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Efficacy of the Osteopathic Treatment in Parkinson's Disease

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Abstract

Parkinson's Disease (PD) is a neurodegenerative disorder characterized by the loss of dopaminergic neurons in the *substantia nigra*. Several studies were carried out in time on osteopathic treatments in patients with PD, demonstrating an improved motor function, albeit short lived. Our trial was aimed at assessing the potential efficacy of the Osteopathic Manipulative Treatment (OMT) on mobility, posture, and gait in patients with moderate PD, as well as the importance of "taking charge" of the patient for the Quality of Life (QoL) of individuals with PD.

Materials and methods. 32 subjects aged 76±7.284 were divided in two groups: group B (n=17) received the OMT, followed by the SHAM treatment; group A (n=15) received the SHAM treatment, then the OMT. The study was designed as a nine-week cross-over trial, with group cross-overperformed after a one-week wash-out. All the subjects underwent a baseline neurological blind evaluation at four weeks and post cross-over. The ADL, IADL, GDS, and GPE scales were also administered.

Results. 16 subjects completed the study, 32 subjects participated in the first four weeks only. An improvement of the mean and standard deviation parameters was observed in the UPDRS and the TUG test in patients receiving the OMT. A decrease of the dysfunction degree was observed in both groups upon the osteopathic evaluation.

Conclusions. The data show the potential usefulness of the OMT in PD with respect to stiffness, mobility, posture and where the patient is taken charge of. Further studies will be needed to disprove the goal of the trial.

Keywords: Parkinson's Disease (PD), Osteopathic Manipulative Treatment (OMT), Quality of Life (QoL)

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Introduction

Parkinson's Disease (PD) is a neurodegenerative disorder with a 0.3% prevalence in industrialized countries, characterized by slow, yet progressive development and by tremor, bradykinesia, and stiffness. Its cause is still unknown and a neuropathological examination reveals a loss of dopaminergic neurons in the *substantia nigra*. Levodopa has been the golden standard for the treatment of PD ever since the 1960s, but long-term treatment with this medication involves changes in the motor response with a severe impact on the patient's QoL [1]. Osteopathic Manipulative Treatment (OMT) sessions in patients with PD brought about significant improvements in terms of muscle stiffness, albeit short lived [2, 3], thus supporting the assumption that osteopathy can restore the balance of body tissues [4] with subsequent improvement of the QoL of patients and their families.

Materials and methods

Sample. The study was a blind Randomized Controlled Trial (RCT) carried out on a sample of 32 subjects, including 16 males and 16 females, with moderate and stable PD and aged 76±7.284 on average. The recruited subjects were referred to a neurologist and then treated at the SOMA (Institute of Osteopathy SOMA, in Milan, Italy), subject to their consent and completion of the Privacy form. The subjects were randomized to two groups (Group A and Group B).

Table 1. *Trial Design*

	T0	4 weeks	T1	Cross-over after 4 weeks	T2
Group **B**	Neurological evaluation	4OMT	Neurological evaluation + Wash-out	4SHAM	Neurological evaluation
Group **A**	Neurological evaluation	4SHAM	Neurological evaluation + Wash-out	4OMT	Neurological evaluation

Trial procedures and timeline

The study was designed as a nine-week cross-over trial, with group cross-over after a one-week wash-out so that all the subjects were submitted to both the 4 OMT sessions, once a week for four weeks according to the protocol, and the 4 SHAM sessions, at the same time intervals and with hand placement on the same body regions as in the OMT group. In particular, group B received the osteopathic treatments during the first month and the SHAM treatments during the second month, whereas group A received the SHAM treatments in the first month and the osteopathic treatments in the second month (Tab. 1). All the subjects were submitted to blind neurological evaluation at baseline (T0), after one month (T1), and post cross-over (T2) to assess their motor skills, posture, and gait (Unified Parkinson's Disease Rating Scale (UPDRS), TUG). At the same time, daily life skills and depressive symptoms were also evaluated (ADL, IADL, GDS), and the treatment appreciation questionnaire was administered (GPE). Logistic issues prevented the completion of the original project on all 32 patients; therefore, 16 patients participated in part one of the trial only (T0, 4-week treatment without cross-over), whereas the other 16-patient sample completed the initial cross-over project.

