Scandinavian Journal of Pain 9 (2015) 11–21

Contents lists available at ScienceDirect

Scandinavian Journal of Pain

journal homepage: www.ScandinavianJournalPain.com

Clinical pain research

Cognitive behaviour therapy in women with fibromyalgia: A randomized clinical trial☆

Bo Karlsson*, Gunilla Burell, Ulla-Maria Anderberg, Kurt Svärdsudd

Uppsala University, Department of Public Health and Caring Sciences, Family Medicine and Preventive Medicine Section, Uppsala, Sweden

HIGHLIGHTS

- Patients with fibromyalgia were treated with cognitive behaviour therapy tailored for coping with stress and pain.
- Cognitive behaviour therapy resulted in better life control, less depression, stress and fatigue.
- Pain intensity was not affected by cognitive behaviour therapy according to this protocol.
- The effects of therapy were maintained and enhanced during one year of follow up.
- Behaviour responses to pain are important for monitoring and not only for ratings of pain.

ARTICLE INFO

Article history:
Received 7 October 2014
Received in revised form 21 April 2015
Accepted 26 April 2015

Keywords:
Chronic pain
Stress management
Depression
Vital exhaustion
Multidimensional pain inventory

ABSTRACT

Background and aims: Stress has been pointed out as an important influential factor in the development and maintaining of the fibromyalgia syndrome (FMS). Since stress may worsen the pain experience, the development of individual strategies for coping with stress is essential to reduce the impact of FMS on daily life. The aim of the study was to investigate whether a group based stress management cognitive behaviour therapy (CBT) programme could influence self-reported stress, wellbeing and life control, as well as self-reported pain behaviour in female FMS patients.

Methods: 48 female FMS patient were randomized into a cognitive behaviour therapy treatment group ($n = 24$) and a waitlist control group ($n = 24$). When the 6 months waitlist period was over the control group received the same CBT programme. This allowed two analytical approaches, one based on the randomized controlled trial design and one based on a before-and-after design to improve the statistical power of the study. Four psychometric instruments were used: The West Haven-Yale Multidimensional Pain Inventory (three parts, MPI-1 to MPI-3), the Maastricht Questionnaire, the Everyday Life Stress, and the Montgomery-Åsberg Depression rating scale – self-reported. Primary outcome was the MPI-1 dimension 'life control', secondary outcomes were the MPI-1 dimensions 'interference', 'affective distress' and 'support from spouses or significant others', the various MPI-2 dimensions, the 'general activity level' in the MPI-3 dimension, and 'vital exhaustion', 'stress behaviour', and 'depression'. The only tertiary outcome was the MPI-1 dimension 'pain severity'.

Results: In the RCT design the West Haven-Yale Multidimensional Pain Inventory dimensions 'life control', 'interference from pain', 'affective distress', 'support from spouses or significant others', and 'distracting responses' and ratings for depression improved in the treatment group as compared with the control group. In the before-and after design these improvements were maintained and enhanced during 1-year follow-up, and so was the 'vital exhaustion' and 'stress behaviour'. 'Pain severity' was rated higher after the intervention.

Conclusions: Cognitive behaviour therapy improved the life control in a female population with FMS. Coping behaviour in response to chronic pain was improved at the same time and in spite of higher

Abbreviations: ACR, American College of Rheumatology; FMS, fibromyalgia syndrome; CBT, cognitive behaviour therapy; MADRS-S, Montgomery-Åsberg Depression Rating Scale – self-reported; MPI, Westhaven-Yale Multidimensional Pain Inventory; MPI-S, Westhaven-Yale Multidimensional Pain Inventory Swedish version; RCT, randomized clinical trial.

☆ The trial is registered with Clinicaltrials.gov: NCT01004458.

* Corresponding author at: Department of Public Health and Caring Sciences, P.O. Box 564, SE-751 22 Uppsala, Sweden. Tel.: +46 70 227 81 26; fax: +46 18 471 66 75.
E-mail addresses: bo.karlsson@pubcare.uu.se (B. Karlsson), gunilla.burell@pubcare.uu.se (G. Burell), ullamariaanderberg@gmail.com (U.-M. Anderberg), kurt.svardsudd@pubcare.uu.se (K. Svärdsudd).

http://dx.doi.org/10.1016/j.sjpain.2015.04.027

subjective ratings of pain. Positive effects were seen on depression, vital exhaustion and stress behaviour. The effects of therapy were maintained and enhanced during the follow up period. It appears that women with FMS after the CBT treatment, according to this protocol obtained tools leading to better acceptance of their disorder.

Implications: FMS is a disorder with great therapeutic challenges. Total abolishment of pain symptoms is extremely difficult or impossible to achieve. Thus, the development of individual strategies for coping with pain is essential to reduce its impact on daily life. Since stress may worsen the pain experience, coping with stress might be a promising route to accomplishing that goal. In evaluations of interventions for pain it is important to monitor the effect on behaviour responses to pain and not only ratings of pain itself.

