

**TITLE PAGE**

**Title**

**A New Manual Therapy for the Treatment of Back Pain and measure of the “Quality of Life”: An Integrated Approach using Neurostructural Integration Technique – NST, in a hospital context.**

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## ABSTRACT

### **Study:**

A selected group of individuals suffering from back pain were studied over a period of three months throughout which they received applications of a new integrated manual therapy approach called Neurostructural Integration Technique (NST)

### **Purpose:**

To explore the effectiveness of an integrated approach using the Neurostructural Integration Technique (NST), as applied to specific muscles, tendons, ligaments and nerves.

### **Procedures used:**

39 patients with recurrent or chronic back pain were treated at the Bergamo Hospital in Italy. Measurement of pain intensity (VAS), Quality of Life (3 different questionnaires: SEIQoL, EuroQoL, health-VAS) and spinal range of motion were collected before and immediately after treatment, and 3 months after the treatment period.

### **Findings:**

Of 36 participants who presented at follow-up 81.8% had not resorted to any other therapy between the termination of NST treatment and follow-up. NST improved the following evaluation scores (pain-VAS from 6 to 2, SEIQoL from 59.4 to 70.6, EuroQoL from 63.5 to 79.2, health-VAS from 66.9 to 79.2) with significant variation ( $p < 0.01$ ). The difference in ROM showed less significant improvement.

### **Conclusions:**

NST provides significant and sustainable improvement for individuals suffering from back pain. The implementation and integration of manual therapy and dialog concerning QoL can assist in directing focus on well-being initially for self and subsequently for relationships.

## KEY POINTS

- An observational trial was performed with individuals suffering from back pain.
- Five sessions of a new manual therapy called Neurostructural Integration Technique (NST) were applied to each participant.
- All participants improved significantly in terms of pain reduction, quality of life. The results attained were maintained three months later, but not significantly in terms of ROM.

## **A New Manual Therapy for the Treatment of Back Pain and measure of the “Quality of Life”: An Integrated Approach using Neurostructural Integration Technique – NST**

### **INTRODUCTION**

#### **The problem of back pain**

Approximately 80% of individuals suffer from back pain during their working lives (Frymoyer 1996). In some cases spinal pain syndromes have specific semiotic and symptomatic characteristics compared to physical damage that can be diagnosed by investigation with the appropriate instruments. In other cases the spinal column is identified as the source of symptoms that do not correspond to “objective” clinical observations and in yet other cases patients present a sense of general discomfort identified with certain postural disorders (Carragee and Hannibal 2004). The widespread diffusion of lumbalgia and problematical back pain at all levels indicates that this is a phenomenon of epidemic proportions. Many researchers (Waddel et al. 1984; Kare et al. 2005, among others) who have investigated this phenomenon claim that the most common clinical treatments have failed and that the role of conventional medicine should be subject to critical re-examination.

This failure can be attributed to various factors including: excessive emphasis given to structural diagnosis compared to the holistic clinical situation of the patient excessive prescription of bed rest; excessive prescription of surgical interventions; insufficient emphasis given to the functional, postural and psychosomatic aspects of the condition; insufficient importance given to prevention, to timely re-educational intervention and to active treatment (Thomas et al. 2004).

The assumption at the basis of the search for new multidisciplinary approaches is that back pain is not only influenced by its pathological nature (structural genetics and kinetic aptitudes) but also by psychological and social components: beliefs, psychological stress, patients' reaction to the condition (Ostelo et al.2006). One area of research has focused on the effectiveness of biofeedback techniques when there is no clear relationship between tissue damage and pain. In these cases the normal timeframes and techniques applied for healing tissue damage have demonstrated a tendency to be unsuccessful. The extreme subjectivity of the components comprising the genesis of the symptom (anatomical, neuro-physiological, psycho-social) have justified an approach that involves the construction of a taxonomical classification of both problem and patient in order to identify the appropriate therapeutic remedy (O'Sullivan 2005). Currently, modern therapeutic and rehabilitative concepts require a focus of attention not only on structural alterations, but also on the patient suffering from the pain, thus factoring in psychological, social and environmental factors and their relationship to tissue damage (Sherri and Rossignol 2006; Mombelli 2000; Affiatati et al. 2000; Andersson & McNeill 1989; Borman et al. 2003; McCracken 2002). It can also be claimed that the importance of social costs and the relationship between costs and benefits of potentially incongruous therapeutic approaches should not be underestimated (Korthals-de Bos 2003).