Session description

Each session is characterized by pre- and post-treatment osteopathic evaluation. For both groups, the operator places his/her hands on the same anatomical landmarks; the only difference is that the SHAM treatments are performed without therapeutic purposes. Each session lasts 30 minutes, and takes place according to a pre-defined protocol.

Osteopathic evaluation

- Zink evaluation (Compensated = 0; Uncompensated = 1);
- Atlanto-occipital evaluation (Score 0 = no dysfunction; 1 = minor dysfunction; 2 = moderate dysfunction; 3= severe dysfunction);
- Upper thoracic outlet, sternum, and cervical fascia evaluation;
- Thoracic diaphragm evaluation;
- Pelvis evaluation;
- Craniosacral evaluation (Compressed = 1; Uncompressed = 0).

The Somatic Dysfunction is diagnosed via perceptual palpation and intersegmental motion test to identify the parameters known by the acronym TART, following the SOAP criteria (Outpatient Osteopathic SOAP Note Form), which provide for recording the clinical signs of somatic dysfunctions according to the following scores: 0 – no dysfunction, 1– minor dysfunction, 2 – moderate dysfunction, 3 – severe dysfunction.

Group B was administered the following treatment protocol:

Osteopathic Manipulative Treatment: condylar decompression; reciprocal tension membrane rebalancing; myofascial relaxation of thoracic diaphragm, upper thoracic outlet, cervical fascia, and sternum; respiratory diaphragm relaxation; sacrum-abdomen rebalancing.

Purposes of the implemented techniques

1) *Condylar decompression*. This technique promotesan in-depthrelaxation, which also expands to *dura mater* level.
1) *Reciprocal tension membrane rebalancing*. This technique allows to reduce dural tensions and to restore the balance of the central axis also involving neurovegetative pathways [5].
2) *Myofascial relaxation of upper thoracic outlet, cervical fascia, and sternum*. Patients with PD display stiffness of the cervicodorsal column, which involves the upper trapezius, scalene, sternocleidomastoid, supra- and subhyoid, and pectoralis minor muscles. These stretching sessions promote myofascial relaxation of the thoracic outlet [6].
1) *Myofascial relaxation of the diaphragm*. These techniques are aimed at reducing tensions in the diaphragm and in the musculoskeletal structures it grafts into (upper lumbar vertebrae, top six ribs, xiphoidending of the sternum). Moreover, because the diaphragm has myofascial connections with the lower limbs via the psoas and the quadratus lumborum muscles, these structures are also affected [7]. Another important feature of the myofascial diaphragm treatment is the pumping action that ensures the balance between thoracic and abdominal pressure, thus promoting lymph circulation and abdomen and lower-limb drainage [8].
3) *Sacrum-abdomen rebalancing*. The abdominal wall often contracts and hurts in patients with PD. This technique establishes a relation between the sacrum bone and the abdominal wall in view of rebalancing intrinsic movements between the sacrum and the abdomen, thus reducing tensions. If associated with the diaphragm relaxation technique, this approach helps to reduce the typical camptocormia [9]. Group A was submitted to the SHAM treatment, instead:

SHAM treatment. In this technique, the hands are placed in the same position as in the above-described techniques. However, since there is no " intention" to affect the dysfunctions, the operator takes an observing approach without producing any stimulation imitating osteopathic techniques.

Inclusion and exclusion criteria. The subjects that achieved a score of ≥14 in the Mini Mental Test, a score ≤ 75 /128 in the UPDRS scale (Part III), and a score between 2 and 3 out of 5 in the Hoehn and Yahr scale were included in the trial. On the other hand, subjects with dementia (Mini Mental Test <14), cancer or known consequences of fracture were excluded.

