

Ph.D. THESIS SUMMARY

THE IMPACT OF MINDFULNESS STRATEGIES IN CHRONIC PAIN

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(2) This is to certify by Igna Raluca Ioana that:

(a) The thesis includes the original research work of Igna Raluca Ioana (author) towards the Ph.D.; the research was scientifically supervised by Professor Ph.D. Daniel David;

(b) Parts of the thesis were already published; appropriate citations for these publications were included in the thesis.

(c) The thesis was written according to the academic writing standards (e.g., appropriate scientific acknowledgements and citations have been made in the text by the author of the thesis). All the txt of the thesis and its summary was written by Igna Raluca Ioana who assumes the responsibility for the academic writing.

(3) All the Tables and Figures are numbered within the corresponding chapter.

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Keywords: chronic pain, chronic pain treatments, cognitive-behavioral treatment of chronic pain, mindfulness, mindfulness-based interventions for chronic pain, emotion regulation, pain intensity.

CHAPTER I. THEORETICAL BACKGROUND

1.1 Chronic pain – a public health issue

Chronic pain refers to pain that is maintained after an injury heals and lasts for more than three months. It is related to a persistent or degenerative disease or to an unidentifiable cause. Chronic pain may be caused by the body's response to acute pain and in the presence of continued stimulation of nociceptors with changes that occur within the nervous system. Pain is a subjective phenomenon and the only way to assess it is when a person who experience it says it is present. The personal discomfort of pain is the most authentic source of information about the pain's location, intensity, precipitating or aggravating factors and procedures that bring relief (International Association for Study of Pain).

1.1.1. Prevalence and quality of life

Considering that pain is such a costly and widespread problem, being reported by the WHO (World Health Organization) as the most costly health problem, new costeffective ways of relieving pain are readily embraced. Data suggest that 10%-20% of the population with pain symptoms suffer from chronic pain; 14% of these need medication; 6% report high levels of disability because of pain and 2/3 report pain in several regions of the body. The most common are: back pain (cervical and dorsal), headaches and joints (WHO). Chronic pain is on the 5th place in terms of hospital costs and on the 1st place regarding the absenteeism at work place and disability.

It is also associated with emotional problems (e.g., anxiety, depression) and the effective treatment of pain associated with chronicity often requires the efforts of interdisciplinary teams with expertise in medicine, psychology, pharmacology, physical modalities, and exercise (Bradley et al., 2003).

1.2. Treatment of chronic pain

The conventional treatment of chronic pain is divided into three phases: first, the recovery phase – physiokinetotherapy, second medication (neuropathic, nociceptive), and third cognitive-behavioral therapy. Considering the fact that the pain intensity is not always in proportion with the damaged tissue and that in time constant pain leads to emotional problems, the prevalence of psychological disorders being higher for this population than for the general population, there is a stringent need of an efficient multidimensional approach.

1.2.1. Physiotherapy and kinetotherapy in chronic pain.

In the literature, studies regarding the effectiveness of physiotherapy is rather limited. There are some studies that evaluates the efficiency of different therapeutic procedures, but the parameters, exposure time and number of sessions is very ambiguous. Usually, the most common forms of physiotherapy are: continuous current (galvanic, ionisation), low-frequency current (diadynamic current), ultrasonophoresis and transcutaneous electrical nerve stimulation (Radulescu, 1991).

The kinetotherapy programs involve techniques of lumbar spine protection, stabilization and fortification that demonstrates significant improvements of chronic lumbar pain (Lewis et al., 2005).

1.2.2. Pharmacotherapy in chronic pain

Eighty percent of chronic pain sufferers reported that they experience breakthrough pain from activity, a phenomenon recently emphasized by Svendsen et al. (2005), and 64% of those currently using prescription pain medications reported that their pain medications were inadequate at times to control their pain. The standard drug treatment are the weak and strong opioid classes of analgesics, but some have failed to provide relief.

1.2.3. Cognitive-behavioral therapy in chronic pain

Cognitive-behavioral therapy (CBT) interventions are often used as adjunct treatments with standard medical care to help patients with chronic illnesses better manage their pain and distress or improve function. The major goal of cognitive behavioral therapy (CBT) is to replace maladaptive patient coping skills, cognitions, emotions, and behaviors with more adaptive ones.

Examining the literature in order to see the value of programs in treating chronic pain has confirmed the effectiveness and efficacy of cognitive-behavioral therapy in treating various negative elements of the chronic pain experience. Whether it is rheumatoid arthritis or low back pain (where the tissue damage and trauma do not appear always similar with the reports of pain), cognitive and behavioral approaches have been implemented in order to moderate pain and disability (Johnson & Kazantzis, 2004). Morley, Eccleston and Williams (1999) found in their meta-analysis of CBT treatment that compared to other active treatments in reducing pain experience, behavioral manifestations of pain and improving coping, CBT is much more effective.

1.2.4. Limits of cognitive-behavioral therapy (CBT)

A meta-analysis that encompassed 26 studies of the efficacy of cognitivebehavioral therapy on chronic pain (Morley et al., 1999) attested the fact that CBT was superior to other forms of intervention. When searching for results of its efficacy, several aspects were taken into account: the reduction of pain intensity, the reduction of irrational beliefs (related to pain) and the reduction of maladaptive behaviors (related to pain). For all these aspects only a medium mean effect size was found (ES = 0.46).

1.2.5. Mindfulness-based strategies

In the recent years there has been considerable research interest in mindfulness as a protective factor with regard to the effects of difficult life events.

Mindfulness is defined as "the awareness that emerges through paying attention on purpose, in the present moment, and non-judgmentally to things as they are" (Kabat-Zinn, 1993).

It means that it aids the development of two facets of executive functions: the first is sustained attention, the ability to focus attentional resources on specific stimuli in specific manner, the second being attention switching, the ability to deliberately switch the attentional focus between stimuli. It has been hypothesized that enhancement in these two abilities will result in better ability to monitor and self-regulate mental and emotional states (also known as metacognition and metaemotion) thus, leading to a greater psychological well-being (Chambers et al., 2008).

