RESEARCH ARTICLE

Does the Global Postural Re-Education Affect the Psychological and Postural Aspects of Alzheimer Disease Patients? A Six Months Quasi-Experimental Study

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Abstract: ***Objective*:** To study the implementation of Global Postural Re-education as a rehabilitative alternative in residence facilities for seniors with Alzheimer, and to verify its effect on psychological and cognitive symptoms.

***Methods*:** A quasi-experimental design was employed using month-follow-up assessments at 1,3, and 6 months respectively. Ninety elderly people participated in the composition of the study sample: 69 women and 21 men aged from 67 to 89 years (80.2 ±5.5), grouped in two phases: mild and moderate, according to Alzheimer severity. Patients in both groups received the same treatment twice a week for consecutively 24 weeks. Three follow-up medium-long term assessments were performed at intervals of 1, 3, and 6 months. Outcome measures included Mini-Mental State Examination, Geriatric Depression Scale, Quality of Life in Alzheimer Disease, Barthel Index, and Tinetti Scale.

***Results*:** The severity of groups therapy interaction showed significant changes in four outcome measures as *cognition* [F(1,88)=60.26; *p*=.000; partial η2= 0.406], *depression* [F(1,88)=8.24; *p*=.005; partial η2= 0.086], *life quality* [F(1,88)= 10.45; *p*=.002; partial η2= 0.106] and *equilibrium* [F(1,88)= 6.96; *p*=.010; partial η2= 0.073]. No changes were found for autonomy [F(1,88)= 1.10; *p*=.297; partial η2= 0.012]. These changes between the two groups were observed at the sixth month follow-up assessment.

***Conclusion*:** Global postural reeducation could be useful as a complementary rehabilitation treatment in Alzheimer patients.

Keywords: Postural treatment, Alzheimer's disease, aging, cognition, quasi-experimental study, rehablitation.

1. INTRODUCTION

From the standpoint of a deteriorating pathology, Alzheimer's Disease (AD) significantly compromises the quality of life of affected individuals and their families. Recent studies suggest that patients with mild to moderate dementia can still provide a reliable assessment of their levels of well-being [1-4].

This situation has spurred the growth of scientific research for a cure, as well as for the prevention of this pathology, by trying to identify the risk factors and protective factors for the onset of the pathology. Among the most studied risk factors is the decline of cognitive abilities (the individual's cognition) [5].

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The connection between physical exercise and the cognitive and psychological capabilities of patients with Alzheimer's disease (AD) has been strengthened by recent observational and predictive epidemiological studies. [6] Structured physical activity greatly improves muscle tone, flexibility, dynamic balance, posture, deambulation, and decreases the risk of fall [7, 8].

In the elderly at risk of falling, physical activity based on muscle activation and muscle strengthening improves the individual's equilibrium. As a consequence, the number of falls decreases [9]. In addition, physical activity has demonstrated benefits for balance, walking, and the musculature related to the cognitive behavior of individuals with AD [10].

In a recent systematic review, where fourteen studies were accessed to evaluate the effectiveness of yoga as a neuromuscular intervention of balance with people at risk of falls divided into six areas: TBI, CVA, dementia and Alzheimer Disease-type dementia, MS, Parkinson Disease,

and community-dwelling older adults; 13 of them found statistically significant results for improvement of balance with the use of yoga [11].

These findings influence not only the psycho and physiological aspects of Alzheimer's patients but their quality of life as well.

A recent study discusses the effectiveness of focused cognitive training, exercise, and multimodal training of older adults and their effects on postural and gait outcomes.

Consistent with the principle of neural overlap, current research on cognitive training suggests that targeting processes, such as dividing attention and inhibition, lead to improved balance and gait in older adults [12].