### **The utilisation of manual therapies**

The role of manual techniques has been the object of attention and study for many years with positive but controversial results if compared to other conventional and non conventional therapies (Assendelf et al. 2006; Aure et al. 2003; Macfarlane et al. 2006; Larsen et al. 2002; Hurwitz et al. 2003). The list of alternative therapies is a very long one: it goes from simple educational/informative intervention to techniques that need specific preparation (manual

therapy, exercises), to recent multidisciplinary approaches that have evolved from the nearly always positive experience of the spinal/structural schools. For unspecified back pain the European Guidelines recommend a brief treatment with manipulation and mobilization as therapeutic options.<sup>i</sup>

The literature provides ample evidence that intensive multidisciplinary bio-psychosocial treatment can improve pain and functional limitations in patients suffering from back pain (Guzman et al. 2006; Nordin et al. 2006). An integrated approach that also integrates an active phase for the patient is also encouraged in the acute phase.

### **NST (Neurostructural Integration Technique)**

Among the various "non conventional" proposals for the treatment of musculo-skeletal pain, NST has been practiced in Italy for over 10 years (Nixon-Livy 2000; Scognamiglio and Fortis 2004). The NST technique in Italy has been promoted by the writer and the Milan *Istituto di Psicomatica Integrata* [Institute of Integrated Psychosomatics] (*IPSI*)<sup>ii</sup> which, through its clinical and teaching activity, has become a national benchmark. This innovative technique that integrates various theoretical approaches such as osteopathy, cranio-sacral therapy and Chinese medicine, was developed by Tom Bowen in Australia during the late 1950s to early 1980s and elaborated on by Michael Nixon-Livy in the early 1990s for the treatment of back pain, neck pain, joint limitations, visceral disorders and neurovegetative disorders (orthostatic vasoregulation, perspiration).

The technique consists of the application of varying sequences of precise cross fibre rolling movements (called PRI-moves or proprioceptive rolling impulse movements) to pre-determined muscles, tendons, ligaments and nerves (in particular areas rich in neuromuscular

spindle cells and Golgi tendon organs). This application activates self-regulatory mechanisms within the neuromuscular, cranio-sacral and autonomic nervous systems. The sequence of stimuli proceeds in a hierarchical sense commencing at the sacro-lumbar spine prior to progressing to the thoracic and cervical spines and finally cranium. The stimulus may then proceed to the upper and lower extremities as presenting symptoms necessitate. The main aim of NST is to release the neuromuscular restrictions and compensations that underlie the pain condition. If release is not effected the technique provides for the stimulus of muscles, tendons, ligaments and nerves at deeper levels in subsequent sessions. The treatment is typically performed on a physiotherapist's massage table.

The work undertaken to date by Nixon-Livy and IPSI indicates that the number of sessions required to obtain a significant and sustainable reduction of symptoms varies from 2-6. Further relevant data including case study reports can be obtained from Nixon-Livy (2000) and from an initial research project (Scognamiglio and Fortis 2004). NST was initially applied in Australia where from the late 1950s to mid 1990s it was known as soft tissue osteopathy, an unofficial term coined by Thomas Ambrose Bowen its original developer. Although since the 1990s NST has been practiced with substantial success in Australia, Belgium, Canada, France, Germany, Hungary, Italy, Ireland, Israel, New Zealand, Portugal, Spain, Switzerland, United Kingdom and USA, there are no previous scientific publications on the subject registered by Pubmed.

### **MATERIALS AND METHODS**

In 2004 the Health Department of the Lombardy Region (Italy) instituted a funding programme for observational studies on the effectiveness of alternative therapies. IPSI participated in the programme through a pilot study undertaken in the Department of

Neuroscience of the *Ospedali Riuniti di Bergamo* [Bergamo Hospital]. The purpose of the study was to evaluate the effectiveness of the use of a new manual method (NST) in an integrated setting that included data obtained from research on patients' current quality of life.

An experimental clinic for the "Manual Therapy for Spinal Pain" attached to the Bergamo hospital was opened. Participants were obtained by referral from colleagues (mainly orthopaedic specialists, neurologists, neurosurgeons, family physicians), and individuals who agreed to try this type of treatment.

### **Inclusion criteria**

Subjects of both sexes, with chronic (longer than 12 weeks) or sub-acute (from 6 to 12 weeks) backache related to pain in different regions of the back, who had not responded to any other previous treatments. Subjects assuming NSAID, cortisone or minor analgesics, were included.