Recently, cognitive and behavioral approaches that incorporate mindfulness and acceptance-based strategies have shown promise in the treatment of various disorders especially in anxiety (Batten & Hayes, 2005; Dalrymple & Herbert, 2007; Roemer, Orsillo, & Salters-Pedneault, 2008), depression (Teasdale and al., 2000), stress (Kabat-

Zinn, 1993), pain (Kabat-Zinn, 1982), eating disorders (Shapiro, Schwartz, & Bonner, 1998). Although these approaches have demonstrated promising results, further research is needed to more precisely elucidate the ways in which mindfulness practice may enhance treatment for different kinds of disorders.

1.2.6. Relevance of mindfulness strategies

Because mindfulness interventions have gained more and more popularity in the recent years also in medical as in other clinical settings, the question of how best to examine the effects of such intervention has become important. Mostly the research has been predominantly focused on mindfulness-based and mindfulness-integrated therapies (Kabat-Zinn, 1982, Segal, Williams, & Teasdale, 2002; Hayes, Strosahl, & Wilson, 1999) that have incorporated mindfulness practice or techniques into clinical treatment protocols. All this research has made an important contribution because it has demonstrated that mindfulness-based interventions may have significant health benefits in a large sample of clinical and non-clinical populations (Baer, 2003). Although these results are promising there are still questions that concern not only the mental health benefits of mindfulness but also the mechanisms that are truly underneath this changes.

Therefore, clarifying the mechanisms that support this phenomenon can represent an important step for obtaining a better perspective over the mindfulness process and its beneficial effects and a better understanding of how clinical interventions can be improved through these strategies.

1.2.7. Mechanisms of change taken into consideration

Because the field of mindfulness is engaged in the development of models and theories to sustain or justify the beneficial results these techniques show in the studies, we selected four mechanisms that have been investigated and could explain the change mindfulness has proven in different disorders. These are: exposure, focus, observation and self-observation or self-monitoring.

1. Exposure.

The literature is full with evidence of the efficacy of exposure in treating a variety of disorders (Barlow & Craske, 2000). The capacity to observe or witness

a variety of disorders (Barlow & Craske, 2000). The capacity to observe of witness impartially to the contents of one's consciousness enables a person to experience even very strong emotions with greater objectivity and less reactivity. This capacity serves as a counter to the habitual tendency to avoid or deny difficult emotional states thereby increasing exposure to such states. Through mindfully attending to negative emotional states, one learns experientially and phenomenologically that such emotions need not to be feared or avoided and that they eventually pass away (Segal, Williams, & Teasdale, 2002). This experience eventually leads to the "extinction of fear responses and avoidance behaviors previously elicited by these stimuli" (Baer, 2003).

2. Focus of attention.

By focusing the attention on the senzations or description of thoughts, without trying to avoid them, but trully imerse in that state of attention is leading to the reduction of emotional reactivity (Kabat-Zinn, 1992) and cognitive distortions and biases in the processing of information. "Mindful" attention and awareness, have been concurrently associated with both lower anxiety (Vujanovic, Zvolensky, Bernstein, Feldner, & McLeish, 2007) and depressive symptoms (Zvolensky et al., 2006).

3. Observation.

Different authors attested that mindfulness practice leads to changes in thinking patterns or in attitudes towards their own thoughts. For example, Kabat-Zinn (1992) suggested that observation without judgments of value of the pain and anxiety related thoughts can lead to the understanding of the fact that these are "just thoughts" and not reflections of reality and do not call for escape or avoidance behaviors.

4. Self-observation (acceptance).

People are able to attend to the emotion, and choose to self-monitor in ways that foster greater health and well-being. Through consciously (intention) bringing awareness (attention) and acceptance to experience in the present moment, people are better able to use a wider, more adaptive range of coping skills (Shapiro et al., 2006).

1.2.8. Compatibility with cognitive-behavioral therapy

Mindfulness is compatible with cognitive-behavior therapy in several ways:

1. it teaches close observation of the present experience and the relationships between cognitions, sensations, emotions, behaviors and external events. Mindfulness is not the same as self-monitoring because self-monitoring is done with a self-criticism attitude and with the purpose of changing particular types of experiences.

2. mindfulness techniques teaches decentering, which has been recognized for years as a central component of cognitive therapy.

Instead of changing the content of thoughts and feelings so that they lead to more adaptive behaviors, mindfulness-based approaches encourage a different relationship to thoughts alone, teaching a decentered relationship to bodily sensations and emotional states as well as cognitions (Hayes, 2004).

1.2.9. Critical remarks and further advances in the field of mindfulness

Studies are necessary in order to separate and compare the various active ingredients in mindfulness-based such as cognitive behavioral elements. Another line of inquiry is examining the central construct of mindfulness itself to determine if the development of "mindfulness" is what actually leads to the positive changes that have been observed. This step can be facilitated through the recent development of valid and reliable measures of mindfulness. A testable theory of the mechanisms involved in the process of mindfulness itself is needed to explain whether and how mindfulness affects change and transformation.

CHAPTER II. RESEARCH AIMS AND OVERALL METHODOLOGY

Taking in consideration that the cognitive-behavioral interventions present just a medium effect size as treatment for chronic pain and considering that mindfulness strategies do not present sufficient data to be considered an efficient techniques in the management of chronic pain the general objective of the research is to investigate the efficacy of these techniques in chronic pain on both its components: emotional and physical (evaluation of pain intensity). Also we intend to test the efficiency of these strategies inside a CBT protocol in the case of chronic low back pain in order to see if CBT intervention can be upgraded with the help of these techniques.

The first objective of this research was to identify the effectiveness of these mindfulness-based interventions into the field of chronic pain. In order to reach this objective, the method of quantitative meta-analysis was used (Study 1).

