

*“PILOT STUDY TO COMPARE THE EFFECTIVENESS OF A  
MINDFULNESS SELF-COMPASSION INTERVENTION  
VERSUS A COGNITIVE-BEHAVIOURAL INTERVENTION TO  
IMPROVE SELF-CARE AND QUALITY OF LIFE  
IN A CHRONIC PAIN SAMPLE”*

**Date:** 1<sup>st</sup> February, 2017

## **STUDY PROTOCOL**

**Title: “Pilot Study to Compare the Effectiveness of a Mindfulness Self-Compassion Intervention Versus a Cognitive-Behavioural Intervention to Improve Self-care and Quality of Life in a Chronic Pain Sample”**

**Date:** 1<sup>st</sup> February, 2017

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## **SCIENTIFIC BACKGROUND**

Between 10-23% of people suffer of chronic pain in our country (1,2). In Spain, the duration and intensity of pain is higher than in the rest of European countries (2). The most important issue is the impact of chronic pain on life of the millions of people who suffer this condition and their relatives. Chronic pain is an important health problem, and it is frequently associated to great emotional distress, physical and social impairment, and reduction of quality of life. 29% of people with chronic pain come to have depression (2).

Pain is a bio-psychosocial phenomenon, and we must approach to chronic pain with this frame. The International Association for the Study of Pain defines pain as “a sensitive and emotional disturbing experience, which is associated to a real or potential tissue injury, or that it is describe as caused by this injury”. Chronic pain is a multidimensional phenomenon, which implies physical states and psychological variables. Pain has an affective and sensorial dimension, and it is frequently accompanied by the desire to stop, reduce or scape from its presence (4).

Chronic pain has not a protective function, as acute pain has. Chronic pain is a nosological entity itself, produces null functionality, and it is frequently physically, psychologically and socially destructive.

The holistic view of the phenomenon of pain implies a multidisciplinary intervention, in which physician, social workers, psychologist, physiotherapist... cooperate. Nonetheless, this kind of multidisciplinary intervention is not well implanted in our country yet.

The definition of chronic pain by the International Association for the Study of Pain meant a change regarding previous definitions, introducing two new concepts: first of all, it considers that pain is not just a nociceptive experience, but that it is also integrated by emotional and subjective components; and moreover, that pain may exist without somatic cause.

Memory, emotions, thoughts and expectations influence how the person perceives pain. Cerebral regions implied in emotion also participate in neural circuits that control directly the pathways of pain (5).

General experience is that pain comes to occupy a central place in life of the person who has it. Attention is permanently focused on the painful sensation. Attention processing is altered and is involved in the chronic pain syndromes pathogenesis.

The emotional state regulates pain, and also produces cognitive biases, and it is related to poor cognitive flexibility and experiential avoidance, which dominates the experience of the individual. Psychological flexibility is associated to lower pain intensity and lower interference of the pain in daily life, also to lower anxiety and depression and to better physical and mental functioning (6).

It has also been found a higher tendency to process pain situation as with lack of control, with tendency to rumination, consequences magnification and negative expectations. This processing style has been named "catastrophising". The use of passive coping strategies is associated to higher pain, worse functioning and negative mood (7). People who use active coping strategies to cope with pain have better functioning.

Another interesting psychological construct to the management of pain is "mindfulness". Mindfulness is defined as a "non-elaborative awareness, without judgement, focus on the present moment, with total acceptance of each thought, sensation or emotion that emerges in the attention field". Applied to the fear avoidance model, responding to pain with a "mindful" approach leads to a better mood and functioning.

Different groups of chronic pain patients share the same cognitive mechanisms of maladaptive coping with pain, as "catastrophising", and pain anticipation, as well as similar central mechanisms and neural networks of pain anticipation, which suggests that up-down processing is shared in different types of pain. This suggests the existence of common cerebral mechanisms and cognitive functioning in different types of chronic pain. Because of that, it is important to carry out studies that recruit patients according to their levels of maladaptive functioning, mental suffering and pain interference in daily life, and not according to the type or anatomy of pain or tissue injury.

Psychological treatments for chronic pain has been developing since the 60s: behavioural therapy, cognitive therapy, "third wave therapies" (Acceptance and Commitment Therapy and Mindfulness". It is common to find programs with multiples components: stimulation, graduate exercise, mindfulness, and coping strategies... (8). In general, clinical guidelines based on evidence for fibromyalgia recommend multicomponent treatments (8).

Cognitive-behavioural approaches to chronic pain have been the predominant psychological treatments in the last 30 years. These approaches focus on create a cognitive and behavioural change in order to help the person with chronic pain to suffer less, cope better and use less medical services for his/her pain. These programs look for reducing pain by modifying physical sensations, catastrophising thoughts and maladaptive behaviour (9).

