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DOCTORAL THESIS

PSYCHOLOGICAL FACTORS, PAIN AND FUNCTION IN INDIVIDUALS WITH CHRONIC SHOULDER PAIN

JAVIER MARTÍNEZ CALDERÓN

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PSYCHOLOGICAL FACTORS, PAIN AND FUNCTION IN INDIVIDUALS WITH CHRONIC SHOULDER PAIN

Thesis submitted for the fulfillment of the requirements for the degree of doctor in physiotherapy by the University of Málaga and doctor in medical sciences by the University of Antwerpen

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UNIVERSIDAD
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Prof. Dr. Alejandro Luque Suárez,

CERTIFICA

Que la tesis doctoral titulada "Psychological Factors, Pain and Function in Individuals with Chronic Shoulder Pain" ha sido realizada bajo mi dirección por Don Javier Martínez Calderón, reuniendo las condiciones apropiadas en cuanto a contenido y rigor científico para ser presentada a trámite de lectura.

Y para que conste, firmo en Málaga a 16 de febrero de 2019.

Prof. Dr. Alejandro Luque Suárez

Faculty of Medicine and Health Sciences

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Prof. Dr. Mira Meeus

DEDICATION

To Mar, who has given me the inspiration and courage to be a researcher and a writer. Without you, I would not be who I am.

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ENGLISH ABSTRACT

The current doctoral thesis, entitled "Psychological factors, pain and function in individuals with chronic shoulder pain" has been conducted under the co-supervision regime between the University of Malaga, Spain and the University of Antwerp, Belgium. Therefore, a summary in English is exposed on the content of this.

During the **first chapter**, this doctoral thesis shows us a deep vision about the importance of pain in our society. Pain is a major public health priority. It is considered one of the most frequent causes to seek health care. Traditionally, the International Association for the Study of Pain has defined pain as “an unpleasant sensory and emotional experience associated with actual/potential tissue damage or described in terms of such damage”. Everyone will experience pain at some point in their lifetime. Annually, estimations suggest that one in five adults have acute or subacute pain, whereas one in ten adults endure chronic pain. The pain experience of every individual is extremely complex. Pain is undeniably subjective. Indeed, people who have similar diagnostic criteria often perceive pain in a different manner. As a consequence of pain subjectivity, the term “pain” has acquired a broad range of dimensions in order to cover all the sensations that an individual feel when is in pain. In this sense, intensity, severity, affect and sensitivity are probably the most studied dimensions of pain. Pain intensity describes how intense we perceive pain on a specific moment. Pain intensity is the most noteworthy dimension of pain, which is often assessed through unidimensional self-reported scales. The numerical pain rating scale and the visual analogue scale are the most common tools used to measure pain intensity. However, certain factors such as the context or culture influences how intense an individual perceives its pain. Pain contains multidimensional attributes and subtle connotations such as aching or burning among others. Thereby, pain

intensity should not be considered a linear phenomenon and exclusively quantified through unidimensional tools. In this context, pain severity and pain affect have emerged as multidimensional dimensions of pain which include the term “pain intensity”. Both are commonly assessed through multidimensional self-reported scales. Pain severity involves pain intensity and pain interference with daily activities. Pain affect refers to pain intensity and the emotional changes that an individual feel when he/she is in pain. Pain sensitivity is a relevant dimension of pain. It describes the tendency to react to standardized experimental or pathological stimuli. When repeated or intense noxious stimuli (actual or potential tissue damaging events) occur, pain hypersensitivity emerges. Pain hypersensitivity is characterized by allodynia (increased sensitivity for normally non-painful stimuli) and hyperalgesia (noxious stimuli produce an exaggerated and prolonged response to pain). Pain hypersensitivity is initially an adaptive process that arouse our alert systems in situations where there is a potential risk of damage. When tissues heal, pain hypersensitivity returns to normal baseline values. However, some individuals report pain hypersensitivity after the tissues heal, even in asymptomatic areas where the primary pain input did not occur. This phenomenon represents the sensitization of the central nervous system which is probably a key driver in syndromes such as fibromyalgia or chronic fatigue syndrome. Acute pain (pain present for less than three months) is very common worldwide. Unfortunately, certain individuals show an inadequate control of its acute pain, developing chronic pain and pain-related symptoms. Many factors are involved in how an individual perceives, processes, interprets and copes with its pain experience. Thus, not only sensory and emotional factors, but also cognitive, behavioural and social factors are considered important in the distressful experience of pain. Some of these factors may favour maladaptive responses to pain, which may suppose a bridge in the transition and perpetuation to chronicity. But first, what is chronic pain?

Chronic pain refers to pain that persists or recurs more than three months, once the normal healing process has occurred. Chronic pain is a global issue which affects up to 34% of population. The socioeconomic burden occasioned by chronic pain is enormous. Biopsychosocial consequences are critical. Certain individuals reject their chronic situation. These individuals are often socially excluded which may lead to unpleasant results in terms of insomnia, depression, opioid overuse, suicidal ideation and premature mortality. In this sense, numerous surgical and conservative interventions have been proposed in order to improve the poor prognosis of chronic pain. However, chronicity continues to increase. Chronic musculoskeletal pain is the most prevalent chronic pain sondition and it is also a huge concern in clinical practice. Indeed, more than 20% of individuals with this condition annually consult a health professional. Additionally, chronic musculoskeletal pain is viewed as the fourth global burden on health in terms of economic costs and psychosocial consequences. In this sense, a large number of conservative and surgical interventions have been proposed to improve chronic musculoskeletal pain and its pain-related outcomes. However, its recurrence and persistence are frequent. Certain chronic musculoskeletal symptoms, such as widespread pain, are not associated with a tissue damage or a pathophysiological reason. This causes that the course of chronic musculoskeletal pain is unpredictable which entails an immense challenge for clinicians and researchers.

The present doctoral thesis focused on a specific type of musculoskeletal pain, shoulder pain. Shoulder pain is the third most common musculoskeletal pain condition after low back and neck pain. Interestingly, a large percentage of individuals with shoulder pain disorders consult a health professional. However, roughly 50% of them develop chronic shoulder pain.

A great deal of factors influences the delay of recovery in individuals with shoulder pain which cause a negative circle of more pain, frustration, disability and emotional distress. In this sense, there is a large amount of research focused on how biological, psychological and social factors that surround an individual with chronic pain are fundamental in the prognosis of this. Within these factors, psychological factors seem to be key in how an individual perceives, interprets and responds to their chronic pain. Given these considerations, the acquisition of in-depth knowledge about the impact that psychological factors play in the perpetuation of chronic shoulder pain is essential in order to design targeted interventions that promote the increase of protective factors such as pain self-efficacy and resilience. With this, people with chronic shoulder pain can establish active coping strategies that facilitate the control of their pain and adherence to rehabilitation programs such as exercise programmes. For this reason, the current doctoral thesis aimed to evaluate the role that psychological factors play in pain and disability in individuals with chronic shoulder pain. This first chapter serves as background and justification for the development of the present doctoral thesis.

The **second chapter** lists the general and specific objectives of this doctoral thesis. The first general aim was to explore the current state of knowledge about the role that psychological factors (especially cognitive and emotional factors) play in individuals with shoulder pain. The second general aim was to determine the potential associations between a set of psychological factors (specifically pain catastrophizing, pain self-efficacy, kinesiophobia or fear of movement and emotional distress) and chronic shoulder pain intensity and pain-related variables such as disability.

The **third chapter** aimed to respond the first general objective of this doctoral thesis. In this context, a systematic review was performed in order to analyse the role that psychological factors play in the perpetuation of chronic shoulder pain intensity and disability in operative and non-operative samples. A systematic search was conducted in PubMed, AMED, CINAHL, PubPsych and EMBASE from the incception of these databases until July 2017. Longitudinal studies which evaluated the role that psychological factors play in the perpetuation of chronic shoulder pain intensity and disability were included. The risk of bias across the included studies was assessed through the Newcastle Ottawa scale. The overall quality and strength of the evidence per outcome (pain intensity and disability) was examined through the GRADE approach. A total of 27 longitudinal studies satisfied our inclusion criteria, and thus, were included in this systematic review. The total sample was of 11,176 individuals with chronic shoulder pain. The risk or bias was variable across the included studies. The quality and the strength of the evidence was very low. Higher levels of self-efficacy, resilience and expectations of recovery were significantly associated with lower levels of pain intensity and disability. Conversely, higher levels of emotional distress, depressive symptoms, anxiety, preoperative concerns, fear-avoidance beliefs, somatization and pain catastrophizing were significantly associated with higher levels of pain intensity and disability. Our results suggest that psychological factors may influence the perpetuation of pain intensity and disability in individuals with chronic shoulder pain. Nevertheless, the overall quality and strength of the evidence in terms of inconsistency, risk of bias and imprecision of results was very low, and hence, further research in this field is required. This article was published in the year 2018 in the journal **BMJ Open**.

The **fourth chapter** also aimed to satisfy the first general objective of this doctoral thesis. Therefore, another systematic review focused specifically on pain beliefs was conducted, since inside of psychological factors, cognitive and emotional factors has been shown as key factors and modulables through a long battery of conservative interventions such as physiotherapy. The objective of this systematic review was to evaluate the association between pain beliefs, pain intensity and disability in individuals with acute, subacute and chronic shoulder pain. A systematic search was established in PubMed, EBSCOhost, AMED, CINAHL, EMBASE and PubPsych from the inception of these databases until July 2017. Grey literature was also searched. The selection of studies was based on cross-sectional and longitudinal observational studies that explored the association and the predictive value that pain beliefs play in shoulder pain intensity and disability. A total of thirty-three articles were included with a total sample of 10,293 individuals with shoulder pain. In the cross-sectional analysis, higher levels of catastrophic thoughts in response to pain and kinesiophobia were significantly associated with higher levels of pain intensity and disability. On the other hand, in this same analysis, higher levels of expectations of recovery and self-efficacy beliefs were significantly associated with lower levels of pain intensity and disability. In the longitudinal analysis, higher baseline levels of catastrophic thoughts in response to pain, fear-avoidance beliefs and kinesiophobia predicted the perpetuation of pain intensity and disability over time. Conversely, greater baseline levels of expectations of recovery and self-efficacy beliefs predicted the reduction in the progression of pain intensity and disability over time. Evidence suggests that pain beliefs are associated with and predict to the course of pain intensity and disability in shoulder pain. However, the overall quality and strength of the evidence in terms of inconsistency, risk of bias and imprecision of the results was very low through the included studies. Further research using higher quality longitudinal designs and procedures are needed in order to draw firm conclusions in this regard. This article was published in the year 2018 in the journal **Musculoskeletal Science & Practice**.

The **fifth chapter** is a proposal to address the second general objective of the current doctoral thesis. In this sense, a study protocol was developed to determine the role that psychological factors play in the prognosis of chronic shoulder pain through a prospective cohort study. The study was designed to have a longitudinal perspective, with a follow-up of 12 months. This study will be carried out in four primary care centres as well as a hospital. It will include a total of 307 participants older that 18 years old with chronic shoulder pain. The following variables will be assessed: pain intensity, disability, pain self-efficacy, kinesiophobia, fear of pain, catastrophic thoughts in response to pain and expectations of recovery among others. A total of four measurement points will be taken: at baseline; 3 months; 6 months and 12 months follow-up. This article was published in the year 2017 in the journal **BMJ Open**.

The **sixth chapter** was addressed to satisfy the second general objective of the present doctoral thesis. In this context, a cross-sectional observational study was developed which showed two aims. The first objective was to explore the potential associations between a set of psychological factors (catastrophic thoughts in response to pain, pain self-efficacy and emotional distress) and experimental pain measures (local and generalized pain hypersensitivity). The second objective was to evaluate the potential associations between the aforementioned psychological factors and pain intensity and disability in individuals with chronic shoulder pain. A total of 90 participants with chronic shoulder pain meet our inclusion criteria and therefore, they were included in this study. Pain hypersensitivity was assessed through the pressure pain threshold, a measure which was obtained using a pressure algometry. Pain intensity and disability were evaluated with the "The Shoulder and Disability Index" questionnaire. Pain self-efficacy was explored through the questionnaire "The Pain Self-Efficacy Questionnaire". Pain catastrophizing was evaluated using the "The Pain Catastrophizing Scale" questionnaire. Emotional distress was assessed through the questionnaire "The Hospital Anxiety and Depression Scale". Multivariate regression analyses were performed to determine the potential associations between psychological factors and both pain measurements (clinical and experimental), as well as the level of disability. All analyses were adjusted by gender. In the regression analysis, higher levels of pain self-efficacy were associated with lower levels of local pain hypersensitivity ($p = 0.046$), lower levels of pain intensity ($p <0.001$) and higher levels of function ($p <0.001$). On the other hand, higher levels of catastrophic thoughts in response to pain were associated with higher levels of pain intensity ($p <0.001$) and higher levels of disability ($p = 0.002$). In addition, higher levels of emotional distress were associated with higher levels of pain intensity ($p <0.001$). In conclusion, this cross-sectional study showed preliminary evidence about the association between a battery of psychological factors, specifically catastrophic thoughts in response to pain, pain self-efficacy and emotional distress, with measures of clinical and experimental pain as well as the presence of disability in individuals with chronic shoulder pain.

The **seventh chapter** was also developed to cover the second general objective of the present doctoral thesis. In this chapter, a second cross-sectional observational study was conducted. This study focused on a specific variable, kinesiophobia, due to its vital importance in the perception, processing, interpretation and coping of chronic musculoskeletal pain. In this sense, the aim of this study was to explore the potential association between kinesiphobia and both pain intensity and disability in individuals with chronic shoulder pain. A total of 65 individuals with chronic unilateral subacromial pain were included in this study. Pain intensity and disability were evaluated through the "The Shoulder and Disability Index" questionnaire. Kinesiophobia was explored using the "The Tampa Scale for Kinesiophobia short-form" questionnaire. A multivariate regression analysis was performed to detect potential associations between kinesiophobia, pain intensity and disability. The analysis was adjusted for range of movement free pain, gender and age. In the regression analysis, higher levels of kinesiophobia were associated with higher levels of pain intensity and disability (standardized $\beta = 0.35$ $p < 0.01$). This association remained significant after the adjustment for range of movement free pain, gender and age. In conclusion, this cross-sectional study provides preliminary evidence about the association between kinesiophobia with pain intensity and disability in individuals with chronic shoulder pain. Nevertheless, the predictive value of kinesiophobia on the maintenance of chronic shoulder pain and disability could not be determined due to the cross-sectional nature of the present study. Further longitudinal cohorts studies in this field are warranted.

The **eighth chapter** was elaborated to conduct a general discussion of the findigngs obtained in this doctoral thesis. The limitations of the present doctoral thesis were also mentioned in this chapter. The general objectives of this thesis were: (i) to explore the state of the art about the role that psychological factors (especially cognitive and emotional factors) play in the progression and maintenance of chronic shoulder pain and disability and; (ii) determine potential associations between psychological factors (specifically catastrophic thoughts in response to pain, kinesiophobia, pain self-efficacy and emotional distress) and chronic shoulder pain and disability. A total of two systematic reviews were carried out and published with the aim of satisfying the first general objective of the doctoral thesis. The first systematic review explored all available evidence considering the role that psychological factors play in the perpetuation of pain intensity and disability in individuals with chronic surgical and non-surgical shoulder pain. After the analysis of 27 observational longitudinal cohort studies, higher baseline levels of self-efficacy beliefs, resilience and expectations of recovery predicted lower levels of pain intensity and disability over time. On the other hand, higher baseline levels of emotional distress, depressive symptoms, anxiety, pre-surgical concerns, fear-avoidance beliefs, somatization and catastrophic thoughts in response to pain predicted higher levels of pain intensity and disability over time.

The second systematic review was also published and aimed to evaluate the cross-sectional association and the longitudinal predictive value that pain beliefs play in pain shoulder pain intensity and disability. A total of 33 observational studies were analysed. Higher levels of catastrophic thoughts in response to pain and kinsiophobia were cross-sectionally associated with higher levels of pain intensity and disability. Greater levels of self-efficacy beliefs and expectations of recovery were concurrently associated with lower levels of pain intensity and disability. Additionally, greater baseline levels of catastrophic thoughts in response to pain, fear-avoidance beliefs and kinesiophobia predicted greater levels of pain intensity and disability over time. Conversely, higher baseline levels of self-efficacy beliefs and expectations of recovery predicted lower levels of pain intensity and disability over time. Both systematic reviews highlighted the essential role that psychological factors play in the progression and maintenance of chronic shoulder pain and disability. In line with our results, a large amount of evidence has underlined the relevance of psychological factors in the transition and perpetuation of chronic musculoskeletal pain and disability.

A total of two cross-sectional observational studies were conducted to satisfy our second general objective. First, a cross-sectional study was developed to explore potential associations between psychological factors (pain self-efficacy, catastrophic thoughts in response to pain and emotional distress) with measures of pain and disability in individuals with chronic shoulder pain. This study concluded that higher levels of pain self-efficacy were associated with lower levels of local pain hypersensitivity, pain intensity and disability. These results are in line with previous evidence, which underline the role that self-efficacy beliefs play in individuals with chronic pain. This study also revealed that higher levels of catastrophic thoughts in response to pain were associated with higher levels of pain intensity and disability. Greater levels of emotional distress were also associated with higher levels of pain intensity. These results have been supported by prior evidence.

Another cross-sectional study was also carried out in order to satisfy the second general aim of this doctoral thesis. The objective was to evaluate the potential association between kinesiophobia with both pain intensity and disability in individuals with chronic shoulder pain. This study highlighted that higher levels of kinesiophobia are associated with higher levels of pain intensity and disability. This association remained significant after the adjustment for range of movement free pain, gender and age. These results agree with a large amount of evidence, which underline the role of kinesiophobia in individuals with chronic musculoskeletal pain.

From a physiotherapy perspective, patient's and physiotherapist's beliefs, their attitudes and emotions are key factors in clinical decision-making. These cognitive and emotional factors are modifiable through different conservative interventions. The current doctoral thesis highlighted the importance of psychological factors in the persistence of chronic musculoskeletal pain and disability, particularly chronic shoulder pain. Therefore, the findings of this doctoral thesis should encourage physiotherapists to assess and treat these factors in their clinical practice.

Psychological interventions such as pain neuroscience education and cognitive-functional therapy delivered by physiotherapists combined with physiotherapy interventions such as exercise plans, are emerging approaches to modify cognitive and emotional factors in the field of musculoskeletal pain. The benefits of psychological interventions delivered by physiotherapists are promising. However, certain aspects must be previously covered by physiotherapists before delivering these interventions. First, physiotherapists must be trained in the management of these therapies by a psychologist or other qualified health professional. Second, an average of 100 hours of training must be acquired by each physiotherapist before delivering this type of therapy. These premises are necessary to favour a better education for individuals with chronic musculoskeletal pain in order to reduce the uncertainty surrounding their entire painful process, and therefore, help them to have a better control of their pain experience. This information could aid to improve the effectiveness of this type of intervention, and therefore, reduce the current prognosis of this condition.

The present doctoral thesis presented certain limitations that must be recognized. First, both systematic reviews were elaborated with a high degree of methodological rigor. However, meta-analyses could not be conducted due to the presence of huge heterogeneity in terms of clinical and methodological aspects through the included studies in both systematic reviews. Therefore, the overall association size regarding the association between psychological factors affecting both pan intensity and disability could not be determined. Second, certain modifications were elaborated in both cross-sectional studies considering our study protocol. For example, measures of pain hypersensitivity were posteriorly included. Pain hypersensitivity is a relevant factor in shoulder disorders, and thus, the inclusion of a specific measurement of this variable was necessary in order to cover more dimensions of shoulder pain as well as avoiding possible biases. Additionally, the tampa scale for kinesiophobia replaced the scale of fear-avoidance components since the tampa scale for kinesiophobia is the most widely used questionnaire to assess kinesiophobia in individuals with chronic pain. Third, both observational studies were cross-sectional in nature. Therefore, the predictive value that psychological factors play in the perpetuation of chronic shoulder pain could not be determined. Fourth, the current doctoral thesis focused on adults with shoulder pain. In this sense, the results should not be extrapolated to other populations.

The **ninth chapter** shows the prospective of this doctoral thesis. The prospective is focused on chronic musculoskeletal pain. Why focus our future research agenda on chronic musculoskeletal pain?

The most prevalent chronic pain condition is chronic musculoskeletal pain. Many interventions have been proposed to improve chronic musculoskeletal pain symptoms. However, its recurrence and persistence are frequent, which results in an enormous challenge for clinicians and researchers. The specific mechanisms that impact the development and course of chronic musculoskeletal pain remain unclear. Psychological factors are probably the most influential factors in the perception, processing, interpretation and coping with chronic pain. Inside of psychological factors, cognitive and emotional factors are modifiable through different conservative interventions. Thus, the acquisition of deep knowing and understanding about how these factors influence the transition and perpetuation of chronic musculoskeletal pain is required. This information will allow to design targeted interventions in order to reduce (e.g. pain-related fear) or enhance (e.g. pain self-efficacy) these factors which may help to improve the current prognosis of this condition. In this sense, our research group has already conducted certain publications and future research agenda is planned as follows:

1. To determine the state of knowledge about the role that kinesiophobia plays in chronic musculoskeletal pain and pain-related outcomes (systematic review published in British Journal of Sport Medicine: Luque-Suarez A, Martinez-Calderon J, Falla D. Role of kinesiophobia on pain, disability and quality of life in people suffering from chronic

musculoskeletal pain: a systematic review. Br J Sports Med. 2018 pii: bjsports-2017-098673. doi: 10.1136/bjsports-2017-098673.)

Kinesiophobia is defined as an excessive, irrational and debilitating fear to carry out a physical movement, due to a feeling of vulnerability to a painful injury or reinjury. Kinesiophobia has been considered one of the most important psychological factors in the adjustment of chronic pain and disability. The aim of this systematic review was to explore the level of association between kinesiophobia and pain, disability and quality of life in people with chronic musculoskeletal pain as well as to analyse the prognostic value of kinesiophobia on pain, disability and quality of life in this population. A systematic review of the literature including an appraisal of the risk of bias using the adapted Newcastle Ottawa Scale was conducted. An electronic search of PubMed, AMED, CINAHL, PsycINFO, PubPsych and grey literature was undertaken from inception to July 2017. Eligibility criteria was based on observational studies exploring the role of kinesiophobia (measured with the Tampa Scale for Kinesiophobia) on pain, disability and quality of life in people with chronic musculoskeletal pain. Sixty-three articles (mostly cross-sectional) (total sample=10 726) were included. We found strong evidence for an association between higher levels of kinesiophobia and greater levels of pain intensity and disability and moderate evidence between higher levels of kinesiophobia and higher levels of pain severity and low quality of life. Higher levels of kinesiophobia predicts the progression of disability overtime, with moderate evidence. Higher levels of kinesiophobia also predicts greater levels of pain severity and low levels of quality of life at 6 months, but with limited evidence. Kinesiophobia does not predict changes in pain intensity. The results of this review encourage clinicians to consider kinesiophobia in their preliminary assessment. More longitudinal studies are needed, as most of the included studies were cross-sectional in nature.

2. To determine the state of knowledge about the role that pain catastrophizing plays in chronic musculoskeletal pain and pain-related outcomes (systematic review published in Clinical Journal of Pain: Martinez-Calderon J, Jensen MP, Morales-Asencio JM, Luque-Suarez A. Pain Catastrophizing and Function in Individuals with Chronic Musculoskeletal Pain: A Systematic Review and Meta-Analysis. Clin J Pain. 2019 35(3):279-293. doi: 10.1097/AJP.0000000000000676.).

Pain catastrophizing is the most consistent psychosocial factor predicting of adjustment to chronic pain and may contribute to the development and long-term maintenance of chronic pain. The aim of this review was systematically review and critically appraise the concurrent and longitudinal associations between pain catastrophizing and both pain intensity and disability in individuals with chronic musculoskeletal pain. An electronic search of PubMed, Scopus, AMED, CINAHL, PsycINFO, and PubPsych databases, as well as grey literature was undertaken from the inception until March 2018. Cross-sectional and longitudinal studies reporting on the associations between measures of pain catastrophizing, pain intensity, and disability were selected for review. A total of eighty-five observational studies (92% cross-sectional) were included with a total sample of 13,628 participants with chronic musculoskeletal pain. Higher levels of pain catastrophizing levels were often, but not always, significantly concurrently associated with and prospectively predicted both chronic pain and disability, with very low-quality of the available evidence after applying the GRADE approach. Heterogeneity was large after conducting multiple meta-analyses. Despite the very low quality of the available evidence, the general consistency of the findings highlights the potential role that pain catastrophizing may play in delaying recovery from chronic musculoskeletal pain. Research that uses higher quality study designs and procedures would allow for more definitive conclusions regarding the impact of pain catastrophizing on pain and function.

3. To determine the state of knowledge about the role that self-efficacy beliefs play in chronic musculoskeletal pain and pain-related outcomes (systematic review published in The Journal of Pain: Martinez-Calderon J, Zamora-Campos C, Navarro-Ledesma S, Luque-Suarez A. The Role of Self-Efficacy on the Prognosis of Chronic Musculoskeletal Pain: A Systematic Review. J Pain. 2018 19(1):10-34. doi: 10.1016/j.jpain.2017.08.008.). Evidence suggests that self-efficacy can play an essential role as a protective factor as well as a mediator in the relationship between pain and disability in people suffering from chronic musculoskeletal pain. This study systematically reviewed and critically appraised the role of self-efficacy on the prognosis of chronic musculoskeletal pain. Study selection was based on longitudinal studies testing the prognostic value of self-efficacy in chronic musculoskeletal pain. The Newcastle- Ottawa Scale, the Cochrane Collaboration's tool and the Methodological Index for Non-Randomized Studies checklist were used to evaluate the risk of bias of included studies. A total of 27 articles met the inclusion criteria. Our results suggest that higher self-efficacy levels are associated with greater physical functioning, physical activity participation, health status, work status, satisfaction with the performance, efficacy beliefs, and lower levels of pain intensity, disability, disease activity, depressive symptoms, presence of tender points, fatigue, and presenteeism. Despite the low quality of evidence of included studies, clinicians should be encouraged identify people with chronic musculoskeletal pain who present low self-efficacy levels before prescribing any therapy. It may help clinicians in their clinical decision-making and timely and specific consultations with—or referral to—other health care providers.

4. To explore the role that cognitive and emotional factors play in the persistence of chronic musculoskeletal pain and pain-related outcomes (project ongoing).

Our previous systematic reviews as well as a great deal of evidence underlined the relevance of cognitive and emotional factors in the persistence of chronic musculoskeletal pain. In this sense, our research group decided to develop an ambitious project where the research questions were focused on how cognitive and emotional factors affect both chronic musculoskeletal pain and pain-related outcomes such as disability. A broad set of factors has been assessed such as optimism, pain self-efficacy, kinesiophobia, expectations of recovery or pain acceptance among others. Currently, a total of 200 individuals with chronic musculoskeletal pain has been assessed.

The **tenth chapter** corresponds to the conclusions obtained in this doctoral thesis, which are as follows.

1. Psychological factors are prognostic factors of better (e.g. self-efficacy beliefs) or poorer (e.g. emotional distress) prognosis of chronic shoulder pain intensity and disability in samples with operative and non-operative chronic shoulder pain.
2. Greater levels of negative pain beliefs such as pain catastrophizing and fear-avoidance beliefs are associated with and predict to greater levels of shoulder pain intensity and disability over time.
3. Greater levels of positive pain beliefs such as self-efficacy beliefs are associated with and predict to lower levels of shoulder pain intensity and disability over time.
4. Greater levels of pain self-efficacy are concurrently associated with lower levels of chronic shoulder pain intensity, local pain hypersensitivity and disability.
5. Greater levels of pain catastrophizing are cross-sectionally associated with greater levels of chronic shoulder pain intensity and disability.

6. Greater levels of emotional distress are concurrently associated with higher levels of chronic shoulder pain intensity.

7. Greater levels of kinesiophobia are cross-sectionally associated with greater levels of chronic shoulder pain intensity and disability.

SPANISH ABSTRACT

La presente tesis doctoral, con título *"Factores psicológicos, dolor y función en individuos con dolor crónico de hombro"* ha sido realizada en régimen de cotutela entre la Universidad de Málaga, España y la Universidad de Amberes, Bélgica. A continuación, se expone un resumen en castellano sobre el contenido de esta.

Durante el **primer capítulo**, la presente tesis doctoral nos muestra una visión profunda de la importancia del dolor en nuestra sociedad, más específicamente el dolor crónico. El dolor crónico supone una enorme carga tanto para el individuo como para la sociedad. En este sentido, numerosos tratamientos quirúrgicos y conservadores han sido llevados a cabo para mejorar el pobre pronóstico del dolor crónico. Sin embargo, la cronicidad sigue en aumento. Dentro del dolor crónico, el dolor musculoesquelético es el más prevalente, siendo el principal motivo de asistencia a fisioterapia. La presente tesis doctoral se centró en un tipo concreto de dolor musculoesquelético, el dolor de hombro. El dolor de hombro es el tercer tipo de dolor musculoesquelético más común tras el dolor lumbar y de cuello. Interesantemente, un gran porcentaje de los individuos que padecen dolor de hombro acuden a consulta. Sin embargo, aproximadamente el 50% de ellos desarrollan dolor crónico de hombro. El hombro es una articulación muy compleja, donde numerosos factores influyen en que el pronóstico de un individuo con dolor de hombro no mejore, comenzando un circulo negativo de más dolor, discapacidad, y depresión. Por ello, existe una gran corriente investigadora centrada en como los factores biológicos, psicológicos y sociales que rodean a un individuo con dolor crónico son fundamentales en el pronóstico de este. Dentro de estos factores, los factores psicológicos parecen ser claves en cómo un individuo percibe, interpreta y responde ante su dolor crónico. Dadas estas consideraciones, la adquisición de un conocimiento profundo sobre el impacto de los

factores psicológicos en la perpetuación del dolor de hombro crónico es de vital importancia para diseñar intervenciones dirigidas que promuevan el aumento de factores protectores como la autoeficacia del dolor y la resiliencia. Con esto, las personas con dolor de hombro crónico pueden establecer estrategias de afrontamiento activas que faciliten el control de su dolor y la adhesión a programas de rehabilitación como el tratamiento con ejercicios. Es por ello, que esta tesis doctoral centro su investigación en el rol que los factores psicológicos juegan sobre el dolor y la discapacidad en individuos con dolor crónico de hombro. Este primer capítulo nos sirve de antecedente y de justificación para la elaboración de la presente tesis doctoral.

El **segundo capítulo** enumera los objetivos generales y específicos de la presente tesis doctoral. El primer objetivo general fue explorar el estado de conocimiento actual acerca del rol que los factores psicológicos (especialmente los factores cognitivos y emocionales) juegan en individuos con dolor de hombro. El segundo objetivo general fue determinar las potenciales asociaciones existentes entre una serie de factores psicológicos (específicamente los pensamientos catastrofistas en respuesta al dolor, la autoeficacia a realizar actividades a pesar del dolor, la kinesiofobia o miedo al movimiento y el estrés emocional) y el dolor crónico de hombro y variables asociadas a ese dolor como puede ser la discapacidad.

El **tercer capítulo** va dirigido a responder el primer objetivo general de la presente tesis doctoral. Por ello, se llevó a cabo una revisión sistemática con el objetivo de detectar el rol de los factores psicológicos en la perpetuación de la intensidad del dolor y de la discapacidad en individuos con dolor crónico de hombro. Una búsqueda sistemática fue realizada en PubMed, AMED, CINAHL, PubPsych y EMBASE desde el inicio de estas bases de datos hasta julio de 2017. Estudios fueron incluidos en la revisión si ellos presentaron un diseño longitudinal y analizaron el rol que los factores psicológicos juegan sobre la intensidad del dolor y la discapacidad en individuos con dolor crónico de hombro. El riesgo de sesgo de cada uno de los estudios incluidos fue valorado a través del uso de la escala Newcastle Ottawa. El nivel de la evidencia para cada una de las variables de esta revisión (intensidad del dolor y discapacidad) fue examinado aplicando la calificación o Recomendaciones de Evaluación, Desarrollo y Enfoque de evaluación (Sistema GRADE). Se incluyeron un total de 27 artículos con una muestra de 11,176 individuos con dolor crónico de hombro. El riesgo o el sesgo fue variable a través de los estudios incluidos. La calidad de la evidencia fue muy baja. Niveles altos de autoeficacia, resiliencia y expectativas de recuperación se asociaron significativamente con niveles bajos de intensidad del dolor y discapacidad. Inversamente, altos niveles de estrés emocional, síntomas depresivos, ansiedad, preocupaciones preoperatorias, comportamientos de evitación como respuesta al miedo, somatización y respuestas catastróficas ante el dolor se asociaron significativamente con mayores niveles de intensidad del dolor y discapacidad. Nuestros resultados sugieren que los factores psicológicos pueden influir en la perpetuación de la intensidad del dolor y discapacidad en individuos con dolor crónico de hombro. Sin embargo, la evidencia en términos de inconsistencia, riesgo de sesgos e imprecisión de los resultados es muy baja y más investigaciones en este campo son necesarias. Este artículo fue publicado en el año 2018 en la revista **BMJ Open**.

El **cuarto capítulo** va dirigido también a responder el primer objetivo general de la presente tesis doctoral. Por ello, se llevó a cabo otra revisión sistemática centrada específicamente en las creencias asociadas al dolor, ya que se ha visto como dentro de los factores psicológicos, los factores cognitivos y emocionales son claves, y además modulables a través de diversas estrategias de tratamiento que pueden aplicarse desde el campo de la fisioterapia. El objetivo de esta revisión sistemática fue evaluar la asociación entre las creencias asociadas al dolor, la intensidad del dolor y la discapacidad en individuos con dolor agudo, subagudo y crónico de hombro. Una búsqueda sistemática fue establecida en PubMed, EBSCOhost, AMED, CINAHL, EMBASE y PubPsych, además de en la literatura gris desde el inicio de esas bases hasta julio de 2017. La selección de estudios se basó en estudios observacionales tanto transversales como longitudinales que exploraron la asociación y el valor predictivo de las creencias del dolor sobre la intensidad del dolor y la discapacidad en el dolor de hombro. Un total de treinta y tres artículos fueron incluidos con una muestra total de 10,293 individuos con hombro el dolor. En el análisis transversal, niveles más altos pensamientos catastrofistas en respuesta al dolor y kinesiofobia fueron significativamente asociados con mayores niveles de intensidad del dolor y discapacidad. Por otro lado, en este mismo análisis, elevados niveles de expectativas de recuperación y de autoeficacia para llevar a cabo actividades a pesar del dolor se asociaron significativamente con menores niveles de intensidad del dolor y discapacidad. En el análisis longitudinal, niveles altos de pensamientos catastrofistas en respuesta al dolor, comportamientos de evitación como respuesta al miedo y kinesiofobia al comienzo del estudio predijeron la perpetuación del dolor y la discapacidad. Inversamente, mayores niveles de expectativas de recuperación y de autoeficacia para llevar a cabo actividades a pesar del dolor al comienzo predijeron la reducción de la progresión del dolor y la discapacidad. La evidencia sugiere que las creencias de dolor están asociadas y predicen el curso del dolor y la discapacidad en el dolor de hombro. Sin embargo, la evidencia en términos de inconsistencia, riesgo de sesgo e imprecisión de los resultados fue muy baja a través de los estudios incluidos. Investigaciones adicionales que utilicen diseños y procedimientos longitudinales de mayor calidad son necesarios para establecer conclusiones firmes en este sentido. Este artículo fue publicado en el año 2018 en la revista **Musculoskeletal Science & Practice**.

Viendo los resultados obtenidos en el tercer y cuarto capítulo, el **quinto capítulo** es una propuesta para abordar el segundo de los objetivos generales de la actual tesis doctoral. En este sentido, se desarrolló un protocolo de estudio para determinar el rol de los factores psicológicos en el pronóstico del dolor crónico de hombro a través de un estudio de cohortes prospectivo. El estudio mostrará un diseño longitudinal, con un seguimiento de 12 meses. Se llevará a cabo en 4 centros de atención primaria y un hospital. Se incluirán 307 participantes de entre 18 y 70 años con dolor crónico de hombro (3 meses o más). Las variables que se medirán serán dolor, discapacidad, autoeficacia, kinesiofobia, miedo relacionado con el dolor, pensamientos catastrofistas en respuesta al dolor, ansiedad, depresión, expectativas de recuperación, entre otras variables en cuatro puntos de medición: al comienzo del estudio, a los 3, 6 y 12 meses de seguimiento. Este artículo fue publicado en el año 2017 en la revista **BMJ Open.**

El **sexto capítulo** fue dirigido a abordar el segundo objetivo general de la presente tesis doctoral. En este contexto, se elaboró un estudio observacional transversal que presente a dos objetivos. El primero fue explorar las potenciales asociaciones entre una serie de factores psicológicos (pensamientos catastrofistas en respuesta al dolor, autoeficacia para realizar actividades a pesar del dolor y estrés emocional) y medidas de dolor experimental (hipersensibilidad al dolor local y generalizada). El segundo objetivo fue evaluar las potenciales asociaciones entre los factores psicológicos previamente mencionados y la intensidad del dolor y la discapacidad en individuos con dolor crónico de hombro. Un total de 90 participantes con dolor crónico de hombre reunieron los criterios de inclusión y fueron admitidos en el presente estudio. El umbral de presión al dolor determinó la presencia de hipersensibilidad al dolor. Para evaluar esta medida, se utilizó un algómetro por presión. La intensidad del dolor y la Discapacidad se evaluaron con el cuestionario "The Shoulder and Disability Index". La autoeficacia para realizar actividades a pesar del dolor se exploró a través del cuestionario "The Pain Self-Efficacy Questionnaire". El catastrofismo se evaluó usando el cuestionario "The Pain Catastrophizing Scale". El estrés emocional de exploró a través del cuestionario "The Hospital Anxiety and Depression Scale". Varios análisis de regresión multivariante fueron realizados para determinar las potenciales asociaciones entre los factores psicológicos y ambas mediciones de dolor (clínico y experimental), además del nivel de discapacidad. Todos los análisis fueron ajustados por género. En el análisis de regresión, mayores niveles de autoeficacia para realizar actividades a pesar del dolor fueron asociados con menores niveles de hipersensibilidad al dolor local ($p=0.046$), menores niveles de intensidad del dolor ($p<0.001$) y mayores niveles de funcionalidad ($p<0.001$). Por otro lado, mayores niveles de pensamientos catastrofistas en respuesta al dolor fueron asociados a mayores niveles de intensidad del dolor ($p<0.001$) y mayores niveles de discapacidad ($p=0.002$). Además, mayores niveles de estrés emocional fueron asociados a mayores niveles de intensidad del dolor ($p<0.001$). En conclusión, este estudio transversal mostró evidencia preliminar acerca de la asociación entre una serie de factores psicológicos, específicamente los pensamientos catastrofistas en respuesta al dolor, la autoeficacia a realizar actividades a pesar del dolor y el estrés emocional, con medidas de dolor cínico y experimental además de la presencia de discapacidad en individuos con dolor crónico de hombro.