However, emerging evidence suggests that multi-component exercise, programs that include resistance, aerobic, and balance training, provide greater benefits for physical and cognitive function in women with mild cognitive impairment (MCI) than single component exercise. Concretely, forty community-dwelling older women with MCI were allocated to a control and an experimental group. Twelve weeks of multicomponent exercise program (aerobic, resistance, and balance exercise) for 60 minutes duration per day with approximately 3 sessions per week was executed for the 20 women of the experimental group, and the control group received only an educational program about the cognitive improvement and fall prevention once a week. Concluding, the experimental group had better results in improvement of attention, dual-task ability, reduced risk of falling [13].

In addition, it has been investigated that simple cognitive loads can lead to dual-task motor facilitation relative to no-load conditions, while more complex cognitive loads lead to proportionally greater costs in postural stability and a range of spatiotemporal parameters of gait [12].

Based on this scientific evidence, this study aims to implement a Global Postural Re-education approach (GPR) as a rehabilitative alternative.

The GPR principles consist in a global treatment of the patient's equilibrium through individual collaboration (active) in the adoption of suitable postures. These postures have affected not only the painful symptoms of musculature problems, but also corrected postural attitudes, respiration, and proprioception [14-16].

In this study, we test the following hypothesis:

The application of the GPR method (based on global stretching) on AD patients can:

(1) Influence positively psychological and cognitive symptoms. [17, 18] and

(2) Improve life quality autonomy and equilibrium of AD patients, according to the severity (mild and moderate AD affection phase).

2. METHODS

2.1. Study Design

A quasi-experimental, pre-post test study design was employed with two intervention groups, without a control group. Three follow-up monitory protocols were performed to assess medium-long term psychological improvement at intervals of 1, 3, and 6 months. This study has been designed and reported according to the CONSORT recommendations for reporting a clinical trial (Fig. **1**). A total sample size of 90 participants was needed with the power =0.8; α=0.05, and an effect size=0.3 for two-tailed t-test parameters.

2.2. Participants

After completing baseline surveys and cognitive function assessments, 90 elderly people participated in this study sample: 69 women and 21 men aged from 67 to 89 years (mean age = 80.21, SD = 5.49) classified into two groups according to mild and moderate Alzheimer Phase severity and considered through inferential analysis (1^{st} Phase = 36 patients, 2^{nd} Phase = 54 patients).

The participants of this study were divided into mild and moderate Alzheimer phases in accordance with: a) the medical collaboration which referred to each criterion reflected in the diagnosis; b) the Alzheimer disease association indications [19]; c) the degree to which symptoms interfere with one's ability to carry out everyday activities; d) duration of the disease; e) period of the deteriorate; f) time of stay in residence, g) gravity of symptoms, h) a clinical dementia rating score of 1 or 2 [20].

Patients with fractures, neuromuscular disease, or neurological disease were excluded. The examined participants were selected in the senior residences of Murcia (Spain) and Tirana (Albania) according to the NINCDS-ADRDA criteria. [21]

The Ethics Review Board of the Catholic University of Murcia approved this study (protocol No: 6573) which was performed in accordance with the principles of the Declaration of Helsinki of the World Medical Association and its revision in 2013. All the participants provided informed consent. The study protocol was prospectively registered at www.clinicaltrials.gov (trial registration number *NCT03732053).*

2.3. Procedure

2.3.1. Baseline Assessment

Clinical history and physical examination were conducted by the physiotherapists in accordance with the participants before the implementation of GPR treatment. Patients that met the inclusion criteria were evaluated in five tests as psychological, mental and physiological tests. Upon completion of the initial assessment and baseline testing, the physiotherapists contacted the caregivers not involved in the study who managed the organization of the two groups participation.