### **Exclusion criteria**

Pregnant women, subjects with tumours being treated with chemotherapy and/or radiotherapy, subjects treated with one or more psychotropic drugs and subjects already selected for surgery were excluded. Subjects currently being treated with morphine derivatives, muscular relaxants (that could alter the semiotic and symptomatic results), physiotherapy or other forms of non conventional therapies like acupuncture, osteopathy, etc. were also excluded.

### **Instruments for the measurement of objective data**

At the first meeting the participant's medical history and relevant clinical documentation were recorded. Participants were supplied with information about the treatment and the consent form for participation in the study.

Neurological and kinesiological parameters used to evaluate the participant's clinical condition were measured by the following tests:

ROM 1: Test that consisted in bending the torso forward while maintaining the lower limbs completely straight and then measuring the vertical distance between the tip of the middle fingers and the ground (Clarkson and Gilewich 1991).

ROM 2: "Straight leg lifting test" or "Lasegue test" - measurement of the vertical distance between the heel and the treatment table (Hoppenfeld 1985). This set of data was recorded but was not subject to analysis since only two participants presented a positive result.

ROM 3: Test of lateral bending of the torso while maintaining the frontal plane - measurement of the vertical distance between the tip of the middle fingers and the ground on each side (Clarkson and Gilewich 1991).

ROM 4: Neck rotation test - measurement of the distance from the tip of the chin and the lateral extremity of the acromioclavicular joint with immobilized shoulders, on both sides (Clarkson and Gilewich 1991).

Measurements were taken in centimetres. These values were collected in order to provide quantitative data on the improvement of functional limitations correlated to the symptoms.

The Participants' use of medication was recorded in each specific case.



### **Instruments for the measurement of subjective data**

The quantitative evaluation of pain was obtained by VAS (analogous visual in centimetres). For quality of life appraisal two generic evaluation scales were chosen: SEIQoL, a more subjective scale, with domains chosen by the participant (O'Boyle et al. 1992; Hickey et al. 1996; Nunnally and Bernstein 1994); and EURO-QoL (with preset domains), a scale that has been validated in the Italian language for some time, which also includes a VAS for the subjective perception of health, simply indicated as "subjective" value in the graph (The Euro-QoL Group 1990; Brooks 1996; Roset et al. 1999; Kind et al. 1999).

The evaluation scales were applied before treatment, at the end of treatment and on follow-up. They were not applied by the same physician who carried out the treatment.

### **Structure and development of the treatment**

Each participant who completed the study received five NST sessions. The clinical tests were carried out prior to the first session and after the last session. The clinical tests and subsequent subjective evaluations were repeated at the three month follow-up. Additionally, information regarding possible pathological manifestations and side effects as well as any pharmacological treatment received after the last session was gathered. Information was returned to participants and the referring professionals after the termination of treatment.

The response to treatment was measured through changes in the subjective and objective parameters. Recourse or otherwise to other therapies between the last NST session and follow-up was selected as a measure of comparison.

The study was carried out over a 20 month period: the clinic was opened in November 2004 and closed in July 2006.

### **Statistical analysis**

Statistical analysis was carried out using Epi info 3.3.2. For the analysis of the categorical variables the statistical significance was measured with Chi square 2-tailed, or, for frequencies less than 5, with the Fisher exact test. For numerical variables the means for comparison and evaluation were performed with the ANOVA test subsequent to the evaluation of the homogeneity of the samples being analysed.

## **RESULTS**

In total 39 participants were chosen (14 females and 25 males) with an average age of 47 years (range 28-80). All participants suffered from back pain, without instrumental evidence of anatomic lesions with or without other painful sites. 36 participants completed the therapeutic protocol but only 33 completed the study including the follow-up and they are the subject of the present analysis (see recruitment chart – Table1).

Of the three participants who did not complete the treatment, one withdrew from the study before commencing treatment, fearing side effects from the technique. Two participants left the study without completing the full course of treatment, one at the second treatment (did not consider worthwhile continuing on the grounds that there was no noticeable

improvement after the first treatment), one at the fourth treatment (decided to follow other options subsequent to emotional reaction).

The demographic characteristics and the clinical situation of the participants are described in Tables 1 and 2. Of the sample, 25 participants were undertaking different kinds of therapy at the time of joining the study: six with NSAID, one with cortisone, three with minor analgesics, 15 with non conventional therapies (herbs, homeopathy, salts, flowers of Bach, acupuncture) while eight participants (24.2%) were not undertaking any therapy. Only six participants were still using therapy at follow-up (as specified in Table 2).

