance system (static mood) _ Pstural Stability _limits of stability _weight move _ random ceck	subjects balance level	3 biodex Balance system (static mood) _ Pstural Stability _limits of stability _weight move _ random ceck _ weight percentage _labyrinth ceck	km/h x 12 min subjects balance level

Before starting the study protocol, all participants performed a workout with the physiotherapist and kinesiologist to familiarize with the exercises, tools and devices that will be used later.

Clinical Measures

FIM™ is an international scale of nursing care and disability of person and consists in 18 items to evaluation of the Activities of Daily Living (ADL). The score from 1 to 7 defines the level of self-sufficiency (1=complete dependence →7= complete self-sufficiency). The complete score (from 1 to 126) represents different specific indicators of the Rehabilitation (Hamilton et al., 1987).

Tinetti Balance Evalutation (TMT) is composed of two distinct components, including a balance subscale (9 items, 16 points) and a gait subscale (8 items, 12 points). Therefore, there are 17 items, each of which is rated on a scale of 0 to 2, and the maximum possible score is 28 points. The total time taken to perform the TMT is about 10 minutes per participant (Tinetti, 1986).

Berg Balance Scale (BBS) was developed as a performance-oriented measure of balance in the elderly. It assesses static balance in a sitting and standing position, as well as dynamic balance during transitions and standing. Individuals who are able to maintain their balance for each task score higher on this outcome. The BBS consists of 14 items that are scored on a scale of 0 to 4. A score of 0 is given if the participant is unable to perform the activity, and a score of 4 is assigned if the participant is able to perform the activity based on the criteria assigned to it. The maximum total score of the test is 56. The items include simple mobility activities (e.g. transfers, standing unsupported, sit-to-stand) and more difficult task (e.g. tandem standing, turning 360°, single-leg stance) (Blum & Korner-Bitensky, 2008).

Timed Up and Go (TUG) is one of the most high-performance test used in a clinical settings to assess functional mobility. This incorporates a series of tasks necessary for independent living (Mancini & Horak, 2010) . The test requires participants to get up from a standard chair, walk 3 meters, turn around, go back to the chair and sit down, after the command “go” (Podsiadlo & Richardson, 1991). Participants were instructed to walk quickly, but in the safest way possible. Each participant performed two TUG tests and the best performance was taken into consideration. The time was measured in seconds from "go" to stop, when the participant's back touched the back of the chair, the shorter time was taken indicating a better ability to balance.

Six Minutes Walking Test (6MWT) is a submaximal test of aerobic capacity, used to measure the maximum distance a person can quickly walk on a flat, hard surface in a period of 6 minutes. The test is considered a better measure of exercise endurance than maximal exercise capacity, it’s a useful tool for its ease of administration and the similarity with normal daily activities (Lord & Menz, 2002).

Hospital Anxiety and Depression Scale (HADS) is a 14-item questionnaire measuring both anxiety (HADSA) and depression (HADS-D) on two separate seven-item subscales, ranging from 0 (minimum symptom load) to 21 (maximum symptom load) points. It was assumed that a score ≥8 points in HADS-A/HADS-D testified the presence of clinically significant symptoms of anxiety and depression (Djukanovic, Carlsson & Årestedt, 2017).

European Quality of Life Scale (EQ-5D) is a standardized measure of health-related quality of life that can be used in a wide range of health conditions and treatments. The EQ-5D consists of a descriptive system and the EQ VAS. The descriptive system includes five elements: mobility, self-care, habitual activities, pain/discomfort and anxiety/depression. The EQ VAS records the patient’s self-assessed health on a vertical visual analogue scale. This can be used as a quantitative measure of the health outcome that reflects the judgement of the patient himself. The scores in these five elements can be presented as a health profile or can be converted into a single summary index number (utility) that reflects preference over other health profiles (Balestroni & Bertolotti, 2012).

Diagnostic Tools

Balance Sistem™ SD (Biodex Medical System Inc., NY, USA): This test is designed to assess how well an older adult is using sensory inputs when one or more sensory systems are compromised. In condition one, all sensory systems (i.e., vision, somatosensory, and vestibular) are available for maintaining balance. In condition two, vision has been removed and the older adult must rely on the somatosensory and vestibular systems to balance. In condition three, the somatosensory system has been compromised and the older adults must use vision and the vestibular system to balance. In condition four, vision has been removed and the somatosensory system has been compromised. The older adults must not rely primarily on the vestibular inputs to balance.