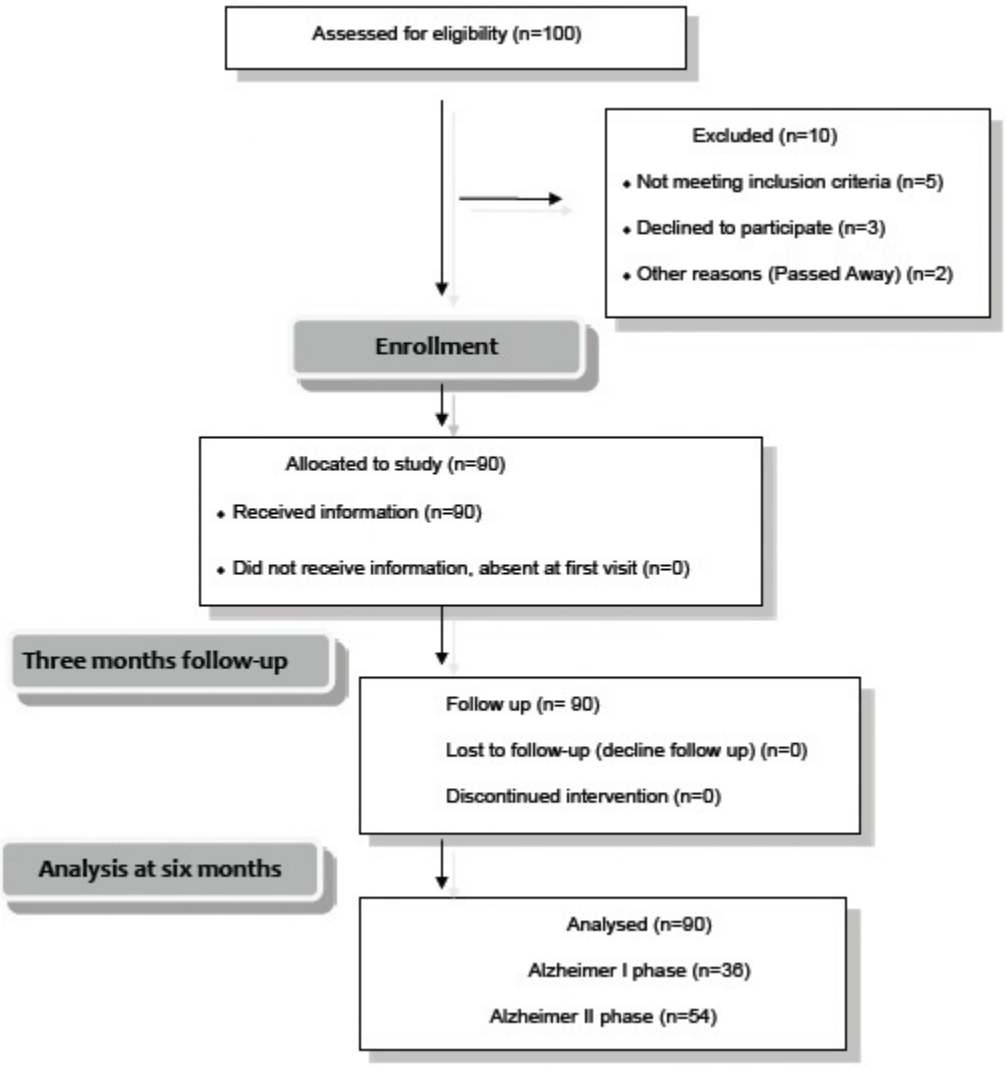


Fig. (1). CONSORT Flow diagram: enrollment and progress of participants through the study.

2.4. Main Outcome Measures

These assessments were performed through standardized study-specific tests related to the participant cognition and psychological symptoms, examined in 3 stages, as showed the neuropsychological, depressive, social, and autonomic signs and symptoms of AD-related to research participants. All of them can be rationally considered as the fundamental variables of the study as they express the current neuro-conjunction capacity and advancement in time. Moreover, through respective descriptions it can be provided the study situation, the average and the standard deviation of the neuropsychological and physiological characteristics of the participants. Here is the case of:

- Mini-Mental State Examination [22, 23] (MMSE): The version of 30 elements was used to obtain a global measure of cognitive function [23].
- Quality of Life in Alzheimer's disease [24-26] (QoL-AD): It consists of 13 elements referring to the perception that patients have concerning various aspects of their life: mood, health, cognition, environment and functional capacity [25, 26].
- Geriatric Depression Scale [27, 28] (GDS): The version of 15 items was used, which given its length, can be validly and reliably resolved by patients themselves, in the quality of a self-report questionnaire aiming to investigate the possible presence of depressive symptoms [28].
- Barthel Index [29-31] (BI): It is used to measure performance in the basic activities of daily life. The maximum score used is 100 points and refers to the patient's independence in all basic daily living activities. [30, 31]
- Tinetti Scale [32-34] (TS): The equilibrium subscale has been applied, which consists of 7 elements and

has a score between 0 and 13. The highest scores indicate a better balance [33, 34].

