

LISBOA · PORTO · VISEU

TRANSLATION AND VALIDATION OF THE PAIN SENSITIVITY QUESTIONNAIRE FOR THE HEALTHY PORTUGUESE POPULATION

Dissertação apresentada à Universidade Católica Portuguesa para obtenção do grau de mestre em Neuropsicologia

Por

Joana Maria da Silva Alves

(Lisboa, 2021)



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TRADUÇÃO E VALIDAÇÃO DO QUESTIONÁRIO DE SENSIBILIDADE À DOR PARA A POPULAÇÃO PORTUGUESA SAUDÁVEL

Dissertação apresentada à Universidade Católica Portuguesa para obtenção do grau de mestre em Neuropsicologia

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Joana Maria da Silva Alves

Sob a orientação de Rita Canaipa, PhD e Roi Treister, PhD

(Lisboa, 2021)

Abstract

Several clinical and experimental procedures have been developed with the aim to assess pain sensitivity. The Pain Sensitivity Questionnaire (PSQ) developed by Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht (2009) is the first instrument of self-assessment of pain in healthy individuals and demonstrated that it is possible to assess pain sensitivity using a questionnaire. This instrument was not yet validated for the portuguese population.

The PSQ was translated according to the international guidelines and then presented to a group of 289 healthy individuals. Factorial analysis indicated, as in the original version, a two-component solution (PSQ-Minor and PSQ-Moderate). The internal consistency and convergent validity were good.

Results from a subsample of 42 healthy individuals matched with 42 fibromyalgia patients (FM) were compared to assess the sensitivity of the questionnaire. The results demonstrated that FM group scored significantly higher on all PSQ-PT (Healthy PSQ-PT Total: M=4,67, SD=1,68; Healthy PSQ-PT Minor: M=3,80, SD=1,89; Healthy PSQ-PT Moderate: M=5,70, SD=1,77) and FM group (FM PSQ-PT Total: M=6,86, SD=1,99, FM PSQ-PT Minor: M=6,45, SD=2,41, FM PSQ-PT Moderate: M=7,57, SD=1,78) were significant for all items and Scores (p<0,000).

Finally, a comprehensive experimental pain testing, including different modalities (cold, heat and pressure) and different measures (pain thresholds, pain intensity ratings and *Cold Pressor Test*) and neuropsychological assessment (*Digit Span*) was performed in 12 healthy individuals with the aim of providing clues for future experimental studies. In this pilot study it was found correlations between cognitive functioning and cold pain threshold (Υ =0.70, p<0.00; Υ =-0.689, p<0.05).

In summary, the portuguese version of the PSQ demonstrated a clinically relevant factorial structure, good internal consistency, convergent validity. Based on these findings the portuguese version of PSQ seems to be a good questionnaire to assess pain sensitivity. for improving diagnose, assessment, clinical and research settings.

Keywords: Cognition, experimental pain measurement, pain sensivity, PSQ, fibromyalgia

Resumo

Vários métodos clínicos e experimentais foram desenvolvidos com o objetivo de avaliar a sensibilidade à dor. O Pain Sensitivity Questionnaire (PSQ) desenvolvido por Ruscheweyh, Marziniak, Stumpenhorst, Reinholz e Knecht (2009) é o primeiro instrumento de autoavaliação da dor em indivíduos saudáveis e demonstrou ser possível avaliar a sensibilidade à dor através de um questionário. Este instrumento ainda não foi validado para a população portuguesa.

O PSQ foi traduzido de acordo com as diretrizes internacionais e apresentado a um grupo de 289 indivíduos saudáveis. A análise fatorial indicou, como na versão original, uma solução de dois componentes (PSQ-Minor e PSQ-Moderate). A consistência interna e a validade convergente foram boas.

Os resultados de uma subamostra de 42 indivíduos saudáveis emparelhados com 42 pacientes com fibromialgia (FM) foram comparados para avaliar a sensibilidade do questionário. Os resultados demonstraram que o grupo FM teve pontuação significativamente mais alta em todos os PSQ-PT (PSQ-PT saudável total: M = 4,67, DP = 1,68; PSQ-PT saudável Minor: M = 3,80, DP = 1,89 ; PSQ-PT saudável Moderate: M = 5,70, DP = 1,77) e grupo FM (FM PSQ-PT Total: M = 6,86, DP = 1,99, FM PSQ-PT Minor: M = 6 , 45, DP = 2,41, FM PSQ-PT Moderate: M = 7,57, DP = 1,78) foram significativos para todos os itens e scores (p <0,000).

Finalmente, uma avaliação experimental abrangente de dor, incluindo diferentes modalidades (frio, calor e pressão) e diferentes medidas (limiares de dor, classificações de intensidade de dor e o *Cold Pressor Test*) e avaliação neuropsicológica (*Digit Span*) foi realizada a 12 indivíduos saudáveis com o objetivo de fornecer pistas para os estudos experimentais futuros. Neste estudo piloto foram encontradas correlações entre o funcionamento cognitivo e o limiar de dor frio ($\Upsilon = 0.70$, p <0.00; $\Upsilon = -0.689$, p <0.05).

Palavras-chave: Cognição, medição experimental da dor, sensibilidade à dor, PSQ, fibromialgia

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Para ti...

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<u>1. Introduction</u>

Pain is difficult to measure. Several clinical and experimental procedures have been developed with the aim to assess pain sensitivity. One of the most useful questionnaires assessing pain is the Pain Sensitivity Questionnaire developed by Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht (2009). This was the first instrument of self-assessment of pain in healthy individuals and demonstrated that it is possible to assess pain sensitivity using a questionnaire. Being of rapid application, it also has the advantage of not including applications involving any type of pain stimulation (Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht, 2009).

Even though its recognized value this questionnaire was not yet translated and validated to the portuguese population. Accordingly, the aim of the current study is to translate and validate the Pain Sensitivity Questionnaire for the healthy portuguese population.

This dissertation describes the theoretical background, aims, methods and procedures of three studies. The decision to include these different studies in the same project was done to minimize the burdensome of subjects because using a different approach would imply more lab sessions and task procedures. This should also avoid the need of recruitment of an increased number of participants.

The first study was the translation and validation of the key questionnaire, Pain Sensitivity Questionnaire, developed to assess pain sensitivity. Initially the translation of the Pain Sensitivity Questionnaire from the German language into the portuguese language was be carried out according to the best procedures. After this we assessed the Portuguese Version of PSQ internal consistency and factorial structure, and its convergent validity correlating its scores with Pain Catastrophizing Scale (PCS-PT), State-Trait Anxiety Inventory (STAI-PT) and The Hospital Depression and Anxiety Scale (HADS-PT).

The second study was developed with the aim to assess the sensitivity of the questionnaire comparing the results of the portuguese version of PSQ between healthy control group and a matched chronic pain population (fibromyalgia group).

The third study aim was to perform a pilot study investigating the relation between the PSQ-PT results and experimental pain sensitivity, clinical questionnaires and neuropsychological performance of a healthy group. This study involved the assessment of thermal pain thresholds and pressure pain thresholds as well as the intensity of pain, mainly from heat phasic pain, heat tonic pain and cold tonic pain. Beyond the portuguese version of Pain Sensitivity Questionnaire participants also completed the following relevant questionnaires: Pain Catastrophizing Scale (PCS-PT); State-Trait Anxiety Inventory (STAI-PT) and The Hospital Depression and Anxiety Scale (HADS-PT) and Digit Span.

2. Literature review

2.1 Pain characterization

The International Association for the Study of Pain (IASP) defined pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage". In 2020 this terminology was changed to "an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage".

Pain is multidimensional concept and it includes three dimensions, the sensitive, the cognitive and the emotional that will act at the motor level. These are in constant interaction because, as pain is an experience, it depends, for example, on the discrimination achieved by the sensory dimension, the affectivity by the emotional dimension and how it was evaluated by the cognitive dimension (Melzack and Casey, 1968). The experience of pain is unique and personal because different individuals may experience the same noxious stimulus in different ways (Fillingim, 2005). Several factors can modulate pain. such as psychological, environmental, genetic and physiological factors (Turk & Monarch, 2002). These are constantly interacting and mutually influencing (Dionne, Bartoshuk, Mogil & Witter, 2005).

Pain behaviours can occur due to several reasons, the most common are due to bodily interventions, functional problems, or pain-related complaints. These behaviours can be tested from clinical observation (Frederickson, Lynd and Ross, 1978). LeResche, in 1982, verified that the facial movements adults perform when they feel acute pain are quite regular, and the same was verified in children in the study of Izard, Huebner, Risser, McGinnis and Dougherty (1980) making it possible to assess pain from facial expressions.

2.2 Painreceptors

The nature, intensity, duration and location of the painful stimulus are recognized and decoded by the central nervous system at the sensory receptors, defined by nociceptors. These are sensory receptor neurons sensitive to harmful stimuli or tissue damage and mediate pain, which respond to chemical agents released from traumatized tissues. There are three main classes of nociceptors: thermal, mechanical and polymodal (Martin, 2012).

Thermal nociceptors / thermoreceptors are activated by temperatures below 5° and above 45°. The mechanics / mechanoreceptors are activated by mechanical stimuli of tissue damage that, when they have a large and very myelinated axon, form the A α and A β fibers. The thermoreceptors and puridoreceptors form the A δ fibers, which, because they are little myelinated, allow a faster information conduction to the posterolateral ventral nucleus (VPL) of the thalamus, responsible for the processing of primary pain. C fibers are not myelinated and allow for prolonged pain processing. These, C fibers are polymodals activated by harmful thermal or mechanical stimuli (Martin, 2012).

2.3 Pain pathways

The anterolateral spinothalamic system is the main system involved in pain. This comprises the anterior spinothalamic route and the lateral spinothalamic route (Martin, 2012).

In the anterior spinothalamic tract the first neuron in the dorsal root of the spinal cord sends painful information to the second neuron in the dorsal horn of the spinal cord that crosses in the white commissure in the anterior funiculus. In the posterolateral ventral nucleus (VPL) of the thalamus, the third neuron, allows the discrimination of the sensory characteristics of pain, mainly under rough touch and pressure in the primary somatosensory cortex (1,2,3 Brodmann), as previously mentioned. In the lateral spinothalamic tract, the painful information sent to the second neuron in the dorsal horn of the spinal cord crosses in the white commissure in the lateral funiculus, instead of the anterior funiculus, where its function is to detect and transmit somatosensory information about pain and temperature (Martin, 2012).

For the discrimination of emotional aspects involved in pain, the posterior ventromedial nucleus of the thalamus sends the information to the posterior insular lobe, the medial dorsal thalamus nucleus to the anterior cingulate circunvolution and the parabraquial nucleus to the amygdala (Martin, 2012).

Regarding excitation and control of pain feedback, the brainstem is the main neuronal structure. This system is divided into the spinoreticular pathway, where neurons in the reticular formation send information to the intralaminar thalamic nuclei, which allow the processing of nociceptive information and the spinomesencephalic pathway, which ends at the midbrain roof and in the periaqueductal gray substance (Martin, 2012).

Visceral pain is mediated in the dorsal horn, decussating at the bulb and ascending in the brainstem, medial lemniscus and thalamus (Martin, 2012).

2.4 Pain and Cognition

Cognition and pain are associated both in healthy individuals and in patients with chronic pain (Eccleston, 2013).

When we assess pain, whether acute or chronic, it is necessary to assess cognition as well. As previously mentioned, pain involves a cognitive dimension as the assessment of this experience depends on the cognitive assessment of the imagined or experienced stimulus based on memories, beliefs, learning previously experienced by the subject. Therefore, studies in this area include a battery of neuropsychological tests in conjunction with pain rating scales (VAS e/ou NRS) (Ersek, Cherrier, Overman and Irving, 2004; Moriarty, McGuire and Finn, 2011).

The neuropsychological battery must consist of several tests such as learning and delayed evocation of stories, learning and evocation of figures, total learning and evocation differs free age from *California Verbal Learning Test*, *Phonological Fluency*, *Trail Making Test* (A and B), *The Wisconsin Card Sorting Test* (WCST) and *Digit Vigilance Test*. From the *Wechsler Adult Intelligence Scale* (WAIS) subtests used are *Arithmetic*, *Digit Span*, *Symbol Digit* and *Symbol Search* (Medina et al., 2018).

The most affected cognitive functions related to pain are attention, executive functions, which include working memory, semantic memory and episodic memory (Moriarty, McGuire and Finn, 2011; Kratiz et al., 2015).

Studies in the area between pain and cognition have shown that attention seems to be the cognitive function most affected by pain, as it assesses the real or potential control mechanisms of tissue damage, which can lead to worse performance in cognitive tests that assess this important cognitive function, especially in fibromyalgia (Eccleston and Crombez, 1999; Grisart and Van der Linden, 2001; Legrain et al., 2009). Difficulties in selective attention, inattention, processing speed, inhibitory control, flexibility, working memory, verbal memory and short term, also, seems to be associated with depression (Gelonch et al., 2018). It should be noted that changes in psychomotor skills can be explained by levels of fatigue in chronic pain patients (Suhr, 2003).

Studies in this area suggest that performance on tasks that assess working memory is associated with pain intensity. These data are important insofar as stimuli perceived as painful can interfere in people's daily lives, even if they do not have a diagnosis of chronic pain (Eccleston, 2013; Anderson et al., 2021).

In the 2013 study by Hood, Pulvers and Spady, it was theorized that acute pain negatively affects working memory. The authors verified that the experimental groups, which included men and women, in subjective pain ratings evaluate the experimental test for acute pain (cold pressor task) as more painful compared to the control group (men and women) (F(1, 74) = 70.57, P < .001, $\eta^2 = .49$).

Participants in the experimental group (men and women) had worse scores on the test that assessed working memory (Letter-Number Sequencing) compared to the control groups during the experimental acute pain test (t (37) = -4,71, P <0,0001) (Hood, Pulvers and Spady, 2013).

In the same study, when comparing women with men, the authors found that women in the experimental group had worse scores on the test that assessed working memory compared to the control groups and the experimental group consisting of men (t (1, 36) = 2.50, P = .02, d = .81). They concluded, then, that working memory seems to be one of the cognitive functions most impaired by acute pain, especially in women (Hood, Pulvers and Spady, 2013).

In 2011 Oosterman et al. developed a important study that compare neuropsychological test performance between chronic pain and control groups. In this it was verified that the group with chronic pain has worse performance in neuropsychological tests, mainly in Digit Span Backward [t (64) = 2.01, P<0.05], which assesses working memory. The level of pain intensity, also, was associated with Digit Span Backward (r = -0,38, P <0,05). The authors argue that these results may be influenced by the person's attention capacity, as the performance in working memory tests increases when the variable attention is controlled. These seem to demonstrate that attentional demands of chronic pain and level of pain intensity influence working memory.

In 2021 Procento, Rand, Stewart and Hirsh studied the influence of pain catastrophizing (Trait-Level and State-Level) in working memory between a chronic pain group and a control group. The results indicated that the pain group has worse performance in verbal and non-verbal working memory compared to the healthy group when reported greater state-level catastrophizing, this effect being increased when people with chronic pain have higher trait-level catastrophizing.

2.5 Chronic Pain

When the pain lasts more than three months or the time exceeds the expected healing time, it becomes chronic (McCormick and Frampton, 2019).

Chronic pain can develop due to several factors such as brain damage, lack of some type of enzymes, we have the example of Fabry's disease, genetic conditions or without explainable cause (Simons, Elman & Borsook, 2014).

Chronic pain requires a multidisciplinary approach. This approach should consist of pain specialists, general practitioners, psychologists, neurologists, social workers, nurses, psychiatrists, family members, volunteers and other specialists (IASP, 2010).

Fordyce et al. (1973) developed the basic principles for the treatment of chronic pain. These authors were based on the classic works of Skinner on the conditional operant. The authors refer to operants as responses / behaviors of the patient caused by pain, and in the case of chronic pain they theorize that these same behaviors may have been reinforced to the point that they continue to occur after the harmful stimulus does not exist.

