Effect of individually tailored bio-psycho-social workplace interventions on Chronic Musculoskeletal Pain, Stress and Work Ability Among Laboratory Technicians: Randomized Controlled Trial Protocol

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Competing interest
The study was funded by a commercial organization.

Talent/model release
Consent for publication has been obtained from the person modelling the pictures in this article.

Author’s contributions
KJ and LLA conceived the study and recruited the company. KJ, MB, ES and MDJ designed and planned the experimental test procedure. GS, mc and LLA are PhD supervisors.
Disclosure

This study protocol was submitted for external peer review before participant testing was completed.
ABSTRACT

Background
Among laboratory technicians, the prevalence of neck and shoulder pain is widespread possibly due to typical daily work tasks such as pipetting, preparing vial samples for analysis, and data processing on a computer including mouse work - all tasks that require precision in motor control and may result in extended periods of time spent in static positions.

In populations characterized by intense chronic musculoskeletal pain and diagnosed conditions in conjunction with psycho-physiological symptoms such as stress-related pain and soreness and other disabling conditions, multifactorial approaches applying a combination of individually tailored physical and cognitive strategies targeting the areas most needed, may be an effective solution to the physical and mental health challenges.

The aim of this study is therefore to investigate the effect of an individually tailored bio-psycho-social intervention strategy on musculoskeletal pain, stress and work disability in lab technicians with a history of work-related musculoskeletal pain and situational stress at a large pharmaceutical company in Denmark.

Methods/Design
In this single-blind two-armed parallel-group randomized controlled trial with allocation concealment, participants receive an individualized multifactorial intervention or “usual care” for 10 weeks at the worksite. Inclusion criteria: 1) female laboratory technician (18-67 years of age) and 2) Pain intensity ≥ 3 (0-10 Visual Analogue Scale) lasting ≥3 months with a frequency of ≥3 days per week in one or more of the following regions: i) back ii) neck, iii) shoulder iv) elbow and v) hand. Exclusion criteria: 1) life-threatening disease and 2) pregnancy. Thus, we aim to include participants with more severe chronic conditions such as fibromyalgia and myofascial pain syndrome.

We will implement an individualized strategy addressing bio-psycho-social elements of musculoskeletal pain with the following components (group EX); i) increasing physical capacity through strength- and motor control training; ii) lowering stress through selective attention practice and learning de-catastrophizing pain management strategies through cognitive training.

The primary outcome is difference in intensity of perceived musculoskeletal pain during the last week (average value of back, neck, shoulder, elbow and hand) assessed by questionnaire (visual analogue scale 0-10) between the experimental- and the usual care group.

Discussion
This study will provide experimental evidence to guide workplace initiatives designed towards reducing chronic musculoskeletal pain and stress.

**Trial registration number**

NCT02047669.

**Keywords**

Musculoskeletal disorders, Occupational health and performance, neck pain, shoulder pain, elbow pain, hand pain, Repetitive work, Stress, Work ability
INTRODUCTION

Musculoskeletal pain comprises a major socioeconomic burden on public health systems in North America and Europe [1]. Pain in the upper extremity account for the majority (20-30%) of health complaints in the adult working population [2,3]. Repetitive movement tasks with static contractions and compromised body postures are unavoidable in many occupations and are related to neck and shoulder pain. Neck and shoulder pain have been a primary outcome in several investigations examining the effects of physical exercise on musculoskeletal pain in the upper extremity [4–7]. In some occupational groups (e.g. office workers) with a high prevalence of pain and disability in the upper extremity [8,9], strength training is believed to be a clinically sound approach to implement at the worksite to counter the negative effects of static and repetitive work tasks [10,11]. In other occupational environments such as among laboratory technicians, the prevalence of neck and shoulder pain is also widespread due to typical daily work tasks such as pipetting, preparing vial samples for analysis, and data processing on a computer including mouse work—all tasks that require precision in motor control—in particular of hand-eye coordination—and may result in extended periods of time spent in static working postures. For laboratory technicians, moderate to strong support exists suggesting that high-intensity strength training, relying on principles of progressive overload, can successfully be implemented, reducing the prevalence of non-chronic musculoskeletal pain of the upper extremity [12]. However, when dealing with populations suffering from more intense chronic (lasting more than 3 months) musculoskeletal pain and diagnosed conditions in conjunction with psychophysiological symptoms such as stress-related pain and soreness, lack of concentration ability, insomnia and other disabling conditions, strategies other than high-intensity strength training may be more effective in reducing pain. One interesting multifactorial approach is to perform individual needs analyses and subsequently applying a combination of physical and cognitive strategies individually tailored in such a way, that the participant would be offered targeted training and rehabilitation in the area most needed.