The second objective was to establish the efficiency of mindfulness strategies in comparison to other cognitive strategies used in emotion regulation. Because chronic pain patients present a higher prevalence of psychological disorders (e.g. anxiety, depression) than the general population, Study 2 aimed to clarify the efficiency of mindfulness strategies on the emotion regulation process.

The next objective was to ascertain the efficacy of mindfulness strategies on pain intensity, the other important component of pain. Study 3 was conducted to test mindfulness on pain intensity and pain tolerance in order to clarify the benefits that this strategy can bring.

The following study aimed to test the benefits of a treatment as usual with cognitive-behavioral therapy and mindfulness techniques and a treatment as usual and cognitive-behavioral therapy referred to treatment as usual for chronic low back pain.

Altogether, Study 4 highlights the idea of the possibility of improving the validated treatment protocol of CBT for chronic pain through mindfulness techniques.

CHAPTER III. ORIGINAL RESEARCH

Study 1. Highlighting the effectiveness of mindfulness-based interventions in chronic pain. A meta-analytic review.

Aims

Because mindfulness interventions have been used as a treatment method for chronic pain, the current meta-analysis intends to assess the effectiveness of these popular interventions in reducing the level of chronic pain and the associated problems (eg. anxiety/depression/disability) and, furthemore, the increasing level of vitality/quality of life. We analysed the data extracted from the studies that implemented mindfulness-based interventions and that presented standardized measure instruments.

Method

Medline, PubMed, Cohchrane, PsycInfo, ScienceDirect, EBSCO data bases were searched and 13 studies were included in the final review. Topics reviewed included: (1) a form of mindfulness intervention or procedure, (2) a control group or pre- and post-intervention data, (3) measures of pain and/or at least one emotional component, (4) sufficient data in order to calculate the effect size analysis (eg. means and standard deviations, *t* or *F* values, change scores, frequencies, or probability levels).

We calculated two separate meta-analyses. The first included all clinical studies with the effect size based on the comparison between the experimental and the control groups. The second analysis used data from both experimental studies (applying only results from the mindfulness intervention) and pretest-posttest design studies (in which no control group existed). For both analyses, we calculated separate mean effect sizes for mental and physical health.



Figure 1. QUORUM flow chart.

Results

Clinical studies

	Ν	d	95%-CI	Р
Mental health	186	0.54	0.39-0.68	<.0001
Physical health	93	0.53	0.23-0.81	<.0004

Note. N = number of subjects, d = mean effect size, 95%-CI = 95% confidence intervals, P = P values (two-tailed) calculated for the difference between mindfulness and control groups on mental health and physical health variables for all clinical studies.

Experimental studies

	Ν	d	95%-CI	Р
Mental health	649	0.50	0.43-0.56	<.0001
Physical health	358	0.42	0.34-0.50	<.0001

Note. N = number of subjects, d = mean effect size, 95%-CI = 95% confidence intervals, P = P values (two-tailed) calculated for the difference between mindfulness and control groups on mental health and physical health variables for all experimental studies.

The results suggest the utility of mindfulness-based interventions as an intervention for the chronic pain condition. The consistent and relatively strong level/medium of effect sizes across the different types of sample indicates that mindfulness interventions might enhance general features of coping with distress and disability in everyday life.

Discussions

In both investigations, improvements were consistently seen across a spectrum of standardized mental health measures including psychological dimensions of quality of life scales, depression, anxiety, catastrophic evaluations, and acceptance of pain. Likewise, similar benefits were also found for health parameters of physical well-being, such as level of pain intensity and physical disability, although physically oriented measures were less frequently assessed in the overall studies.

Study 2. Comparing cognitive strategies over the process of emotional regulation Aims

Because pain has such a great impact on people's affective state, the second study is pursuing to make render the efficiency of mindfulness strategies in comparison with other cognitive strategies over the process of emotion regulation.

As no study yet has compared mindfulness with several effective (antecedentfocused) strategies, the goal of the current study was to examine the impact of a brief cognitive instruction like mindfulness vs. other strategies (i.e., reappraisal, imagery, rational, irrational) on emotional responses and automatic thoughts of college students in response to aversive emotional stimuli. We did not introduce any control group accounting on the fact that reappraisal and attentional distraction (imagery) had already proven their efficiency in earlier studies. Because so far mindfulness has not been investigated in relation to multiple forms of efficient strategies we conducted an exploratory study to see, first, if mindfulness obtains similar results as reappraisal, imagery and rational statement, in terms of emotional response (reduced level of negative emotions and distress) and negative automatic thoughts (reduced level of negative automatic thoughts). We were interested, as well, in seeing if we could find any differences between pre- and post-intervention between groups at the level of negative emotions.

Method

Participants were 177 (154 female and 23 male) undergraduate students. The age of subjects ranged from 19 to 44 (M = 21.57, SD = 3.79).

Procedure. An experimental design was used. Participants were randomly assigned to one of the five experimental conditions (mindfulness, reappraisal, imagery, rational statements, irrational statements). Participants read the instruction for 5 minutes prior to exposure to very distressful images (IAPS).

Measures. Participants were asked to complete the following questionnaires: *Attitude and Belief Scale II* (DiGiuseppe et al., 1988); *Automatic Thoughts Questionnaire* (Hollon & Kendall, 2007); *Profile of Mood States Short Version* (DiLorenzo, Bovbjerg, Montgomery, Valdimarsdottir, & Jacobsen, 1999); *Profile of Affective Distress* (Opris & Macavei, 2007); *Visual Analogue Scale* (VAS) was used to measure the degree in which the participants were able to apply the strategies during the visualization of the images.

Results

Results at post-hoc analysis show that strategies discriminate from each other at the level of negative dysfunctional emotions, and distress (anger component). *Negative dysfunctional emotions:* F(4, 145) = 2.94, p = .022 significant differences between reappraisal and irrational statement (MD = -6.87, SE = 2.44, p=.045) and a near significant score between mindfulness and irrational statement (MD = -6.23, SE = 2.44, p=.086), meaning that in reappraisal condition differences in the reduction of negative dysfunctional emotions were found (and almost for the mindfulness group as well) compared to irrational condition.