Begin timing each trial using a stopwatch. The trial is over when (a) the participant opens his/her eyes in an eyes closed condition, (b) raises arms from sides, (c) loses balance and requires manual assistance to prevent a fall. This test provides some insight into whether each of the sensory system available for balance are being used effectively. Failure to maintain balance in condition two indicates that the older adults is visually dependent. They are not using somatosensory inputs to maintain balance when eyes are closed. Failure to maintain balance in conditions 3 and 4 indicate that the visual and/or vestibular system is not being used to maintain balance; *Walking Analysis*: The Biodex Gait Trainer™ 3 is an instrumented deck that issues both audio cueing and visual biofeedback to prompt patients into their correct gait pattern. Step length, step speed and right-to-left time distribution (step symmetry) are directly addressed; patient footfall is compared to desired footfall step after step, both on the display in real time and documented in an easy to read histogram. The Gait Trainer 3 compares the tested patient's step length, step speed, and step symmetry to age- and gender-based normative data.

Statistical analysis

Statistical analysis was performed using IBM SPSS version 24 (SPSS Inc, Armonk, NY, USA) software. To perform the data analysis, the participants will be categorized as "fallers" (with one or more falls) and "non fallers," according to fall occurrences during the 6 month follow-up period. The statistical approach was according to the level of measurement for the variables. Discrete variables were expressed as median values and continuous variables were expressed as mean and standard deviation (SD). Differences in data between "fallers" and non fallers" analyzed by Student's t test for independent samples or Wilcoxon Test. Shapiro–Wilk tests were conducted before the statistical analysis and showed that the data were not normally distributed. A Friedman's 2-way analysis of variance (ANOVA) was performed. Paired Wilcoxon tests were performed on all significant results.

Results

All participants completed a baseline demographic and health history questionnaire that included age, sex, race, health history. Anthropometric measures included height, weight, and body mass index. Participants' mean ratings in the standardized testing protocol at T0 (prior to intervention) and T1 (following the intervention). The expert operators that performed the testing sessions were not blinded to the treatment. No adverse effects of training were reported.

Table 3 presents the characteristics of the total sample and separately for adapted physical activity program. The study included 46 patient of 58 (19 man and 27 women, 60,5±1,3 yrs) : Multiple Sclerosis (16 pz, 6 men - 10 women); Emiplegia by Stroke (10 pz, 4 men-6 women); Parkinson Disease (20pz, 9 men-11women); 12 of the 58 patients not assessed for eligibility into the study.

Table 3. Participant characteristics and admission to APA program and APA-D program at T0 level.

Variables		All	APA	APA-D
age, years, mean (SD)		60.5 ±1,3		
male/female, n		19/27		
MS, n		16		
PD, n		20		
Stroke, n		10		
quality life	FIM	101,3	96	106,6
	HANDS_a	8,73	9,17	8,3
	HANS_b	8,54	9,17	7,91
	Euro_Qol	53,91	52,6	55,21
Balance	TINETTI	17,15	15,82	18,47
	BERG	33,52	28,56	38,47
	TUG	32,97	30,78	35,17
	COP	268,18	267,71	267,71
Walking	6MWT	174,1	164,86	183,34
	ciclo/passo	0,54	0,54	0,53

APA group

All of the patients were able to perform the program and testing session. The measures at 3 different moments during valuation action were showed in Table 4.

Primary outcome measures to reduce the risk of fall to improve the autonomy in the ADLs.— Considering the scale ranges, participants reported at both times (T1-T2) high well-being scores, especially in Balance variables: *Tinetti* score showed a significant improvement of risk of fear of falls after treatment, T0: 15,82, T1: 21,73; T2: 21; T0vsT1: 30,9%; T1vsT2: 3,2). The sum score of the 14 items of BBS indicated that the individuals had a higher risk of falling at T0 , but after treatment decrease the risk (*Berg*: T0: 28,56, T1: 39,95; T2: 37,73; T0vsT1: 30%; T1vsT2: 5,6). Also improves the execution time of the TUG (T0:30,78; T1:24,95;T2:25,95;T0vsT1: 18,3%; T1vsT2: 4,4). The *Cop* variable , while remaining in the pathological values, shows a slight improvement after treatment (T0:267,71; T1:102,96;T2:105,65;T0vsT1: 52,1%; T1vsT2: 3,9).

