European Journal of Physical and Rehabilitation Medicine 2017 December;53(6):825-32
DOI: 10.23736/S1973-9087.17.04647-0

ORIGINAL ARTICLE

Effectiveness of aquatic therapy for the control of pain and increased functionality in people with Parkinson's disease: a randomized clinical trial

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ABSTRACT

BACKGROUND: Gait, balance disorders and pain associated with Parkinson's disease represent important therapeutic challenges, as they are related with an increased risk of falls, together with disability and physical decline.
AIM: To compare the effects of an aquatic ai chi training program on the perception of pain, the maintenance of balance and the functional independence of patients with Parkinson's disease.
DESIGN: A single-blind randomized controlled trial.
SETTING: Parkinson's associations and municipal pools.
POPULATION: Thirty individuals from two Parkinson's associations in Spain participated in the study. Inclusion criteria: individuals diagnosed with Parkinson's disease in stages 1 to 3 (Hoehn and Yahr Scale), older than 40 years, in the off phase (not medicated) and with a score greater or equal to 24 on the Mini-Mental State Examination Scale, without any medical contraindications and who accepted the study norms.
METHODS: The experimental group (N.=15 patients) participated in a program of aquatic ai chi. The control group (N.=15) received therapy on dry land. The intervention lasted 10 weeks with sessions held twice weekly. The pain VAS, Tinetti, Berg, Test Get Up and Go, Five Times Test and Unified Parkinson's Disease Rating Scale were used.
RESULTS: Significant differences were found between the baseline and one-month follow up assessments in pain perception values ($F=26.89$, $P<0.001$), and the Tinetti Test ($F=21.57$, $P<0.001$) in the experimental group compared to the control group ($P<0.05$) with the exception of the FTSTS ($P=0.006$). In the control group, improvements were only seen on the VAS Pain Scale ($F=8.3$, $P=0.004$) and these were less significant than the changes found in the experimental group. Regarding the scores obtained on the UPDRS scale in the experimental group, there were significant differences in activities of daily living and motor examination, with the exception of mentation, behavior and mood.
CONCLUSIONS: An aquatic ai chi program appears to be a valid treatment option for patients diagnosed with mild to moderate Parkinson's disease for the treatment of pain, balance and functional capacity.
CLINICAL REHABILITATION IMPACT: Physical exercise performed in water has positive effects on some of the necessary elements that contribute towards improved biomechanical gait patterns in our patients with Parkinson's disease.

(*Cite this article as:* Pérez de la Cruz S. Effectiveness of aquatic therapy for the control of pain and increased functionality in people with Parkinson's disease: a randomized clinical trial. Eur J Phys Rehabil Med 2017;53:825-32. DOI: 10.23736/S1973-9087.17.04647-0)

Key words: Postural balance - Parkinson disease - Pain - Rehabilitation - Exercise.

The gait and balance disorders associated with Parkinson's disease represent important therapeutic challenges,[1] as they are related with an increased risk of falls, together with disability and physical decline.[2] Pain constitutes another disabling symptom of Parkinson's disease, and one that frequently goes unnoticed in clinical practice.[3] It is known that early stages of the disease are frequently accompanied by back and neck pain, which can be a result of the rigidity of the shoulder girdle; as well as leg pain, due to restless leg syndrome or dystonias.[2] In the advanced stages of the disease, pain can be caused by dyskinesia, akathisia, off-period dystonia (40%) and musculoskeletal, joint or radicular pain (20%).[4]

Some researchers have suggested that the neuroprotective effects of exercise may decrease the risk of developing Parkinson's disease, as well as slow down the progression of the neurodegeneration.[3] Despite the increasing attention given to therapeutic exercise for Parkinson's disease, few practical guidelines have been developed regarding its clinical application.[5] Several types of exercises are currently recommended, including tai chi, yoga and pilates, among others.[6]

Hydrotherapy has proven to be effective for different gait rehabilitation programs however, there is little available information on the effect of physical exercise performed in water.[7]

