Castellano Tejedor, Carmina; Costa Requena, Gemma; Palacios, Pilar Lusilla; Palacios González, Ana; Camprubí Roca, Laura; Ginés Puertas, Alex; Barnola Serra, Elisa
A Multidisciplinary Approach for Patients with Non-specific Chronic Low Back Pain: Study Protocol and Preliminary Findings
Universidad de Almería
Almería, España

Available in: http://www.redalyc.org/articulo.oa?id=56041784009
A Multidisciplinary Approach for Patients with Non-specific Chronic Low Back Pain: Study Protocol and Preliminary Findings

Carmina Castellano Tejedor*, Gemma Costa Requena, Pilar Lusilla Palacios
Hospital Universitari Vall d’Hebron, Universitat Autònoma de Barcelona, España
Ana Palacios González, Laura Camprubí Roca, Alex Ginés Puertas, Elisa Barnola Serra
Hospital Universitari Vall d’Hebron, Barcelona, España

ABSTRACT

Non-specific chronic low back pain is a frequent cause for disability and a recurrent cause for medical consultation with high costs to public health. Although physiotherapy usually reduces disability and pain-related anxiety-depressive symptoms, many patients still report partial improvement and recurrent and disabling pain episodes. Therefore, a new approach to rehabilitate chronic low back pain that includes other modulating psychosocial factors is necessary. This article presents preliminary findings from the chronic low back pain study protocol (N= 71; Clinical Trials Reference NCT01993355) aimed to assess the effects on patients’ health-related quality of life of two complementary interventions to standard physiotherapy (n= 22); sophrology (n= 26) and cognitive-behavioral group intervention (n= 23). After 6 months, intervention groups showed no improvements in any of the variables assessed. Only the control group showed lower mean scores for self-perceived pain. Characteristics of the interventions (e.g. specific contents, abilities trained, intensive planning, group format, etc.) could explain these counterintuitive results. More research is needed to investigate the efficacy, efficiency and specific characteristics of multidisciplinary interventions that better address the needs of this population with chronic low back pain.

Key words: chronic low back pain, quality of life, physiotherapy, cognitive-behavioral therapy, sophrology.

Novelty and Significance

What is already known about the topic?
• Pain is a complex phenomenon that involves physical and psychological factors. Chronic low back pain is one of the leading causes for sick leaves in Europe that generates high costs for both the individual and the medical system.
• Most treatments have failed to rehabilitate and recover functional restoration of these patients at long-term.
• Multidisciplinary approaches have shown to be more effective to reduce pain recurrence.

What this paper adds?
• This paper presents a well-integrated multidisciplinary functional restoration program, aimed to reduce pain related disability and increase health-related quality of life.

Pain is a complex phenomenon resulting from the interaction of sensory, cognitive and affective components. Pain has been a central theme in health sciences’ research, since it is one of the most common causes of disability and also one of the main reasons that most frequently lead the individual to seek medical assistance. It is a fact that its study and its proper management could reduce socio-economic costs and human suffering. In Europe, more than 400 per 10000 registered patients consult for low back pain. All age groups and both genders are affected; however, it is more prevalent in people 45-64 years and among women (Itz, Geurts, van Kleef, & Nelemans, 2013; Juniper, Le, & Mladsi, 2009). Low back pain pathogenesis can be diverse: organic, non-specific etiology and psychological causes.

* Correspondence concerning this article: Carmina Castellano-Tejedor, Departamento de Psiquiatría, Hospital Universitario Vall d’Hebron, CIBERSAM, Paseo Vall d’Hebron 119-129, 08035 Barcelona, España. Email: ccastellano@vhebron.net
Considering the underlying organic causes of low back pain, two differentiations can be made: 1) malignant (neoplastic) and 2) non-malignant etiology (musculo-skeletal and neurological): e.g. osteoporosis, fractures, infections, structural deformity, inflammatory diseases, nerve root compression or cauda equine syndrome. Although 15% of low back pain cases are often related to specific causes such as those described above, 85% of the remaining cases are of non-specific etiology, with pain not attributable to any of the above-mentioned pathologies. Non-specific chronic low back pain (CLBP) refers to low back pain not attributable to a recognizable, known specific pathology (e.g. tumor, infection, fracture, osteoporosis, structural deformity, inflammatory disorder, radicular or cauda equine syndrome) that persists for a period >3-6 months (Balagué, Mannion, Pellisé, & Cedraschi, 2012). The International Association for the Study of Pain (1979) also describes it as an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.