The principal outcome of the study is the reduction in the number of participants in the sample receiving other types of treatment. At the commencement of the study 24.2% of participants were not receiving any treatment. At follow-up the percentage of participants not receiving other types of treatment had increased to 81.8%. For this outcome, the statistical analysis demonstrates a non-significant association between the characteristics of the participants and the results achieved. The unvaried analysis showed statistical significance only for age (tendency to better results for participants under 50) and the length of time suffering from pain (better responses from participants who had been suffering from pain for less than 24 months).

**Table 1**

		<b>Number of participants</b>	<b>Percentage</b>
		36	
<b>Age</b>	<b>Average age</b>	47	
<b>Educational qualifications</b>	<b>0 = without diploma</b>	16	44.4%
	<b>1 = diploma or degree</b>	20	55.6%
<b>Martial status</b>	<b>0 = married</b>	24	66.7%
	<b>1 =non married</b>	12	33.3%
<b>Description of pain</b>	<b>Cephalalgia</b>	10	
	<b>Cervicobrachial</b>	27	

<b>symptom</b>	<b>Lumbosciatalgia</b>	30	
	<b>Other</b>	15	
	<b>Mixed</b>	29	
<b>Localisation of pain</b>	<b>0 &lt;= 2 pain sources</b>	25	69.4%
	<b>1 &gt;2 pain sources</b>	11	30.6%
<b>VAS</b>	<b>1 = 0-3 light</b>	5	13.9%
	<b>2 = 4-6 medium</b>	15	41.7%
	<b>3 = 7-10 serious</b>	16	44.4%
<b>Duration of symptoms</b>	<b>0 = &lt; 24 months</b>	15	41.7%
	<b>1 &gt; 24 months</b>	21	58.3%
.....	<b>Completed treatment</b>	36	
	<b>Completed treatment + Follow-up</b>	33	