Emotional distress. Anger level: F(4,145) = 2.58, p = .039 – significant difference between reappraisal and irrational statements (MD = -3.41, SE = 1.16, p=.032), and a near significant difference between mindfulness and irrational (MD = -3.05, SE = 1.16, p=.074).

We wanted to investigate whether there was a difference before (baseline) and after the exposure to the images at the level of negative dysfunctional emotions, particularly if strategies were able to change something and which one did so. There was a significant difference in the scores for baseline (M = 19.96, SD = 8.18) and post-exposure (M = 23.30, SD = 9.64); t(149) = -5.080, p = .000. F(4, 145) = 3.947, p = .005, and the post-hoc showed that only reappraisal compared to irrational had a significance of (MD = 7.04, SE = 2.02, p = .020), and a marginal significance was present between mindfulness and irrational (MD = 5.74, SE = 2.02, p = .096).

Discussions

An important finding of this exploratory study is the fact that mindfulness could be considered efficient among other strategies tailored for reducing emotional negative response. Differences for the four strategies (mindfulness, reappraisal, imagery, rational statement) were found between reappraisal and irrational and almost significant between mindfulness and irrational statement. These results mean that compared to irrational group, reappraisal and mindfulness led to reduction at the level of negative dysfunctional emotions. A significant difference was found between reappraisal and irrational group at the level of anger, meaning that after being exposed to the distressing images the reappraisal group presented a lower level of anger than irrational group. Mindfulness group presented as well this kind of difference compared to irrational group, but it did not demonstrate such significant statistical impact as reappraisal group did. Although we expected to find differences at the level of negative automatic thoughts, neither group presented significantly higher or lower rates.

No significant differences were found at the level of irrational beliefs between groups that might have explained the results found for negative dysfunctional emotions.

The results found on reappraisal are consistent with the literature that asserts this strategy as being the most efficient in regulating emotions (Dandoy & Goldstein, 1990; John & Gross, 2004). Having almost similar results as reappraisal, we can allege that mindfulness could be as much efficient when it comes to negative emotion regulation process, even better than imagery and rational statements. More studies are required in order to confirm this, considering the restricted number of group subjects.

Another interesting finding was the fact that strategies did differ on the impact they had on negative dysfunctional emotions from baseline to post intervention. While the imagery, rational and irrational groups presented a small or significant growth (irrational) at the level of negative dysfunctional emotions from pre- to post-intervention reappraisal and mindfulness showed small or no changes. This means that although the significant difference was between reappraisal and irrational and almost significant between mindfulness and irrational, these two strategies show that they incorporate protective factors on how people perceive stressing or distressing situations.

As a conclusion for this study we can ascertain that although mindfulness is considered to be a technique that does not teach directly how to regulate mood, but mindfulness's results on negative dysfunctional emotions (the fact that they did not change pre- to post-intervention despite distressful situation) could be interpreted in the way that mindfulness might change one's beliefs about the nature and meaning of an emotion resulting in automatic changes over emotions, increasing tolerance towards negative emotions, reducing thus the magnitude of unpleasant emotions.

Study 3. Investigating mindfulness strategies in an induced pain condition Aims

As we have observed from the previous study, mindfulness strategies are potentially beneficial on reducing negative dysfunctional emotions, so the next step was to investigate whether these strategies have a beneficial effect on reducing the other component of pain: pain intensity level.

Thus, the purpose of the present study is to compare the efficiency of a mindfulness strategy versus a distraction strategy on perceived pain intensity, distress and tolerance time. Because the studies done so far on mindfulness/acceptance, attentional control and induced pain have concentrated more on pain intensity, length of time and distress, we also conducted this experiment in order to find out to what degree these variables are influenced by evaluative thoughts and dysfunctional attitudes.

Method

Participants that took part at the experiment were 69 (58 female and 11 male) undergraduate students. The age of subjects ranged from 19 to 44 (M = 22.40, SD = 4.33).

Procedure. An experimental design was used. Participants were randomized in one of the three groups (mindfulness, distraction, control) and strategies were given to them 3 days prior to experiment that consisted in introducing one hand into a cold (3°C) water tank. Participants had to stay into the experimental task as much time as possible.

Measures. Attitude and Belief Scale II (DiGiuseppe et al., 1988); Automatic Thoughts *Questionnaire* (Hollon & Kendall, 2007); Profile of Mood States Short Version

(DiLorenzo, Bovbjerg, Montgomery, Valdimarsdottir, & Jacobsen, 1999); Profile of

Affective Distress (Opris & Macavei, 2007); The Pain Anxiety Symptoms Scale

(McCracken and Dhingra, 2002); Attitude and Belief Scale, short version (David, 2007);

Dysfunctional Attitude Scale (Weissman & Beck, 1978); Visual Analogue Scale (VAS)

was used to measure the degree in which the participants felt pain at a particular moment. **Results**

Results show that at the level of *pain intensity*, the groups did not differentiate among each other (F(2, 66) = 1.42, p = .249). At the level of *Endurance to pain (time)*. the analysis demonstrated that the period of time participants endured pain differed between groups, (F(2, 66) = 3.97, p = .023). The difference was found between mindfulness and control group (MD = 5.73, SE = 2.13, p=.033), meaning that those in mindfulness group endured pain for longer time than those in control group.

Then a significant correlation was found between negative dysfunctional emotions and dysfunctional attitudes, self-downing, awfulizing and total irrational score. Results show that only self-downing (global evaluation) was significant r(51) = .164, p = .003, explaining 16% of the variance.

We also wanted to see if differences from pre- to post- intervention occurred within groups at the level of emotions and we found significant differences at the level of negative dysfunctional emotions (PAD) (t(53) = 2.098, p = .041), negative functional emotions (PAD) (t(53) = 5.463, p = .000), positive emotions (PAD) (t(53) = -4.867, p = .000) and for the total general distress (POMS) (t(53) = 2.336, p = .023). This results show that from pre- to post-intervention participants presented a lower level of negative dysfunctional emotions, a lower level of negative functional emotions, a higher level of negative functional emotions and a lower level of overall distress. But between groups at the end of intervention we found no differences from pre- to post (all p's > .05).