Recent meta-analysis reveal that Cognitive-Behavioural Therapy (CBT) has a beneficial effect on the standard patient, in a wide range of outcomes measures. CBT for chronic pain is a therapy with evidence and empirical support. However, CBT benefits to chronic pain are not as big and

general as they could or should be, having only a small size effect on disability. Not all patients respond to CBT (9). Moreover, much of the benefits are not maintained in the long term (8). Because of that, other types of interventions are appearing in order to try to demonstrate their effectiveness and cover the limitations of CBT. Among these new interventions we can find “Third wave therapies”, as Acceptance and Commitment Therapy (ACT) and Mindfulness-based therapies. ACT focuses on promoting psychological flexibility. It implies conscious acceptance and no judgement of the experiences, personal values identification and appropriate action to the goals sustained by these values. Until the date, it exists randomized clinical trials that demonstrate the effectiveness of ACT for chronic pain (10). Although ACT, Mindfulness-Based Stress Reduction programs (MBSR) and Mindfulness-based Cognitive Therapy (MBCT) can be distinguished by their theoretical assumptions, they share common basic concepts as acceptance and mindfulness. Recent meta-analysis conclude that therapies based on acceptance and mindfulness for chronic pain produce low to moderate size effects similar to those achieved by CBT (11).

Mindfulness improves emotional regulation, decreases experience avoidance and fear, modulates pain perception and stimulates structural and functional cerebral changes toward a better adaptation to pain. Mindfulness-based interventions have demonstrated their effectiveness to manage chronic pain in many studies (12).

The construct “self-compassion” is currently acquiring attention in the investigation due to its strong link to psychological health (13). However, investigation on self-compassion is still taking its first steps; and most investigation has been carried out with no clinical population. “Self-compassion” concept means “be touched by the own suffering”(12). Self-compassion can be understood as a useful strategy for emotional regulation in which painful feelings are not avoided but taken into account with consciousness, kindness, understanding and a common humanity feeling.

Mindfulness in the context of self-compassion implies to be aware of the own pain experience in a balanced way. Clinical investigation indicates that people who are self-compassionate have better psychological health than people who are not (13). Being self-compassionate implies having the skills to cope with life stressors in an effective way, for example with chronic pain (13; 15). It has been demonstrated that self-compassion training promotes self-care capacity in people with VIH or Diabetes Mellitus (16,17).

Neff and Germer have developed a specific program to increase self-compassion called “Mindful Self-Compassion” (MSC), which can be applied to general population and to certain clinical population (13). In no clinical population, MSC has demonstrated significant benefits in self-compassion and depression.

In spite of the promising results of interventions based on acceptance and self-compassion, we have still little data that allow back them as an effective intervention to the psychological approach to chronic pain.

## **OBJECTIVES AND HYPOTHESIS**

The objective of this study is to analyse the effectiveness of the MSC program versus the CBT program in order to improve self-care, compassionate relation to oneself, quality of life in a chronic pain patient’s sample. Both treatments are conducted in groups, are psychotherapeutic oriented, both have an 8 weeks duration, weekly frequency, 2 and a half hours per session.

The principal hypothesis of this investigation is:

- MSC program will be, at least, as effective as the CBT program in order to improve self-care capacity and self-compassion in chronic pain patients (decreasing self-criticism, isolation feelings, and thoughts over-identification) at the post-treatment time and in a 6-months follow-up.

Secondary hypothesis:

- MSC program will be, at least, as effective as CBT program in order to improve quality of life, and acceptance capacity; and as effective as CBT to reduce catastrophizing, daily life interference, anxiety and depression in a chronic pain patients simple, at the post-treatment time and a 6 months follow-up.

- We also hypothesize that MSC program will be, at least, as effective as CBT program in order to maintain the achieved benefits in a 6 months follow-up.

- Treatment satisfaction will be higher in MSC program, being treatment adherence higher in this program than in CBT program.

## **METHODS**

We wrote a investigation protocol which has already been approved by the Research Ethics Committee of Hospital Universitario La Paz, Madrid.

This is a prospective experimental study; blind randomized, with parallel groups and final blind analysis with, at least, 64 patients with chronic pain.

All patients will be assessed at the pre-intervention moment, at the post-intervention moment (8 weeks), and in a 6 months follow-up.

This is a pre-post experimental design with which we intend to compare the effectiveness of 2 psychotherapeutic treatments for chronic pain. The two arms of treatment of this Randomized Clinical Trial are:

a) Mindful Self-Compassion Program (MSC)

b) Cognitive-Behavioural Program for chronic pain (CBT).

Both treatments are conducted by experimented clinicians with wide experience in chronic pain. We will conduct 8 therapeutic groups in total (4 for each arm treatment), with approximately 15 people per group.

We have estimated that we need a N=64 in order to detect significant differences in the principal outcome (self-care and self-compassion) with a size effect=0.5, SD=0.6, alpha=0.05 and power=90%.

During the investigation we will create a Data Base in accordance with current regulations. Data will be use following the principles contained in the Organic Law 15/1999, 13th December, of Personal Data Protection. All data will be electronically introduced in this database and data analysis will be conducted using SPSS 18.0.

It will be conducted an exploratory study of all variables previous to statistical analysis in order to identify anomalous data.

It has been done a first-step approximation to the behaviour and variability of the main outcome of the study with a 30 patients simple randomized to both arms in order to estimate the necessary N of the study.

Descriptive analysis of qualitative variables will be expressed in terms of frequencies and percentage, and analysis of quantitative variables will be expressed in terms of mean, standard deviation, median and interquartile range. The analysis will be conducted by intention to treat. Comparison of qualitative variables between groups of interventions or between segmentation factors will be conducted with Fisher test. We will apply t-Student, Mann-Whitney, ANOVA or Kruskal-Wallis test in quantitative variables, depending on the normality of the variable (tested with Kolmogorov-Smirnov-Lilliefords test) and the number of compared categories..

Analysis of the changes along the treatment on principal and secondary outcomes of effectiveness will be conducted through a General Lineal Model (ANOVA with repeated measures), which allows checking if there are statistical significant differences in these changes based on arm of intervention.

Regression models will be conducted in order to identify prognostic factors.

Variables "Treatment satisfaction" and "adherence to treatment" will be compared using t-Student test for independent samples for patients who complete the treatment.

Aetiology of chronic pain will be taken into account when it is known.

Given the shortage of studies until the date referred to the effects of interventions based on self-compassion in chronic pain patients, the results of this study may give empirical date about the effectiveness and the need of mindful-self-compassion-based interventions, integrated in a multidisciplinary, approach to improve quality of life and self care in chronic pain patients.

Now, we go on to describe the two arms of treatment tested in this study:

- Mindfulness Self-Compassion (MSC) is a standardized program to increase self-compassion. It has been developed by Neff and Germer. The structure of the program is similar to de Mindfulness-Based Stress Reduction program (MBSR), with duration of sessions between 2 and 2 hours and a half. The frequency of the sessions is one per week for 8 weeks, with practical and experiential exercises in sessions and between sessions. The MSC program focuses primary on helping patients to develop self-compassion, and it includes Mindfulness just as a secondary component. The MSC program will be conducted by a clinician trained in this specific program.

- CBT: It has been adapted a Cognitive-Behavioural Intervention for Chronic Pain by Moix and Kovacs. Our program will have 8 sessions, with duration of sessions between 2 and 2 hours and a half. The frequency of the sessions is one per week for 8 weeks, with homework between sessions. During these 8 sessions we will train the following techniques: psycho-education about pain, relaxation training, cognitive restructuring training, solving problem training, psycho-education about emotions, interpersonal skills and time organization.

There we present the variables of the study:

Primary Outcome Measure:

- Self-Compassion: Self-Compassion Scale (SCS, long version). Self-compassion and Self-care. Self-kindness, Common Humanity and Mindfulness.

[Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

Secondary Outcome Measures:

- Acceptance: Chronic Pain Acceptance Questionnaire (CPAQ). Activity engagement, Pain

willingness. [Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Pain Interference: Pain interference in daily life. Brief Pain Inventory (BPI): pain intensity and impact of pain in daily life. [Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Pain Intensity: Analogical Visual Scale.[Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Catastrophising: Pain Catastrophising Scale (PCS). Rumination, magnification of consequences and hopelessness [Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Quality of life: SF-36. Physical function, physical role, body pain, general state of health, vitality, social function, emotional role and mental health.[Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Anxiety and Depression Levels of anxiety and depression. Symptomatology. Hospital Anxiety and Depression Scale (HADS). [Time Frame: At the beginning of the intervention, at the end of the intervention and at a 6 months follow-up]

- Satisfaction with the treatment Satisfaction with the treatment (CRES-4) [Time Frame: At the end of the intervention]

- Adherence to the treatment Adherence to the treatment (Number of sessions that one patient attends) [Time Frame: At the end of the intervention]

Other Pre-specified Outcome Measures:

- Socio-demographic Data: Age, gender, marital status, family life, job status, time with pain, type of pain, psychiatric history, course pain expectation, number of visits to emergency units in the last 3 months, number of visited doctors in the last 3 months. [Time Frame: At the beginning of the intervention]

Inclusion and exclusion criteria are as follow:

- Inclusion Criteria:
  - Older than 18 years old.
  - Being in treatment in the Chronic Pain Unit at Hospital Universitario La Paz because of having a chronic pain of more than 3 months of duration, no matter the aetiology.
  - Capable of understanding and giving his or her written informed consent.
  - Significant levels of distress and disability related to the pain at the beginning of treatment, assessed by clinical interview and HADS (> or = 8).
  - Significant levels of pain interference in daily life assessed by sub-scale of interference of the Brief Pain Inventory (> or = 5).
  - Significant levels of "catastrophising" at the beginning of the treatment assessed by Pain Catastrophising Scale (PCS) (> or = 30).
  - Patients that meet criteria for Mixed Adaptive Disorder, mild to moderate Depressive Disorder or Dysthymia, assessed by clinical interview conducted by a psychiatry of the Chronic Pain Unit or Mental Health Centre.
- Exclusion Criteria:
  - Intellectual disability or cognitive impairment or dementia.
  - Insufficient knowledge of the language to understand and participate on the intervention program.

- Serious mental illness in acute state at the moment of the beginning of the intervention.
- Substance abuse in the last 6 months.
- Autolytic ideas at the moment of the assessment.
- Previous training in mindfulness or CBT techniques.

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