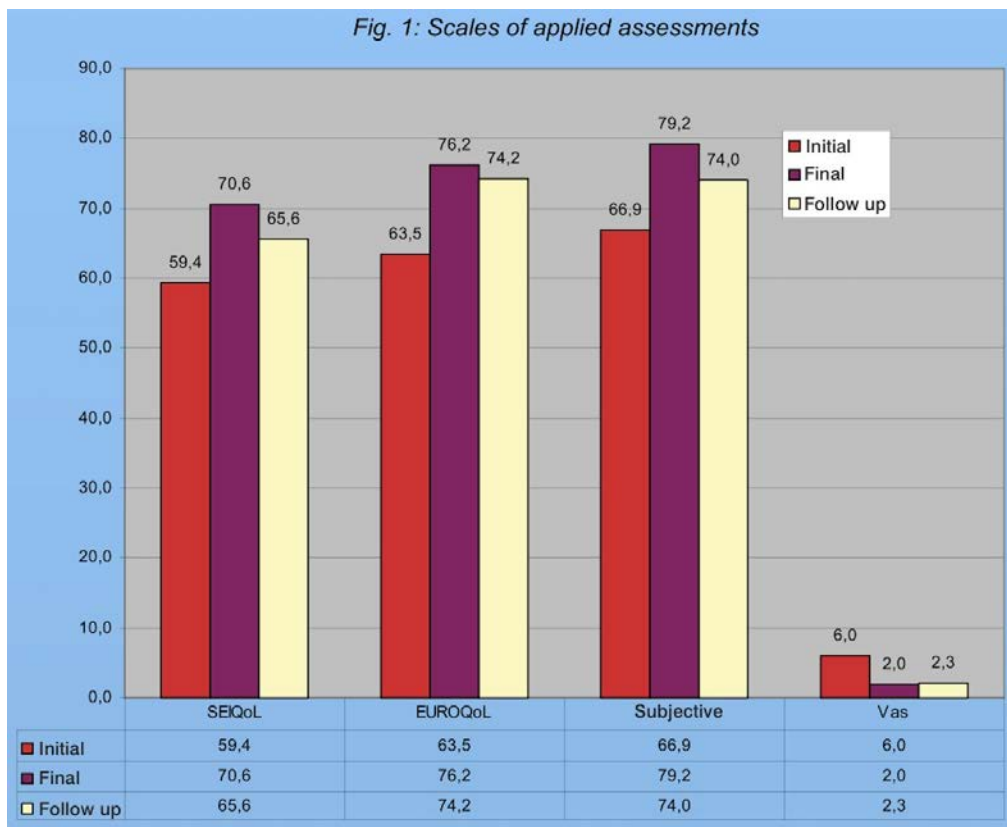
Table 2

		<b>Number of participants</b>	<b>Percentage</b>
<b>Therapy being undertaken at time of joining study</b>	<b>NSAID</b>	6	
	<b>Cortisones</b>	1	
	<b>Minor analgesics</b>	3	
	<b>Non conventional therapies</b>	15	
<b>Prior therapies undertaken</b>	<b>Pharmacological</b>	15	
	<b>Conventional physical</b>	28	
	<b>Non conventional physical</b>	22	
	<b>Other</b>	3	
<b>Instrumental investigations</b>	<b>Specialist</b>	26	
	<b>Family physician</b>	25	
	<b>Functional</b>	5	
	<b>Other</b>	7	

Figure 1 shows an improvement in the whole sample with respect to evaluation scores obtained before commencing treatment. The ANOVA shows significant variations ( $p < 0.01$ ) for all the scales when comparing the initial data with data obtained on termination of treatment and at follow-up where a slight decrease in the value of all the measured scales can be observed. The slight deterioration in terms of benefits for the participants at follow-up compared to the end of treatment values is not statistically significant but it appears in all evaluation scales.

The sample was divided into two groups in accordance with the achievement of the first outcome (no pharmacological therapy between the end of the treatment and follow-up). A certain degree of subjective improvement in the scores of the scales was observed even in the sub-group of participants who did not complete the first stage. Given the limited number of participants this datum is not significant from a statistical point of view so it has not been represented in the graph. The progress of participants classified into categories was observed, as shown in the schedule. In the analysis, only age (best results for patients under 50 years of age) and duration of pain (best response in the group of subjects with duration of pain less than 24 months) provide results within the limits of statistical significance.