Physical activity

Our research group has previously shown clinically relevant reductions in neck/shoulder/arm pain in response to 10–20 weeks of strength training using kettlebells [13,14], elastic resistance bands [15,16] or free weight exercises [10,11,17] in office workers and laboratory technicians, which cements the positive effect of simple strength training in people with musculoskeletal pain [12]. However, although strength training reduced the intensity of musculoskeletal pain with moderate to large effect sizes subjects did typically not become pain-free. Furthermore, all of these studies excluded employees with severe musculoskeletal diseases. From a theoretical
point of view, increasing the physical capacity of laboratory technicians could reduce the relative load placed upon them during work and thereby reduce the musculoskeletal strain but in contrast, targeted strength training interventions may not be feasible in people suffering from clinically diagnosed conditions such as carpal tunnel syndrome or other severe conditions. In such cases, a different approach may be necessary, as typical progressive strength training protocols may be too strenuous and thereby not be a viable treatment method. Alternatively, it might be more beneficial for some individuals to drive the intervention strategy towards basic joint mobility and the practice of precise motor control in close combination with targeted drills to relieve pain symptoms.

Fear avoidance
While a model that focuses upon structural and biomechanical abnormalities may help explain and alleviate musculoskeletal pain it cannot sufficiently explain more severe states of chronic pain and its associated disability. Therefore, a bio-psycho-social model may provide a better understanding of the mechanisms at play and its influencing factors. The International Association for the Study of Pain (IASP) defines pain as: "An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage", which has brought attention towards fear as a psychological factor greatly influencing chronic pain [18]. The literature shows a host of physiologic mechanisms by which injuries lead to nociceptive responses and ultimately to pain but not all nociceptive signals are perceived as pain and not every pain sensation originates from nociception [19–21]. This point towards a centrally governed control mechanism that ultimately “decides” if a stimulus is perceived as painful or not. Psychological research on the effect of fear and anxiety on chronic pain has been extensively recognised. Pain-related fear and anxiety can best be defined as the fear that emerges when stimuli that are related to pain are perceived as a threat [22]. The fear and anxiety response comprises psycho-physiological (e.g. heightened muscle reactivity), behavioural (e.g. escape and avoidance behaviour), as well as cognitive (e.g. catastrophizing thoughts) elements. Thus, the fear of pain, fear of work-related activities, fear of movement, and fear of (re) injury have been described as often occurring in patients suffering from chronic pain. In such cases, learning de-catastrophizing coping strategies through cognitive behavioural training and re-educating the body-self neuromatrix [19, 20, 23, 24] may serve as valuable intervention strategies to implement with people showing movement related fear-avoidance behaviour [25, 26].

Fatigue and stress
There is evidence supportive of the relationship between musculoskeletal pain and fatigue. For instance, chronic pain accounts for up to 34% of self-reported activity limitations in patients suffering from Chronic Fatigue Syndrome (CFS) [27] and it is suggested that myalgia and arthralgia could be considered an important subclass of CFS [28]. The research in CFS shows that widespread and consistent pain is common. For instance, a population-based study revealed that 94% of the persons diagnosed with CFS reported muscle aches and pain and 84% reported joint pain [29]. CFS patients reported having muscle pain in 85 out of 114 instances and 74 patients complained of arthralgia [30]. Women with trapezius myalgia also suffer higher fatigue levels compared to healthy controls even at rest [31]. Given the amount of convincing data on the relationship between severe chronic fatigue and musculoskeletal pain [32] it may be appropriate to fit fatigue as an element of chronic musculoskeletal pain in a bio-psycho-social intervention strategy.