El **séptimo capítulo** fue también desarrollado para cubrir el segundo objetivo general de la presente tesis doctoral. En este capítulo, se realizó un segundo estudio observacional transversal. Este estudio se centró en una variable en concreto, la kinesiofobia, debido a su vital importancia en la percepción, procesamiento, interpretación y afrontamiento del dolor crónico músculoesquelético. En este sentido, el objetivo de este estudio fue explorar la potencial asociación entre la kinesiofobia y ambas mediaciones: intensidad del dolor y discapacidad en individuos con dolor crónico de hombro. Un total de 65 individuos con dolor crónico subacromial unilateral reunieron los criterios de inclusión y fueron admitidos en este estudio. Intensidad del dolor y discapacidad fueron evaluadas a través del cuestionario "The Shoulder and Disability Index". La kinesiofobia fue explorada usando el cuestionario "The Tampa Scale for Kinesiophobia short-form". Un análisis de regresión multivariante fue realizado para detector potenciales asociaciones entre la kinesiofobia, la intensidad del dolor y la discapacidad. El análisis fue ajustado por el rango de movimiento del hombro libre de dolor, el género y la edad. En el análisis de regresión, mayores niveles de kinesiofobia fueron asociados a mayores niveles de intensidad del dolor y la discapacidad (estandarizado $\beta = 0.35$ $p<0.01$). Esta asociación permaneció significativa después de ajustar por el rango de movimiento del hombro libre de dolor, el género y la edad. En conclusión, este estudio transversal provee evidencia preliminar acerca de la asociación entre la kinesiofobia con la intensidad del dolor y la discapacidad en individuos con dolor crónico de hombro. Sin embargo, el valor predictor de la kinesiofobia en el mantenimiento del dolor crónico de hombro y la discapacidad no pudo ser determinado debido a la naturaleza transversal del presente estudio. Nuevos estudios observacionales de cohortes longitudinales en este campo son necesarios.

Tras el resumen de los distintos estudios realizados en sus correspondientes capítulos, en el **octavo capítulo** presentamos una discusión general de la tesis doctoral, así como sus limitaciones. Los objetivos generales de la presente tesis fueron: (i) explorar el estado del arte acerca del rol que los factores psicológicos (especialmente los factores cognitivos y emocionales) juegan en la progresión y mantenimiento del dolor crónico de hombro y la discapacidad y; (ii) determinar potenciales asociaciones entre los factores psicológicos (específicamente los pensamientos catastrofistas en respuesta al dolor, la kinesiofobia, la autoeficacia para realizar actividades a pesar del dolor y el estrés emocional) y el dolor crónico de hombro y la discapacidad en individuos con dolor crónico de hombro. Un total de dos revisiones sistemáticas fueron llevadas a cabo y publicadas con el objetivo de satisfacer el primer objetivo general de la tesis doctoral. La primera revisión sistemática exploró toda la evidencia disponible considerando el rol que los factores psicológicos juegan en la perpetuación de la intensidad del dolor y la discapacidad en indivudos con dolor crónico de hombro quirúrgicos y no quirúrgicos. Después del análisis de 27 estudios observacionales de cohortes longitudinales, mayores niveles en línea base de autoeficacia, resiliencia y expectativas de recuperación predijeron menores niveles de intensidad del dolor y la discapacidad en el tiempo. Por otro lado, mayores niveles en línea base de estrés emocional, síntomas depresivos, ansiedad, preocupaciones previas a la intervención quirúrgica, creencias miedo-evitación, somatización y pensamientos catastrofistas en respuesta al dolor predijeron mayores niveles de intensidad del dolor y discapacidad en el tiempo.

La segunda revisión sistemática también fue publicada y tuvo como objetivo evaluar la asociación transversal y el valor predictor longitudinal de las creencias asociadas al dolor afectando ambas, intensidad del dolor y discapacidad en individuos con dolor de hombro. Un total de 33 estudios observacionales fueron analizados. Mayores niveles de pensamientos catastrofistas en respuesta al dolor y kinesiofobia fueron transversalmente asociados con mayores niveles de intensidad del dolor y discapacidad. Mayores niveles de autoeficacia y de expectativas de recuperación fueron transversalmente asociados con menores niveles de intensidad del dolor y discapacidad. Adicionalmente, mayore niveles en línea base de pensamientos catastrofistas en respuesta al dolor, creencias miedo-evitación y kinesiofobia predijeron mayore niveles de intensidad del dolor y discapacidad en el tiempo. Inversamente, mayores niveles en línea base de autoeficacia y de expectativas de recuperación predijeron menores niveles de intensidad del dolor y discapacidad en el tiempo. Ambas revisiones sistemáticas resaltaron el esencial rol que los factores psicológicos juegan en la progresión y el mantenimiento del dolor crónico de hombro y la discapacidad. En línea con nuestros resultados, una gran cantidad de evidencia ha resaltado la importancia de los factores psicológicos en la transición y perpetuación del dolor crónico músculoesquelético y la discapacidad.

Un total de dos estudios observacionales transversales fueron realizados para satisfacer nuestro segundo objetivo general. Primero, un estudio transversal fue elaborado para explorar las potenciales asociaciones entre los factores psicológicos (autoeficacia para realizar actividades a pesar del dolor, pensamientos catastrofistas en respuesta al dolor y el estrés emocional) con medidas de dolor y discapacidad en individuos con dolor crónico de hombro. Este estudio concluyó que mayores niveles de autoeficacia para realizar actividades a pesar del dolor fueron asociados a menores niveles de intensidad del dolor y de hipersensibilidad del dolor local, así como a mayores niveles de funcionamiento. Estos resultados están en línea con previa evidencia, la cuál resalta el rol que la autoeficacia juega en individuos con dolor crónico. Este estudio también reveló que mayores niveles de pensamientos catastrofistas en respuesta al dolor fueron asociados a mayores niveles de intensidad del dolor y discapacidad. Mayores niveles de estrés emocional fueron asociados a mayores niveles de intensidad del dolor. Estos resultados también han sido apoyados por evidencia previa.

Abordando este Segundo objetivo general, otro estudio transversal fue desarrollado para evaluar la asociación entre kinesiofobia y la intensidad del dolor y la discapacidad en individuos con dolor crónico de hombro. Este estudio resaltó que mayores niveles de kinesiofobia son asociados con mayores niveles de intensidad del dolor y discapacidad. Esta asociación permaneció significativa después de ajustar por el rango de movimiento del hombro libre de dolor, el género y la edad. Estos resultados están de acuerdo con una gran cantidad de evidencia, la cuál resalta el papel de la kinesiofobia en individuos con dolor crónico músculoesquelético.

Desde una perspectiva fisioterapéutica, las creencias de los pacientes y de los fisioterapeutas, sus actitudes y emociones son factores claves en la toma de decisiones clínicas. Estos factores cognitivos y emocionales son modificables a través de diferentes intervenciones conservadoras. La actual tesis doctoral resaltó la importancia de los factores psicológicos en la persistencia del dolor crónico músculoesquelético y la discapacidad, particularmente el dolor crónico de hombro. Por consiguiente, los hallazgos de esta tesis doctoral deberían animar a los fisioterapeutas a evaluar y tratar estos factores en su práctica clínica diaria.

Intervenciones psicológicas como la educación del dolor basado en la neurociencia y la terapia cognitivo-funcional entregadas por fisioterapeutas combinadas con intervenciones fisioterapéuticas tales como programas de ejercicio, son emergentes enfoques para modificar factores cognitivos y emocionales en el campo del dolor músculoesquelético. Los beneficios de las intervenciones psicológicas entregadas por fisioterapeutas son prometedores. Sin embargo, ciertos aspectos deben previamente ser cubiertos por los fisioterapeutas antes de entregar este tipo de terapias. Primero, fisioterapeutas deben ser entrenado en el manejo de estas terapias por un psicólogo u otro profesional sanitario cualificado. Segundo, un promedio de 100 horas de entrenamiento debe ser adquirido por cada fisioterapeuta antes de entregar este tipo de terapia. Estas premisas son necesarias para favorecer una mejor educación a los individuos con dolor crónico músculoesquelético con el objetivo de reducir la incertidumbre que rodea todo su proceso doloroso, y por lo tanto, ayudar a un mejor control de su experiencia dolorosa. Esta información podría ayudar a mejorar la efectividad de este tipo de intervención, y por ello, reducir el actual pronóstico de esta condición.

La presente tesis doctoral presentó una serie de limitaciones de deben ser reconocidas. Primero, ambas revisiones sistemáticas fueron elaboradas con un alto grado de rigor metodológico. Sin embargo, metaanálisis no pudieron ser elaborados debido a la presencia de una enorme heterogeneidad en términos de aspectos clínicos y metodológicos a través de los estudios incluidos en ambas revisiones sistemáticas. Por ello, el tamaño global de la asociación considerando la asociación entre los factores psicológicos afectando a la intensidad del dolor y a la discapacidad no pudo ser determinado. Segundo, ciertas modificaciones fueron elaboradas en ambos estudios transversales considerando nuestro protocolo de estudio. Por ejemplo, las medidas de hipersensibilidad al dolor fueron posteriormente incluidas. La hipersensibilidad al dolor es un factor relevante en trastornos del hombro, y por ello, la inclusión de una medición de esta variable era necesaria con el objetivo de cubrir más dimensiones del dolor de hombro además de evitar posibles sesgos. Adicionalmente, la tampa scale for kinesiophobia reemplazó la escala de componentes de miedo-evitación desde que la tampa scale for kinesiophobia es el cuestionario más utilizado mundialmente para evaluar la presencia de kinesiofobia en individuos con dolor crónico. Tercero, ambos estudios observacionales fueron transversales en naturaleza. Por consiguiente, el valor predictor que los factores psicológicos juegan en la perpetuación del dolor crónico de hombro no pudo ser determinado. Cuarto, la actual tesis doctoral estuvo centrada en adultos con dolor de hombro. En este sentido, los resultados no deberían extrapolarse a otras poblaciones.

El **noveno capítulo** nos lleva a la prospectiva de esta tesis doctoral. La prospectiva va enfocada al dolor crónico músculoesquelético. ¿Por qué centrar nuestra futura investigación en el dolor crónico músculoesquelético? La condición de dolor crónico más prevalente es el dolor musculoesquelético crónico. Se han propuesto muchas intervenciones para mejorar los síntomas del dolor musculoesquelético crónico. Sin embargo, su recurrencia y persistencia es frecuente, lo que resulta en un enorme desafío para los clínicos e investigadores. Los mecanismos específicos que afectan el desarrollo y el curso del dolor musculoesquelético crónico siguen sin estar claros. Los factores psicológicos son probablemente los factores más influyentes en la percepción, el procesamiento, la interpretación y el manejo del dolor crónico. Dentro de los factores psicológicos, los factores cognitivos y emocionales son modificables a través de diferentes intervenciones conservadoras. Por lo tanto, se requiere la adquisición de un conocimiento profundo y la comprensión de cómo estos factores influyen en la transición y la perpetuación del dolor musculoesquelético crónico. Esta información permitirá diseñar intervenciones dirigidas para reducir (por ejemplo, el miedo relacionado con el dolor) o mejorar (por ejemplo, la autoeficacia del dolor) estos factores que pueden ayudar a mejorar el pronóstico actual de esta afección. En este sentido, nuestro grupo de investigación ya ha realizado ciertas publicaciones y la agenda de investigación futura se planifica de la siguiente manera:

1. Determinar el estado del conocimiento sobre el papel que desempeña la kinesiofobia en el dolor musculoesquelético crónico y los resultados relacionados con el dolor (revisión sistemática publicada en British Journal of Sport Medicine: Luque-Suarez A, Martinez-Calderon J, Falla D. Role of kinesiophobia on pain, disability and quality of life in people suffering from chronic musculoskeletal pain: a systematic review. Br J Sports Med. 2018 pii: bjsports-2017-098673. doi: 10.1136/bjsports-2017-098673.) La kinesiofobia se define como un miedo excesivo, irracional y debilitante para llevar a cabo un movimiento físico, debido a una sensación de vulnerabilidad ante una lesión dolorosa o una nueva lesión. La kinesiofobia ha sido considerada uno de los factores psicológicos más importantes en el ajuste del dolor crónico y la discapacidad. El objetivo de esta revisión sistemática fue explorar el nivel de asociación entre la kinesiofobia y el dolor, la

discapacidad y la calidad de vida en personas con dolor musculoesquelético crónico, así como analizar el valor pronóstico de la kinesiofobia sobre el dolor, la discapacidad y la calidad de vida en esta población. Se realizó una revisión sistemática de la literatura que incluye una evaluación del riesgo de sesgo mediante la escala de Newcastle Ottawa adaptada. Se realizó una búsqueda electrónica de PubMed, AMED, CINAHL, PsycINFO, PubPsych y literatura gris desde el inicio hasta julio de 2017. Los criterios de elegibilidad se basaron en estudios observacionales que exploran el papel de la kinesiophobia (medida con la Escala de Tampa para Kinesiophobia) sobre el dolor, la discapacidad y Calidad de vida en personas con dolor musculoesquelético crónico. Se incluyeron sesenta y tres artículos (en su mayoría de sección transversal) (muestra total = 10 726). Encontramos pruebas sólidas de una asociación entre los niveles más altos de kinesiofobia y los niveles más altos de intensidad y discapacidad del dolor y la evidencia moderada entre los niveles más altos de kinesiofobia y los niveles más altos de severidad del dolor y baja calidad de vida. Los niveles más altos de kinesiofobia predicen la progresión de la discapacidad a lo largo del tiempo, con evidencia moderada. Los niveles más altos de kinesiofobia también predicen mayores niveles de severidad del dolor y bajos niveles de calidad de vida a los 6 meses, pero con evidencia limitada. La kinesiofobia no predice cambios en la intensidad del dolor. Los resultados de esta revisión alientan a los médicos a considerar la kinesiofobia en su evaluación preliminar. Se necesitan más estudios longitudinales, ya que la mayoría de los estudios incluidos fueron de carácter transversal.

2. Determinar el estado del conocimiento sobre el papel que desempeña el dolor catastrofista en el dolor musculoesquelético crónico y los resultados relacionados con el dolor (revisión sistemática publicada en Clinical Journal of Pain: Martinez-Calderon J, Jensen MP, Morales-Asencio JM, Luque-Suarez A. Pain Catastrophizing and Function in Individuals with Chronic Musculoskeletal Pain: A Systematic Review and Meta-

Analysis. Clin J Pain. 2019 35(3):279-293. doi: 10.1097/AJP.0000000000000676.). El catastrofismo del dolor es el factor psicosocial más consistente que predice el ajuste al dolor crónico y puede contribuir al desarrollo y mantenimiento a largo plazo del dolor crónico. El objetivo de esta revisión fue revisar sistemáticamente y evaluar críticamente las asociaciones concurrentes y longitudinales entre el dolor catastrofista y la intensidad del dolor y la discapacidad en individuos con dolor musculoesquelético crónico. Se realizó una búsqueda electrónica de las bases de datos PubMed, Scopus, AMED, CINAHL, PsycINFO y PubPsych, así como literatura gris desde el inicio hasta marzo de 2018. Estudios transversales y longitudinales que informan sobre las asociaciones entre las medidas de catastrofismo del dolor, intensidad del dolor y la discapacidad fueron seleccionados para su revisión. Se incluyeron un total de ochenta y cinco estudios observacionales (92% de corte transversal) con una muestra total de 13,628 participantes con dolor musculoesquelético crónico. Los niveles más altos de dolor y los niveles catastrofistas a menudo, aunque no siempre, se asociaron de manera significativa y predijeron prospectivamente tanto el dolor crónico como la discapacidad, con una calidad muy baja de la evidencia disponible después de aplicar el enfoque GRADE. La heterogeneidad fue grande después de realizar múltiples metaanálisis. A pesar de la muy baja calidad de la evidencia disponible, la consistencia general de los hallazgos resalta el papel potencial que puede desempeñar el catastrofismo del dolor para retrasar la recuperación del dolor musculoesquelético crónico. La investigación que utiliza diseños y procedimientos de estudios de mayor calidad permitiría conclusiones más definitivas con respecto al impacto que los pensamientos catastrofistas en respuesta al dolor tienen sobre el dolor y la función.

3. Determinar el estado del conocimiento sobre el papel que juegan las creencias de autoeficacia en el dolor musculoesquelético crónico y los resultados relacionados con el

dolor (revisión sistemática publicada en The Journal of Pain: Martinez-Calderon J, Zamora-Campos C, Navarro-Ledesma S, Luque-Suarez A. The Role of Self-Efficacy on the Prognosis of Chronic Musculoskeletal Pain: A Systematic Review. J Pain. 2018 19(1):10-34. doi: 10.1016/j.jpain.2017.08.008.). La evidencia sugiere que la autoeficacia puede desempeñar un papel esencial como factor de protección y como mediador en la relación entre el dolor y la discapacidad en personas que padecen dolor musculoesquelético crónico. Este estudio revisó sistemáticamente y evaluó críticamente el papel de la autoeficacia en el pronóstico del dolor musculoesquelético crónico. La selección del estudio se basó en estudios longitudinales que probaron el valor pronóstico de la autoeficacia en el dolor musculoesquelético crónico. La escala de Newcastle-Ottawa, la herramienta de la Colaboración Cochrane y la lista de verificación del Índice metodológico para los estudios no aleatorios se utilizaron para evaluar el riesgo de sesgo de los estudios incluidos. Un total de 27 artículos cumplieron los criterios de inclusión. Nuestros resultados sugieren que los niveles más altos de autoeficacia se asocian con un mayor funcionamiento físico, participación en la actividad física, estado de salud, estado laboral, satisfacción con el rendimiento, creencias de eficacia y niveles más bajos de intensidad del dolor, discapacidad, actividad de la enfermedad, síntomas depresivos, presencia De puntos sensibles, fatiga y presentismo. A pesar de la baja calidad de la evidencia de los estudios incluidos, se debe alentar a los médicos a identificar a las personas con dolor musculoesquelético crónico que presentan niveles bajos de autoeficacia antes de prescribir cualquier terapia. Puede ayudar a los clínicos en la toma de decisiones clínicas y consultas oportunas y específicas con, o derivación, a otros proveedores de atención médica.

4. Explorar el papel que desempeñan los factores cognitivos y emocionales en la persistencia del dolor musculoesquelético crónico y los resultados relacionados con el

dolor (proyecto en curso). Nuestras revisiones sistemáticas anteriores, así como una gran cantidad de evidencia, subrayaron la relevancia de los factores cognitivos y emocionales en la persistencia del dolor musculoesquelético crónico. En este sentido, nuestro grupo de investigación decidió desarrollar un proyecto ambicioso en el que las preguntas de la investigación se centraban en cómo los factores cognitivos y emocionales afectan el dolor musculoesquelético crónico y los resultados relacionados con el dolor, como la discapacidad. Se ha evaluado un amplio conjunto de factores, tales como optimismo, autoeficacia del dolor, kinesiofobia, expectativas de recuperación o aceptación del dolor, entre otros. Actualmente, se ha evaluado un total de 200 individuos con dolor musculoesquelético crónico.

El **décimo capítulo** corresponde a las conclusiones obtenidas en la presente tesis doctoral, la cuáles son las siguientes.

1. Los factores psicológicos son factores pronósticos de mejor (por ejemplo, creencias de autoeficacia) o de peor (por ejemplo, angustia emocional) pronóstico de la intensidad del dolor y discapacidad en individuos con dolor crónico de hombro quirúrgico y no quirúrgico.

2. Mayores niveles de creencias de dolor negativas, como los pensamientos catastrofistas en respuesta al dolor y las creencias de evitación del miedo, se asocian y predicen mayores niveles de intensidad del dolor y la discapacidad a lo largo del tiempo.

3. Mayores niveles de creencias de dolor positivas, como las creencias de autoeficacia, se asocian y predicen a niveles más bajos de intensidad del dolor y la discapacidad a lo largo del tiempo.

4. Mayores niveles de autoeficacia del dolor se asocian simultáneamente con niveles más bajos de intensidad del dolor, hipersensibilidad al dolor local y discapacidad en individuos con dolor crónico de hombro.

5. Mayores niveles de pensamientos catastrofistas en respuesta al dolor se asocian de forma transversal con mayores niveles de intensidad del dolor y discapacidad en individuos con dolor crónico de hombro.

6. Mayores niveles de estrés emocional se asocian simultáneamente con niveles más altos de intensidad del dolor en individuos con dolor crónico de hombro.

7. Mayores niveles de kinesiofobia son asociados transversalmente con mayores niveles de intensidad del dolor y discapacidad en individuos con dolor crónico de hombro.

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GLOSSARY OF ACRONYMS

International prospective register of systematic reviews = PROSPERO

Pressure Pain Threshold = PPT

Range of Movement = ROM

Shoulder Pain = SP

The Grading of Recommendations Assessment, Development and Evaluation = GRADE

The Fear-avoidance Components Scale = FACS

The Hospital Anxiety and Depression Scale = HADS

The Newcastle Ottawa Scale = NOS

The Numerical Rating Scale = NRS

The Pain Catastrophizing Scale = PCS

The Pain Self-Efficacy Questionnaire = PSEQ

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses = PRISMA

The Self-Administered Comorbidity Questionnaire = SCQ

The Shoulder Pain and Disability Index = SPADI

The Tampa Scale for Kinesiophobia short-form = TSK-11

The Word Health Organization Health and Work Performance Questionnaire = HPQ

CHAPTER I

BACKGROUND

1.1 Pain: impact, pain-related concepts and transition to chronicity

Pain is a major public health priority (1). It is considered one of the most frequent causes to seek health care (2). Traditionally, the International Association for the Study of Pain has defined pain as “an unpleasant sensory and emotional experience associated with actual/potential tissue damage or described in terms of such damage (3)”. Everyone will experience pain at some point in their lifetime. Annually, estimations suggest that one in five adults have acute or subacute pain, whereas one in ten adults endure chronic pain (3–6). The pain experience of every individual is extremely complex. Pain is undeniably subjective (3). Indeed, people who have similar diagnostic criteria often perceive pain in a different manner (7). As a consequence of pain subjectivity, the term “pain” has acquired a broad range of dimensions in order to cover all the sensations that an individual feel when is in pain. In this sense, intensity, severity, affect and sensitivity are probably the most studied dimensions of pain (8–12).

Pain intensity describes how intense we perceive pain on a specific moment (13). Pain intensity is the most noteworthy dimension of pain (14), which is often assessed through unidimensional self-reported scales. The numerical pain rating scale and the visual analogue scale are the most common tools used to measure pain intensity (10). However, certain factors such as the context or culture influences how intense an individual perceives its pain (15,16). Pain contains multidimensional attributes and subtle connotations such as aching or burning among others (17). Thereby, pain intensity should not be considered a linear phenomenon and exclusively quantified through unidimensional tools (18). In this context, pain severity and pain affect have emerged as multidimensional dimensions of pain which include the term “pain intensity” (9). Both are commonly assessed through multidimensional self-reported scales (10). Pain severity involves pain intensity and pain interference with daily activities (19). Pain affect refers to pain intensity as well as the emotional changes that an individual feel when he/she is in pain (13).

Pain sensitivity is also a relevant dimension of pain. It describes the tendency to react to standardized experimental or pathological stimuli (20). When repeated or intense noxious stimuli (actual or potential tissue damaging events) occur (21), pain hypersensitivity emerges (22). Pain hypersensitivity is characterized by allodynia (increased sensitivity for normally non-painful stimuli) and hyperalgesia (noxious stimuli produce an exaggerated and prolonged response to pain) (23). Pain hypersensitivity is initially an adaptive process that arouse our alert systems in situations where there is a potential risk of damage (12). When tissues heal, pain hypersensitivity returns to normal baseline values (22). However, some individuals still report pain hypersensitivity after the tissues heal, even in asymptomatic areas where the primary pain input did not occur (24). This phenomenon represents the sensitization of the central nervous system which is probably a key driver in syndromes such as fibromyalgia or chronic fatigue syndrome (24).

Acute pain (pain present for less than three months) is very common worldwide (1,25). Unfortunately, certain individuals show an inadequate control of its acute pain, developing chronic pain and pain-related symptoms. Many factors are involved in how an individual perceives, processes, interprets and copes with its pain experience (26). Thus, not only sensory and emotional factors, but also cognitive, behavioural and social factors are considered important in the distressful experience of pain (27). Some of these factors may favour maladaptive responses to pain (26,28), which may suppose a bridge in the transition and perpetuation to chronicity. But first, what is chronic pain?

1.2 Chronic Pain: definition, prevalence and burden

Chronic pain refers to pain that persists or recurs more than three months, once the normal healing process has occurred (4). Chronic pain is a global issue which affects up to 34% of population (29–31). This condition is a huge source of human suffering and disability (1), which is a common reason to visit a health professional (2,32). The socioeconomic burden occasioned by chronic pain is also enormous (33). The annual direct (e.g. hospitalization) and indirect (e.g. disability allowance) costs amount to €30 billion in Europe and $635 billion in the United States (34–36). Biopsychosocial consequences are also critical (37–40). Certain individuals reject their chronic situation, immersing themselves in a vicious cycle of passive coping strategies such as sedentarism or victim thinking (41). These individuals are often socially excluded (42) which may lead to unpleasant results in terms of insomnia, depression, opioid overuse, suicidal ideation and premature mortality (43–46).

In conclusion, chronic pain is a deleterious condition which can be a prominent comorbidity of several chronic diseases such as pain-related cancer and headache (33), but also a disease in its own (47) as well as a human right issue (48). Currently, chronic musculoskeletal pain is globally considered the most prevalent and disabling chronic pain condition (29,31,49).

1.3 Chronic musculoskeletal pain: definition, prevalence and burden

Chronic musculoskeletal pain is chronic pain localised in muscles, bones, joints or tendons that is associated with substantial emotional distress (e.g. frustration) and/or functional disability (e.g. reduced participation in social roles) (50,51). It considered the second cause (21.3%) of physical and work disability after mental and behavioural disorders (23.2%) (33,49,52,53). The global prevalence of chronic musculoskeletal pain is considerable, which ranges from 11.4% to 60% (54). Older women with obesity and sedentary style are probably the most vulnerable population to endure chronic musculoskeletal pain (33,54).

Chronic musculoskeletal pain is also a huge concern in clinical practice (55). Indeed, more than 20% of individuals with this condition annually consult a health professional (55–57). Additionally, chronic musculoskeletal pain is viewed as the fourth global burden on health (33,53) in terms of economic costs (58,59) and psychosocial consequences (60–63). In this sense, a large number of conservative and surgical interventions have been proposed to improve chronic musculoskeletal pain and its pain-related outcomes (64–66). However, its recurrence and persistence are frequent (54). Certain chronic musculoskeletal symptoms, such as widespread pain, are not associated with a tissue damage or a pathophysiological reason (67). This causes that the course of chronic musculoskeletal pain is unpredictable which entails an immense challenge for clinicians and researchers (68).

Many factors are implied in the development and maintenance of chronic musculoskeletal pain and disability (69,70). Therefore, the acquisition of a deep knowledge about which factors favour the reduction of passive coping strategies, and hence, the development of positive health behaviours such as confidence and motivation are needed in order to face the obstacles caused by chronic musculoskeletal pain. This information will facilitate the implementation of targeted interventions which aim to reduce the persistence of chronic musculoskeletal pain.

1.4 Shoulder pain: definition, impact and associated factors

Shoulder pain (SP) is defined as musculoskeletal pain which arises in or around the shoulder joints and/or its soft tissues (71). It is considered the third cause of chronic musculoskeletal pain after spine and knee pain (33,54). Shoulder pain is also a frequent and growing reason to seek musculoskeletal care (72–74). Surgical and conservative interventions have been proposed to enhance SP outcomes (75–79). However, almost 50% of all new episodes of SP present recurrence or persistence of symptoms after twelve months (80). According to this, the direct and indirect costs occasioned by shoulder disorders are enormous which have roughly entailed $7 billion in the United States (81).

Interestingly, the global prevalence of SP highly differs across populations (1% to 67%) (82). The lack of consensus in establishing specific diagnosis for SP may account for the huge variability between prevalence figures (83). Traditionally, pathoanatomic medical models (84,85) have established diagnostic categories for SP. These models consider the tissue pathology as responsible for SP and disability (85). Rotator cuff tendinopathy, subacromial pain syndrome, adhesive capsulitis, glenohumeral instability, shoulder impingement syndrome, full thickness rotator cuff tears and labral tears are commonly used in general practice (84,86). These diagnostic labels have their merit in prognosis, defining the need for concrete interventions such as surgery. Nonetheless, the complexity of SP is more profound, and thence, a model where SP categories are exclusively based on tissue-specific signs is unreliable and ineffective in order to guide targeted clinical-decision making (86,87).

Biopsychosocial factors are involved in the onset and progression of SP and disability (88–94). Inside of these factors, psychological factors are probably the most influential factors in the perception, interpretation and control of chronic pain (28,95–97). Indeed, psychological factors are considered more relevant than biomedical or biomechanical factors in the persistence of chronic pain symptoms (28,95). But what is the extension in which psychological factors influence the development and maintenance of chronic musculoskeletal pain in general, particularly chronic SP?

1.5 Psychological factors and chronic musculoskeletal pain

The pain experience is a subjective and unique process. Nociceptive input is commonly unrelated to pain perception (98,99). Indeed, recent advances in pain research have revealed the importance of cognitive and emotional factors in the perception and nociceptive processing in the brain. In the context of chronic pain, Malfliet et al. (100) summarized all the available evidence in order to explore the association between brain alterations and pain-related cognitions and emotions. They underlined that individuals with greater levels of pain catastrophizing showed more altered brain areas which are involved in the processing, attention and top-down inhibition of pain. Pain-related cognitive, emotional and behavioural factors have received a great deal of attention in the last two decades (28,96,101–108). Specifically in chronic musculoskeletal pain, the Fear-Avoidance Model of pain (95,109) proposes that cognitive (e.g. pain beliefs) and emotional (e.g. pain-related fear) factors are fundamental in the development and maintenance of chronic musculoskeletal pain and pain-related outcomes such as pain interference with daily activities (110–114).

Pain-related fear (113,115,116) and pain catastrophizing (114) are probably the two psychological factors more investigated in the context of chronic musculoskeletal pain. Pain-related fear is a wide construct which include fear of pain, fear-avoidance beliefs, pain-related anxiety, fear of movement and kinesiophobia. For example, kinesiophobia is defined as an excessive, irrational and debilitating fear to execute a determined movement or activity due to a feeling of vulnerability to endure a painful injury or reinjury (117). Luque-Suarez et al. (113) compiled all the available literature in order to analyse the role of kinesiophobia in chronic musculoskeletal pain and pain-related outcomes. Kinesiophobia was cross-sectionally associated with and longitudinally predicted more pain intensity and lower function and quality of life over time. Pain catastrophizing is conceptualized as a tendency to have overly negative thoughts in response to pain or pain-related cues (118). Martinez-Calderon et al. (114) recently conducted a systematic review with meta-analysis to evaluate all the available evidence regarding the role that pain catastrophizing plays in chronic musculoskeletal pain and disability. They found that pain catastrophizing is concurrently and longitudinally associated with more pain intensity and disability. These maladaptive factors favour the use of passive coping strategies such as hypervigilance or avoidance behaviours (95). These behaviours have been associated with the perpetuation of chronic pain, disability and pain-related distress (28,95,105).

In contrast, there are also pain-related cognitive and emotional factors characterized by facilitating the control of pain and functioning despite pain (101,104,119). For instance, pain self-efficacy refers to the belief that one has the ability to persevere, cope with and complete a determined action while in pain (120). Martinez-Calderon et al. (119) systematically reviewed and critically assessed the role of self-efficacy beliefs in chronic musculoskeletal pain and pain-related outcomes. They underscored that greater levels of self-efficacy beliefs were associated with more function, physical activity participation, health status, work status and lower pain intensity, disability, disease activity, depressive symptoms, fatigue and presenteeism.

To conclude, pain-related cognition and emotions are essential in how individuals with chronic musculoskeletal pain perceive and modulate their chronic pain process. Every individual will determine its pain experience based fundamentally on prior pain experiences and pain-related cognitions, memories, emotions and beliefs (95). Once a judgment has been elaborated, individuals will use particular coping strategies (passive or active) to deal with their pain which will affect their physical and emotional welfare (121). Given these considerations, the acquisition of a deep knowledge about how psychological factors impact in the perpetuation of chronic musculoskeletal pain is the vital importance in order to design targeted interventions which promote the increase of protective factors such as pain self-efficacy and resilience. With this, individuals with chronic musculoskeletal pain may establish active coping strategies that facilitate the control of their pain and the adherence to rehabilitations programmes such as exercise therapy.

1.6 Justification of the thesis

This chapter has highlighted the detrimental impact that chronic pain has on society and how psychological factors play a key role in the maintenance of chronic pain and disability. Precisely in chronic SP, many individuals misunderstand their pain process (122). This uncertainty favours the increase of maladaptive cognitive and emotional factors in response to pain which facilitate the use of passive coping strategies such as immobilization of the shoulder. It creates a negative spiral of SP experience (122) that contributes to the suffering and growth of SP chronicity. In this sense, a large amount of evidence has underlined the association of pain catastrophizing, kinesiophobia and fear of pain among others with SP and pain-related outcomes (123–131).

However, the presence of methodological flaws is relevant across these studies in terms of risk of bias, imprecision and inconsistency between results such as statistical significance and direction of obtained results. For example, two studies reported that fear-avoidance beliefs were statistically associated with more disability (128,129). On the other hand, the association was not statistically significant in three studies (131–133). Additionally, greater levels of pain catastrophizing at baseline predicted more (125) or lower (134) pain intensity at six months. Thus, although a great deal of research has investigated the role that psychological factors play in SP samples, certain questions remain unanswered. For instance, a critical appraise about which specific psychological factors impact in the onset, transition and maintenance of chronic SP is required in order to detect potential gaps of knowledge and methodological flaws. This analysis will allow to obtain stronger conclusions than those achieved by any original article (135). Furthermore, the association of psychological factors not only with SP intensity but also with other pain dimensions such as pain sensitivity is needed. With this, a bigger picture about all the dimensions which involve the SP experience could be covered. This information may help to improve the current prognosis of this condition.

CHAPTER II

AIMS OF THE THESIS

2.1 General Aims

(i) To explore the state of art about the role that psychological factors (especially cognitive and emotional factors) play in the progression and maintenance of chronic SP and disability.

(ii) To determine potential associations between psychological factors (specifically pain catastrophizing, pain self-efficacy, kinesiophobia and emotional distress) and both SP and SP-related outcomes in individuals with chronic SP.

2.2 **Specific Aims**

(i) To conduct a systematic review in order to evaluate all the available evidence regarding the role that psychological factors play in the perpetuation of pain intensity and disability in surgical and non-operative samples with chronic SP.

(ii) To carry out a systematic review in order to explore all the available literature considering the association and the predictive value that pain beliefs play in pain intensity and/or disability in individuals with acute, subacute and chronic SP.

(iii) To elaborate a study protocol investigating the influence of psychological factors (specifically pain catastrophizing, pain self-efficacy kinesiophobia and emotional distress) on the natural course of chronic SP: a prospective cohort study.

(iv) To analyse potential associations between clinical and experimental SP and measures of pain catastrophizing, pain self-efficacy and emotional distress in individuals with chronic SP.

(v) To evaluate potential associations between kinesiophobia and both pain intensity and disability in individuals with chronic SP.

CHAPTER III

PSYCHOLOGICAL FACTORS AND CHRONIC SHOULDER PAIN: A SYSTEMATIC REVIEW

Open Access Research

BMJ Open

The role of psychological factors in the perpetuation of pain intensity and disability in people with chronic shoulder pain: a systematic review

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ABSTRACT

Introduction Chronic shoulder pain is a very complex syndrome, and the mechanisms involved in its perpetuation remain unclear. Psychological factors appear to play a role in the perpetuation of symptoms in people with shoulder chronicity. The purpose of this systematic review is to examine the role of psychological factors in the perpetuation of symptoms (pain intensity and disability) in people with chronic shoulder pain.

Methods and analysis A systematic search was performed on PubMed, AMED, CINAHL, PubPsych and EMBASE from inception to July 2017. Longitudinal studies with quantitative designs analysing the role of psychological factors on pain intensity, disability or both were included. The methodological quality of the included studies was evaluated with an adapted version of the Newcastle Ottawa Scale. The level of evidence per outcome was examined using the Grading of Recommendations Assessment, Development and Evaluation approach.

Results A total of 27 articles were included with a sample of 11 176 people with chronic shoulder pain. The risk of bias ranges from 7/21 to 13/21 across the studies. The quality of the evidence was very low. High levels of self-efficacy, resilience and expectations of recovery were significantly associated with low levels of pain intensity and disability. Inversely, high levels of emotional distress, depressive symptoms, anxiety, preoperative concerns, fear-avoidance beliefs, somatisation and pain catastrophising were significantly associated with high levels of pain intensity and disability.

Discussion Our results suggest that psychological factors may influence the perpetuation of pain intensity and disability, with very low evidence. A meta-analysis was not carried out due to the heterogeneity of the included studies so results should be interpreted with caution.

PROSPERO trial registration number CRD42016036366.

Strengths and limitations of this study

- ► The use of a prespecified protocol registered on the International Prospective Register of Systematic Reviews, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses checklist, the Grading of Recommendations Assessment, Development and Evaluation approach to evaluate the overall quality and the strength of the evidence, and the adapted Newcastle Ottawa Scale to determine the risk of bias in each study.
- ► It is possible that some studies were not identified even though both a comprehensive and a robust search strategy were carried out.
- ► Reported bias was found in several included studies.
- ► The quality of the evidence was very low.
- ► The results of the present study are not robust, and conclusions should be interpreted with caution.

INTRODUCTION

Chronic shoulder pain (CSP) is very common in both the general[1] and the working population.[2] The prevalence and the socioeconomic impact of CSP is high.[3] It ranges from 1% to 67% across different populations.[4] People with CSP report a broad variability in symptoms such as pain, insomnia and/or disability.[3] Personal, occupational, psychological, social and biological factors have been associated with the delay in recovery from CSP.[4 5] CSP is a very complex syndrome, and the mechanisms involved in its perpetuation remain unclear. Indeed, recovery rates are poor, with roughly 60% of patients with CSP reporting persistence of symptoms 12 months after onset.[6]

Contemporary approaches, from a biopsychosocial perspective, have emerged to analyse why many people do not recover after an acute episode of pain.[7–9] In this context, psychological factors seem to play a key role in the explanation as to why musculoskeletal pain becomes chronic, once the tissue damage has healed.[10–13] Over the last decades, the fear-avoidance (FA) model of pain has been largely explored.[14–16] When it is specifically applied to musculoskeletal pain,[15] it proposes that people who have musculoskeletal pain and a trait tendency to have

3.1 Introduction

Chronic SP is very common in both the general (136) and the working population (137). The prevalence and the socioeconomic impact of chronic SP is high (81). It ranges from 1% to 67% across populations (82). People with chronic SP report a broad variability of symptoms such as pain, insomnia and disability (81). Personal, occupational, psychological, social and biological factors have been associated with the delay in recovery from chronic SP (82,88). Chronic SP is a very complex syndrome, and the mechanisms involved in its perpetuation remain unclear. Indeed, recovery rates are poor, with roughly 60% of individuals with chronic SP reporting persistence of symptoms 12 months after onset (138).

Contemporary approaches, from a biopsychosocial perspective, have emerged to analyse why many people do not recover after an acute episode of pain (26,139,140). In this context, psychological factors seem to play a key role in the explanation as to why musculoskeletal pain becomes chronic, once the tissue damage has healed (141–144). Over the last decades, the fear-avoidance model of pain has been largely explored (95,109,145). When it is specifically applied to musculoskeletal pain (109), it proposes that people who have musculoskeletal pain and a trait tendency to have fearful and catastrophic thoughts, have a greater likelihood of developing chronic pain.

The model conveys how people who perceive pain as a threat, often exhibit protective behaviours (e.g. hypervigilance) in order to prevent a potential new injury/re-injury (109). In the acute stage of the recovery process, these behaviours can be adaptive (146). However, they become maladaptive once pain remains for a long time (147). This unsuitable confrontation of the pain experience leads to a greater disuse of the affected area, causing physical and psychological consequences which provoke more pain and disability (115,147). In this stage, all aspects involving fear (pain-related fear, kinesiophobia, hypervigilance and pain catastrophizing) are intensified. This vicious cycle directly interferes in the person's recovery, which reduces treatment adherence and preserves the negative pain experience (95). Inversely, people with musculoskeletal pain who report high levels of psychological factors which are thought to be protective (e.g. self-efficacy) are presumed to manage their pain better and, therefore, have a greater chance for recovery (143).