In the face of the COVID-19 pandemic, Eccleston et al. (2020) defends the usefulness of online programs to help chronic pain patients, during quarantine, as they can be accessed directly at home, at reduced cost. The validation of the PSQ-Online it was performed by this pandemic time (McIntyre et al., 2020).

2.5.1 Fibromyalgia

According to Wolf et al., (1990) fibromyalgia (FM) is a chronic pain syndrome that is characterized by the presence of generalized musculoskeletal pain.

The main symptoms are pain and fatigue, and other symptoms such as cognitive deficits, sleep and gastrointestinal disorders, depression and anxiety (Wolfe, et al., 2010). Portuguese studies show a prevalence of this syndrome of 1.7% (Branco, et al., 2016), and worldwide it is 3 to 6% of the population affected by this condition (Di Tella, et al., 2015).

Changes in peripheral and central pain processing have been reported (Oklander, et al., 2013) and high variability in clinical pain (Harris, et al., 2005).

Throughout the literature, it has been theorized that people diagnosed with fibromyalgia present changes in connectivity in the prefrontal cortex, anterior cingulate cortex, insula, hypothalamus and periaqueductal gray matter, regions that are related to pain processing and perception (Borchers and Gershwin, 2015).

Studies show that in FM there seems to be changes in brain chemistry, such as an increase in the concentrations of Glutamate in the cerebrospinal fluid and in the substance P. On the other hand, there seems to be a decrease in the concentrations of gamma-aminobutyric acid (inhibitory neurotransmitter), serotonin, norepinephrine and dopamine. There also seem to be changes in the hypothalamic-pituitary-adrenal (HPA) axis, thus justifying the presence of stress as one of the symptoms of the syndrome (Borchers and Gershwin, 2015).

Fibromyalgia patients complain of deep muscle pain and muscle fatigue when performing tasks with low intensity. These complaints seem to be justified by the changes observed in the functionality of the A δ and C fibers (Borchers and Gershwin, 2015).

According to Borchers and Gershwin (2015) patients with fibromyalgia also present symptoms of hypersensitivity, such as exaggerated sensitivity of pain or sensation of pain with typically non-painful stimuli.

According to Malin and Littlejohna (2012) the subject's personality, due to different life events, can provoke pathological psychological responses, which may influence dimensions such as pain, sensitivity, sleep quality, cognition. This pattern is seen in people who suffer from fibromyalgia. Because of this there's a high prevalence

of psychiatric disorders, mainly, depressive and anxiety disorders. Disorders such a bipolar affective disorder and post-traumatic stress disorder can also be observed. It should be noted that suicidal behaviors are considered a risk factor for the population suffering from chronic, including patients with fibromyalgia (Galvez-Sánchez, Duscheke and Paso, 2019).

The cognitive deficits associated with this syndrome are related to difficulties in general screening measures of cognition, in terms of attention, learning and memory. These difficulties in terms of cognition seem to be associated with the symptoms of fatigue and depressive and/or anxiogenic symptoms, which are quite present in a picture of fibromyalgia (Legrain et al., 2009; Moriarty, McGuire and Finn, 2011).

Arnold (2010) states that treatments are divided into two major groups, pharmacological and non-pharmacological. Regarding non-pharmacological approaches, the recommendation is treatment based on cognitive-behavioral therapy and physical exercise. In order to help the patient learn to self-manage his condition, teach him strategies so that he is able to deal with fibromyalgia and achieve a good quality of life (Kwiatek, 2017).

2. 6 Pain Assessment

2.6.1 Pain Assessment in clinic

Pain is a subjective and personal experience and so it is difficult to measure. There are several procedures for testing pain, and the most used are psychophysics, evaluation scales (questionnaires) and behavioural observations (Chapman et al., 1985).

According to Scott and Huskisson (1976) one of the most used one-dimensional scale in pain is the *Visual Analog Scale* (VAS) where a line with well-defined intervals is presented graphically, being a good scale to measure the individual's subjective pain experience. In this the subject is asked to indicate in the line the intensity of the pain felt, which can vary between non-painful and extremely painful (Chapman et al., 1985). *Numerical Rating Scales* (NRS) are other of the one-dimensional scales used to quantify pain intensity. They consist of a marked line, horizontally or vertically, with numbers from 0 to 10 (or 0 to 100), where 0 corresponds to no pain, 5 (or 50) to moderate pain, and 10 (or 100) to the worst pain imaginable. Individuals are asked to verbally or

graphically indicate the number that represents the intensity of pain they have experienced (Sinatra, De Leon-Cassasola, Ginsberg, Viscusi & McQuay, 2009).

The Verbal Rating Scale (VRS) is a one-dimensional ordinal scale, also used to quantify pain intensity. This is made up of four to six adjectives where the person is asked to evaluate the pain experienced from four pain intensities, ranging from 0 to 3, where 0 corresponds to no pain, 1 to mild pain, 2 to moderate pain and 3 to severe pain (Sinatra, De Leon-Cassasola, Ginsberg, Viscusi & McQuay, 2009).

The McGill Pain Questionnaire is one of the most used multidimensional pain assessment measure. It was developed with the purpose of evaluating the pain experience in a multidimensional way. The authors selected words that described the different ways of experiencing pain. Those words were divided into three classes: sensory, affective and evaluative, which were also subdivided into sixteen classes. Accordingly, each subject is asked to assign a value to each word, representing the intensity, ranging from the lowest pain to the greatest pain possible, on a numerical scale. The final version consisted of a questionnaire where the participant's medical information was requested and, where he feels the pain, he must indicate it in a drawing representing the human body. Then the participant must indicate which word best represents his experience of pain, how this varies over time and, finally, classify it from 1 to 5, where number 1 represents mild, 2 discomforting, 3 distressing, 4 horrible and 5 excruciating, a present pain intensity (PPI) (Melzack, 1975).

Another of the most widely used multidimensional scales for assessing pain is the *Wisconsin Brief Pain Questionnaire*. Initially patients' clinical history is requested, then, as in the previous questionnaire, and in a human body drawing, they indicate where they feel the pain, then they are asked to evaluate from 0 to 10, where 0 corresponds to "no pain "and 10 a" pain as bad as you can imagine ". Next, information is asked about the medications and treatments they do to combat pain and how patients feel they are acting to decrease pain. Finally, they assess how pain interferes with their daily lives, such as how they act at the level of humour, interpersonal relationships, sleeping capacity, or contentment they feel about their own lives (Daut, Cleeland & Flanery, 1983).

2.6.2 Pain assessment in laboratory settings

Contrary to the questionnaires, experimental pain can be assessed after the induction of a painful stimulus. These measures allow the assessment of pain sensitivity (Fillingim, King, Ribeiro-Dasilva, Rahim-Williams & Riley, 2009).

Several paradigms have been developed. In the pain Thresholds paradigm, the subject is asked to identify when an increasing stimulus moves from pain-free to painful. Pain tolerance can also be evaluated, which is done by asking the subject to endure as long as possible a painful experience. It is usually performed using the cold pressor test, where the participant puts his hand in cold water and tries to take the maximum time with the immersed hand in this water (Chapman et al., 1985).

Horn-Hofmanna, Kunza, Maddena, Schnabela and Lautenbachera (2018) theorize the relevance of the dynamic paradigms that evaluate experimental pain and particularly the descending pain modulatory system. Generally, they can be divided into two methods: "Temporal Summation of Pain" (TSP) and "Conditioned Pain Modulation" (CPM). According to the same authors Temporal Summation of Pain consists of increased pain response when stimuli are applied repetitively over a given period of time compared to the application of a single stimulus. In CPM the stimulus that is being tested is conditioned by a conditioned stimulus, the latter aiming to influence the perception of pain (Yarnitsky et al., 2010).

2.6.2.1. Pain sensitivity

Throughout the literature, it is theorized that pain sensitivity varies according to age group. From studies with children and adolescents it was found that younger children tend to have greater sensitivity to pain (Tumi, Johnson, Dantas, Maynard, Tashani, 2017).

Children between 6 and 12 years old tend to have lower pain thresholds when the noxious stimulus is hot or pressured, compared to pre-adolescents and adolescents. Especially girls who, in general, have lower pain thresholds to harmful stimuli of heat, cold and pressure and, equally, lower tolerance to the latter (Blankenburg et al., 2010).

The following year, Blankenburg et al. (2011) evaluated somatosensory perception among children aged 7 to 14 years and found that younger children tend to have lower thresholds for painful stimuli of heat, pressure and stings. However, in most

studies involving stinging stimuli there are no differences between boys and girls (Tumi et al., 2017).

Differences in pain sensitivity have also been evaluated in studies with adults. Younger adults seem to have higher pressure pain thresholds compared to the elderly, with no differences when noxious stimuli are heat. However data are inconsistent throughout the literature (Tumi et al., 2017).

2.7. The Pain Sensitivity Questionnaire-PSQ

Pain is difficult to measure. Several clinical and experimental procedures have been developed with the aim to assess pain sensitivity. One of the most useful questionnaires assessing pain is the Pain Sensitivity Questionnaire developed by Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht (2009). It was developed with the aim of evaluating, specifically, the intensity of the pain. It consists of 17 items, interleaved among the fourteen items that refer to painful situations for most people (refers to the PSQ-total, which consists of the total average of all the remaining 14 items after item analysis), and three items that usually do not refer to painful situations. Item 5 corresponding to "Imagine you take a shower with lukewarm water", item 9 corresponding to "Imagine walking across a cool tiled floor with bare feet" and item 13 corresponding to "Imagine you shake hands with someone who has a normal grip" describe daily situations usually not involving pain. On the other hand, the other items are related to painful situations, for example item 2 "Imagine you burn your tongue on a very hot drink", item 7 "Imagine you grazed your knee falling off your bicycle" or item 16 "Imagine you are wearing sandals and someone with heavy boots steps on your foot". Participants are asked to evaluate, to what extent, certain situations of everyday life are painful in a scale ranging from 0 to 10, where 0 corresponds to the "absence of pain" and 10 to "the highest possible pain". It should be noted that the participants are suggested that the fear or aversion they may feel when imagining themselves in that situation does not affect the evaluation performed. The PSQ takes between 5 to 10 minutes.

From the factorial analysis of the questionnaire two factors were found that explained 55 % of the total variance. Factor 1 that refers to extremely painful conditions, called PSQ-moderate, included the individual mean of the items and mean score between 4 and 6. On the other hand, factor 2, corresponding to situations of mild pain titled PSQ-

minor, corresponds to the individual average of the items and the average rating <4. In the first validation of the PSQ, a Cronbach's value of 0.92 was obtained for the PSQ-total, 0.81 for PSQ-minor and 0.91 for the PSQ-moderate, thus demonstrating a good internal consistency. This questionnaire also shows a good test-retest reliability, where coefficients were obtained from 0.83 for the PSQ-total, 0.86 for the PSQ-minor and 0.79 for the PSQ-moderate. Concerning the results of the PSQ, statistically significant correlations were found between this and the experimental classifications of pain intensity (r = 0.56, p <0.001). However, the same did not happen for pain thresholds (r = 0.03). Significant correlations were found between the PSQ and all the experimental pain intensity classifications such as pinprick, phasic heat 47 ° C, phasic heat 48 ° C, tonic heat, tonic cold and cold pressor test. Convergent validity was good because PSQ total score (r=0.45, p < 0.01), PSQ Minor (r=0.38, p < 0.01) and PSQ Moderate (r=0.43, p < 0.01) showed positive correlation with PCS (pain-specific measure) (Ruscheweyh et al., 2009).

The PSQ-total (32.2% of the variance) was found to be a better predictor of the intensity of experimental pain than psychological factors such as depression, anxiety and catastrophization (Ruscheweyh et al., 2009).

Specifically, in the validation of PSQ for the English language (PSQ-E), a linear regression analysis was performed to test if the PSQ-E predicts the visual analogue scale (VAS), which allows to evaluate the pain experience. After two injections of lidocaine substance at the subcutaneous level, pain ratings on a visual analog scale (VAS 1 and VAS 2) were obtained. In general, results quite similar to the validations described above were obtained, once PSQ-E-minor significantly predicted VAS 1 (r = 0.26, P <0.01) and the same for VAS 2 (r = 0.34, P <0.001) (Sellers et al., 2013).

In the validation of the PSQ for the Norwegian language, a Cronbach's value of 0.85 for PSQ-minor, 0.90 for PSQ-moderate and 0.93 for PSQ-total was obtained, as in previous studies, good internal consistency and good reliability were obtained. Statistically significant correlations were found between PSQ of healthy participants and those of the experimental pain sensitivity, mainly in the cold pressor. The same was verified for PSQ-total and PSQ-minor in cold pressor pain tolerance. However, the experimental heat pain threshold is not correlated with the PSQ. It was verified, then, that it meets the original validation (Valeberg et al., 2017).

In the validation of PSQ for the different languages (Ruscheweyh et al., 2012; Sellers et al., 2013; Valeberg et al., 2017) results are quite similar to the validations described above were obtained, as in previous studies, good internal consistency and good reliability were obtained. In all PSQ validations, both with healthy participants and with chronic pain participants, the results agreed with the original version of the PSQ.

Similar to PSQ scores in healthy population, BDI, STAI and PCS scores were higher in the chronic pain patients. In chronic mixed pain patients statistically, significant correlations were found between PSQ-minor scores (2.7 ± 1.4), which was significantly different from the healthy group (T [255] = 2.9, P < .01, d = 0.36) (Ruscheweyh et al., 2012).

Significant correlations were found between PSQ scores in chronic population and the experimental classifications of pain intensity, such as phasic heat 47°C, phasic heat 48°C, pinprick and tonic cold (r = 0.71, p <.001) and also between PSQ and the pain thresholds of heat pain and pressure pain (r = -0.52, p <0.001). PSQ-minor was shown to be the best predictor of experimental pain intensity (52.3% of the variance) and pain thresholds (26.2% of the variance), and PSQ-total was also a good predictor (21.3% of variation in the threshold of experimental pain and 58.3% of variation in the score of intensity of experimental pain) compared to psychological factors such as depression, anxiety and catastrophism (Ruscheweyh et al., 2012).

In summary, for all these reasons, the PSQ proves to be a good instrument in the evaluation of pain sensitivity, therefore it is very important to validate this one into the portuguese language. Accordingly, the aim of the current study is to translate and validate the Pain Sensitivity Questionnaire for the healthy Portuguese Population. Specifically, it is aim to assess if the results in portuguese version of the Pain Sensitivity Questionnaire are related to the results of the experimental pain sensitivity assessment.

3. Aims of the Study

3.1 Aim of the 1st Study

The aim of the current study is to translate and validate the Pain Sensitivity Questionnaire for the healthy Portuguese Population. Specifically, will assess the Portuguese Version of PSQ (PSQ-PT) internal consistency and factorial structure, and its convergent validity correlating its scores with *Pain Catastrophizing Scale*, *State-Trait Anxiety Inventory* and *The Hospital Depression and Anxiety Scale*.

3.2 Aims of the 2nd Study

The aim of the second study described in this dissertation is to compare the results of the described in first study (PSQ-PT) between healthy group and a matched fibromyalgia group (FM Group). We hypothesize that the FM group will show increased mean scores in all the scores of the portuguese version of this questionnaire. Besides, we will assess the relations between PSQ in these groups and *Pain Catastrophizing Scale*, *State-Trait Anxiety Inventory* and The *Hospital Depression and Anxiety Scale*.

3.3 Aims of the 3rd Study

The aim of the third study of the current dissertation is to assess if the *Pain Sensitivity Questionnaire* have the expected relations with the theoretical related questionnaires and pain sensitivity measures.