Ai chi consists of a series of aquatic exercises created by Jun Konno in Japan in 1996, based on the combination of tai-chi and qi qong concepts. During ai chi sessions, an instructor verbally and visually teaches a combination of movements involving the upper and lower limbs and the trunk in a slow and coordinated rhythm. Participants practice these movements while standing in shoulder-depth water. Since its development, specific therapeutic applications of the technique have arisen, leading to the introduction of the term clinical ai chi.[7]

The purpose of this study was threefold 1) to apply two different physiotherapy protocols (dry land treatment and Ai Chi aquatic therapy) in order to test the effect of these on lower limbs pain, balance and quality of life in patients with Parkinson's disease; 2) to evaluate the effectiveness of these programs on the clinical symptoms of the disease; and 3) to develop a methodological proposal, based on the results obtained.

Materials and methods

Study design

This randomized controlled trial followed a prospective design as we sought to study the effect of a type of therapy (aquatic ai chi) on a population of patients with Parkinson's and therefore we followed the participants' evolution from baseline, to post-intervention and until a one month follow-up.

Recruitment

Thirty individuals diagnosed with Parkinson's disease from two Parkinson's associations in Spain, participated in the study. They received treatment on dry land or aquatic ai chi sessions in water.

Fifteen of these (6 men and 9 women, with a mean age of 67.53 years and SD±9.89) were randomly assigned to an intervention group (aquatic ai chi) and 15 participants (7 men and 8 women, with a mean age of 66.80 years and SD ±5.267) received treatment on dry land.

All study participants met the following inclusion criteria: individuals diagnosed with Parkinson's disease in stages 1 to 3 (Hoehn and Yahr Scale) [8] while in the OFF-medication phase (in absence of the effects of medication), older than 40 years, receiving stable dopaminergic therapy over the previous four weeks and with a score greater or equal to 24 on the Mini-Mental State Examination Scale,[9] without any medical contraindications and who accepted the study norms (regular assistance to the treatment sessions and active participation). The exclusion criteria were: individuals who did not comply with the abovementioned criteria, and the presence of articular and/or muscular lesions in the lower limbs affecting independent gait.

Allocation procedures

The randomization procedure was performed for the overall sample using stratified randomization controlling for the Hoehn & Yahr stage,[8] employing Excel software (Microsoft Excel 2013: Microsoft Corp. Redmond WA) (Figure 1).

Ethical procedures

The procedures were performed according to the Declaration of Helsinki, and approved by the Committee of Bioethics of the main author's institution (Spain). The participants signed informed consent forms prior to participation in the study. This trial was registered at ClinicalTrials.gov on November 2, 2016 (pending registration number confirmation).

Assessment procedures

The participants received an initial assessment on dry land lasting 30-45 minutes, performed by a physiotherapist not involved in the study. Evaluations were performed OFF-dose, after withholding medication for 12 hours.

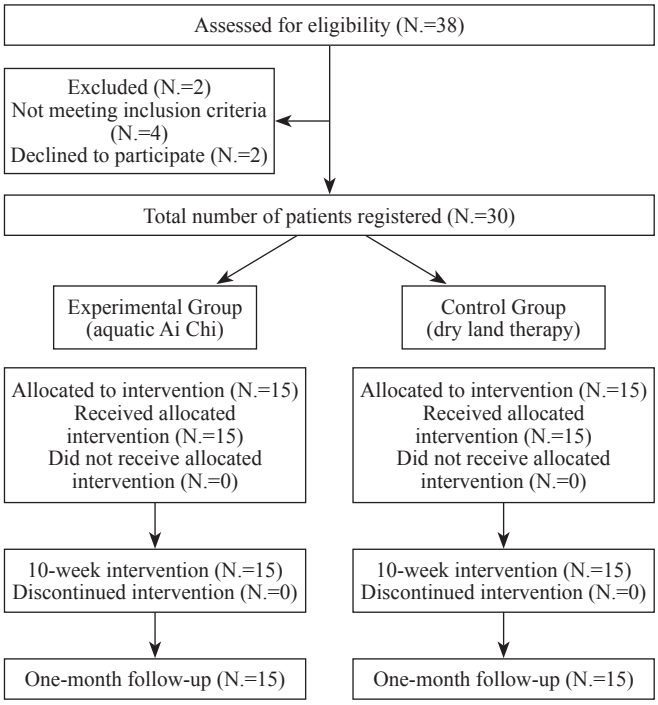

Figure 1.—Study flow diagram.

Timetable norms were disclosed as well as recommendations regarding appropriate clothing for the activity. A baseline assessment was performed prior to commencing therapy. This was repeated upon completion of all sessions while a follow-up assessment took place one month later. The physiotherapist who evaluated the patients was external to the study and blinded to the intervention received by the study participants.

Measures

Three assessments were analyzed in each group (baseline, post-treatment and one-month follow-up). The Visual Analog Scale (VAS) for pain was used [10] as the main study outcome. Pain assessments were performed based on a score (0-10) that the participants assigned to their own pain.

The use of the Berg Balance Scale (BBS) for the assessment of functional capacity is recommended in patients with Parkinson's who are at the initial and intermediate stages of the illness, as this scale produces a single score that is easily interpreted.[11] The Tinetti Scale [12] and Five Times Sit-to-Stand Test (FTSTS) [13]

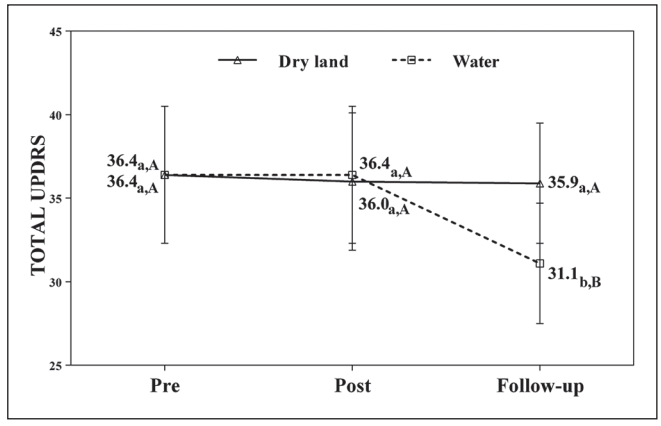

Figure 2.—Group interaction and time outcome variables.
a-b: Different lowercase letters indicate statistically significant differences between time points in the same group (Bonferroni correction); A-B: different letters indicate statistically significant case differences between groups at the same time point (Bonferroni correction).

are useful tools for the detection of disorders affecting gait and balance. A lower score on both scales equals a greater risk of falling or the suspicion of underlying pathology affecting balance and gait.[11]

We also timed how long the subject took to stand up from a chair, walk at their preferred speed for a 3-meter distance, turn, return to the chair and sit down again.[14] The Timed Get up and Go test (TGUGT) has been developed for evaluating the basic functional mobility and the walking ability (dynamic balance) of elderly subjects.

The unified scale for the assessment of Parkinson's disease was also used (UPDRS), which consists of 4 sections: 1) mental status; 2) activities of daily living; 3) motor aspects; 4) complications. Studies to date indicate that, in order to evaluate the progression of Parkinson's disease and the success of therapy, the UPDRS is a reference tool, as well as being a sensitive scale regarding therapeutic interventions (Figure 2).[15]

Interventions

DRY LAND THERAPY

The participants assigned to the dry land therapy group (control group) received 20 twice-weekly sessions in total, over a period of 10 weeks. All the participants within this group participated in all sessions. These sessions consisted of group sessions of supervised training lasting 45 minutes each, performed at

the gym of each of the participating centers (Parkinson Associations). These comprised a 10-minute warm-up that included exercises for gait, trunk mobility and exercises involving the upper and lower limbs. The central part of the sessions consisted of 25 minutes of strength training and aerobic exercises, both individual and in groups. Each session was performed with a specific intensity goal, in order to end with a cooling down period, comprising 10 minutes of functional exercises based on activities of daily living, balance exercises, facial muscle exercises, proprioceptive exercises, muscle relaxation and stretching. During each session, emphasis was placed on training the trunk and lower limbs with the goal of improving the overall posture. The training incorporated predominantly standing poses and a floor and balance series, thereafter more advanced poses and transitions were incorporated into the training.

Aquatic ai chi

The 15 patients assigned to the aquatic therapy group (experimental group) received 20 twice-weekly sessions in total, during the same period as the control group. These 20 sessions were performed in municipal pools and consisted of group sessions lasting 45-minutes. The intervention was performed by an expert physiotherapist trained in clinical Ai Chi, with seven years' experience who was not involved in the study.

The sessions took place in a pool measuring 25x6 m, at a depth of 110-145 cm. The water temperature was 30 °C (with variations of less than 1.5°) and the room temperature was 27.5 °C (with variations of less than 1.5°). The proportions of the pool were ideally suited for collective treatment.

The sessions were designed with a gradual increase in difficulty. Initially, a recreational warm-up activity was performed, followed by 35 minutes dedicated to practicing the Ai Chi Program.[7] At the end of the session there was a calming down activity. The exercises were performed in a specific order, until completion of the 19 possible movements (in which exercises with trunk rotation, standing balance, single-legged balance were performed, all of which were repeated with an emphasis on functional reaching tests in protected conditions, teaching patients how to activate postural responses to external perturbations).

Statistical analysis

The statistical analysis was performed by an external expert. The means and standard deviations were calculated to define the characteristics of the sample under study. The normality of the sample was proven via the Kolmogorov-Smirnov Test. The U Mann-Whitney Test for independent samples was used to perform a comparison between patients from each group, and to prove that the protocols for aquatic therapy and dry land treatment had different effects. Power calculation analyses (G-power) indicated that a sample size of 15 participants per group was required to detect an effect size of Cohen's d=0.56 for reduction in the UPDRS motor score (5 points decrease) in the exercise group compared with the control group (power=0.8, alpha=0.05, correlation with covariate=0.05). The sample size calculation allowed a 10% drop-out rate.

Three assessments were analyzed in each group (baseline, post-treatment and one-month follow-up). To analyze the effect of each therapy, the Wilcoxon, Friedman or t-Student Test for related samples was performed, according to each case.

The statistical analysis was performed using the statistical program SPSS v.23. Normality of the data was verified, and therefore parametric statistics were used.

Results

The final sample comprised 30 participants with Parkinson's disease, of whom 13 subjects were men (43.3%), and 16 were women (53.33%). Table I displays the socio-demographic characteristics of the population under study, and the characteristics of each group.

All participants completed all sessions, and adherence of the proposed program was achieved. No adverse events were found related to the intervention. It is important to note that all medications were kept unchanged during the observation period. A series of changes were observed in the variables under study (Table II) upon completion of the program. In the experimental group, significant differences were found in the pain variables post treatment (P<0.001), as well as the variables related to static and dynamic balance, with the exception of the FTSTS, in which no differences were found between the assessments performed at baseline, post-treatment and at the one-month follow-up (P=0.001). In the control group, improvements were

TABLE I.—*Sociodemographic characteristics of the study population.*

Variables	Experimental group			Control group		
	Mean	SD	Min-max	Mean	SD	Min-max
Age	66.80	5.267	59-79	67.53	9.89	52-80
Height (cm)	163.87	7.633	150-178	167.2	17.67	153-177
Weight	68.33	10.533	52-89	70.57	13.18	54-100
Body Mass Index	25.32	2.333	22-30	26.22	3.101	22-33
Diagnosis (years)	6.2	2.541	2-11	6.7	3.225	2-13
Hoehn & Yahr Scale	2.82	0.22	2-3	2.66	1.02	2-3
UPDRS	36.4	16.53	18-69	36.40	15.16	20-68

TABLE II.—*Comparisons VAS. BERG. Five times test and Test Get up and Go scales.*

Variables	Measure Mean (SD)			Intra-subject effects †	
	Pre	Post	Post-2	Time F(d.f.); P value (eta²)	Treatment*time F(d.f.); P value (eta²)
VAS				F (1.3;37.2)=25.98; P<0.001 (0.487)	F (1.3;36.86)=8.7; P=0.005 (0.233)
Dry (N.=15)	5.8 (1.2)	5.3 (1.0)	5.5 (1.2)		
Aquatic (N.=15)	5.5 (1.8)	4.1 (1.3)	4.0 (0.8)		
Total	5.6 (1.5)	4.7 (1.1)	4.7 (1.0)		
BERG				F (1.3;37.4)=19.62; P<0.001 (0.412)	F (1.3;37.41)=19.6; P<0.001 (0.412)
Dry (N.=15)	39.4 (8.8)	39.4 (8.8)	39.4 (8.8)		
Aquatic (N.=15)	40.0 (9.6)	44.1 (7.5)	47.9 (4.8)		
Total	39.7 (9.1)	41.8 (8.4)	43.6 (8.2)		
FTSTS				F (1.8;49.9)=8.15; P=0.001 (0.225)	F (1.8;49.94)=6.0; P=0.006 (0.177)
Dry (N.=15)	18.3 (5.1)	18.2 (4.5)	18.0 (4.3)		
Aquatic (N.=15)	17.7 (5.9)	16.0 (5.8)	14.1 (3.7)		
Total	18.0 (5.4)	17.1 (5.2)	16.0 (4.4)		
TGUG				F(1.7;47.6)=11.70; P<0.001 (0.295)	F(1.7;47.59)=11.7; P<0.001 (0.295)
Dry (N.=15)	11.5 (2.7)	11.5 (2.6)	11.5 (2.7)		
Aquatic (N.=15)	11.6 (2.8)	9.1 (3.3)	8.8 (2.5)		
Total	11.5 (2.7)	10.3 (2.9)	10.1 (2.6)		

df: degrees of freedom. Eta²: partial eta squared (Effect size). † Greenhouse-Geisser estimate.
VAS: Visual Analog Scale; BERG: Berg Balance Scale; FTSTS: Five Times Sit-To-Stand; TGUG: Timed Get Up and Go.

only seen on the VAS pain scale, and these were less significant than the changes found in the experimental group (P=0.006).

In the experimental group, the significant changes registered during the post-treatment assessment were maintained one month after finishing the program. The absolute values of the Tinetti Test did not reveal differences compared to the results obtained post-treatment. However, significant differences were found between the baseline and one-month follow-up assessments (F 21.57, P<0.001)

Table III displays the scores obtained on the UPDRS Scale, for each of the sections on the scale, as well as the total score. In the experimental group, there were significant differences in almost all the sections under study (section one: mentation, behavior and mood; section two: activities of daily living; section three: motor examination), with the exception of section four: complications of therapy. When analyzing the global results of the scale, the experimental group demonstrated statistically significant differences post-treatment, compared with those obtained in the control group, in which no improvement was found.

Discussion

Physical exercise has the potential of helping Parkinson's disease patients on a motor level (gait, balance, strength) and on a non-motor level (depression, apathy, fatigue, constipation) and may help reduce the complications associated with immobility (*i.e.* cardiovascular complications and osteoporosis).[16] This study is main-

TABLE III.—*Results for the Unified Scale for the Assessment of Parkinson's disease (UPDRS) and Tinetti Scale.*