The role of psychological factors on pain intensity and disability in people with chronic SP has been evaluated (125,130,133,148–150). The findings of these studies have shown a possible relationship between the factors and the outcomes previously mentioned. People with Chronic SP who mismanage their pain experience may create a negative spiral of pain perception, which could mean healing delays, brain alterations (151) and cognitive-behavioural changes (152). Therefore, research efforts need to be focused on obtaining more knowledge and understanding about how psychological factors are associated with a poor or better prognosis in people with Chronic SP.

This understanding is crucial to acquire a clear picture of the process involved in Chronic SP. This may aid in improving the current poor prognosis of this condition. To our knowledge, this is the first synthesis of evidence that explores the role of psychological factors on pain intensity and disability in people with Chronic SP. A systematic review may help to diminish the uncertainty caused by the heterogeneity of specific studies and may permit the formation of firm conclusions through an exhaustive synthesis of data (135).

3.2 Objectives

The aim of this study was to answer the following PECOS (P, population; E, exposure; C, comparator; O, outcome; S, study design) question through a systematic review of the literature on longitudinal studies (S): which is the role of psychological factors (E) on pain intensity and disability (O) in people with chronic SP (P)?

3.3 Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (153). The abstract was carried out using the PRISMA reporting guidelines for abstracts (http://www. prisma-statement. org/ Extensions/ Abstracts. Aspx). The systematic review protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO: CRD42016036366).

3.3.1 Patient and public involvement

Patients and or public were not involved.

3.3.2 Data sources and search strategy

A systematic search was performed by two independent reviewers (JMC and ALS) from inception to August 2016 using optimised search strategies in the following electronic databases: PubMed, AMED, CINAHL, PubPsych and EMBASE. An update of the search strategy was carried out on July 2017. A manual search of relevant eligible studies, to select any studies missed during the electronic search, was also carried out using cross-references identified both in journals associated with the topic of this review, and in reference lists within both original and review articles.

A sensitive search strategy using relevant search terms that were developed from Medical Subject Headings (MeSH), and keywords generated from the subject headings, as follows: ‘chronic pain’ (MeSH Terms), ‘surgery’ (MeSH Terms), ‘arthroscopy’ (MeSH Terms), ‘shoulder pain’ (MeSH Terms), ‘rotator cuff’ (MeSH Terms), ‘fear’ (MeSH Terms), ‘catastrophization’ (MeSH Terms), ‘depression’ (MeSH Terms), ‘anxiety’ (MeSH Terms), ‘self-efficacy’ (MeSH Terms), adhesive capsulitis, frozen shoulder, psychological factors, kinesiophobia, coping, expectations, were used. The complete search strategy report is shown in **appendix A**.

The grey literature, such as NHS Evidence, New York Academy of Medicine Grey Literature Report, Grey Source, Open Grey and Google Scholar (154) were explored to detect any relevant unpublished work. To gather any other non-published data, researchers were contacted directly. References were exported, and duplicates were removed using citation management software (Mendeley desktop V.1.17.4).

3.3.3 Eligibility criteria

The PECOS framework above mentioned was followed to determine which studies were included in the present systematic review. Each study had to meet the following inclusion criteria:

(i). Longitudinal studies (prospective and retrospective) (S) examining the role of psychological factors (E) on pain intensity, disability or both (O) in people with Chronic SP (P). Studies with a non-exposed cohort (C) to satisfy all the PECOS criteria. However, no included study reported a non-exposed cohort.

(ii). Studies whose participants were adults diagnosed with Chronic SP (>3 months).

(iii). Studies written in English.

(iv). No restriction was applied on the participants' gender or ethnicity.

(v). Studies that reported a follow-up at least 6 weeks after intervention.

(vi). Studies recruiting participants from any setting (general population, primary, secondary or tertiary care).

(vii). Studies providing at minimum an association between psychological factors and pain intensity, disability or both through a quantitative design.

The exclusion criteria were as follows:

(i). All studies that did not include a longitudinal design (e.g., cross-sectional studies).

(ii). Studies exploring psychological factors in people with acute or subacute SP.

(iii). Studies evaluating psychological factors in people with Chronic SP due to spinal cord injury, stroke, rheumatoid arthritis or cancer.

(iv). Studies aimed at modifying levels of psychological factors through any therapy.

(v). Studies investigating the psychometric properties of psychological factors assessment measures.

3.3.4 Study selection

All studies identified by the search strategy were screened using our eligibility criteria. Two independent reviewers (JMC and ALS) carried out the first stage, which involved the screening of articles by title and abstract. The same reviewers undertook the second stage, screening the full text. In cases of disagreement, a decision was made by consensus or, when necessary, a third reviewer (JMMA) was consulted. A short checklist was adapted to the present review to guide the selection of relevant studies (see **appendix B**) (155).

3.3.5 Data extraction

Two independent reviewers (JMC and ALS) extracted the following relevant data from each study: study details (first author, year of publication), sample size, characteristics of participants (mean age, mean duration of symptoms), metric of psychological factors measures, metric of outcome (pain intensity and disability) measures, duration of follow-up and study design. If there was any discrepancy between reviewers, a third reviewer was consulted (JMMA). When necessary, an email was sent to the original authors to provide further information on participants' data.

3.3.6 Quality assessment

Two independent reviewers (JMC and ALS) assessed the risk of bias of the included studies using the Newcastle Ottawa Scale (NOS) (156). The NOS is a reliable and valid tool for assessing the quality of non-randomised studies (156). Due to none of the included studies used as non-exposed cohort, we decided to use an adapted version of the NOS, which was developed to evaluate the quality of any observational design (157).

This adapted version has been used for previous systematic reviews (157) and includes four domains of risk or bias assessment: methods for selecting study participants (selection bias), methods to control for confounding (performance bias), statistical methods (detection bias) and methods for exposure and outcome assessment (information bias). Seven items compose the four domains. Each item is scored from 0 (high risk) to 3 (low risk) points. Therefore, the maximum score for each study could be 21 points.

To assess the overall quality and the strength of the evidence per outcome, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was used (158). In brief, the GRADE classification was carried out according to the presence, or not, of the following identified factors: (i) risk of bias, (ii) inconsistency of results, (iii) indirectness, (iv) imprecision and (v) other considerations (e.g., reporting bias). Two reviewers (JMC and ALS) judged whether these factors were present for each outcome. The GRADE approach was only applied when at least the three studies informed of every outcome.

3.3.7 Statistical analysis

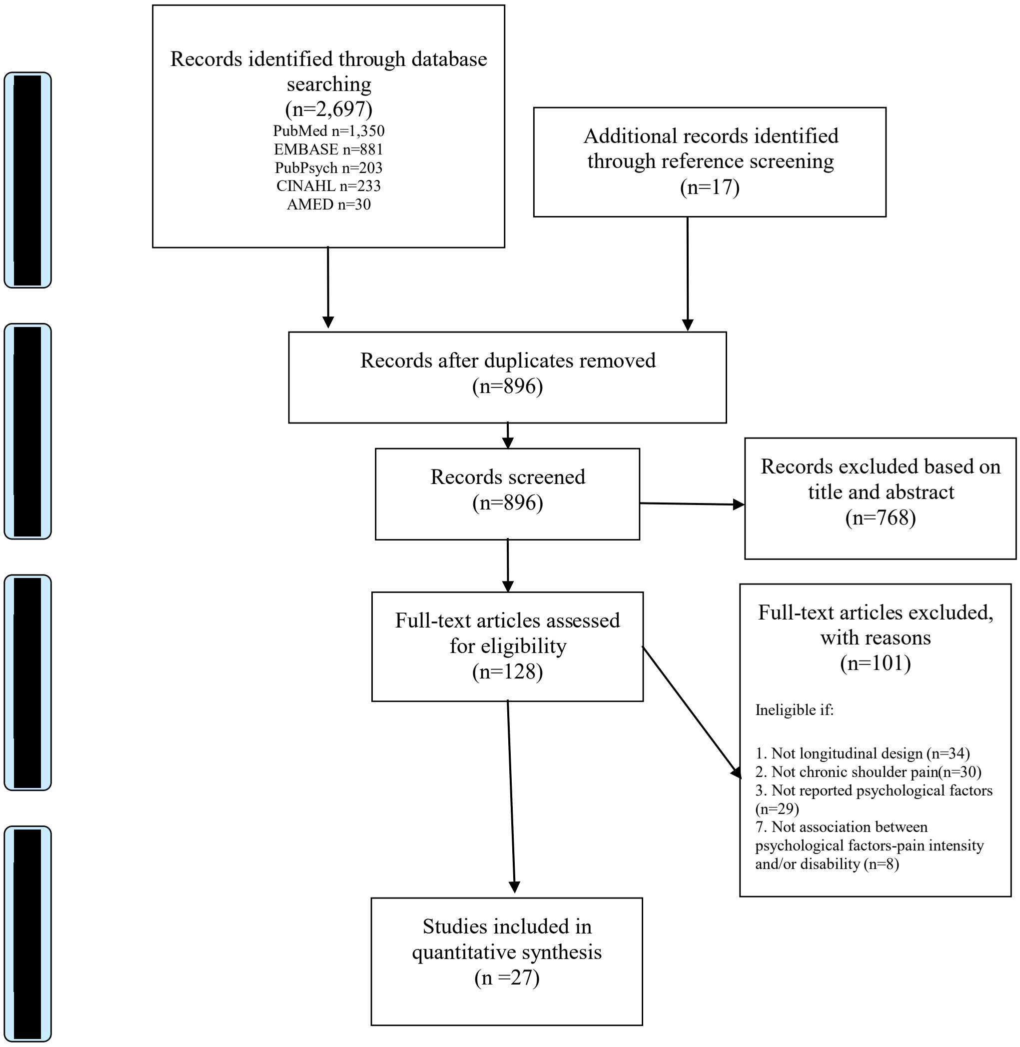
For the primary analysis, studies were grouped per outcome (pain intensity and disability). A meta-analysis could not be carried out as the heterogeneity was too high in terms of participant characteristics (mean age and duration of symptoms), sample size, metric of outcome measures, metric of psychological factors measures, and statistical methods used in most of the potentially eligible studies. Consequently, a descriptive quantitative analysis (the most relevant summary measure with a precise estimate) was provided for every study. For the studies that reported results with several degrees of adjustment for confounders, in different models, the estimate was extracted from the model that showed the best adjustment. GRADEpro software (159) and Review Manager (RevMan) V.5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) software were used to process data during the review.

3.4 Results

3.4.1 Study characteristics

A total of 2697 citations were identified through electronic databases, with 17 additional studies identified through reference screening. The authors screened 896 titles and abstracts, with 128 full-text articles finally being evaluated. The number of studies retrieved from each database and the number of studies excluded in each screening phase are shown in **Figure 1**. The full reference of excluded studies in the last screening (n=101) is reported in **appendix C**. The conflict of interests of included studies is reported in **appendix D**.

Figure 1. Flow diagram of review process.



A total of 27 longitudinal studies (18 prospective cohort studies; 6 retrospective cohort studies and 3 secondary data analyses) with a total of 11,176 participants with chronic SP satisfied our inclusion criteria and were included in this review. Seventeen studies explored the role of psychological factors in people with chronic SP presurgery and postsurgery (127,148,149,160–173). Ten studies evaluated this role in people with chronic SP without surgery (125,126,130,131,133,134,150,174–176). The outcome measures included in this review were pain intensity (125–127,130,131,134,148,150,161–176) and disability (125,126,130,131,133,148–150,160–165,167–176). Psychological factors were: depressive symptoms

(125,127,130,134,150,163–165,167–170,172), anxiety (125,127,130,134,165,166,168–170,172,175), emotional distress (125,126,172–176), self-efficacy (126,130,134,176), expectations of recovery (126,130,148,149,160,161,171), pain catastrophizing (125,127,131,133,134,166,167), somatisation (125,172), fear of pain (166), kinesiophobia (166), optimism (131), pain acceptance (134), preoperative concerns (149), sleep disturbances (168), coping with pain (125), internal and external locus of control (125) and resilience (162). The characteristics of the included studies are reported in **Table 1**.

Table 1. Characteristics of included studies

First Author	Year	No of participants	Mean age (years)	Mean duration of symptoms	Psychological factor measures	Outcome measure: pain intensity	Outcome measure: disability	Data collection (follow-up)	Study design
Badcock et al. (175)	2002	4002 (304 with unilateral shoulder pain) (142 completed the follow-up)	47.7	≥one year-three years≤	Anxiety (HADS-A); depressive symptoms (HADS-D); emotional distress (HADS)	Five-point Likert scale	Disability questionnaire	(T1) at baseline; (T2) twenty-four months	L (prospective cohort study)
Chester et al. (130)	2018	1030 (772 completed all follow-ups)	57 (SD 15)	14 months (SD 28)	Pain self-efficacy (PSEQ); expectations of recovery (not reported); anxiety (not reported); depressive symptoms (not reported)	SPADI and QuickDASH	SPADI and QuickDASH	(T1) at baseline; (T2) six weeks; (T3) six months	L (prospective cohort study)
Cho et al. (168)	2015	58 (47 completed all follow-ups)	57 (SD 8)	25 months (SD 36)	Anxiety (HADS-A); depressive symptoms (HADS-D); sleep disturbances (PSQI)	VAS	ASES	(T1) at baseline (before surgery); (T2) three months; (T3) six months; (T4) twelve months after surgery	L (prospective cohort study)

Cho et al. (169)	2017	60 (46 completed the follow-up)	65.7 (SD 10.1)	8.0 years (SD 9.8 years)	Anxiety (HADS-A); depressive symptoms (HADS-D)	VAS	ASES	(T1) at baseline (before surgery); (T2) three months; (T3) six months; (T4) twelve months after surgery	L (prospective cohort study)
Coronado et al. (131)	2017	78 (63 completed the follow-up)	38.8 (SD 14.9)	<6 months	Pain catastrophizing (PCS); fear-avoidance beliefs (FABQ); optimism (LOT-R)	BPI	Penn-F	(T1) at baseline; (T2) three months	L (secondary data analysis)
Dekker et al. (170)	2016	86 (44 completed all follow-ups)	53.6 (depressed group); 56.2 (non-depressed group)	More than 3 months	Anxiety (HADS-A); depressive symptoms (HADS-D)	VAS and OSS	OSS	(T1) at baseline; (T2) six weeks; (T3) six months after surgery	L (retrospective cohort study)
Ekeberg et al. (126)	2010	106 (104 completed the follow-up)	52 (SD 12)	Between six months-more than twenty-four months	Emotional distress (HSCL); self-efficacy for pain (seven-point ordinal scale); expectations of recovery (seven-point ordinal scale)	SPADI	SPADI	(T1) at baseline; (T2) six weeks after intervention	L (secondary data analysis)
Engebretsen et al. (176)	2010	104 (94 completed the follow-up)	48 (SD 10.7)	3 months->12 months	Emotional distress (HSCL); pain self-efficacy (four items from ASES)	SPADI	SPADI	(T1) at baseline; (T2) twelve months	L (prospective cohort study)

George et al. (166)	2008	59 (47 completed the follow-up)	50.3 (SD 15.0)	More than 3 months	Fear of pain (FPQ-III); kinesiophobia (TSK-11); pain catastrophizing (PCS); anxiety (STAI)	BPI	-	(T1) at baseline (pre-surgery); (T2) three-five months after surgery	L (prospective cohort study)
Gill et al. (150)	2013	2,337 (206 with CSP completed all follow-ups)	51.1 (SD 3.0)	More than 3 months	Depressive symptoms (CES-D)	SPADI	SPADI	(T1) at baseline; (T2) median forty-eight months	L (prospective cohort study)
Henn III et al. (148)	2007	125	56.2 (SD 11.4)	16.0 months (SD 25.9)	Preoperative expectations (MODEMS)	VAS and DASH	SST, VAS, and DASH	(T1) at baseline; (T2) twelve months after surgery	L (retrospective cohort study)
Jawa et al. (171)	2016	74	60.8	More than 3 months	Preoperative expectations (list of 10 items)	VAS	ASES	(T1) at baseline; (T2) minimum of thirty-six months after surgery	L (retrospective cohort study)
Karlsson et al. (134)	2016	57	43 (SD 8.5)	8.5 years	Anxiety (HADS-A); depressive symptoms (HADS-D); pain catastrophizing (PCS); fear-avoidance beliefs (FABQ); general self-efficacy (GSES); pain self-efficacy (PSEQ); pain acceptance (CPAQ)	NRS	-	(T1) at baseline; (T2) four-six months; (T3) twelve months after intervention	L (secondary data analysis)

Koorevaar et al. (172)	2016	315	52 (SD 16)	32 months (SD 40)	Emotional distress, anxiety, depressive symptoms, and somatisation (4DSQ)	DASH and seven-point Likert scale	DASH and seven-point Likert scale	(T1) at baseline; (T2) twelve months after surgery	L (prospective cohort study)
Kromer et al. (133)	2014	90 (88 completed the follow-up)	51.8 (SD 11.2)	84.7% more than 3 months	Pain catastrophizing (PCS); fear-avoidance beliefs (FABQ)	-	SPADI	(T1) at baseline; (T2) three months after intervention	L (prospective cohort study)
Macfarlane et al. (174)	1998	135 (92 completed the follow-up)	18-74	More than 3 months	Emotional distress (GHQ)	One item: “Do you have shoulder pain today?”	Disability questionnaire	(T1) at baseline; (T2) thirty-six months	L (prospective cohort study)
Oh et al. (149)	2012	128	58.8	More than 3 months	Preoperative expectations (MODEMS); preoperative concerns (64 items with a four-point Likert scale)	-	SST and Constant-Murley score	(T1) at baseline; (T2) mean 13.7 months (ranging 12-37 months) after surgery	L (prospective cohort study)
Potter et al. (173)	2015	89 (70 completed the follow-up)	60 (SD 2)	More than 3 months	Emotional distress (DRAM divided in: ZUNG questionnaire and MSPQ)	VAS	ASES	(T1) at baseline; (T2) twelve months after surgery	L (prospective cohort study)
Razmjou et al. (160)	2011	185 (160 completed the follow-up)	57 (SD 11)	Mean 43.42-46.48 months	Preoperative expectations (MODEMS)	-	WORC, ASES, and QuickDASH	(T1) at baseline; (T2) six months after surgery	L (prospective cohort study)

Reilingh et al. (125)	2008	587 (242 with chronic shoulder pain at baseline)	52.9 (SD 13.3)	>3 months	Pain catastrophizing, coping with pain, internal and external locus of control (PCCL); anxiety, depressive symptoms, somatization, and emotional distress (4DSQ)	NRS	SDQ	(T1) at baseline; (T2) six weeks; (T3) three months; (T4) six months	L (prospective cohort study)
Styron et al. (161)	2015	467 (436 complete the follow-up)	66.6 (SD 10.3)	20.9 months	Expectations of recovery (ten-point Likert scale);	PSS pain subscore	PSS function subscore and SF-12-PCS score	(T1) at baseline; (T2) six months after surgery	L (prospective cohort study)
Tokish et al. (162)	2017	70	65 (SD 10)	More than 3 months	Resilience (BRS)	ASES	ASES, SANE and Penn	(T1) at baseline; (T2) twenty-four months (minimum) after surgery	L (retrospective cohort study)
Valencia et al. (127)	2011	59 (48 completed the follow-up)	50.39 (SD 14.92)	More than 3 months	Depressive symptoms (BDI); anxiety (STAI); pain catastrophizing (PCS)	BPI	-	(T1) at baseline; (T2) three months after surgery	L (prospective cohort study)
Valencia et al. (167)	2014	78 (73 completed all follow-ups)	43.25 (SD) to 51.35 (SD 20.73)	68.98 (SD 68.59) to 88.78 (SD 137.13) weeks	Depressive symptoms (PHQ-9); pain catastrophizing (PCS)	BPI	DASH	(T1) at baseline; (T2) three months (T2) six months after surgery	L (prospective cohort study)
Werner et al. (163)	2016	150	71.6 (SD 8.8)	More than 3 months	Depressive symptoms (from database registry)	ASES	ASES	(T1) at baseline; (T2) twenty-four months	L

								(minimum) after surgery	(retrospective cohort study)
Werner et al. (164)	2017	616	67.0 (SD 7.4)	More than 3 months	Depressive symptoms (measurement instrument not reported)	ASES	ASES, SF-12-PCS	(T1) at baseline; (T2) twenty-four months after surgery	L (retrospective cohort study)
Yeoman and Wigderowitz (165)	2012	31	54.6	Twenty-six months	Depressive symptom (HADS-D); anxiety (HADS-A)	VAS	OSS	(T1) at baseline; (T2) two weeks; (T3) three weeks; (T4) six weeks after surgery	L (prospective cohort study)

Note: L: longitudinal; SPADI: the Shoulder Pain and Disability Index; SST: the Simple Shoulder Test; DASH: the Quick Disability of the Arm, Shoulder and Hand Questionnaire; HADS: the Hospital Anxiety and Depression Scale; PSEQ: the Pain Self-Efficacy Scale; PSQI: the Pittsburgh Sleep Quality Index; ASES: the American Shoulder and Elbow Surgeons' Scale; OSS: the Oxford Shoulder Score; HSCL: the Hopkins Symptoms Checklist; ASES: Arthritis Self-Efficacy Scale; MODEMS: the Musculoskeletal Outcomes Data Evaluation and Management System Questionnaire; PCS: the Pain Catastrophizing Scale; FABQ: the Fear Avoidance Beliefs Questionnaire; GSES: the General Self-Efficacy Scale; CPAQ: the Chronic Pain Acceptance Questionnaire; 4DSQ: the Four-Dimensional Symptom Questionnaire; LOT-R:

Life Orientation Test-Revised; BPI: Brief Pain Inventory; Penn-F: Pennsylvania Shoulder Score function subscale; GHQ: the General Health Questionnaire; DRAM: the Distress Risk Assessment Method questionnaire; ZUNG questionnaire: modified zung depression scale; MSPQ: Modified Somatic Perceptions Questionnaire; WORC: the Western Ontario Rotator Cuff index; SDQ: Shoulder Disability Questionnaire; PCCL: the 43-item Pain Coping and Cognition List; 4DSQ: the 50-item Four-Dimensional Symptoms Questionnaire; PSS: the Penn Shoulder Score; SF-12: the General Health-Related Quality of life Physical Component Summary (PCS) Score; BRS: the Brief Resilience Scale; SANE: Single Assessment Numeric Evaluation; STAI: the State Trait-Anxiety Index; FPQ-III: the Fear of Pain Questionnaire; TSK: the Tampa Scale for Kinesiophobia; PHQ-9: the Patient Health Questionnaire; BDI: the Beck Depression Inventory.

3.4.2 Methodological quality

The degree to which studies met the quality criteria varied considerably, ranging from 7/21 to 13/21. The risk of bias assessment for the included studies is presented in **Table 2**.

Table 2. Methodological quality of included studies (The Newcastle Ottawa Scale (NOS) adapted version)

First Author	Year	Selection bias	Performance bias		Detection bias		Information bias		Total score
		A	*B*	*C*	*D*	*E*	*F*	*G*	
Badcock et al.	2002	1	0	2	1	0	2	2	8/21
Chester et al.	2018	3	3	2	2	0	0	2	12/21
Cho et al.	2015	2	3	0	1	0	2	2	10/21
Cho et al.	2017	2	3	0	1	0	2	2	10/21
Coronado et al.	2017	1	0	2	2	2	3	2	12/21
Dekker et al.	2016	2	3	0	1	0	2	2	10/21

Ekeberg et al.	2010	1	0	2	2	3	2	2	12/21
Engebretsen et al.	2010	1	0	3	2	3	2	2	13/21
George et al.	2008	1	0	1	2	0	2	2	8/21
Gill et al.	2013	1	0	3	2	3	2	2	13/21
Henn III et al.	2007	1	0	2	2	3	2	2	12/21
Jawa et al.	2016	1	0	0	0	3	1	2	7/21
Karlsson et al.	2016	0	0	2	2	3	3	2	12/21
Koorevaar et al.	2016	1	0	2	2	3	3	2	13/21
Kromer et al.	2014	1	0	2	2	3	3	2	13/21
Macfarlane et al.	1998	1	0	2	0	0	2	2	7/21
Oh et al.	2012	1	0	0	1	3	2	2	9/21
Potter et al.	2015	1	0	0	2	0	3	2	8/21
Razmjou et al.	2011	2	1	1	2	1	3	2	12/21
Reilingh et al.	2008	1	0	3	2	0	2	2	10/21
Styron et al.	2015	1	0	2	1	1	1	2	8/21
Tokish et al.	2017	1	0	0	0	3	1	2	7/21
Valencia et al.	2011	1	0	0	1	0	3	2	7/21
Valencia et al.	2014	1	0	2	2	3	3	2	13/21
Werner et al.	2016	1	0	1	1	3	1	2	9/21
Werner et al.	2017	2	3	1	1	3	1	2	13/21

Yeoman et al.	2012	2	3	0	0	3	3	2	13/21

Note: A = Is the source population (cases, controls, cohorts) appropriate and representative of the population of interest?; B = Is the sample size adequate and is there sufficient power to detect a meaningful difference in the outcome of interest?; C = Did the study identify and adjust for any variables or confounders that may influence the outcome?; D = Did the study use appropriate statistical analysis methods relative to the outcome of interest?; E = Is there little missing data and did the study handle it accordingly?; F = Is the methodology of the outcome measurement explicitly stated and is it appropriate?; G = Is there an objective assessment of the outcome of interest?

3.4.3 The role of psychological factors in the perpetuation of symptoms (pain intensity and disability) in people with chronic SP

After analysing the risk of bias for the included studies, the strength and the quality of the evidence for each outcome was determined using the GRADE approach. Since observational studies were included and methodological limitations, inconsistencies, indirectness of evidence, imprecisions of results and other issues were presented, a very low level of evidence was found for each outcome (**Table 3**). A description of the statistical results is reported in **Appendix E** for pain intensity and in **Appendix F** for disability.

Table 3. Summary of findings and Quality of evidence assessment

Summary of findings			Quality of evidence assessment (GRADE)						
Outcome	No of studies	No. of participants	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Level of evidence	Importance
Depressive symptoms									
Pain intensity	14	9,466	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Disability	12	9,350	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Anxiety									
Pain intensity	11	6,344	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Disability	8	6,169	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Emotional distress									

Pain intensity	7	5,336	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Disability	7	5,336	Very serious[1]	Serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Self-efficacy									
Pain intensity	4	1,297	Serious[1]	Serious[2]	Very serious[3]	Serious[4]	N/A	Very low	Critical
Disability	3	1,240	Serious[1]	Serious[2]	Very serious[3]	Serious[4]	N/A	Very low	Critical
Expectations of recovery									
Pain intensity	5	1,802	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Disability	7	2,115	Very serious[1]	Very serious[2]	Very serious[3]	Very serious[4]	Reporting bias detected [5]	Very low	Critical
Pain catastrophizing									
Pain intensity	6	918	Very serious[1]	Serious[2]	Serious[3]	Very serious[4]	N/A	Very low	Critical
Disability	4	833	Serious[1]	Very serious[2]	Very serious[3]	Serious[4]	Reporting bias detected [5]	Very low	Critical

Note: 1. Randomized trials (lack of allocation concealment; lack of blinding; incomplete accounting of patients and outcomes events; selective outcome reporting bias; other limitations; observational studies (failure to develop and apply appropriate eligibility criteria; flawed measurement of both exposure and outcome; failure to adequate control confounding; incomplete follow-up; non-presence of an unexposed cohort) 2. Point estimates vary widely across studies; confidence intervals show minimal or no overlap. 3. Differences in population, differences in intervention, differences in outcome, indirect comparison. 4. Optimal information size (OIS) criterion is not met and the sample size is small; OIS criterion is met but the 95% CI around an effect does not exclude 1.0 (wide confidence intervals); 95% CI is not reported. 5. Outcome data not included in the predictive model.

3.4.4 The role of psychological factors on pain intensity in people with chronic SP without surgery

The role of psychological factors on pain intensity in people with chronic SP without surgery was explored in 9 studies (125,126,130,131,134,150,174–176). High levels of self-efficacy (130,176) and expectations of recovery (130) were significantly associated with low levels of pain intensity. High levels of emotional distress (176) depressive symptoms (130,150) anxiety (130), fear-avoidance beliefs (134) and pain catastrophizing (125) were significantly associated with high levels of pain intensity. There was no statistical relationship between optimism, somatisation, coping with pain, internal and external locus of control or pain acceptance and pain intensity in people with chronic SP without surgery.

3.4.5 The role of psychological factors on pain intensity in people with chronic SP presurgery and postsurgery

The role of psychological factors on pain intensity in people with chronic SP presurgery and postsurgery was analysed in 15 studies (127,148,161–173). High levels of resilience (162) and preoperative expectations (148,161) were significantly associated with low levels of pain intensity. High levels of depressive symptoms (127,163,164,170,172), anxiety (165,170,172), pain catastrophizing (127,166), emotional distress (172) and somatisation (172) were significantly associated with high levels of pain intensity. There was no statistical relationship between sleep disturbances, fear of pain, kinesiophobia and pain intensity in people with chronic SP presurgery and postsurgery.

3.4.6 The role of psychological factors on disability in people with chronic SP without surgery

The role of psychological factors on disability in people with chronic SP without surgery was evaluated by 9 studies (125,126,130,131,133,150,174–176). High levels of self-efficacy (130,176) and expectations of recovery (130) were significantly associated with low levels of disability. High levels of depressive symptoms (130,150,175), anxiety (130,175), emotional distress (175,176) and pain catastrophizing (131) were significantly associated with high levels of disability. There was no statistical relationship between coping with pain, internal and external locus of control, optimism, fear-avoidance beliefs or somatisation and disability in people with chronic SP without surgery.

3.4.7 The role of psychological factors on disability in people with chronic SP presurgery and postsurgery

The role of psychological factors on disability in people with chronic SP presurgery and postsurgery was reported by 15 studies (148,149,160–165,167–173). High levels of resilience (162) and preoperative expectations (148,149,161) were significantly associated with low levels of disability. High levels of depressive symptoms (163,164,170,172), anxiety (170,172), emotional distress (172), preoperative concerns (149) and somatisation (172) were significantly associated with high levels of disability.

There was no statistical relationship between sleep disturbances and disability in people with chronic SP presurgery and postsurgery.

3.5 Discussion

3.5.1 Statement of principal findings

The objective of this systematic review was to explore the role of psychological factors in the perpetuation of symptoms (pain intensity and disability) in people with chronic SP, based on the analysis of longitudinal studies. Our results suggest that there is a relationship between high levels of self-efficacy, resilience and expectations of recovery with low levels of pain intensity and disability. Inversely, there is also a relationship between high levels of emotional distress, depressive symptoms, anxiety, preoperative concerns, fear-avoidance beliefs, somatisation or pain catastrophizing and high levels of pain intensity and disability in people with chronic SP. Nevertheless, the quality and the strength of evidence was very low, and the risk of bias was substantial so firm conclusions could not be drawn.

3.5.2 Comparison with other studies

Our findings suggest that people with chronic SP who present certain psychological features (e.g. depressive symptoms or fear) are prone to develop greater levels of pain intensity and disability. This statement is in accordance with previous systematic reviews in chronic pain conditions (177–180) and with the fear-avoidance model of pain (95,109,145).

In brief, this model argues that people with high levels of pain catastrophizing or fear, perceive their pain as a threat. Interestingly, they develop avoidance behaviours to prevent this real or potential injury or re-injury. Defensive escape behaviours are an adaptive response when a real or potential aversive outcome is imminent (181). However, in chronic stages, these behaviours become maladaptive, which facilitates the physical inactivity of the affected area (109). In the case of people with chronic SP, the disuse of the affected shoulder could diminish the ability to carry out daily life activities such as driving a vehicle, holding an object and/or or sleeping properly. A vicious cycle starts to emerge, as people with chronic SP might not understand how to confront their pain in different situations, and why that pain is not disappearing, even after a conservative treatment or surgical procedure.

This could increase the levels of depressive symptoms, anxiety and fear, which affects the way in which the individuals perceive their pain experience, and therefore may cause more pain intensity and disability (109). Inversely, our results also suggest that people with chronic SP who present high levels of self-efficacy and expectations of recovery, may be able to have both better control and management of their lives (103). People with chronic SP may be able to confront any daily situation that minimises the potential impact of the negative psychological factors mentioned above (e.g. pain catastrophizing). Several systematic reviews have explored the role of self-efficacy (103,119) and expectations of recovery (182) in patients with chronic pain. Jackson et al. (103) concluded after analysing 86 studies that self-efficacy has a significant reverse association with disability, emotional distress and pain severity. Martinez-Calderon et al. (119) reported that high levels of self-efficacy predict greater physical functioning, physical activity participation, health status and low pain intensity, disability and depressive symptoms, in chronic musculoskeletal pain. Ellis et al. (182) found a positive short-term association between expectations of recovery and patient’s satisfaction and functional outcomes, after lumbar spine surgery. Therefore, the findings reported by our study and previous reviews

(103,177–180,182) seem to support the potential role that psychological factors play favouring the perpetuation of pain intensity and disability in people with chronic SP, and minimising these symptoms based on their potential protective factors, for example, self-efficacy or expectations of recovery.

However, despite these promising findings, a lack of uniformity in terms of significance still exists, and our conclusions should be taken with caution. Several reasons could explain this issue. First, contrary to the fear-avoidance model of pain, pain intensity has been considered as a robust and unique predictor of disability (183,184), with it itself being a threatening experience that drives escape and avoidance (185). Second, the number and duration of episodes, fluctuations of symptoms, healthcare use and the biopsychosocial profile of every individual with chronic SP, can vary considerably. Therefore, these individual differences in the development and the course of symptoms in people with chronic SP should be kept in mind when interpreting the contribution of each psychological factors during different stages of pain to convey a more comprehensive picture of this entity.

3.5.3 Strengths and weaknesses of the study

The strengths of this systematic review included the use of a prespecified protocol registered on PROSPERO, the PRISMA checklist, the GRADE approach to evaluate the overall quality and strength of the evidence, and the adapted NOS to determine the risk of bias in each study. There are several limitations that should be mentioned, as follows: (i) despite this review having been designed to be comprehensive with a robust search strategy that used a long variety of MeSH terms, as well as a manual search and grey literature, it is possible that some studies were not identified; (ii) some psychological factors are quite broad in definition and may increase the risk of finding conflicting evidence in their association with outcomes; (iii) risk of bias was reported in most of the included studies (table 2). For instance, reporting bias was revealed in some included studies and this could limit the findings of the present systematic review; (iv) a meta-analysis was not carried out because the heterogeneity of the included studies was too high, consequently the results of the present study are not robust, and conclusions should be interpreted with caution; (v) the causality and the impact of psychological factors in pain intensity and disability in this population cannot be determined due to the observational nature of the included studies (cohort studies without a non-exposed cohort), as well as the very low evidence of the obtained findings, and hence, firm conclusions could not be drawn; (vi) some shoulder presentations (e.g. traumatic) were not considered as criteria in our search strategy, giving rise to the possibility of missing potential articles; (vii) despite the post-traumatic stress disorder profile being considered a relevant factor in other musculoskeletal conditions, for example, whiplash, this profile was not considered as a criteria in our search strategy; (viii) understanding about how psychological factors influence the transition from acute to chronic SP could be very important in establishing preventive strategies; however, this review did not include longitudinal studies examining the transition from acute to chronic SP.

3.5.4 Implications for clinical practice

Many psychological factors included in this study are considered a barrier to the adherence to treatment in different pain conditions (186,187). However, psychological factors such as self-efficacy or pain catastrophizing are considered modifiable factors that may facilitate pain relief and function recovery (188,189). Therefore, clinicians and surgeons should be encouraged to identify these factors, through an assessment of the psychological profile of every individual with chronic SP, in the first consultation.

Obtaining this information may be relevant to assist health providers in clinical decision-making with the aim of targeting which interventions (e.g. pharmacological and/or behavioural) could be appropriate in enhancing positive (e.g. self-efficacy) or reducing negative (e.g. pain catastrophizing) psychological factors.

3.5.5 Implications for further research

Despite the promising results found in this systematic review, a clear gap seems to exist in the literature which should be filled. This is based mainly on the flaws observed in most of the included studies in this review. Hence, some recommendations to guide future research are: (i) further studies prospectively analysing the role of psychological factors on pain intensity and disability in people with chronic SP including a non-exposed cohort; (ii) studies examining the role of psychological factors on chronic SP standardising metrics to assess psychological factors and outcome measures; (iii) studies establishing specific definitions for each psychological factors construct (e.g. a clear distinction between fear of pain, fear-avoidance beliefs or kinesiophobia); (iv) studies targeting modifiable psychological factors through biopsychosocial approaches; (v) studies exploring the role of psychological factors on treatment adherence in people with chronic SP; (vi) as chronic SP is a complex entity, a long list of factors (biological, biomechanical, occupational, contextual, environmental) apart from the psychological ones should be kept in mind prior to developing observational and experimental studies. Cluster analysis and mediation analysis are examples that may help to determine the importance of each factor.

3.6 Conclusion

This systematic review provides information about the role of psychological factors on pain intensity and disability in people with chronic SP. The available evidence suggests that there is a relationship between high levels of self-efficacy, resilience or expectations of recovery and low levels of pain intensity and disability. Inversely, there is also a relationship between high levels of emotional distress, depressive symptoms, anxiety, preoperative concerns, fear-avoidance beliefs, somatisation or pain catastrophizing and high levels of pain intensity and disability in people with chronic SP. Nevertheless, due to the very low quality of the evidence, firm conclusions cannot be drawn, and further research is needed.

CHAPTER IV

PAIN BELIEFS AND ACUTE, SUBACUTE AND CHRONIC SHOULDER PAIN: A SYSTEMATIC REVIEW

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Review article

The association between pain beliefs and pain intensity and/or disability in people with shoulder pain: A systematic review

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ABSTRACT

Background: Pain beliefs might play a role in the development, transition, and perpetuation of shoulder pain.
Objective: To systematically review and critically appraise the association and the predictive value of pain beliefs on pain intensity and/or disability in shoulder pain.
Methods: An electronic search of PubMed, EBSCOhost, AMED, CINAHL, EMBASE, and PubPsych, and grey literature was searched from inception to July 2017. Study selection was based on observational studies exploring the association and the predictive value of pain beliefs on pain intensity and/or disability in shoulder pain.
Results: A total of thirty-three articles were included with a total sample of 10,293 participants with shoulder pain. In the cross-sectional analysis, higher levels of pain catastrophizing and kinesiophobia were significantly associated with more pain intensity and disability, whereas higher levels of expectations of recovery and self-efficacy were significantly associated with lower levels of pain intensity and disability. In the longitudinal analysis, higher levels of pain catastrophizing, fear-avoidance and kinesiophobia at baseline predicted greater pain intensity and disability overtime. Higher levels of self-efficacy and expectations of recovery at baseline predicted a reduction in levels of pain intensity and disability overtime.
Conclusions: Evidence suggests that pain beliefs are associated with and predict the course of pain intensity and disability in shoulder pain. However, the overall body of the evidence after applying the GRADE approach was very low across studies. Further research using higher quality longitudinal designs and procedures would be needed to establish firm conclusions.

1. Introduction

Shoulder pain (SP) is a highly prevalent musculoskeletal pain condition (Luime et al., 2004; McBeth and Jones, 2007). The socioeconomic burden of SP is considerable, being a common cause of sick absence and disability (Pribicevic, 2012; Virta et al., 2012). However, almost 60% still report persistence of symptoms (mostly pain intensity and disability) twelve months after the onset (van der Windt et al., 1996; Winters et al., 1999).