Pain and cognition are related and the most affected cognitive functions are attention and executive functions, which include working memory (Kratiz et al.,2015). Accordingly, it is important to assess if the scores of PSQ-PT are related to cognitive function, so, we will assess the relations between PSQ and *Digit Span*.

4. Methods

4.1 Method of the 1st Study

4.1.1 Participants of the 1st Study

Two hundred and eighty-nine participants (n=289) of several areas of Portugal were recruited, using the webpage method. This was a convenience sample. Participants meeted the following criteria: (1) age above 18 years; (2) sufficient knowledge of the portuguese language. (3) Healthy, without presenting physical pathologies involving pain.

4.1.2 Procedure of the 1st Study

The study was conducted in accordance with the Declaration of Helsinki and with the approval of the Ethical Board of the Catholic University of Portugal (see appendice 9.1).

4.1.2.1 Translation Procedures

Initially the translation of the Pain Sensitivity Questionnaire from the German language into the portuguese language that was carried out, based on the best recommended guidelines. This translation includes several steps, initially two portuguese independent translators, fluent in German, carry out the translation of the original scale, written in German, into the portuguese language. Then a third portuguese translator compares the two previous translations and wrote a report explaining whether he chose one of the previous translations, if a hybridization of the two translations was performed or if a new translation was created. From the translation chosen by the third translator, a translation into the original language, in this case from portuguese to German, was done by a German translator who was fluent in portuguese. The latter was compared with the original questionnaire in order to guarantee equivalence and coherence between the original and the portuguese version. Finally, the final version was evaluated by three portuguese specialists in the area of pain. The questionnaires were provided to the subjects in one of two formats, by using a webpage specifically related to the study or by paper, personally (first and second studies). Informed consent was provided to all study participants (see appendice 9.2). Participants completed all the questionnaires. It should be mentioned that using the webpage method, this was done using specific academic tools which can guarantee the confidentiality and security of the data. After completing the questionnaires, the subjects were invited to participate in the second part of the study. If they would like to be contacted and participate in the lab session (third study), they sended an email to the research team expressing their availability.

4.1.3 Instruments of the 1st Study

4.1.3.1 Sociodemographic questionnaire

Sociodemographic questionnaire requests information regarding age, sex, civil status, years of education, body mass index (BMI), dominant hand, medication, about pain history and about medical history, specially. psychiatric disease and neurologic condition.

4.1.3.2 Pain Sensitivity Questionnaire

This consists of 17 items, interspersed between the fourteen items that refer to painful situations for most people and three items that usually do not refer to painful situations. From a scale of 0 to 10, where 0 corresponds to the "absence of pain" and 10 to the "highest possible pain", participants were asked to evaluated to what extent certain situations of daily life are painful (Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht, 2009).

<u>4.1.3.3 State-Trait Anxiety Inventory (STAI) (Spielberger, Gorsuch, Lushene, Vagg &</u> <u>Jacobs, 1983)</u>

This questionnaire consists of 40 items, divided into two forms, the form Y-1 and the form Y-2, both constituted by 20 items each. In the form Y-1 is intended to assess the state anxiety, is how the person feels at that exact moment and the Y-2 form to assess the trace anxiety, thus evaluating how the person feels overall The Portuguese version has good psychometric qualities and was used (Santos e Silva, 1997).

4.1.3.4 The Hospital Depression and Anxiety Scale (HADS)(Zigmond & Snaith 1983)

Is an instrument to determines levels of depression and anxiety in individuals with no psychiatric condition. This instrument is composed by four-point Likert scale (0-3) with two subscales: depression and anxiety, with seven items each. The answers are based on how the subjects felt the last seven days. The results formed a range from 0 to 21, for each subscale with the higher score (16-21) indicating higher levels of depression and anxiety and in the other hand low scores means there is no presence of anxious or depression pathology (0-7). The Portuguese version of this instrument was validated by McIntyre et al. in 1999. This instrument demonstrated good psychometric properties.

4.1.3.5 Pain Catastrophizing Scale (PCS) (Sullivan, Bishop & Pivik, 1995)

This assesses pain and catastrophizing using 13 items divided into three dimensions: rumination, magnification and discouragement. Participants assess to what extent thoughts, feelings or perceptions are related to pain on a scale ranging from 0 to 4. Final score ranges from 0 points to 52 points. (Azevedo et al., 2007).

4.1.4 Statistics of the 1st study

Data was collected and processed via Excel (Microsoft Corp, Redmond, WA, USA), and was analysed by using the SPSS software version 25 (SPSS, Inc., Chicago, IL, USA). The normal distribution was tested using the *Kolmogorov–Smirnov test*. Descriptive statistics were used to present demographic characteristics. Internal validity was assessed by Cronbach's alpha. Factorial Analysis was performed. Exploratory factor analysis (EFA) with principal components extraction was performed on the responses of all 289 participants with varimax rotation, with factor weights rejected if the difference was less than 1. This method was repeated until a factor structure was formed. Pearson's correlations were used to assess correlations between questionnaires. Statistical significance was defined as $p \le 0.05$ and $p \le 0.001$.

4.2 Methods of the 2nd study

4.2.1 Participants of the 2nd study

This study included 42 healthy participants and 42 FM participants recruited from portuguese FM patients' associations. In order to compare the results of the PSQ-PT and other related questionnaires, an age, gender, BMI, education and civil status matched healthy control subsample of 42 participants was obtained from study 1.

All participants meeted the following criteria: (1) age above 18 years and (2) sufficient knowledge of the portuguese language. The FM Group also meeted the inclusion criteria: diagnose of fibromyalgia.

Exclusion criteria was the presence of diagnosed neurologic or psychiatric condition in both group.

4.2.2 Instruments of the 2nd study

Pain Sensitivity Questionnaire (Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht, 2009) Pain Catastrophizing Scale (PCS-PT), State-Trait Anxiety Inventory (STAI-PT) and The Hospital Depression and Anxiety Scale (HADS-PT). The full description can be found in the first study methods.

4.2.3 Statistic of the 2nd study

Data was collected and processed via Excel (Microsoft Corp, Redmond, WA, USA) and was analysed by using the SPSS software version 25 (SPSS, Inc., Chicago, IL, USA). The normal distribution was tested using the *Kolmogorov–Smirnov test*. Descriptive statistics were used to present demographic characteristics. Parametric t-student test was followed for independent samples. Pearson's correlations were used to assess correlations between groups and questionnaires. Statistical significance was defined as $p \le 0.05$.

4. 3 Methods of the 3rd study

<u>4.3.1 Participants of the 3rd study</u>

The 12 participants, 3 male and 9 females, were recruited. The sample was of convenience, the major part were students.

Inclusion criteria were: 1) Age between 18-35 years, 2) Healthy, without presenting physical pathologies that induce pain and 3) mentally and cognitively healthy, no history of any disorder. Exclusion criteria were: 1) Blind or subjects with very poor sight due to the importance of the visual perception in this studies, 2) Presence of any active acute pain at the time of the studies, 3) consume of any medication that affects pain and 4) presence of any active illness at the time of the studies.

4.3.2. Instruments of the 3rd study

4.3.2.1. Experimental Pain Assessment

4.3.2.1.1. Pain thresholds

Heat and cold pain thresholds were tested with *Medoc TSA-II*. A probe were attached to the skin of the participant, where an adaptation temperature of $30 \circ C$ to $32 \circ C$ was set. During this test, the temperature increased and decreased, and the subject was asked to press on a keyboard if the stimulus refers to heat or cold. Three stimuli was applied on each forearm. The average of all measurements was the value of the pain threshold of cold and heat.

Pressure pain thresholds was tested with the Wagner KP100 Algometer where, in the participant's trapezius muscle, a force that was increased 0.5 kg/cm2 was applied. The participant was asked to say "stop" at the moment the stimulus becomes painful. The average of all measurements corresponded to the value of the pain threshold for the pressure (Ruscheweyh et al., 2009).

4.3.2.1.2. Pain intensity assessment

Phasic heat stimuli at 47°C and 48°C was tested with *Medoc TSA-II*. Heat stimuli were applied to the non-dominant arm for 3 seconds from a thermode. Lower temperatures were applied (44-47°C) between heat stimuli to avoid memory effects during the classification of successive identical stimuli. After each application, each experimental subject was asked to evaluated the pain intensity on a numerical rating scale [0-100]. The mean of the four classifications collected at each temperature was used as the phasic pain classification at 47°C and 48°C.

Heat tonic stimuli was tested by a probe (*Medoc TSA-II*) on the dominant forearm where hot pain stimuli with a fixed temperature of 46.5°C were applied over 20 seconds. Participants were instructed to assess, on a numerical rating scale [0-100], the pain they felt as soon as the temperature reached the plateau, 10 seconds and 20 seconds.

In the *Cold Pressor Test* the participants were instructed to immersed their nondominant hand in a cold-water box and then to keep it submerged for as long as they could (up to a safety limit of 3 minutes). Participants were asked to rate their pain on a Numerical Rating Scale [0-100], from = "not painful" to "maximum of pain felt" each 30 seconds. Before immerging the hand on the water the NRS was score with 0. The time of the hand withdrawal was then registered as cold pain tolerance. For safety, in case the participants feel uncomfortable with the pain during the test, they were instructed that they can remove their hands from the cold water at any time during the test.

4.3.2.1.3. Pain tolerance

Heat tolerance was tested with *Medoc TSA-II* where a probe was attached to the skin of the participant. During this test, the temperature increased and the subject was asked to clicked the button of the computer to stop stimulation when the heat reached a point of unbearable pain. The tolerance was recorded as the intensity of the stimulus, regarding the moment when the subject clicked the button of the computer to stop stimulation.

4.3.2.2. Pain Sensitivity Questionnaire (Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht, 2009) Pain Catastrophizing Scale (PCS-PT), State-Trait Anxiety Inventory (STAI-PT) and The Hospital Depression and Anxiety Scale (HADS-PT). The full description can be found in the first study methods.

4.3.2.3. Neuropsychological Assessment

4.3.2.3.1. Digit Span

Digit Span Test is divided into two: number memory in forward order and number memory in reverse order, each consisting of seven series and two trials (Wechsler, 1997). In the first one, a certain number of digits was read aloud and the individual was asked to repeat it in direct order, while in the second the digits they were read aloud, and the same participant was asked to say it in reverse order. This test was interrupted after two incorrect answers in two attempts in a series. The score was assigned to the series in which the examinee got both attempts right (Garcia, 1984; Guerreiro, 1998).

4.3.3. Statistic of the 3rd study

Data was collected by paper and analysed by using the SPSS software version 25 (SPSS, Inc., Chicago, IL, USA). The normal distribution was tested using the *Kolmogorov–Smirnov test*. Descriptive statistics were used to present demographic characteristics. Spearman's correlations were used to assess correlations between questionnaires. Statistical significance is defined as $p\leq0.05$ and $p\leq0,001$.

5. Results

5.1. Results of the 1st study

Table 1.

Demographic Characterization of the First Study's Population (n=289)

	Total sample	Total Sample Frequency (%)
	Mean (SD)	
Age	33,90 (14,506)	
Gender		
Female		177 (61,2)
Male		112 (38,8)
Civic Status		
Single		174 (60,2)
Married		66 (22,8)
Divorcer		17 (5,9)
Civic Partnership		32 (11,1)
Widow/Widower		0 (0)
BMI		
Extreme Thinness		0 (0)
Slight Thinness		15 (5,2)
Normal Weight		157 (54,3)
Pre-obese		78 (27)
Obese (type 1)		24 (8,3)
Obese (type 2)		9 (3,1)
Obese (type 3)		4 (1, 4)

Education		
Until 4th grade	2 (0,7)	
Until 6th grade	5 (1,7)	
Until 9th grade	27 (9,3)	
High School	122 (42,2)	
Degree	90 (31,1)	
Master	40 (13,8)	
PhD	3 (1)	

This study assessed 289 participants and the demographic data can be found in Table 1.

The age of the participants in the control group was M=33.90 (SD =14.509). Regarding their gender, 177 women were enrolled (61,2%) and 112 men (38.8%). The civil status on the total cohort, 174 (60.2%) of the participants were single, 66 (22.8%) were married; 17 (5.9%) were divorced; 32 (11.1%) were living in a civil partnership and no one were widowed. In this study the level of education of the participants are: 2 (0.7%) participants had 4th grade, 5 (1,7%) had 6th grade, 27 (9,3%) had 9th grade. 122 (42.2%) had high school and 133 (45.9 %) had superior education.

Regarding their BMI (Body Mass Index), we can observe that most of the participants 157 (54.3%) were within the normal weight. We have also recorded 15 (5.2%) participants that were below the normal range, and 78 (27%) participants were above normal weight.

Table 2.

Mean and SD pain scores of The Pain Sensitivity Questionnaire (n=289)

PSQ Itens	Mean (SD)
Item 1	6,21 (2,02)
Item 2	5,56 (2,03)
Item 3	3,67 (1,85)

Item 4	6,69 (1,99)
Item 5	1,09 (1,93)
Item 6	3,51 (2,12)
Item 7	4,40 (2,11)
Item 8	5,68 (2,25)
Item 9	1,55 (2,17)
Item 10	3,99 (2,26)
Item 11	3,52 (2,12)
Item 12	4,58 (2,43)
Item 13	0,85 (1,64)
Item 14	2,65 (2,30)
Item 15	5,84 (2,35)
Item 16	5,65 (2,32)
Item 17	5,88 (2,34)
PSQ Total	4,84 (1,60)
PSQ Minor	3,76 (1,65)
PSQ Moderate	5,50 (1,67)

The table 2 presents the mean score and standard deviation of PSQ original for all participants (n=289) for each item.

The mean and standard deviation of subscores of the portuguese version of the pain sensitivity questionnaire are PSQ-PT Total: M=4.84 and SD=1.60, PSQ-PT Minor: M=3.76 and SD=1.65 and PSQ-PT Moderate: M=5.50 and SD=1.67.

Item 1 ("Imagine you bump your shin badly on a hard edge, for example, on the edge of a glass coffee table. How painful would that be for you?") and Item 4 ("Imagine you trap your finger in a drawer.") are the ones with the highest average values.

On the other hand, item 5 ("Imagine you take a shower with lukewarm water.") and item 13 ("Imagine you shake hands with someone who has a normal grip.") were the ones with the lowest score.

Table 3.

The 2 component solution of the Principal Component Analysis of PSQ (n=289)

	1	2
Item 1	0,718	
Item 2	0,758	
Item 4	0,849	
Item 5		0,802
Item 8	0,755	
Item 9		0,814
Item 10	0,580	
Item 11		0,603
Item 12	0,640	
Item 13		0,870
Item 14		0,693
Item 15	0,727	
Item 16	0,758	
Item 17	0,777	

Table 3 describes an exploratory factorial analysis based on the "Principal Components Method" (PCM), that was conducted to validate the construct and the orthogonal rotation of Varimax factors. From the factorial analysis of the questionnaire, two factors were found. Factor 1 that refers to extremely painful conditions, called PSQ-moderate, included the individual mean of the items and mean score between 4 and 6 (Items 1 ("Imagine you bump your shin badly on a hard edge, for example, on the edge of a glass coffee table"); 2 ("Imagine you burn your tongue on a very hot drink"); 4 ("Imagine you trap your finger in a drawer"); 8 ("Imagine you accidentally bite your tongue or cheek badly while eating"); 15 ("Imagine you pick up a hot pot by inadvertently grabbing its equally hot handles");

16 ("Imagine you are wearing sandals and someone with heavy boots steps on your foot") and 17 ("Imagine you bump your elbow on the edge of a table ("funny bone")")). On the other hand, factor 2, corresponding to situations of mild pain titled PSQ- minor, corresponds to the individual average of the items and the average rating <4 (Items: 10 ("Imagine you have a minor cut on your finger and inadvertently get lemon juice in the wound"); 11 ("Imagine you prick your fingertip on the thorn of a rose"); 12 ("Imagine you stick your bare hands in the snow for a couple of minutes or bring your hands in contact with snow for some time, for example, while making snowballs") and 14 ("Imagine you shake hands with someone who has a very strong grip").