The link between musculoskeletal pain and situational stress should also be taken into account [33]. Stress can have widespread effects on emotional, physical, cognitive and behavioural wellbeing. Typical symptoms of stress include frustration, fatigue, headaches, painful and tense muscles, chest pain and rapid heartbeat, forgetfulness and disorganization [34–36]. These symptoms are similar to how CFS is defined by the Centers for Disease Control and Prevention (CDCP), who defines it as "a complex illness characterized by prolonged debilitating fatigue and multiple non-specific symptoms including headaches, recurrent sore throats, fever, muscle and joint pain, and neurocognitive complaints" [32]. Based on psychological research a bio-psycho-social intervention strategy aimed at reducing musculoskeletal pain by taking fatigue and situational stress into account seems appropriate to investigate, as psychosomatic research shows an isomorphic- (same time increases in pain lead to same time increases in stress and vice versa), consequence- (increases in pain precede increases in stress), and a precursor (increases in stress precede increases in pain) stress-pain relationship [33]. This supports a psychological theory of using individually tailored multifactorial interventions in chronic pain rehabilitation settings.

Relevant grounds exist to investigate whether a multifactorial and individually tailored intervention consisting of a physical and psychological training regimen is feasible and effective compared with a more traditional approach focusing on ergonomic initiatives and generalized exercises in laboratory technicians with chronic musculoskeletal pain. The aim of this study is therefore to investigate the effect of an individually tailored bio-psycho-social intervention strategy versus company policy ergonomics and on-going exercise initiatives on musculoskeletal pain, stress and work disability in lab technicians with a history of work-related musculoskeletal pain and stress.
METHODS

Trial design

This trial follows a single-blind randomized controlled design with allocation concealment in a two-armed parallel group format among laboratory technicians in Denmark. The participants are parallel-assigned to receive either the experimental training or follow company policies for 10 weeks at the worksite. The study duration is March 2014 (baseline testing) to July 2014 (follow-up testing) (with 1-year follow-up scheduled for March 2015).

Ethics

Ethical approval has been obtained from The Danish National Committee on Biomedical Research Ethics (The local ethical committee of Frederiksberg and Copenhagen; H-3-2010-062) as part of the research program "Implementation of physical exercise at the workplace (IRMA)". The trial "Implementation of physical exercise at the Workplace (IRMA09) – Laboratory technicians" was registered in the ClinicalTrials.gov register (NCT02047669) prior participant enrolment.

Participant recruitment

A recruitment questionnaire on musculoskeletal pain, stress and work disability are sent out to 752 laboratory technicians in a division of a large pharmaceutical company in Denmark. Based on previous work [11, 37] we conservatively estimate a recruitment level of 10-15% or 75-110 participants with chronic musculoskeletal pain. The included participants must be, at the time of enrolment, suffering from chronic musculoskeletal pain (lasting for at least 3 months) of the back, neck, shoulder, elbow or hand to participate in the study. They must have a pain intensity of ≥3 (0-10 Visual Analogue Scale) during the last week and a pain frequency of ≥3 days.

We will not exclude participants due to disease unless contraindications for all elements of the intervention exist. Instead, participants with typical exclusion criteria, e.g. severe hypertension, will be allowed to participate in the less strenuous part of the intervention if their own doctor clears them. Thus, special emphasis of the individually tailored intervention will be to offer interventions for all employees with chronic pain regardless of co-morbidities unless contraindications exist. Life-threatening disease and pregnancy are considered contraindications to the testing and training and we will therefore exclude such participants.

All participants will be informed about the purpose and content of the project and must provide their written informed consent to participate in the study. All experimental conditions conform to The Declaration of Helsinki.

Randomization
The clinical examination and associated questionnaire will form basis for the randomized group allocation of the participants. By computer generation of a random numbers table (SAS) the participants are allocated to either an experimental intervention (group EX) or a reference group following company on-going initiatives including standard ergonomic policy (group R). Participants are informed about their particular group allocation by email after the baseline data acquisition and informed that the researchers do not know what treatment model works best. Participants of both groups are instructed to not reveal their particular intervention to the assessors. Should the experimental treatment prove to be superior to the standard company policy the reference group is offered the experimental treatment after follow-up testing.

Blinding

Due to the interventional trial design, participants and instructors (i.e. strength, mobility and motor control instructors, meditation instructors) cannot be blinded to group allocation. However, outcome assessors and data analysts will be blinded.

Interventions

We aim to implement an experimental approach, multifactorial and tailor-made to the individual addressing bio-psycho-social elements of musculoskeletal pain; increasing the level physical activity through strength training, mobility training, and motor control training. Lowering stress and fatigue through selective attention training, learning de-catastrophizing pain management strategies through cognitive training and fear avoidance belief counselling and participating in group based physical and/or mental exercise to increase social interaction through guided activity.

Experimental intervention (Group EX)

The experimental intervention design has four elements. Each treatment modality is described in detail below.

Strength training

The strength training is targeted towards the site of musculoskeletal pain. Simple elastic resistance exercises for the neck/shoulder, arm, wrist and hand are utilized. The program design follows a progressive training model with variable resistance and/or contraction type and speed. The supervising instructor will adjust the exercises to fit the individual. Figure 1 shows the elastic tubing exercises. 2 sets of 10-20 repetitions of each exercise are performed.
Precise motor control training

The motor control training is based on simple isolated dynamic joint mobility movements inspired by the precise execution of tai chi and qi-gong [38] and integrated following the principles of motor learning [39, 40]. The supervising instructor will adjust the level of difficulty as well as implement alternative exercises for other body regions to fit the individual and target the site of pain. Figure 2(e-k) shows seven key motor control movement sequences utilized. Motor control exercises e and f are applied more frequently to participants complaining primarily of neck and upper back pain. Exercises g and i are applied more frequently to participants with shoulder pain, and h and j are applied to participants with arm/elbow/hand pain. Finally, exercise k is primarily applied to participants complaining of lumbar/sacroiliac pain. 2-3 sets of 3-5 repetitions done at a “super slow” speed (15-30 sec. per repetition) are performed in each direction focusing on creating a smooth continuous motion in progressively larger circles.

Selective attention training

Selective attention training is comprised of two separate but mutually supportive elements- a passive and an active. The passive element is based on basic meditation techniques with a focus on becoming aware of the body. This meditation exercise, known as a body scan, is verbally guided by the instructor and does not involve any movement. In a meditational body scan the participants will be lying down with closed eyes. The instructor will start the guided attention at the toes and feet and work up through the legs, hips, torso, arms, hands, fingers and head and for each segment ask the participants to notice the different sensations (heat, cold, restlessness etc.) from each specific area.

The active element is comprised of attention solely on breathing. The participants will either be lying down, sitting, standing or walking outside in nature focusing on their breathing pattern. The instructor informs the participants that they may experience a wide array of different thoughts but the goal is to let these thoughts pass by, returning the attention towards the breathing.

Together, the passive and active meditation techniques comprise selective attention training and is utilized to indirectly reduce musculoskeletal pain by reducing stress and fatigue [33, 35, 41–44]. The selective attention training is done in a group-based setting.

Cognitive and behavioural training

Educational pain management sessions will focus on re-educating the body-self neuromatrix of the participants by affecting the neurosignature responsible for
generating the pain. As pain is multidimensional and related to previous experience with pain, the management sessions will focus on understanding patterns of behaviour that may trigger pain in the individual [45, 46]. To combat fear-avoidance behaviour, education and counselling about fear of movement, the positive effects of movement as well as de-catastrophizing pain are the main focus areas [22, 47–52]. The instructors will individualize the cognitive and behavioural element of the intervention and relate the counselling about fear-avoidance behaviour to the specific work tasks encountered by laboratory technicians in their daily activities as well as to their leisure time activities. The cognitive and behavioural training elements are divided between the instructors in such a way that the selective attention training instructor will focus primarily on pain de-catastrophizing counselling and guidance and the strength and motor control instructor will focus primarily on fear-avoidance behaviour counselling and education.

**Individualized treatment model**

The recommended amount of each intervention element will be tailor-made to fit the individual based on the baseline questionnaire elements about pain, stress and work ability, as well as the baseline clinical examination by a physical therapist specializing in musculoskeletal pain. Based on the screening questionnaire replies in the experimental group participants receive an email with information about their own "stress score" (Cohen's Perceived stress) and body regions with chronic pain. