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Applicability of the Minimal Clinically Important Difference in the activities of daily living, motor sections, and quality of life in individuals with Parkinson's disease after aquatic physical therapy intervention: a pilot study

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Abstract

Introduction. Define the applicability of the Minimal Clinically Important Difference (MCID) in the activities of daily living (ADLs), motor sections, and quality of life (QOL) in people with Parkinson's disease (PD) after an aquatic physical therapy (APT) intervention.

Methods. A total of 11 individuals participated in this pilot study. They were of both genders, mean age 70.73 ± 10.67 years, diagnosed with idiopathic PD, and classified in stages 1 to 4 on the Hoehn & Yahr scale. The volunteers were assessed, before and after the APT intervention, with the Unified Parkinson's Disease Rating Scale (UPDRS), sections II (ADLs) and III (motor sections), in addition to Parkinson's Disease Questionnaire-39 (PDQ-39) (QOL). The APT comprises multicomponent exercises developed throughout a 12-week period, in twice-a-week 40-minute sessions. The data were analysed with the Wilcoxon test and MCID values described in the literature.

Results. There were no statistically significant changes in the results found ($p > 0.05$), but they neared the MCID values in both scales.

Conclusions. Different forms to analyse a study are necessary to elucidate the applicability of MCID values in detecting an improvement or worsening in the clinical condition of people with PD.

Key words: Parkinson's disease, physical exercise, hydrotherapy, Minimal Clinically Important Difference

Introduction

Parkinson's disease (PD) is a chronic and neurodegenerative disorder that causes the loss of dopaminergic neurons in the substantia nigra. The aging process is intricately connected to this disease because such neurons are lost increasingly faster as the year's pass [1].

As a result, the cardinal signs of the disease appear, namely: bradykinesia, tremor at rest, muscle stiffness, and postural instability [2]. Some nonmotor symptoms – such as depression, sleep disorders, olfactory disorders, and constipation – may also be associated, being identified in both prodromal periods and PD diagnosis [3]. Although it is sometimes not associated with PD, these signs may have a considerable impact on these people's quality of life (QOL) [4]. Hence, PD-related complications can change their social interactions and will certainly affect their functioning and motor functions to perform the activities of daily living (ADLs) [5].

After a clinical diagnosis, the therapy involves pharmacological and/or surgical measures, as well as a multiprofessional approach [6] – neither of which alone is enough. Thus, physical therapy with physical/motor and functional stimulation of the person with PD seeks to promote health, prevent complications, and stimulate kinetic/functional recovery related to the signs and symptoms of the disease [7]. To this end, physical therapy uses functional physical exercises that work simultaneously on functioning and motor functions, aiming to make them more independent to perform the ADLs, with repercussions on the QOL [8].

One of the specialties in physical therapy is the aquatic physical therapy (APT), which unites the therapy's processes and procedures to the water's physical and thermal properties – in this case, in a heated pool used as an integrative and complementary therapeutic health resource [9]. Besides furnishing kinetic/functional recovery, the aquatic environment provides a strategy for diversified and safe therapy exercises. The individuals not only report being pleased with it but are also motivated to adhere to the therapy because of the positive factor of the work in small groups [10].

Nevertheless, the patients' adherence still poses a challenge to aquatic intervention in PD [11]. Hence, for samples with a smaller representation of the population, the statistical probability of the results of the study (traditionally used with p significance values) do not always reflect the participants' actual improvement [12].

Therefore, other methods have been employed to assess the results in studies with patients – one of which is the Minimal Clinically Important Difference (MCID) [13]. In order not to depend exclusively on statistically significant results, the MCID is an option capable of detecting the slightest positive or negative clinical change resulting from a treatment. It considers administered assessment instruments, generating

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a clear clinical impact on the patient and their relatives [12, 13]. The MCID has been already employed in studies that used other scales treatment methods [14, 15]. However, few studies use the MCID in the analysis of the results regarding the benefits of the APT for the signs and symptoms of PD.

Hence, this pilot study aimed to elucidate the applicability of the MCID values in the ADLs, motor sections, and QOL in people with PD after the APT intervention.

Subjects and methods

This pilot study is an integral part of a single blind (blind assessor) quantitative quasi-experimental research with a convenience sample [16]. The data collection (physical therapy assessments) and the intervention (APT) took place in a Public Rehabilitation Center with a heated pool in Curitiba, Paraná.

Participants

The individuals were recruited at the Association of People with Parkinson's disease from Paraná (APPP), after consented to participate in the study. The inclusion criteria were: people of both genders; with a clinical diagnosis of PD, classified in stages 1 to 4 on the Hoehn and Yahr scale (H&Y) [17]; with a medical certificate to practice an aquatic physical activity; capable of performing the preestablished tests; and being in the on-phase of the medication. The exclusion criteria encompassed having any other diagnosis that might interfere with the physical/functional assessments; any cognitive, visual, or auditory deficit that kept them from following the instructions; contraindications to the use of a heated pool; disagreeing with the informed consent form; and having their medication prescription changed during the time of this study.

Assessment instruments

The Unified Parkinson's Disease Rating Scale (UPDRS), section II, which addresses ADLs and comprises 13 items, was used as an interview, adopting 2-point MCID for participants without body balance deficit, and 3-point for those with a change in balance [13]. In addition, the UPDRS section III was used, which addresses motor sections and comprises 14 items with neurological assessments on both sides of the body, adopting the 5-point MCID [13]. The purpose of the scale is to quantify the seriousness of the symptoms of PD. Its score ranges from 0 (normal) to 4 (serious) – i.e., the maximum value indicates greater impairment by the disease, whereas the minimum indicates the least impairment [18].

The Parkinson's Disease Questionnaire 39 (PDQ-39) was also used, as it is specific for assessing the QOL in PD. It has 39 items with five possible answers each, namely: never; seldom; sometimes; often; always, or cannot do at all [1]. The scores in each item range from 0 (never) to 4 (always, or cannot do at all). The total score ranges from 0 to 100 – the highest scores referring to the greater difficulties [18]. The 4.72-point MCID was adopted [19].

Aquatic exercises program

The intervention lasted 12 weeks, with two 1-hour sessions a week. Each session consisted of 20 minutes to verify the vital signs before and after immersion, then 40 minutes in the pool, heated to approximately 33°C.

The APT program was based on the aquatic intervention phases proposed by Israel (2000). It involved different moments: accommodation (A), familiarization with the liquid environment (F), relaxation (R), specialized therapeutic exercises (E) – phase with the most specificity for the prescription and practice of multicomponent physical exercises – and global organic conditioning (Cd) [20].

Each APT session comprised: 1) gait training, walking forward, backward, and sideways, besides hopping and jogging (10 minutes); 2) lower limb strength and power training with flexion/extension and abduction/adduction movements of the hip, in progressive speed, series, and load, using aquafins (10 minutes); 3) balance training, walking to overcome obstacles, performing tandem gait, sagittal and transverse rotations, with increasingly unstable and difficult tasks (15 minutes); 4) relaxation with a sequence of three Ai Chi movements, which also increased in complexity (5 minutes).

Statistical analysis

The statistical analysis used the Shapiro-Wilk normality test, whereas the comparisons used the Wilcoxon nonparametric test. The MCID was also used to assess the results. For the analysis, the values before and after the intervention were subtracted from the mean of the UPDRS II and III and the PDQ-39, to compare this result with the reference values in the literature [13, 21].

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Ethics Committee of the Department of Health Sciences at the Federal University of Paraná, Curitiba, Brazil (approved No.: 66781417.4.0000.0102, certificate No.: 2.200.372). The study is stored in the Brazilian Clinical Trials Registry (No.: RBR-6hnqcv) and complies with Resolution 466/12 of the Brazilian National Health Council.

Informed consent

Informed consent has been obtained from the legal guardians of all individuals included in this study.

Results

The study sample included 11 participants of both genders, mean age 70.73 ± 10.67 years; there were seven males (64%) and four females (36%). As for the classification of the severity of PD, no participant had H&Y = 1; four people had H&Y = 2 (36.36%); three participants had H&Y = 3 (27.28%); and four had H&Y = 4 (36.36%).

In the assessment with the UPDRS, sections II (ADLs) and III (motor sections), the significance was of $p = 0.50$ and $p = 0.53$, respectively. In comparison with the MCID value, the participants achieved 1.00 in the mean of section II, with a 3-point MCID reference value for participants with H&Y = 2 or above [13]. Individually, five participants achieved the MCID for the ADLs (45.45%). In section III, there was a difference of 1.27 in the mean, with a 2.50-point MCID reference value [13]. Individually, only two (18.18%) achieved the MCID. Lastly, in the PDQ-39 scale, the statistical probability of difference was $p = 0.18$ and, in the comparison with the 4.72-point MCID reference value [21], the mean in the scale was 4.57 points. Five participants achieved the MCID for QOL (45.45%). The mean, standard deviation, and confidence interval values for all the sections are shown in Table 1.

Table 1. Results of the participants' UPDRS (ADLs and motor) and PDQ-39 (QOL)

Items assessed	UPDRS II (ADLs)		UPDRS III (motor sections)		PDQ-39 (QOL)	
	Before	After	Before	After	Before	After
Mean ± *SD*	14.18 ± 5.54	13.18 ± 4.55	15.27 ± 5.74	13.82 ± 5.65	26.24 ± 14.98	21.67 ± 7.95
95% confidence interval	10.45–17.90	10.12–16.24	11.41–19.13	10.02–17.61	16.17–36.31	16.33–27.02
Minimum–maximum	3.00–24.00	7.00–23.00	10.00–30.00	4.00–24.00	10.31–64.16	13.37–36.93
MCID result	1		1.45		4.57	
MCID reference	3		5		4.72	

UPDRS – Unified Parkinson's Disease Rating Scale, sections II and III (ADLs – activities of daily living),
PDQ-39 – Parkinson's Disease Questionnaire 39 (QOL – quality of life), MCID – minimal clinically important difference

Discussion

This study demonstrated that APT is safe for people with PD. However, in the ADLs, motor sections, and QOL assessments, there were no statistically significant changes in the comparison between the periods before and after the intervention ($p > 0.05$). On the other hand, regarding the MCID, five participants achieved the difference for clinical improvement in the ADLs, and two had clinical improvement for motor assessment [13]. Meanwhile, the QOL was relatively close to the reference value [21], with five participants surpassing the MCID.

As PD advances, motor performance decreases, potentially limiting the functional capacities. On the other hand, a positive repercussion on the motor signs is associated with these peoples' independence to perform the ADLs [21]. In this regard, this study showed a mean improvement of 7.05% in ADLs after the intervention and 9.5% in the motor outcome. Hence, to improve this aspect, it is indicated that the training be focused on functional activities that the person can perform in their everyday lives. Training day-to-day activities – which must be performed as intensely as possible according to each person's capacity – has a clinically relevant effect on the ADLs [22]. The APT program, with activities such as pivoting, pelvic and scapular girdle dissociation, sit to stand, and others, mimics everyday situations with increasing complexity and/or intensity as the person manages to perform the activity without difficulty.

The water has physical and thermal properties, such as hydrostatic pressure, resistance (viscosity, superficial tension, and turbulence), and buoyancy. Stimulating the ADLs in this aquatic environment contributes to performing activities and movements on land, enabling them to carry out the ADLs. Hence, the potential physical/functional gains trained in the aquatic environment can be transferred to the land environment as motor and functional skills [23].

The study by Yamaguchi et al. [7] aims to analyse the effects of an APT program on the functional motor skills of 11 individuals with PD, modified UPDRS, sections II and III after four months of twice-a-week sessions. This result portrays the need for the person with PD to remain physically active, as well as the benefits furnished to motor learning in the aquatic environment.

The study by Volpe et al. [24] presented significant benefits only in the UPDRS, section II after two months of hydrotherapic treatment, five times a week. In contrast, the study by Ayán and Cancela [25], after comparing two groups of aquatic exercises group and muscle resistance group, the results showed that the muscle resistance group had a significant positive change in the UPDRS section III means.

Interventions with multicomponent physical exercises envisage the possibility that more instigating aquatic physical exercises – at the muscular, balance, and gait level – provide neuromusculoskeletal adaptations with repercussions on the motor exploration of people with PD [25]. In the present study, the initial exercises progressed to exercises requiring more muscle strength and power, also increasing in complexity in the balance functional goals and agility in the gait exercises.

Physical exercise for people with PD probably relates to neuroplasticity and increased brain neurotrophic factors, such as the brain-derived neurotrophic factor (BDNF), improving cognition, protecting against dopaminergic neurotoxins, and increasing the grey matter, thus furnishing neuroprotection [26]. The scores on a chronic disease scale, such as PD, are influenced by its severity; hence, it is highly valuable to maintain or reduce such values by making them perform physical exercises and become more active [19]. Regarding this, other studies presented individuals in H&Y stages 1 to 3 [11, 25] or 2 to 3 [24, 27] – differently from this one, which had participants classified in stages 1 to 4 of the disease. This is particularly significant considering that participants in H&Y 4 have serious impairments and motor difficulties and need to participate in physical therapy intervention programs.

QOL is related to health. It is defined as the person's understanding of their disease and its impact on their lives, encompassing personal satisfaction in addition to physical, emotional, social, and functional well-being [28]. In the present study, the QOL improved by 17.42%, on average, after the APT. To improve the QOL in PD, either short or long high-intensity training is recommended [23]. Moreover, regular physical exercise in general, lasting more than 150 minutes a week, also improved the QOL [19].

Nevertheless, it should be kept in mind that social relationships and personal characteristics, such as sleep quality, psychological state and cognitive condition, can impact the perception of the QOL – with potentially different results according to one's personal satisfaction at the time of the assessment [29]. This can be one of the biases that explain the difficulty found by research in the aquatic environment in PD to improve the QOL.

The study by Carroll et al. [11], whose aim was to assess the effects of aquatic physical exercises on gait variability and incapacity in comparison with usual care, did not find a significant difference in the QOL of people with PD. The study by Villegas and Israel [27] aimed to assess the effect of the Ai Chi method on functioning, posture, and quality of life of people with PD, after 12 weeks of twice-a-week sessions. In it, the experimental group ($n = 8$ participants) did not present significant difference either, after aquatic intervention for QOL.

On the other hand, Kurt et al. [30] observed a significantly superior improvement in the QOL of the participants in their study's Ai Chi group when compared with the land exercise group. Such a factor can be justified by the higher training frequency, which took place five times a week. That is a relevant condition; however, it could hardly be achieved in Brazilian circumstances because of environmental factors, such as the participants' access to transportation and availability to take part in studies.

In this sense, it is noticeably necessary to go beyond the traditional quantitative analysis with statistical significance when assessing people with PD and other neurodegenerative diseases. Perspectives that include the magnitude of the therapeutic effects are a differential in a more encompassing analysis of such specific cases as the neurodegenerative diseases. In such cases, overcoming small motor challenges can improve the performance of everyday functional tasks and the QOL as PD progresses [13, 14].

A minimal change in treatment is important, whether perceived by the therapist or the patient. Thus, the MCID can demonstrate an improvement or even worsening of the patient's condition that is not noticeable in a statistical analysis. This reveals that, contrary to the binary view resulting from statistical significance, the proposed APT intervention tends to improve or stabilize its participants' motor condition. If more studies presented MCID values, it would be possible to observe its clinical relevance, or at least the tendency of the participants with progressive diseases to improve or worsen when practicing exercises. In both negative and positive cases, this could encourage people with PD to continue practicing physical exercises and eventually make them part of their lifestyle.

Limitation

Concerning limitations, this study had the sample size, already present in various aquatic environment studies. Nonetheless, using the MCID contributes to the analysis of smaller groups, enabling clinical improvement or worsening to be identified after a period of APT intervention. Including a control group that did not participate in the aquatic activities would also favour the comparisons. However, the assessments used in the study were validated for PD, with standardized procedures and an independent assessor.

Conclusions

This study has contributed to analyses with the MCID, making it possible to compare it with the reference values. Hence, improvement or worsening regarding the ADLs, motor exploration, and QOL was denoted in a group with PD who participated in an APT program. Thus, it was verified that using the MCID in the outcomes analysed was favourable to the clinical improvement of this study's participants. Such an improvement was verified despite the disease being progressive, and the statistical analysis not being sensitive enough to detect such changes.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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