Exploratory factor analysis with principal components extraction, was conducted on the responses of all 289 healthy participants.

The first factorial analysis generated a 2 factors scale, a KMO of 0.928 revealed data adequacy, while the Bartlett test (X2[120] = 3056,810; p < 0.001) confirmed stability. The 2 factors which were obtained, explained 62.56% of the total variance. The variance of each item was determined including a 0.50 minimum commonality value. Following the exploratory factorial analyses (EFA), the third item was removed ("Imagine your muscles are slightly sore as the result of physical activity.").

After removing this item, KMO was 0.928, revelling data adequacy, the Bartlett test was X2[120] = 3056,810; p < 0.001 and explained 62,557% of the total variance). Following the exploratory factorial analyses (EFA), the seventh item was removed ("Imagine you grazed your knee falling off your bicycle:").

After removing this item was found a KMO of 0,927 and a Bartlett test of X2[435] = 2847,383; p < 0.001 that explained 63,97% of the total variance. Following the exploratory factorial analyses (EFA), the sixth item was removed ("Imagine you have mild sunburn on your shoulders.").

After removing this item was found a KMO of 0,923 and a Bartlett test of X2[435] = 2677,609; p < 0.001 that explained 65,367 % of the total variance.

In the PSQ-PT, a Cronbach's value of 0.95 was obtained for the PSQ-total, 0.95 for PSQ-minor and 0.97 for the PSQ-moderate demonstrating a good internal consistency.

Table 4.

Scores of the clinical questionnaires for total first study group (n=289)

	Mean (SD)
Pain Sensitivity Questionnaire	
PSQ Total	4,5 (1,61)
PSQ Minor	3,69 (1,91)
PSQ Moderate	5,5 (1,67)
Pain Catastrophizing Scale	
PCS Total	6,69 (1,99)
State-Trait Anxiety Inventory	
STAI Total	1,09 (1,93)
STAI Y1	3,51 (2,12)
STAI Y2	4,40 (2,11)
Hospital Scale of Depression and Anxiet	У
HADS Anxiety Subscore	5,68 (2,25)
HADS Depression Subscore	1,55 (2,17)

Table 4 describes the participants' mean scores in instruments that are importantly related to pain sensivity.

The mean score for STAI Total was M=5,68 (SD=2.25) and for the HADS Anxiety Subscore was M=1,09 (SD=1,93) which is below the cutoff point (7) demonstrating did not show presence of anxiety. The same was confirmed for depression (M=1.55, SD=2.17).

The participants did not show presence of Pain Catastrophizing because the mean of the PCS results was M=6.69 (SD=1.99).

Table 5.

Correlation between PSQ-PT and PCS, STAI and HADS of the participant's of the first study (n=289)

	PSQ-PT Total	PSQ-PT Minor	PSQ-PT Moderate
Pain Catastrophizing Scale			
PCS Total	0,304**	0,290**	0,292**
State-Trait Anxiety Inventory			
STAI Total	0,015	0,052	0,001
STAI Y1	0,046	0,076	0,028
STAI Y2	-0,020	0,021	-0,029
Hospital Scale of Depression			
and Anxiety			
HADS Anxiety Subscore	0,075	0.107	0,070
HADS Depression Subscore	0,049	0,090	0,021

**Pearson correlations is significant at the 0,001 level

Table 5 describes the presence or absence of correlation between PSQ-PT and the questionnaires used in this first study.

The results of PSQ-PT total score (r=0.304, p < 0.01), PSQ-PT Minor (r=0.290, p < 0.01), and PSQ-PT Moderate (r=0.292, p < 0.01), showed positive correlation with Pain Catastrophizing Scale total score. The State-Trait Anxiety Inventory, The Hospital Depression and Anxiety Scale did not show correlation with the PSQ-PT.

5.2. Results of the 2nd study

Table 6.

Demographic Characterization of the Second Study's Population (n=84)

	Healthy Group	Healthy Group	FM Group	FM Group
	Mean (SD)	Frequency (%)	Mean (SD)	Frequency (%)
	n=42		n=42	
Age	47,19 (8,40)		47,38 (8,40)	
Gender				
Female		42 (50,0)		42 (50,0)
Civic Status				
Single		11 (13,1)		5 (6,0)
Married		19 (22,6)		19 (22,6)
Divorced		5 (6,0)		8 (9,5)
Civic Partnership		7 (8,3)		6 (7,1)
Widow/Widower		0 (0)		1 (1,2)
BMI				
Extreme Thinness		0 (0)		0 (0)
Slight Thinness		1 (1,2)		1 (1,2)
Normal Weight		35 (21,4)		17 (20,2)
Pre-obese		29 (17,9)		14 (16,7)
Obese (type 1)		11 (6)		6 (7,1)
Obese (type 2)		6 (3,6)		3 (3,6)
Obese (type 3)		2 (1,2)		1 (1,2)
Education				
Until 4th grade		0 (0)		0 (0)
Until 6th grade		2 (2,4)		1 (1,2)
Until 9th grade		6 (7,1)		7 (8,3)
High School		12 (14,3)		11 (13,1)
Degree		18 (1,4)		12 (14,3)
Master		2 (2,4)		11 (13,1)
PhD		2 (2,4)		0 (0)

The sample's characterization data can be found in table 6. All participants were women (n=84). In this 2nd study results were compared between healthy/control group, with a total of 42 healthy participants (n=42) and a FM group comprising of 42 participants (n=42).

The single participants in the healthy group was 11 (3.1%) and in the FM group was 5 (6.0%); married participants, in both groups, was 19 (22.6%); the divorced participants in the healthy group was 5 (6.0%) and in the FM group was 8 (9,.7%); the civil partnership participants in the healthy group was 7 (8.3%) and in the FM group was 6 (7.1%) and in healthy group no one were widowed and one person in FM group were widowed.

Regarding their BMI (Body Mass Index) most of the participants of the study, 29 (57,3%) were above normal weight and 35 (21.4%) in the healthy group and 17 (20,2%) in FM group were within the normal weight.

In this study the level of education of the participants, in both groups, are not less then 4th garde. The level of education of the participants in healthy group are: 2(2,4%) had 6th grade, 6(7,1%) had 9th grade, 12(14.3%) had high school and 4(4.8%) had superior education. For the FM group are: 1(1,2%) had 6th grade, 7(8,3%) had 9th grade, 11(13,1%) had high school and 23(27.4%) had superior education.

PSQ-PT	Healthy Group	FM Group	t	р
	Mean (SD)	Mean (SD)		
	n=42	n=42		
Item 1	6,62 (2,12)	7,98 (2,27)	2,934	0,006
Item 2	6,17 (2,09)	7,05 (2,37)	1,806	0,075
Item 4	6,76 (2,15)	8,36 (1,79)	3,705	0,000
Item 8	5,26 (2,49)	7,24 (2,31)	3,768	0,000
Item 9	1,50 (1,76)	4,52 (3,37)	5,162	0,000
Item 10	4,00 (2,21)	6,02 (2,72)	3,737	0,000
Item 11	3,48 (2,18)	5,88 (2,86)	4,331	0,000
Item 12	4,86 (2,27)	7,31 (2,14)	5,013	0,000
Item 13	1,17 (1,65)	4,50 (3,14)	6,087	0,000
Item 14	2,88 (2,59)	6,62 (3,04)	6,074	0,000
Item 15	6,02 (2,33)	7,62 (2,07)	3,315	0,001
Item 16	6,10 (2,42)	8,14 (1,62)	4,563	0,000
Item 17	5,95 (2,32)	7,98 (1,99)	4,281	0,000
PSQ Total	4,67 (1,68)	6,86 (1,99)	5,453	0,000
PSQ Minor	3,80 (1,89)	6,45 (2,41)	5,620	0,000
PSQ Moderate	5,70 (1,77)	7,57 (1,78)	4,828	0,000

Table 7.The Pain Sensitivity Questionnaire- Portuguese Version (n=84)

In table 7, the mean scores for each item and each group can be found. The higher value for FM group (M=8,36, SD=1,79) and for control group (M=6,76, SD=2,15) was item 4 ("Imagine you trap your finger in a drawer.") and the lower mean value for both groups was item 13 ("Imagine you shake hands with someone who has a normal grip.") (FM group: M=4,50, SD=3,14; Healthy Group; M=1,17, SD=1,65).

Differences of the mean values between control group (Healthy PSQ-PT Total: M=4,67, SD=1,68; Healthy PSQ-PT Minor: M=3,80, SD=1,89; Healthy PSQ-PT Moderate: M=5,70, SD=1,77) and FM group (FM PSQ-PT Total: M=6,86, SD=1,99, FM PSQ-PT Minor: M=6,45, SD=2,41, FM PSQ-PT Moderate: M=7,57, SD=1,78) were

significant for all items and Scores (p<0,000), except for item 2 ("Imagine you burn your tongue on a very hot drink.") (p=0,075).

Table 8.

Mean and standard deviation of the main outcome measures of the questionnaires used in second study (n=84)

Questionnaires	Healthy Group Mean (SD) n=42	FM Grroup Mean (SD) n=42	р
Pain Catastrophizing Scale			
PCS Total	17,76 (12,69)	29,33 (13,02)	0,000
State-Trait Anxiety Inventory			
STAI Total	69,05 (20,52)	94,57 (24,75)	0,000
STAI Y1	34,36 (10,91)	48,79 (13,42)	0,000
STAI Y2	34,26 (10,40)	44,36 (12,19)	0,000
Hospital Scale of Depression and			
Anxiety			
HADS Anxiety Subscore	6,33 (4,45)	11,41 (4,60)	0,000
HADS Depression Subscore	4,67 (3,63)	9,19 (3,99)	0,000

Mean pain scores of all the clinical characterization scales and subscales for both FM and healthy control can be found in table 8. T-tests were performed in order to assess if the differences were significant.

Mean values for Pain Catastrophizing Scale (M=29,33; SD=13,02) in FM were higher than in the healthy group (M=17,76; SD=12,69). Additionally, we can observe that there are significant differences between groups (p<0.000).

Mean values for State-Trait Anxiety Inventory (M=94,57; SD=24,75) in FM were higher than in the healthy group (M=69,05; SD=20,52). Additionally, we can observe that there are significant differences between groups (p<0.000).

Mean values for HADS Anxiety Subscore (M=11,41; SD=4,60) in FM were higher than in the healthy group (M=6,33; SD=4,45). Additionally, we can observe that there are significant differences between groups (p<0.000). For HADS Depression Subscore (M=9,19; SD=3,99) in FM were higher than in the healthy group (M=4,67; SD=3,63). Additionally, we can observe that there are significant differences between groups (p<0.000).

Table 9.

	Healthy	Healthy	Healthy	FM	FM	FM
	Group	Group	Group	Group	Group	Group
	PSQ	PSQ	PSQ	PSQ	PSQ	PSQ
	Total	Minor	Moderate	Total	Minor	Moderate
Pain Catastrophizing Scale						
PCS Total	-,148	-,030	-,197	-,062	-,070	-,019
State-Trait Anxiety Inventory						
Total STAI	,189	,317*	,069	,058	,076	,058
Hospital Scale of Depression						
and Anxiety						
HADS Anxiety Subscore	,174	,296	,058	-,036	-,029	-,031
HADS Depression Subscore	,306**	,369*	,238	,197	,214	,203

Correlation between PSQ-PT and PCS, STAI and HADS (n=84)

**Pearson correlations is significant at the 0,001 level; *Pearson correlations is significant at the 0,05 level

The table 9 describes the presence or absence of correlation between fibromyalgia group and healthy control and PSQ-PT and the questionnaires used in this second study.

The PSQ-PT Total for healthy participants was not correlated with PCS, STAI and HADS anxiety subscore for both groups. Only the total score of the PSQ-PT for healthy participants was correlated with HADS Depression subscore (r=0,306, p<0.05).

The PSQ-PT Minor was not correlated with PCS and HADS anxiety subscore for both groups, but was correlated with STAI (r=0,317, p<0.05) and HADS Depression subscore (r=0,369, p<0.05) for healthy group.

The PSQ-PT Moderate was not correlated with PCS, STAI and HADS anxiety subscore for both groups.

5.3. Results of the 3rd study

Table 10.

	Total sample	Total Sample Frequency (%)
	Mean (SD)	
Age	22,08 (7,051)	
Gender		
Female		9 (75)
Male		3 (25)
Civic Status		
Single		11 (91,7)
Married		0 (0)
Divorcer		0 (0)
Civic Partnership		1 (8,3)
Widow/Widower		0 (0)
BMI		
Extreme Thinness		0 (0)
Slight Thinness		12 (100)
Normal Weight		0 (0)
Pre-obese		0 (0)
Obese (type 1)		0 (0)
Obese (type 2)		0 (0)
Obese (type 3)		0 (0)
Education		

Demographic Characterization of the Third Study's Population (n=12)

Until 4th grade	0 (0)
Until 6th grade	0 (0)
Until 9th grade	0 (0)
High School	11 (91,7)
Degree	1 (8,3)
Master	0 (0)
PhD	0 (0)

This third study, a pilot study, assessed 12 participants and the demographic data can be found in Table 10.

The participants mean ages were M=22.08 (SD =7.051). Regarding their gender, 9 women were enrolled (75,0%) and 3 men (25.0%). Regarding the civil status on the total cohort, 11 (91.7%) of the participants were single and 1 (8.3%) were living in a civil partnership.

All of the participants in this study were within the normal weight (100%). In this study the level of education of the participants are: 11 (91.7%) had high school and only 1 person (8.3 %) had superior education.

Table 11.

PSQ Itens	Mean (SD)
Item 1	5 (2,088)
Item 2	4,417 (1,505)
Item 4	4,666 (1,435)
Item 5	0,250 (0,621)
Item 8	4,250 (1,864)
Item 9	1 (1,477)
Item 10	3,166 (2,289)
Item 11	2,666 (1,669)
Item 12	4,50 (0,621)
Item 13	0,250 (0,621)
Item 14	1,50 (1,087)

The Pain Sensitivity Questionnaire- Portuguese Version (n=12)

Item 15	5,333 (1,922)
Item 16	4,333 (1,825)
Item 17	4,583 (2,065)
PSQ Total	3,51 (1,14)
PSQ Minor	2,95 (1,48)
PSQ Moderate	4,35 (1,19)

The table 11 presents the mean score and standard deviation of PSQ-PT for all participants (n=12) for each item.

The mean and standard deviation of subscores of the portuguese version of the pain sensitivity questionnaire in this study are PSQ-PT Total: M=3.51 and SD=1.14, PSQ-PT Minor: M=2.95 and SD=1.48 and PSQ-PT Moderate: M=4.35 and SD=1.19.

The item 5 ("Imagine you take a shower with lukewarm water.") and item 13 ("Imagine you shake hands with someone who has a normal grip.") were the ones with the lowest score. The item 15 ("Imagine you pick up a hot pot by inadvertently grabbing its equally hot handles") where the highest score.

	Mean (SD)	Minimum	Maximum
Heat Pain Thresholds (°C)	45,64 (1,67)	42,07	47,73
Cold Pain Thresholds (°C)	5,56 (7,51)	42,07 0	24,23
Pressure Pain Threshold [kg/cm ²]	67,05 (25,19)	29	100
<i>Heat Tolerance</i> ($^{\circ}C$)	50,16 (1,10)	47,40	51,40
Heat phasic stimuli 47°C [0–100]	49,01 (19,25)	21,43	77,14
Heat phasic stimuli 48°C [0–100]	64,49 (17,70)	38,57	90,71
Tonic stimuli [0–100]	55,83 (18,55)	33,33	90
Cold pressor test [0–100]	22,95 (3,12)	20	30,30

Table 12. Total and subscale scores of the experimental pain sensitivity tests (n=12)

Descriptive statistics on pain sensitivity measurement can be found in table 12.

The mean thresholds to heat was M= 45.64°C, SD=1.67°C and tolerance to heat M= 50.16°C, SD=1.10°C. Also the mean thresholds to cold reported was M=5.56°C, SD=7.51°C. The mean of the pain pressure threshold was M=67.05, SD=25.19 [kg/cm²]. The mean of the tonic stimuli was M=55.83, SD=18.55.

The mean of the heat phasic stimuli 47°C was M=49.01°C, SD=19.25°C and the heat phasic stimuli 48°C was M=64.49°C, SD=17.70°C. The mean of the cold pressor test was M=22.945, SD=3.12.

	0		
	Mean (SD)	Minimum	Maximum
CPT NRS 0	0 (0)	0	0
CPT NRS 30	16,67 (23,19)	0	70
CPT NRS 60	24,75 (29,19)	0	90
CPT NRS 90	30,92 (34,77)	0	100
CPT NRS 120	31,92 (34,77)	0	100
CPT NRS 150	29,75 (34,96)	0	100
CPT NRS 180	25,23 (23,65)	0	100

Table 13. Cold Pressor Test and Numeric Pain Rating Scale [0-100] (n=12)

The table 13 presents Cold Pressor Test and Numeric Pain Rating Scale used in the study.

The minimum pain score given by a subject was of 0 (no pain) and the highest pain score was 100 (maximum perceived pain). Before immerging the hand on the water the NRS was score with 0. After 30 seconds the mean pain score was M=16.67, SD=23.196; after 60 seconds M=24.75, SD=29.19; after 90 seconds M=30.92, SD=34.77; after 120 seconds M=31.92, SD=34.77; after 150 seconds M=29.75, SD=34.96 and after 180 seconds M=25.23, SD=23.65.

Table 14. Total and subscale scores of the Questionnaires used (n=12)

	Mean (SD)	Minimum	Maximum
Pain Catastrophizing Scale			
PCS Total	15,17 (11,49)	0	47
State-Trait Anxiety Inventory			
STAI Total	66,17 (13,47)	40	92
STAI Y1	29,25 (5,70)	20	38
STAI Y2	36,92 (8,44)	20	54
Hospital Scale of Depression and Anxiety			
HADS Anxiety Subscore	7,33 (4,99)	1	18
HADS Depression Subscore	3,45 (0)	0	12

Table 14 describes the participants' mean scores in instruments that are importantly related to pain sensivity.

The participants did not show presence of Pain Catastrophizing because the mean of the PCS results was M=15.17 (SD=11.496). The mean score for STAI was M=66,17 (SD=13.469) and for the HADS Anxiety Subscore M=7,33 (SD=4,997) which is above the cutoff point (7) demonstrating presence of anxiety. The same was not confirmed for depression (M=3.33, SD=3.345).

Total and subscale scores of Digit Span (n=12)

Table 15.

	Mean (SD)	Minimum	Maximum
Digit Span			
Forward recall	6,17 (,72)	5	7
Backward recall	4,92 (,90)	4	7

The table 15 presents subscale scores of the neuropsychological test, Digit Span, used. The students showed for a forward recall a mean of M=6,167, SD=0,718 with a

maximum of 7 digits and a minimum of 5 digits. For backward recall it was M=4,917, SD=0,90 with a maximum of 7 digits and minimum of 4 digits.

Table 16.

Correlation between PSQ-PT and PCS, STAI and HADS and Cognitive Test and Experimental Pain Sensitivity Testing (n=12)

	PSQ-PT	PSQ-PT	PSQ-PT		
	Total	Minor	Moderate		
Experimental Pain Sensitivity Testing					
Heat Pain threshold	-0,009	-0,062	0,079		
Cold Pain Threshold	,632*	,699*	0,489		
Pressure Threshold	-0,297	-0,144	-0,322		
Tonic Stimulation	0,285	0,390	0,245		
Phasic heat 47°C	-0,094	-0,344	0,208		
Phasic heat 48 ^a C	0,052	-0,088	0,243		
Cold Pressor Test	0,232	0,105	0,295		
Pain Catastrophizing Scale					
PCS Total	0,515	0,338	,613*		
State-Trait Anxiety Inventory					
Total STAI	0,326	0,223	0,407		
Total Y1	0,350	0,276	0,365		
Total Y2	0,284	0,169	0,403		
Hospital Scale of Depression and					
Anxiety					
HADS Anxiety Subscore	,588*	0,488	0,548		
HADS Depression Subscore	,666*	0,515	,677*		
Digit Span					
Forward recall	-0,209	-0,314	-0,183		
Backward recall	0,367	0,236	0,514		

*Spearman correlations is significant at the 0,05 level; **Spearman correlations is significant at the 0,001 level

The table 16 presents Correlation between PSQ-PT and pain measures, PCS, STAI and HADS and cognitive test (*Digit Span Test*).

The results of PSQ-PT Total showed positive correlation with HADS anxiety subscore (Υ =0.588, p < 0.05) and HADS depression subscore (Υ =0.666, p < 0.05). The same occur with the cold threshold (Υ =0.632, p < 0.05).

The results of PSQ-PT Minor showed positive correlation, only, with cold threshold (Υ =0.699, p < 0.05).

The results of PSQ-PT Moderate showed positive correlation with PCS (Υ =0.613, p < 0.05) and with HADS depression subscore (Υ =0.677, p < 0.05).

Table 17.

Correlation between Cognitive Test and Experimental Pain Sensitivity Testing (n=12)

	Digit Span		
	Forward recall	Backward recall	
Experimental Pain Sensitivity			
Testing			
Heat Pain threshold	0,275	0,518	
Cold Pain Threshold	689*	0,221	
Pressure Threshold	0,089	0,073	
Tonic Stimulation	-0,318	0,153	
Phasic heat 47°C	-0,198	0,526	
Phasic heat 48 ^a C	-0,450	0,465	
Cold Pressor Test	-0,358	0,491	

The table 17 presents correlation between working memory and pain measures.

No relations between neuropsychological task (Digit Span Test) and pain measures were found. Except for the Digit Span Forwarded correlated negatively with cold threshold (Υ =-0.689, p<0.05).

6. Discussion

The aim of this study was to translate and validate the PSQ questionnaire for the portuguese population. The results indicated that, has we expected, the structure for the portuguese version of the PSQ is a 2-component solution (factor 1 that refers to extremely painful conditions, called PSQ-moderate and factor 2, corresponding to situations of mild pain titled PSQ- minor). The Portuguese version of PSQ indicated good internal consistency.

6.1 Fist Study

6.1.1 Factorial Analysis

The original validation of the Pain Sensitivity Questionnaire was developed by Ruscheweyh, Marziniak, Stumpenhorst, Reinholz and Knecht (2009). The Portuguese validation was conducted in a large group of healthy individuals (n=289), via online, like in the validation performed by McIntyre et al. (2020).

The exploratory factor analysis with principal components extraction, was conducted based on the responses of all 289 participants. The PSQ-PT have two-factor solution (factor 1 and 2) that explained 65,367 % of the total variance (see table 3).

Factor 1, that refers to extremely painful conditions, called PSQ-PT Moderate, included the items: 1 ("Imagine you bump your shin badly on a hard edge, for example, on the edge of a glass coffee table"), 2 ("Imagine you burn your tongue on a very hot drink"); 4 ("Imagine you trap your finger in a drawer"); 8 ("Imagine you accidentally bite your tongue or cheek badly while eating"); 10 ("Imagine you have a minor cut on your finger and inadvertently get lemon juice in the wound"); 12 ("Imagine you stick your bare hands in the snow for a couple of minutes or bring your hands in contact with snow for some time, for example, while making snowballs"); 16 ("Imagine you are wearing sandals and someone with heavy boots steps on your foot") and 17 ("Imagine you bump your elbow on the edge of a table ("funny bone")"). The same was verified in the original PSQ (Ruscheweyh et al., 2009) and in the validation of the arabic version of PSQ (Abdaljawwad and Al-Groosh, 2021). The items 1("Imagine you bump your shin badly on a hard edge, for example, on the edge of a glass coffee table.") and 4 ("Imagine you

trap your finger in a drawer."), as in the original validation of the PSQ (Ruscheweyh et al., 2009), they were the ones with the highest scores by the participants, suggesting that these situations seem to be the most painful for the study population (see table 2).

Factor 2 corresponding to situations of mild pain titled PSQ-PT Minor that included items: 5 ("Imagine you take a shower with lukewarm water."); 9 ("Imagine walking across a cool tiled floor with bare feet."); 11 ("Imagine you prick your fingertip on the thorn of a rose"); 13 ("Imagine you shake hands with someone who has a normal grip.") and 14 ("Imagine you shake hands with someone who has a very strong grip").

In the Portuguese population, during the PSQ factor analysis process, due to the commonality values being less than 0.50, suggesting that the same items correlated with more than one factor, three items were excluded: item 3 ("Imagine that your muscles are slightly sore from physical activity), item 6 ("Imagine you have slight burns on your shoulders") and item 7 ("Imagine you rubbed your knee falling off the bike"). These results are in line with what was verified in the Polish validation, where these three items are also correlated with more than one factor (Latka et al., 2019).

In the original PSQ (Ruscheweyh et al., 2009) items 5 ("Imagine you take a shower with lukewarm water."), 9 ("Imagine walking across a cool tiled floor with bare feet.") and 13 ("Imagine you shake hands with someone who has a normal grip.") are related to everyday situations that tend not to be painful. In the present study, items 5 and 13 are the ones with lower averages compared to the other items of the questionnaire (see table 2), however, during the exploratory factor analysis (see table 3) they were included and it was found that the portuguese participants tend to consider everyday situations as midly painful (PSQ-Minor) rather than non-painfull stimulus (see table 3). In the polish validation, the same was found, where items 5, 9 and 13 were also considered by the study population as midly painful (Latka et al., 2019). These results may be related to the positive correlation observed between PSQ-PT and Pain Catastrophizing Scale total score (see table 5), suggesting that higher levels of catastrophizing may be associated, in this study, with higher scores in the pain sensitivity questionnaire.

In Portuguese data, there is 65.367% of the total variance explained. In the original questionnaire two factors were found that explained 55% of the total variance (Ruscheweyh et al., 2009), in the Norwegian version, also, yielded at two factor solution, explaining 58% of the variance (Valeberg et al., 2017), in the validation of the PSQ-

online, 59% of the total variance was obtained (McIntyre et al., 2020) and the Polish version of PSQ has 2-component that explained 70.69% of the total variance (Latka et al., 2019). When comparing these data with those from Portugal, it is suggested that the PSQ-PT and PSQ-Polish, with a total variance explained above 60%, seem to be the ones that best explain the model. This similarity is also verified, between the PSQ-PT and the PSQ-Polish (Latka et al., 2019) in the 2 component solution, where, in both, the PSQ-Moderate is constituted by the items: 1, 2, 4, 8, 15, 16 and 17 and the PSQ-Minor for items: 5, 9, 11, 13 and 14.

6.1.2 Internal Consistency

In the portuguese version of the Pain Sensitivity Questionnaire a Cronbach's value of 0.95 was obtained for the PSQ-total, 0.95 for PSQ-minor and 0.97 for the PSQ-moderate demonstrating a good internal consistency.

The results of the first study are in line with the original version of the PSQ, where a Cronbach's value of 0.92 was obtained for the PSQ-total, 0.81 for PSQ-minor and 0.91 for the PSQ-moderate, demonstrating a good internal consistency (Ruscheweyh et al., 2009). In the validation of Norway, similar results were observed (PSQ-Total: Cronbach's $\alpha = 0.92$; PSQ-moderate: Cronbach's $\alpha = 0.90$; PSQ-minor: Cronbach's $\alpha =$ 0.85) (Valeberg et al., 2017), the same was verified in the validation in Mandarin (PSQ-Total: Cronbach's $\alpha = 0.90$; PSQ-moderate: Cronbach's $\alpha = 0.86$; PSQ-minor: Cronbach's $\alpha = 0.81$) (Quan et al., 2017). The Dutch PSQ, also, had a reliability internal consistency for this questionnaire (PSQ-Total: Cronbach's $\alpha = 0.90$; PSQ-moderate: Cronbach's $\alpha = 0.86$; PSQ-minor: Cronbach's $\alpha = 0.82$) (Van Boekel et al., 2020). In the last validation of this questionnaire the results are, also, similar to the portuguese data (PSQ-Total: Cronbach's $\alpha = 0.918$; PSQ-moderate: Cronbach's $\alpha = 0.881$; PSQ-minor: Cronbach's $\alpha = 0.867$) (Abdaljawwad and Al-Groosh, 2021).

In the PSQ validations between chronic and healthy pain groups, there were also results similar to those in Portugal regarding internal consistency. In Iranian validation the Cronbach's values of the pain group (LDH) demostrantig a good internal consistency (PSQ-Total: Cronbach's $\alpha = 0.84$; PSQ-moderate: Cronbach's $\alpha = 0.84$; PSQ-minor: Cronbach's $\alpha = 0.85$), the same, for healthy group (PSQ-Total: Cronbach's $\alpha = 0.81$; PSQ-moderate: Cronbach's $\alpha = 0.82$; PSQ-minor: Cronbach's $\alpha = 0.80$) (Azimi et al., 2016). The same was verified in the French validation where, in the pain group, Cronbach's alpha values were obtained identical to those of the present study (PSQ-Total: Cronbach's $\alpha = 0.927$; PSQ-moderate: Cronbach's $\alpha = 0.886$; PSQ-minor: Cronbach's $\alpha = 0.866$) and similar values for healthy volunteers (PSQ-Total: Cronbach's $\alpha = 0.906$; PSQ-moderate: Cronbach's $\alpha = 0.871$; PSQ-minor: Cronbach's $\alpha = 0.852$) (Dualé et al., 2019). In Polish validation the Cronbach's α was 0.96 (Latka et al., 2019) and, finally, in the validation of the PSQ-Online it was verified the same (PSQ total: Cronbach's $\alpha = 0.93$; PSQ minor: Cronbach's $\alpha = 0.84$; PSQ moderate: Cronbach's $\alpha = 0.90$) (McIntyre et al., 2020) demonstrated a good internal consistency of the questionnaire in study.

6.1.3 Convergent Validity

The results of PSQ-PT total score (r=0.304, p < 0.01), PSQ-PT Minor (r=0.290, p < 0.01), and PSQ-PT Moderate (r=0.292, p < 0.01) showed positive correlation with *Pain Catastrophizing Scale* (pain-specific measure). No correlations were found between PSQ-PT (all subscores) and *The Hospital Depression and Anxiety Scale* (HADS-PT) and *State-Trait Anxiety Inventory* (STAI- PT), measures of depression and anxiety. This results demonstrated a good convergent validity of PSQ-PT (see table 5).

The positive correlation between the PCS and all PSQ scores in this study was also verified in the original validation of the questionnaire PSQ total score (r=0.45, p < 0.01), PSQ Minor (r=0.38, p < 0.01), and PSQ Moderate (r=0.43, p < 0.01) (Ruscheweyh et al., 2009). The same was verified in the validation in Mandarin (PSQ-total: r=0.268, p < 0.01; PSQ-Minor: r=0.273, p < 0.01; PSQ-Moderate: r=0.231, p < 0.01) (Quan et al., 2017). This association was also observed in the validation of Arabica (PSQ-total: r = 0.506, p < 0.001; PSQ-moderate: r = 0.466, p < 0.001; PSQ-minor: r = 0.407, p < 0.003) (Abdaljawwad and Al-Groosh, 2021).

The results of the first study suggest that there may be an association between the pain sensitivity questionnaire and catastrophizing, that is, catastrophizing tends to influence the perception of the intensity of a painful stimulus where these individuals tend to focus excessively on pain and lack of control over it based on beliefs and/or thoughts related to previous painful experiences (Sullivan, et al. 1995; Sullivan et al., 2004).

6.2 Second Study

The aim of the second study was to compare the results of the PSQ-PT between a healthy control group and a chronic pain group (fibromyalgia patients).

In this study fibromyalgia patients had higher scores in PSQ-PT compare to healthy participants (PSQ-total scores: FM group: 6.86 ± 1.99 , control group: 4.67 ± 1.68 ; PSQ-Moderate scores: FM group: 7.57 ± 1.78 , control group: 5.70 ± 1.77 ; PSQ-Minor scores: FM group: 6.45 ± 2.41 , control group: 3.80 ± 1.89 , p < .000) (see table 7).

The results of the second study are in line with those verified in the validation of the PSQ for a population with chronic pain, where, regardless of the diagnosis, the PSQ-Total scores (PSQ-total scores: control: 3.4 ± 1.1 , chronic pain: 4.0 ± 1.7 , T [317] = 4.1, P < .001) ant the PSQ-minor (PSQ-minor scores: control: 2.2 ± 1.0 ; chronic pain: $2.9 \pm$ 1.5, T[317] = 4.9, P < .001) were significantly higher (Ruscheweyh et al., 2012). In the validation of the Iranian PSQ for patients with chronic pain (with lumbar disc herniation patients-LDH) similar results were verified (LDH group: PSQ-Total=5.9 ±1.9, PSQ-Moderate = 6.4 ± 1.8 , PSQ-Minor = 5.3 ± 2.0 ; Healthy control group: PSQ-Total = 3.1 ± 1.1 , PSQ-Moderate= 3.9 ± 1.1 , PSQ-Minor= 2.1 ± 1.0 , p < 0.001) (Azimi et al., 2016). In the study of Azimi and Benzel (2016), also with patients with LDH, confirmed the results, verified in the aforementioned validation (LDH group: PSQ-Total= 6.0 ±1.6, PSQ-Moderate = 6.5 ± 1.7 , PSQ-Minor = 5.4 ± 1.9). In the validation of the PSQ for women with persistent pelvic pain (PPP) the results are also in line with those observed in previous studies (PPP group: PSQ-Total= 4.5 ± 14 , PSQ-Moderate= 5.8 ± 1.6 , PSQ-Minor= 3.2 ± 1.5 ; Healthy control group: PSQ-Total= 3.4 ±1.0, PSQ-Moderate= 4.7±1.4, PSQ-Minor= 2.2±0.9) (Grundström et al., 2019).

In this study fibromyalgia patients had higher scores in each item of PSQ-PT compare to healthy participants, except for item 2 ("Imagine you burn your tongue on a very hot drink.") (see table 7).

Item 4 ("Imagine you trap your finger in a drawer.") was the higher value for both groups in the second study (FM group: M=8,36, SD=1,79; Healthy group: M=6,76, SD=2,15) and item 13 ("Imagine you shake hands with someone who has a normal grip.") was the lower mean value for both groups (FM group: M=4,50, SD=3,14; Healthy Group:

M=1,17, SD=1,65) (see table 7). These values are in line with what was verified in the first study of this dissertation, where item 4 concerns the PSQ-PT Moderate and the item13 a non-painful stimulus (see table 2). However, it is important to note that the average of item 13 in the group with fibromyalgia was higher than expected because, on a scale of 0–10 the average was very close to the value 5, which corresponds to pain "average", suggesting that even situations that are described in the original questionnaire as non-painful (Ruscheweyh et al., 2009) in patients with a diagnosis of fibromyalgia these may be interpreted as moderately painful.

In this study, between groups, there were no significant differences in the means of the item 2 ("Imagine you burn your tongue on a very hot drink.") (see table 7). When analyzing the means of this item among the fibromyalgia group (M=7.05, SD=2.37) and the healthy group (M=6.17, SD=2.09) we verified that they are very close to the value that originates the score of the PSQ-Moderate (the individual mean of the items and mean score between 4 and 6) (Ruscheweyh et al., 2009), that in the first study of this dissertation it seems to be related to extremely painful everyday situations (PSQ-PT Moderate) (see table 3). Therefore, it is possible that all participants in the second study (n= 84) associate the situation described in this item with painful stimuli.

Chronic pain group (FM group) scored significantly higher on all the questionnaires PCS, STAI and HADS compare to matched healthy participants (Pain Catastrophizing Scale: FM group: 29.33 ± 13.02 , healthy group: 17.76 ± 12.69 ; State-Trait Anxiety Inventory: FM group: 94.57 ± 24.75 , healthy group: 69.05 ± 20.52 ; HADS Anxiety Subscore: FM group: 11.41 ± 4.60 , healthy group: 6.33 ± 4.45 ; HADS Depression Subscore: FM group: 9.19 ± 3.99 , healthy group: 4.67 ± 3.63 , p<0.000) (see table 8). These results are in line with what was verified in the validation of the PSQ for a population with chronic pain, where these scored significantly higher on all the questionnaires (BDI, STAI and PCS) compare to matched healthy participants (p<0.001) (Ruscheweyh et al., 2012). In the validation of the Iranian PSQ for patients with chronic pain (LDH) there were similar results (LDH group: 26.1 ± 10.1 , healthy group: 13.1 ± 9.2 , p<0.001) (Azimi et al., 2016). In the validation of the PSQ for women with persistent pelvic pain, the results are in line with the other validations, as the group of patients had higher scores in both HADS subcores compared to healthy women (HADS Anxiety Subscore: PPP group: 9.9 ± 4.4 , healthy group: 4.7 ± 3.4 ; HADS Depression Subscore: PPP group: 7.9 ± 4.3 ,

healthy group: 2.3 ± 2.4 , p<0.001) (Grundström et al., 2019). Together, this results suggesting worst clinical status in chronic pain condition comparing to the healthy group.

This results seems to be according to the literature in this area because patients with fibromyalgia seem to have symptoms of hypersensitivity which may increase their sensitivity to everyday hypotheses that, for the healthy population, are not perceived as painful, as the average of the scores of the PSQ-Minor (minor painful) of the FM group was superior to the PSQ-Moderate (moderately painful) from the control group (see table 7). Also, they seem to have a greater predisposition to the development of signs and symptoms associated with psychiatric disorders such as depression and anxiety (Borchers and Gershwin, 2015; Malin and Littlejohna, 2012; Galvez-Sánchez, Duscheke and Paso, 2019; Wolfe, et al., 2010)

The results of this study do not fully meet expectations since, according to the PSQ validations for chronic pain, it was expected that the PSQ-PT and psychological tests were associated only in patients with fibromyalgia. In the first validation for chronic pain the STAI-Trait (r=0,19, p<0.05) is correlated with greater pain sensitivity only in patients (Ruscheweyh et al., 2012). In the validation of the PSQ for women with persistent pelvic pain it was found that the group of patients has higher scores, in both subscores of HADS, compared to healthy women (Grundström et al., 2019). In the French validation of the questionnaire, similar results were found where the PSQ-F Total was positive correlated with HADS Depression subscore (rho=0,259, p<0.05), HADS Anxiety subscore (rho=0,243, p<0.05), the PSQ-F Minor was, also, positive correlated with HADS Depression subscore (rho=0,292, p<0.05) and HADS Anxiety subscore (rho=0,243, p<0.05) e o PSQ-F Moderate was positive correlated with HADS Depression subscore (rho=0,219, p<0.05) and HADS Anxiety subscore (rho=0,231, p<0.05) only for patients (Dualé et al., 2019). However, when analyzing the correlations between the PSQ-PT and the psychological tests, the PSQ-PT Total was positive correlated with HADS Depression subscore (r=0,306, p<0.05) and the PSQ-PT Minor was correlated with STAI (r=0,317, p<0.05) and HADS Depression subscore (r=0,369, p<0.05), only for healthy participants (see table 9). Similar results were verified in the original validation of the PSQ, where there was a positive association only between the PSQ-Minor and depressive symptoms (BDI: r = 0.39, p < 0.01) e/ou ansiogénica (STAI-State: r = 0.34, p < 0.05) in healthy participants (Ruscheweyh et al., 2009).

6.3 Third Study

The third aim of this dissertation was to develop a pilot study that could allow the study of the relations between pain and cognition and the scores in the portuguese version of the PSQ. It should be noticed that these results were based on a small sample (n=12), so, only exploratory proposes they were conducted.

6.3.1 PSQ and experimental tests

The descriptive statistics of the pilot study indicated that pain sensitivity measurement was similar for thresholds between the participants of the third study and the original validation of PSQ (Ruscheweyh et al., 2009) (Heat pain thresholds: PSQ-PT: 45.64 ± 1.67 [°C], PSQ-O: 46.4 ± 1.8 [°C] and Cold pain thresholds: PSQ-PT: 5.56 ± 7.51 [°C], PSQ-O: 6.2 ± 5.3 [°C] (see table 12).

The results of the third study indicated that cold pain threshold showed positive correlation with PSQ-PT Total (Υ =0.632, p < 0.05) and PSQ-PT Minor (Υ =0.699, p < 0.05) in healthy subjects (see table 16). These are in line with what was found in the original PSQ, where the subscore minor, only in the individual items, is also positively correlated with the cold pain threshold (r = 0.34, p < 0.05) (Ruscheweyh et al., 2009). Also in the Chinese validation, correlations between the pain thresholds ant the PSQ (PSQ-C Total: r = 0.296, p < 0.01; PSQ-C Minor: r = 0.324, p < 0.01 and PSQ-C Moderate: r = 0.235, p < 0.05) (Quan et al., 2017). The results seem to indicate that the scores obtained from the Pain Sensitivity Questionnaire in the portuguese version, especially when the items correspond to everyday situations involving mild pain (PSQ-Minor), seem to depend on the participant's subjective experience when assessing when a cold stimulus becomes painful (cold pain thresholds).

However, in the same study, there were no correlations between the experimental tests (tonic stimulation, phasic heat in 47°C and 48°C and in cold pressor test) and the PSQ-PT (see table 16). These results are contrary to those verified in the original validation where PSQ (all scores) were significantly correlated to experimental pain intensity ratings (r = 0.56, p < 0.001) (Ruscheweyh et al., 2009), in the dutch validation, also, there was a statistically significant correlation between the PSQ-scores and the pain

intensity ratings (rho = 0.22 to 0.40) (Boekel et al., 2020). The same correlation was verified in the Norwegian validation (r = 0.36, p < 0.05) (Valeberg et al., 2017).

6.3.2. PSQ scores and measures of depression (HADS depression subscore), anxiety (STAI and HADS anxiety subscore) and pain catastrophizing (PCS)

In third study the mean score for the HADS questionnaires for anxiety subscore was 7.33 ± 4.997 (scoring above 7) and for depression subscore was 3.33 ± 3.345 (scoring below 7) and os scores do STAI was 66.17 ± 13.469 (scoring in a maximum of 80) (see table 14). This results sugerem that participants in this study seem to have symptoms of anxiety but not depressive symptoms. These are in line with the validation performed by Grundström et al. (2019) where anxiety subscore scores for healthy women was M=4.7 \pm 3.4 and for depression subscore was 2.3 ± 2.4 .

When analyzing the results of PSQ-PT Total we observed the presence of positive correlation with all HADS subscores (HADS anxiety subscore: Υ =0.588; HADS depression subscore: Υ =0.666, p < 0.05) and the PSQ-PT Moderate showed positive correlation with subscore depression from HADS questionnaire (Υ =0.677, p < 0.05), that is, it seems that the higher the Pain Sensitivity Questionnaire score, the greater the probability of the person presenting anxiogenic and/or depressive symptomatology (see table 16).

This results are consistente with theory because limbic system are involved in pain, especially, in the discrimination of emotional aspects involved in pain (Martin, 2012) and i tis important to note that several factors can modulate pain such as psychological factors like anxiety (Turk & Monarch, 2002).

The PSQ-PT Moderate, also, showed positive correlation with PCS (Υ =0.613, p < 0.05) (see table 16). In the validation in Mandarin, the results were similar to those in Portugal with positive correlations between the PCS and the PSQ-M Moderate (r=0.231, p < 0.01) (Quan et al., 2017). In the validation of Arabica, this correlation was also verified (PSQ-moderate: r = 0.466, p < 0.001) (Abdaljawwad and Al-Groosh, 2021). These data are partially in line with what was verified in the original validation of the questionnaire, where this correlation was verified between all PSQ subscores (PSQ total score: r=0.45; PSQ Minor: r=0.38; PSQ Moderate: r=0.43, p < 0.01) (Ruscheweyh et al.,

2009). These results suggest that catastrophizing seems to increase when the situations experienced are related to very painful situations.

6.3.3. Pain and Neuropsychological Assessment (Digit Span)

Participants in this study performed better in Digit Span Forwarded recall (M=6.17, SD=.72) compared to the Digit Span Backward recall (M=4.92, SD=.90) (see table 15). However, when analyzing the association between this test and experimental pain sensitivity testing, there is a negative correlation with the threshold when the stimulus is cold (Υ = -0.689, p<0.05) (see table 17). These results seem to indicate that cognition and pain have a negative influence, that is, the performance of participants in the digit span forwarded recall test seems to be worse when the stimulus or experience is related to cold stimuli.

Procento, Rand, Stewart and Hirshes em 2021 carried out the first study that aimed to understand the relationship between pain catastrophizing and working memory. The authors found that the pain group had greater catastrophizing compared to the healthy group. This cognitive process seems to be associated with worse performance in working memory tasks and mediating and moderating roles in pain-related WM deficits. Therefore, when analyzing the results of this last study, the worst performance in Digit Span forwarded recall may also be associated with the positive correlation verified between the PSQ-PT and PCS (Υ =0.613, p < 0.05) (see table 16).

6.4 Limitations

The limitation of the present study was the lack of participants for the presencial session which, consequently, led to the lack of information about the validation study and the test-retest of the pain sensivity questionnaire for healthy portuguese population. Another limitation was in the time interval because we were in a pandemic situation due to COVID-19 and the study included presencial sessions.

The second study should have been developed with a larger sample of fibromyalgia participants to matched with the healthy participants of the first study. The conclusions of the study are small compare to the others validations of *Pain Sensitivity Questionnaire*.

In the original validation (Ruscheweyh et al., 2009), Chinese (Quan et al., 2017), Arabic (Abdaljawwad and Al-Groosh, 2021) and Iranian (Azimi et al., 2016), items: 3 ("Imagine that your muscles are slightly sore from physical activity), 6 ("Imagine you have slight burns on your shoulders") and 7 ("Imagine you rubbed your knee falling off the bike") are for PSQ-Minor. The same was not verified in the PSQ-PT because the communality values of item 3 (0.41), item 6 (0.49) and item 7 (0.45) were lower than the value of the desired community (0.5), having been excluded from the final factorial structure of the PSQ-PT, however, the author recommends not to exclude any item from the questionnaire as it may alter the questionnaire itself.

In the results of the third study, it was not studied in depth whether a lower performance in tests that assess working memory, specifically the Digit Span, is associated with the cold stimulus due to a possible catastrophizing of pain by the participants.

6.5 Future studies

In future studies, it is important to increase the representativeness of the study groups in order to increase information about the test-retest of *the pain sensitivity questionnaire* for the healthy portuguese population.

It is, also, important to carry out the experimental protocol with other pain modalities, such as electrical pain and correlate them with other psychological ones, as in the original validation (Ruscheweyh et al., 2009) we have BDI and SCL-90-R so that the portuguese data can be directly compared to the original validation data.

The increase in the number of fibromyalgia participants, it is also important, in order to carry out the validation of the portuguese version of the Pain Sensitivity Questionnaure for this chronic pain population, it is also important to validate the PSQ-PT for other populations with chronic pain.