Variables	Measure Mean (SD)			Intra-subject effects †	
	Pre	Post	Post-2	Time F (d.f.); P value (eta²)	Treatment*time F (d.f.); P value (eta²)
TINETTI				F (1.3;37.5)=12.81; P<0.001 (0.314)	F (1.3;37.45)=20.1; P<0.001 (0.418)
Dry (N.=15)	19.3 (6.6)	19.0 (6.4)	19.0 (6.0)		
Aquatic (N.=15)	19.1 (6.2)	21.7 (5.8)	22.1 (5.4)		
Total	19.2 (6.4)	20.3 (6.1)	20,5 (5.7)		
UPDRS I				F (1.1;25.3)=28.82; P<0.001 (0.368)	F (1.1;24.7)=23.27; P<0.001 (0.389)
Dry (N.=15)	4.27 (2.8)	4.07(2.3)	4.07 (2.3)		
Aquatic (N.=5)	4.13 (2.7)	4.13 (2.7)	4.13 (2.7)		
Total	4.2 (2.7)	4.1 (2.5)	4.1 (2.5)		
UPDRS II				F (1.2;27.7)=27.85; P<0.001 (0.097)	F (1.1;27.68)=22.2; P<0.001 (0.347)
Dry (N.=15)	13.20 (5.8)	13.07 (5.7)	13.07 (5.7)		
Aquatic (N.=15)	13.33 (6.1)	13.33 (6.1)	13.33 (6.1)		
Total	13.26 (5.9)	13.20 (5.9)	13.20 (5.9)		
UPDRS III				F (1.1;29.6)=29.11; P<0.001 (0.097)	F (1.1;29.29)=23.1; P<0.001 (0.354)
Dry (N.=15)	15.13 (7.1)	15.07 (7.1)	15.07 (7.1)		
Aquatic (N.=15)	15.33 (7.5)	15.33 (7.5)	15.33 (7.5)		
Total	15.23 (7.3)	15.20 (7.3)	15.20 (7.3)		
UPDRS IV				F (1.0;27.9)=28.58; P=0.001 (0.368)	F (1.0;27.86)=21.7; P=0.001 (0.453)
Dry (N.=15)	3.80 (2.1)	3.80 (2.1)	3.80 (2.1)		
Aquatic (N.=15)	3.47 (2.4)	3.47 (2.4)	3.47 (2.4)		
Total	3.63 (2.2)	3.63 (2.2)	3.63 (2.2)		
UPDRS total				F(1.1;29.9)=29.85; P<0.001 (0.516)	F(1.1;29.86)=23.2; P<0.001 (0.453)
Dry (N.=15)	36.4 (15.2)	36.0 (14.9)	35.9 (14.5)		
Aquatic (N.=15)	36.4 (16.5)	36.4 (16.5)	31.1 (13.1)		
Total	36.4 (15.6)	36.2 (15.4)	33.5 (13.8)		

d.f.: degrees of freedom. Eta²: partial eta squared (Effect size). † Greenhouse-Geisser estimate.
UPDRS: Unified Scale for the Assessment of Parkinson's Disease.

ly centered on determining whether exercise in water maximizes the reported benefits obtained on dry land.

Pain is a very common symptom in Parkinson's disease, which is associated with depression, and can lead to a reduced quality of life as well as decreased patient autonomy. Indeed, previous studies have demonstrated that these factors may predict poorer results on the pain scales.[17, 18] Chronic pain can have a distracting effect on the individual, interfering with the cognitive processes necessary for fall prevention. Tinetti *et al.*[19] and Stubbs *et al.*[18] point to an association between pain and falls. A lower score on the VAS pain scale is a meaningful outcome, as it is related with a lower risk of falls (lower pain scores are related to improved balance and fewer falls),[20] which is in line with our findings regarding improvements in pain and balance post-intervention. Micke *et al.*[21] discovered that the prevalence of foot pain was significantly higher in elderly people who suffer from higher fall rates, which is similar to the results reported in the meta-analysis by Stubbs *et al.*[18] and Mickle *et al.*,[21] in which feet and chronic pain were presented as two very important risk factors worth considering during the assessments performed by health professionals.

Furthermore, the mean VAS baseline scores registered by the participants of this study coincide with the values reported in other studies performed in Spain. However, it is important to stress that the difference we found between the initial and end score was 1.5 points, on average. This difference is not so evident when compared to reports from other studies, bearing in mind that, for a clinical effect to be relevant, there needs to be a change of 2 or 3 points.[18] We cannot affirm that the decrease in reported pain corresponds to a decrease in pain at the level of the lower limbs or whether it represents a decrease in pain located elsewhere, or even a general perception of reduced pain affecting the whole body. Another scale revealed poor results in the lower limb strength assessments (in our case, the FTSTS), which has been strongly related with a risk for falling. This was demonstrated by Cugusi *et al.* and Ayán and Cancela [21, 22] in their study

performed with patients similar to ours, albeit with a smaller sample, in which they concluded that an improvement in the lower limb strength values was related to a decrease in the number of falls, and, therefore, to improvements in motricity and quality of life.