Some authors (Balagué et al., 2012; Rozenberg, 2008) have highlighted several individual and psychological factors as key elements inducing the pain to become chronic. In this sense, several psychological factors have shown to be related to pain perception: 1) thoughts and emotions that can directly influence physiological responses (such as psychological distress, somatic reactions, etc) and 2) cognitive-behavioral variables that can modulate pain perception, management and coping (such as feelings of helplessness or catastrophism that can increase pain perception, whereas self-efficacy and social support can decrease it); (Martínez Pintor & Durany Pich, 2010).

The “Pain Gate Control Theory” addresses pain perception considering three dimensions: 1) the sensory-discriminative dimension, 2) the motivational-affective dimension, and 3) the cognitive-evaluative dimension (Melzack & Wall, 1965). The sensory-discriminative dimension is the physiological entry of inputs and determines the amount and the quality of sensory stimulation that generates the experience of pain. The motivational-affective dimension characterizes pain as unpleasant and aversive, favoring emotional responses to escape or avoid noxious inputs. Finally, the cognitive-evaluative dimension is responsible of integrating pain experience as a whole. Integration occurs at the cortical level and involves superior processes such as attention, memory, and other complex cognitive processes like appraisal or beliefs. This latter dimension adds the individual subjectivity to the experience of being in pain. In short, the final perception of pain has an onset in sensory stimulation, an intermediate affective-motivational modulation, and a superior integration that grants subjectivity to the experience. Thus, psychological variables not only act as a reaction to the symptom, but are an essential part of the experience of pain. In this sense, mood states and emotions (e.g. anxiety and depression) as well as cognition (e.g. attention, memory or cognitive patterns) are the most studied psychological variables in relation to perceived pain. Therefore, a psychological approach with CLBP patients is fully justified (Osborne, Raichle, & Jensen, 2006; Rodríguez Franco & Cano García, 2001).

The concept of pain has evolved over the years, but currently, there is great consensus in considering it as a multi-dimensional, complex and subjective phenomenon that includes psychological factors as intrinsic dimensions (Quintner, Cohen, Buchanan, Katz, & Williamson, 2008). Consequently, when speaking about CLBP management,
the biopsychosocial approach should be preferred over more simplistic ones (Rodríguez Blanco, Fernández San Martín, Balagué Corbella, et al., 2010). This approach focuses on a multidimensional comprehension of the individual, his/her health and its determinants. Based on this approach, other psychosocial therapies in combination with standard physiotherapy have started to be considered when rehabilitating and treating CLBP. In all cases, the goal is the same: to reduce the impact of chronic pain in people’s life and to promote their health-related quality of life (HRQoL).

In this sense, some studies have used relaxation techniques (not based in medication) to decrease pain perception and to foster well-being in CLBP patients. Sophrology is a specific relaxation technique that involves body and mind exercises (Badra, 1970; Manna, 1981). Sophrology is a structured method that usually combines physical exercises (such as muscle relaxation, deep breathing, simple body movements, etc) with other psychological techniques (such as concentration, visualization, or “scanning the emotions and intern states”). Its philosophy is to consider the person as a whole, body and mind, from a holistic approach (Badra, 1970). Its final purpose is to foster well-being in the individual through these corporal integration exercises. Nevertheless, there are scarce studies assessing its effectiveness in reducing CLBP symptoms and, as far as we know, no studies have compared this technique to other approaches such as cognitive-behavioral group therapy (Tocheport, 2012).

Cognitive-Behavioral Therapy (CBT) has been extensively used in chronic pain as co-adjuvant intervention of physical and medical treatments. Most of the studies have proved its efficacy to reduce pain perception and increase HRQoL and well-being among patients (Lamb, Hansen, Lall, et al., 2010; Lunde, Nordhus, & Pallesen, 2009; Morley, Eccleston, & Williams, 1999). But still some discrepancies exist, and not all the studies have proved its efficacy in reducing pain or fostering HRQoL (Du et al., 2011).