The results of study 2 suggest that healthy women in everyday situations involving pain seem to be positively associated with depressive symptoms. However, this association was expected to be verified in women with a diagnosis of fibromyalgia. It should be noted that no study, as far as we are aware, apart from the second study in this dissertation, has analyzed this association in detail. For this reason it will be important to understand the association between PSQ-PT Total and depressive symptoms among healthy portuguese women compared to women with fibromyalgia.

The study carried out by Ruscheweyh, Dany, Marziniak and Gralow in 2015 was the first that investigated if basal pain sensitivity, using the PSQ, predicted the outcome of multidisciplinary pain management program. The results of the PSQ scores and results of experimental pain testing were significantly correlated with pain thresholds (heat pain threshold: r=20.45, P<0.001, pressure pain threshold; r=20.29, P<0.05), contrary to what was previously verified. However, it is important to note that pain threshold studies are still not clear as to their importance in clinical practice, and it is necessary to investigate in more detail what their impact on clinical pain is (Nielsen, Staud & Price, 2009). These suggest that it is necessary to clarify the relationship between the *Pain Sensitivity Questionnaire* and the pain threshold between healthy subjects and subjects with a diagnosis of chronic pain.

The most affected cognitive functions related to pain are attention and executive functions (Moriarty, McGuire and Finn, 2011; Kratiz et al., 2015) so the protocol should include other neuropsychological tests, for example, the Trail Making Test (A and B) and the Wisconsin Card Sorting Test (WCST), sugeridos por Medina et al. (2018) to assess the neuropsychological profile associated with a sensitivity to pain. It would be, also importante, to study in depth whether a worse performance in tests that assess working memory is associated with a cold pain stimulus due to a possible pain catastrophizing, as verified in the study by Procento et al. (2021).

7. Conclusion

The aim of this thesis was to translate and validate the *Pain Sensitivity Questionnaire* for the portuguese population. The Portuguese version of this questionnaire was developed according to the international guidelines and then presented to healthy individuals. Principal component analysis suggested two components, similar to the original version (PSQ-Minor and PSQ-Moderate) and it was found that this version demonstrated a good internal consistency and convergent validity.

The factor analysis of the PSQ-PT is in line with the results of the validations carried out previously. In all of them there were a two-component solution the factor 1, called PSQ-moderate, refers to extremely painful conditions and factor 2, called PSQ-

Minor, refers to situations of mild pain (Abdaljawwad and Al-Groosh, 2021; Azimi et al., 2016; Dualé et al., 2019; Latka et al., 2019; McIntyre et al., 2020; Quan et al., 2017; Ruscheweyh et al., 2009; Ruscheweyh et al., 2012; Valeberg et al., 2017).

The mean and standard deviation of subscores of the portuguese version of the *pain sensitivity questionnaire* are similiar between the first study (see table 2) and the thrid study (see table 11) of this dissertation where participants from the last study are included in the sample from the first study (PSQ-PT Total: 1st study: 4.84 ± 1.60 , 3rd study: 3.51 ± 1.14 ; PSQ-PT Minor: 1st study: 3.76 ± 1.65 , 3rd study: 2.95 ± 1.48 ; PSQ-PT Moderate: 1st study: 5.50 ± 1.67 , 3rd study: 4.35 ± 1.19). In the third study, it was found that the item 5 ("Imagine you take a shower with lukewarm water.") and item 13 ("Imagine you shake hands with someone who has a normal grip.") were the ones with the lowest score (see table 11) meeting what was verified in the first study of this dissertation (see table 2). These results suggest that the portuguese version of the PSQ seems to be as good as the original questionnaire to assess pain sensitivity because the measured variable is similar over time.

The second study suggest that PSQ-PT demonstrates sensitivity and is a useful instrument in discriminating between healthy and individuals suffering from fibromyalgia. In this study, the results of the PSQ-PT was compare a healthy control group with a fibromyalgia-matched group by sociodemographic characteristics. Like in the *Pain Sensitivity Questionnaire* in chronic pain patients (Ruscheweyh et al., 2012) the results showed an increased mean in fibromyalgia group compare to healthy group. The results, also, demonstrated that fibromyalgia group scored significantly higher on all the questionnaires used (PCS, STAI and HADS), suggesting as expected, worst clinical status in this condition (Ruscheweyh et al., 2012; Sellers et al., 2013; Valeberg et al., 2017) and, also, may be an indicator that depression and/or anxiety seem to increase pain sensitivity in everyday situations, especially those involving midly pain. Thus, demonstrating the importance of psychological factors in the area of pain (Turk and Monarch, 2002).

The last study (a pilot study) allowed the study of the relations between pain and cognition and the scores in the portuguese version of the PSQ. Digit Span Forwarded are correlated with cold threshold which seems to indicate that when the cold increases short term memory decreases. This results suggest that pain and cognition are related and cognitive functions may be affected by this, congruente throughout what is theorized (Kratiz et al., 2015).

In summary, this was the first study (first sudy) to demonstrate the importance of the *Pain Sensitivity Questionnaire* for the healthy portuguese population (PSQ-PT) as the data suggest that it allows for a correct assessment of pain sensitivity in healthy people, in line with what was seen in previous validations. This is also the first study (second study) to investigate whether pain sensitivity with the *Pain Sensitivity Questionnaire* allows us to assess patients with a diagnosis of fibromyalgia and, also, the first a study (third study) of the relations between the scores of the PSQ, experimental assessment of pain and cognitive function working memory (*Digit Span*).

8. References

- Arnold, L. (2010). The Pathophysiology, Diagnosis and Treatment of Fibromyalgia. Psychiatric Clinics of North America, 33(2), 376-408. doi: 10.1016/j.psc.2010.01.001
- Abdaljawwad, A. A., & Al-Groosh, D. H. (2021). Development and Validation of the Arabic Version of the Pain Sensitivity Questionnaire (PSQ). International Medical Journal, 28(1), 33-36.
- Anderson, S. R., Witkin, J. E., Bolt, T., Llabre, M. M., Ashton-James, C. E., & Reynolds Losin, E. A. (2021). Modeling neural and self-reported factors of affective distress in the relationship between pain and working memory in healthy individuals. Neuropsychologia, 153, 107766. doi:10.1016/j.neuropsychologia.20
- Azevedo, L. F., Pereira, A. C., Dias, C., Agualusa, L., Lemos, L., Romão, J., Patto, T., Vaz-Serra, S., Abrunhosa, R., Carvalho, C. J., Cativo, M. C., Correia, D., Correia, J., Coucelo, G., Lopes, B. C., Loureiro, M. C., Silva, B. & Castro-Lopes, J. M. (2007). Tradução, Adaptação Cultural e Estudo Multicêntrico de Validação de Instrumentos para Rastreio e Avaliação do Impacto da Dor Crónica. Retrieved November 25, 2018, from <u>http://www.aped-</u> dor.org/images/revista_dor/pdf/2007/n4.pdf
- Azimi, P., Azhari, S., Shahzadi, S., Nayeb Aghaei, H., Mohammadi, H. R., & Montazeri,
 A. (2016). Outcome Measure of Pain in Patients with Lumbar Disc Herniation:
 Validation Study of the Iranian version of Pain Sensitivity Questionnaire. Asian spine journal, 10(3), 480–487. https://doi.org/10.4184/asj.2016.10.3.480
- Azimi P, Benzel EC (2016) Cut-Off Value for Pain Sensitivity Questionnaire in Predicting Surgical Success in Patients with Lumbar Disc Herniation. PLoS ONE 11(8): e0160541. doi:10.1371/journal.pone.0160541
- Blankenburg, M., Boekens, H., Hechler, T., Maier, C., Krumova, E. et al. (2010). Reference values for quantitative sensory testing in children and adolescents: Developmental and gender differences of somatosensory perception. Pain 149, 76–88.)
- Blankenburg, M., Meyer, D., Hirschfeld, G., Kraemer, N., Hechler, T. et al. (2011). Developmental and sex differences in somatosensory perception–a systematic

comparison of 7- versus 14-year-olds using quantitative sensory testing. Pain 152, 2625–2631.

- Branco, J. C., Rodrigues, A. M., Gouveia, N., Eusébio, M., Ramiro, S., ... Machado, P. M. (2016). Prevalence of rheumatic and musculoskeletal diseases and their impact on health-related quality of life, physical function and mental health in Portugal: results from EpiReumaPt– a national health survey. RMD Open, 2(1), e000166. doi:10.1136/rmdopen-2015-000166
- Borchers, A. T., & Gershwin, M. E. (2015). Fibromyalgia: A Critical and Comprehensive Review. Clinical Reviews in Allergy & Immunology, 49(2), 100–151. doi:10.1007/s12016-015-8509-4
- Chapman, C. R., Casey, K. L., Dubner, R., Foley, K. M., Gracely, R. H., & Reading, A. E. (1985). Pain measurement: An overview. Pain, 22(1), 1-31.
- Daut, R. L., Cleeland, C. S., & Flanery, R. C. (1983). Development of the Wisconsin Brief Pain Questionnaire to assess pain in cancer and other diseases. Pain, 17(2), 197–210. doi:10.1016/0304-3959(83)90143-4
- Di Tella, M., Castelli, L., Colonna, F., Fusaro, E., Torta, R., Ardito, R. B., & Adenzato, M. (2015). Theory of Mind and Emotional Functioning in Fibromyalgia Syndrome: An Investigation of the Relationship between Social Cognition and Executive Function. PLOS ONE, 10(1), e0116542. doi:10.1371/journal.pone.0116542
- Dionne, R. A., Bartoshuk, L., Mogil, J., & Witter, J. (2005). Individual responder analyses for pain: does one pain scale fit all? Trends in Pharmacological Sciences, 26(3), 125–130. doi:10.1016/j.tips.2005.01.009
- Dualé, C., Bauer, U., Storme, B., Eljezi, V., Ruscheweyh, R., Eschalier, S., ... Guiguet-Auclair, C. (2019). Adaptation transculturelle et validation française du questionnaire de sensibilité à la douleur (Pain Sensitivity Questionnaire). Canadian Journal of Anesthesia/Journal Canadien D'anesthésie. doi:10.1007/s12630-019-01377-w
- Eccleston, C. (2013). A normal psychology of everyday pain. Int. J. Clin. Pract. 67, 47– 50.

- Eccleston, C., Blyth, F, Dear, B., Fisher, E., Keefe, F., Lynch, M., Palermo, T., Reid, M. & Williams, A. (2020). Managing patients with chronic pain during the COVID-19 outbreak: considerations for the rapid introduction of remotely supported (eHealth) pain management services. Pain, 161(4), 889-893, doi: 10.1097/j.pain.00000000001885
- Eccleston, C., Crombez, G. (1999). Pain demands attention: a cognitive-affective model of the interruptive function of pain. Psychol. Bull. 125, 356–366.
- El Tumi, H.; Johnson, M.I.; Dantas, P.B.F.; Maynard, M.J.; Tashani, O.A. (2017). Agerelated changes in pain sensitivity in healthy humans: A systematic review with meta-analysis. European Journal of Pain, (), –. doi:10.1002/ejp.1011
- Ellingson, L. D., Colbert, L. H., & Cook, D. B. (2012). Physical Activity Is Related to Pain Sensitivity in Healthy Women. Medicine & Science in Sports & Exercise, 44(7), 1401–1406. doi:10.1249/mss.0b013e318248f648
- Ersek, M., Cherrier, M.M., Overman, S.S., Irving, G.A. (2004). The cognitive effects of opioids. Pain Manag. Nurs. 5, 75–93.
- Fillingim, R. B. (2005). Individual differences in pain responses. Current Rheumatology Reports, 7(5), 342–347. doi:10.1007/s11926-005-0018-7
- Fillingim, R., King, C., Ribeiro-Dasilva, M., Rahim-Williams, B. & Riley, J. (2009). Sex, Gender, and Pain: A Review of Recent Clinical and Experimental Findings. The journal of pain: official journal of the American Pain Society, 10, 447-85. doi:10.1016/j.jpain.2008.12.001.
- Frederickson, L.W., Lynd, R.S. & Ross, J., (1978). Methodology in the measurement of pain, Behav. Ther., 9, 486-488.
- Galvez-Sánchez, C. M., Duschek, S., & Reyes del Paso, G. A. (2019).Psychological impact of fibromyalgia: current perspectives. Psychology Research and Behavior Management, Volume 12, 117–127. doi:10.2147/prbm.s178240
- Gatchel, R., Peng, P., Peters, M., Funchs, P., & Turk, D. (2007). The Biopsychosocial Approach to Chronic Pain: Scientific Advances and Future Directions. Pychological Bulletin, 133(4), 581-624, doi:10.1037/0033-2909.133.4.581

- Garcia, C. (1984). A Doença de Alzheimer: problemas do diagnóstico clínico. Tese de doutoramento apresentada à Universidade de Lisboa, Lisboa.
- Guerreiro, M. (1998). Contributo da neuropsicologia para o estudo das demências. Dissertação de doutoramento, Universidade de Lisboa, Faculdade de Medicina de Lisboa.
- Grundström, H., Larsson, B., Arendt-Nielsen, L., Gerdle, B., & Kjølhede, P. (2019). Associations between pain thresholds for heat, cold and pressure, and Pain Sensitivity Questionnaire (PSQ) scores in healthy women and in women with persistent pelvic pain. European Journal of Pain. doi:10.1002/ejp.1439
- Harris, R. E., Williams, D. A., McLean, S. A., Sen, A., Hufford, M., Gendreau, R. M., ... Clauw, D. J. (2005). Characterization and consequences of pain variability in individuals with fibromyalgia. Arthritis & Rheumatism, 52(11), 3670–3674. doi:10.1002/art.21407
- Hood, A., Pulvers, K., & Spady, T. J. (2013). Timing and Gender Determine If Acute Pain Impairs Working Memory Performance. The Journal of Pain, 14(11), 1320– 1329. doi:10.1016/j.jpain.2013.05.015
- Horn-Hofmann, C., Kunza, Maddena, M., Schnabela, E-L. & Lautenbachera, S. (2018). Interactive effects of conditioned pain modulation and temporal summation of pain—the role of stimulus modality. PAIN, 159, 2641–2648
- International Association for the Study of Pain (Associação Internacional para o Estudo da Dor) - IASP. Guia para o Tratamento da Dor em Contextos de Poucos Recursos. USA: IASP; 2010. 418p
- Kwiatek, R. (2017). Treatment of fibromyalgia. Australian Prescriber, 40(5), 179-183, doi:10.18773/austprescr.2017.056
- Latka, D., Miekisiak, G., Kozlowska, K., Olbrycht, T., Chowaniec, J., Latka, K., ... Jarmuzek, P. (2019). Translation, validation, and cross-cultural adaptation of the Polish version of the pain sensitivity questionnaire. Journal of Pain Research, Volume 12, 969–973. doi:10.2147/jpr.s189427
- Legrain, V., Damme, S.V., Eccleston, C., Davis, K.D., Seminowicz, D.A., Crombez, G.

(2009). A neurocognitive model of attention to pain: behavioral and neuroimaging evidence. Pain 144, 230–232.

- LeResche, L. (1982). Facial expression of pain: a study of candid photographs, J. nonverb. Behav., 7, 46-56.
- Lezak, M. D., Howieson, D.B., Loring, D.W. (2004). Neuropsychological Assessment. New York: Oxford University Press
- Malin, K., & Littlejohn, G. (2012). Personality and Fibromyalgia Syndrome. The Open Rheumatology Journal, 6(1), 273–285. doi:10.2174/1874312901206010273
- Martin, J. H. (2012). Neuroanatomy: Text and atlas, Fourth Edition. McGraw-Hill
- McIntyre, M. H., Kless, A., Hein, P., Field, M., & Tung, J. Y. (2020). Validity of the cold pressor test and pain sensitivity questionnaire via online self-administration. PLOS ONE, 15(4), e0231697. doi:10.1371/journal.pone.0231697
- Medoc (2012). TSA-200I: Neurosensory Analyzer Model TSA-II. Medoc Ltd. Retrieved November 30, 2018 from <u>https://psychologie.unibas.ch/fileadmin/user_upload/psychologie/Forschung/N-</u> Lab/TSA2OperationManual.pdf
- Melzack, R. (1975). The McGill Pain Questionnaire: Major properties and scoring methods. Pain, 1(3), 277–299. doi:10.1016/0304-3959(75)90044-5
- Mylius, V., Pee, S., Pape, H., Teepker, M., Stamelou, M., Eggert, K., ... Möller, J. C. (2016). Experimental pain sensitivity in multiple system atrophy and Parkinson's disease at an early stage. European Journal of Pain, 20(8), 1223–1228. doi:10.1002/ejp.846
- Nielsen, C. S., Staud, R., & Price, D. D. (2009). Individual Differences in Pain Sensitivity: Measurement, Causation, and Consequences. The Journal of Pain, 10(3), 231– 237. doi:10.1016/j.jpain.2008.09.010
- Oaklander, A. L., Herzog, Z. D., Downs, H. M., & Klein, M. M. (2013). Pain, 154(11), 2569–2571.

- Oosterman, J. M., Derksen, L. C., van Wijck, A. J. M., Veldhuijzen, D. S., & Kessels, R. P. C. (2011). Memory Functions in Chronic Pain. The Clinical Journal of Pain, 27(1), 70–75. doi:10.1097/ajp.0b013e3181f15cf5
- Procento, P. M., Rand, K. L., Stewart, J. C., & Hirsh, A. T. (2021). Pain Catastrophizing Mediates and Moderates the Link Between Acute Pain and Working Memory. The Journal of Pain, 22(8), 981–995. doi:10.1016/j.jpain.2021.03.138
- Quan, X., Fong, D. Y. T., Leung, A. Y. M., Liao, Q., Ruscheweyh, R., & Chau, P. H. (2017). Validation of the Mandarin Chinese Version of the Pain Sensitivity Questionnaire. Pain Practice, 18(2), 180–193. doi:10.1111/papr.12587
- Ruscheweyh, R., Dany, K., Marziniak, M., & Gralow, I. (2015). Basal Pain Sensitivity does not Predict the Outcome of Multidisciplinary Chronic Pain Treatment. Pain Medicine, 16(8), 1635–1642. doi:10.1111/pme.12750
- Ruscheweyh, R., Marziniak, M., Stumpenhorst, F., Reinholz, J., & Knecht, S. (2009). Pain sensitivity can be assessed by self-rating: Development and validation of the Pain Sensitivity Questionnaire. Pain. 146. 65-74. 10.1016/j.pain.2009.06.020.
- Ruscheweyh, R., Verneuer, B., Dany, K., Marziniak, M., Wolowski, A., Çolak-Ekici, R.,
 ... Knecht, S. (2012). Validation of the Pain Sensitivity Questionnaire in chronic pain patients. Pain, 153(6), 1210–1218. doi:10.1016/j.pain.2012.02.025
- Santos, S. C. e Silva, D. R. (1997). Adaptação do State-Trait Anxiety Inventory (STAI) – Form Y para a população portuguesa: Primeiros dados. Revista Portuguesa de Psicologia, 32, 85-98.
- Scott, J. & Huskisson, E. C. (1976) Graphic representation of pain, Pain, 2, 175-184.
- Sellers, A. B., Ruscheweyh, R., Kelley, B. J., Ness, T. J., & Vetter, T. R. (2013).
 Validation of the English Language Pain Sensitivity Questionnaire. Regional Anesthesia and Pain Medicine, 38(6), 508–514. doi:10.1097/aap.0000000000000007
- Spielberger, C. D., Gorsuch, R. L., Lushene, R., Vagg, P. R., & Jacobs, G. A. (1983). Manual for the State-Trait Anxiety Inventory. Palo Alto, CA: Consulting Psychologists Press.

- Stubbs, Brendon; Thompson, Trevor; Solmi, Marco; Vancampfort, Davy; Sergi, Giuseppe; Luchini, Claudio; Veronese, Nicola (2016). Is pain sensitivity altered in people with Alzheimer's disease? A systematic review and meta-analysis of experimental pain research. Experimental Gerontology, 82, 30–38. doi:10.1016/j.exger.2016.05.016
- Sullivan, M. J., Adams, H., & Sullivan, M. E. (2004). Communicative dimensions of pain catastrophizing: social cueing effects on pain behaviour and coping. Pain, 107(3), 220-226. doi: S0304395903004536
- Sullivan MJL, Bishop SR, Pivik J. (1995). The Pain Catastrophizing Scale: Developmentand Validation. Psychol Assess, 7(4): 524-32.
- Sung, S., Vijiaratnam, N., Chan, D. W. C., Farrell, M., & Evans, A. H. (2018). Pain sensitivity in Parkinson's disease: Systematic review and meta-analysis.
 Parkinsonism & Related Disorders, 48, 17–27. doi:10.1016/j.parkreldis.2017.12.031
- Valeberg, B. T., Pedersen, L. M., Girotto, V., Christensen, V. L., & Stubhaug, A. (2017). Validation of the Norwegian Pain Sensitivity Questionnaire. Journal of pain research, 10, 1137-1142. doi:10.2147/JPR.S129540
- Van Boekel, R. L. M., Timmerman, H., Bronkhorst, E. M., Ruscheweyh, R., Vissers, K. C. P., & Steegers, M. A. H. (2020). Translation, Cross-Cultural Adaptation, and Validation of the Pain Sensitivity Questionnaire in Dutch Healthy Volunteers. Pain Research and Management, 2020, 1–10. doi:10.1155/2020/1050935
- Sinatra, R. O., De Leon-Cassasola, O. A., Ginsberg. B., Viscusi, E. R., & McQuay, H. (2009). Acute Pain Management. Cambridge: Cambridge University Press. doi:10.1017/CBO9780511576706
- Treister, R., Eaton, T., Trudeau, J., Elder, H., & P Katz, N. (2017). Development and preliminary validation of the focused analgesia selection test to identify accurate pain reporters. Journal of Pain Research, 10, 319-326. https://doi.org/10.2147/JPR.S121455
- Treister, R., Lawal, O., Schecter, J., Khurana, N., Bothmer, J., Field, M., Harte, S., Kruger, G., & Katz, N. (2018). Accurate pain reporting training diminishes the

placebo response: results from a randomized, double-blind, crossover trial. Plos One 1. https://doi.org/10.1371/journal.pone.0197844

- Treister, R., Lodahl, M., Lang, M., Tworoger, S. S., Sawilowsky, S., Oaklander,& A .L.Initial development and validation of a patient-reported symptom survey for small-fiber polyneuropathy. J Pain. 2017 May; 18(5): 556–563. doi: 10.1016/j.jpain.2016.12.014
- Verhoeven, K., Stefaanl, V. D., Christopherl, E., Dimitri, M. L. R., Valéryl, L., & Geertl, C. (2011). Distraction from pain and executive functioning: An experimental investigation of the role of inhibition, task switching and working memory. European Journal of Pain, 15(8), 866–873. doi:10.1016/j.ejpain.2011.01.009
- Wechsler D. (1997). Wechsler Memory Scale–Third Edition manual. San Antonio, TX: The Psychological Corporation.
- Wolfe, F., Smythe, H. A., Yunus, M. B., Bennett, R. M., Bombardier, C., Goldenberg, D. L., ... Sheon, R. P. (1990). The american college of rheumatology 1990 criteria for the classification of fibromyalgia. Arthritis & Rheumatism, 33(2), 160–172. doi:10.1002/art.1780330203
- Yarnitsky D, Arendt-Nielsen L, Bouhassira D, Edwards RR, Fillingim RB, Granot M, Hansson P, Lautenbacher S, Marchand S, Wilder-Smith O. (2010) Recommendations on terminology and practice of psychophysical DNIC testing. Eur J Pain, 14:339.
- Zigmond AS, Snaith RP. The Hospital and Anxiety Depression Scale. Acta Psychiatr Scand 1983;7:361-370

9. APPENDICES

9.1. ETHICAL COMMITTEE OF THE UNIVERSIDADE CATÓLICA PORTUGUESA (COMISSÃO DE ÉTICA PARA A SAÚDE, NUMBER 020 FROM 17TH OF JULY 2019)



Parecer sobre o projeto nº 020

Comissão de Ética para a Saúde da Universidade Católica Portuguesa

Mandato 2018/2021

Projeto de Investigação

Na reunião do dia 17 de julho de 2019 a CES-UCP esteve reunida e apreciou do ponto de vista ético os elementos submetidos pela investigadora. Sobre a apreciação redige o parecer que agora se apresenta.

Titulo: Directing attention to internal and external clues and its relations to pain reporting variability

Investigador Principal: Rita Canaipa

Orientador: -----

Resumo

Este projeto tem como objetivo principal verificar se os indivíduos com maior tendência para focar a atenção em pistas internas ou externas diferem na sua precisão na avaliação da dor. Esta avaliação implica também a validação para a população portuguesa de dois instrumentos (questionários), um para avaliação da dor e outro relacionado com a existência de polineuropatias que podem estar na etiologia de algumas condições de dor: *Pain Sensivity Questionnaire* e *The MGH Symptom Screen for Small-Fiber Polyneuropathy.*

Estiveram presentes na reunião nº 8 da CES-UCP

Presidente: Doutora Mara de Sousa Freitas Vice-Presidente: Doutora Mª Emília Pinto dos Santos Doutora Mª Teresa Marques Dr. António Faria Vaz Doutor Pe. Jerónimo Santos Trigo Doutor Pedro Garcia Marques

Conclusão

Ouvido o Relator e o plenário da reunião do dia 17 julho de 2019, realizada no 5º piso da UCP, esta CES delibera, por unanimidade, emitir **Parecer favorável.** O estudo tem bastante interesse científico e clínico, está bem delineado e é enquadrado numa parceria com investigadores da Universidade de Haifa, Israel. No geral, os procedimentos a adotar estão corretos e são adequados sob o ponto de vista ético.

Esta CES solicita à Investigadora Principal que, aquando da conclusão do estudo, lhe seja enviada uma síntese dos resultados obtidos e respetivas conclusões, via eletrónica, para o correio eletrónico da CES UCP.

A Presidente,

Have de souse Friends Mara de Sousa Freitas

17/7/2019

9.2. INFORMED CONSENT



CONSENTIMENTO INFORMADO PARA PARTICIPAR NO ESTUDO

Avaliação de dor em sujeitos saudáveis

O presente estudo tem como investigador principal a Prof^a Dra. Rita Canaipa do Instituto de Ciências da Saúde da Universidade Católica Portuguesa (Cédula Profissional Ordem dos Psicólogos Portugueses n^o 6567) e do Prof. Dr. Roi Treister e da Prof Dra Liat Honigman da Universidade de Haifa. A sua participação neste estudo é inteiramente voluntária. Deve ler a informação que se segue e colocar questões sobre aquilo que não entender antes de decidir se participa ou não neste estudo.

Objetivos do Estudo

Este estudo tem como objetivo compreender os mecanismos de avaliação da dor em sujeitos saudáveis. É conhecido que a avaliação da dor é muito subjetiva e que os estudos para desenvolver novos medicamentos e terapias têm dificuldade em compreender se os doentes realmente conseguem revelar a dor que sentem e as eventuais melhorias que obtém. Este estudo tem, por isso, como objetivo compreender de que forma os sujeitos relatam a sua dor e se isso se relaciona com dificuldades na utilização das escalas de medição ou de particularidades na sua sensibilidade à dor.

Procedimentos

Pediremos a sua colaboração no preenchimento de alguns questionários que avaliam questões relacionadas com a sua saúde e com as suas vivências emocionais. Será ainda realizada uma tarefa cognitiva, uma avaliação dos parâmetros musculares e ser-lhe-á pedido que participe em tarefas em que lhe são aplicados estímulo térmicos e de pressão de intensidade variável no seu braço, mas sempre em níveis considerados moderados, estímulos esses que deverá avaliar tendo em conta a intensidade que sentiu.

Todos os estímulos aplicados durante o estudo terão intensidades variáveis, mas serão no máximo de dor moderada, **nunca atingindo níveis de dor intensa**. Caso algum estímulo seja de intensidade que considere mais elevada, poderá pedir para retirar o equipamento e o seu pedido será **imediatamente** aceite. Estes estímulos são seguros, não implicando qualquer dano nos tecidos nem quaisquer consequências físicas ou emocionais a longo prazo. **PODERÁ PARAR A ESTIMULAÇÃO ASSIM QUE O ENTENDA.**

Haverá um ponto em que terá de provar soluções aquosas, sem as ingerir, se por alguma razão não o conseguir fazer, seja por motivo de alergia ou enjoo ou outro motivo, a tarefa será interrompida, sem qualquer tipo de penalização.

Interrupção da sua participação pelo investigador

Os investigadores podem ser forçados a interromper a sua participação neste estudo. Tal poderá acontecer se alguns procedimentos não se realizarem adequadamente, ou devido a inadequações das suas características, por razões de segurança ou por outras razões relevantes para o seu bem-estar ou para o bom desenvolvimento do projeto de investigação. Contudo, será sempre informado se essa situação se colocar.

Benefícios previstos do projeto de investigação

Este estudo pretende ajudar a esclarecer de que forma as pessoas avaliam a sua dor. Nesse sentido, os resultados obtidos poderão trazer informação importantes para estudos futuros que procurem desenvolver e testar novas terapias para o tratamento da dor. Contudo, deste estudo não se esperam benefícios diretos para o seu estado de saúde. Por outro lado, também não são de esperar quaisquer consequências negativas para o seu bem-estar físico ou psicológico.

Privacidade e Confidencialidade

As únicas pessoas que terão acesso à informação que nos fornecer serão os membros de investigação. Nenhuma informação sobre si será facultada a qualquer outra pessoa se não assinar consentimento escrito para tal, exceto obviamente, se estiver em causa alguma situação de risco para si enquanto se realizarem os procedimentos do estudo (por exemplo, se se magoar durante o estudo e necessitar de atendimento médico).

Quando os resultados deste projeto de investigação forem publicados ou apresentados em conferências, não será fornecida qualquer informação que possa revelar a sua identidade.

Participação e desistência

A sua participação neste estudo em inteiramente **VOLUNTÁRIA**. Escolher participar ou não neste estudo não altera a sua relação com os investigadores nem com as instituições participantes. Se decidir participar poderá, no entanto, retirar o seu consentimento e desistir dessa participação em qualquer fase do estudo sem que tais relações se alterem.

Novos dados

Durante o curso do estudo será informado caso surjam novos dados que alterem os riscos ou benefícios da participação neste estudo e que, por consequência, possam implicar alterações na sua decisão sobre a participação neste projeto. Se tal ocorrer, ser-lhe-á pedido novo consentimento informado.

Identificação dos investigadores

Caso tenha alguma dúvida relacionada com o estudo ou necessite de entrar em contacto com os investigadores poderá fazê-lo para:

Prof. Dra. Rita Canaipa <u>rita.canaipa@ics.lisboa.ucp.pt</u> ou pelo telemóvel 966538648.

Assinatura do participante da investigação

Declaro que eu, _____

	(nome)
com o número de identificação	li e compreendi a
informação relativa ao projeto de investigação acima. Foi-me dada a oportu	nidade de colocar
questões, as quais foram devidamente esclarecidas. Foi-me dada uma cópia o	deste documento.

AO ASSINAR ESTE DOCUMENTO ASSUMO ACEITAR PARTICIPAR VOLUNTARIAMENTE NO ESTUDO NELE DESCRITO.

Assinatura:

Data: _____

Assinatura do investigador

Expliquei o estudo ao participante e respondi a todas as suas questões. Considero que compreende a informação apresentada neste documento e consente livremente participar neste estudo.

_____ (nome do investigador)

Assinatura: _____

Data: _____