An improvement of meters was registered 6MWT, the data showed a significant contribution of physical performance (T0:164,86;m T1:196,95;T2:188,47;T0vsT1: 17,5%; T1vsT2: 4,4) but the Ciclo/passo variable was confirmed pathological values (T0: 0.54, T1: 0,74; T2: 0,68; T0vsT1: 25%; T1vsT2: 7,2). At T1, all participants showed significant improvements in their physical performance, the only statistical significant difference between T1 vs T0 was found on the risk of falls. Secondary outcome measures Quality of life.— the VAS score of EuroQol questionnaire showed an improve level (T0: 52,6, T1: 71,52; T2: 72,17; T0vsT1: 30,1%; T1vsT2: 3,6). Anxiety and depression dimensions showed a good trend in T1, while social well-being ratings were somewhat increase to T1 and follow-up at 6 mouth (HANDS_a: T0: 9,17, T1: 6,86; T2: 7,08; T0vsT1: 27,7%; T1vsT2: 6,6. HANDS_b: T0: 52,6, T1: 6,91; T2: 7,08; T0vsT1: 27,7%; T1vsT2: 6,6.) . One-way repeated ANOVAs were performed to compare scores at T0 and T1 for psychological variables.

Table 4. Participant characteristics and admission to APA program at T0 level

Scala	T0	T1	T2	T0_T1%	P	T1_T2%	
FIM	96	101,39	100,56	A 5,8	0,000	D 4	0,001
Tinetti	15,82	21,73	21	A 30,9	0,000	D 3,2	0,000
Berg	28,56	39,95	37,73	A 30	0,000	D 5,6	0,000
TUG	30,78	24,95	25,95	D 18,3	0,000	A 4,4	0,002
Cop	267,71	102,96	105,65	D 52,1	0,000	A 3,9	0,000
6MWT	164,86	196,95	188,47	A 17,5	0,000	D 4,4	0,000
Ciclo/passo	0,54	0,74	0,68	A 25	0,000	D 7,2	0,000
HADS-A	9,17	6,86	7,08	D 27,7	0,000	A 6,6	0,197
HADS-B	9,17	6,91	7,08	D 24,2	0,000	A 9	0,206
EuroQol	52,6	71,52	72,17	A 30,1	0,000	D 3,6	0,495

APA-D group

Primary outcome measures to reduce the risk of fall to improve the autonomy in the ADLs.— The risk of FOF , at both times (T1-T2) for the balance variables, registered an high score, especially in: *Tinetti* (T0: 18,47, T1: 22,17; T2: 21,04; T0vsT1: 17,3%; T1vsT2: 5,3), BBS (*Berg*: T0: 38,47, T1: 46,69; T2: 44,65; T0vsT1: 18,2%; T1vsT2: 4,4) and for time of TUG (T0:35,17; T1:29,78;T2:30,65;T0vsT1: 14,4%; T1vsT2: 4). The *Cop* variable , while remaining in the pathological values, shows a slight improvement after treatment (T0:267,71; T1:102,96; T2:105,65; T0vsT1: 52,1%; T1vsT2: 3,9). Data showed (Tab. 5) a significant contribution of physical performance with improvement of meters in 6MWT in T1 and also at 6 month follow-up (T0:183, 34m , T1:229,34;T2:226,73) An improvement level was registered for Ciclo/passo (T0: 0.54, T1: 0,74; T2: 0,68; T0vsT1: 25%; T1vsT2: 7,2). Secondary outcome measures Quality of life.— EroQol VASscore questionnaire showed an improve level in (T0: 52,6, T1: 71,52; T2: 72,17; T0vsT1: 30,1%; T1vsT2: 3,6). Anxiety and depression dimensions showed no pathological trend in T1 and at 6 month follow up (HADS_a: T1: 7,04; T2: 7,21; HADS_b: T1: 6,56; T2: 6,91).