In spite of these gaps and contradictions in scientific literature, an increasing body of research suggests the potentialities of multidisciplinary psychosocial approaches (such as relaxation therapies/sophrology, CBT and motivational interviewing techniques) combined with standard medical treatment (that is, physiotherapy and pharmacy) in achieving better short/mid-term results on perceived pain reduction and better HRQoL (Du, Yuan, Xiao, Chu, Qiu, & Quian, 2011; Heapy, Stroud, Higgins, & Sellinger, 2006; Rodríguez Blanco et al., 2012; Vong, Cheing, Chan, So, & Chan, 2011). Therefore, it seems necessary to provide empirical evidences in this field, which will facilitate a better clinical management for this population. This article presents the CLBP study protocol of the Hospital Universitari Vall d’Hebron. The aim of this study is to compare three intervention groups and try to explore which approach helps better to improve CLBP patients’ HRQoL and reduce their perceived pain and pain-related disability.

**METHOD**

**Participants**

The study sample will be selected from the patients’ waiting list to start rehabilitation therapy (physiotherapy) for CLBP in the therapeutic area of the previously referred hospital. Three different groups will be set up according to their position in the...
waiting list (non-random selection): the first 22 consecutively patients in the waiting list will be part of the “control group”, the following 22 patients in the waiting list will be part of the “intervention group 1-sophrology” and the next 22 patients will constitute the “intervention group 2-CBT”. All patients will be telephonically approached by the main researcher of the study. Due to the existing waiting list of patients and human resources as well as space limitations (availability of the therapeutic area), not all the intervention could be running at the same time. Therefore, the order of patients in the waiting list will be respected to start interventions.

In this initial contact study objectives and procedures will be explained to potential participants. If they agree to participate, an assessment appointment will be set up. If they are not willing to participate in the study, they will continue with their standard physiotherapy program according to the regular schedule of the therapeutic area. Inclusion criteria for patients are: (1) non-specific CLBP diagnosis -meaning, low back pain of variable intensity ≥6 months of evolution not attributable to specific causes- and (2) age between 18-80 years old both genders included. Exclusion criteria for patients are: (1) specific CLBP, (2) patients previously treated with physiotherapy and/or surgery for CLBP, (3) cognitive impairment (MEC ≤23 points), (4) not stabilized psychiatric disorders (e.g. psychosis), (5) not treated psychopathological disorders (e.g. depression (BDI >15 points), etc), (6) addictive behaviors (DAST-10 ≥3 points); (Bedregal et al., 2006), alcoholism or other drug abuse (e.g. opiates and/or benzodiazepines), (7) fibromyalgia and/or chronic fatigue and (8) other serious physical comorbidities (e.g. morbid obesity, severe cardiomyopathy, etc).

Approval of the authority legally representing the centre and ethics committee of the Hospital was obtained. There are no foreseeable risks to participating in this study. For each eligible subject a written informed consent will be requested (Marks, 2010). The research complies with the Helsinki Convention norms and its subsequent amendments.

**Instruments**

Medical (psychological and medical history, substance use/abuse, physical exploration of CLBP) and demographical data (gender, civil status, socioeconomic status and academic level) will be collected in a semi-structured interview as well as the following data:

- **As primary outcome measure** The Short Form-12 items version 2 (SF-12v2) questionnaire was used to measure HRQoL including items from various physical and psychological domains: Physical functioning, role limitations because of physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations because of emotional problems, and mental health. Responses are scored from 0 to 100 (M= 50, SD= 10) and the Physical Component Summary (PCS) scale and the Mental Component Summary (MCS) scale were calculated. Higher scores indicate better HRQoL (Alonso, 2002; Rebollo, 2008; Vilagut, Valderas, Ferrer, Garín, López García, & Alonso, 2008).

- **As secondary outcome measures** a visual analogue scale was used (from 0= No pain to 10= an unbearable pain) to rate intensity of perceived pain; The Oswestry Disability Index (ODI) for CLBP (Oswestry Low Back Pain Disability Questionnaire) was used to measure patients’ impairment and pain-related disability (e.g. how badly pain has affected his/her life) (Fairbank, Couper, Davies, & O’Brien, 1980); The State-Trait Anxiety Inventory (STAI) was used to screen and measure trait and state anxiety.
(Spielberger, Carretero Dios, de los Santos Roig, & Buela Casal, 2002); and the Beck Depression Inventory short-form (BDI) was used to screen and measure characteristic attitudes and symptoms of depression (Nuevo, Dunn, Dowrick, et al., 2009).

