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"Effectiveness of Global Postural Reeducción in subjects with Neck pain. Randomized Controlled Trial" (Prof. Paolo Pillastrini – University of Bologna - Italy)

*Background*

... when I went to Buenos Aires in 2012, at the end of my lecture in the last RPG Congress, I presented a slide, in which I shared with all of the attendants my wish about the scientific evolution of the Global Posturale Reeducción in the Rehabilitation and Physiotherapy professional communities and associations... Now I finally completed and published this research study. Publication was on "Physical Therapy", one of the most prestigious Journals in the "Rehabilitation" category of the "ISI Web of Knowledge" database.

*Aim and Methods*

We conducted a Randomized Controlled Trial, whose purpose was to examine the effectiveness of the application of Global Posturale Reeducción compared to a Manual Therapy intervention in adult patients with Chronic Nonspecific Neck Pain. The study protocol was registered in the Clinical Trial Registry of the U.S. National Institute of Health (NCT01947231) and was approved by the Independent Ethics Committee in Clinical Research of the University of Bologna. From September 2013 to April 2014, 108 outpatients diagnosed with Chronic Non Specific Neck Pain at the S.Orsola-Malpighi University Hospital were eligible to participate. According to inclusion and exclusion criteria, 94 subjects were enrolled in this study.

*Participants*

Participants were included if they fulfilled the following criteria: Chronic Non Specific Neck Pain lasting for at least 3 months, aged 18 to 80 years of both genders, able to read and speak Italian. Exclusion criteria were: acute or subacute Neck Pain, specific cause of Neck Pain (e.g. systemic, rheumatic, neuromuscular diseases), central or peripheral neurological signs, cognitive impairment, spinal surgery, or physical therapy treatments in the last 6 months prior to baseline assessment.

*Demographic data*

Basic demographic data (age, gender, and Body Mass Index), smoking habits, physical activities, marital status and referred pain were collected at baseline. All outcome measures were captured at baseline, immediately post-intervention (Time 1), and at 6-months post-intervention (Time 2) by an assessor blinded to group assignment. The sequence of testing for the outcome measures was randomized among patients. The trial was designed according to the CONSORT publishing guidelines. 47 patients were assigned to Manual Therapy, while 47 patients were assigned to Global Posturale Reeducción program. All of the randomization procedures were concealed and conducted by the study statistician.

*Interventions*

Both Global Posturale Reeducción and Manual Therapy interventions lasted 9 sessions, one hour each, with one-to-one supervision, once or twice a week according to patients' needs. Three physiotherapists with expertise in Global Posturale Reeducción provided the Global Posturale Reeducción treatment, whereas five physiotherapists experts in Neck Pain treatment carried out the Manual Therapy program. Before starting this study, some practice sessions

were organized to standardize the procedures among the physiotherapists, including agreement among different examiners on how the cervical ROM measurement would be calculated. All patients in both groups received advice to follow written ergonomic suggestions and to repeat the exercises taught in the first physical therapy session at home twice a week for 15 minutes.

### *Global Postural Reeducation*

In this study only two lying postures were used from the eight different therapeutic postures of Global Postural Reeducation method: the supine posture with legs extension and the supine posture with hip flexion. During Global Postural Reeducation treatment, manual traction was applied both to lumbar and cervical areas, and isometric contractions of the stiff muscles were requested to induce post-isometric relaxation. Each posture was held for about 20 minutes. At the end of each session, subjects were requested to correct their standing posture and to perform simple cervical movements maintaining the corrected posture for a total of ten minutes. The final parts of each session aimed to facilitate the integration of the postural correction into daily functional activities.

### *Manual Therapy*

The Manual Therapy program included a combination of different techniques. Axial cervical general traction and mobilization of muscle fascia were performed for at least 30 minutes. Then, passive mobilization was applied to the cervical spine using Maitland's technique for posterior to anterior accessory movements by applying the Physical Therapist's thumbs to the spinous process with a rhythmic gentle pressure. Only slow, grade II movements were performed from C0-C1 to C7-T1 for approximately one minute for each cervical level. Therapeutic massage was applied to neck and shoulders areas as final technique for approximately fifteen minutes using almond oil.

### *Outcomes*

Outcome measurements were collected by three researchers who were blinded to treatment at baseline and at two follow-up examinations: at the end of the treatment and after six months. The primary outcomes of this study were pain and disability. Mean rates of perceived pain during the last 24 hours were measured by using a 0-100 Visual Analogue Scale, while cervical disability was rated using the Italian version of the Neck Disability Index. The Neck Disability Index is the most used questionnaire for measuring neck disability. The secondary outcomes were: kinesiophobia, perceived effect of the intervention, patient satisfaction, and cervical ROM.

### *Statistical analysis*

Descriptive statistics of the recorded characteristics and the outcome measures at baseline were calculated. Continuous variables were expressed as mean and standard deviation (SD), while categorical variables were expressed as absolute and percentage frequencies. In order to assess baseline homogeneity of the two groups, two-tailed Student's t tests for continuous variables, and Chi-square tests for categorical variables were performed. The between-groups differences were the estimated mean differences in scores (with 95%CI) at each time between the two groups. The between-groups effect sizes were calculated using Cohen's d. An effect size greater than 0.8 was considered large, approximately 0.5 was considered moderate, and less than 0.2 was considered small. An intention-to-treat analysis was conducted in order to assess the effect of dropout patients on the results of the baseline-adjusted mixed models considering VAS and NDI-I outcomes as dependent variables. Two scenarios were defined,

based on different imputing techniques for the missing scores at Time 1 and Time 2. Worst-case scenario: average observed improvement from baseline was assigned to Manual Therapy dropout patients, while average observed worsening was assigned to Global Posturale Reeducation dropout patients. Best-case scenario: average observed improvement from baseline was assigned to Global Posturale Reeducation dropout patients, while average observed worsening was assigned to Manual Therapy dropout patients.

### *Results*

94 patients were enrolled in the study and randomized to a treatment group. One patient assigned to the Global Posturale Reeducation group dropped out before the first visit, leaving 93 subjects in our initial sample (46 in the Global Posturale Reeducation group and 47 in the Manual Therapy group; mean age:  $47.5 \pm 11.3$  years; 23.7% male). Outcome measurements were completed on 89 subjects at Time 1 (44 in the Global Posturale Reeducation group and 45 in the Manual Therapy group), while 87 subjects were examined at Time 2 (43 in Global Posturale Reeducation and 44 in Manual Therapy). The between-groups effect size for the unadjusted difference from baseline, according to Cohen's *d* values, were moderate or large for VAS at Time1, for NDI and TSK at Time 2 and for TSK-2, ROM flexion and extension and ROM lateral flexion at both Time1 and Time 2. All of the remaining between-group effect sizes were less than moderate. In our intention-to-treat analysis, in the worst-case scenario, the baseline-adjusted between-groups differences in scores are only significant for VAS at Time 1 ( $P=0.0260$ ), but not for Neck Disability Index at Time 2 ( $P=0.0784$ ), while in best-case scenario all between-groups effects were significant (all,  $P < 0.05$ ). With respect to the subjective perception of improvement measured by the Global Perceived Effect questionnaire and satisfaction with physical therapy treatment measured by the Physical Therapy Patients Satisfaction Questionnaire at Time 1, satisfaction in general appeared to be very high for both groups. No relevant differences in perceived effect and satisfaction were found for the Global Posturale Reeducation group compared to the Manual Therapy group.

### *Discussion*

The results of this study showed that Global Posturale Reeducation was more effective than Manual Therapy for improving pain and disability at 6 month follow-up. Cervical spine ROM showed very different results between groups. This finding may be interpreted in light of other studies regarding changes in muscular activation pattern following cervical pain. Increased activity of superficial muscles, and decreased activity of the deep muscles have been observed in Neck Pain subjects. Furthermore, co-activation of agonists and antagonists have been observed. We can hypothesize that Global Posturale Reeducation sessions may promote a pattern of muscle activation that has positive consequences on cervical ROM and may enhance the recruitment of the deep cervical flexor muscles. This study showed better results on pain and disability following Global Posturale Reeducation procedures; nevertheless, in the absence of a control group, we cannot comment about the difference between any type of treatment and natural course of Neck Pain. In fact, epidemiological studies showed that close to 50% of patients will continue to have pain or recurrences for several months after first episode, and treatment appears to have little effect on persistence of Neck Pain.

### *Conclusions*

The results of this randomized clinical trial suggest that Global Posturale Reeducation was more effective than Manual Therapy for improving pain and disability in patients with Chronic Nonspecific Neck Pain at long-term follow up at six months.