1. Introduction

The fibromyalgia syndrome (FMS) is a chronic pain disorder, for which classification criteria were established by the American College of Rheumatology (ACR) in 1990 [1]. The two major criteria are a history of widespread pain for three months or more, and tenderness in at least 11 out of 18 defined tender points. In addition to pain, most FMS patients suffer from fatigue, sleep disturbances, cognitive problems and a variety of symptoms such as backache, nausea, diarrhoea, constipation [2,3], resulting in disability and reduced quality of life [4].

Co-morbidity with psychiatric diagnoses, such as depression and anxiety disorders, is common. Approximately one out of three FMS patients have a depression diagnosis. FMS has a female preponderance, female to male ratio 10:1 [5,6].

Evidence has been presented that FMS has its origins in the central rather than the peripheral nervous system or the musculoskeletal system [7–9]. There is also evidence that FMS is a stress-related disorder [9–11]. A strong relationship to stress-related morbidity, low levels of serotonin, and perturbed pain processing peptide levels found in FMS patients, have been forwarded as evidence [12–14].

Stress involves the individual's mobilization of resources to deal with threat and challenge. The stress concept includes both stressor (load/challenge) and response. There is no universally accepted definition of stress. However, a useful and widely adopted definition is to regard stress as a process in terms of external challenges, coping resources and perception of coping resources, and the dynamic interplay of these over time [15,16]. The formulation has its origin in the conceptualization proposed by Lazarus and Folkman [17]. This definition of stress provides a useful framework for the present study.

According to a bio-psycho-motor model [18] at least three behaviour subsystems: communicative pain behaviours, protective pain behaviours, and social response behaviours, are integral components of pain. The bio-psycho-motor model is an improvement as compared to earlier models because its emphasis on behaviours as central to the distress of chronic pain. It implies a chain of events and consequences: tissue damage – pain sensation – reflective/automatic and operant pain behaviours – functional impairment and distress – reduced activities – disability. When pain leads to disabling consequences in a person's everyday life, the pain sensation per se – or even the presence of tissue damage – may not be the main determining factor. Therefore, in pain assessment and treatment, focus must be placed on functional analyses of the resulting behaviours: communicative, protective, and social responsive. Both communicative (e.g. facial expressions and vocalizations) and protective (withdrawal, escaping, holding, rubbing, postural adaptations) can be viewed as reflexive and automatic.

The magnitude and expressiveness of such responses are also influenced by social and cultural norms, as well as the afflicted person's beliefs, fear, and expectations. Social responses to communication of pain may play a role in the development and maintenance of pain-related disability [18], independent of the pain level per se, by selective reinforcement of pain behaviours. Since dysfunction may arise in behavioural systems separate from pain sensation, treatments targeting pain sensation might not always yield the best outcomes. On the contrary, disability may be reduced in the absence of reduction in pain.

A CBT manual, developed on a theoretical framework with a focus on affective and behaviour consequences of pain, as well as cognitive and behaviour strategies for coping with pain and stress, was used in the present study. The prime hypothesis was that this version of CBT in female FMS patients influences the MPI-1 dimension 'life control'. The secondary hypothesis was that CBT influences the MPI-1 dimensions 'interference', 'affective distress' and 'support from spouses or significant others', the various MPI-2 dimensions, the 'general activity level' in the MPI-3 dimension, and 'vital exhaustion', 'stress behaviour', and 'depression'. The tertiary hypothesis was that CBT influences the MPI-1 dimension 'pain severity'.

2. Material and methods

2.1. Study population

The study was performed in a municipality in central Sweden with approximately 22,000 inhabitants in 2001–2003. The study population was recruited by advertising in the local daily newspaper and an information meeting with the local branch of the Fibromyalgia Patient Association.

Responding female women with FMS were invited to an examination at the coordinating primary health care centre. Inclusion criteria were age 18–64 years, being Swedish-speaking, and fulfilment of the 1990 ACR criteria [1] (generalized pain for more than three months, distributed in all four body quadrants, and at least 11 tender points in typical locations). Exclusion criteria were major psychiatric or somatic disease, and substance abuse.

Information was sought on duration of generalized pain as well as time since possible FMS diagnosis. Tender points were assessed manually by finger top pressure of 40 N/cm^2 by one physician (BK). History of severe psychiatric or somatic disease was obtained from medical records, in addition to information from the patient during the screening examination. No formal testing of psychological disorders or symptoms was done during this examination. A physiotherapist experienced in FMS tender point assessment validated the diagnostic procedure.

Among the 54 female patients recruited, six patients were excluded after these procedures. Two did not fulfil the diagnostic criteria, two had a serious mental disorder, and two declined participation after receiving further information about the study. The remaining 48 women agreed to participate and were using a random block design allocated into two groups, group 1 ($n = 24$) and group 2 ($n = 24$). The randomization was performed with the SAS