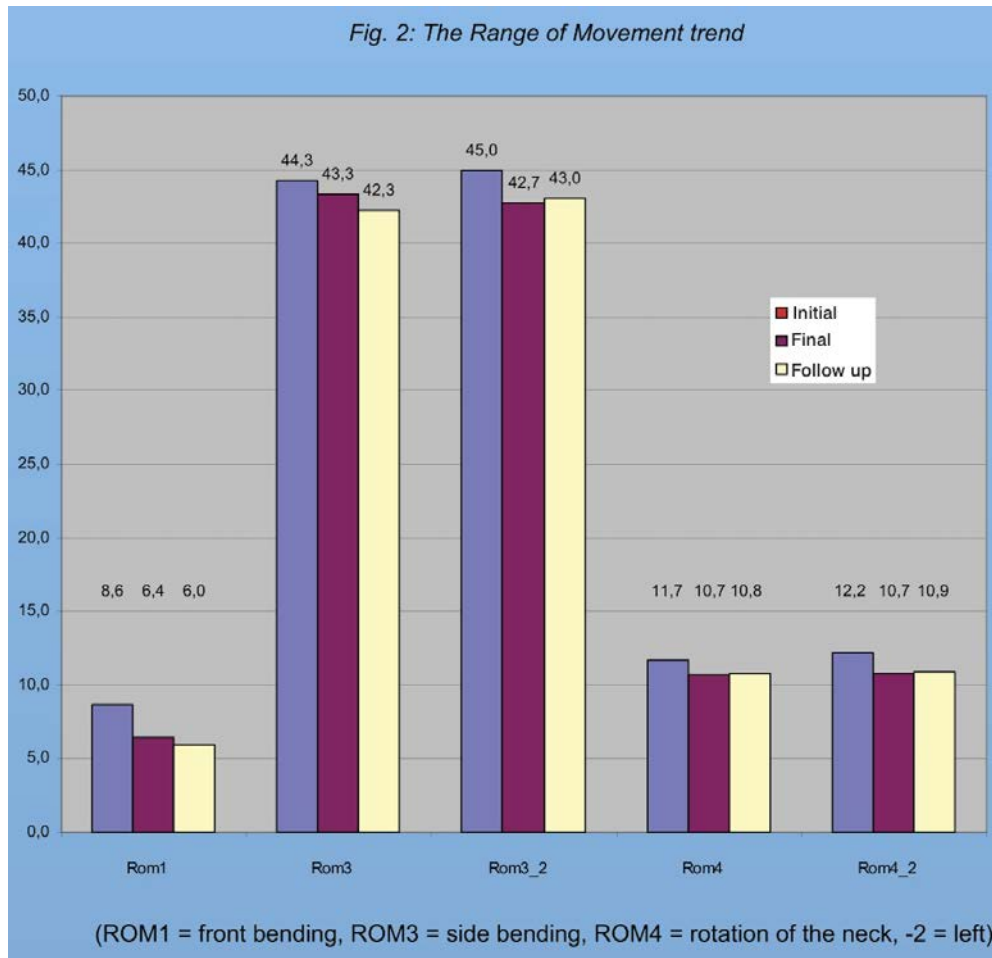
**Figure 1 Evaluation scores applied**



(\*) The unit measure of the EUROQoL scale was divided by 10 to make the graph more uniform in presenting the differences.

With regard to the measurement of "objective" results (measurement of the Range Of Motion) all participants demonstrate a constant improvement in performance averages even if not statistically significant. Figure 2 shows the improvement in mean Range of Motion.

**Figure 2: Change in Range of Motion**



The suffix \_2 after the specified Rom indicates “on the left side”. Absence of suffix indicates right side.

## DISCUSSION

Despite the absence of a control group, the statistical analysis has shown significant results.

A good result can be observed in terms of the reduction in the application of pharmacological therapies. In fact, 81% of participants did not resort to medication between the end of the

cycle of NST sessions and follow-up, compared to 24.2% at the beginning of the cycle. This datum is interesting considering the widespread application of pharmacological therapies before the commencement of treatment. It can be observed that while the pain VAS shows a statistically significant score reduction after the application of the therapeutic protocol, the various ROM tests show less definitive and not statistically significant results with respect to VAS. It is not possible, at this point, to provide a precise clinical explanation for the objective improvement shown by the increase in Range of Motion, nor does the study present a large enough sample to ascertain whether the ROM results are meaningful. These data however suggest the working hypothesis that even a small improvement in degree of mobility can, in itself, be an excellent clinical result that explains the marked reduction in VAS.

With regard to the statistically significant improvement in the mean value of the result on the scale that expresses the subjective perception of the quality of life, a linear correlation can be noticed by comparison to pain VAS.

SEIQoL has shown a less linear behaviour related to VAS improvement with respect to the other scales of self-evaluation of the quality of life (EUROQoL and health VAS). This datum is particularly interesting given the peculiarity of SEIQoL in which the five fields of self-evaluation can change over time – at each stage the participant was free to choose ranges already expressed or new ranges by which to self-evaluate. The SEIQoL categories and their importance in the determination of the quality of life are chosen in relation to personal life priorities. Consequently this datum is probably influenced by participant strategies of subjective adaptation to the problem. The analysis of the meaning that a scale presenting a greater degree of subjective liberty can have in the evaluation of clinical improvement in

patients with skeletal and/or muscular pain will need to be undertaken through a qualitative evaluation of the selected SEIQoL fields.

Although it was not possible to significantly correlate some of the clinical variables obtained from the anamnesis of the sample with clinical improvement (and thus not possible to predict which categories of patients would probably present a better response to NST treatment), it is possible to claim that NST has not caused any clinical worsening. Rather, it has provided important clinical improvements for the whole sample. The clinical importance that can be attributed to this manual technique in relation to an integrated setting that combines the theme of pain with that of the quality of life remains an open question.

The quality analysis of the SEIQoL answers has shown an increase in the “self care” and “free time” areas and a decrease in the “relationship” area during treatment. Relationships became more important again at follow up: it seems that more attention is paid to self during treatment and more interest is displayed in others once health improves.

Although NST has been used for 50 years and has been systematised over the past 13 years, it has not had to date substantial exposure in medical literature. However, the application of NST in an integrated setting that includes the collection of information about quality of life has demonstrated encouraging outcomes in back pain treatment. Irrespective of the therapeutic principle that has brought about the result, the result is a statistically significant one. An additional working hypothesis is that the reduction of pain and the improvement of the quality of life have a linear correlation with increase in somatic "flexibility".



The slight decrease in improvement values, without loss of statistical significance, observed after the termination of treatment (see Figure 1) demonstrates a discrete maintenance of benefits obtained. Further evaluation one year after the termination of treatment in order to determine long term maintenance could prove a worthwhile exercise. The question remains whether there is an appropriate time to repeat the treatment in the sense of maintaining the benefits obtained, without the need to resort to other therapies.

Further larger scale randomized studies with a control group are required in order to better define these variables.

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