

# The Journal of Pain

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### Critical Review

#### 199 Reporting of Sample Size Calculations in Analgesic Clinical Trials: ACTION Systematic Review

Andrew McKeown, Jennifer S. Gewandter, Michael P. McDermott, Joseph R. Pawlowski, Joseph J. Poli, Daniel Rothstein, John T. Farrar, Ian Gilron, Nathaniel P. Katz, Allison H. Lin, Bob A. Rappaport, Michael C. Rowbotham, Dennis C. Turk, Robert H. Dworkin, and Shannon M. Smith

Sample size calculations determine the number of participants required to have sufficiently high power to detect a given treatment effect. In this review, the authors examined the reporting quality of sample size calculations in 172 publications of double-blind randomized controlled trials of noninvasive pharmacologic or interventional pain treatments. Results show that sample size calculations and the required elements—such as treatment effect to be detected and power level—were incompletely reported. A lack of transparency may raise questions about the appropriateness of the calculated sample size. More detailed information should be reported to encourage improved design of clinical trials.

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#### ON THE COVER

These images demonstrate sectioned spinal cords in transected mice. To determine whether an injury-specific promoter can enhance antinociception and drive expression of mu-opioid receptor in specific populations of afferent neurons, as opposed to constitutive expression with a nonspecific promoter, the authors compared animals infected with a galanin promoter virus to those infected with a cytomegalovirus promoter virus. This article presents evidence that promoter selection is an important component in successful gene expression in an injury- and population-specific manner. See Smith et al, page 283.

## Original Reports

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### **Diurnal and Nocturnal Skin Temperature Regulation in Chronic Complex Regional Pain Syndrome**

Johanna C. M. Schilder, Sjoerd P. Niehof, Johan Marinus, and Jacobus J. van Hilten

Skin temperature changes due to vasomotor disturbances are important features of complex regional pain syndrome (CRPS). Because this phenomenon has only been studied under controlled conditions, information on daily circadian variability is lacking. Also, studies in chronic CRPS patients with abnormal posturing, in which coldness of the affected extremity is more common, do not exist. This report examined the response to external heating as well as circadian temperature changes in the affected legs of 14 chronic CRPS patients and in 17 controls. Findings show that chronic CRPS patients have a normal vasodilatory response to external heating and that skin temperature differences, which were highly variable during daytime, disappeared during sleep. This suggests that part of the vasomotor regulation in these patients is still functional.

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### **Threatening Social Context Facilitates Pain-Related Fear Learning**

Kai Karos, Ann Meulders, and Johan W. S. Vlaeyen

This study investigated the effects of a threatening and a safe social context on learning pain-related fear, a key factor in the development and maintenance of chronic pain. Researchers measured self-reported pain intensity, pain expectancy, pain-related fear, and behavioral measures of avoidance. The authors report that a threatening social context leads to stronger acquisition of pain-related fear and simultaneous contextual fear but does not affect pain intensity ratings. This knowledge may aid in the prevention of chronic pain and anxiety disorders and shows that social context might modulate pain-related fear without immediately affecting pain intensity itself.

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### **Presurgical Psychosocial Predictors of Acute Postsurgical Pain and Quality of Life in Children Undergoing Major Surgery**

Jennifer A. Rabbitts, Cornelius B. Groenewald, Gabrielle G. Tai, and Tonya M. Palermo

Limited research has examined presurgical risk factors for poor outcomes in children after major surgery. Regression analysis revealed that presurgery sleep duration and parental catastrophizing were significantly associated with mean pain intensity reported by children 2 weeks after surgery. This study addresses a gap in the literature. Child anxiety, parental pain catastrophizing, and sleep patterns are potentially modifiable factors that predict poor outcomes; knowledge of these factors may enable identification of children at risk for poorer outcomes and guide development of prevention and intervention strategies for such children.

## **235 The Role of Parent Psychological Flexibility in Relation to Adolescent Chronic Pain: Further Instrument Development**

Dustin P. Wallace, Lance M. McCracken, Karen E. Weiss, and Cynthia Harbeck-Weber

The parental role in relation to a young person with chronic pain can be significant, particularly with regard to daily functioning. Studies of parent functioning and influences on pain have examined many variables, including pain beliefs, worry, catastrophizing, illness behavior, encouragement, and parental protective responses. Psychological flexibility, defined as the capacity to persist with or change behavior while recognizing influences on behavior, may provide a basis for further investigating the role of responses. The Parent Psychological Flexibility Questionnaire is a promising but preliminary measure of this construct. This model may help tie parental responses to adolescent distress and disability and may help clarify the development and maintenance of disability within the context of chronic pain.

## **247 Parasympathetic Reactivity in Fibromyalgia and Temporomandibular Disorder: Associations With Sleep Problems, Symptom Severity, and Functional Impairment**

Tory A. Eisenlohr-Moul, Leslie J. Crofford, Thomas W. Howard, Juan F. Yepes, Charles R. Carlson, and Reny de Leeuw

Despite evidence of autonomic disturbances in chronic multisymptom illnesses such as temporomandibular joint disorder and fibromyalgia, additional work is needed to characterize the role of parasympathetic reactivity in these disorders. Given the high levels of comorbidity with psychiatric disorders characterized by stronger parasympathetic decline than controls, it was hypothesized that individuals with temporomandibular joint disorder and fibromyalgia would respond similarly. As predicted, patients showed greater parasympathetic decline during psychosocial assessment. This may demonstrate a tendency to readily perceive danger in safe environments.

## **258 Can Experimentally Induced Positive Affect Attenuate Generalization of Fear of Movement-Related Pain?**

Nicole Geschwind, Michel Meulders, Madelon L. Peters, Johan W. S. Vlaeyen, and Ann Meulders

Recent experimental data show that associative learning processes are involved not only in the acquisition but also in the spreading of pain-related fear. Clinical studies suggest involvement of positive affect in resilience against chronic pain. Surprisingly, the role of positive affect in associative learning in general, and in fear generalization in particular, has received scant attention. This work investigated the extent to which positive affect influences the spreading of pain-related fear inhibition. The authors report that increasing positive affect in the acute pain stage may limit the spread of pain-related fear, thereby potentially inhibiting transition to chronic pain conditions.

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**Pregnancy Is Characterized by Widespread Deep-Tissue Hypersensitivity Independent of Lumbopelvic Pain Intensity, a Facilitated Response to Manual Orthopedic Tests, and Poorer Self-Reported Health**

Thorvaldur Skuli Palsson, Darren Beales, Helen Slater, Peter O'Sullivan, and Thomas Graven-Nielsen

During pregnancy, between 72 and 84% of women develop lumbopelvic pain (LPP) to some extent. While common in pregnancy, the sensitization factors underlying the condition are largely unknown. This study characterized the somatosensory profile of pregnant and nonpregnant women and the relationship between pain, hypersensitivity, and commonly used manual clinical tests. Results demonstrate that pain sensitivity increases during pregnancy, likely owing to the physical changes the body undergoes during pregnancy but also owing to changes in emotional health. This should be accounted for in clinical management of pregnant women with LPP.

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**Injury-Specific Promoters Enhance Herpes Simplex Virus–Mediated Gene Therapy for Treating Neuropathic Pain in Rodents**

Sherika N. Smith, Candler Paige, Kandy T. Velazquez, Terika P. Smith, Srinivasa N. Raja, Steven P. Wilson, and Sarah M. Sweitzer

Chronic neuropathic pain often decreases quality of life, incurs high medical costs, and is difficult to treat. The efficacy of current treatments varies across individuals and is associated with adverse side effects. Gene therapy is currently being explored as a therapeutic approach for the treatment of neuropathic and cancer pain. To determine whether an injury-specific promoter can enhance antinociception and drive expression of mu-opioid receptor transgene in specific populations of afferent neurons, as opposed to constitutive expression with a nonspecific promoter, the authors compared animals infected with a galanin promoter virus to those infected with a cytomegalovirus promoter virus.

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**Physical and Psychological Correlates of Fatigue and Physical Function: A Collaborative Health Outcomes Information Registry (CHOIR) Study**

John A. Sturgeon, Beth D. Darnall, Ming-Chih J. Kao, and Sean C. Mackey

Fatigue contributes to physical dysfunction in chronic illness and chronic pain populations but remains relatively poorly understood. This study characterized the independent contributions of self-reported ratings of pain intensity, sleep disturbance, depression, and fatigue to ratings of physical function and pain-related interference among patients with chronic pain. These relationships were examined as a path modeling analysis of self-report scores obtained from 2,487 individuals. The results identify potential targets for future treatment of fatigue in chronic pain and may provide directions for future clinical and theoretical research.

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