Both protocols were based on a series of common clinical approaches and techniques, mainly emphasizing work on trunk mobility, with rotations, movement in different planes, displacements of the center of gravity far from the base of support, vertical control, and balance exercises targeted towards improving performance during daily activities. Trunk mobility plays a very important role in postural adjustment and normal postural activity during functional activities such as turning in bed, getting up from a chair or leaning forward. Other authors have corroborated these findings.[21]

A systematic review on the influence of aquatic therapy on the mobility of individuals with neurological illnesses, including Parkinson's found that aquatic therapy improves the dynamic balance and gait speed of these individuals.[23] Other studies [23-25] have shown significant improvements in postural stability and fewer falls in patients with neurological disorders such as multiple sclerosis, among others, performing aquatic therapy programs, compared to patients who performed therapy on dry land. The positive results obtained in the experimental group suggest that an aquatic therapy intervention using Ai Chi is appropriate for the improvement of balance and gait in patients with Parkinson's disease.

Water is an ideal therapeutic environment for achieving these objectives. One of the possible reasons for the superior results in water could be related to water temperature, as warm water can have a therapeutic effect on rigidity. Several studies confirm that Parkinsonian rigidity, which has a central origin, is alleviated with a peripheral stimulus, such as heat.[26]

The aquatic ai chi therapy intervention resulted in a decrease in the postintervention values of the UPDRS scale, and these positive results were maintained one month after the completion of treatment. The combination of sections two (activities of daily living) and three (motor examination) of this scale correspond to 73% of the total score. Therefore, despite only assessing the total score, it is likely that the changes found are mainly due to improvements in these two sections. A different result was reported in the study by Amano *et al.*, who failed to find differences when applying a therapy similar to ai chi to patients with Parkinson's disease, albeit on dry land.[27] These contrasting results highlight the influence that the therapeutic environment has on the individual, which, in the case of this study, corresponds to water-based therapy. In patients who are similar to our sample, the decrease in dystonia and dyskinesia found in UPDRS part IV, may correlate with a reduction in pain and improvement in gait, as confirmed in the assessment taken post-therapy and at the one month follow-up.

The positive changes in motricity after a program of clinical ai chi in water are related to the performance of tasks that require a rhythmic pattern and constant postural adjustments, and which involve a learning effect. In this sense, the advantages of physical exercise in water include the possibility of performing a greater variety of movements, with greater ease and low impact, due to the hydrostatic pressure and flotation, all within an environment that is leisurely and pleasant. Furthermore, it is an ideal environment for working in groups, which may have had a positive effect by enhancing motivation and compliance.

The results of this study indicate that a program of aquatic ai chi performed twice a week, during ten weeks may be a possible treatment for pain and balance dysfunction in Parkinsonian patients in a moderate stage of disease, with the potential to improve postural stability, reduce fall rates and improve quality of life, as well as reducing pain and disabling symptoms.

Limitations of the study

There were several limitations related with the design of this study, mainly due to the reduced sample size, which may exaggerate the magnitude of the effects reported, and therefore does not provide certainty. The relatively short follow-up is a further limitation and would be important to consider in future designs. Furthermore, these effects are only applicable to patients of similar characteristics to those of our sample. Therefore, future studies involving larger sample size are needed to investigate the effect in this area.

Conclusions

Based on all the above, our results indicate that physical exercise performed in water has positive effects on

some of the necessary elements that contribute towards improved biomechanical gait patterns in our patients with Parkinson's disease. This is therefore a rehabilitation option that is worth consideration by neurologists and health professionals working in the field of neurorehabilitation, as long as the necessary resources for its implementation are available. Future randomized controlled studies with greater samples are required to confirm these findings.

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

Acknowledgments.—I would like to thank Antonio F. Bravo for his guidance regarding the statistical analysis for this study. Thanks also to AIS and JJG for their help conducting the study intervention, and to both collaborating associations for their support. Finally, a special note of thanks to Isabel Quintero for her assistance with the write-up and translation of this paper.

Article first published online: June 19, 2017. - Manuscript accepted: June 15, 2017. - Manuscript revised: May 29, 2017. - Manuscript received: January 14, 2017.