One important finding was at the level of perceived speed with which time passes between groups. The difference between the real time spent in the experimental condition was significantly different than the estimation of time spent in the experimental condition F(2, 59) = 83.18, p = .000. And this significant difference was found between all three groups (all p's = .000). The mean estimation of time for: mindfulness was about 5.5 minutes (M = 5.54, SD = 2.86) meaning that participants estimated less time spent in the experimental condition than they actually did; for imagery was about 1 minute (M = .63, SD = 1.26), thus participants estimated almost the same amount of time that was spent in the experimental condition; while for control group the estimated time was longer with almost 3 minutes (M = -2.85, SD = 2.20) than the time spent in the experimental condition.

Discussions

The results of the present study indicate the fact that mindfulness can successfully be used for prolonging the time used by a person in a painful condition. We found that in an induced pain condition participants using mindfulness strategy showed a longer pain tolerance than those using distraction or no strategy.

However, these results do not stand valid when we talk about pain intensity (the measure of pain sensations perceived during the task), general distress or more specific negative dysfunctional emotions. These results are consistent with previous findings where mindfulness or acceptance strategies demonstrated better results on pain tolerance compared to control-based, placebo, suppression or other strategies (Gutierrez, Luciano, Rodriguez, & Fink, 2004; Marcks & Woods, 2005; Masedo & Esteve, 2007) but not on the intensity of pain or related distress (Hayes et al., 1999).

As no study to date investigated the way automatic and evaluative thoughts predict subjective pain and distress in an experimental setting like the one we used, our analyses focused on finding out if these predictors stand the test for subjective pain and associated distress. Results showed that none of these (negative automatic thoughts, dysfunctional attitudes, irrational beliefs) predict the intensity of pain perceived by subjects. Only self-downing was found to be a good predictor for negative dysfunctional emotions.

Another finding was that within groups emotions did change from pre- to postintervention in the way that the level of negative dysfunctional emotions and overall distress (but also negative functional emotions) lowered, while the positive emotions augmented. This could be explained by the fact that not being a threatening situation and successfully completing the task at the end participant's positive emotions increased.

One important and essential finding was that mindfulness strategy had a significant effect on the estimation of time spent in the experimental condition, perceiving it as passing more slowly than it actually was. The findings for mindfulness group shows that an awareness of our present experience may impact the way we perceive the passage of time, while not being aware (mindfully speaking) of these present experiences tends to lead to a different temporal interval estimation (as being longer than the actual physical time). Mindfulness technique could have potentially benefits on how people perceive time, giving the chronic pain population a better sense of control over their condition.

Study 4. A clinical trial of efficiency between treatment as usual and mindfulnessbased cognitive behavioral therapy (MCBT), treatment as usual and cognitivebehavioral therapy (CBT) and treatment as usual (PHM) for chronic low back pain

Aims

The motivation of the present study was to cover the missing pieces of the research area regarding the effectiveness of mindfulness-based techniques and also to improve the benefits of CBT strategies over chronic pain and its associated problems, through a clinical trial. Thus, we evaluated the effectiveness of interventions like CBT vs. MCBT in the reduction of intensity of pain and associated emotional (e.g. anxiety,

depression, anger) and cognitive (e.g. catastrophizing, absolutistic beliefs, rumination, fear of pain) problems and in the increase of vitality/quality of life. We also measured general irrational beliefs and pain-related irrational belies, awareness and acceptance and considered them as potential mediating variables.

Method

Participants. A total of 68 patients (mean age of 47, 36=females and 32=males) participated in this clinical trial (25 were part of the CBT group, 18 were part of the MCBT group and 25 were part of the PHM group). All participants received beyond psychological intervention (MCBT and CBT group), pharmacological and physiotherapy treatment. The control group received only pharmacological and physiotherapy treatment. **Therapists and evaluators.** Sixteen therapists, in total, with a formal training in

Cognitive Behavioral Therapy provided treatment in both conditions (eight for CBT and eight for MCBT). Protocols that described each session for the two treatment conditions were available for each therapist. Baseline and final session assessments were completed. **Procedure.** Participants were recruited through Cluj-Napoca Recovery Hospital (Romania) primary care. Patients included in the trial were those reporting pain for at least 3 months, with pain severity ratings of at least 5/10 on a visual analogue scale. Patients were diagnosed with vertebrate discopathy or discal hernia (chronic back pain). **Treatment conditions.** Participants were included in a 6 session intervention program,

with 2 meetings per week. Participants that were in the control group were also evaluated twice a week with the self-report scales.

Treatment duration and format. Both psychological treatments (CBT and MCBT) were delivered in an individual format. Each session lasted 60 minutes.

Treatment components. Both treatments included:

(a) An expectancy component. In order to rise the expectancy level of therapeutic change we included in both interventions a session dedicated to upgrade the expectations for the results of the therapy (CBT intervention included the virtual reality system with the program of "SnowWorld" (Hoffman, 2004) and the MCBT intervention included an exercise of mindfulness entitled the "mind-watching" exercise (Hayes & Smith, 2005)).

(b) Cognitive restructuring of irrational beliefs about pain. The targeted irrational beliefs were: pain-catastrophizing, low frustration tolerance related to pain, absolutistic beliefs about treatment and healing, and negative global evaluation of self.

(c) A physical activity component. Behavioral activation or exposure to activities that are avoided due to irrational beliefs that pain is a condition that must always be closely supervised, thus leading to the vicious cycle of avoidance in which pain is maintained. This component was introduced from the second session immediately after conceptualization of fear-avoidance behaviors and of their effect on their quality of life.

All three interventions are described in summary below.

