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CLINICAL TRIAL PROTOCOL

Applying contemporary neuroscience in exercise interventions for chronic spinal pain: treatment protocol☆

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Abstract
Background: Nonspecific chronic spinal pain (nCSP) is a common problem within the chronic pain population and is characterized by high social, economic and personal impact. To date, therapists are still struggling in adequately treating these types of patients, as seen in the small and short-term benefits of frequently applied primary care treatments. It is remarkable that despite the well-documented presence of abnormalities in central nociceptive processing in nCSP patients, the implementation of this knowledge in clinical practice is still nearly non-existent.
Methods: This paper provides the treatment protocol used in a large randomized controlled trial that aimed to assess the effectiveness of a modern neuroscience approach compared to usual care evidence-based physiotherapy. This comprehensive pain neuroscience treatment program combines pain neuroscience education and cognition-targeted exercise therapy.
Conclusion: Based on previous small-scaled studies, this treatment protocol is expected to normalize central alterations by addressing central nervous system dysfunctions, psychological factors, as well as peripheral dysfunctions in a broader biopsychosocially-driven framework.

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Introduction

Nonspecific chronic spinal pain (nCSP) accounts for a large proportion of the chronic pain population and includes, i.e. chronic low back pain, failed back surgery, chronic whiplash associated disorders, and chronic non-traumatic neck pain.[1,2] Besides its high prevalence (31% and 22% in women and men respectively in Belgium), nCSP is severely disabling and characterized by tremendous personal and socioeconomic impact, with long-term sick-leave, low quality of life and high socio-economic costs.[3] No wonder that research on the most efficient and affordable strategies to deal with nCSP has been strongly advocated.[4–6] To meet this need, a large randomized controlled trial investigating the effectiveness of such modern approach is currently ongoing. The protocol of this study is published[7] and registered online (clinicaltrials.gov NCT02098005). However, these documents are focussed on the global study design without giving details on treatment aspects. Therefore, this paper aims at giving full transparency regarding the experimental treatment used in this study. This multicentre randomized controlled trial was approved by the local ethics committees of University Hospital Ghent (ID: 2013/1133) and University Hospital Brussels (ID: 2013/385).

Why using a modern neuroscience approach?

nCSP management should aim at achieving and maintaining a clinically important reduction in pain and disability, with optimal cost-effectiveness and minimal inconveniences. Yet, systematic reviews on the most frequently applied primary care treatments for nCSP (i.e. mobilization, manipulation, exercise therapy, back schools, NSAID's, TENS, etc.) report small, short-term benefits when compared to no, sham or other forms of treatment.[4,8–12] Physiotherapy in nCSP is often limited to a biomedical (i.e. neuromuscular training) or psychological model (i.e. graded exposure, graded activity, etc.), without accounting for the underlying pain mechanisms and the present understanding of modern pain neuroscience.[13] These types of therapy are focused either on input mechanisms (treating peripheral elements like joints and muscles) or output mechanisms (motor control), while there is less attention for the well documented abnormalities in central nociceptive processing mechanisms [14–22].

These central nociceptive processing abnormalities include alterations in brain activity and morphology, hyperexcitability of the central nervous system and central sensitization.[13,22–26] This knowledge provides arguments for choosing a challenging new direction by developing novel clinical strategies targeting the brain and aiming at normalizing central alterations. This approach may increase the effect sizes and socioeconomic impact of treatment of nCSP.

Inspired by this state of the art, treatment should aim at addressing central nervous system dysfunctions,[27,28] psychosocial factors,[13,29] as well as peripheral dysfunctions in a broader biopsychosocially-driven framework. Although the problem in nCSP is not related to a dominant 'input' mechanism, there is still compelling evidence for impaired motor control.[30–35] Therefore, therapy should focus primarily at central nociceptive processing problems, in a balanced combination with targeting specific 'output' mechanisms given the maladaptive movement and activity strategies these patients display. This can be implemented in a modern neuroscience approach by using a comprehensive pain neuroscience treatment program comprising pain neuroscience education (PNE) followed by cognition-targeted exercise therapy.[13] The randomized controlled trial investigating the effectiveness of this approach is currently ongoing.[7] Here we provide the detailed experimental treatment protocol of this study.

The modern neuroscience approach

Step 1: pain neuroscience education

Both the practical application and positive clinical effects of PNE have been described extensively in nCSP and other chronic pain populations.[36–44] PNE aims at reconceptualizing pain, by explaining that all pain is in the brain and that, rather than local tissue damage, hypersensitivity of the central nervous system may be the cause of the pain problem. PNE enables patients to understand the controversy surrounding their pain, including the lack of objective biomarkers or imaging findings.

Based on cost-effectiveness arguments,[42] preference was given to the combination of a group, an online and an individual session completed with an informational leaflet to read at home, as an individual session of PNE is more effective for reducing pain and disability, but a group session is more cost-effective. General principles of PNE were explained in the group session, using examples and metaphors based on the individual experiences of the participating persons. Groups were kept small (i.e. 6 persons/group) in order to maintain an interactive and individualized approach. Between the group and individual session, the patient was asked to read an informational leaflet and to complete an online session. An example of the latter can be found at www.retrainpain.org in several languages. This online session[45] covers the same information as the group session in order to facilitate deep learning and was adapted with different questions to assess the knowledge, perceptions and opinions of the patient regarding the PNE content. The information extracted from these questions was used to optimize and to individualize the third (individual) PNE session to increase its effectiveness. In addition to the educational sessions, the Neurophysiology of Pain test was used as part of the intervention to ascertain the quality of the education program by further discussing the patients' misinterpretations upon completion of the questionnaire.[46,47]

As such, PNE was used to reach therapeutic alliance between the patient and his/her therapist, which is a crucial milestone in the modern neuroscience approach of nCSP. PNE includes a transfer of knowledge, which enables applying the time-contingent approach that is a critical feature of the following step (cognition-targeted exercise training). An example of the communication preparing the patient for the exercise training can be found in Box 1. Implementing this next step is essential, as PNE as a sole treatment has rather small effect sizes.[38] Once the patient has adopted new beliefs and cognitions, exercise therapy with special emphasis on cognitions and perceptions

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