Outcomes. *Primary***:** mobility (UPDRS); gait (TUG); *secondary:* disability and quality of life (ADL, IADL); depression (GDS)

Blinding. In order to ensure blind evaluation, the trial was carried out by three osteopaths, including one operator and two evaluators. The latter two did not attend the treatment sessions and were not informed about the patients' relevant group. The neurologist did not know which treatment the patients were receiving and they, in turn, did not know which group they belonged to.

Measurement scales. Different scales were administered at T0, T1, and T2, namely: UPDRS (part III), TUG, ADL, IADL, GDS, and GPE.

UPDRS. Part III of the scale was administered at baseline (T0), after four weeks, (T1), and after eight weeks of treatment (T2). In this scale, which is focused on motor skills in PD, scores from 0 (no symptoms) to 4 (most severe conditions) are attributed to each evaluation item. The total score, obtained as the sum of all the items, has a maximum value of 128. Changes at T0, T1, and T2 were evaluated by means of inferential statistical analysis.

Up&GoTest (TUG). The evaluator performed the test at baseline (T0), after four treatment sessions, (T1), and after eight treatment sessions (T2). The test measures the time it takes for an individual to rise from a chair, walk on a three-metre distance, perform a 360° turn, return to the chair, and sit down. A normal time is between 7 and 10 seconds.

ADL, IADL. These scales, administered at baseline (T0), after four treatment sessions, (T1), and after eight treatment sessions (T2), were filled in by the patient or, if unable, by his/her caregiver. In the ADL scale one point is attributed to each independent function, so as to obtain a total score ranging from 0 (full dependence) to 6 (independence in all functions). Similarly, the IADL scale ranges from 0 (full dependence) to 8 (independence in all functions). The data obtained from these scales was used to calculate the mean and the standard deviation.

GDS. The GDS was also administered at baseline (T0), after four treatment sessions, (T1), and after eight treatment sessions (T2), having patients fill it in personally wherever possible. The scale provides for 30 questions with answers "YES/NO" for a total score ranging from 0 (no depression) to 30 (severe depression). A score between 1 and 10 is considered as normal, a score between 11 and 19 points out to "medium depression," and a score between 20 and 30means "severe depression" [9]. The data obtained was used to calculate the mean and the standard deviation.

GPE. Upon completing the eight treatment sessions (T2), the evaluator administered this treatment appreciation scale with scores ranging from 1 (the performed treatment definitely improved my disorder) to 7 (the performed treatment definitely made my disorder worse). Based on the collected data, the rate of satisfied vs. dissatisfied patients was calculated.

Results

Randomization resulted into the creation of two non-homogeneous groups by gender, age, and disease severity: group A included 10 men and 5 women; group B included 6 men and 11 women.

UPDRS. The mean value and the standard deviation for the total score of the UPDRS were calculated in order to evaluate changes between T0, T1, and T2 (Tab. 2). The 10 patients that completed the eight-week trial were considered.

The inferential analysis performed on the scores of the UPDRS allowed to ascertain whether statistically significant results were obtained for the analyzed parameters.

The result of score comparison at T0-T1 for group B in the first four weeks (OMT) has a P-value = 0.001. If, on the other hand, the UPDRS score is compared at T1-T2 by means of inferential analysis for group B in the SHAM treatment period, the results are not statistically significant, with $p > 0.05$.

Up&Go Test (TUG) The mean value and the standard deviation for the TUG test at T0, T1, and T2 were like wise calculated, also considering the 10 patients that completed the eight-week trial (Tab. 3).

The inferential analysis allowed to establish statistical significance between T0 and T1 for group B in the first four weeks (OMT), with p=0.03. On the other hand, a T1-T2 comparison in the TUG test, also with inferential analysis, for group B during the SHAM treatment period did not provide statistically significant results, with $p > 0.05$.