In addition, a general physical examination was performed to know the state in which muscle chains were found, also studying the asymmetric imbalances of posture and the curves of the back, looking for a global and individualized analysis of each person, since it is a personalized therapy with a maximum duration of 60 minutes [35].

2.4. Intervention

A non-random convenience sampling was used for each group. The treatment implemented to the patients with AD grouped in mild and moderate was the GPR which lasted about 40 minutes in repeated sessions of 2-3 meetings per week completing a total of, 72 sessions during a six-month study period.

2.5. Global Postural Reeducation (GPR)

After the general physical examination, which was repeated at the beginning of each session, the GPR treatment was applied.

This intervention included two lying postures from the eight different therapeutic postures of the GPR method [18, 36] (Table **1**): the supine posture with the leg in frog position and in extension, which progressively stretches the anterior muscle chain for the first three months and the supine posture with hip flexion which stretches the posterior muscle chain for the other three lasted months.

Specifically, the treatment consisted of a global neck pompage, relaxed lying patient associated with deep diaphragmatic breathing in all cases and supine frog position for the first 3 months. In this first period the treatment posture is characterized by a progression from the flexion to extension and against flexion of both hips and knees, which was combined with the patient arms too.

During the second period of the treatment the position of patients' therapy with AD was modified. It was addressed by changing the position of the legs with the frog on-air posture for the last 3 months, associated with deep diaphragmatic breathing, whereas in this second posture, the progression of legs includes hip flexion and knee extension, always with the patient lying supine in bed therapy.

The data were provided by the GPR treatment physiotherapists (Table **1**).

During the GPR treatment, as mentioned before, manual cervical and lumbar traction areas were applied, and isometric contractions of the stiff muscles were elicited to induce post-isometric relaxation [36, 37]. At the end of each session, the participants were requested to correct their standing posture related to the entire cervical, spine, and pelvis region. This method helped as a post rehabilitative evaluation. The final part of each session (diaphragmatic breathing in combination with manual traction) aimed to facilitate the integration of the global postural correction into daily functional activities [38].

2.6. Statistical Analysis

The statistical analysis was carried out by using the Mixed Factorial ANOVA procedure. The effects of postural therapy were verified 3 times (1-3-6 months). An ANOVA of repeated measures was performed with the group as an inter-subject factor and time as an intra-subject factor. The value of the significance was corrected according to the Bonferroni approach for multiple comparisons (95% confidence level, p-value <.05). Partial eta squared (η2partial) was calculated as a measure of effect size wereη2 partial = 0.01-0.059 (small),0.06-0.139 (medium), and ≥ 0.14 (large).

For sample size calculation, a prior sample size two--tailed t-test calculation for the participants was performed using G*Power 3.1.9.2 and the following parameters: ANOVA- repeated measures within-between interaction as a statistical test, an effect size of 0.3(medium), an alpha of 5% and 80% of the power.

All analyses were performed using the statistical program SPSS (SPSS Inc., Chicago, IL, USA), version 20.0.

3. RESULTS

The results of this study showed significant differences between the two monitored groups, according to the level of severity of AD.