Mindfulness-based Cognitive Behavioral Therapy for chronic pain (MCBT):

<u>Session 1:</u> (Obtaining information from the patient + mindfulness strategy + conceptualization of mindfulness effect)

<u>Session 2:</u> (Detailing the list of problems + identification of maladaptive beliefs related to pain and activity + conceptualization)

<u>Session 3:</u> (Disputing beliefs, evaluations and biases related to pain and activity + Mindfulness strategies + progressive muscle relaxation) <u>Session 4</u>: (Disputing irrational expectancies through the help of exposure tasks/activities + mindfulness strategies)

<u>Session 5:</u> (Checking the exposure tasks and the associated beliefs + checking the use of mindfulness strategies)

<u>Session 6: (Teaching the patient to become its own therapist)</u>

Cognitive Behavioral Therapy for chronic pain (CBT):

<u>Session 1:</u> (Obtaining information from the patient + VR - ,,Snow World" + conceptualization of VR effect)

<u>Session 2:</u> (Detailing the list of problems + identification of maladaptive beliefs related to pain and activity + conceptualization)

<u>Session 3:</u> (Disputing beliefs, evaluations and biases related to pain and activity + progressive muscle relaxation)

<u>Session 4:</u> (Disputing irrational expectancies through the help of exposure tasks/activities)

Session 5: (Checking the exposure tasks and the associated beliefs)

<u>Session 6:</u> (Teaching the patient to become its own therapist)

Pharmacotherapy (PHM):

Participants from treatment as usual group were evaluated with the same measures as the intervention groups at the beginning of the treatment and after 14 days, the same period of time the other two groups received evaluations.

Measures. Assessment included measures of pain intensity, catastrophic beliefs associated with pain (pain catastrophizing beliefs), automatic negative thoughts and general irrational beliefs, emotional distress (anxiety, depression, anger), mindfulness level, quality of life and expectations: *Automatic Thoughts Questionnaire* (Hollon & Kendall, 2007); *Profile of Mood States Short Version* (DiLorenzo, Bovbjerg, Montgomery, Valdimarsdottir, & Jacobsen, 1999); *The Pain Anxiety Symptoms Scale* (McCracken and Dhingra, 2002); *Visual Analogue Scale* (VAS) was used to measure pain intensity; *McGill Pain Questionnaire* (Melzack & Torgerson, 1971); *Mindful Attention Awareness Scale* (Brown and Ryan, 2003); *The Chronic Pain Acceptance Questionnaire* (McCracken et al., 2004); *The Pain Catastrophizing Scale* (Sullivan et al., 1995); *General Attitudes and Beliefs Scale – short version* (Lindner, Kirkby, Wertheim, & Birch, 2007); *The State-Trait Anxiety Inventory* (Spielberger, 1983); *Beck Depression Inventory II* (Beck, Steer, & Brown, 1996).

Results

There were no significant differences between intervention groups (CBT, MCBT) and reference condition (PHM) at post-treatment, except for the pain intensity scores F(2, 66) = 3.07, p = .05 (McGill), F(2, 66) = 3.82, p = .027 (VAS). Post hoc analyses showed, for pain intensity (McGill), just a near significant difference between CBT and PHM (MD = 6.49, SE = 2.88, p=.08). The significant score was the one evaluated with VAS between MCBT and PHM (MD = 1.35, SE = .52, p=.04).

The results for the other outcomes are as follows: *anxiety* F(2, 67) = 1.60, p = .209; *depression* F(2, 66) = .23, p = .789; *anger* F(2, 68) = .16, p = .853; *overall distress* F(2, 68) = .03, p = .965; *well-being (emotional)* F(2, 68) = .39, p = .674, *well-being (functional)* F(2, 68) = .18, p = .832.

Pain intensity Outcome

Step 1: The Efficacy Test. Results in the outcome study showed significant differences between groups for pain intensity and for other outcomes between pretreatment and post-treatment, for all treatments. Considering that all three treatments were active conditions, we proceed to the next step in analyzing potential mediators for change.

Step 2: Intervention Specificity. This next step looks to assess the relationship between treatment and change in the hypothesized mediators. We compared pretreatment and post-treatment scores on these measures on the total sample, for each treatment condition, using paired sample *t* tests. The results showed that negative automatic thoughts (ATQ), global self evaluation (GABS), absolutistic beliefs (GABS), general irrational beliefs (GABS), fear of pain (PASS), general irrational beliefs about pain (PASS) did not reach statistical significance (all *ps* > .05). Only mindfulness (MAAS) (t(62) = -3.365, p = .001), and pain catastrophizing scale (PCS) (t(49) = 4.147, p = .000), showed significant difference.

Then we wanted to see which condition produced this change and found that all conditions presented it at the level of these two mediators (all p's < .05), except pharmacotherapy, which did not present significant differences at the level of mindfulness.

Next, when we compared between-groups changes on these post-treatment measures with pre-treatment scores on each variable as covariate, we found only CPAQ in the MCBT condition as higher than the CPAQ in the PHM condition F(2, 58) = 4.32, p = .018). The others were not statistically significant (all ps > .05). What these results show, so far, is that MCBT led to a more significant change at the level of pain acceptance, as compared to PHM treatment.

Step 3. Psychopathology Test. The next relationship that we explore is between the mediators and outcomes, trying to highlight a temporal relationship between changes in mechanisms and outcomes. Thus, we calculated residual change scores from pretreatment to post-treatment, meaning the treatment change, for pain, associated emotional problems (anxiety, depression, anger, overall distress) and well-being and each mediating variable. Table 4 presents only the correlations between treatment change in the (hypothesized) mediating variables and treatment in pain and well-being in each treatment condition.

Results show that the changes in pain intensity for all treatment groups are related to changes in irrational beliefs (precisely with global self evaluations), but not in acceptance.

Step 4: Mediation Test. This step tries to answer the question of whether intervention effects can be accounted for by the hypothesized mechanisms of change. We were not able to run a mediation analysis as there was no correlation between acceptance and pain. Therefore, following Jacobson et al. (1996) and Szentagotai, David, Lupu, & Cosman (2008), we formulated conclusions regarding the mechanisms of change on the basis of steps one to three.