**Procedure**

The study will comprise the following stages:

1. **Pre-intervention assessment** (Baseline): Pre-intervention measures for the whole sample.

2. **Intervention** (see Table 1):
   - **Control group** (treatment as usual): a program of standard low back pain physiotherapy will be offered to all patients included in this group, according to current protocols in the reference hospital. Physiotherapy will be lead by one physiotherapist and the program will include educational, physical, manual and movement therapy exercises (flexibility, low-to-moderate muscular exercises, etc.), aimed to improve patients’ functional capacity and reduce disability (e.g. to recover daily routines, return to work, be able to manage with housework, to walk or step stairs, etc.).
   - **Intervention Group 1**: A combination of physiotherapy and relaxation techniques-sophrology program of exercises will be offered in this group by one experienced physiotherapist specialized in relaxation techniques and sophrology. Sophrology consists of a set of physical and relaxation exercises that include breathing methods, visualization, modification of states of consciousness, etc., with the ultimate goal of enhancing balance between body and mind, improve HRQoL and well-being, and reduce perceived pain intensity.
   - **Intervention Group 2**: A combination of physical therapy and CBT will be offered in this group. CBT (in combination with motivational interviewing techniques) is aimed to facilitate psychological adjustment, coping, and foster self-management of CLBP and related psychological symptoms, with the ultimate goal of increasing patients’ HRQoL and well-being. The CBT intervention will be lead by one clinical psychologist and one psychiatrist as co-therapist.

3. **Post-intervention assessment**: Follow-up measures for the whole sample will be scheduled at 6 months after the end of treatment.

**Design**

The main objective of this study will be to assess the effects on CLBP patients’ HRQoL (SF-12v2) of three specific interventions, standard physiology intervention, relaxation techniques/sophrology intervention (group 1), and CBT in combination with motivational interviewing principles (group 2). It is hypothesized that groups receiving these complementary interventions (intervention groups 1 and 2) will significantly improve the self-management of their pain and this will facilitate a decrease in perceived pain and improvements in HRQoL. A pre-post longitudinal design will be carried out. The main outcome variable will be HRQoL (SF-12v2). The project will be performed in three stages: first, the assessment of the initial (pre-intervention) sample; second intervention; and third, follow-up assessments at month 6 after the end of each intervention.

**Data analyses**

Accepting an alpha risk of 0.05 and a beta risk of 0.2 in a bilateral contrast, it takes 22 subjects in each group to detect a minimum difference of 10 points between
two groups, assuming that there are three groups and a standard deviation of 10 in the main variable mean values (HRQoL assessed with the SF-12v2). Thus, it is necessary to recruit a minimum sample of 66 participants who met inclusion criteria. They will be subsequently assigned to each group (control group, intervention group 1 and intervention group 2) according to their position on the waiting list to start physiotherapy.

Data will be analyzed using the statistics package PASW. To describe the sample, the variables will be subject to descriptive analysis (frequencies, central tendency and dispersion measures). The main variables (primary and secondary measures) will be subject to comparative analysis according to the intervention period group (baseline/pre-intervention vs. post-intervention at 6 months) and regression models will be performed with the two dimensions of HRQoL as dependent variables and the rest of the factors measured as independent variables (VAS for pain, ODI, STAI and the BDI). The factor “hours per intervention” will be controlled for these analyses.

**Results**

A total of 93 patients were approached to participate in the study. Among them, 22 (23.65%) did not participate. Attrition was due to voluntary discharge from the rehabilitation services. Finally, 71 patients (76%) participate in the study and were randomized to the different groups. The demographic information as well as medical data is summarized in Table 2.