Table 5. Participant characteristics and admission to APA-D program

Scala	T0	T1	T2	T0_T1%	P	T1_T2%	p
FIM	106,6	110,56	108,73	A 3,6	0,000	D 1,7	0,000
Tinetti	18,47	22,17	21,04	A 17,3	0,000	D 5,3	0,000
Berg	38,47	46,69	44,65	A 18,2	0,000	D 4,4	0,000
TUG	35,17	29,78	30,65	D 14,4	0,000	A 4	0,002
Cop	267,71	102,96	105,6	D 48,8	0,000	A 3,9	0,000
6MWT	183,34	229,34	226,73	A 22,1	0,000	D 4,6	0,480
Ciclo/passo	0,53	0,70	0,65	A 24,7	0,000	D 7,6	0,000
HADS-A	8,3	7,04	7,21	D 12,7	0,000	A 3,9	0,248
HADS-B	7,91	6,56	6,91	D 31	0,001	A 21,3	0,065
EuroQol	55,21	76,73	73,69	A 35,1	0,000	D 6,2	0,042

Discussion

The aim of the present study was to reduce the risk of falling to improve autonomy in the ADL and global health status by comparing the effectiveness of two specific physical activity programs in patients with neurological disabilities. The main finding of this study show that the exercise program APA-D, consisting of adapted physical activities performed with devices, such as sensorized treadmill and Balance board platform, was more efficient in patients with neurological disability. Both groups, in the T1 phase, showed an increase level of performance and health status, though the APA_D group presented a more pronounced decrease in the risk of fear of fall for balance variable (T0_T1 %: Tinetti: 30%; Berg: 30%; Tug: 18,3%; Cop: 52,1%). Both groups increased 6MWT in the T1 phase. Technology has reached a sophisticated level with the recent and ongoing development of wearable devices that are specifically able to assess gait and balance deficits, that are common in neurological patients (Vienne, Barrois, Buffat, Ricard & Vidal,2017; Maetzler, Klucken & Horne,

2016). As these devices are very expensive, the present study shows that using less expensive tools it is possible to create a physical activity program adapted to patients suffering from Parkinson's disease, multiple sclerosis and stroke, achieving good results.

The evaluation of neurological deficits is often based on qualitative parameters collected by treating physicians and by rehabilitation professionals or with semi-quantitative scoring instruments. Scientific evidence shows that an adequate exercise program can improve these deficits (Ahlskog, 2011; Alonso-Frech, Sanahuja & Rodriguez, 2011; Earhart & Falvo, 2013; Frazzitta, 2013; Konerth & Childers, 2013). A 2010 Cochrane Review (Mehrholz et al., 2010) assessed the importance of treadmill training. The analysis included eight studies involving 203 participants. It has been found that treadmill training increases walking speed, walking pace and walking distance. There is a great uncertainty about how gait and gait quality are linked to the stability and fall . While there is evidence to suggest that the slowing of age-related gait is an independent predictor of falls, others interpret the slowing of gait as an adaptive mechanism to prevent slips and falls, which in turn would reduce the risk of falls (Quach et al., 2011: van Schooten et al., 2016). The present study can help clarify these problems by increasing the specificity of balance prediction from a performance that is quantified by measure of the walking speed on treadmill. Taken together, these results showed that people with ND use conservative strategy during the APA_D program to compensate for postural instability. Surprisingly, there were few significant alterations observed in the APA group at 6 months follow up on the balance variables and risk of fear of fall. We have hypothesized that the traditional physical activity program extend the benefits of physical performance obtained with the APA program.

A meta-analysis from 2010 comprising 40 studies concludes that physical training reduces symptoms of anxiety in people with chronic illnesses, including cardiovascular disease, fibromyalgia, multiple sclerosis, mental disorders, cancer, and chronic obstructive pulmonary disease (Herring, O'Connor & Dishman, 2010). Secondary outcome measures of the Quality of life and Anxiety/depression dimensions showed an improve level for both groups, also at 6 month follow up. Physical activity represents a cornerstone in the primary prevention of at least 35 chronic conditions. However, over the past two decades, considerable knowledge has accumulated concerning the significance of exercise as the first-line treatment of several chronic diseases.

Conclusions

Today exercise is considered like a "drug" also in the diseases that do not primarily manifest with disorders of the locomotive apparatus (Booth, Roberts & Laye, 2012). Our results demonstrate fall risks relationship with "functional tests" currently used to measure dynamic balance, and its accuracy in predicting falls in neurologic subjects. There are some limitations of the present study that must be recognized when interpreting the results. To the best of our knowledge, this is one of the few cross-sectional studies in a clinical setting that covers a comparable composition of neurological diseases with the most common comorbidities. Our overall cohort does not represent a wide range and a representative number of patients.

Conflicts of interest - The authors haven't any conflicts of interest to declare.

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