Tabel 2.

Paired samples t tests for pre-treatment – post-treatment values on outcome variables, for each treatment condition.

Variable		CBT			MCBT		PHM			
	M(SD)	t	Р	М	t	Р	M(SD)	t	Р	
				(SD)						
McGill(pain)	2.85	5.90	.562	2.61	1.37	.187	4.85	2.08	.048	
	(21.59)			(8.05)			(11.67)			
VAS(pain)	3.24	9.83	.000	6.00	2.15	.046	4.71	14.18	.000	
	(1.58)			(11.83)			(1.65)			
STAI	1.00	4.19	.000	2.05	1.54	.140	4.88	1.61	.119	
	(14.72)			(10.56)			(15.78)			
POMS(anxiety)	.27	0.28	.780	3.88	3.53	.003	2.52	2.05	.051	
	(4.52)			(4.66)			(6.13)			
BDI	2.04	1.14	.264	4.00	2.53	.021	2.40	1.31	.201	
	(8.16)			(6.69)			(9.12)			
POMS(depression)	3.44	1.58	.132	5.88	2.94	.009	2.62	1.20	.240	
	(9.24)			(8.49)			(10.66)			
POMS (distress)	5.94	1.22	.236	13.05	3.38	.004	8.66	1.69	.104	
	(20.54)			(16.35)			(25.09)			
Anger Self-Report	1.00	0.25	.803	2.05	0.82	.420	4.88	1.54	.135	
	(14.72)			(10.56)			(15.78)			
FACT(emotional)	1.77	2.06	.050	.77	1.36	.190	.88	1.20	.242	
	(3.65)			(2.41)			(3.66)			
FACT(functional)	-1.00	93	.364	-1.38	-1.78	.093	12	-0.17	.865	
	(4.55)			(3.31)			(3.47)			

Note. CBT = Cognitive Behavior Therapy; MCBT = Mindfulness-based Cognitive Behavior Therapy; PHM = Pharmacotherapy; McGill (pain) = McGill Pain Questionnaire; VAS (pain) = Visual Analogue Scale for pain; STAI = The State-Trait Anxiety Inventory (the scale for state anxiety); POMS (anxiety) = Profile of Mood States (anxiety subscale); BDI = Beck Depression Inventory; POMS (depression) = Profile of Mood States (depression subscale); POMS (distress) = Profile of Mood States (distress score); Anger Self-Report = a visual analogue scale measuring the level of anger; FACT = The Functional Assessment Scale (emotional = the level of emotional well being; functional = the level of functional well being).

Tabel 4.

P · · · · / P ···				,		0 (- / -	0			0 1	
	McGil VAS			FACT			FACT					
		1					emotiona			functiona		
								1			1	
Treatment	CBT	MCB	PHM	CBT	MCB	PHM	CBT	MCBT	PHM	CBT	MCBT	PHM
mechanis		Т			Т							
m of												
change												
(pre-post)												
GABS	.469*	.545*	.597*	.291	.128	.475*	133	.407	.362	260	431	187
Global	(.037	(.019)	*	(.179	(.614)	(.016	(.600)	(.094)	(.075)	(.297	(.074)	(.372
Self-Eval)	. ,	(.002))	. ,)		. ,	. ,))
GABS	.214	343	.343	.434*	124	.072	.529*	210	.285	282	518*	.013
Abs.	(.380	(.164)	(.093)	(.044	(.624)	(.732	(.029)	(.404)	(.167)	(.273	(.028)	(.950
Beliefs)))))
GABS	202	.061	.428*	.396	.079	.296	.491	.008	.312	337	604**	.014
Total	(.408	(.810)	(.033)	(.084	(.757)	(.193	(.063)	(.976)	(.129)	(.202	(.008)	(.946
Irrational)))))
PCS	.239	.176	.484*	.327	.329	.368	.470	.013	.524*	493	.255	091
	(.325	(.484)	(.014)	(.159	(.182)	(.071	(.090)	(.959)	*	(.052	(.307)	(.665
)))			(.007)))
CPAQ							-					
	.265	.030	.342	.076	243	.206	.796*	149	.508*	.401	.076	.055
	(.304	(.905)	(.095)	(.764	(.332)	(.323	*	(.554)	(.010)	(.156	(.766)	(.795
)))	(.002)))
MAAS		-										
	047	.771**	321	255	209	097	420	482*	.088	029	.302	.158
	(.854	(.000)	(.117)	(.278	(.405)	(.645	(.119)	(.043)	(.675)	(.915	(.223)	(.451
))))

Correlations between treatment mechanisms of change (pre-post) and treatment (prepost) pain (McGill and VAS) and well-being (FACT) change in each treatment group.

Note. CBT = Cognitive Behavior Therapy; MCBT = Mindfulness-based Cognitive Behavior Therapy; PHM = Pharmacotherapy; GABS Global Self-Eval = General Attitudes Beliefs Scale (score for global self evaluation subscale); GABS Abs. Beliefs = General Attitudes Beliefs Scale (score for absolutistic beliefs subscale); GABS Total Irrational = General Attitudes Beliefs Scale (total score); PCS = Pain Catastrophizing Scale; CPAQ = Chronic Pain Acceptance Questionnaire; MAAS = Mindfulness Attention Awareness Scale.

Discussions

Results have confirmed only one outcome at the end of the treatment. Only pain changes significantly more in MCBT group as compared to PHM group. This means that at the end of sessions patients in MCBT group reported lower levels of pain intensity than patients in PHM group. Also CBT showed differences at this outcome, but with just nearly significant.

The fact that only pain was significantly reduced, shows that at the end of intervention neither one of the interventions did better than the other for the other outcomes investigated (anxiety, depression, anger, overall distress, well-being).

Watching the data, we can observe that changes in pain intensity from pretreatment to post-treatment, follow a similar pattern to changes in specific cognitions, more precisely in those cognitions that relate to the acceptance of pain. Except chronic pain acceptance, the difference between treatment and mediators is similar for all groups.