Osteopathic evaluation

A total of 6 parameters were evaluated. The evaluation according to *Zink* highlighted the postural change in patients, who shifted from an "uncompensated" to a "compensated" pattern. In particular, 40% of the "uncompensated" patients restored a "compensated" pattern between T0 and T1, whereas the pattern remained unchanged between T1 and T2 (Tab. 1-3). The treatment of the *atlanto-occipital* joint did not result in any changes between T0 and T1, whereas 30% of patients with moderate-severe dysfunction improved to a minor or no dysfunction between T1 and T2. The treatment of the *upper thoracic outlet* in the T0-T1 period resulted into a 20% decrease of patients with moderate-severe dysfunction, and an additional 20% decrease was observed in the T1-T2 period. The treatment of the *respiratory diaphragm* resulted into a 20% decrease of patients with moderate-severe dysfunction in the T0-T1 period, whereas a 10% increase was observed in the T1-T2 period. As to the *pelvis*, no differences were noticed between T0 and T1, whereas a 10% increase of patients with minor or no dysfunction was recorded between T1 and T2. An analysis of the qualitative trend of the Primary Respiratory Mechanism (PRM) based on the craniosacral motion parameters highlighted full improvement in both variables. Upon completing the 4 OMT sessions, as well as upon completing the 4 SHAM sessions, 100% of patients had a physiological PRM.

Table 2. *Unified Parkinson's Disease Rating Scale (UPDRS)*

B	T0	T1	T2
UPDRS MEAN	27.3	23.7	24.7
UPDRS–standard deviation	14.91494403	13.73600298	15.76952053

Table 3. *Up&Go Test (TUG)*

B	T0	T1	T2
TUG MEAN	14	13.375	15.875
TUG – standard deviation	3.422613872	4.138236339	5.617256575

Table 4. ***SHAM Group. UPDRS***

A	T0	T1	T2
UPDRS MEAN	34.16666667	34.66666667	27.83333333
UPDRS- standard deviation	20.17341485	21.04914883	23.18117052

Table 5. *Up&Go Test (TUG)*

A	T0	T1	T2
TUG MEAN	20	19.5	20.16666667
TUG- standard deviation	18.28660712	18.47971861	18.08221963

SHAM Group. ***UPDRS.*** The mean value and the standard deviation for the total UPDRS score were calculated in order to estimate their changes between T0, T1, and T2. The 6 patients that completed the eight-week trial were considered (Tab.4).

An inferential analysis was performed on the UPDRS score, which allows to ascertain whether the results for the analyzed parameters are statistically significant. The analysis did not highlight any statistically significant results during the first four weeks of the trial in a comparison between T1 and T0, when the patients were receiving the SHAM treatment, with p>0.05. A further analysis was performed comparing T2 and T1, whengroup A patients were receiving the OMT. The results are statistically significant, with p= 0.028.

Up&Go Test (TUG) The mean value and the standard deviation for the TUG test were likewise calculated at T0, T1, and T2, considering the 6 patients that completed the eight-week trial.

An inferential analysis was performed on the TUG test scores, which allows to ascertain whether the results for the analyzed parameters are statistically significant. The analysis highlighted no statistical significance between T1 and T0 for group A in the first four weeks (SHAM), with p>0.05. The same applies to the comparison between T2 and T1, which did not highlight any statistically significant data in the second four weeks, when the patients were receiving the OMT, with p>0,05.

Osteopathic evaluation

A total of 6 parameters were evaluated: the evaluation according to *Zink* highlighted a postural change in patients that changed from an "uncompensated" to a "compensated" pattern at T1-T2 (OMT). The pattern remained unchanged between T0 and T1 (SHAM). Following the SHAM treatment of the *atlanto-occipital* joint, 50% of the patients got worse between T1 and T2, developing from a minor or no dysfunction to a moderate-severe dysfunction. All the patients had a minor or no dysfunction between T1 and T0. The SHAM treatment of the *upper thoracic outlet* did not change the baseline condition at T0, and the sample remained with a minor or no dysfunction. No change at the three times considered was observed for the SHAM treatment of the *respiratory diaphragm* either. The SHAM treatment of the *pelvis* region resulted into a 17% increase of patients with moderate-severe dysfunction at T1-T0. An analysis of the qualitative trend of the *Primary Respiratory Mechanism (PRM)* based on the craniosacral motion parameters highlighted full improvement in both variables. Upon completing the 4 SHAM sessions (T1) and the 4 OMT sessions (T2), 100% of patients enjoyed physiological craniosacral motion.