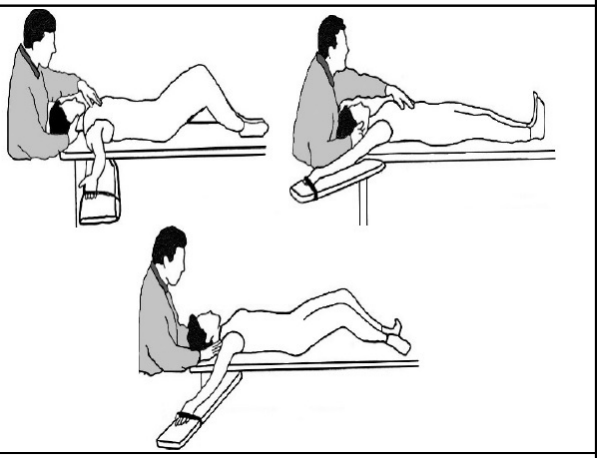
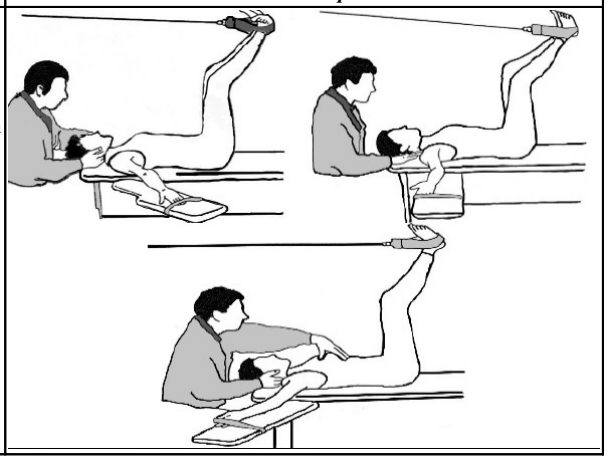
No significant differences were found in the BI averages [F(1, 88)=1.09;*p*=.299] and TS [F(1,88)=0.035; *p*=.852)]. While in MMSE averages [F(1,88)=62.76; *p*=.000], GDS [F(1, 88)=7.79; *p*=.006] and QoLAD averages [F(1,88)=11.7; *p*=.001] showed significant differences. Specifically, Table **2** shows the clinical characteristics of patients belonging to each group.

The ANOVA results at three measurement times showed a significant dynamic in all the results. A significant increase in the measurements among the observation times was observed in MMSEof AD persons [F**(1,98)=** 11.34; *p*=.001; partialη2= 0.113], which showed the differences between the three measure times.

A medium effect size also was found in the BI [F(1,98)=9.08; *p*=.003; partialη2=0.093] and TS [F (1,98) =7.91; *p*=.006; partial η2= 0.082] results, observing a greater difference between the first, third and six months of intervention.

In the GDS depressive symptoms, a significant increase was observed in the averages among the different times of treatment with a large effect size [F (1,98)=30.60; *p*=.000; partialη2= 0.256], showing differences between the three measure times. Another outcome with a large effect size was the QoL-AD, in which significant differences were observed in terms of the different times of treatment [F(1,98)=35.98; *p*=.000; partialη2= 0.288] (Table **3**).

Table 1. Global postural reeducation (GPR) treatment protocol.

Rehabilitation Program in GPR Group		**Posture Positions**
Treatment Protocol	**Duration**	***First Posture Protocol***
Baseline- 3 months supine position legs in frog position arms opened **the therapist in cranio-caudal direction and in harmony with the diaphragmatic respiration** **Therapist-guided stretch for the correction of variations in dorsal curve prolonged tension of muscles chains** neck pompage / correlation with diaphragmatic breathing	40 min 40 min 30 min 30 min 10 freq /30 min 90 sec/3 min	
3 -6 Months	40 min	***Second Posture protocol***
supine position legs flexed hips flexed arms opened **Therapist in the same position and with attention of the posterior muscle chain** with **the maximum elongation of the latissimus dorsi** diaphragmatic breathing neck pompage / correlation with diaphragmatic breathing	40 min 40 min 40 min 40 min 10 freq /30 min 90 sec/3 min	

Figures source: https://rpg.org.ar/aarpg/bibliografia/
Souchard, Philippe. *Rééducation posturale globale*. Elsevier Masson, 2011.

Table 2. Difference between two intervention groups clinical characteristics.

-	**Differential Groups Severity**						
-	**1° Phase**	**(*n* = 36)**	**2° Phase**	**(*n* = 54)**	**-**		
Outcomes	***M***	***SD***	***M***	***SD***	***F***	***p***	***η2partial***
MMSE	23.47	1.46	19.81	2.49	62.76	.000	0.416
GDS	6.06	1.88	4.80	2.22	7.79	.006	0.081
QoL-AD	35.78	4.92	32.37	4.39	11.77	.001	0.118
BI	93.61	8.07	91.48	10.30	1.09	.299	0.012
TS	11.03	1.36	10.96	1.74	0.03	.852	0.000

Note: *n*= participants, MMSE= Mini Mental State Examination, GDS= Geriatric Depression Scale,QoL-AD = Quality of life in Alzheimer's disease, BI=Barthel Index, TS= Tinetti Scale.

The severity of groups therapy interaction has showed significant changes in four outcome measures such as MMSE [F(1,88)=60.26; *p*=.000; partialη2= 0.406], GDS [F(1,88)=8.24; *p*=.005; partial η^2= 0.086], QoL-AD [F(1,88)= 10.45; *p*=.002; partialη^2= 0.106] and TS [F(1,88)= 6.96; *p*=.010; partial η2= 0.073] except the autonomy BI [F(1,88)= 1.10; *p*==.297; partial η^2= 0.012]. This difference between the two groups was observed through the monitoring and at the sixth month follow-up (Table **4**).

Table 3. Time effectiveness of postural therapy on outcome variables.

-	Measurement Moments						-			Pairs Comparison (Bonferroni)		
	1 month		3 months		6 months		-			1-3 months	1-6 months	3-6 months
Outcomes	***M***	***SD***	***M***	***SD***	***M***	***SD***	***F***	***p***	***η2* partial**	***p***	***p***	***p***
MMSE (0 -30)	21.31	2.79	21.44	2.77	21.94	2.81	11.34	.001	0.113	.012	.000	.000
GDS (0-15)	5.24	2.11	5.1	2.23	4.08	2.18	30.60	.000	0.256	.068	.000	.000
QoL-AD(0-52)	33.86	4.81	33.91	4.75	35.31	5.37	35.98	.000	0.288	.287	.000	.000
BI (0-100)	92.72	9.21	92.78	9.15	93.67	8,59	9.08	.003	0.093	.002	.004	.004
TS (0-13)	11.07	1.56	11.37	1.56	11.96	1.49	7.91	.006	0.082	.000	.000	.000

Note: MMSE= Mini Mental State Examination, GDS= Geriatric Depression Scale, Qol-AD = Quality of life in Alzheimer's disease, BI=Barthel Index, TS= Tinetti Scale.

Table 4. Outcome's analysis in three evaluation moments according to the groups' severity.

-	Measurement moments																	
	1 month				-	3 months				-	6 months				-			
	1° Phase(*n*=36)		2° Phase (*n*=54)			1°Phase(*n*=36)		2°Phase(*n*=54)			1°Phase(*n*=36)		2°Phase(*n*=54)					
Outcomes	***M***	***SD***	***M***	***SD***	***Cohen's d***	***M***	***SD***	***M***	***SD***	***Cohen's d***	***M***	***SD***	***M***	***SD***	***Cohen's d***	***F***	***p***	***η2 partial***
MMSE (0-30)	23.5	1.50	19.85	2.49	**1.77**	23.5	1.50	20.02	2.49	**1.69**	24.00	1.6	20.57	2.61	**1.58**	60.26	.000	0.406
GDS (0-15)	5.97	1.82	4.76	2.16	**0.60**	5.94	1.92	4.54	2.27	**0.66**	4.72	2.36	3.65	1.96	**0.49**	8.24	.005	0.086
Qol-AD	35.83	4.88	32.54	4.32	**0.71**	35.92	4.78	32.57	4.27	**0.73**	37.14	5.17	34.09	5.19	**0.58**	10.45	.002	0.106
BI (0-100)	93.75	7.87	92.04	10.02	**0.18**	93.75	7.87	92.13	9.93	**0.18**	95.28	6.54	92.59	9.55	**0.32**	1.10	.297	0.012
TS (0-13)	11.11	1.32	11.04	1.71	**0.04**	11.44	1.34	11.31	1.70	**0.08**	12.00	1.37	11.93	1.57	**0.04**	6.96	.010	0.073

Note: MMSE= Mini Mental State Examination, GDS= Geriatric Depression Scale, Qol-AD = Quality of life in Alzheimer's disease, BI=Barthel Index, TS= Tinetti Scale.

Through the independent samples *t* test, Cohen's *d* determined an improvement with a large effect size in the 1st Phase Group for the MMSE outcome during the first period of the treatment.

GDS outcome showed an improvement with medium effect size during the third month of the intervention for the 2nd Phase Group. The same situation was presented for the QoL-AD outcome which showed a medium effect size for the 2nd Phase Group during the third month of the treatment.

Barthel index showed an improvement with a large effect size at the sixth month of the treatment for the 1st Phase Group.

TS shown an improvement with a large effect size at the third month of the treatment for the 1st Phase Group.

In addition, the results of Pearson correlations between these improvements in the total group indicate that the improvement in MMSE is significantly correlated with the improvement of QoL-AD (r = 0.394, *p*= .001). The improvement of BI is significantly correlated with the improvement of MMSE, QoL-AD and TS (*p*=.001 in all cases), while the GDS scale has not shown correlations in improvements. The analysis of these correlations is reflected in Table **5**.

4. DISCUSSION

The study results showed that the GPR technique was effective in patients with AD, since it improved cognitive, autonomy, balance, neuropsychological and depressive symptoms.

Sampling homogeneity could represent a beneficial aspect in the meaningful results. Another aspect of the GPR implementation technique, which may have positively impacted the study, is the proactive patient's cooperation during the treatment, in order to auto correct the wrong postures, combined with postural harmonious breathing cycles. A good postural control allows the patient motor control, balance and breakdown of the wrong postural habits. In this regard, Schwenk *et al.* suggested that intensive postural treatment significantly improves functional performance, which is a distinctive sign of life quality and independence associated with mobility [39].

Special attention was paid to the research design and development of this study, with the aim of preventing the methodological deficiencies reported in systematic reviews. Standardized tests, included physical treatment, cognition, proprioception, were used for this purpose [23, 26, 31] and a clear definition of cases was given by considering homogeneous samples concerning cognitive abilities, included the confirmed dementia diagnosis [40]. These significant results could be caused due to the positive influences of postural therapy in orientation and relaxation of the depressive symptoms. Tovar Torres argues that the relaxation is the door to discover oneself, a parenthesis in activity, in agitation, a pause in which the person is freed from this feverish, mechanical, and automatic activity [41]. Everly and Lating report that anxiety can be reduced as learning to relax muscles

Table 5. Relationship between the improvements of different variables during the sixth month of therapy.

-	Pearson Correlations			
-	**QoL-AD**	**GDS**	**BI**	**TS**
MMSE	.394**	0.182	.305**	0.165
Qol-AD	-	.046**	.583**	.419**
GDS	-	-	-.163	-.102
BI	-	-	-	.701**

Note: **.Correlation is significant at the 0.01 level, *. Correlation is significant at the 0.05 level. Abbreviations: Qol-AD = Quality of life in Alzheimer's disease, GDS= Geriatric Depression Scale, MMSE= Mini Mental State Examination, BI=Barthel Index, TS= Tinetti Scale.

tension increases. Tension and effort are accompanied by a shortening of muscle fibers [42]. Muscle tone reduction leads to a decrease in the activity of the central nervous system and relaxation is the opposite state of arousal and hence can be considered an adequate remedy for the prophylaxis of psychosomatic illnesses [43]. It also contributes to the improvement of the patients postural balance, which results in a significant improvement in life quality. Proske and Gandevia [44] claims that postural therapy helps the patient to focus on the feelings arisen from their body during a movement or the assumption of a certain posture. Monticone *et al*. [45] suggest that the main postural objective is the enhancement of movement quality, which guarantees the patient a personalized therapeutic approach by recovering body harmony. They globally approach the patient, considering that the postural, emotional, cognitive and perceptive alterations modify a complete functional system.

Postural therapy draws attention to each part of the body by educating the patients to rediscover themselves and could improve that image by learning to perceive the body as a whole, the patient can be aware of every element of their body, as an integral part of the whole [46]. Only in this way, the patient can also actively participate in the re-education of respective positions, finding a new body harmony [18].

With regard to the postural treatment attitude, not all postures are easy to fit with the pathology typology or even patients general condition. In this way, the first and second treatment postures were selected as the most adequate ones in the treatment of individuals with AD. Accordingly, the supine patient position enabled the patients total control. Interestingly, these postures are deployed when diseases symptomatology is still evident therefore, postural corrections must be necessarily and adequately calibrated [47]. They are also recommended in situations where it is necessary to act on respiratory dysfunction (limiting the torso excursion). Active patient participation in posture positioning is a prerequisite for the performance of the above-mentioned technique, which cannot be applied to children or non-collaborative elderly people.

On the other side, it is not possible to standardize the number and articulation of therapeutic sessions as they depend on the patient's momentum conditions. Although in many other studies, patients have been subjected to 1-2 weekly sessions in acute or sub-acute phases, [36, 48] it is not possible to take into consideration this week-treatment frequency.

Meanwhile, the retention of GPR results over time was confirmed in the study of Paolucci *et al.* with long follow-ups periods, concretely of 1 year [49]. No studies were found to investigate the effect of autonomous posture, managed at home after the physiotherapist's training (the so-called "auto-posture"), although therapeutic reasoning would suggest them in long-term treatments in order to reduce health costs.

According to the significant results of the other studies mentioned, the effectiveness of this therapy could also be due to improvements in ventilation and cerebral oxygenation. These two aspects are interrelated since the static balance contributes to major respiratory excursions and vice versa [50].

In relation to our hypothesis, it could be said that the GPR positively influences the psychological and cognitive symptoms of AD patients referring to the MMSE and GDS results.

The results of this study should be considered with caution due to some methodological limitations. For example, our results cannot totally guarantee a relevant improvement of the dementia symptoms by the GPR treatment, given the lack of control in our experiment. In other additional randomized controlled trial implemented with a longer follow-up time and control treatment, more reliable results will be presented. Moreover, we used a convenience sample, not a random sample, which also compromises the generalization of the results.

CONCLUSION

In conclusion, GPR could be effective in the improvement of life quality, autonomy and equilibrium of AD patients, referring to the Qol-AD, Barthel index and TS results and may help in the non-pharmacological management of the AD.

However, further research is needed to confirm the promising results of this study.

AUTHORS' CONTRIBUTIONS

Jasemin Todri designed and conducted the study, supervised the data collection, performed the data analysis, interpretation, and writing of the manuscript. Ardita Todri advised in designing and conducting the study, performed the data analysis and interpretation, and critically revised the manuscript. Orges Lena conducted the study, contributed to

the interpretation of data and revised the manuscript. Juan Martínez Fuentes helped in the revision of this manuscript. All authors have read and approved the final manuscript.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was approved by the Catholic University of Murcia Ethic Committee (approval no: 6573), Spain. The study was registered in Clinicaltrials.gov Identifier: *NCT03732053*.

HUMAN AND ANIMAL RIGHTS

No animals were used in this study. The study on humans was conducted in accordance with the ethical rules of the Helsinki Declaration of 1975 and Good Clinical Practice.

CONSENT FOR PUBLICATION

Informed consent was obtained from all participants.

STANDARDS OF REPORTING

CONSORT guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The data supporting the findings of the article is available in this article.

FUNDING

None.

CONFLICT OF INTEREST

The authors declare no conflict of interest, financial or otherwise.

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