In this context, research has been targeting the question why some people, but not others, recover after developing an acute episode of SP (Badcock et al., 2002; Cho et al., 2015; Gill et al., 2013). Many factors such as biological, social, biomechanical, and psychological are associated with poor outcomes in SP (Kuijpers et al., 2004; Pribicevic, 2012). From a cognitive-behavioural perspective, individuals with musculoskeletal pain who show a trait tendency to have fearful and catastrophic thoughts in response to pain, could have more difficulties to exert any control over their pain (Sandborgh et al., 2016). These individuals have greater risk to develop chronic pain and disability than individuals who do not show this tendency (Leeuw et al., 2007).

Beliefs about pain play a role in the development, transition, and perpetuation of musculoskeletal pain in general (Leeuw M et al., 2007; Main et al., 2010; Wertli et al., 2014a,b,c,d), and in SP complaints particularly (Feleus et al., 2007; George et al., 2007; Reilingh et al., 2008). Specifically in SP, George et al. (2007) reported that fear is associated with pain intensity and disability in healthy people after induced pain. Feleus et al. (2007) showed that higher levels of kinesiophobia at baseline were associated with more shoulder complaints at twelve months. Reilingh et al. (2008) showed that higher levels of pain catastrophizing at baseline were associated with the perpetuation of

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4.1 Introduction

Shoulder pain is a highly prevalent musculoskeletal pain condition (136,190). The socioeconomic burden of SP is considerable, being a common cause of sick absence and disability (82,191). However, almost 60% still report persistence of symptoms (mostly pain intensity and disability) twelve months after the onset (138,192). In this context, research has been targeting the question why some people, but not others, recover after developing an acute episode of SP (150,168,175). Many factors such as biological, social, biomechanical, and psychological are associated with poor outcomes in SP (82,88).

From a cognitive-behavioural perspective, individuals with musculoskeletal pain who show a trait tendency to have fearful and catastrophic thoughts in response to pain, could have more difficulties to exert any control over their pain (193). These individuals have greater risk to develop chronic pain and disability than individuals who do not show this tendency (109). Beliefs about pain play a role in the development, transition, and perpetuation of musculoskeletal pain in general (109,110,142), and in SP complaints particularly (123–125).

Specifically, in SP, George et al. (124) reported that fear is associated with pain intensity and disability in healthy people after induced pain. Feleus et al. (123) showed that higher levels of kinesiophobia at baseline were associated with more shoulder complaints at twelve months. Reilingh et al. (125) showed that higher levels of pain catastrophizing at baseline were associated with the perpetuation of chronic SP at six months.

A few researches have emerged to explore the association between pain beliefs and several outcome measures such as pain intensity and disability in SP. However, findings remain inconsistent (126–129), regarding the significance and the direction of the obtained results. A systematic review of the association between pain beliefs and pain intensity and/or disability would contribute to a better understanding and clarification of these relationships in individuals with SP. Likewise, the study of the predictive value of pain beliefs on pain intensity and disability, would facilitate a greater understanding of SP mechanisms, and, thus, a better clinical decision-making. The synthesis of the evidence through a systematic review of the literature will permit to achieve stronger conclusions than those achieved by any one study (135). It will help readers who often have broad difficulties to track down and review all the evidence provided by primary studies.

4.2 Objectives

The aim of this study was twofold: (i) to explore the association between pain beliefs with pain intensity and/or disability and, (ii) to analyse the prognostic role that pain beliefs play on pain intensity and/or disability, by performing a systematic review of the literature of observational studies (cross-sectional and longitudinal studies) that address these questions in individuals with SP.

4.3 Methods

The review was conducted according to the Cochrane Handbook for Systematic Reviews Version 5.1.0 (194) and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (153). The systematic review protocol was registered at the International Prospective Register of Systematic Reviews (PROSPERO: CRD 42017072758). The expertise of the team is summarized as follows: systematic reviews experts (JMC and MM); statistician (ALS); reference management and database searching (JMC and ALS); content experts (JMC, FS and ALS).

4.3.1 Data sources and search strategy

When the research aims of the present review were determined, one investigator (JMC) carried out a scoping search to ensure that this aim had not been addressed by previous reviews. The following databases were explored: PROSPERO, Cochrane Library, NICE Evidence Search, and Turning Research into Practice (TRIP). Two investigators (JMC and ALS) independently searched in several electronic databases (PubMed, EBSCOhost, AMED, CINAHL, EMBASE, and PubPsych) from the inception to July 2017 using optimized search strategies. Manual searches of relevant eligible studies were also searched through cross-references identified in journals associated with the topic of this review, and reference lists within both original and review articles, selecting studies missed during the electronic search.

A sensitive search strategy using relevant search terms that were developed from Medical Subject Headings (MeSH), and keywords generated from the subject headings, were used: “shoulder pain” [MeSH Terms], “rotator cuff” [MeSH Terms], “shoulder impingement syndrome” [MeSH Terms], “self-efficacy" [MeSH Terms], “optimism” [MeSH Terms], “pessimism” [MeSH Terms], beliefs, psychological factors, expectations, pain catastrophizing, fear-avoidance, kinesiophobia, fear of pain, fear of movement, helplessness, threat, and acceptance of illness. The complete search strategy report is shown in **Appendix G**. Grey literature was also searched to detect any relevant unpublished work. National Guideline Clearinghouse, Open Grey, and Google Scholar (154) were explored. References were exported, and duplicates were removed using citation management software (Mendeley desktop v1.17.4).

4.3.2 Eligibility criteria

Based on the PICO statement (P=population; I=intervention; C=comparator; O=outcome) (Higgins & Green, 2011) the PECO statement (P=population; E=exposure; C=comparator; O=outcome) was followed by two reviewers (JMC and ALS) independently to determine which studies satisfied the inclusion criteria. Each study had to meet the following inclusion criteria:

(i) Observational studies (cross-sectional and longitudinal) examining the association (cross-sectional analysis) or the predictive value (longitudinal analysis) of pain beliefs on pain intensity and/or disability.

(ii) Adults with a diagnosis of SP.

(iii) Recruited from any setting (general population, primary, secondary, or tertiary care).

(iv) No restrictions were applied regarding participants' gender, ethnicity, and the duration of follow-up.

(v) Pain beliefs were selected according to previous evidence (112,142,143,195).

(vi) Only English-language studies.

Exclusion criteria were as follows:

(i) Adults with SP due to systemic diseases (e.g. rheumatoid arthritis), neurological disorders (e.g. stroke), and/or chronic non- musculoskeletal pain (e.g. breast cancer).

(ii) Studies trying to modify pain beliefs levels through any therapy.

(iii) Reviews, clinical studies, case-control studies, case reports, editorial, abstracts, and studies investigating psychometric properties of pain beliefs assessment measures.

4.3.3 Study selection

All studies identified by the search strategy were screened using the eligibility criteria. The first step involved the screening of titles and abstracts by two independent reviewers (JMC and ALS). The same pair of reviewers undertook the second screening based on the full text. In cases of disagreement, a decision was made by consensus or, when necessary, a third reviewer (MM) was consulted. A short checklist was developed for the present review, being applied to guide the selection of relevant studies (**Figure 2**) (155).

Figure 2. A short question guide for the selection of relevant studies based on inclusion criteria

Item	Question	Action
1	Did the study use any of the eligible study design (cross-sectional or longitudinal studies)?	Yes, move to the next question No, exclude
2	Did the study involve people with shoulder pain?	Yes, move to the next question No, exclude
3	Was shoulder pain caused by a systemic disease, neurological disorders, and/or chronic non-musculoskeletal pain?	No, move to the next question Yes, exclude
4	Did the study report pain beliefs measures?	Yes, move to the next question No, exclude

5	Did the study show the predictive value of pain beliefs on pain intensity and/or disability, or at least an association between pain beliefs and pain intensity or disability?	Yes, move to the next question No, exclude
6	Did the study try to modify pain beliefs levels through any therapy?	No, Include in the review. Yes, exclude

4.3.4 Data extraction

Two reviewers (JMC and ALS) independently extracted the following relevant data from each included study: study details (first author and year of publication), characteristics of participants (mean age, clinical presentation, and mean duration of symptoms), setting, sample size, pain beliefs measures which have been grouped in this review as cognitive factors (expectations of recovery, self-efficacy, pain catastrophizing, internal and external locus of control, preoperative concerns, optimism, and beliefs about preferences of treatment) and behavioural factors (fear of pain, fear-avoidance, and kinesiophobia) (196–198), outcome (pain intensity and disability) measures, duration of follow-up (in case of longitudinal studies), and study design. If there was any discrepancy between reviewers, a third reviewer was consulted (MM). When necessary, an email was sent to the original authors to obtain further information on participants' data.

4.3.5 Risk of bias assessment

Two reviewers (JMC and ALS) independently analysed the risk of bias of the included studies. The risk of bias of observational studies is commonly assessed with the Newcastle-Ottawa Scale (NOS) (156). The NOS is a reliable and valid tool for assessing the quality of non-randomised studies (156). However, many of the included studies were cross-sectional in nature. Furthermore, none of the longitudinal included studies presented a non-exposed cohort. For that, we decided to evaluate the risk of bias of included studies with an adapted version of the NOS which has been used by previous systematic reviews to evaluate the quality of any observational design (157).

It includes four domains of risk of bias assessment: methods for selecting study participants (selection bias), methods to control for confounding (performance bias), statistical methods (detection bias), and methods of exposure and outcome assessment (information bias). Seven items compose the four domains. Each item is scored from zero (high risk) to three (low risk) points. Therefore, studies with a total score from 0 to 6 were considered as high risk of bias, whereas total score from 7 to 13 and 14 to 21 were considered as moderate and low risk of bias, respectively.

4.3.6 Data synthesis and analysis

Following the proposed objectives for this review, we tried to carry out multiples meta-analyses by pooling the results based on the study design: (1) cross-sectional (first objective) and; (2) longitudinal (second objective) designs. However, there was considerable clinical heterogeneity within the included studies in terms of patient population (age, sample size, clinical shoulder presentation), outcome measures, pain beliefs measures, statistical methods used, and study design. Thus, meta-analyses could not be carried out. Therefore, a narrative synthesis was deemed to analyse the data to respond the aim of this study. The narrative synthesis was separately conducted for cross-sectional and longitudinal studies. In cross-sectional analyses, the association between pain beliefs and pain intensity and/or disability was explored. In longitudinal analyses, the predictive value of pain beliefs in the course of pain intensity and/or disability was analysed.

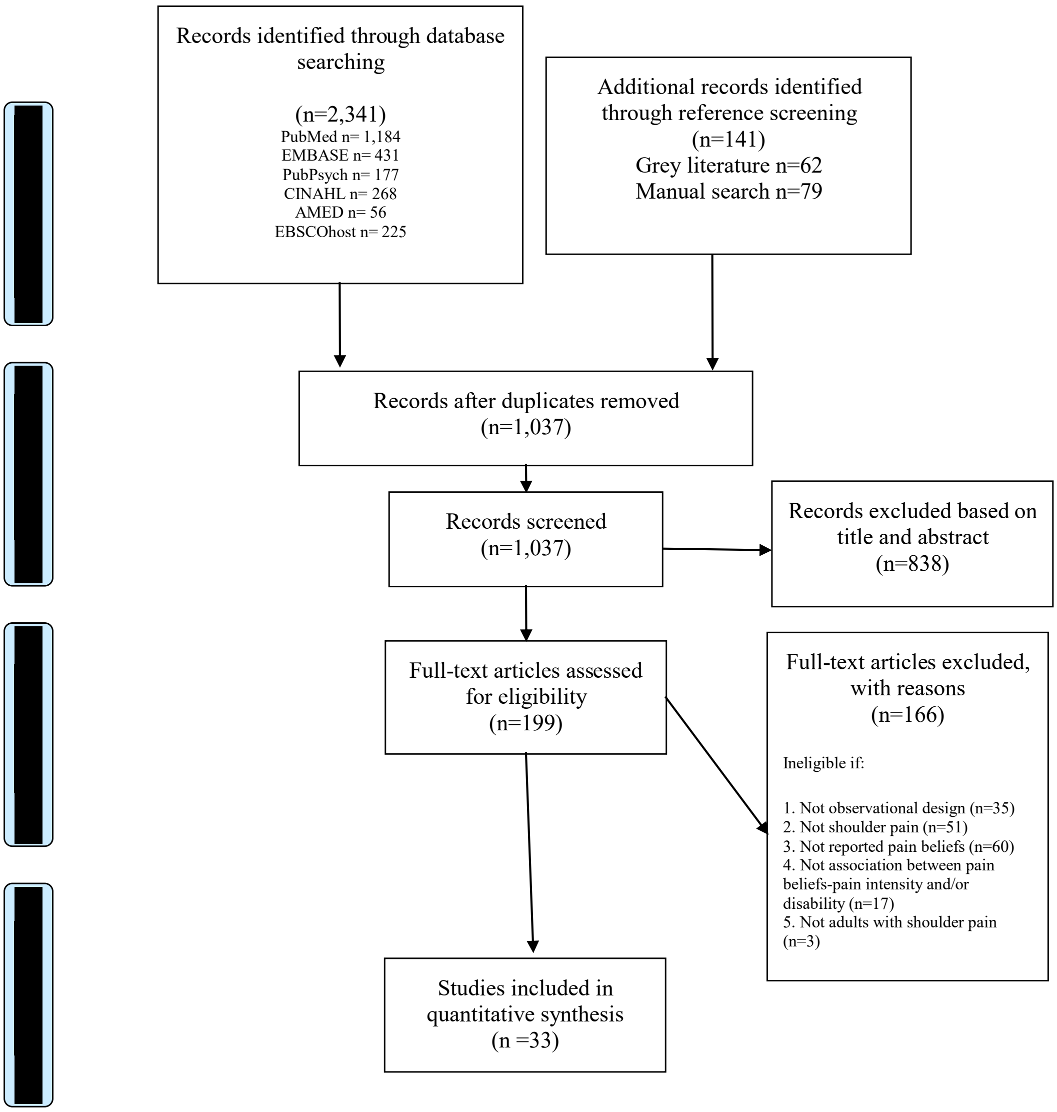
Additionally, two reviewers (JMC and ALS) assessed the overall quality and the strength of the evidence per outcome using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (158). In brief, the GRADE classification was conducted according to the presence, or not, of the following identified factors: (i) risk of bias, (ii) inconsistency of results (iii) indirectness, (iv) imprecision, and (v) other considerations (e.g. reported bias). Review Manager (RevMan) version 5.3 (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) software was used along the review to process data.

4.4 Results

4.4.1 Study characteristics

A total of 2341 citations were identified through electronic databases, with 141 additional studies identified through reference screening and grey literature. One thousand thirty-seven titles and abstracts were screened with 199 full-text articles being evaluated. The number of studies retrieved from each database and the number of studies excluded in each screening phase are shown in **Figure 3**. The full reference of excluded studies in the last screening (n=166) is reported in **Appendix H**.

Figure 3. Flow diagram of review process.



Of the 199 studies that were evaluated, 33 observational studies (twenty-two longitudinal studies and eleven cross-sectional studies) with a total of 10,293 individuals with SP fulfilled our inclusion criteria and were included in this review (**Appendix I**). The outcome measures included in this review were pain intensity and disability. The pain beliefs assessed, were pain catastrophizing, fear-avoidance, kinesiophobia, expectations of recovery, optimism, self-efficacy, fear of pain, internal and external locus of control, preoperative concerns, and beliefs about preferences of treatment. The characteristics of the included studies are reported in **Appendix I**.

4.4.2 Risk of bias

The risk of bias of included studies varied considerably. The risk of bias assessment of all included studies is presented in **Table 4**. The conflict of interest of included studies is also shown in **Table 4**.

Table 4. Risk of bias assessment for observational studies (The Newcastle Ottawa Scale (NOS) adapted version)

First Author	Year	Selection bias		Performance bias	Detection bias		Information bias		Total score	Conflict of interest of included studies
		A	B	C	D	E	F	G		
Chester et al.	2018	3	3	2	2	0	0	2	12/21	NCI
Clausen et al.	2017	1	0	1	1	3	2	2	10/21	NCI
Coronado et al.	2017	1	0	2	2	2	3	2	12/21	NCI
Ekeberg et al.	2010	1	0	2	2	3	2	2	12/21	NCI
Engebretsen et al.	2010	1	0	3	2	3	2	2	13/21	NCI
George et al. a	2008	1	0	1	2	0	2	2	8/21	NR
George et al. b	2009	1	0	2	2	3	2	2	12/21	NR
Henn et al. a	2007	1	0	2	2	3	2	2	12/21	NR
Henn et al. b	2011	1	0	1	1	0	2	2	7/21	NCI
Jawa et al.	2016	1	0	0	0	3	1	2	7/21	NR
Karlsson et al.	2016	0	0	2	2	3	3	2	12/21	NCI

Kennedy et al. a	2006	1	0	2	2	3	2	2	12/21	NR
Kennedy et al. b	2006	1	0	2	2	3	2	2	12/21	NR
Kindler et al.	2011	1	0	0	1	3	2	2	9/21	NR
Kromer et al.	2014	1	0	2	2	3	3	2	13/21	NR
Laslett et al.	2015	1	0	0	1	0	1	2	5/21	NR
Lentz et al.	2009	1	0	1	2	3	3	2	12/21	NR
Menendez et al.	2015	1	0	0	1	3	2	2	9/21	NCI
Oh et al.	2012	1	0	0	1	3	2	2	9/21	NR
O'Malley et al.	2004	1	0	1	1	2	3	2	10/21	NR
Plath et al.	2018	2	3	0	1	3	1	2	12/21	NCI
Razmjou et al. a	2009	2	1	2	2	3	3	2	15/21	NCI
Razmjou et al. b	2011	2	1	1	2	1	3	2	12/21	NCI
Reilingh et al.	2008	1	0	3	2	0	2	2	10/21	NCI
Sindhu et al.	2012	1	0	2	2	1	3	2	11/21	NR
Styron et al.	2015	1	0	2	1	1	1	2	8/21	NR
Tashjian et al.	2004	1	0	1	1	3	2	2	10/21	NR
Thomas et al.	2004	1	0	0	1	3	1	2	8/21	NR
Valencia et al. a	2011	1	0	0	1	0	3	2	7/21	NCI

Valencia et al. b	2014	1	0	2	2	3	3	2	13/21	NCI
Warth et al.	2013	1	0	0	1	3	1	2	8/21	NR
Van der Windt et al.	2007	1	0	2	2	2	2	2	11/21	NCI
Wolfensberger et al.	2016	1	0	2	2	0	1	2	8/21	NCI

Note: A = Is the source population (cases, controls, cohorts) appropriate and representative of the population of interest?; B = Is the sample size adequate and is there sufficient power to detect a meaningful difference in the outcome of interest?; C = Did the study identify and adjust for any variables or confounders that may influence the outcome?; D = Did the study use appropriate statistical analysis methods relative to the outcome of interest?; E = Is there little missing data and did the study handle it accordingly?; F = Is the methodology of the outcome measurement explicitly stated and is it appropriate?; G = Is there an objective assessment of the outcome of interest?; NCI = No conflict of interest; NR = not reported.

4.4.3 Pain beliefs and pain intensity and/or disability in people with SP: synthesis of the evidence

The overall body of the evidence in terms of risk of bias, inconsistency, indirectness, imprecision, and the presence of potential reported bias after applying the GRADE approach was very low across studies (see **Table 5** for cross-sectional studies and **Table 6** for longitudinal studies). Summarizes of the association between pain beliefs with pain intensity and/or disability according to SP complaints is shown in **Appendix J**. Summarizes of the prognostic role that pain beliefs on pain intensity and disability is reported in **Appendix K**.

Table 5. Summary of findings and Quality of evidence assessment (cross-sectional studies)

Summary of findings			Quality of evidence assessment (GRADE)						
Outcome	No of studies	No. of participants	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Level of evidence	Importance
Fear-avoidance									
Pain intensity	1	90	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Kinesiophobia									
Pain intensity	3	358	Serious[1]	Serious[2]	Serious[3]	Very serious[4]	Undetected [5]	Very low	Critical
Disability	2	299	Serious[1]	No[2]	Serious[3]	Very serious[4]	Undetected [5]	Very low	Critical
Fear of pain									
Pain intensity	2	118	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Pain catastrophizing									
Pain intensity	5	406	Serious[1]	No[2]	Serious[3]	Very serious[4]	Undetected [5]	Very low	Critical

Disability	1	139	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Expectations of recovery									
Pain intensity	3	574	Serious[1]	No[2]	Serious[3]	Very serious[4]	Reported bias [5]	Very low	Critical
Disability	4	813	Serious[1]	Serious[2]	Serious[3]	Very serious[4]	Reported bias [5]	Very low	Critical
Self-efficacy									
Pain intensity	1	139	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Disability	1	139	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical

Note: 1. Randomized trials (lack of allocation concealment; lack of blinding; incomplete accounting of patients and outcomes events; selective outcome reporting bias; other limitations); observational studies (failure to develop and apply appropriate eligibility criteria; flawed measurement of both exposure and outcome; failure to adequate control confounding; incomplete follow-up; non-presence of an unexposed cohort) 2. Point estimates vary widely across studies; confidence intervals show minimal or no overlap 3. Differences in population, differences in how to measure pain catastrophizing, differences in how to measure the outcome, indirect comparison, differences in statistical methods used 4. Optimal information size (OIS) criterion is not met and the sample size is small; OIS criterion is met but the 95% CI around an effect does not exclude 1.0 (wide confidence intervals); 95% CI is not reported 5. Outcome data not included in the predictive model.

4.4.4 The association between pain beliefs and pain intensity (cross-sectional analysis)

The association between pain beliefs and pain intensity based on cross-sectional analyses was explored by ten studies (133,166,199–207). A summary of the association between pain beliefs and pain intensity is shown in **Appendix J**.

4.4.5 The predictive value of pain beliefs on pain intensity (longitudinal analysis)

The predictive value of pain beliefs on pain intensity in people with SP based on longitudinal analyses was explored by fourteen studies (125–131,134,148,161,167,171,176,208). A summary of the prognostic role that pain beliefs paly on pain intensity is reported in **Appendix K**.

4.4.6 The association between pain beliefs and disability (cross-sectional analysis)

The association between pain beliefs and disability in people with SP based on cross-sectional analyses was explored by seven studies (201–203,205,207,209,210). A summary of the association between pain beliefs and disability is shown in **Appendix J**.

4.4.7 The predictive value of pain beliefs on disability (longitudinal analysis)

The predictive value of pain beliefs on disability in people with SP based on longitudinal analyses was explored by twenty studies (125,126,128–133,148,149,160,161,167,171,176,208,211–214). A summary of the prognostic role that pain beliefs play on disability is also reported in **Appendix K**.

Table 6. Summary of findings and Quality of evidence assessment (longitudinal studies)

Summary of findings			Quality of evidence assessment (GRADE)						
Outcome	No of studies	No. of participants	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Level of evidence	Importance
Fear-avoidance									
Pain intensity	4	3,658	Serious[1]	Serious[2]	Serious[3]	Serious[4]	Undetected [5]	Very low	Critical
Disability	5	4,278	Serious[1]	Serious[2]	Serious[3]	No[4]	Undetected [5]	Very low	Critical
Kinesiophobia									
Pain intensity	1	314	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Disability	1	314	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Pain catastrophizing									
Pain intensity	6	1,173	Serious[1]	Serious[2]	Serious[3]	Serious[4]	Undetected [5]	Very low	Critical
Disability	6	1,734	Serious[1]	Serious[2]	Serious[3]	Serious[4]	Reported bias [5]	Very low	Critical

Expectations of recovery									
Pain intensity	5	1,802	Serious[1]	Serious[2]	Serious[3]	Serious[4]	Reported bias [5]	Very low	Critical
Disability	10	3,036	Serious[1]	Serious[2]	Serious[3]	Serious[4]	Reported bias [5]	Very low	Critical
Self-efficacy									
Pain intensity	4	1,297	Serious[1]	Serious[2]	Serious[3]	No[4]	Reported bias [5]	Very low	Critical
Disability	3	1,240	Serious[1]	Serious[2]	Serious[3]	No[4]	Reported bias [5]	Very low	Critical
Internal and external locus of control									
Pain intensity	1	587	Serious[1]	No[2]	No[3]	Serious[4]	Undetected [5]	Very low	Critical
Disability	1	587	Serious[1]	Very serious[2]	No[3]	Very serious[4]	Reported bias [5]	Very low	Critical
Optimism									
Pain intensity	1	78	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical
Disability	1	78	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical

Preoperative concerns									
Disability	1	128	Serious[1]	No[2]	No[3]	Very serious[4]	Reported bias [5]	Very low	Critical
Beliefs about preferences of treatment									
Disability	1	207	Serious[1]	No[2]	No[3]	Very serious[4]	Undetected [5]	Very low	Critical

Note: 1. Randomized trials (lack of allocation concealment; lack of blinding; incomplete accounting of patients and outcomes events; selective outcome reporting bias; other limitations); observational studies (failure to develop and apply appropriate eligibility criteria; flawed measurement of both exposure and outcome; failure to adequate control confounding; incomplete follow-up; non-presence of an unexposed cohort) 2. Point estimates vary widely across studies; confidence intervals show minimal or no overlap 3. Differences in population, differences in how to measure pain catastrophizing, differences in how to measure the outcome, indirect comparison, differences in statistical methods used. 4. Optimal information size (OIS) criterion is not met and the sample size is small; OIS criterion is met but the 95% CI around an effect does not exclude 1.0 (wide confidence intervals); 95% CI is not reported 5. Outcome data not included in the predictive model.

4.5 Discussion

The objective of this review was twofold: (i) to explore the association (cross-sectional analysis) between pain beliefs with pain intensity and/or disability and, (ii) to analyse the prognostic role (longitudinal analysis) that pain beliefs play on pain intensity and/or disability in individuals with SP. Cross-sectional analyses reported that: (i) higher levels of pain catastrophizing and kinesiophobia were significantly associated with more pain intensity and disability; (ii) higher levels of expectations of recovery and self-efficacy were significantly associated with lower levels of pain intensity and disability; (iii) there was no statistical significant association between fear of pain and fear-avoidance with pain intensity. The overall body of the evidence after applying the GRADE approach was very low for all the associations. Longitudinal analyses reported that: (i) higher levels of pain catastrophizing at baseline predicted the course of pain intensity and disability; (ii) higher levels of fear-avoidance and kinesiophobia at baseline predicted the course of disability; (iii) higher levels of self-efficacy and expectations of recovery at baseline predicted a reduction of the levels of pain intensity and disability overtime; (iv) there was inconsistency of the results in the predictive value of fear-avoidance on pain intensity; (v) kinesiophobia, optimism, and internal and external locus of control did not predict significant changes in pain intensity; (vi) internal and external locus of control, preoperative concerns, optimism, and beliefs about treatment did not predict significant changes in disability. The overall body of the evidence after applying the GRADE approach was very low for all the relationships.

4.5.1 Comparison with other studies

To our knowledge, this is the first synthesis of the evidence exploring the association and the predictive value that pain beliefs play on pain intensity and/or disability in individuals with SP. Our findings are in accordance with the fear-avoidance model of pain (109). In brief, this model hypothesised that people who show negative beliefs about pain (e.g. catastrophic thoughts) prior to an injury, give a misleading appreciation to its pain experience. This affect the way in which they respond to pain in terms of functional status, adaptation, and development of disability (215). Avoidance behaviours are considered as a normal response against to a stressful event in acute stage (146).

However, recent reviews have shown that the presence of pain beliefs such as fear or pain catastrophizing cause maladaptive escape behaviours, even in acute stage, favouring the transition from acute to chronic pain (110,111,216–218). The brain creates pain as an alarm signal in order to warn to specific body regions of a potential threat (219). Pain beliefs also play a role disturbing certain brain region associated with the processing and attention of pain (100). Therefore, it seems presumable that fearful and catastrophic individuals with SP could have more probability of avoiding certain movements due to the erroneous belief that these activities will cause a potential or real injury/re-injury (123,203).

In this sense, different hypothesises suggest that if an individual with SP shows fear and catastrophize while executing certain activities, this individual will have more risk to develop pain, disability and depression (166,199,220–222). However, our results also showed that if an individual with SP has higher levels of positive pain beliefs such as expectations of recovery and self-efficacy (longitudinal analysis), he/ she will have greater probability to confront their pain experience, which will favour a positive trajectory of recovery (lower levels of pain intensity and disability).

Supporting our results, several reviews have explored the importance of pain beliefs in other musculoskeletal conditions (103,112,119,142,223). Main et al. (142) concluded that pain beliefs such as pain catastrophizing or self-efficacy are a noteworthy part not only in the processing of pain, but also in how people with back disorders respond that pain. Sullivan et al. (223) showed how pain beliefs (e.g. perceived injustice) reduce favourable trajectories of recovery after a whiplash injury. Jia & Jackson (112) reported moderate evidence about the relationship between pain beliefs (e.g. helplessness) and disability, pain severity, and emotional distress. In a recent systematic review, Martinez-Calderon et al. (119) reported that high levels of self-efficacy are associated with low pain intensity and disability in people with chronic musculoskeletal pain.

Despite the guiding results of this and previous reviews (103,112,119,142,223) about the potential association and predictive value of pain beliefs on pain intensity and/or disability in musculoskeletal pain, the overall body of the evidence in the present review after applying the GRADE approach was very low. Therefore, the obtained findings should be interpreted with caution. Several reasons could specifically explain the inconsistency of the results. First, pain intensity may play a moderator role in the relationship between pain beliefs (e.g. pain catastrophizing) and pain-related outcomes, such as pain interference and physical health status, which could drive to avoidance, hypervigilance and physical inability (185,224). This could explain the inconsistency of the results showed in this review when certain negative beliefs such as fear-avoidance were associated with the outcome (pain intensity and disability). Second, multiple pathways are related to the development and perpetuation of pain-related disability. It exists a broad variability in terms of duration of episodes, fluctuations of pain intensity, severity of pain, social and contextual factors, as well as the biopsychosocial profile of every person with musculoskeletal pain (88,225). Thus, it is questionable to think that an individual with SP will develop disability in the simplistic pathway proposed in the fear-avoidance model of pain (225).

4.5.2 Strengths and weaknesses of the study

The strengths of this review included: (i) the use of a pre-specified protocol registered on PROSPERO; (ii) the current guidelines to conduct a systematic review (the Cochrane Handbook for Systematic Reviews Version 5.1.0 and the PRISMA checklist) and; (iii) the use of specific review tools to evaluate the risk of bias and the overall body of the evidence. Likewise, there are some limitations that should be mentioned: (i) some pain beliefs are quite broad in definition. It may increase the risk of inconsistency of the results; (ii) risk of bias was found in most of included studies (see **Table 7**). This could limit the findings of the present systematic review; (iii) the causality and the impact of pain beliefs in pain intensity and disability in this population cannot be determined due to the observational nature of the included studies (cross-sectional and cohort studies without a non-exposed cohort) (iv) some shoulder presentations (e.g. traumatic); were not considered in our search strategy, giving rise to the possible missing of potential articles; (v) despite the post-traumatic stress disorder profile is considered a relevant factor in other musculoskeletal conditions, e.g. whiplash, this profile was not considered as inclusion criteria in the present review; (vi) finally, our conclusion should be interpreted with caution. This is due to the overall body of the evidence after applying the GRADE approach showed very low evidence across studies.

4.5.3 Clinical implications

Pain catastrophizing and fear are considered potential barriers to achieve successful results after applying a therapy (110,111,217,218,226). On the other hand, self-efficacy (188) and expectations of recovery (148) have been shown to facilitate adherence to treatment, which favours the consecution of better outcomes. Interestingly, both (negative and positive pain beliefs) are also known for being modifiable factors (188,189). In that point, our results suggest that people with SP who catastrophize in response to pain, can do it even without much disability, or that people with SP might have substantial fear of movement and avoidance activities, but low levels of pain.

In this sense, clinicians should consider pain beliefs as potential factors during the anamnesis as they may influence the course of pain intensity and disability. However, despite these guiding results, due to the very low evidence of our findings, more longitudinal studies using higher quality study designs and procedures would be needed before advising clinicians whether these modifiable variables can influence specifically pain intensity and disability in individuals with SP.

4.5.4 Future research

The results of the present study may have been influenced by flaws observed in most of the observational studies included in this review. Hence, there are some recommendations to guide future research: (i) further longitudinal studies (including a non-exposed group) analysing prospectively the predictive value of pain beliefs on pain intensity and/ or disability in the transition from acute to chronic SP, and the perpetuation of shoulder chronicity, are needed; (ii) studies focusing on the modification of these factors through biopsychosocial approaches are required to draw causal conclusions; (iii) warranted to help inform development of clinical prediction rules for improvement in prognosis, that encompass biological, psychological and contextual domains.

4.6 Conclusion

This systematic review provided information about the association and the predictive value of pain beliefs on pain intensity and/or disability in individuals with SP. In the cross-sectional analysis, higher levels of pain catastrophizing and kinesiophobia were significantly associated with more pain intensity and disability, whereas higher levels of expectations of recovery and self-efficacy were significantly associated with lower levels of pain intensity and disability. In the longitudinal analysis, higher levels of pain catastrophizing at baseline predicted greater pain intensity and disability overtime. Higher levels of fear-avoidance and kinesiophobia at baseline predicted greater disability during the course of SP. Higher levels of self-efficacy and expectations of recovery at baseline predicted a reduction in levels of pain intensity and disability overtime. In this sense, clinicians should consider pain beliefs as potential factors during the anamnesis as they may influence the course of pain intensity and disability. However, the overall body of the evidence after applying the GRADE approach was very low across studies. Further research using higher quality longitudinal designs and procedures would be needed to establish firm conclusions.

CHAPTER V

INFLUENCE OF PSYCHOLOGICAL FACTORS ON THE PROGNOSIS OF CHRONIC SHOULDER PAIN: PROTOCOL FOR A PROSPECTIVE COHORT STUDY

Open Access Protocol

BMJ Open

Influence of psychological factors on the prognosis of chronic shoulder pain: protocol for a prospective cohort study

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ABSTRACT

Introduction: Shoulder pain is a highly prevalent condition. Psychological factors could play an essential role in the prognosis of chronic shoulder pain (CSP). The aims of the study will be to analyse the level of association between psychological factors and pain-disability at baseline and prospectively to assess their prognostic role; to evaluate the association of pain catastrophising and kinesiophobia at baseline and prospectively in the relationship between pain intensity and disability, or between self-efficacy and disability in patients with CSP; to explore the association of self-efficacy at baseline and prospectively in the relationship between pain intensity and disability, in comparison with kinesiophobia and pain catastrophising.

Methods and analysis: The study is a longitudinal, prospective cohort study with a 12-month follow-up. It will be conducted in 4 primary-care centres and one hospital of the province of Malaga, Spain. 307 participants aged between 18 and 70 years suffering from CSP (3 months or more) will be included. Primary outcomes will include pain, disability and self-efficacy, whereas kinesiophobia, pain-related fear, pain catastrophising, anxiety, depression, patient expectations of recovery, age, gender, duration/intensity of symptoms, educational level and other factors will be predictive measures. Follow-up: baseline, 3, 6 and 12 months.

Ethics and dissemination: The local ethics committee (The Costa del Sol Ethics Committee, Malaga, 28042016) has approved this protocol. Dissemination will occur through presentations at National and International conferences and publications in international peer-reviewed journals.

Trial registration number: NCT02738372; pre-results

Strengths and limitations of this study

- The inclusion of a long battery of psychological factors evaluating their role in the prognosis of chronic shoulder pain.
- The exploration of the mediating power of self-efficacy, kinesiophobia and pain catastrophising in chronic shoulder pain.
- The inclusion of self-efficacy as an outcome measure.
- Some psychological factors such as pain acceptance and psychological distress will be not included in this study.
- Another limitation could be that some psychological factors are quite broad in definition, increasing the risk on finding conflicting evidence on their relationship with outcomes.

INTRODUCTION

Shoulder pain is the third most common musculoskeletal condition presenting to physicians or physiotherapists[1] in primary health-care after low back and neck pain,[2 3] being a significant cause of morbidity,[4] and functional disability in both working[5 6] and general population.[6–8] It affects one in three adults,[7 9 10] accounting 1% of general practitioners' (GPs) consultations in primary care.[11]

Incidence rates range from 11.2 to 29.5 per 1000 person-years,[11–14] and the reported prevalence rates range from 4.7 to 46.7 per 1000 person-years.[10 14 15] Incidence and prevalence rates tend to increase with age,[16] in women,[10 16 17] in persons from lower socioeconomic groups, and in psychologically stressed populations.[18]

Despite the large group of individuals seeking for primary-care services, about 50% of patients with shoulder pain still report persistent pain after 12 months.[9 16 18 19] As a result, socioeconomic burdens are considerable due to extensive use of heath care services, sickness absence, disability pension and loss of productivity,[20–24] as well as patient's suffering.

That is why there is a consensus in the field that research efforts need to be focused on obtaining insight into which prognostic factors play the most important roles in

5.1 Introduction

Shoulder pain is the third most common musculoskeletal condition presenting to physicians or physiotherapists (87) in primary healthcare after low back and neck pain (227,228), being a significant cause of morbidity (229), and functional disability in both working (230,231) and general population (231–233). It affects one in three adults (232,234,235), accounting 1% of general practitioners' consultations in primary care (138). Incidence rates range from 11.2 to 29.5 per 1000 person-years (72,138,236,237), and the reported prevalence rates range from 4.7 to 46.7 per 1000 person-years (72,190,235). Incidence and prevalence rates tend to increase with age (74), in women (74,235,238), in persons from lower socioeconomic groups, and in psychologically stressed populations (136). Despite the large group of individuals seeking for primary-care services, about 50% of patients with SP still report persistent pain after 12 months (74,136,234,239).

As a result, socioeconomic burdens are considerable due to extensive use of health care services, sickness absence, disability pension and loss of productivity (240–244), as well as patient's suffering. That is why there is a consensus in the field that research efforts need to be focused on obtaining insight into which prognostic factors play the most important roles in chronic SP, and how those factors impact on pain and function, as this understanding is crucial to acquire a clear comprehension of all the process involved in chronic SP and to underline pain-treatment effects in seeking to improve the poor prognosis of this entity. Chronic SP is a complex syndrome, and pain chronicity often cannot be explained (solely) by an obvious anatomic defect or tissue damage (245).

A recent review (246) exposed that the effective management of SP relies on a detailed knowledge of peripheral pathology (e.g. adhesive capsulitis, superior labrum anterior to posterior lesion or rotator cuff tendinopathy), as well as on a comprehensive understanding of how pain can be generated, propagated and modified. In this sense, there has been a growing recognition that the degree of chronic pain is influenced by the beliefs, attitudes and expectations of individuals (28,247,248). Given the importance of pain as a mechanism of survival, it is perhaps unsurprising that pain perception is clearly influenced by conscious and unconscious memory, cognitive and emotional functioning and contextual factors that are explicitly included in a biopsychosocial formulation of pain (249). Inside of the biopsychosocial understanding of chronic pain, there is a growing interest, and acceptance in hypothesising that the association between physical impairment, pain intensity and pain-related disability is only moderate, and that psychological factors may influence the experience of pain and its impact and hence may play a crucial role in the maintenance of pain-related problems (28,250).

Currently, some evidence has shown how psychological factors could be associated with the prognosis of chronic SP (125,130,150). Reilingh et al. (125) investigated the course and prognosis of SP in the 6 first months after presentation to the general practitioners. Predictors of a better outcome for chronic SP were lower scores on pain catastrophizing and higher baseline pain intensity (explained variance 21%) (125). Gill et al. (150) examined which factors are predictive of incident, recurrent or resolved SP in a community-based sample from the general population. Findings showed how recurrent SP was associated with depressive symptoms (150). Chester et al. (130) aimed to identify which baseline patient and clinical characteristics are associated with a better outcome, 6 weeks and 6 months after starting a course of physiotherapy for SP. In this study, higher patient expectation of complete recovery compared to slight improvement because of physiotherapy and higher pain self-efficacy were associated with patient-rated outcomes (130).

Therefore, it seems presumable that psychological factors could play a role in people with SP and favour the perpetuation of chronic SP. Self-efficacy has been proposed to predict pain, pain behaviour, physical functioning and disability in chronic musculoskeletal pain (251,252). Furthermore, self-efficacy is considered a stronger mediator of the relationship between pain behaviour, pain intensity and disability than psychological factors such as kinesiophobia and pain catastrophizing (253–255). However, the role of self-efficacy as an outcome measure and as mediator in chronic SP has not been studied yet. Knowing and understanding which psychological factors are specifically involved in the prognosis of chronic SP is challenging to facilitate clinical decision-making and, if necessary, timely, and specific consultation with—or referral to—other healthcare providers (256).

There are four hypotheses in the present study. First, higher levels of psychological factors at baseline and prospectively such as kinesiophobia, pain-related fear, depression, anxiety, patient expectations of recovery and pain catastrophizing are associated with a higher level of pain intensity, and disability, and lower level of self-efficacy. Second, pain catastrophizing and/or kinesiophobia mediate the relationship between pain intensity and disability, or between self-efficacy and disability at baseline. Third, changes in pain catastrophizing and/or changes in kinesiophobia mediate the relationship between changes in pain intensity and changes in disability, or changes in self-efficacy and changes in disability after 12-month follow-ups. Fourth, self-efficacy is the strongest mediator in the relationship between pain intensity and disability at baseline and prospectively.

5.2 Objectives

The aims of the present study will be: (1) to analyse the level of association between psychological factors and pain-disability at baseline and prospectively to assess their prognostic role; (2) to evaluate the association of pain catastrophizing and kinesiophobia at baseline and prospectively in the relationship between pain intensity and disability or between self-efficacy and disability in patients with chronic SP; (3) to explore the association of self-efficacy at baseline and prospectively in the relationship between pain intensity and disability, in comparison with kinesiophobia and pain catastrophizing.

5.3 Methods

5.3.1 Study design and setting

The present study will be a 12-month multicentre, prospective, cohort study that will be carried out between May 2016 and April 2017 in four primary-care centres and one hospital of the province of Malaga, Spain. Several questionnaires assessing different psychological factors will be administrated to these participants. The outcomes will be assessed at baseline (t1) and at 3 follow-ups times (after 3 (t2), 6 (t3) and 12 months (t4)). Ethical approval has been obtained from Costal del Sol Ethics Committee, Malaga, Spain (28042016). The study will be implemented and reported in line with the stands for Standard Protocol Items: Recommendations for Interventional Trials statement.

5.3.2 Participants

A consecutive sample comprised participants with chronic SP will be recruited through physiotherapists from four primary care centres. Physiotherapists, who will be previously instructed by the research team, will screen participants for eligibility. Participants meeting the eligibility criteria will be invited to participate in this study. They will be evaluated at baseline and 3, 6- and 12-months' follow-up.

The inclusion criteria will be:

(i) At least 18-year-old participants.

(ii) Chronic SP (with a pain duration for more than three months) according to the multidimensional diagnostic criteria for chronic pain (257).

(iii) SP defined as subacromial pain syndrome (impingement signs (Neer's, Hawkins, Jobe's tests); painful arc; pain with isometric resistance; weakness; atrophy (tear)) (86).

(iv) SP defined as adhesive capsulitis (spontaneous progressive pain; loss of motion in multiple planes: external rotation most limited; pain at end-range of motion) (86).

(v) SP defined as glenohumeral instability (age usually < 40 years old; history of dislocation or subluxation; apprehension test; relocation test; generalized laxity) (86).

(vi) SP due to other common diagnoses such as rotator cuff tendinopathy, superior labral anterior posterior lesion, acromioclavicular pathology and/or shoulder osteoarthritis and non-specific SP.

Diagnosis were carried out by physiotherapists with 15 years of working experience through clinical tests based on the recommendations of McClure & Michener (86). Magnetic resonance imaging scan and ultrasound examination were conducted by medical doctors in order to discard any potential rotator cuff tears.

The exclusion criteria were:

(i) SP due to systemic diseases such as rheumatoid arthritis.

(ii) SP due to neurological diseases or injuries such as stroke.

(iii) SP originated from the cervical region.

(iv) Participants with SP after post fracture.

(v) Individuals with SP receiving/planned for shoulder surgery.

(vi) Inability to provide informed consent and/or complete written questionnaires.

5.3.3 Procedures: Recruitment

Anonymised age and gender details will be collected for those participants who decline to take part in the project, to assess the external validity of the recruited sample of participants. Eligible participants who will be interested in the study will be asked to provide written informed consent to participate (**Appendix L**). Participants will then complete several questionnaires at baseline, 3, 6 and 12 months after the beginning of the study. Participant data files will be stored in numerical order and in a secure and accessible place and manner. Participant files will be maintained in storage for a period of 3 years after completion of the study.

5.3.4 Outcomes measures

Outcome measures and some of the potential prognostic factors will be measured at baseline and prospectively, with the aim of observing possible associations between potential prognostic factors and pain disability, and self-efficacy at baseline, and prospectively to assess their prognostic role, and if some of them appear as confounding factors.

- **5.3.4.1 Primary Outcome-Pain and function**

The Shoulder Pain and Disability Index (SPADI) is a self-administered index consisting of 13 items divided into two subscales: pain and disability (258). It grades a normal shoulder as 0 and maximally affected as 130, and an 11-point numerical pain rating scale with 0 as normal and 10 as maximal pain. The Spanish version of SPADI, which has been validated for use in Spanish language, was used (259).

- **5.3.4.2 Secondary Outcome-Pain Self-efficacy**

Pain Self-Efficacy Questionnaire (PSEQ) contains 10 questions that will measure the patient's confidence in performing certain activities despite pain. Items are scored on a scale from 0 to 6, with a maximum possible score of 60 points. Lower scores indicate less self-efficacy (120).

- **5.3.4.3 Potential prognostic factors**

Psychological factors will be assessed through four questionnaires at baseline, 3, 6, and 12 months follow-up.

(i) Pain related-fear and kinesiophobia: The Fear-avoidance Components Scale (FACS) is a new patient-reported measure designed to evaluate pain-related fear and kinesiophobia in patients with painful medical conditions. It consists of 20 items that are scored on a 5-point scale (260).

(ii) Pain catastrophizing: The Pain Catastrophizing Scale (PCS) will be included to assess catastrophic thinking about pain. It consists of 13 items describing different thoughts and feelings that individuals may have when experiencing pain. Items are scored on a 5-point scale. A general score and scores on three subscales (e.g. helplessness, magnification and rumination) will be obtained; higher scores indicate more severe catastrophic thoughts about pain (118). The Spanish version of PCS was used (261).

(iii) Anxiety and depression: The Hospital Anxiety and Depression Scale (HADS) is a 14-item scale designed to detect anxiety and depression, independent of somatic symptoms. It consists of two 7-item subscales measuring depression (HADS-D) and anxiety (HADS-A). It uses a 4-point response scale that ranges from 0 (absence of symptoms) to 3 (maximum symptoms), with possible scores for each subscale ranging from 0 to 21 (262). Higher scores indicate higher levels of disorder. The HADS has been widely used as a screening instrument for the detection of comorbid depressive and anxiety disorders in patients with musculoskeletal disorders (262–264). The Spanish version of HADS was used (265,266).

(iv) Patient expectations of recovery will be measured by asking the participants to rate the likelihood that they would resume some form of recovery at 3, 6- and 12-months' follow-up ("How likely is it that within the next 3 months you will have resumed some form of recovery?"). Participants will indicate their response on a scale with the end points (0%) not at all likely to (100%) extremely likely (267).

- **5.3.4.4 Other potential prognostic factors**

(i) Side of shoulder problem (right, left and both) will be coded into three levels: right; left and both.

(ii) Shoulder dominance (right, left and ambidexterity) will be coded into three levels: right; left and ambidexterity.

(iii) History of previous shoulder problems will be measured with a yes/no question.

(iv) Current treatment will be evaluated through a checklist divided in five groups: no treatment; pharmacological treatment; injections; physical therapy and other treatments (massage, reflexology, acupuncture).

(v) Being convinced of this pathology will be measured with a yes/no question.

(vi) Active shoulder range of motion-free of pain will be measured with a manual inclinometer placed in the affected shoulder.

(vii) Comorbidities will be tested with the Self-Administered Comorbidity Questionnaire (SCQ) (268). Patients will be asked if they had one or more medical conditions (from a list of 15 diagnoses). If they gave a positive response, they will be asked whether the condition limited their activity.

(viii) Recurrence of shoulder problem was dichotomised to those patients who had a recurrent episode within the past 12 weeks and those who had a recurrent episode more than 12 weeks. With a simple answer: yes/no.

(ix) The Numerical Rating Scale (NRS) was used to assess each patient's pain intensity at baseline and follow-ups. The NRS scores range from 0 to 10, with 0 representing no pain and 10 representing the worst pain imaginable. The NRS has been shown to have good same-day test–retest reliability (269).

(x) Work status will be coded into five categories of work: (i) unemployment; (ii) sick leave; (iii) retirement; (iv) housewife and (v) active worker.

(xi) Work absenteeism will be measured by the following sentence: how many days (if any) within the previous 4 weeks' care workers had not attended work due to feeling ill and unfit for work. Respondents answered by number of days. Numbers were then grouped into three categories (0=0 days, 1=1–2 days, 2=3 or more days) (270).

(xii) Work performance will be measured by the Word Health Organization Health and Work Performance Questionnaire (HPQ) through the following sentence: How would you rate your overall job performance on the days you worked during the past 4 weeks (28 days)?; responses used a scale ranging from 0 to 10, with higher scores indicating higher work performance in the previous 4 weeks (271).

(xiii) Educational level will be coded into five educational levels: university/college ≥4 years; university/ college 4 years; upper secondary; elementary secondary and no studies (272).

(xiv) Gender, age, height and weight will be reported by self-reported questionnaire.

The summary of potential prognostic factors and outcome measures is presented in **Table 7**.

Table 7. Overview of measurement instruments and time of assessment

Construct	Type	Staff Member	Baseline (T1)	3 months (T2)	6 months (T3)	12 months (T4)
Outcome Measure						
Pain and Function	SPADI	Interviewer	X	X	X	X
Pain self-efficacy	PSEQ	Interviewer	X	X	X	X
Shoulder Problems						
Side of shoulder problem (i) right; (ii) left; (iii) both.	Self-reported questionnaire	Interviewer	X			
Shoulder dominance (i) right; (ii) left; (iii) ambidexterity	Self-reported questionnaire	Interviewer	X			
History of previous shoulder problems	Self-reported questionnaire (yes/no)	Interviewer	X			
What modality of treatment? ((i) no treatment; (ii) pharmacological treatment; (iii) injections; (iv) physical therapy; (v) other treatments (massage, reflexology, acupuncture)	Self-reported questionnaire	Interviewer	X	X	X	X
Have you been convinced of this pathology?	Self-reported questionnaire (yes/no)	Interviewer	X	X	X	X
Potential Prognostic Factors						
Pain-related fear and kinesiophobia	FACS	Interviewer	X	X	X	X
Pain catastrophizing	PCS	Interviewer	X	X	X	X

Active shoulder range of motion-free of pain	Manual Inclinometer	Interviewer	X	X	X	X
Anxiety and depression	HADS	Interviewer	X	X	X	X
Patient's expectations of recovery	Self-reported question (0-100%)	Interviewer		X	X	X
Comorbidities	SCQ	Interviewer	X	X	X	X
Recurrence of shoulder pain	Self-reported questionnaire (yes/no)	Interviewer	X			
Intensity of pain	NRS	Interviewer	X	X	X	X
Work status ((i) unemployment; (ii) sick leave; (iii) retirement; (iv) housewife; (v) active worker)	Self-reported questionnaire	Interviewer	X	X	X	X
Work absenteeism	Self-reported questionnaire	Interviewer	X	X	X	X
Work performance	Question obtaining of HPQ	Interviewer	X	X	X	X
Age and gender	Self-reported questionnaire	Interviewer	X			
Height and weight	Self-reported questionnaire	Interviewer	X			
Educational level: (i) university/college ≥4 years; (ii) university/college 4 years; (iii) upper secondary; (iv) elementary secondary; (v) no studies	Self-reported questionnaire	Interviewer	X			

Note: FACS, Fear-avoidance Components Scale; HADS, Hospital Anxiety and Depression Scale; NRS, Numerical Rating Scale; PCS, Pain Catastrophizing Scale; PSEQ, Pain Self-Efficacy Questionnaire; SCQ, Self-Administered Comorbidity Questionnaire.

5.3.5 Sample size estimation

To contrast the null hypothesis that six potential prognostic factors (kinesiophobia, pain-related fear, pain catastrophizing, anxiety-depression, age and gender) included in the estimation does not explain the primary outcome, ANOVA-test in a multiple linear regression model will be used, considering a significance level of 0.05, and a statistical power of 0.9, assuming that one variable (anxiety-depression (130)) provides a coefficient of determination of 0.31, and for a higher coefficient of 0.36, a sample of 230 patients will be needed. Assuming an expected drop-out rate of 25%, a total number of 307 patients will be needed.

5.3.6 Statistical analysis

Data set will be carried out using SPSS for Windows (V.22; SPSS, Chicago, IL). There will be four measurements in the study, T1=at baseline, T2=3 months, T3=6 months, T4=12 months' follow-up. Kolmogorov– Smirnov test will be used to analyse the normal distribution of the variables ($p>0.05$). Continuous variables will be presented through centrality measures (mean, median), and dispersion (SD and IQR), and categorical variables through frequencies and percentages. Rank sums, Wilcoxon signed Rank test, Mann–Whitney U test and Friedman's test will be used depending on the comparisons to be made, in case of non-normal distribution of variables. For the identification of potential prognostic factors, the psychological variables (kinesiophobia, pain-related fear, pain catastrophizing, anxiety, depression and patient expectations of recovery) and sociodemographic characteristics (age, gender, height, weight, shoulder problems, work status, work absenteeism, work performance, intensity of pain, active shoulder range of motion-free of pain, educational level, treatments received and comorbidities) will be introduced as predictors in a multiple linear regression analysis, taking SPADI as continuous dependent variable. Finally, analysis through COX regression will be conducted to determine the HRs of the aforementioned factors with the presence of pain and disability (using SPADI values to determine this state), through proportional hazard models. A p-value<0.05 will be considered statistically significant.

5.3.7 Data collection and management

To ensure accurate, complete and reliable data, all study related information will be stored securely at the study site. All participant information will be stored in locked file cabinets in areas with limited access. A coded ID number will identify reports, data collection, process and administrative forms only to maintain participant confidentiality.

5.3.8 Modification of the protocol

Any modifications to the protocol that may affect the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes and study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed on by this research group and approved by Costa del Sol Ethics Committee, Malaga, Spain, prior to implementation and notified to the health authorities in accordance with local regulations.

.3.9 Dissemination

The trial is registered in Clinicaltrials.gov: NCT02738372. The results of the study will be disseminated at several research conferences and as published articles in peer-reviewed journals.

5.4 Discussion

The present study will be the first study analysing the role of a long battery of psychological factors (pain-related fear, kinesiophobia, anxiety, depression, patient expectations of recovery and pain catastrophizing) in the prognosis of chronic SP. Previous studies (125,130,150,174,175) have evaluated the influence of several psychological factors on the prognosis of chronic SP. Macfarlane et al. (174) showed how higher levels of psychological distress predicted perpetuation of chronic SP. Badcock et al. (175) reported association between disability and psychological distress after controlling for possible confounders. Reilingh et al. (125) exposed how higher levels of pain catastrophizing predicted recurrence of symptoms in chronic SP. Gill et al. (150) showed how recurrent SP was associated with depressive symptoms. Chester et al. (130) reported how higher patient expectation of complete recovery compared to slight improvement as a result of physiotherapy and higher pain self-efficacy were associated with patient-rated outcomes. These previous studies support the necessity of carrying out the present study, but also the inclusion of several psychological factors, which have not been already evaluated on the prognosis of chronic SP, such as pain-related fear, kinesiophobia and anxiety, justifying the development of this cohort study, because it seems presumable that psychological factors may play an essential role along with biomedical and/or biomechanical factors in the perpetuation of chronicity in patients with chronic SP. Besides that, this will be the first study evaluating self-efficacy as an outcome measure in shoulder region.

Previous studies have explored how psychological factors influence self-efficacy in chronic musculoskeletal conditions (273) and how several therapeutic strategies could improve this psychological construct (274,275). Therefore, the inclusion of self-efficacy as an outcome in this study could be reasonable, because this construct is based on how a person's perceived confidence in the ability of successfully carrying out daily and/or work activities or behaviour despite the pain (276) and people with chronic SP usually have to do many tasks that implicate the movement of their shoulders. That is why, detecting possible factors which contribute to improve or reducing effects of self-efficacy in people with chronic SP may give rise to benefits for this population.

5.4.1 Strengths and weaknesses of the study

The strengths of this study will include a long battery of psychological factors evaluating their role in the prognosis of chronic SP, the exploration of the mediating power of self-efficacy, kinesiophobia and pain catastrophizing in chronic SP, the inclusion of self-efficacy as an outcome measure and the use of the stands for Standard Protocol Items: Recommendations for Interventional Trials checklist to give more quality to the study. The limitations associated with this study must be acknowledged when interpreting the results. First, information bias could be an important limitation of this study. Some participants may have problems to deal with the questionnaires and remember any situation associated with their pain and disability at 3, 6- and 12-months' follow-up. Even so, some participants might be more likely to deny participation or abort follow-up. However, adding a drop-out rate of 20% in sample size calculation should alleviate this risk. Furthermore, some psychological factors such as pain acceptance and psychological distress will be not included in this study, because it takes too much time to carry out all the self-reported questionnaires, and participants may not respond clearly. Another limitation could be that some psychological factors are quite broad in definition, increasing the risk on finding conflicting evidence on their relationship with outcomes.

5.4.2 Clinical and research implications of study findings

The early identification of which psychological factors have higher predictive value in people with chronic SP may assist clinicians in decision-making, and timely and specific consultations with—or referral to—other healthcare providers, and to researchers in exploring which psychological factors could be the most predictive power in shoulder region, giving rise to the possibility to steer treatments. That is why clinicians should be encouraged to identify patients with chronic SP who show psychological symptoms in the preliminary assessment, as this approach might increase the possibility to consider other therapeutic interventions rather than physical therapies for chronic SP, for example, pain neuroscience education.

5.4.3 Future research

Further studies analysing prospectively the influence of psychological factors on the prognosis of chronic SP including several factors such as pain acceptance, psychological distress and/or coping with pain are needed. As chronic SP is a complex multifactorial condition, future investigations should consider the combination, and interaction of a cluster of factors to increase their predictive value, and to determine the importance of each factor. Even though the effect caused by psychological factors on the prognosis of chronic SP could be relevant, further research evaluating the effects of these factors on the prognosis of chronic SP, and the possible mediating power of these factors in this entity, as well as their clinical usefulness is required.

5.5 Conclusion

Despite the neuroanatomical and biomechanical basis of SP is interminable and not completely understood, this prospective cohort study may contribute to a new vision about the role played by pain-related fear, kinesiophobia, anxiety, depression and pain catastrophizing in the prognosis of chronic SP, and how self-efficacy, kinesiophobia and pain catastrophizing mediate the relationship between symptoms, increasing the body of knowledge in this field.

CHAPTER VI

ASSOCIATION BETWEEN CLINICAL PAIN AND EXPERIMENTAL PAIN SENSITIVITY WITH PSYCHOLOGICAL FACTORS IN CHRONIC SHOULDER PAIN: A CROSS-SECTIONAL STUDY

6.1 Introduction

Shoulder pain (SP) is a very common musculoskeletal disorder (190), leading to functional disability (277,278) and health loss (277). The prevalence of SP is considerable (136,190). Prevalence reports range from 7% to 47% (136,190,235,239,279), with a life-time prevalence of up to 67% (190,227). Shoulder complaints are often associated with sleep disturbances (280), depression (280), work absenteeism (281) and healthcare utilization (e.g. opioid consumption) (282). Individuals with SP often consult primary care (72,73). Unfortunately, a great percentage of SP (60%) presented in general practice do not completely recover 12 months after the onset (138). This provokes enormous direct and indirect economic costs related to SP chronicity (191,283,284), which affects both the individual and society (239,283).

Pain hypersensitivity is a key factor to explain the persistence of symptoms in some individuals with SP (151,285). Local pain hypersensitivity is initially an adaptive process which alerts us to potentially harmful situations (12). When tissues heal, local pain hypersensitivity returns to normal baseline values (22). However, pain hypersensitivity can persist after the tissues heal, propagating to other body areas, unrelated to tissue input (24). This phenomenon is known as generalized pain hypersensitivity (23). Clinically, generalized pain hypersensitivity is measured by experimental, mechanical, thermal and chemical methods (286). It is characterized by hypersensitivity to particular stimuli such as heat or cold (286), but also by fatigue, stress-intolerance, etc. (287).

Generalized pain hypersensitivity is common in individuals with chronic SP (151,285,288). For example, Noten et al. (151) reported in their review that individuals with chronic SP disorders such as subacromial impingement syndrome or rotator cuff pathology often report greater generalized mechanical pain hypersensitivity when compared with healthy controls (151). Unfortunately, the complexity of these pain processing mechanisms is enormous (289,290). Many factors such as sociodemographic (82), genetic (291), psychological (292), occupational (137) and biomechanical (293) factors, among others, may be all involved in the development and maintenance of SP and disability. Of all these factors, psychological factors are probably the most influential in determining how individuals with chronic pain perceive, process, interpret and cope with their pain (95,294). A large body of evidence underlines that psychological factors are associated with more clinical (113,119) and experimental (295,296) pain. For example, pain catastrophizing has been associated with greater experimental pain (presence of generalized pain hypersensitivity) in chronic low back pain (296). Kinesiophobia is considered to be associated with and predict more clinical pain intensity and disability in chronic musculoskeletal pain (113). Inversely, a recent review (119) showed that psychological factors, considered to be "protective" such as pain self-efficacy, predict a better prognosis (lower levels of pain intensity and disability) in samples with chronic musculoskeletal pain. Thus, these factors become targeted outcomes in clinical practice (297,298).

Specifically in chronic SP, psychological factors such as emotional distress or positive expectations of recovery have been associated with respectively poorer or better SP outcomes (292). However, a very low evidence was obtained, and further high-quality research was recommended. Additionally, while the association between psychological factors and pain hypersensitivity has been explored in subacute SP (Kindler LL, Valencia C, Fillingim RB, George SZ, 2011), to our knowledge, this association has been not studied in individuals with chronic SP yet. The understanding of the underlying causes, specifically the role that psychological factors play in clinical and experimental pain, may be crucial in designing targeted interventions which may lead to better outcomes for this population.

6.2 Objectives

The aims of the present cross-sectional study were: (i) to explore the potential association between psychological factors (pain self-efficacy, pain catastrophizing, emotional distress) and experimental pain measures (local and generalized pain hypersensitivity measured with pressure algometry) in individuals with chronic SP; (ii) to further investigate the potential association between the psychological factors previously mentioned and clinical SP intensity and function, measured through self-reported questionnaires.

6.3 Methods

6.3.1 Design

A cross-sectional design was carried out. This study was performed and reported according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) criteria (http://www.strobe-statement.org) (299). The study was also conducted according to the Declaration of Helsinki. Ethical approval was obtained from the "X" Ethics Committee (28042016).

6.3.2 Participants

A convenience sample of 90 individuals with chronic SP were recruited through physiotherapists from four primary care centres. Physiotherapists, who were previously instructed by the research team, screened participants for eligibility. Participants meeting the eligibility criteria were invited to participate in this study.

The inclusion criteria were:

(i) At least 18-year-old participants.

(ii) Chronic SP (with a pain duration for more than three months) according to the multidimensional diagnostic criteria for chronic pain (257).

(iii) SP defined as subacromial pain syndrome (impingement signs (Neer's, Hawkins, Jobe's tests); painful arc; pain with isometric resistance; weakness; atrophy (tear)) (86).

(iv) SP defined as adhesive capsulitis (spontaneous progressive pain; loss of motion in multiple planes: external rotation most limited; pain at end-range of motion) (86).

(v) SP defined as glenohumeral instability (age usually < 40 years old; history of dislocation or subluxation; apprehension test; relocation test; generalized laxity) (86).

(vi) SP due to other common diagnoses such as rotator cuff tendinopaty, superior labral anterior posterior lesion, acromioclavicular pathology and/or shoulder osteoarthritis and non-specific SP.

Diagnosis were carried out by physiotherapists with 15 years of working experience through clinical tests based on the recommendations of McClure & Michener (86). Magnetic resonance imaging scan and ultrasound examination were conducted by medical doctors in order to discard any potential rotator cuff tears.

The exclusion criteria were:

(i) SP due to systemic diseases such as rheumatoid arthritis.

(ii) SP due to neurological diseases or injuries such as stroke.

(iii) SP originated from the cervical region.

(iv) Participants with SP after post fracture.

(v) Individuals with SP receiving/planned for shoulder surgery.

(vi) Inability to provide informed consent and/or complete written questionnaires.

6.3.3 Procedures

Physiotherapists screened participants for eligibility and explained the study protocol. Afterwards, selected participants were requested to sign an informed consent form. They completed a set of self-reported questionnaires assessing clinical SP intensity, function, pain catastrophizing, pain self-efficacy, emotional distress and sociodemographic data. Afterwards pressure algometry was evaluated to determine the presence of local and/or generalized pressure pain hypersensitivity.

6.3.4 Measurements

(i) Demographic data: Age, gender, height, affected shoulder side, dominant shoulder, duration of symptoms, work status, shoulder diagnostic label, current treatment and level of education were collected through a self-reported questionnaire. Pain intensity was measured on an 11-point numeric rating (NRS) scale (0-10), with greater scores indicating more pain intensity. Presence of comorbidities were evaluated through the Self-Administered Comorbidity Questionnaire (SCQ) (268), including the presence or not (with yes/no answer) of several medical conditions such as cancer or heart problems.

(ii) Clinical SP intensity and function were assessed using the Shoulder Pain and Disability Index (SPADI). This tool is a standardized 13-item questionnaire, with two subdomains: a pain scale (5 items) and a function scale (8 items). The composite SPADI score ranges from 0 to 100, with greater scores reflecting worse pain and function. The minimal clinically important difference for SPADI has been reported as 8 points (300). The Spanish version of SPADI, which has been validated for use in Spanish language, was used (259). The Spanish version tool presents an internal consistency of 0.96 Cronbach's α.

(iii) Experimental pain sensitivity procedures: local and generalized pressure pain hypersensitivity were assessed by pressure pain threshold (PPT) assessments. PPT assessments were conducted using a hand-held pressure algometer with a 1-cm-diameter probe (Commander™ Algometer de JTECH Medical). PPTs were assessed unilaterally (only on the affected shoulder) at both upper trapezius and infraspinatus to evaluate the presence of local pain hypersensitivity and at the anterior tibialis to evaluate the presence of generalized pain hypersensitivity following the criteria of Travell and Simons for trigger points diagnosis (301,302). A standardized protocol for evaluating PPTs was used (303,304). A rate of 1 kg/s was applied. Participants were instructed to report the precise moment when the sensation changed from pressure to slightly unpleasant pain. The amount of pressure in kilograms (kg) on that precise moment was recorded. This process was repeated twice unilaterally at each site, with a 1-minute rest interval. The average of these two measurements was used as PPT in the data analysis. Lower PPT scores indicate the presence of greater pain hypersensitivity. The test-retest reliability of PPT measurements has been established in previous studies (305,306).

(iv) Pain Self-efficacy: The Pain Self-Efficacy Questionnaire (PSEQ) evaluated the presence of self-efficacy for pain. This tool contains 10 items measuring the one confidence to perform certain activities despite pain (120). Each item is scored using a 7-point Likert scale, where 0 = not confident at all and 6 = completely confident. The total score ranges from 0 to 60, with greater scores indicating greater self-efficacy for pain. PSEQ presents an internal consistency of 0.92 Cronbach's α (251).

(v) Pain catastrophizing: The Pain Catastrophizing Scale (PCS) evaluated catastrophic thinking about pain. It consists of 13 items describing different thoughts and feelings that individuals may have when experiencing pain. Each item is scored on a 5-point scale, where 0 = not at all and 4 = all the time. A general score and scores on three subscales (helplessness, magnification, and rumination) are obtained. The total score ranges from 0 to 65, with greater scores indicating greater pain catastrophizing. The Spanish version of PCS was used (261). The Spanish version tool has shown an internal consistency of 0.79 Cronbach's α (261).

(vi) Emotional distress: The Hospital Anxiety and Depression Scale (HADS) evaluated the presence of emotional distress. This tool contains 14 items, seven concerning anxiety (HADS-A) and seven for depression (HADS-D). Each item is scored using a 4-point Likert scale, where 0= absence of symptoms and 3= maximum symptoms. Scores for each subscale ranges from 0 to 21 (262), considering the total scores the emotional distress construct. Greater scores indicate greater emotional distress. The Spanish version of HADS was used (265,266). The Spanish version tool has shown an internal consistency of 0.84

Cronbach's α for HADS-D, 0.85 Cronbach's α for HADS-A and 0.90 Cronbach's α for HADS total score (265,266).

6.3.5 Data Analysis

Descriptive and exploratory statistics and the Kolmogorov-Smirnov test were carried out to analyse the distribution and normality of the variables. Pearson's correlation analyses were conducted to determine whether there was a significant association between psychological measures (pain catastrophizing, pain self-efficacy, emotional distress) and both clinical and experimental SP and the presence of disability.

Linear multivariate regression models were built to observe the direct association between psychological factors with both clinical and experimental SP and the presence of disability. Those independent variables (duration of symptoms, level of education, presence of comorbidities, pain catastrophizing, pain self-efficacy and emotional distress) which reported a statistical significance in the bivariate analysis, were put into the models through regression by forward steps, using SPADI-pain, SPADI-function and local and generalized PPTs measures as dependent variable. All models were adjusted for gender, since gender differences exist between individuals with chronic pain (307–309).

Changes in R^2 were estimated, as well as collinearity, autocorrelation, homoscedasticity and linearity through correlation matrix, Durbin-Watson's coefficient, tolerance, VIF and analysis of residuals. A p-value less than 0.05 was used to determine significance. Post-hoc power analyses were carried out to evaluate the statistical power (1-β) obtained in the different regression models. All the analyses were carried out with SPSS 25 statistical package (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

6.4 Results

6.4.1 Sample characteristics

More than half of participants were females (73%). The mean age of the whole sample was 55 years (males 55 (SD 11.07) and females 56 (SD 9.63)). Most of participants reported SP symptoms for more than 12 months. The most common SP diagnosis was subacromial pain syndrome. Gender differences were statistically significant for sociodemographic data such as height and work status. Considering clinical and experimental pain, gender differences were also statistically significant for both local and generalized pressure pain hypersensitivity as well as SP intensity when measured with SPADI. Females reported more clinical (greater SPADI scores) and experimental (lower PPTs) pain when compared with males. The rest of variables did not differ by gender (**Table 8**).

Table 8. Sample characteristics expressed by mean and standard deviation

	Male (n=24) Mean (SD)	Female (n=66) Mean (SD)	p
Age (yrs)	55.00 (11.07)	56.00 (9.63)	0.213
Height (m)	1.74 (0.08)	1.59 (0.07)	<0.001**
PPT upper trapezius (kg/cm²)	7.78(5.26)	3.85 (2.15)	<0.001**
PPT infraspinatus (kg/cm²)	7.53(.,95)	3.97 (2.05)	0.002**

PPT anterior tibialis (kg/cm²)		10.25(5.77)	6.61 (4.05)	0.002**
Pain intensity (NRS) (0-10)		5.92 (2.84)	6.67 (2.08)	0.327
Pain and function (SPADI total score 0-100)		62.17(28.81)	80.56 (26.90)	0.005**
Affected shoulder	Right (n=54)	14 (58.33)	40 (60.60)	0.516
	Left (n=36)	10 (41.66)	26 (39.39)	
Dominant Shoulder	Right (n=83)	24 (100)	59 (89.39)	0.104
	Left (n=7)	0 (0)	7 (10.60)	
Duration of symptoms				0.664
	3-6 months	2 (8.33)	9 (13.63)	
	6-12 months	6 (25.00)	12 (18.18)	
	>12 months	16 (66.70)	45 (68.18)	
Shoulder diagnostic label				0.262
	Subacromial impingement syndrome	20 (83.333)	47 (71.21)	
	Calcific tendinitis of shoulder	1 (4.16)	9 (13.63)	
	Supraspinatus tears	2 (8.33)	2 (3.03)	
	Adhesive capsulitis	1 (4.16)	8 (12.12)	
Work status				0.038*
	Active	10 (41.66)	24 (36.36)	
	Unemployed	5 (20.83)	9 (13.63)	
	Sick leave	6 (25)	5 (7.57)	

	Retired	2 (8.33)	10 (15.15)	
	Work home	1 (4.16)	18 (27.27)	
Level of education				0.519
	Illiteracy	1 (4.16)	9 (13.63)	
	Primary school	11 (45.83)	22 (33.33)	
	High school	10 (41.66)	28 (42.42)	
	University	2 (8.33)	7 (10.60)	
Current treatment				0.778
	No treatment	0 (0.00)	1 (1.51)	
	Oral drugs	2 (8.33)	4 (6.06)	
	Physiotherapy	22 (91.66)	61 (92.42)	
PSEQ final score		40.58 (17.70)	36.48 (14.44)	0.113
PCS final score		22.96 (14.54)	22.30 (14.01)	0.834
HADS final score		18.96 (5.46)	20.36 (6.43)	0.243
Comorbidities				
Hearth diseases	No	20 (83.33)	60 (90.90)	0.255
	Yes	4 (16.66)	6 (9.09)	
Arterial hypertension	No	19 (79.16)	52 (78.78)	0.609

	Yes	5 (20.83)	14 (21.21)	
Lung diseases	No	22 (91.66)	62 (93.93)	0.510
	Yes	2 (8.33)	4 (6.06)	
Diabetes	No	19 (79.16)	51 (77.27)	0.548
	Yes	5 (20.83)	15 (22.72)	
Kidney disease	No	22 (91.66)	62 (93.93)	0.510
	Yes	2 (8.33)	4 (6.06)	
Liver disease	No	24 (100)	65 (98.48)	0.733
	Yes	0 (0.00)	1 (1.51)	
Anaemia	No	23 (95.83)	56 (84.84)	0.148
	Yes	1 (4.16)	10 (15.15)	
Cancer	No	24 (100)	62 (93.93)	0.282
	Yes	0 (0.00)	4 (6.06)	
Diagnostic of depression	No	21 (87.50)	58 (87.87)	0.607
	Yes	3 (12.50)	8 (12.12)	
Generalized pain	No	10 (41.66)	37 (56.06)	0.166
	Yes	14 (58.33)	29 (43.93)	
Osteoporosis	No	24 (100)	60 (90.90)	0.146
	Yes	0 (0.0)	6 (9.09)	
Fracture	No	21 (87.50)	62 (93.93)	0.274
	Yes	3 (12.50)	4 (6.06)	

ROM= range of movement; PPT= pressure pain threshold; SPADI= the shoulder pain and disability index; NRS= the numerical pain rating scale; PSEQ= the pain self-efficacy questionnaire; PCS= the pain catastrophizing scale; HADS= the Hospital anxiety and depression scale; SD= standard deviation; p= p-value; Differences statistically significant: *p<0,05; **p<0,001.

6.4.2 Relation between both clinical and experimental (local and generalized pressure pain hypersensitivity) pain and psychological measures

Correlations between both clinical and experimental (local and generalized pain hypersensitivity) pain and psychological measures are reported in **Table 9**.

Table 9. Correlations between both clinical and experimental (local and generalized pain hypersensitivity) pain and psychological measures

	PPT at the infraspinatus	PPT at the upper trapezius	PPT at the anterior tibialis	SPADI-pain	SPADI-function	NRS
PSEQ total score	0.24*	0.28*	0.12	-0.43**	-0.55**	-0.48**
PCS total score	-0.11	-0.19	-0.06	0.41**	0.34**	0.38**
HADS total score	0.01	-0.04	0.05	0.10	0.13	0.28**

PPT= pressure pain threshold; SPADI= the shoulder pain and disability index; NRS= the numerical pain rating scale; PSEQ= the pain self-efficacy questionnaire; PCS= the pain catastrophizing scale; HADS= the Hospital anxiety and depression scale; Differences statistically significant: *p<0,05; **p<0,001.

6.4.3 Regression analyses-preliminary analyses

Three regression analyses were conducted using PPTs (local and generalized), SPADI and NRS as dependent outcomes. Independent variables (PSEQ, PCS, HADS, age, presence of comorbidities, duration of symptoms and level of education) were put into regression models based on the variables which reported a statistical significance in the bivariate analysis. However, presence of comorbidities (except for diagnosis of depression), age, duration of symptoms and level of education did not contribute to explain any dependent outcome. Thus, they were removed from regression models. All models were adjusted for gender.

6.4.4 Analysis I- Experimental pain (local and generalized pressure pain hypersensitivity), pain catastrophizing, pain self-efficacy and depression

Regression analyses were separately conducted for PPT at the infraspinatus, PPT at the upper trapezius and PPT at the anterior tibialis as dependent outcomes. Greater levels of PSEQ were significantly associated with greater PPT at the upper trapezius. The presence of depression was significantly associated with lower PPT at the infraspinatus and lower PPT at the anterior tibialis. The predictive value of regression model for both local PPTs was moderate (PPT at the infraspinatus R^2=0.28; PPT at the upper trapezius R^2=0.30) with a good adjustment for both (PPT at the infraspinatus VIF<1.1 and tolerance over=0.9; PPT at the upper trapezius VIF<1.1 and tolerance over>0.93). The predictive value of regression model for generalized PPT was weak (PPT at the anterior tibialis R^2=0.16) but the adjustment was good (VIF<1.2 and tolerance over>0.81). There was a good statistical power in all the models (Power (1- β) = 0.95) (**Table 10**).

Table 10. Linear regression analysis with PPT at the infraspinatus, PPT at the upper trapezius and PPT at the anterior tibialis as the outcome

	Standardized β	p	95% confidence interval for Standardized β	
			Lower limit	Upper limit

PPT at the infraspinatus				
Gender	-0.44	<0.001*	-4.88	-2.00
Diagnosis of depression	-0.19	0.046*	-4.04	-0.04
PSEQ total score	0.14	0.146	-0.01	0.07
PPT at the upper trapezius				
Gender	-0.45	<0.001*	-5.29	-2.24
PSEQ total score	0.19	0.046*	0.00	0.09
PCS total score	-0.15	0.116	-0.09	0.01
PPT at the anterior tibialis				
Gender	-0.33	0.001*	-5.78	-1.49
Diagnosis of depression	-0.20	0.043*	-5.87	-0.09

Differences statistically significant: *$p<0,05$. Power (1- β) = 0.95 for both models.

6.4.5 Analysis II- Pain intensity (NRS) pain self-efficacy and emotional distress

A regression analysis was built using pain intensity (measured with NRS) as a dependent outcome. Greater pain self-efficacy levels were significantly associated with lower pain intensity. Greater emotional distress levels were significantly associated with more pain intensity. The predictive value of regression model was moderate (R^2=0.39), with a good adjustment (VIF<1.03 and tolerance over>0.95) The statistical power was good (Power (1- β) = 0.96) (**Table 11**).

Table 11. Linear regression analysis with pain intensity measured with NRS as the outcome

	Standardized β	p	95% confidence interval for Standardized β	
			Lower limit	Upper limit
Pain intensity-NRS				
PSEQ total score	-0.54	<0.001*	-0.10	-0.05
HADS total score	0.38	<0.001*	0.07	0.20
Gender	0.05	0.522	-0.61	1.19

Differences statistically significant: *p<0,05. Power (1- β) = 0.96.

6.4.6 Analysis III- Pain intensity (SPADI-pain), function (SPADI-function) pain self-efficacy and pain catastrophizing

A regression analysis was built using pain intensity (SPADI-pain) and function (SPADI-function) as a dependent outcome. Greater pain self-efficacy levels were significantly associated with lower pain intensity and better function. Greater pain catastrophizing levels were significantly associated with more pain intensity and worse function. The predictive value of regression model was moderate for both SPADI-pain (R^2=0.42) and SPADI-function (R^2=0.36) with a good adjustment (VIF<1.03 and tolerance over>0.94) The statistical power was good (Power (1- β) = 0.96) (**Table 12**).

Table 12. Linear regression analysis with pain intensity measured with SPADI-pain as the outcome

	Standardized β	p	95% confidence interval for Standardized β	
			Lower limit	Upper limit
Pain intensity-SPADI-pain				

PSEQ total score	-0.34	<0.001*	-0.35	-0.11
PCS total score	0.35	<0.001*	0.13	0.39
Gender	0.22	0.013*	1.13	9.37
SPADI-function				
PSEQ total score	-0.47	<0.001*	-0.81	-0.38
PCS total score	0.26	0.002*	0.13	0.59
Gender	0.22	0.009*	2.58	17.33

Differences statistically significant: *p<0,05. Power (1- β) = 0.96.

6.5 Discussion

The purpose of this cross-sectional study was twofold: (i) to explore the potential association between psychological factors (pain self-efficacy, pain catastrophizing and emotional distress) and experimental pain (local and generalized pain hypersensitivity) in individuals with chronic SP and; (ii) to further investigate the potential association between these psychological factors and clinical SP intensity and function. Considering the first aim, this study found that: (i) diagnosis of depression was significantly associated with greater local (lower PPT at the infraspinatus) and generalized (lower PPT at the anterior tibialis) pressure pain hypersensitivity and; (ii) greater levels of pain self-efficacy were significantly associated with lower local (greater PPT at the upper trapezius) pressure pain hypersensitivity. Previous evidence, which supports our findings, has highlighted the association between self-efficacy and pain hypersensitivity in low back pain (310). Smart et al. (310) reported that generalized pain hypersensitivity was cross-sectionally associated with lower levels of self-efficacy. The association between depression and pain hypersensitivity has been also underlined (311). Adams and Turk (311) reported that depression is a consistent factor in individuals with chronic pain, specifically in central sensitivity syndromes such as fibromyalgia. On the other hand, pain catastrophizing and emotional distress were not associated with local and generalized pressure pain hypersensitivity. Our sample reported low levels of pain catastrophizing and emotional distress. These results may explain why both psychological factors were not associated with pressure pain hypersensitivity.

Regarding the second aim, our study found that: (i) greater pain self-efficacy levels were significantly associated with lower pain intensity and better function; (ii) greater pain catastrophizing levels were significantly associated with more pain intensity and worse function and; (iii) greater emotional distress levels were significantly associated with more pain intensity. Pain self-efficacy refers to the belief that one can execute a determined action while in pain (120). Pain Self-efficacy is probably the resilient factor which has received more empirical attention in the context of chronic pain (103,119). Supporting our results, Jackson et al. (103) reported that self-efficacy was associated with lower pain and better function through the analysis of 86 heterogeneous chronic pain samples. Martinez-Calderon et al. (119) underlined that baseline self-efficacy predicts lower pain intensity and better function over time, through the analysis of 27 longitudinal chronic musculoskeletal pain samples.

A large amount of evidence also reinforces the significant role that pain catastrophizing (312–314), anxiety (315) and depression (312) play in chronic pain outcomes. Pain catastrophizing and pain-related anxiety facilitate hypervigilance and avoidance behaviours (95,316). With these behaviours, sedentarism and immobilization become common in individuals with chronic pain. In the long term, this situation favours the development and maintenance of disability which has been associated with more pain and depression states (95). Our results support the association between greater pain catastrophizing levels with both greater levels of pain intensity and worse function. But greater emotional distress levels were only associated with more pain intensity. Multiple pathways can determine the development and persistence of chronic pain and pain-related disability. The number and duration of episodes, fluctuations of symptoms, the biopsychosocial profile of every individual and how they use health care, can vary considerably in individuals with chronic pain (26,307,317,318). These factors may mediate and moderate the association between emotional distress with disability in chronic SP.

The findings of this study highlight the importance of pain self-efficacy, pain catastrophizing and emotional distress in how individuals with chronic SP process their pain. Clinicians should pay attention to these factors when both assessing and treating people with chronic SP. This study presents several limitations which must be recognized. All factors were simultaneously assessed due to the cross-sectional nature of this study. For that, the impact that psychological factors play on clinical and experimental pain cannot be determined. Further prospective cohort studies are needed to clarify how these factors are interrelated overtime. These studies will be valuable for the development of targeted interventions in chronic SP populations. The sample size was small (n=90). This fact caused that analyses of the mediator role that both pain catastrophizing and pain self-efficacy may play in the relationship between depression and both clinical and experimental pain were not carried out. Further research including large chronic SP samples are required. Pain catastrophizing, pain self-efficacy and emotional distress were evaluated. However, either optimism or fear among other psychological factors were not investigated. Evidence underlies the importance of these factors in chronic SP (292).

Further research exploring the predictive value of these factors through prospective designs in SP outcomes, are warranted.

6.6 Conclusion

This cross-sectional study provided preliminary evidence about the association between psychological factors and both clinical and experimental pain in individuals with chronic SP. Greater levels of pain self-efficacy were significantly associated with lower local (greater PPT at the upper trapezius) pressure pain hypersensitivity. Additionally, greater levels of pain self-efficacy were associated with lower pain intensity and better function. Greater levels of pain catastrophizing were associated with more pain intensity and worse function. Greater levels of emotional distress were only associated with more pain intensity. However, the causality between these factors cannot be established because the cross-sectional nature of this study. Future investigations in this field are needed.

CHAPTER VII

THE ROLE THAT KINESIOPHOBIA PLAYS IN CHRONIC SHOULDER PAIN INTENSITY AND DISABILITY: A CROSS-SECTIONAL STUDY

7.1 Introduction

Shoulder pain (SP) is the third most common form of chronic musculoskeletal pain after low back and neck pain (49,54). The global prevalence of SP highly differs across populations which ranges from 1% to 67% (82). The direct (e.g. pain treatments) and indirect (e.g. loss productivity) economic costs occasioned by shoulder disorders are enormous. These have roughly entailed $7 billion in the United States (81). Individuals with chronic SP usually seek musculoskeletal care (73,74). In this sense, a large amount of surgical and conservative interventions has been proposed in order to improve chronic SP and pain-related outcomes (75–79). Unfortunately, recurrence and persistence of symptoms are frequent twelve months after the onset (80).

The course of chronic SP is often unpredictable. Certain individuals show a mismatch between pathology and pain perception (319). Furthermore, a great deal of research supports the relevance of biopsychosocial factors in the onset and progression of SP and disability (88–92,94). In this context, health professional should acknowledge that chronic SP is a complex interaction of biopsychosocial factors and their clinical decision-making should reflect it. This information allows to design targeted interventions which may reduce the current prognosis of this condition. Psychological factors are probably the most influential factors in the perception, processing, interpretation and control of chronic musculoskeletal pain (28,95). Specifically in chronic SP, Martinez-Calderon et al. (292) compiled all the available evidence regarding the role that psychological factors play in the perpetuation of chronic SP intensity and disability. They concluded that greater baseline levels of emotional distress, fear-avoidance beliefs and pain catastrophizing among others predicted greater pain intensity and disability over time. Inside of psychological factors, fear is one of the most investigated factors in the last two decades (95,109,116).

Kinesiophobia, the extreme of fear of movement, is defined as an excessive, irrational, and debilitating fear to execute a determined movement or activity due to a feeling of vulnerability to a painful injury or re-injury (117). Kinesiophobia is often associated with escape behaviours such as hypervigilance or avoidance (320). For example, evidence has shown how kinesiophobia is related to altered motor behaviours (321) which may mask the real functional capacity of certain individuals when they face a stressful movement or event (322). Particularly in chronic musculoskeletal pain, a large amount of research (113) underlined that kinesiophobia is concurrently associated with and longitudinally predict more pain intensity and lower function and quality of life over time. Kinesiophobia also mediates the relationship between pain intensity and disability in musculoskeletal pain (323).

In clinical setting, kinesiophobia is considered a barrier of physical activity (324) as well as a moderator of the effect of certain interventions such as physiotherapy (325,326), surgery (326) and biopsychosocial education (327). Consequently, kinesiophobia becomes a targeted outcome in clinical practice (328–331). The role that kinesiophobia plays in chronic SP intensity and disability has been explored (201,203,208). Nonetheless, a call for research in this field is warranted. A scarce number of studies have evaluated the concurrent association between kinesiophobia and chronic SP outcomes (201,203,208). The samples were enormously heterogeneous in terms of pain duration and diagnostic label. Only one of these studies added SP intensity as outcome (208). Additionally, inconsistencies were evident when studies considered the relationship between kinesiophobia and shoulder function. For example, Lentz et al. (203) reported an association between kinesiophobia and disability whereas Clausen et al. (201) revealed a lack of relationship between both variables.

7.2 Objectives

Given these considerations, the aim of the present study was to explore the concurrent association between kinesiophobia with both pain intensity and disability in individuals with chronic SP.

7.3 Methods

7.3.1 Study design

The present cross-sectional study was conducted according to the Declaration of Helsinki and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement for observational studies (332). Ethical approval was obtained from the Ethics Committee of the Health Care District where the primary care centers were located (PI9/012014).

7.3.2 Recruitment

General practitioners performed the recruitment in three primary care centers. Thereafter, the research team instructed physiotherapists who assessed participants for eligibility. Eligible participants were invited to participate and provide a written informed consent. Physiotherapists also collected the anonymized age and gender for eligible participants who declined to take part in this study in order to evaluate the external validity of the recruited sample.

7.3.3 Participants

A consecutive sample of 65 individuals with chronic unilateral subacromial pain syndrome satisfied the eligibility criteria and were included in the present study. Diagnosis were carried out by physiotherapists with 15 years of working experience through clinical tests based on the recommendations of McClure & Michener (86). Magnetic resonance imaging scan and ultrasound examination were conducted by medical doctors in order to discard any potential rotator cuff tears.

The inclusion criteria were:

(i) At least 18-year-old participants.

(ii) Chronic SP (with a pain duration for more than three months) according to the multidimensional diagnostic criteria for chronic pain (257).

(iii) Unilateral pain located in the anterior and/or lateral shoulder region (333).

(iv) SP defined as subacromial pain syndrome (impingement signs (Neer's, Hawkins, Jobe's tests) (334); painful arc; pain with isometric resistance; weakness; atrophy (tear)) (86).

The exclusion criteria were:

(i) SP due to systemic diseases such as rheumatoid arthritis.

(ii) SP due to neurological diseases or injuries such as stroke.

(iii) SP originated from the cervical region.

(iv) SP defined as adhesive capsulitis (spontaneous progressive pain; loss of motion in multiple planes: external rotation most limited; pain at end-range of motion) (86).

(v) SP defined as glenohumeral instability (age usually < 40 years old; history of dislocation or subluxation; apprehension test; relocation test; generalized laxity) (86).

(vi) SP due to other common diagnoses such as rotator cuff tendinopaty, superior labral anterior posterior lesion, acromioclavicular pathology and/or shoulder osteoarthritis and non-specific SP.

(vii) Participants with SP after post fracture.

(viii) Individuals with SP receiving/planned for shoulder surgery.

(ix) Inability to provide informed consent and/or complete written questionnaires.

7.3.4 Sample Size Calculation

Sample size was determined a priori based on the assumption that the association between one variable (kinesiophobia (203)) and SP intensity and disability provides a coefficient of association of 0.35, with a power of 80% and an alpha of .05 as well as a probability of drop-out of 5%. Calculations indicated that a total of 61 individuals were required.

7.3.5 Outcomes Measures

(i) Shoulder pain and function: The Spanish version of Shoulder Pain and Disability Index (SPADI) assessed SP intensity and function (259). This tool is composed for thirteen questions divided into two subdomains, namely pain intensity and function. Each item is scored from 0 (no pain or difficulty) to 10 (worst pain and difficulty). The SPADI total score ranges from 0 to 130 where greater scores indicate worse SP intensity and function. The Spanish SPADI also shows good psychometric properties to assess SP intensity and function in chronic pain (259).

(ii) Kinesiophobia: The Spanish short version of the Tampa Scale for Kinesiophobia (TSK-11) (335) assessed the presence of kinesiophobia. This tool excludes six psychometrically poor questions form the original TSK (336). Every item is scored through a four-point scale from one (strongly disagree) to four (strongly agree). Greater scores on the TSK indicate higher levels of kinesiophobia (336). The Spanish TSK-11 is a valued and reliable tool to assess kinesiophobia in chronic pain samples (337).

(iii) Shoulder range of movement free of pain: An inclinometer assessed the active shoulder ROM-free of pain at shoulder elevation in the scapular plane (338). Participants were instructed to elevate their affected shoulders in a standing, upright position. Afterwards, participants were also asked to communicate to the research team when pain started in order to stop the movement. Three measurement were collected at one-minute intervals and the mean value was calculated.

(iv) Demographic data: Age and gender were gathered through a self-reported questionnaire.

7.3.6 Data Analysis

Descriptive and exploratory statistics and the Kolmogorov-Smirnov test were conducted to analyze the distribution and normality of the variables. Pearson's correlation analyses were performed to determine potential associations between kinesiophobia, SP intensity and disability, ROM free of pain and demographic data. A linear multivariate regression model was built to observe direct associations between kinesiophobia and SPADI total score (SP intensity and disability) which was used as dependent outcome. The model was adjusted for ROM free of pain, gender and age. Changes in adjusted R^2 were estimated, as well as collinearity, autocorrelation, homoscedasticity and linearity through correlation matrix, Durbin-Watson's coefficient, tolerance, VIF and analysis of residuals. A p-value less than 0.05 was used to determine significance. All the analyses were carried out with SPSS 25 statistical package (IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.).

7.4 Results

7.4.1 Sample characteristics

More than half of participants were females (63.1%). The mean age of the whole sample was 46.37 (SD10.60). All the individuals reported chronic unilateral subacromial pain syndrome (**Table 13**).

Table 13. Sample characteristics expressed by mean and standard deviation (N=65)

	Mean (Standard deviation (SD))
Age	46.37 (10.60)
Mean ROM free of pain	87.93 (29.01)
TSK-11 total score	29.66 (8.68)
% SPADI total	60.39 (18.97)

Note: ROM= range of movement; TSK-11= the tampa scale for kinesiophobia short-form; SPADI= the shoulder and disability index.

7.4.2 Relation between ROM free of pain, kinesiophobia, demographic variables and SP intensity and disability

Correlations between SP intensity and disability, ROM free of pain, kinesiophobia and sociodemographic data are reported in **Table 14**.

Table 14. Pearson correlations between ROM free pain, SP intensity and disability, kinesiophobia, age and gender (N=65)

	SPADI total score	Mean ROM free pain	Age	Gender	TSK-11 total score
TSK-11 total score	0.30*	-0.12	-0.05	0.12	-
Mean ROM free pain	-0.21	-	-0.22*	0.06	-0.12
SPADI total score	-	-0.21	0.21*	-0.18	0.30*
Age	0.21*	-0.22*	-	0.23*	-0.05
Gender	-0.18	0.06	0.23*	-	0.12

Note: ROM= range of movement; TSK-11= the tampa scale for kinesiophobia short-form; SPADI= the shoulder and disability index. Differences statistically significant: *p<0.05; **p<0.001.

7.4.3 Multivariate lineal regression analysis in order to evaluate the association between kinesiophobia and both SP intensity and disability (adjusted for ROM free of pain, gender and age)

A linear multivariate regression analysis was conducted in order to explore the association between kinesiophobia and both SP intensity and disability. SPADI total score was included in the model as dependent outcome. This analysis was adjusted for ROM free of pain, gender and age. Greater levels of kinesiophobia were significantly associated with greater levels of SPADI total score (Standardized β = 0.35 $p<0.01$). The predictive value of the regression model for SPADI total score was small (R^2=0.19). The adjustment was good for SPADI total score (Durbin-Watson's coefficient= 1.85; VIF<1.15 and tolerance over=0.9) (**Table 15**).

Table 15. Multivariate linear regression analysis with SPADI total score as the outcome

	Unstandardized B	Standardized β	p	95% confidence interval for Standardized β Lower limit	Upper limit
SPADI total score					
TSK-11 total score	0.76	0.35	<0.01*	0.26	1.26
Mean ROM free of pain	-0.05	-0.08	0.47	-0.20	0.09
Gender	-11.50	-0.29	0.01*	-20.70	-2.29
Age	0.51	0.28	0.02*	0.08	0.94

Note: ROM= range of movement; TSK-11= the tampa scale for kinesiophobia short-form; SPADI= the shoulder and disability index. Differences statistically significant: *$p<0.05$.

7.5 Discussion

The purpose of this cross-sectional study was to explore the concurrent association between kinesiophobia with both SP intensity and disability in individuals with chronic SP. This study revealed that greater levels of kinesiophobia were significantly associated with greater levels of SP intensity and disability after adjusting for ROM free pain, gender and age. In the context of chronic musculoskeletal pain, a large amount of research supports the results found in our study. Luque-Suarez et al. (113) compiled all the available literature in order to evaluate the role that kinesiophobia plays in chronic musculoskeletal pain and pain-related outcomes. After the analysis of 63 observational studies, kinesiophobia was cross-sectionally associated with and longitudinally predicted more musculoskeletal pain intensity and disability over time. Particularly in chronic SP, Lentz et al. (203) explored the concurrent association between kinesiophobia and shoulder function. They concluded that greater levels of kinesiophobia among other factors (e.g. pain intensity) contributed to explain a 33% of the total variance in the increase of shoulder disability.

The fear-avoidance model of pain (95,109) hypothesises that individuals with SP who show certain levels of kinesiophobia have more probability to develop chronic SP and disability. Kinesiophobia favours hypervigilance and avoidance behaviours (109). In this sense, fearful SP individuals often immobilize their shoulder in order to avoid certain movements which are thought to be dangerous. Exercise produces huge benefits in individuals with chronic musculoskeletal pain (339,340). Nevertheless, these maladaptive behaviours are a barrier to practise exercise (324) which leads to develop more pain, disability and emotional distress over time (115). Our study and previous one (203) cannot confirm this model due to the findings are based on cross-sectional analyses and the samples already report chronic pain. Further studies which explore the longitudinal role that kinesiophobia plays in individuals with acute and subacute SP in order to evaluate whether kinesiophobia is a relevant predictor in the development of chronic SP and disability are required.

Additionally, Clausen et al. (201) recently investigated if kinesiophobia is associated with shoulder function in a heterogeneous subacromial shoulder impingement sample with acute, subacute and chronic SP. This study found that kinesiophobia is associated with shoulder function, but its influence was small (2.6–4.5%, $p< .05$) and disappeared after adjusting for pain, sociodemographic and impairment variables. In our study, the association between kinesiophobia and SP intensity and disability remained significant (standardized $\beta= 0.35$ $p<0.01$) after the adjustment for multiples covariates. Although function measures such as ROM free of pain did not contribute to explain the association between kinesiophobia and both SP intensity and disability, gender and age were considered important covariates. This is in line with previous evidence which underline the importance of gender and age in chronic pain (307–309,341). Further longitudinal cohort studies which evaluate the role that kinesiophobia plays in the maintenance of chronic SP and disability including a broad set of biopsychosocial factors as mediators of this relationship are needed. This information will permit to have a big picture about all the aspects which may facilitate the perpetuation of chronic SP and disability.

The findings of the current study highlight the importance of kinesiophobia in individuals with chronic SP and disability. Although the association size was moderate (standardized $\beta= 0.35$ $p<0.01$) and the results were based on a cross-sectional analysis, kinesiophobia moderates the effect of different interventions in individuals with musculoskeletal pain (325–327). Thereby, physiotherapists should be encouraged to pay attention to this factor in their clinical practice. They can decrease kinesiophobia through a set of interventions such as cognitive-functional therapy which has shown promising results in reducing kinesiophobia on chronic low back pain samples (298). There are certain limitations in this study which should be mentioned. The current study was cross-sectional in nature. Thus, all factors were simultaneously assessed and the predictive value that kinesiophobia plays in the maintenance of chronic SP and disability cannot be determined. Further prospective cohort studies are needed to clarify how these factors are interrelated over time. The association size was moderate which may be due to the presence of a small sample size (N=65). Further research which include large chronic SP samples are required. Although kinesiophobia was investigated, a broad list of psychological factors such as fear-avoidance beliefs of self-efficacy were not assessed which are considered mediators of the relationship between musculoskeletal pain and disability (323). Further research that explore the predictive value of these factors through prospective designs in SP outcomes, are warranted.

7.6 Conclusion

This cross-sectional study provided preliminary evidence about the association between kinesiophobia and chronic SP intensity and disability. Greater levels of kinesiophobia were associated with greater levels of chronic SP intensity and disability. This association remained significant after the adjustment for potential covariates such as ROM free pain, gender and age. Nevertheless, the predictive value that kinesiophobia plays in chronic SP cannot be determined due to the cross-sectional nature of this study. Future investigations in this field which cover the flaws mentioned in the current study are required.

CHAPTER VIII

GENERAL DISCUSSION

8.1 Main findings and research discussion

The general aims of the present thesis were: (i) to explore the state of art about the role that psychological factors (especially cognitive and emotional factors) play in the progression and maintenance of chronic SP and disability and; (ii) to determine potential associations between psychological factors (specifically pain catastrophizing, pain self-efficacy, kinesiophobia and emotional distress) and both chronic SP and disability in individuals with chronic SP.

A total of two systematic reviews were conducted and published in order to satisfy our first general aim (292,342). Firstly, a systematic review explored all the available evidence regarding the role that psychological factors play in the perpetuation of chronic SP intensity and disability (292). After the analysis of 27 longitudinal cohort studies, greater baseline levels of self-efficacy beliefs, resilience and expectations of recovery predicted lower levels of pain intensity and disability over time. On the other hand, this study also concluded that greater baseline levels of emotional distress, depressive symptoms, anxiety, preoperative concerns, fear-avoidance beliefs, somatization and pain catastrophizing predicted more pain intensity and disability over time.

Secondly, another systematic review was also performed and published in order to evaluate the concurrent association and longitudinal prediction of pain beliefs affecting both SP intensity and disability based on the analysis of 33 observational studies (342). Greater levels of pain catastrophizing and kinesiophobia were cross-sectionally associated with more pain intensity and disability, whereas greater levels of expectations of recovery and self-efficacy beliefs were concurrently associated with lower levels of pain intensity and disability. Additionally, greater baseline levels of pain catastrophizing, fear-avoidance beliefs and kinesiophobia predicted more pain intensity and disability over time. Greater baseline levels of self-efficacy beliefs and expectations of recovery predicted a reduction of pain intensity and disability over time.

Both systematic reviews underlined the essential role that psychological factors play in the progression and maintenance of chronic SP and disability. In line with our results, a large amount of research have also highlighted the importance of psychological factors in the transition and perpetuation of chronic musculoskeletal pain and disability (110–114,119,343–345).

A total of two cross-sectional studies were performed in order to satisfy our second general aim. Firstly, a cross-sectional study was conducted to explore the potential associations between psychological factors such as pain self-efficacy, pain catastrophizing and emotional distress with both disability and clinical and experimental pain measurements. This study concluded that greater levels of pain self-efficacy were associated with better function and lower levels of SP intensity and local pain hypersensitivity. These results are in line with previous evidence which underscored the role that self-efficacy beliefs play in individuals with chronic pain (103,119). This study also revealed that greater levels of pain catastrophizing and emotional distress were associated with higher levels of SP intensity. Greater levels of pain catastrophizing were associated with worse function as well. These results have been also supported by prior evidence (114,311).

Secondly, another cross-sectional study was carried out in order to evaluate the concurrent association between kinesiophobia with both chronic SP intensity and disability. This study underlined that greater levels of kinesiophobia are associated with higher levels of SP intensity and disability. This association remained significant after the adjustment for multiples covariates. These results are in agreement with a large amount of research which highlights the potential role that kinesiophobia plays in individuals with chronic musculoskeletal pain (113).

8.2 Clinical implications

From a physiotherapy perspective, patient's and physiotherapist's beliefs, attitudes and emotions are noteworthy factors in clinical-decision making (327,346,347). These cognitive (e.g. pain beliefs) and emotional (e.g. fear) factors are modifiable through different conservative interventions (188,298). The current doctoral thesis underlined the relevance of psychological factors in the persistence of chronic musculoskeletal pain and disability, particularly in individuals with chronic SP. Thus, the findings of this doctoral thesis should encourage physiotherapists to assess and treat these factors in their clinical practice.

Psychological interventions such as pain neuroscience education (348,349) and cognitive-functional therapy (298) delivered by physiotherapists combined with physiotherapy treatments (e.g. exercise plans (188)) are emerging approaches to modify cognitive (e.g. pain beliefs) and emotional (e.g. pain-related fear) factors in musculoskeletal pain (350). The benefits of psychological interventions delivered by physiotherapists are promising (350). However, certain issues should be previously covered. First, physiotherapists must be trained by a psychologist or other health professional in the management of these skills (350). Second, an average of 100 hours must be also acquired by physiotherapists before applying these interventions (351). These premises are needed in order to favour a better education to individuals with chronic musculoskeletal pain in order to reduce the uncertainty about their pain process, and thus, facilitate the control of their pain experience. This information may aid to improve the effectiveness of these interventions (352), and therefore, decrease the current prognosis of this condition (298).

8.3 Limitations of the doctoral thesis

There are certain limitations in this doctoral thesis that must be recognized. First, both systematic reviews were elaborated to have a rigorous methodology. Nevertheless, meta-analysis cannot be conducted due to the huge clinical and methodological heterogeneity across the included studies in both systematic reviews. Thus, the global association size regarding the association between psychological factors affecting both SP intensity and disability cannot be determined. Additionally, some modification regarding out study protocol were conducted in both cross-sectional studies. First, measures of pain hypersensitivity were posteriorly introduced. Pain hypersensitivity is a relevant factor in shoulder disorders (151,285), and therefore, the inclusion of a proxy of pain hypersensitivity was necessary in order to cover further SP dimensions as well as avoid possible bias. Second, PSEQ does not have to a Spanish version. In this sense, two native speakers independently conducted the translation to Spanish. However, the psychometric properties of the Spanish version of PSEQ were not obtained. Furthermore, the tampa scale for kinesiophobia short-form replaced the fear-avoidance components scale as a measurement to assess kinesiophobia due to the tampa scale for kinesiophobia is considered the most commonly tool to explore the presence of kinesiophobia in chronic pain. Third, the inter and intra-variability for the specific test conducted in the inclusion criteria were not calculated. Fourth, diabetes mellitus, thyroid pathology and worker compensation were not considered exclusion criteria. However, these affections can have a negative effect on the progress of the shoulder disease. Fifth, both observational studies were cross-sectional in nature. Thus, the predictive value that psychological factors play in the perpetuation of chronic SP cannot be determined. Sixth, the current doctoral thesis was focused on adults with SP, and hence, the results should not be extrapolated to other populations.

CHAPTER IX

PROSPECTIVE

9.1 Why focus our future research agenda on chronic musculoskeletal pain?

The most prevalent chronic pain condition is chronic musculoskeletal pain (29). Many interventions have been proposed to improve chronic musculoskeletal pain symptoms (64–66,353). However, its recurrence and persistence is frequent (49,54), which results in an enormous challenge for clinicians and researchers (68). The specific mechanisms that impact the development and course of chronic musculoskeletal pain remain unclear. Psychological factors are probably the most influential factors in the perception, processing, interpretation and coping with chronic pain (96,97). Inside of psychological factors, cognitive and emotional factors are modifiable through different conservative interventions (188,298). Thus, the acquisition of deep knowing and understanding about how these factors influence the transition and perpetuation of chronic musculoskeletal pain is required. This information will allow to design targeted interventions in order to reduce (e.g. pain-related fear) or enhance (e.g. pain self-efficacy) these factors which may help to improve the current prognosis of this condition. In this sense, our research group has already conducted certain publications and future research agenda is planned as follows:

9.2 To determine the state of knowledge about the role that kinesiophobia plays in chronic musculoskeletal pain and pain-related outcomes (systematic review published in British Journal of Sport Medicine: Luque-Suarez A, Martinez-Calderon J, Falla D. Role of kinesiophobia on pain, disability and quality of life in people suffering from chronic musculoskeletal pain: a systematic review. Br J Sports Med. 2018 pii: bjsports-2017-098673. doi: 10.1136/bjsports-2017-098673.)

Kinesiophobia is defined as an excessive, irrational and debilitating fear to carry out a physical movement, due to a feeling of vulnerability to a painful injury or reinjury. Kinesiophobia has been considered one of the most important psychological factors in the adjustment of chronic pain and disability. The aim of this systematic review was to explore the level of association between kinesiophobia and pain, disability and quality of life in people with chronic musculoskeletal pain as well as to analyse the prognostic value of kinesiophobia on pain, disability and quality of life in this population. A systematic review of the literature including an appraisal of the risk of bias using the adapted Newcastle Ottawa Scale was conducted. An electronic search of PubMed, AMED, CINAHL, PsycINFO, PubPsych and grey literature was undertaken from inception to July 2017. Eligibility criteria was based on observational studies exploring the role of kinesiophobia (measured with the Tampa Scale for Kinesiophobia) on pain, disability and quality of life in people with chronic musculoskeletal pain. Sixty-three articles (mostly cross-sectional) (total sample=10 726) were included. We found strong evidence for an association between higher levels of kinesiophobia and greater levels of pain intensity and disability and moderate evidence between higher levels of kinesiophobia and higher levels of pain severity and low quality of life. Higher levels of kinesiophobia predicts the progression of disability overtime, with moderate evidence. Higher levels of kinesiophobia also predicts greater levels of pain severity and low levels of quality of life at 6 months, but with limited evidence. Kinesiophobia does not predict changes in pain intensity. The results of this review encourage clinicians to consider kinesiophobia in their preliminary assessment. More longitudinal studies are needed, as most of the included studies were cross-sectional in nature.

Role of kinesiophobia on pain, disability and quality of life in people suffering from chronic musculoskeletal pain: a systematic review

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ABSTRACT

Objective (1) To explore the level of association between kinesiophobia and pain, disability and quality of life in people with chronic musculoskeletal pain (CMP) detected via cross-sectional analysis and (2) to analyse the prognostic value of kinesiophobia on pain, disability and quality of life in this population detected via longitudinal analyses.

Design A systematic review of the literature including an appraisal of the risk of bias using the adapted Newcastle Ottawa Scale. A synthesis of the evidence was carried out.

Data sources An electronic search of PubMed, AMED, CINAHL, PsycINFO, PubPsych and grey literature was undertaken from inception to July 2017.

Eligibility criteria for selecting studies Observational studies exploring the role of kinesiophobia (measured with the Tampa Scale for Kinesiophobia) on pain, disability and quality of life in people with CMP.

Results Sixty-three articles (mostly cross-sectional) (total sample=10 726) were included. We found strong evidence for an association between a greater degree of kinesiophobia and greater levels of pain intensity and disability and moderate evidence between a greater degree of kinesiophobia and higher levels of pain severity and low quality of life. A greater degree of kinesiophobia predicts the progression of disability overtime, with moderate evidence. A greater degree of kinesiophobia also predicts greater levels of pain severity and low levels of quality of life at 6 months, but with limited evidence. Kinesiophobia does not predict changes in pain intensity.

Summary/conclusions The results of this review encourage clinicians to consider kinesiophobia in their preliminary assessment. More longitudinal studies are needed, as most of the included studies were cross-sectional in nature.

Trial registration number CRD42016042641.

INTRODUCTION

Most people suffer from musculoskeletal pain at least once in their lifetime.[1] As such, musculoskeletal pain is a highly prevalent and costly condition.[1] It is the second most common cause of disability in the general population.[2] There are many established factors (physical, biological, cognitive, behavioural, social, occupational) associated with poor prognosis following the onset of musculoskeletal pain[1 3] which helps to explain why many people do not recover after an episode of acute musculoskeletal pain, often resulting in a downward spiral of negative physical, social and psychological consequences.[4] Among the many biopsychosocial factors which contribute to the experience and impact of pain, negative or maladaptive psychological factors (eg, fear) are among the most important.[5–8]

Fear is considered to be a relevant factor in order to understand how acute pain becomes chronic for some people and why pain and associated outcomes (eg, disability) persist once the tissue damage has healed.[9 10] In this sense, the fear-avoidance (FA) model of pain is one of the frameworks which has received more empirical attention in order to explain the development and persistence of disability following an acute episode of musculoskeletal pain.[9 11] According to this model, individuals with a trait tendency to have fear and catastrophic thoughts in response to pain are more at risk of developing chronic musculoskeletal pain (CMP) after an injury compared with individuals who do not have this tendency.[9] These individuals over-react in response to actual or potential threats, developing avoidance behaviours (eg, hypervigilance) which aim to prevent a new injury/reinjury.[9] Fear in relation to pain has been described with a variety of conceptual definitions among which pain-related fear, FA beliefs, fear of movement and kinesiophobia are the most commonly used.[12]

Physical inactivity is a potential factor for developing and maintaining CMP,[13] whereas physical activity has positive benefits in decreasing pain and disability in some CMP conditions, that is, lower limb osteoarthritis.[14] However, people with CMP often show fear of movement,[15 16] which limits the adequate execution of a movement or exercise and leads to more sedentary behaviour.[17] Such fear imposes a barrier when exercise is prescribed as part of management resulting in significant clinical implications including reduced adherence to treatment and perseverance of a negative experience with pain.[11]

Kinesiophobia (also known as fear of movement) is defined as an excessive, irrational and debilitating fear to carry out a physical movement, due to a feeling of vulnerability to a painful injury or reinjury.[18] Both constructs are very similar,[12] and essentially they have the same clinical relevance. While kinesiophobia is usually assessed with the Tampa Scale for Kinesiophobia (TSK), there is not a specific tool to assess fear of movement.[12] The prevalence of kinesiophobia in persistent pain ranges from 50% to 70%.[19 20] It can be acquired through two forms: a direct aversive experience (eg, pain or trauma) or social learning (observation and instruction).[21] Kinesiophobia may be associated with pain

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9.3 To determine the state of knowledge about the role that pain catastrophizing plays in chronic musculoskeletal pain and pain-related outcomes (systematic review published in Clinical Journal of Pain: Martinez-Calderon J, Jensen MP, Morales-Asencio JM, Luque-Suarez A. Pain Catastrophizing and Function in Individuals with Chronic Musculoskeletal Pain: A Systematic Review and Meta-Analysis. Clin J Pain. 2019 35(3):279-293. doi: 10.1097/AJP.0000000000000676.).

Pain catastrophizing is the most consistent psychosocial factor predicting of adjustment to chronic pain and may contribute to the development and long-term maintenance of chronic pain. The aim of this review was systematically review and critically appraise the concurrent and longitudinal associations between pain catastrophizing and both pain intensity and disability in individuals with chronic musculoskeletal pain. An electronic search of PubMed, Scopus, AMED, CINAHL, PsycINFO, and PubPsych databases, as well as grey literature was undertaken from the inception until March 2018. Cross-sectional and longitudinal studies reporting on the associations between measures of pain catastrophizing, pain intensity, and disability were selected for review. A total of eighty-five observational studies (92% cross-sectional) were included with a total sample of 13,628 participants with chronic musculoskeletal pain. Higher levels of pain catastrophizing levels were often, but not always, significantly concurrently associated with and prospectively predicted both chronic pain and disability, with very low-quality of the available evidence after applying the GRADE approach. Heterogeneity was large after conducting multiple meta-analyses. Despite the very low quality of the available evidence, the general consistency of the findings highlights the potential role that pain catastrophizing may play in delaying recovery from chronic musculoskeletal pain. Research that uses higher quality study designs and procedures would allow for more definitive conclusions regarding the impact of pain catastrophizing on pain and function.

Pain Catastrophizing and Function In Individuals With Chronic Musculoskeletal Pain

A Systematic Review and Meta-Analysis

Javier Martinez-Calderon, MSc, Mark P. Jensen, PhD,† Jose M. Morales-Asencio, PhD,‡§ and Alejandro Luque-Suarez, PhD*§*

Objectives: Pain catastrophizing (PC) is the most consistent psychosocial factor predicting of adjustment to chronic pain and may contribute to the development and long-term maintenance of chronic pain. The aim of this review was systematically review and critically appraise the concurrent and longitudinal associations between PC and both pain intensity and disability in individuals with chronic musculoskeletal pain (CMP).

Materials and Methods: An electronic search of PubMed, Scopus, AMED, CINAHL, PsycINFO, and PubPsych databases, as well as gray literature, was undertaken from inception until September 2018. Cross-sectional and longitudinal studies reporting on the associations between measures of PC, pain intensity, and disability were selected for review.

Results: A total of 85 observational studies (92% cross-sectional) were included, with a total sample of 13,628 participants with CMP. Very low-quality evidence (based on the GRADE criteria) indicated that higher levels of PC were often, but not always, significantly associated with and prospectively predicted both chronic pain intensity and disability. Heterogeneity was large after conducting multiple meta-analyses.

Discussion: Despite the very low quality of the available evidence, the general consistency of the findings highlights the potential role that PC may play in delaying recovery from CMP. Research that uses higher quality study designs and procedures would allow for more definitive conclusions regarding the impact of PC on pain and function.

Key Words: chronic pain, musculoskeletal pain, catastrophizing, psychological factors, systematic review

(*Clin J Pain* 2018;00:000–000)

The lifetime incidence of musculoskeletal pain is very high; almost everyone experiences acute musculoskeletal pain at least once.[1] Chronic musculoskeletal pain (CMP) is perhaps the most common type of chronic pain.[1] It is associated with substantial costs to both individuals and society.[2–4] CMP is also very complex, and the mechanisms that contribute to its maintenance and impact remain unclear. Biological, social, psychological, physical, and environmental factors have all been found to be associated with the development and maintenance of CMP.[5,6] These research findings are consistent with a contemporary definition of pain as "… a distressing experience associated with actual or potential tissue damage with sensory, emotional, cognitive, and social components."[7]

Among the many biopsychosocial factors found to contribute to the experience and impact of pain, negative or maladaptive psychological factors (eg, fear of pain) are among the most important.[8–11] Pain catastrophizing (PC) is the psychological factor that has probably received the greatest empirical attention in the last 2 decades.[11–17] PC has been conceptualized as a tendency to have overly negative thoughts in response to pain o bnr pain-related cues.[11,18] PC is currently understood as a multidimensional construct with 3 unique but interrelated components—pain magnification, rumination, and helplessness—based on the components/subscales of the measure most commonly to assess PC.[18] Rumination in this context is a cognitive process involving the tendency to maintain a focus on pain and its impact. Magnification represents is a tendency to exaggerate the severity and threat of pain. Helplessness is characterized by a belief that the individual with pain is unable to cope with that pain.[18]

A number of models of chronic pain give PC a central role as a factor that contributes to the development and maintenance of chronic pain.[19–22] For example, PC is hypothesized as a key driver in the Fear-Avoidance Model of pain.[19,20] In brief, this model proposes that individuals with a trait tendency to catastrophize in response to pain are at greater risk to develop CMP after an injury than individuals who do not have this tendency. According to this model, people prone to catastrophizing tend overreact in response to actual or potential threats, focus more on pain, and experience higher levels of pain intensity. They are also hypothesized to avoid activities which they have learned to associate with pain. Because of activity avoidance, their muscles and tendons may weaken, which can then make them less tolerant of activity in general, and more prone to actual injury (and pain) in the future. Evidence supporting the Fear-Avoidance Model of pain is growing. For example, several systematic reviews have shown the importance of fear and PC as precursors in the transition to chronic pain,[13,23,24] as well as in the perpetuation of pain chronicity.[25–27]

Another model, the Communal Coping Model,[11] argues that for some individuals, PC is a coping strategy used to elicit reinforcement and support from others. Although some

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9.4 To determine the state of knowledge about the role that self-efficacy beliefs play in chronic musculoskeletal pain and pain-related outcomes (systematic review published in The Journal of Pain: Martinez-Calderon J, Zamora-Campos C, Navarro-Ledesma S, Luque-Suarez A. The Role of Self-Efficacy on the Prognosis of Chronic Musculoskeletal Pain: A Systematic Review. J Pain. 2018 19(1):10-34. doi: 10.1016/j.jpain.2017.08.008.).

Evidence suggests that self-efficacy can play an essential role as a protective factor as well as a mediator in the relationship between pain and disability in people suffering from chronic musculoskeletal pain. This study systematically reviewed and critically appraised the role of self-efficacy on the prognosis of chronic musculoskeletal pain. Study selection was based on longitudinal studies testing the prognostic value of self-efficacy in chronic musculoskeletal pain. The Newcastle- Ottawa Scale, the Cochrane Collaboration's tool and the Methodological Index for Non-Randomized Studies checklist were used to evaluate the risk of bias of included studies. A total of 27 articles met the inclusion criteria. Our results suggest that higher self-efficacy levels are associated with greater physical functioning, physical activity participation, health status, work status, satisfaction with the performance, efficacy beliefs, and lower levels of pain intensity, disability, disease activity, depressive symptoms, presence of tender points, fatigue, and presenteeism. Despite the low quality of evidence of included studies, clinicians should be encouraged identify people with chronic musculoskeletal pain who present low self-efficacy levels before prescribing any therapy. It may help clinicians in their clinical decision-making and timely and specific consultations with—or referral to—other health care providers.

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Critical Review

The Role of Self-Efficacy on the Prognosis of Chronic Musculoskeletal Pain: A Systematic Review

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Abstract: **Evidence suggests that self-efficacy can play an essential role as a protective factor as well as a mediator in the relationship between pain and disability in people suffering from chronic musculoskeletal pain. This study systematically reviewed and critically appraised the role of self-efficacy on the prognosis of chronic musculoskeletal pain. Study selection was on the basis of longitudinal studies testing the prognostic value of self-efficacy in chronic musculoskeletal pain. The Newcastle-Ottawa Scale, the Cochrane Collaboration's tool, and the Methodological Index for Non-Randomized Studies checklist were used to evaluate the risk of bias of included studies. A total of 27 articles met the inclusion criteria. Our results suggest that higher self-efficacy levels are associated with greater physical functioning, physical activity participation, health status, work status, satisfaction with the performance, efficacy beliefs, and lower levels of pain intensity, disability, disease activity, depressive symptoms, presence of tender points, fatigue, and presenteeism. Despite the low quality of evidence of included studies, clinicians should be encouraged identify people with chronic musculoskeletal pain who present low self-efficacy levels before prescribing any therapy. It may help clinicians in their clinical decision-making and timely and specific consultations with—or referral to—other health care providers.**

Perspective: ***This article presents promising results about the role of self-efficacy on the prognosis of chronic musculoskeletal pain. However, because of the low quality of evidence of included studies, these findings should be taken with caution, and further research is needed.***

Key words: *Chronic pain, musculoskeletal pain, prognosis, self-efficacy, systematic review.*

Chronic pain is an enormous global health problem. It has been estimated that 1 in 5 adults suffer from pain each year, with 1 in 10 adults developing chronicity.[41] One of the most common forms of chronic pain is chronic musculoskeletal pain (CMP). It is a highly prevalent, disabling, and costly condition, with a substantial socioeconomic burden to individuals, employers, health care systems, and society.[11,57,60,76] The prevalence of CMP ranges from 13.5% to 47% of the general population.[19] People with CMP often show a detrimental effect on their social as well as family environments.[27] This situation is associated with an inability to carry out work, social, recreational, and household tasks,[36,47] negatively affecting their quality of life.[11,73] Despite its worldwide prevalence and the high social and economic weight, a clear understanding of its etiology and pathogenesis remains elusive.

There are several reasons that could explain why there is not a consensus in the treatment of this condition. First, CMP is characterized by the presence of central sensitization,[48,64,81] which makes people with CMP report different levels of pain, although similar radiological or pathological conditions are presented.[55] Second, evidence

This report is registered at PROSPERO International prospective register of systematic reviews: CRD42016036366.All authors have made a substantial scientific contribution to the study and they.

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The authors have no conflicts of interest to declare.

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9.5 To explore the role that cognitive and emotional factors play in the persistence of chronic musculoskeletal pain and pain-related outcomes (project ongoing).

Our previous systematic reviews as well as a great deal of evidence underlined the relevance of cognitive and emotional factors in the persistence of chronic musculoskeletal pain. In this sense, our research group decided to develop an ambitious project where the research questions were focused on how cognitive and emotional factors affect both chronic musculoskeletal pain and pain-related outcomes such as disability. A broad set of factors has been assessed such as optimism, pain self-efficacy, kinesiophobia, expectations of recovery or pain acceptance among others. Currently, a total of 200 individuals with chronic musculoskeletal pain has been assessed.

CHAPTER X

CONCLUSIONS

The current doctoral thesis concluded that:

(i) Psychological factors are prognostic factors of better (e.g. self-efficacy beliefs) or poorer (e.g. emotional distress) prognosis of chronic SP intensity and disability in samples with operative and non-operative chronic SP.

(ii) Greater levels of negative pain beliefs such as pain catastrophizing and fear-avoidance beliefs are associated with and predict to greater levels of SP intensity and disability over time.

(iii) Greater levels of positive pain beliefs such as self-efficacy beliefs are associated with and predict to lower levels of SP intensity and disability over time.

(iv) Greater levels of pain self-efficacy are cross-sectionally associated with lower levels of chronic SP intensity, local pain hypersensitivity and disability.

(v) Greater levels of pain catastrophizing are cross-sectionally associated with greater levels of chronic SP intensity and disability.

(vi) Greater levels of emotional distress are cross-sectionally associated with higher levels of chronic SP intensity.

(vii) Greater levels of kinesiophobia are cross-sectionally associated with greater levels of chronic SP intensity and disability.

CHAPTER XI

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Pain. 2013;29(11):929–38.

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CHAPTER XII

APPENDICES

12.1 Appendix A: Search strategy (original article: "The role of psychological factors in the perpetuation of pain intensity and disability in people with chronic shoulder pain: a systematic review")

1. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND psychological factors AND chronic pain). ti,ab; 299

2. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND psychological factors AND surgery). ti,ab; 330

3. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND psychological factors AND arthroscopy). ti,ab; 21

4. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND fear AND chronic pain). ti,ab; 62

5. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND fear AND surgery). ti,ab; 50

6. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND fear AND arthroscopy). ti,ab; 8

7. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND kinesiophobia AND chronic pain). ti,ab; 28

8. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND kinesiophobia AND surgery). ti,ab; 18

9. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND kinesiophobia AND arthroscopy). ti,ab; 5

10. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND pain catastrophizing AND chronic pain). ti,ab; 55

11. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND pain catastrophizing AND surgery). ti,ab; 46

12. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND pain catastrophizing AND arthroscopy). ti,ab; 4

13. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND coping AND chronic pain). ti,ab; 70

14. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND coping AND surgery). ti,ab; 52

15. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND coping AND arthroscopy). ti,ab; 3

16. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND depression AND chronic pain). ti,ab; 224

17. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND depression AND surgery). ti,ab; 262

18. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND depression AND arthroscopy). ti,ab; 13

19. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND anxiety AND chronic pain). ti,ab; 143

20. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND anxiety AND surgery). ti,ab; 185

21. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND anxiety AND arthroscopy). ti,ab; 9

22. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND self-efficacy AND chronic pain). ti,ab; 31

23. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND self-efficacy AND surgery). ti,ab; 39

24. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND self-efficacy AND arthroscopy). ti,ab; 6

25. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND expectations AND chronic pain). ti,ab; 25

26. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND expectations AND surgery). ti,ab; 88

27. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Shoulder pain AND expectations AND arthroscopy). ti,ab; 20

28. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND psychological factors AND chronic pain). ti,ab; 19

29. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND psychological factors AND surgery). ti,ab; 56

30. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND psychological factors AND arthroscopy). ti,ab; 18

31. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND fear AND chronic pain). ti,ab; 2

32. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND fear AND surgery). ti,ab; 26

33. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND fear AND arthroscopy). ti,ab; 5

34. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND kinesiophobia AND chronic pain). ti,ab; 5

35. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND kinesiophobia AND surgery). ti,ab; 0

36. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND kinesiophobia AND arthroscopy). ti,ab; 0

37. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND pain catastrophizing AND chronic pain). ti,ab; 6

38. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND pain catastrophizing AND surgery). ti,ab; 5

39. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND pain catastrophizing AND arthroscopy). ti,ab; 1

40. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND coping AND chronic pain). ti,ab; 2

41. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND coping AND surgery). ti,ab; 16

42. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND coping AND arthroscopy). ti,ab; 1

43. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND depression AND chronic pain). ti,ab; 13

44. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND depression AND surgery). ti,ab; 81

45. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND depression AND arthroscopy). ti,ab; 14

46. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND anxiety AND chronic pain). ti,ab; 8

47. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND anxiety AND surgery). ti,ab; 32

48. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND anxiety AND arthroscopy). ti,ab; 6

49. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND self-efficacy AND chronic pain). ti,ab; 3

50. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND self-efficacy AND surgery). ti,ab; 16

51. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND self-efficacy AND arthroscopy). ti,ab; 6

52. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND expectations AND chronic pain). ti,ab; 8

53. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND expectations AND surgery). ti,ab; 97

54. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Rotator cuff AND expectations AND arthroscopy). ti,ab; 32

55. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND psychological factors AND chronic pain). ti,ab; 9

56. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND psychological factors AND surgery). ti,ab; 7

57. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND psychological factors AND arthroscopy). ti,ab; 1

58. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND fear AND chronic pain). ti,ab; 2

59. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND fear AND surgery). ti,ab; 6

60. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND fear AND arthroscopy). ti,ab; 2

61. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND kinesiophobia AND chronic pain). ti,ab; 0

62. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND kinesiophobia AND surgery). ti,ab; 0

63. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND kinesiophobia AND arthroscopy). ti,ab; 0

64. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND pain catastrophizing AND chronic pain). ti,ab; 0

65. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND pain catastrophizing AND surgery). ti,ab; 2

66. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND pain catastrophizing AND arthroscopy). ti,ab; 1

67. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND coping AND chronic pain). ti,ab; 0

68. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND coping AND surgery). ti,ab; 2

69. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND coping AND arthroscopy). ti,ab; 1

70. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND depression AND chronic pain). ti,ab; 8

71. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND depression AND surgery). ti,ab; 29

72. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND depression AND arthroscopy). ti,ab; 3

73. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND anxiety AND chronic pain). ti,ab; 4

74. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND anxiety AND surgery). ti,ab; 15

75. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND anxiety AND arthroscopy). ti,ab; 2

76. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND self-efficacy AND chronic pain). ti,ab; 2

77. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND self-efficacy AND surgery). ti,ab; 5

78. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND self-efficacy AND arthroscopy). ti,ab; 1

79. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND expectations AND chronic pain). ti,ab; 2

80. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND expectations AND surgery). ti,ab; 13

81. PubMed, EMBASE, PubPsych, CINAHL, AMED; (Adhesive capsulitis OR frozen shoulder AND expectations AND arthroscopy). ti,ab; 4

12.2 Appendix B: A short question guide for the selection of relevant studies based on inclusion criteria (original article: “The role of psychological factors in the perpetuation of pain intensity and disability in people with chronic shoulder pain: a systematic review”)

Item	Question	Action
1	Did the study use any of the eligible study design?	Yes, move to the next question No, exclude
2	Did the study involve people with chronic shoulder pain?	Yes, move to the next question No, exclude
3	Did the study report psychological measures?	Yes, move to the next question No, exclude
4	Did the study include a longitudinal design?	Yes, move to the next question No, exclude
5	Did the study include at least one association between psychological factors-pain intensity and/or disability?	Yes, include study No, exclude

12.3 Appendix C: Excluded studies in the last screening (n=101) (original article: "The role of psychological factors in the perpetuation of pain intensity and disability in people with chronic shoulder pain: a systematic review")

Not longitudinal design

1	Bagheri F, Ebrahimzadeh MH, Moradi A, Bidgoli HF. Factors Associated with Pain, Disability and Quality of Life in Patients Suffering from Frozen Shoulder. Arch Bone Jt Surg. 2016 Jun;4(3):243-7.
2	Barlow JD, Bishop JY, Dunn WR, Kuhn JE; MOON Shoulder Group, Baumgarten KM, Brophy RH, Carey JL, Holloway BG, Jones GL, Ma BC, Marx RG, McCarty EC, Poddar SK, Smith MV, Spencer EE, Vidal AF, Wolf BR, Wright RW. What factors are predictors of emotional health in patients with full-thickness rotator cuff tears? J Shoulder Elbow Surg. 2016 Nov;25(11):1769-1773. doi: 10.1016/j.jse.2016.04.007.
3	Fink Barnes LA, Grantham WJ, Meadows MC, Bigliani LU, Levine WN, Ahmad CS. Sports activity after reverse total shoulder arthroplasty with minimum 2-year follow-up. Am J Orthop (Belle Mead NJ). 2015 Feb;44(2):68-72.
4	Barth RJ. CORR Insights(®): Clinician and Patient-Reported Outcomes Are Associated With Psychological Factors in Patients With Chronic Shoulder Pain. Clin Orthop Relat Res. 2016 Sep;474(9):2040-3. doi: 10.1007/s11999-016-4970-5.
5	Bilberg R, Nørgaard B, Overgaard S, Roessler KK. Patient anxiety and concern as predictors for the perceived quality of treatment and patient reported outcome (PRO) in orthopaedic surgery. BMC Health Serv Res. 2012 Aug 8;12:244. doi: 10.1186/1472-6963-12-244.
6	Cho CH, Jung SW, Park JY, Song KS, Yu KI. Is shoulder pain for three months or longer correlated with depression, anxiety, and sleep disturbance? J Shoulder Elbow Surg. 2013 Feb;22(2):222-8. doi: 10.1016/j.jse.2012.04.001.
7	Cho CH, Seo HJ, Bae KC, Lee KJ, Hwang I, Warner JJ. The impact of depression and anxiety on self-assessed pain, disability, and quality of life in patients scheduled for rotator cuff repair. J Shoulder Elbow Surg. 2013 Sep;22(9):1160-6.

	doi: 10.1016/j.jse.2013.02.006.
8	Clausen MB, Witten A, Holm K, Christensen KB, Attrup ML, Hölmich P, Thorborg K. Glenohumeral and scapulothoracic strength impairments exists in patients with subacromial impingement, but these are not reflected in the shoulder pain and disability index. BMC Musculoskelet Disord. 2017 Jul 17;18(1):302. doi: 10.1186/s12891-017-1667-1.
9	Cole BJ, Cotter EJ, Wang KC, Davey A. Patient Understanding, Expectations, and Satisfaction Regarding Rotator Cuff Injuries and Surgical Management. Arthroscopy. 2017 Aug;33(8):1603-1606. doi: 10.1016/j.arthro.2017.03.004.
10	Das De S, Vranceanu AM, Ring DC. Contribution of kinesophobia and catastrophic thinking to upper-extremity-specific disability. J Bone Joint Surg Am. 2013 Jan 2;95(1):76-81. doi: 10.2106/JBJS.L.00064.
11	Ding H, Tang Y, Xue Y, Yang Z, Li Z, He D, Zhao Y, Zong Y. A report on the prevalence of depression and anxiety in patients with frozen shoulder and their relations to disease status. Psychol Health Med. 2014;19(6):730-7. doi: 10.1080/13548506.2013.873814.
12	Hagiwara Y, Sekiguchi T, Yabe Y, Sugawara Y, Watanabe T, Kanazawa K, Koide M, Itaya N, Tsuchiya M, Tsuji I, Itoi E. Living status, economic hardship and sleep disturbance were associated with subjective shoulder pain in survivors of the Great East Japan Earthquake: A cross sectional study. J Orthop Sci. 2017 May;22(3):442-446. doi: 10.1016/j.jos.2016.12.027.
13	Henn RF 3rd, Ghomrawi H, Rutledge JR, Mazumdar M, Mancuso CA, Marx RG. Preoperative patient expectations of total shoulder arthroplasty. J Bone Joint Surg Am. 2011 Nov 16;93(22):2110-5. doi: 10.2106/JBJS.J.01114.
14	Hiscock N, Bell S, Coghlan J. Pain, depression and the postoperative stiff shoulder. BMC Musculoskelet Disord. 2015 Dec 4;16:376. doi:

	10.1186/s12891-015-0841-6.
15	Kindler LL, Valencia C, Fillingim RB, George SZ. Sex differences in experimental and clinical pain sensitivity for patients with shoulder pain. Eur J Pain. 2011 Feb;15(2):118-23. doi: 10.1016/j.ejpain.2010.06.001.
16	Lentz TA, Barabas JA, Day T, Bishop MD, George SZ. The relationship of pain intensity, physical impairment, and pain-related fear to function in patients with shoulder pathology. J Orthop Sports Phys Ther. 2009 Apr;39(4):270-7. doi: 10.2519/jospt.2009.2879.
17	Mancuso CA, Altchek DW, Craig EV, Jones EC, Robbins L, Warren RF, Williams-Russo P. Patients' expectations of shoulder surgery. J Shoulder Elbow Surg. 2002 Nov-Dec;11(6):541-9.
18	Martinez-Calderon J, Struyf F, Meeus M, Morales-Ascencio JM, Luque-Suarez A. Influence of psychological factors on the prognosis of chronic shoulder pain: protocol for a prospective cohort study. BMJ Open. 2017 Mar 6;7(3):e012822. doi: 10.1136/bmjopen-2016-012822.
19	Menendez ME, Baker DK, Oladeji LO, Fryberger CT, McGwin G, Ponce BA. Psychological Distress Is Associated with Greater Perceived Disability and Pain in Patients Presenting to a Shoulder Clinic. J Bone Joint Surg Am. 2015 Dec 16;97(24):1999-2003. doi: 10.2106/JBJS.O.00387.
20	Miranda H, Viikari-Juntura E, Heistaro S, Heliövaara M, Riihimäki H. A population study on differences in the determinants of a specific shoulder disorder versus nonspecific shoulder pain without clinical findings. Am J Epidemiol. 2005 May 1;161(9):847-55.
21	Nyman P, Palenius K, Panula H, Mälkiä E. Patients' experiences of shoulder problems prior to and following intervention. Physiother Theory Pract. 2012 Apr;28(3):221-31. doi: 10.3109/09593985.2011.598220.

22	Park HB, Lin SK, Yokota A, McFarland EG. Return to play for rotator cuff injuries and superior labrum anterior posterior (SLAP) lesions. Clin Sports Med. 2004 Jul;23(3):321-34, vii. Review.
23	Plath JE, Saier T, Feucht MJ, Minzlaff P, Seppel G, Braun S, Hatch D, Imhoff AB. Patients' expectations of shoulder instability repair. Knee Surg Sports Traumatol Arthrosc. 2017 Mar 13. doi: 10.1007/s00167-017-4489-7.
24	Potter MQ, Wylie JD, Greis PE, Burks RT, Tashjian RZ. Psychological distress negatively affects self-assessment of shoulder function in patients with rotator cuff tears. Clin Orthop Relat Res. 2014 Dec;472(12):3926-32. doi: 10.1007/s11999-014-3833-1.
25	Razmjou H, Lincoln S, Axelrod T, Holtby R. Factors contributing to failure of rotator cuff surgery in persons with work-related injuries. Physiother Can. 2008 Spring;60(2):125-33. doi: 10.3138/physio.60.2.125.
26	Roh YH, Lee BK, Noh JH, Oh JH, Gong HS, Baek GH. Effect of depressive symptoms on perceived disability in patients with chronic shoulder pain. Arch Orthop Trauma Surg. 2012 Sep;132(9):1251-7. doi: 10.1007/s00402-012-1545-0.
27	Roh YH, Noh JH, Oh JH, Baek GH, Gong HS. To what degree do shoulder outcome instruments reflect patients' psychologic distress? Clin Orthop Relat Res. 2012 Dec;470(12):3470-7. doi: 10.1007/s11999-012-2503-4.
28	Saccomanno MF, Sircana G, Cazzato G, Donati F, Randelli P, Milano G. Prognostic factors influencing the outcome of rotator cuff repair: a systematic review. Knee Surg Sports Traumatol Arthrosc. 2016 Dec;24(12):3809-3819.
29	Nelson N, Churilla JR. Physical activity, fear avoidance, and chronic non-specific pain: A narrative review. J Bodyw Mov Ther. 2015 Jul;19(3):494-9. doi: 10.1016/j.jbmt.2015.02.001.
30	Sundstrup E, Jakobsen MD, Brandt M, Jay K, Aagaard P, Andersen LL.

	Associations between biopsychosocial factors and chronic upper limb pain among slaughterhouse workers: cross sectional study. BMC Musculoskelet Disord. 2016 Feb 27;17:104. doi: 10.1186/s12891-016-0953-7.
31	Tashjian RZ, Henn RF, Kang L, Green A. The effect of comorbidity on self-assessed function in patients with a chronic rotator cuff tear. J Bone Joint Surg Am. 2004 Feb;86-A(2):355-62.
32	Warth RJ, Briggs KK, Dornan GJ, Horan MP, Millett PJ. Patient expectations before arthroscopic shoulder surgery: correlation with patients' reasons for seeking treatment. J Shoulder Elbow Surg. 2013 Dec;22(12):1676-81. doi: 10.1016/j.jse.2013.05.003.
33	Wolfensberger A, Vuistiner P, Konzelmann M, Plomb-Holmes C, Léger B, Luthi F. Clinician and Patient-reported Outcomes Are Associated With Psychological Factors in Patients With Chronic Shoulder Pain. Clin Orthop Relat Res. 2016 Sep;474(9):2030-9. doi: 10.1007/s11999-016-4894-0.
34	Wright V, Haq AM. Periarthritis of the shoulder. I. Aetiological considerations with particular reference to personality factors. Ann Rheum Dis.1976 Jun;35(3):213-9.

<u>Not chronic shoulder pain</u>

1	Bot AG, Vranceanu AM, Herndon JH, Ring DC. Correspondence of patient word choice with psychologic factors in patients with upper extremity illness. Clin Orthop Relat Res. 2012 Nov;470(11):3180-6. doi: 10.1007/s11999-012-2436-y.
2	Cassou B, Derriennic F, Monfort C, Norton J, Touranchet A. Chronic neck and shoulder pain, age, and working conditions: longitudinal results from a large random sample in France. Occup Environ Med. 2002 Aug;59(8):537-44.
3	Asenlöf P, Söderlund A. A further investigation of the importance of pain cognition and behaviour in pain rehabilitation: longitudinal data suggest

	disability and fear of movement are most important. Clin Rehabil. 2010 May;24(5):422-30. doi: 10.1177/0269215509353264.
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12.4 Appendix D: Conflict of interest of included studies (original article: "The role of psychological factors in the perpetuation of pain intensity and disability in people with chronic shoulder pain: a systematic review")

First Author	Conflict of interest
Badcock et al.	Not reported
Chester et al.	No conflict of interest
Cho a et al.	No conflict of interest
Cho b et al.	No conflict of interest
Coronado et al.	No conflict of interest
Dekker et al.	Not reported
Ekeberg et al.	No conflict of interest
Engebretsen et al.	No conflict of interest
George et al.	Not reported
Gill et al.	Not reported
Henn III et al.	Not reported
Jawa et al.	Not reported
Karlsson et al.	No conflict of interest
Koorevaar et al.	No conflict of interest
Kromer et al.	Not reported
Macfarlane et al.	Not reported

Oh et al.	No reported
Potter et al.	No conflict of interest
Razmjou et al.	No conflict of interest
Reilingh et al.	No conflict of interest
Styron et al.	Not reported
Tokish et al.	Not reported
Valencia et al. a	No conflict of interest
Valencia et al. b	No conflict of interest
Werner a et al.	Not reported
Werner b et al.	No conflict of interest
Yeoman et al.	No conflict of interest

12.5 Appendix E: Summary of the statistical results about the association between psychological factors and pain intensity (longitudinal analysis)

THE ROLE OF PSYCHOLOGICAL FACTORS IN THE PERPETUATION OF PAIN INTENSITY IN PEOPLE WITH CHRONIC SHOULDER PAIN

The association between fear-avoidance and pain intensity	Baseline fear-avoidance beliefs (physical activity subscale)-pain intensity at three months: B[95%CI]= -0.01[-0.20 to 0.19] p=0.090 (131) Baseline fear-avoidance beliefs-pain intensity at baseline: r= 0.04 p=0.75; **at four-six months: r= -0.33 p=0.029**; at twelve months: r= -0.29 p=0.08 (134)
The association between fear of pain and pain intensity	Baseline fear of pain-pain intensity at three-five months: standardized B= 0.08 p=0.584 (166)
The association between kinesiophobia and pain intensity	Baseline kinesiophobia-pain intensity at three-five months: standardized B= -0.15 p=0.329 (166)
The association between pain catastrophizing and pain intensity	Baseline pain catastrophizing-pain intensity at three months: B[95%CI]= 0.11[-0.11 to 0.32] p=0.213 (131) **Baseline pain catastrophizing-pain intensity at three months after surgery: standardized B=0.34 SE=0.04 p=0.04** (127) **Baseline pain catastrophizing-pain intensity at three-five months: standardized B= 0.53 p=0.001** (166) **Baseline pain catastrophizing-pain intensity at six months: Mean[95%CI]= -0.62[-1.03 to -0.20] p=0.001** (125) Baseline pain catastrophizing-pain intensity at six months after surgery: standardized B= 0.05 SE= 0.03 p=0.70 (167) Baseline pain catastrophizing-pain intensity at baseline: r=0.02 p=0.88; at four-six months: r= -0.20 p=0.21; at twelve months: r= -0.06 p=0.73 (134)
The association between self-efficacy and pain intensity	Baseline pain self-efficacy-pain intensity at six weeks after intervention: B[95%CI]= 0.9[-0.2 to 1.9] p=0.1 (126) **Baseline pain self-efficacy-pain intensity at six months: B[95% CI] = −0.36[−0.50 to −0.22] p<0.001** (130) **Baseline pain self-efficacy-pain intensity at twelve months: B[95% CI]= 6.0[2.0 to 9.9] p=0.004** (176) Baseline pain self-efficacy-pain intensity at baseline: r= -0.10 p=0.45; at four-six months: r= 0.10 p=0.51; at twelve months: r= -0.20 p=0.23 (134)

	Baseline general self-efficacy-pain intensity at baseline: r=0.12 p=0.37; at four-six months: r= 0.21 p=0.18; at twelve months: r= 0.19 p=0.27 (134)
The association between expectations of recovery and pain intensity	Baseline expectations of recovery-pain intensity at six weeks after intervention: B[95%CI]= 2.3[-8.0 to 12.6] p=0.66 (126) **Baseline expectations of recovery-pain intensity at six months:** much improved: B[95% CI]= -5.21[-1.80 to 8.61] p=0.003**; slightly improved: B[95% CI]= −12.43[−8.20 to −16.67] p<0.001;** no changes/worse: B[95% CI] = −0.94[−8.53 to 6.66] p=0.809 (130) **Baseline expectations of recovery-pain intensity at six months (PSS pain subscore): Mean[95%CI]= 1.99[0.17 to 3.82] p=0.033** (161) **Preoperative expectations-pain intensity at twelve months: VAS B=9.91 p=0.005; DASH: B=11.93 p<0.001** (148) Association between preoperative expectations and pain intensity at a minimum of three years was not reported (171)
The association between optimism and pain intensity	Baseline optimism (in the model with pain catastrophizing)-pain intensity at three months: B[95%CI]= -0.01[-0.20 to 0.19] (131) Baseline optimism (in the model with fear-avoidance beliefs)-pain intensity at three months: B[95%CI]= -0.04[-0.22 to 0.15] (131)
The association between internal and external locus of control and pain intensity	Baseline external locus of control-pain intensity at six months: 3-4: Mean[95%CI]= -0.79[-1.60 to 0.02] p=0.06; >4: Mean[95%CI]= 0.21[-0.92 to 1.35] p=0.71 (125)
The association between pain acceptance and pain intensity	Baseline pain acceptance-pain intensity at baseline: r= -0.14 p=0.32; at four-six months: r= 0.14 p=0.40; at twelve months: r= -0.00 p=0.99 (134)
The association between coping and pain intensity	Association between coping and pain intensity at six months was not reported (125)
The association between resilience and pain intensity	**Postoperative resilience-pain intensity (ASES): r=0.41-0.44 p<0.004** (162)
The association between sleep disturbances and pain intensity	Baseline sleep disturbances-pain intensity at twelve months after surgery: coefficient[95%CI]= 0.040[-0.082 to 0.163] p=0.664 (168)

The association between somatisation and pain intensity	Baseline somatisation-pain intensity at six months: Mean[95%CI]= -0.16[-1.01 to 0.68] p=0.71 (125) Baseline somatisation-pain intensity (DASH) at twelve months: coefficient[95%CI]= -3.00[-10.53 to 4.52] p=0.43; pain intensity at twelve months (Likert scale): coefficient[95%CI]= -0.12[-0.62 to 0.37] p=0.63 (172) Somatisation at twelve months-pain intensity (DASH) at twelve months: **coefficient[95%CI]= -14.37[-21.23 to -7.51] p<0.001**; pain intensity at twelve months (Likert scale): coefficient[95%CI]= -0.37[-0.82 to -0.83] p=0.11 (172)
The association between emotional distress and pain intensity	Emotional distress-pain intensity at six weeks after intervention: B[95%CI]= 7.4[-3.0 to 17.8] p=0.16 (126) **Baseline emotional distress-pain intensity at twelve months: B [95% CI] = 10.3 [-1 to 21.6] p=0.073** (176) Baseline emotional distress-pain intensity (DASH) at twelve months: coefficient[95%CI]= 0.30[-6.09 to 6.7] p=0.93; pain intensity at twelve months (Likert scale): coefficient[95%CI]= 0.31[-0.12 to 0.74] p=0.16 (172) Emotional distress at twelve months-pain intensity (DASH) at twelve months: **coefficient[95%CI]= -20.63[-27.25 to -14.00] p<0.001**; pain intensity at twelve months (Likert scale): **coefficient[95%CI]= -0.95[-1.39 to -0.51] p<0.001** (172) Baseline emotional distress (ZUNG questionnaire)-pain intensity at twelve months: B=-0.18 p=0.084; Baseline emotional distress (MSPQ)-pain intensity at twelve months: B= -0.10 p=0.658 (173) Baseline emotional distress-pain intensity at three years: GHQ score 0-1: OR[95% IC]= 1.0; GHQ score 2-4: OR[95%CI]= 0.8[0.3 to 2.7]; GHQ score ≥5: OR[95%CI]= 2.6[0.8 to 7.7] (174) Changes in emotional distress and changes in pain intensity at twenty-four months were not reported (175) Association between emotional distress and pain intensity was not reported (125)
	Baseline depressive symptoms-pain intensity two weeks post-surgery: r=0.463; three weeks: r= 0.261; six weeks r= 0.191 (165) **Baseline depressive symptoms-pain intensity at three months after surgery: standardized B=0.33 SE=0.06 p=0.04** (127) Baseline depressive symptoms-pain intensity at six months after surgery: standardized B= 0.18 SE= 0.05 p=0.15 (167)

The association between depressive symptoms and pain intensity	**Baseline depressive symptoms-pain intensity at baseline (r= 0.309 p<0.05); six weeks (r= 0.376 p<0.01); six months after surgery (r= 0.508 p<0.01)** (170) **Baseline depressive symptoms-pain intensity (OSS) at baseline (r= -0.319 p<0.01); six weeks (r= -0.490 p<0.01); six months after surgery (r= -0.626 p<0.01)** (170) **Baseline depressive symptoms-pain intensity at forty-eight months (median): no depression: OR= 1; depressive symptoms: OR[95% CI] = 1.96 [1.07–3.58] p=0.029** (150) Baseline depressive symptoms-pain intensity at twelve months after surgery: coefficient[95%CI]= -0.073[-0.298 to 0.152] p=0.515 (168) Baseline depressive symptoms-pain intensity at twelve months after surgery: coefficient[95%CI]= -0.016[-0.276 to 0.244] p=0.899 (169) Baseline depressive symptoms-pain intensity at baseline: r= 0.14 p=0.29; at four-six months: r= -0.19 p=0.22; at twelve months: r= -0.11 p=0.95 (134) Baseline depressive symptoms-pain intensity (DASH) at twelve months: coefficient[95%CI]= -4.68[-14.72 to -5.36] p=0.36; pain intensity at twelve months (Likert scale): coefficient[95%CI]= 0.09[-0.56 to 0.74] p=0.78 (172) Depressive symptoms at twelve months-pain intensity (DASH) at twelve months: **coefficient[95%CI]= -16.59[-23.86 to -9.32] p<0.001**; pain intensity at twelve months (Likert scale): **coefficient[95%CI]= -0.79[-1.26 to -0.32] p=0.001** (172) **Baseline depressive symptoms-pain intensity at a minimum of twenty-four months: OR[95%CI]= 11.2[2.0 to 61.3] p=0.005** (163) **Baseline depressive symptoms-pain intensity (ASES) at twenty-four months: p=0.018** (164) Changes in depressive symptoms and changes in pain intensity at twenty-four months were not reported (175) Association between depressive symptoms and pain intensity was not reported (125)
	Baseline anxiety-pain intensity **two weeks post-surgery: r= 0.026 p<0.05**; three weeks: r= 0.364; six weeks r= 0.301 (165) Baseline anxiety-pain intensity at three months after surgery: standardized B= -0.22 SE=0.04 p=0.26 (127) Baseline anxiety-pain intensity at three-five months: standardized B= 0.07 p=0.646 (166)

The association between anxiety and pain intensity	**Baseline anxiety-pain intensity at baseline (r= 0.309 p<0.05); six weeks (r= 0.376 p<0.01); six months after surgery (r= 0.508 p<0.01)** (170) **Baseline anxiety-pain intensity (OSS) at baseline (r= -0.319 p<0.01); six weeks (r= -0.490 p<0.01); six months after surgery (r= -0.626 p<0.01)** (170) Baseline anxiety-pain intensity at twelve months after surgery: coefficient[95%CI]= 0.115[-0.053 to 0.283] p=0.174 (168) Baseline anxiety-pain intensity at twelve months after surgery: coefficient[95%CI]= -0.010[-0.363 to 0.142] p=0.382 (169) Baseline anxiety-pain intensity at baseline: r= 0.16 p=0.26; at four-six months: r= -0.18 p=0.22; at twelve months: r= -0.26 p=0.13 (134) Baseline anxiety-pain intensity (DASH) at twelve months: coefficient[95%CI]= -6.25[-13.84 to 1.30] p=0.10; pain intensity at twelve months (Likert scale): coefficient[95%CI]= -0.27[-0.75 to 0.21] p=0.27 (172) Anxiety at twelve months-pain intensity (DASH) at twelve months: **coefficient[95%CI]= -11.62[-19.15 to -4.10] p=0.003**; pain intensity at twelve months (Likert scale): coefficient[95%CI]= -0.46[-0.94 to 0.19] p=0.06 (172) Changes in anxiety and changes in pain intensity at twenty-four months were not reported (175) Association between anxiety and pain intensity was not reported (125)

Note: *Significant results are showed in bold. B= Beta coefficient; p= P value; SE= Standard Error; OR= Odds Ratio; r= Pearson's Coefficient of Correlation; CI= Confidence Interval.

12.6 Appendix F: Summary of the statistical results for the association between psychological factors and disability (longitudinal analysis)

THE ROLE OF PSYCHOLOGICAL FACTORS IN THE PERPETUATION OF DISABILITY IN PEOPLE WITH CHRONIC SHOULDER PAIN

The association between fear-avoidance and disability	Baseline fear-avoidance (physical activity subscale)-disability (function) at three months: B[95%CI]= -0.13[-0.31 to 0.05] p=0.092 (131) Baseline fear-avoidance beliefs-disability at three months: B[95%CI]= -0.102[-1.14 to -0.36] p=0.305 VIF= 1.51 (133)
The association between pain catastrophizing and disability	**Baseline pain catastrophizing-disability (function) at three months: B[95%CI]= -0.19[-0.37 to -0.01] p<0.05** (131) Baseline pain catastrophizing-disability at three months: B[95%CI]= 0.083[-0.23 to 0.59] p=0.381 VIF=1.40 (133) Baseline pain catastrophizing-disability at six months after surgery: standardized B= 0.23 SE= 0.24 p=0.11 (167) Association between baseline pain catastrophizing-disability at six months was not reported (125)
The association between self-efficacy and disability	Baseline pain self-efficacy-disability at six weeks after intervention: B[95%CI]= 0.9[-0.2 to 1.9] p=0.1 (126) **Baseline pain self-efficacy-disability at six months follow-up: B[95% CI] = −0.36 [−0.50 to −0.22] p<0.001** (statistical data of QuickDASH not reported) (130) **Baseline pain self-efficacy-disability at twelve months: B[95% CI] = 6.0 [2.0 to 9.9] p=0.004** (176)
The association between expectations of recovery and disability	Baseline expectations of recovery-disability at six weeks after intervention: B[95%CI]= 2.3[-8.0 to 12.6] p=0.66 (126) **Baseline expectations of recovery-disability at six months:** much improved: B[95% CI] = -5.21 [-1.80 to 8.61] p=0.003**; slightly improved: B[95% CI] = −12.43 [−8.20 to −16.67] p<0.001;** no changes/worse: B[95% CI] = −0.94 [−8.53 to 6.66] p=0.809 (statistical data of QuickDASH not reported) (130) Preoperative expectations-disability at six months: F value= 1.89 DF (R^2)= 3 p=0.1349 (160) **Baseline expectations of recovery-disability at six months (PSS-function subscore): Mean[95%CI]= 2.65[0.14 to 5.16] p=0.039;** (SF-12-PCS score): Mean[95%CI]= -0.06[-0.78 to 0.65] p=0.858 (161) **Preoperative expectations-disability at twelve months: VAS B=8.30 p=0.023; DASH: B=11.93 p<0.001; SST: B=15.34 p<0.001** (148)

	High expectations at follow-up-disability Constant Murley at baseline: OR[95%CI]= 0.868[0.82 to 0.91] p<0.001 R^2= -0.142; SST: p=0.007 (149) Association preoperative expectations-disability at a minimum of three years was not reported (171)
The association between optimism and disability	Baseline optimism (in the model with pain catastrophizing)-disability (function) at three months: B[95%CI]= 0.05[-0.12 to 0.22] (131) Baseline optimism (in the model with fear avoidance beliefs)-disability (function) at three months: B[95%CI]= 0.10[-0.06 to 0.26] (131)
The association between internal and external locus of control and disability	Association between baseline locus of control-disability at six months was not reported (125)
The association between coping and disability	Association between coping and disability at six months was not reported (125)
The association between resilience and disability	**Postoperative resilience-disability (ASES and Penn): r= 0.41-0.44 p<0.004** (162)
The association between sleep disturbances and disability	Baseline sleep disturbances-disability at twelve months after surgery: coefficient[95%CI]= 0.386 [-1.330 to 0.558] p=0.415 (168)
The association between preoperative concerns and disability	Preoperative concerns-disability Constant Murley: p=0.361; **SST: p= 0.018** (149)
The association between somatisation and disability	Baseline somatisation-disability (DASH) at twelve months: coefficient[95%CI]= -3.00[-10.53 to 4.52] p=0.43; disability at twelve months (Likert scale): coefficient[95%CI]= -0.12[-0.68 to 0.45] p=0.69 (172) Somatisation at twelve months-disability (DASH) at twelve months: **coefficient[95%CI]= -14.37[-21.23 to -7.51] p<0.001**; disability at twelve months (Likert scale): **coefficient[95%CI]=-0.62[-1.13 to -0.10] p=0.02** (172) Association between baseline somatisation-disability at six months was not reported (125)

The association between emotional distress and disability	Emotional distress-disability at six weeks after intervention: B[95%CI]= 7.4[-3.0 to 17.8] p=0.16 (126) **Baseline emotional distress-disability- at twelve months: B[95% CI] = 10.3 [-1 to 21.6] p=0.073** (176) Baseline emotional distress-disability (DASH) at twelve months: coefficient[95%CI]= 0.30[-6.09 to 6.7] p=0.93; disability at twelve months (Likert scale): coefficient[95%CI]= 0.19[-0.31 to 0.69] p=0.45 (172) Emotional distress at twelve months-disability (DASH) at twelve months: **coefficient[95%CI]= -20.63[-27.25 to -14.00] p<0.001**; disability at twelve months (Likert scale): **coefficient[95%CI]=-0.98[-1.49 to -0.47] p<0.001** (172) Baseline ZUNG questionnaire-disability at twelve months: B= 0.44 p=0.262; baseline MSPQ-disability at twelve months: B= -0.40 p=0.645 (173) **Changes emotional distress-changes disability at twenty-four months: r= 0.341 p=0.002** (175) Association between baseline emotional distress-disability at six months was not reported (125) Association between baseline emotional distress-disability at three years was not reported (174)
The association between depressive symptoms and disability	Baseline depressive symptoms-disability two weeks post-surgery: r= 0.206; three weeks: r= 0.947; six weeks: r= 0.405 (165) Baseline depressive symptoms-disability at six months: moderate: B[95% CI] = 2.19 [-0.99 to 5.37] p=0.177**; extreme: B[95% CI] = 12.02 [1.49 to 22.56] p=0.025** (statistical data of QuickDASH not reported) (130) **Baseline depressive symptoms-disability (OSS) at baseline (r= -0.319 p<0.01); six weeks (r= -0.490 p<0.01); six months after surgery (r= -0.626 p<0.01)** (170) Baseline depressive symptoms-disability at six months after surgery: standardized B= 0.16 SE= 0.39 p=0.24 (167) Baseline depressive symptoms-disability at twelve months after surgery: coefficient[95%CI]= 0.235[-1.492 to 1.963] p=0.785 (168) Baseline depressive symptoms-disability at twelve months after surgery: coefficient[95%CI]= 0.140[-2.030 to 2.309] p=0.897 (169) Baseline depressive symptoms-disability (DASH) at twelve months: coefficient[95%CI]= -4.68[-14.72 to -5.36] p=0.36; disability at twelve months (Likert scale): coefficient[95%CI]= 0.07[-0.68 to 0.82] p=0.85 (172) Depressive symptoms at twelve months-disability (DASH) at twelve months: **coefficient[95%CI]= -16.59[-23.86 to -9.32] p<0.001**; disability at twelve months (Likert scale): **coefficient[95%CI]=-0.93[-1.47 to -0.38] p=0.001** (172)

	Baseline depressive symptoms-disability at a minimum of twenty-four months: OR[95%CI]= 11.2[2.0 to 61.3] p=0.005 (163) **Baseline depressive symptoms-disability (ASES) at twenty-four months: p=0.018** (164) **Baseline depressive symptoms-SF-12-PCS at twenty-four months: p=0.006** (164) **Changes depressive symptoms- changes disability at twenty-four months: r= 0.372 p=0.001** (175) **Baseline depressive symptoms-disability at four years (median): no depression: OR= 1; depressive symptoms: OR[95% CI] = 1.96 [1.07–3.58] p=0.029** (150) Association between baseline depressive symptoms-disability at six months was not reported (125)
The association between anxiety and disability	Baseline anxiety-disability two weeks post-surgery: r= 0.087; three weeks: r= 0.817; six weeks: r= 0.341 (165) Baseline anxiety-disability at six months: moderate: B[95% CI] = 2.19 [-0.99 to 5.37] p=0.177**; extreme: B[95% CI] = 12.02 [1.49 to 22.56] p=0.025** (statistical data of QuickDASH not reported) (130) **Baseline anxiety-disability (OSS) at baseline (r= -0.319 p<0.01); six weeks (r= -0.490 p<0.01); six months after surgery (r= -0.626 p<0.01)** (170) Baseline anxiety-disability at twelve months after surgery: coefficient[95%CI]= -0.624[-1.913 to 0.665] p=0.335 (168) Baseline anxiety-disability at twelve months after surgery: coefficient[95%CI]= 0.787[-1.318 to 2.893] p=0.454 (169) Baseline anxiety-disability (DASH) at twelve months: coefficient[95%CI]= -6.25[-13.84 to 1.30] p=0.10; disability at twelve months (Likert scale): coefficient[95%CI]= -0.33[-0.89 to 0.23] p=0.24 (172) Anxiety at twelve months-disability (DASH) at twelve months: **coefficient[95%CI]= -11.62[-19.15 to -4.10] p=0.003**; disability at twelve months (Likert scale): coefficient[95%CI]=-0.47[-1.03 to -0.08] p=0.10 (172) **Changes anxiety-changes disability at twenty-four months: r= 0.265 p=0.017** (175) Association between baseline anxiety-disability at six months was not reported (125)

Note: *Significant results are showed in bold. B= Beta coefficient; p= P value; SE= Standard Error; VIF= Variance Inflation Factor; F= F-statistics; R^2= coefficient of determination; OR= Odds Ratio; r= Pearson's Coefficient of Correlation; CI= Confidence Interval.

12.7 Appendix G: Search Strategy: the following key terms have been searched in all these databases: PubMed, EMBASE, EBSCOhost, PubPsych, CINAHL, AMED. (original article: "The association between pain beliefs and pain intensity and/or disability in people with shoulder pain: a systematic review")

	AND	Total studies retrieved by title and abstract
Shoulder pain	Beliefs	**340**
	Psychological factors	**206**
	Expectations	**205**
	Self-efficacy	**175**
	Pain catastrophizing	**187**
	Fear-avoidance	**124**
	Kinesiophobia	**85**
	Fear of pain	**174**
	Fear of movement	**42**
	Helplessness	**12**
	Optimism	**12**
	Pessimism	**9**
	Threat	**16**
	Acceptance of illness	**6**
	Psychological factors AND beliefs (only in PubMed)	**44**

Rotator cuff	Beliefs	**101**
	Psychological factors	**102**
	Expectations	**142**
	Self-efficacy	**32**
	Pain catastrophizing	**15**
	Fear-avoidance	**6**
	Kinesiophobia	**10**
	Fear of pain	**10**
	Fear of movement	**3**
	Helplessness	**2**
	Optimism	**9**
	Pessimism	**0**
	Threat	**3**
	Acceptance of illness	**2**
Shoulder impingement syndrome	Beliefs	**65**
	Psychological factors	**78**
	Expectations	**42**
	Self-efficacy	**17**
	Pain catastrophizing	**11**
	Fear-avoidance	**15**

	Kinesiophobia	**9**
	Fear of pain	**12**
	Fear of movement	**5**
	Helplessness	**2**
	Optimism	**4**
	Pessimism	**0**
	Threat	**3**
	Acceptance of illness	**2**

12.8 Appendix H: Excluded studies in the last screening (n=166) (original article: "The association between pain beliefs and pain intensity and/or disability in people with shoulder pain: a systematic review")

Not observational design

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Not shoulder pain

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Not adults with shoulder pain

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12.9 Appendix I: Characteristics of included studies

First Author	Study N (completed follow-up) and setting	Mean age (years)	Clinical presentation	Mean duration of symptoms	Psychological factor	Outcome measure: pain intensity and disability	Study design and data collection (follow-up)	Statistical results
Chester et al. 2016 (130)	1030 (772) 11 NHS trusts and social enterprises	57 (SD 15)	Unspecific Shoulder pain	14 months (SD 28)	Pain self-efficacy (PSEQ) Expectations of recovery (not reported)	Pain intensity (SPADI and QuickDASH) Disability (SPADI and QuickDASH)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six months	Baseline expectations of recovery-pain intensity at six months: much improve: B [95% CI] = -5.21 [-1.80 to 8.61] p=0.003; slightly improve: B [95% CI] = −12.43 [−8.20 to −16.67] p<0.001; no changes/worse: B [95% CI] = −0.94 [−8.53 to 6.66] p=0.809 (statistical data of QuickDASH not reported) Baseline self-efficacy for pain-pain intensity at six months: B [95% CI] = −0.36[−0.50 to −0.22] p<0.001 (statistical data of QuickDASH not reported) Baseline expectations of recovery-disability at six months: much improve: B [95% CI] = -5.21[-1.80 to 8.61] p=0.003; slightly improve: B [95% CI] = −12.43[−8.20 to −16.67] p<0.001; no changes/worse: B [95% CI] = −0.94[−8.53 to 6.66] p=0.809 (statistical data of QuickDASH not reported) Baseline self-efficacy for pain-disability at six months: B [95% CI] = −0.36[−0.50 to −0.22] p<0.001 (statistical data of QuickDASH not reported)

Clausen et al. 2017 (201)	157 Arthroscopic Center Amager	54 (SD 13)	Shoulder impingement syndrome	Acute (1.3%); subacute (17.5%); chronic (81.1%)	Kinesiophobia (TSK-11)	Pain intensity (SPADI) Disability (SPADI-F)	C-S	Kinesiophobia-pain intensity: R^2 adj= 55.5% variance adj= 0.5% Kinesiophobia-disability: R^2adj= 47.1% variance adj=-0.1%
Coronado et al. 2017 (131)	78 (63) the University of Florida and Shands Hospital campus and the local surrounding community	38.8 (SD 14.9)	Unspecific shoulder pain	<6 months	Pain catastrophizing (PCS) Fear-avoidance beliefs (FABQ) Optimism (LOT-R)	Pain intensity (BPI) Disability (Penn-F)	Longitudinal (secondary data analysis) (T1) at baseline; (T2) at three months	Baseline fear-avoidance beliefs (physical activity subscale)-pain intensity at three months: B[95%CI] = -0.01[-0.20 to 0.19] p=0.090 Baseline pain catastrophizing-pain intensity at three months: B[95%CI] = 0.11[-0.11 to 0.32] p=0.213 Baseline optimism-pain intensity at three months: B [95%CI] = -0.01[-0.20 to 0.19] Baseline fear-avoidance (physical activity subscale)-disability (function) at three months: B [95%CI] = -0.13[-0.31 to 0.05] p=0.092 Baseline pain catastrophizing-disability (function) at three months: B [95%CI] = -0.19[-0.37 to -0.01] p<0.05 Baseline optimism-disability (function) at three months: B [95%CI] = 0.05[-0.12 to 0.22]
Ekeberg et al. 2010 (126)	106 (104) the outpatient clinic of the	52 (SD 12)	Rotator cuff disease	Between 6 months-more	Pain Self-efficacy (seven-point ordinal scale) Expectations of	Pain intensity (SPADI)	Longitudinal (secondary data analysis)	Baseline expectations of recovery-pain intensity at six weeks after intervention: B[95%CI] = 2.3[-8.0 to 12.6] p=0.66

	Physical Medicine and Rehabilitation Department at University Hospital			than 24 months	recovery (seven-point ordinal scale)	Disability (SPADI)	(T1) at baseline; (T2) at six weeks	Baseline self-efficacy for pain-pain intensity at six weeks after intervention: B[95%CI] = 0.9[-0.2 to 1.9] p=0.1 Baseline expectations of recovery-disability at six weeks after intervention: B [95%CI] = 2.3[-8.0 to 12.6] p=0.66 Baseline self-efficacy for pain-disability at six weeks after intervention: B [95%CI] = 0.9[-0.2 to 1.9] p=0.1
Engebretsen et al. 2010 (176)	104 (94) the outpatient Department of the Physical Medicine and Rehabilitation at University Hospital	48 (SD 10.7)	Subacromial shoulder pain	3 months-> 12 months	Pain Self-efficacy (four items from ASES)	Pain intensity (SPADI) Disability (SPADI)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at twelve months	Baseline pain self-efficacy-pain intensity at twelve months: B [95% CI] = 6.0[2.0 to 9.9] p=0.004 Baseline self-efficacy for pain-disability at twelve months: B [95% CI] = 6.0[2.0 to 9.9] p=0.004
George et al. 2008 a (166)	59 (47) the University of Florida's Orthopaedics Sports Medicine Institute	50.3 (SD 15.0)	Unspecific shoulder pain	-	Fear of pain (FPQ-III) Kinesiophobia (TSK-11) Pain catastrophizing (PCS)	Pain intensity (BPI)	C-S	Kinesiophobia-pain intensity: Standardized B= -0.15 p=0.329 Fear of pain-pain intensity: Standardized B= 0.08 p=0.584 Pain catastrophizing-pain intensity: Standardized B= 0.53 p=0.001
George et al. 2009 b (200)	59	50.4 (SD 14.9)	Rotator cuff disease	-	Fear of pain (FPQ-III)	Pain intensity (BPI)	C-S	Fear of pain-pain intensity: B=0.03 p= 0.81

					Pain catastrophizing (PCS)			Pain catastrophizing-pain intensity: B= 0.43 p<0.01
Henn et al. 2007 (148)	125 Hospital	56.2 (SD 11.4)	Unilateral rotator cuff tear	16.0 months (SD 25.9)	Preoperative expectations (MODEMS)	Pain intensity (VAS and DASH) Disability (SST, VAS, and DASH)	Longitudinal (retrospective cohort study) (T1) at baseline; (T2) at twelve months after surgery	Preoperative expectations-pain intensity at twelve months: VAS B=9.91 p=0.005; DASH: B=11.93 p<0.001 Preoperative expectations-disability at twelve months: VAS B= 8.30 p=0.023; DASH: B= 11.93 p<0.001; SST: B= 15.34 p<0.001
Henn et al. 2011 (202)	116 (98) One tertiary-care teaching institution	67.6 (SD 10.6)	Glenohumeral osteoarthritis	-	Preoperative expectations (the Hospital for Special Surgery's Shoulder Surgery Expectations Survey)	Pain intensity (VAS) Disability (ASES)	C-S	Expectations of recovery (improved activity to exercise or participate in sports)-pain intensity: p<0.05 Expectations of recovery (Improved self-care)-disability: p<0.05
Jawa et al. 2016 (171)	74 Hospital	60.8	Glenohumeral osteoarthritis	-	Preoperative expectations (list of 10 items)	Pain intensity (VAS) Disability (ASES)	Longitudinal (retrospective cohort study) (T1) at baseline; (T2) at minimum of thirty-six months after surgery	Data not reported

Karlsson et al. 2016 (134)	57 The Pain and Rehabilitation Centre at Linköping University Hospital	43 (SD 8.5)	Unspecific shoulder pain	8.5 years	Pain catastrophizing (PCS) Fear-avoidance beliefs (FABQ) General self-efficacy (GSES) Pain self-efficacy (PSEQ)	Pain intensity (NRS)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at four-six months; (T3) at twelve months	Baseline fear-avoidance beliefs-pain intensity at baseline: r= 0.04 p=0.75; at four-six months: r= -0.33 p=0.029; at twelve months: r= -0.29 p=0.08 Baseline pain catastrophizing-pain intensity at baseline: r=0.02 p=0.88; at four-six months: r= -0.20 p=0.21; at twelve months: r= -0.06 p=0.73 Baseline self-efficacy for pain-pain intensity at baseline: r= -0.10 p=0.45; at four-six months: r= 0.10 p=0.51; at twelve months: r= -0.20 p=0.23 Baseline general self-efficacy-pain intensity at baseline: r= 0.12 p=0.37; at four-six months: r= 0.21 p=0.18; at twelve months: r= 0.19 p=0.27
Kennedy et al. 2006 a (211)	361	49.9 (SD 14.9)	Soft tissue shoulder disorders	<4 weeks (24.1%); 4-12 weeks (24.7%); >12 weeks (48.5%)	Expectations of recovery (four Likert-point (get better soon or already better; get better slow; don't know; stay same or get worse)	Disability (DASH)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at three months	Baseline expectations of recovery (client prediction for recovery)-disability at three months: Wald statistic= 27.52 p<0.0001; Baseline expectations of recovery (client estimate of time to return to activity)-disability at three months: Wald statistic= 30.56 p<0.0001
Kennedy et al. 2006 b (212)	361	49.9 (SD 14.9)	Soft tissue shoulder disorders	<4 weeks (24.1%); 4-12 weeks (24.7%); >12	Expectations of recovery (four Likert-point (get better soon or already better; get	Disability (DASH)	Longitudinal (prospective cohort study)	Baseline expectations of recovery (client prediction for recovery)-disability at three months: B [95%CI] = -3.04[-6.23 to 0.15] p=0.0618; baseline expectations of recovery (client estimate of time to return to activity <4 weeks)-disability at

				weeks (48.5%)	better slow; don't know; stay same or get worse)		(T1) at baseline; (T2) at three months	three months: B [95%CI]= 0.75[-5.60 to 7.10] p=0.8164; baseline expectations of recovery (client estimate of time to return to activity ≥4 weeks)-disability at three months: B [95%CI] = 0.95[-3.88 to 5.78] p=0.8164
Kindler et al. 2011 (204)	59 the University of Florida's Orthopaedics Sports Medicine Institute	47.0 (SD 14.6)	Rotator cuff disease	-	Pain catastrophizing (PCS)	Pain intensity (BPI)	C-S	Pain catastrophizing-pain intensity: r= 0.511
Kromer et al. 2014 (133)	90 (88) General practice	51.8 (SD 11.2)	Subacromial shoulder pain	15.3% 2 months or less; 84.7% more than 3 months	Pain catastrophizing (PCS) Fear-avoidance beliefs (FABQ)	Pain intensity (NRS and SPADI) Disability (SPADI)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at three months	Fear-avoidance-pain intensity: r= -0.061 Pain catastrophizing-pain intensity: r=0.318 p<0.01 Baseline fear-avoidance beliefs-disability at three months: B [95%CI] = -0.102[-1.14 to -0.36] p=0.305 Baseline pain catastrophizing-disability at three months: B [95%CI] = 0.083[-0.23 to 0.59] p=0.381
Laslett et al. 2015 (129)	161 (135) Primary care	-	Unspecific shoulder pain	7 (SD 13)	Fear-avoidance beliefs (FABQ)	Pain intensity (SPADI) Disability (SPADI)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six	Baseline fear-avoidance-pain intensity at six months: OR [95%CI] = 1.03[1.00 to 1.07] p=0.08; baseline fear-avoidance-pain intensity at twelve months: OR [95%CI] = 1.01[1.03 to 1.17] p=0.00

							months; (T3) at twelve months	Baseline fear-avoidance-disability at six months: OR [95%CI] = 1.03[1.00 to 1.07] p=0.08; baseline fear-avoidance-disability at twelve months: OR [95%CI] = 1.01[1.03 to 1.17] p=0.00
Lentz et al. 2009 (203)	142 the clinical database of impairment and outcome measures in the Department of Physical Therapy at the UF & Shands Orthopaedic and Sports Medicine Institute	41.4 (SD 18.5)	Unspecific shoulder pain	-	Kinesiophobia (TSK-11)	Pain intensity (NRS and SPADI) Disability (SPADI)	C-S	Kinesiophobia-pain intensity: r= 0.309 p<0.01 Kinesiophobia-disability: Standardized B= 0.172 p=0.026
Menendez et al. 2015 (205)	139 An academic hospital-based shoulder surgeon	58.1 (SD 14.3)	Multiples shoulder pain complaints	18.7 months (SD 26.8)	Pain catastrophizing (PCS) Pain self-efficacy (PSEQ)	Pain intensity (SPADI) Disability (SPADI)	C-S	Pain catastrophizing-pain intensity: B= 0.003 p=0.029 Self-efficacy for pain-pain intensity: B= -0.005 p=0.001 Pain catastrophizing-disability: B= 0.003 p=0.029 Self-efficacy for pain-disability: B= -0.005 p=0.001

Oh et al. 2012 (149)	128 Hospital	58.8	Rotator cuff disease	-	Preoperative expectations (MODEMS) preoperative concerns (64 items with a four-point Likert scale)	Disability (SST and Constant-Murley score)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) mean 13.7 months (ranging 12-37 months) after surgery	Preoperative expectations-disability at a mean of 13.7 months Constant Murley: $p<0.01$ and SST: $p=0.024$ High preoperative concerns-disability at a mean of 13.7 months Constant Murley and SST no significant results
O'Malley et al. 2004 (213)	199 (122) One orthopaedic surgeon's office	51.6 (SD 15.7)	Multiples shoulder pain complaints	Chronic shoulder pain (67%)	Expectations of recovery (PSOE)	Disability (FLEX-SF)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at three months	Baseline expectations of recovery-disability at three months: B= 0.46 $p=0.002$
Plath et al. 2017 (206)	145 the Department of Orthopaedic Sports Medicine (tertiary care facility)	27.6 (SD 8.2)	Shoulder instability	51.2 months (SD 63.9)	Expectations of recovery (six-items)	Pain intensity (VAS)	C-S	Expectations of recovery-pain intensity: Overall n/s
Razmjou et al. 2009 (209)	185 (170) a large academic institution	57 (SD 11)	Rotator cuff disease	Women 45.06 (SD 71) months; men 47.98 (SD 60) months	Expectations of recovery (seven items with a five-point Likert scale)	Disability (WORC, ASES, QuickDASH)	C-S	Expectations for improved activity daily life (no difficulty B= 16.93; moderate expectations B= 2.12; high expectations B= 0.00 $p=0.0038$)

Razmjou et al. 2011 (160)	185 (160) a large academic institution	57 (SD 11)	Rotator cuff disease	Mean 43.42-46.48 months	Preoperative expectations (seven items with a five-point Likert scale)	Disability (WORC, ASES, and QuickDASH)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six months after surgery	Preoperative expectations-disability at six months: working B= 7.06; N/A B= 5.98; light B= 1.07; full B= 0.00 p=0.1349
Reilingh et al. 2008 (125)	587 (242 with chronic shoulder pain at baseline) General practice	52.9 (SD 13.3)	Unspecific shoulder pain	>3 months	Pain catastrophizing, internal and externa locus of control (PCCL)	Pain intensity (NRS) Disability (SDQ)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six months	Baseline pain catastrophizing-pain intensity (acute shoulder pain) at six months: Mean[95%CI] = 1.00[0.44 to 1.57] p=0.01 Baseline pain catastrophizing-pain intensity (chronic shoulder pain) at six months: Mean[95%CI] = -0.62[-1.03 to -0.20] p=0.001 Baseline external locus of control-pain intensity (in acute shoulder pain) at six months: 3-4: Mean[95%CI] = 0.35[-0.63 to 1.32] p=0.49; >4: Mean[95%CI] = 0.22[-0.89 to 1.33] p=0.70 Baseline external locus of control-pain intensity (in chronic shoulder pain) at six months: 3-4: Mean[95%CI] = -0.79[-1.60 to 0.02] p=0.06; >4: Mean[95%CI] = 0.21[-0.92 to 1.35] p=0.71 The predictive value of pain catastrophizing on disability was not reported The predictive value of locus of control on disability was not reported

Sindhu et al. 2012 (128)	3,362 (1,519) Outpatient rehabilitation clinics	54.1 (SD 15.8)	Multiples shoulder pain complaints	Acute 0-21 days (19.2%); subacute 22-90 days (32%); chronic more than 3 months (48.8%)	Fear-avoidance beliefs (FABQ-PA)	Pain intensity (NRS) Disability (CAT)	Longitudinal (secondary data analysis) (T1) at baseline; (T2) at discharge	Baseline high fear-avoidance-change (intake-discharge) pain intensity: Mean (SD): -2.4(2.9); low fear-avoidance-change (intake-discharge) pain intensity: Mean (SD): -2.5(2.7) Baseline low fear-avoidance-low disability at discharge: muscle, tendon, and soft tissue disorders: B= 1.37 p=0.01; osteopathies, chondropaties, and acquired musculoskeletal deformities: B= 5.52 p=0.02
Styron et al. 2015 (161)	467 (436) A large health care system	66.6 (SD 10.3)	Unspecific shoulder pain	20.9 months	Expectations of recovery (ten-point Likert scale)	Pain intensity (PSS pain subscore) Disability (PSS function subscore and SF-12-PCS score)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six months after surgery	Preoperative expectation of recovery-pain intensity at six months (PSS pain subscore): Mean[95%CI] = 1.99[0.17 to 3.82] p=0.033 Preoperative expectation of recovery-disability at six months (PSS-function subscore): Mean [95%CI] = 2.65[0.14 to 5.16] p=0.039; (SF-12-PCS score): Mean [95%CI] = -0.06[-0.78 to 0.65] p=0.858
Tashjian et al. 2004 (210)	199 Hospital	56	Rotator cuff tear	16.95 months (SD 26.57)	Expectations of recovery (MODEMS)	Disability (DASH; SF-36 physical function; SST)	C-S	Expectations of recovery-disability: SF-36-physical function: p=0.046. Data not reported with DASH and SST
Thomas et al. 2004 (214)	207 (195) Nine general practices	58 (SD 14)	Unspecific shoulder pain	No preferences 60 days (IQR 21-120); physiotherapy 40	Beliefs about preference of treatment: one item at baseline: “if you had a free choice, would you	Disability (Shoulder disability questionnaire)	Longitudinal (prospective cohort study)	Baseline beliefs about treatment preferences-disability at six months: Better outcome: no preferences (72%), randomised to treatment preferences (74%); not randomised to treatment preferences (58%); poor outcome: no

				(IQR 21-90); injection 42 (IQR 21-120)	choose to have physiotherapy or an injection?"; one item six months after intervention: "if you had a similar shoulder problem again, which treatment do you prefer?"		(T1) at baseline; (T2) at six months	preferences (21%), randomised to treatment preferences (48%); not randomised to treatment preferences (0)
Valencia et al. 2011 (127)	59 (48) the University of Florida's Orthopaedics Sports Medicine Institute	50.39 (SD 14.92)	Unspecific shoulder pain	-	Pain catastrophizing (PCS)	Pain intensity (BPI)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at three months after surgery	Baseline pain catastrophizing-pain intensity at three months: standardized B=0.34 p=0.04
Valencia et al. 2014 (167)	78 (73) the University of Florida's Orthopaedics Sports Medicine Institute	43.25 (SD) to 51.35 (SD 20.73)	Multiples shoulder pain complaints	68.98 (SD 68.59) to 88.78 (SD 137.13) weeks	Pain catastrophizing (PCS)	Pain intensity (BPI) Disability (DASH)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at six months after surgery	Baseline pain catastrophizing-pain intensity at six months: standardized B= 0.05 p=0.70 Baseline pain catastrophizing-disability at six months: standardized B= 0.23 p=0.11
Warth et al. 2013 (207)	313 Hospital	48.7	Unspecific shoulder pain	-	Expectations of recovery (17 items)	Pain intensity (ASES) Disability (QuickDASH, ASES, and SF-	C-S	Expectations of recovery-pain intensity: decrease AM pain p<0.001; decrease PM pain p<0.001 Expectations of recovery-disability with ASES: Improve ROM p<0.001; reach

						12 physical component)		above shoulder p<0.001; participate in recreation p<0-001; reach sideways p<0.001; carry 10 pounds p<0.001; perform ADLs p<0.001; dress oneself p<0.001 Expectations of recovery-disability with SF-12: reach above shoulder p<0.001; participate in recreation p<0-001; reach sideways p<0.001; carry 10 pounds p<0.001; perform ADLs p<0.001; dress oneself p<0.001 Expectations of recovery-disability with QuickDASH: improve ROM p<0.05; reach above shoulder p<0.001; participate in recreation p<0-001; reach sideways p<0.001; carry 10 pounds p<0.001; perform ADLs p<0.001; dress oneself p<0.001
Van der Windt et al. 2007 (132)	587 (517) Primary care	51.5 (SD 14)	Unspecific shoulder pain	0-2 weeks (14.2%); 3-6 weeks (20.8%); 6-13 weeks (23.7%); more than 13 weeks (41.3%)	Pain catastrophizing (PCCL-Catastrophizing subscale) Fear-avoidance beliefs (FABQ-P)	Disability (SDQ)	Longitudinal (prospective cohort study) (T1) at baseline; (T2) at three months	Baseline fear-avoidance-disability at three months: adjusted 50-75 OR [95%CI] = 1.22[0.81 to 1.83]; >75 OR [95%CI] = 1.12[0.68 to 1.85] Baseline pain catastrophizing-disability at three months: adjusted 20-40 OR [95%CI] = 1.33[0.88 to 1.99]; >40 OR [95%CI] = 1.32[0.78 to 2.24]
Wolfensberger et al. 2016 (208)	314 (158)	18-65 years	Multiples shoulder pain complaints	More than 3 months	Pain catastrophizing (PCS)	Pain intensity (BPI)	Longitudinal (retrospective cohort study)	Baseline kinesiophobia-pain intensity at discharge (four-five weeks): B[95%CI] = 0.01[-0.03 to 0.05] p=0.521

the Clinique Romande de Readaptation	Kinesiophobia (TSK)	Disability (DASH)	(T1) at baseline; (T2) at discharge (four-five weeks)	Baseline pain catastrophizing-pain intensity at discharge (four-five weeks): B[95%CI] = 0.03[0.01 to 0.06] p=0.011 Kinesiophobia-disability (DASH) at discharge (four-five weeks): B [95%CI] = 0.15[-0.14 to 0.44] p=0.310; kinesiophobia-disability (Constant Murley) at discharge (four-five weeks): B [95%CI] = -0.29[-0.51 to -0.06] p=0.013 Pain catastrophizing-disability (DASH) at discharge (four-five weeks): B [95%CI] = 0.30[0.12 to 0.47] p=0.001; pain catastrophizing-disability (Constant Murley) at discharge (four-five weeks): B [95%CI] = -0.19[-0.33 to -0.04] p=0.012

Note: C-S: cross-sectional; PSEQ: the Pain Self-Efficacy Questionnaire; SPADI: the Shoulder Pain and Disability Index; TSK-11: the Tampa Scale for Kinesiophobia-11 items; QuickDASH: Quick Disability of the Arm, Shoulder and Hand Questionnaire; PCS: the Pain Catastrophizing Scale; FABQ: the Fear-Avoidance Beliefs Questionnaire; BPI: the Brief Pain Inventory; Penn-F: Pennsylvania Shoulder Score function subscale; LOT-R: Life Orientation Test-Revised); ASES: Arthritis Self-Efficacy Scale; FPQ-III: the Fear of Pain Questionnaire; NRS: the numerical rating scale; VAS: Visual Analogue Scale; GSES: the General Self-Efficacy Scale; SST: the Simple Shoulder Test; MODEMS: the Musculoskeletal Outcomes Data Evaluation and Management System Questionnaire; ASES: the American Shoulder and Elbow Surgeons; FLEX-SF: the Flexilevel Scale of Shoulder Function; PSOE: Patient Shoulder Outcome Expectancies; WORC: the Western Ontario Rotator Cuff Index; PCCL: the 43-item Pain Coping and Cognition List; CAT: the Shoulder Computerized Adaptive Test; PSS: the Penn Shoulder Score; SF-12-PCS score: the General Health-Related Quality of life Physical Component Summary (PCS) Score; B: Betta Coefficient; r: Pearson's Coefficient of Correlation; R^2: Coefficient of Determination; p: P value; CI: confidence interval.

12.10 Appendix J: Summary of the findings obtained in included studies (cross-sectional analysis) (original article: "The association between pain beliefs and pain intensity and/or disability in people with shoulder pain: a systematic review")

Pain beliefs	Pain intensity						
	Shoulder impingement syndrome	Subacromial shoulder pain	Shoulder instability	Rotator cuff disease	Glenohumeral osteoarthritis	Unspecific Shoulder pain	Multiples shoulder pain conditions
Kinesiophobia	× (Clausen et al., 2017)					× (George et al., 2008) √(Lentz et al., 2009)	
Fear of pain				× (George and Hirsh, 2009)		× (George et al., 2008)	
Fear-avoidance beliefs		×(Kromer et al., 2014)					
Pain catastrophizing		√(Kromer et al., 2014)		√ (George and Hirsh, 2009) × (Kindler et al., 2011)		√ (George et al., 2008)	√(Menendez et al., 2015)
Expectations of recovery			× (Plath et al., 2017)		√ (Henn et al., 2011)	√(Warth et al., 2013)	
Self-efficacy							√(Menendez et al., 2015)

Note: √: results are statistically significant. ×: results are not statistically significant.

Pain beliefs	Disability				
	Shoulder impingement syndrome	Rotator cuff disease	Glenohumeral osteoarthritis	Unspecific Shoulder pain	Multiples shoulder pain conditions
Kinesiophobia	× (Clausen et al., 2017)			√(Lentz et al., 2009)	
Pain catastrophizing					√(Menendez et al., 2015)

12.11 Appendix K: Summary of the findings obtained in included studies (longitudinal analysis). (Original article: "The association between pain beliefs and pain intensity and/or disability in people with shoulder pain: a systematic review")

Baseline pain beliefs	Pain intensity					
	4-5 weeks	6 weeks	3 months	6 months	12 months	At discharge
Self-efficacy		× Rotator cuff disease (Ekeberg et al., 2010)		✓ Unspecific shoulder pain (Chester et al., 2018) × Unspecific shoulder pain (Karlsson et al., 2016)	✓ Subacromial shoulder pain (Engebretsen et al., 2010) × Unspecific shoulder pain (Karlsson et al., 2016)	
Expectations of recovery		× Rotator cuff disease (Ekeberg et al., 2010)		✓ Unspecific shoulder pain (Chester et al., 2018) ✓ Unspecific shoulder pain (Styron et al., 2015)	✓ Rotator cuff disease (Henn et al., 2007)	
Optimism			× Unspecific shoulder pain (Coronado et al., 2017)			
Fear-avoidance beliefs			× Unspecific shoulder pain (Coronado et al., 2017)	✓ Unspecific shoulder pain (Karlsson et al., 2016) ✓ Unspecific shoulder pain (Laslett et al., 2015)	× Unspecific shoulder pain (Karlsson et al., 2016) ✓ Unspecific shoulder pain	× Multiples shoulder pain complaints (Sindhu et al., 2012)

					(Laslett et al., 2015)	
Kinesiophobia	× Multiples shoulder pain complaints (Wolfensberger et al., 2016)					
Pain catastrophizing	✓ Multiples shoulder pain complaints (Wolfensberger et al., 2016)		× Unspecific shoulder pain (Coronado et al., 2017) ✓ Unspecific shoulder pain (Valencia et al., 2011)	× Unspecific shoulder pain (Karlsson et al., 2016) × Unspecific shoulder pain (acute pain) (Reilingh et al., 2008) ✓ Unspecific shoulder pain (chronic pain) (Reilingh et al., 2008) × Multiples shoulder pain complaints (Valencia et al., 2014)	× Unspecific shoulder pain (Karlsson et al., 2016)	
External locus of control				× Unspecific shoulder pain (acute and chronic pain) (Reilingh et al., 2008)		

Note: ✓: results are statistically significant. ×: results are not statistically significant.

Baseline pain beliefs	Disability						
	4-5 weeks	6 weeks	3 months	6 months	12 months	Mean 13.7 months	At discharge
Self-efficacy		× Rotator cuff disease (Ekeberg et al., 2010)		✓ Unspecific shoulder pain (Chester et al., 2018)	✓ Subacromial shoulder pain (Engebretsen et al., 2010)		
Expectations of recovery		× Rotator cuff disease (Ekeberg et al., 2010)	✓ Soft tissue shoulder disorders (Kennedy et al., 2006b) × Soft tissue shoulder disorders (Kennedy et al., 2006a) ✓ Multiples shoulder pain complaints (O'Malley et al., 2004)	✓ Unspecific shoulder pain (Chester et al., 2018) × Rotator cuff disease (Razmjou et al., 2011) ✓ Unspecific shoulder pain (Styron et al., 2015)	✓ Rotator cuff disease (Henn et al., 2007)	✓ Rotator cuff disease (Oh et al., 2012)	
Optimism			× Unspecific shoulder pain (Coronado et al., 2017)				
Fear-avoidance beliefs			× Unspecific shoulder pain (Coronado et al., 2017)	✓ Unspecific shoulder pain (Laslett et al., 2015)	✓ Unspecific shoulder pain (Laslett et al., 2015)		✓ Multiples shoulder pain complaints (Sindhu et al., 2012)

			✗ Subacromial shoulder pain (Kromer et al., 2014) ✗ Unspecific shoulder pain (van der Windt et al., 2007)				
Kinesiophobia	✓ Multiples shoulder pain complaints (Wolfensberger et al., 2016)						
Pain catastrophizing	✓ Multiples shoulder pain complaints (Wolfensberger et al., 2016)		✓ Unspecific shoulder pain (Coronado et al., 2017) ✗ Subacromial shoulder pain (Kromer et al., 2014) ✗ Unspecific shoulder pain (van der Windt et al., 2007)	✗ Multiples shoulder pain complaints (Valencia et al., 2014)			
Preoperative concerns						✗ Rotator cuff disease (Oh et al., 2012)	
Beliefs about treatment				✗ Unspecific shoulder pain (Thomas et al., 2004)			

Note: ✓: results are statistically significant. ✗: results are not statistically significant.

12.12 Appendix L: Written informed consent

CONSENTIMIENTO INFORMADO

D. /ña. ____, de ____ años de edad y con DNI nº __________________, manifiesta que ha sido informado/a sobre los objetivos del Proyecto de Investigación titulado "Influencia de los factores psicológicos y de la neurosensibilización central en el pronóstico del dolor crónico de hombro".

He sido informado/a que mi participación en este estudio no supone ningún perjuicio sobre mi bienestar y salud y de que mis datos personales serán protegidos, de acuerdo a la normativa de protección de datos (Ley 15/1999 de Protección de Datos de Carácter Personal), así como la ley de protección de derechos de los pacientes (Ley 15/2002).

También he sido informado/a que podré abandonar en cualquier momento el estudio, incluso podré retirar mi consentimiento informado si así lo considero oportuno, sin que tenga que dar explicación alguna al motivo del abandono. Dicho abandono no influirá en absoluto a sus cuidados sanitarios.

Tomando ello en consideración, OTORGO mi CONSENTIMIENTO a la realización de cuestionarios y mediciones sobre el dolor musculoesquelético que padezco, y que la información obtenida sea utilizada para cubrir los objetivos especificados en el proyecto.

Málaga, a ______ de ______________de _____

Fdo.