Evaluation scales

The means and the standard deviations of the ADL, IADL, and GDS scales were calculated for each group. The chart below shows that no significant variation occurred in the ADL scale for either group (Tab. 6):

The chart (Tab.7) also shows no significant variation of the IADL scale:

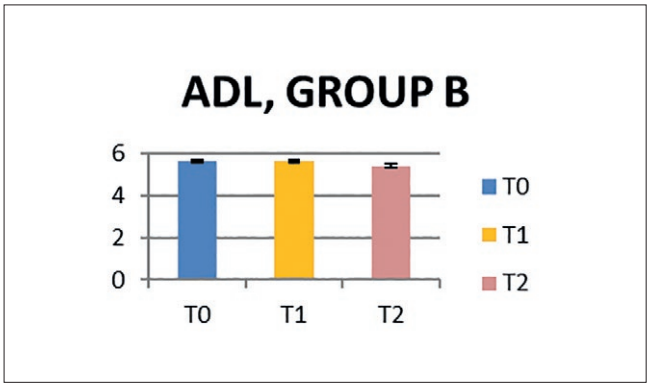
The chart (Tab. 8) shows that no significant variation occurred in the GDS for either group, except a small decrease in group B from T0 to T1 and a small decrease in group A from T0 to T2:

As to the GPE scale (Tab.9) both patient groups expressed a varying degree of satisfaction about the treatment:

Discussion

Groups A (T1-T2) and B (T0-T1) receiving the OMT (Tab. 1-2). An analysis of the data of both groups when receiving the osteopathic manipulative treatment shows that, follow-

Table 6. *ADL Scale*



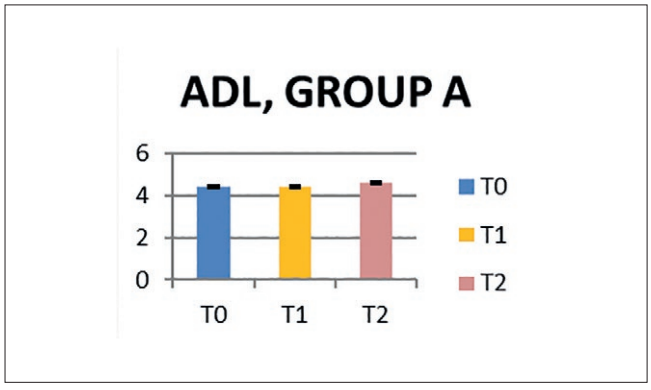
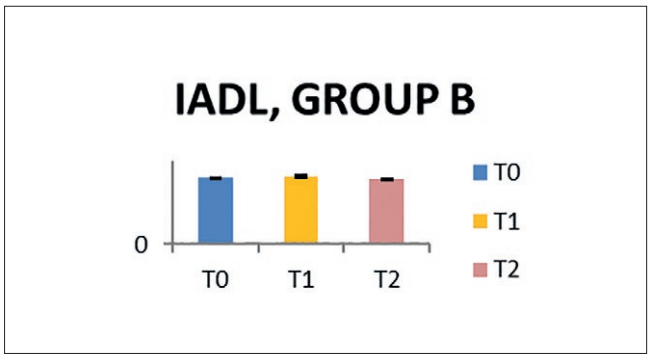


Table 7. *IADL Scale*



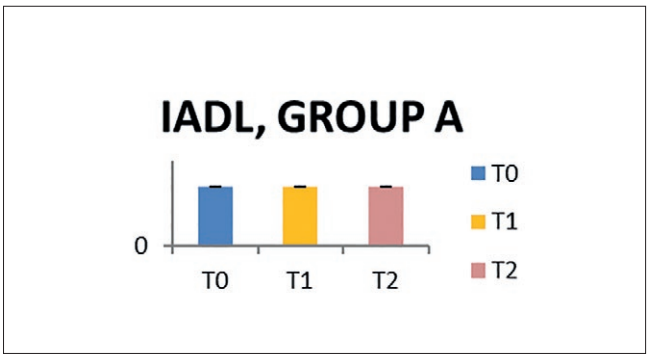
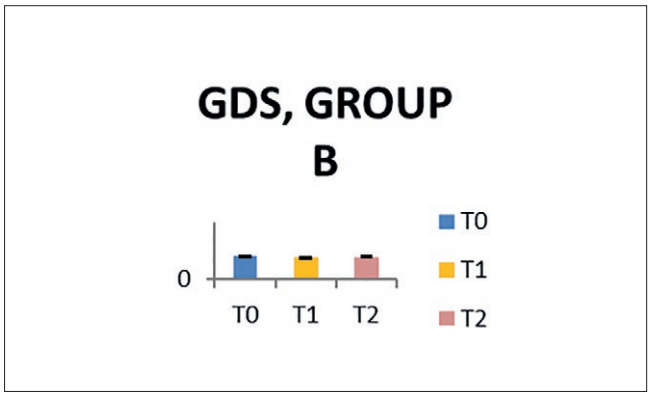


Table 8. *GDS Scale*



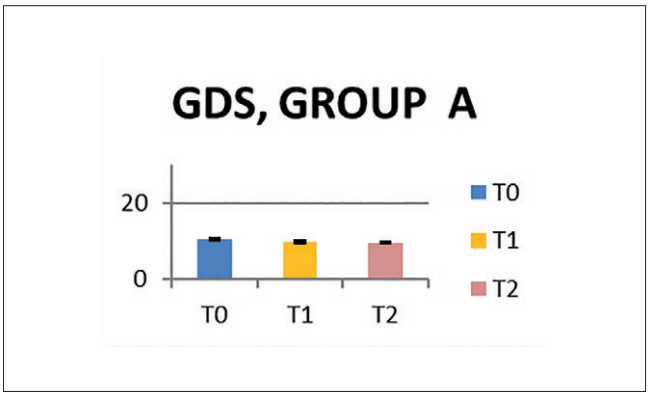
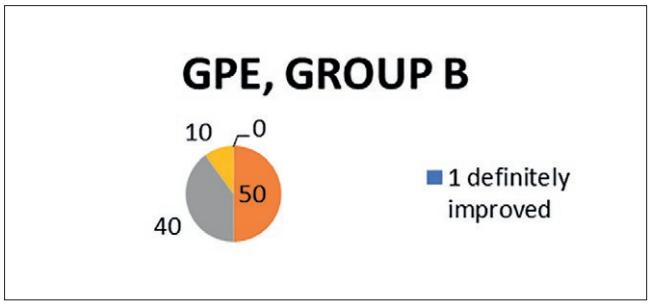
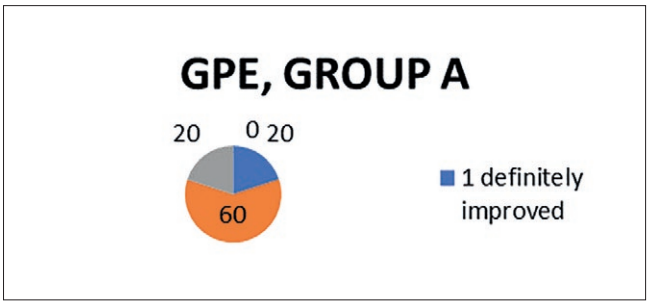


Table 9. *GPE Scale*





ing an inferential analysis, the total UPDRS score achieved a statistically significant improvement, in particular: at T0-T1 in group B with a P-value = 0.0001 and at T1-T2 in group A with a P-value=0.0028. Statistical significance as regards the Up & Go Test (TUG) score was only observed in group B at T0-T1, with p=0.03. On the other hand, no statistical significance was observed in group A in the T1-T2 period. This may be due both to a non-homogeneous sample and to the fact that the group A sample significantly decreased in the T1-T2 period. As to the ADL and IADL scales, indicating the subject's dependence in daily life, mean values remained unchanged in both groups receiving the OMT, however considering that most subjects had obtained the maximum score as early as at baseline. As to the GDS questionnaire, which is used to evaluate the presence and severity of depression-related symptoms in elderly patients, a minimal reduction of the mean score between baseline and end of treatment was observed in both groups receiving OMT. Following the osteopathic manipulative treatment, changes in all body regions were observed, usually with an improvement of the dysfunction degree from severe-moderate to minor-absent. In particular, a physiological PRM was observed in all the patients. The operator reported changes in the TART parameter, specifically in the following regions: respiratory diaphragm and upper thoracic outlet (cervical fascia and sternum). These changes have a positive impact on the quality of life of the treated patients, who report successful accomplishment of minor daily tasks. This obviously results into their satisfaction from the motor and psychological viewpoint.

Groups A (T1-T2) and B (T0-T1) receiving the SHAM treatment (Tab. 4-5). The data analysis in both groups when receiving the SHAM treatment (group A in the T0-T1 period and group B in the T1-T2 period) shows that, following the inferential analysis, the total UPDRS score was not statistically significant, with a P-value >0.05. No statistical significance as regards the Up & Go Test (TUG) score was found either, with a p-value > 0.05 in both groups. As to the ADL and IADL scales, the mean scores remained roughly unchanged in both groups receiving the SHAM treatment. As to the GDS questionnaire, a small decrease of the mean value was observed in group A at T0-T1, whereas it remained almost unchanged in group B at T1-T2. Following the evaluation of the osteopathic district after performing the SHAM treatments, no substantial changes

of the parameters referring to Zink, the diaphragm region, and the pelvic region were observed. On the other hand, a small decrease of the dysfunction grade in some regions was observed, including the atlanto-occipital region and the upper thoracic outlet (cervical fascia/sternum). Like in the OMT patients, the primary respiratory mechanism turned out physiological in all the patients at the end of the four SHAM treatment sessions. Several studies demonstrated the existence of neurobiological correlations of the placebo, both in healthy individuals and in patients with symptoms. The effects of the SHAM treatment seem to be influenced by several psycho-social factors, including patient expectations, patient-physician relations, and therapeutic approaches. These factors seem to have an impact on neurophysiological mechanisms, which cause changes in brain-body interactions via the endocrine, immunological, and autonomous nervous system [10]. At the end of the eight-week treatment, all the subjects were administered the GPE questionnaire (appreciation index): 93% of the subjects gave positive feedback and reported an improvement in their disorder; only 7% said their disorder remained unchanged; no patients reported a deterioration in their condition.

Limits of the study. The study should be continued, both for the SHAM group and the OMT group, with a larger sample, in order to provide empirical information on the extent to which change depends on the patient being "taken charge" of or on the actual osteopathic treatment.

Conclusions

The most significant changes were observed upon the neurological evaluation, with a statistically significant decrease of the UPDRS score, which is useful to review such parameters as mobility, posture, and gait. While the outcomes improved in patients with Parkinson's Disease in the OMT group, unlike in those in the SHAM group, it would be appropriate to expand the sample in order to give a statistical significance to the Up & Go Test. Lastly, this trial highlighted the importance of "taking charge" of the patient as such, since improvements could be observed upon the osteopathic evaluation of patients in the SHAM group as well. The osteopathic manipulative treatment is therefore useful to improve mobility, posture and gait in patients with Parkinson's disease, but a future follow-up of the trial with an expanded sample and over a longer period of time is recommended in order to study the persistence of the treatment's efficacy in time.

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Contribution:
Andrea Bergna – review publications on the subject of the article; development of study design, selection of patients; Livio Bressan – development study design, selection of the patients, analysis and interpretation data; Umberto Solimene – development study design, verification and critical content, scientific editing of the manuscript, Elena Zanfagna, Alessia Ballabio, Andrea Vendramini – selection and treatment of patients