Understanding these mechanisms is vital for the development of new, clinical strategies that aim to improve the results obtained in the treatment of a particular disorder, by confronting the most relevant variables that influence the symptoms of that particular disorder. In this case, identifying which psychological factors were responsible

for the treatment change in chronic pain and the secondary outcomes (anxiety, depression, anger, overall distress, well-being) can help us to further improve the treatment of chronic pain in order to obtain better results than are obtained by now through just pharmacotherapy.

Unfortunately, we can say that the hypothesized variables of change we assumed for MCBT in chronic pain did not prove to be the mechanisms of change for the level of pain intensity. We did find significant differences between groups for pain acceptance, meaning that patients in the MCBT have increased their level of acceptance towards pain compared to patients in pharmacotherapy group. However, these changes are not related to the level of pain intensity at the end of the treatment. This means that change in pain intensity is not due to change in acceptance of pain. Some of the changes in cognitions are related with some changes in outcomes, but they are not due to a relation of mediation. For example, global self evaluation is related to changes in pain for all three groups, meaning that at the end of treatment, reduction in these irrational beliefs was related with reduction in pain intensity. It is an important finding the fact that pharmacotherapy group presented significant similar reduction in global self-evaluation as psychotherapy intervention groups. It is possible that an interpretation for such a significant relation for all three groups to be the one that pain is not only an outcome or a consequence of a belief. It can also be considered as an activating event triggering irrational beliefs of self-evaluation. Consequently, if pain is reduced through medication, related self-evaluation beliefs might be automatically reduced due to the fact that the event that triggered them is no longer there. Obviously, a follow-up investigation would better answer to this problem.

As a final conclusion of this study, the mechanism of change analyses shows that change is due to other mechanisms than those intended in the hypothesis.

CHAPTER IV. GENERAL CONCLUSIONS AND DISCUSSION

This research brought important theoretical contributions related to the efficiency of mindfulness interventions on chronic pain. After clarifying and highlighting some of the relevant theoretical aspects in the field, the step forward was made for bringing an important methodological and practical implication, namely exposing if mindfulness strategies can be used as to enhance cognitive-behavioral therapy for chronic pain. These findings will be discussed bellow.

Theoretical advances

The results of study 1 showed that the utility of mindfulness-based interventions for chronic pain condition could be present. It also indicates that it might enhance general features of coping with distress and disability in every day life. The overall mean effect size was a medium one on reducing physical problems (eg. level of pain intensity, physical disability), psychological problems (eg. anxiety, depression) and improving the well-being.

This study was an attempt to systematically investigate the effectiveness of mindfulness-based interventions in chronic pain testifying their impact on chronic pain condition.

Study 2 was focused on clarifying the role mindfulness strategies have in regard to emotion regulation. Because pain comprises both physical and emotional components, this study focused on specifically investigating the impact of mindfulness in relation to multiple forms of efficient strategies on emotional responses.

The study showed that mindfulness has indicated that could be more efficient than other strategies when it comes to negative emotion regulation process. It is an important step in the attempt of elucidating the efficiency of this strategy, asserting that it might incorporate protective factors on how people perceive distressing situations.

Mindfulness's results on negative dysfunctional emotions could be interpreted in accordance with certain hypotheses (Bishop, 2002), that mindfulness might have an impact on metacognitive processes about emotions, changing thus one's beliefs about the nature and meaning of an emotion and resulting in automatic changes over those emotions, increased tolerance towards negative emotions and reduced level of unpleasant emotions.

Another theoretical clarification was brought by study 3 which demonstrates that mindfulness can be successfully used for prolonging the time spent by a person in a painful condition. Results show that in an induced pain condition, using mindfulness can help you better tolerate pain. The important thing is that mindfulness does not change pain intensity, meaning that although you feel a high level of pain you can still endure the unpleasant physical sensation through the process of being willing to experience unwanted events.

An innovative finding was related to the fact that mindfulness has an impact on the perception of speed with which time passes. Being aware of the "here and now" dimension seems to subjectively slow down our time perception, although we find ourselves in a painful physical situation. As opposed to distraction from pain or no specific instruction, mindfulness has the advantage that allows the unfolding passage of time and is experienced as taking less than it actually does in an uncomfortable situation. This could be an interpretation for why participants were able to stay longer periods of time in the painful condition than the other two groups.

Methodological and practical implications

After previous studies clarified the efficacy of mindfulness strategies on emotion regulation and induced-pain condition, a specific objective of the last study was to augment the effects of CBT over chronic pain by integrating mindfulness strategies and verifying its efficiency through a clinical trial.

What the results of this study showed was that only pain changed more at the end of treatment in MCBT than in PHM group. This means that at the end of treatment neither one of the interventions did better than the other for the other outcomes investigated (anxiety, depression, anger, overall distress, well-being). Within each groups changes from pre- to post-treatment were of course visible for all three conditions, particularly at the level of anxiety. For the current study, this fact shows that whether you apply or not a psychological intervention over pharmacotherapy, changes in emotions occur anyway.

One of the important things this study desired to offer as relevant findings were the psychological factors responsible for treatment change in chronic pain. Yet the study could not offer these results. Chronic pain acceptance was found significantly higher in the MCBT group, but was not found relevant at post-treatment at the level of pain, so it could not have counted as mediator.

Limitations and future directions. The present research is not without limitations. First, only undergraduates students participated in the studies 2 and 3, and in study 3 most of the participants were women. Therefore, these results may not generalize to other age groups, or to men (for the second study).

Second, the study 4 was not a randomized clinical trial, participants being allocated in groups in a non-randomized order, thus results could have been influenced by other external factors as well. Also, the MCBT model might not be a good model, in that it might have not encompassed the best or the necessary amount of mindfulness strategies.

Third, the samples of participants was small in all studies.

Future studies should further investigate the beneficial effects of mindfulness in chronic pain and its mechanisms of change and follow-up data should be taken into account.