Overall and considering the three studied groups altogether (N= 71), statistically significant differences after the different interventions were found. Although the self-perceived pain decreased significantly (M= 6.55, SD= 1.88, range= 2.5-10 vs. M= 5.64, SD= 2.65, range 0-10; p= .012), the physical component (PCS) of HRQoL decreased (M= 37.26, SD= 9.18, range= 18.23 to 56.44 vs. M= 34.02, SD= 9.88, range= 12.33 to 60.18; p= .008) and increased the disability mean scores evaluated by means of the Oswestry scale (M= 24.06, SD= 6.90, range= 13-43 vs. M= 26.45, SD= 7.98, range= 11-49; p= .024) and both the state anxiety (M= 14.84, SD= 10.15, range= 0-47 vs. M= 23.45, SD= 12.91, range 5-58; p<.000) and trait (M= 30.17, SD= 11.17, range= 10-62 vs. M= 33.21, SD= 12.04, range= 13-69; p= .003).
Comparison between groups showed no significant differences for any of the studied variables post-intervention but significant differences were found for baseline’s mean scores for self-perceived pain \( (F_{(2,70)} = 3.212; p = .046) \), mean scores for the PCS \( (F_{(2,70)} = 3.454; p = .037) \) and the disability scores’ measured by means of the Oswestry scale \( (F_{(2,70)} = 6.742; p = .002) \) being the control group the one with worse scores on all these variables at baseline. Descriptive scores for the three groups and differences intragroup pre and post intervention are displayed in Tables 3-5.

**Discussion**

This study is intended to investigate whether groups of CLBP patients receiving physiotherapy plus other psychosocial intervention such as sophrology or CBT, had better prognostic implications in perceived pain, functional impairments and HRQoL. In this article, preliminary findings at 6-months follow up are presented.

Contrary to expectations, at this specific 6-month follow-up period, both intervention groups showed higher post-intervention scores in anxiety (state and trait),
Castellano Tejedor, Costa Requena, Lusilla Palacios, Palacios González, Camprubi Roca, Ginés Puertas, & Barnola Serra

We believe this may be explained because the interventions (both relaxation therapy and CBT) were focused on training the identification and expression of emotions, pain perception and interference of pain in everyday life. All these introspective therapeutic activities can lead to an initial increased awareness of chronic pain and its implications. Therefore, intervention groups could score higher in variables directly related to such variables and have a deeper experience of suffering from and living with pain during the intervention phase (Heapy et al., 2006; Lamb et al., 2010). It is also hypothesized that this first therapeutic approach (CBT and RT-S) served to increase self-awareness and encourage the expression of their problems, but this could not have been enough to learn how to manage and integrate all the resources to obtain substantial improvements.
over their HRQoL and general well-being (Osborne et al., 2006). Additionally, the effectiveness of CBT in CLBP is still under study and several systematic reviews in this field showed contradictory results (Du et al., 2011; Morley et al., 1999).

Therefore, considering our preliminary findings, our hypothesis is not empirically supported. Thus, more research is needed to further investigate on the efficacy, efficiency and specific characteristics of the multidisciplinary intervention that better address the needs of this population with CLBP. However, it is worth mentioning that these are preliminary findings at 6-months after the end of the interventions and still a year follow-up assessment must be carried out to longitudinally study the mid/long term effects of this program.

If long-term results support our hypothesis, it is expected that this multidisciplinary approach would benefit not only patients themselves but society in general, significantly reducing public health costs associated to the treatment and rehabilitation of pain (e.g. less ER consultations, less drug prescriptions, etc.).

Taking into account that CLBP is a severe health problem of multifactorial etiology (biopsychosocial factors) a multidisciplinary approach should be always preferred but empirically evidences of its efficacy and efficiency are required (Du et al., 2011). We believe our study could serve to design more comprehensive and effective treatment programs for CLBP with potentially better outcomes at mid/long-term. The interventions proposed will be aimed not only to relief the symptoms of pain, but to reduce disability, to train patients’ pain self-management, to foster well-being and HRQoL and to prevent secondary complications. Use of other kinds of health practitioners to implement the intervention may be more practical and cost-effective since different variables are considered. It will be important for future studies to investigate the specific cost-effectiveness of such interventions as well as to the long-term impact, before exporting them into other settings in which other kind of chronic pain diagnosis are made.

An important advantage of this study is its multidisciplinary approach. It is focused not only in the physical variables of pain but in the psychological and motivational ones. By doing this, we design a holistic and integrative framework to treat and rehabilitate pain and we focus our target in the individual through a patient-centred approach that will foster patients’ self-management of pain and related limitations.

**References**


Received February 21, 2014
Final Acceptance July 21, 2015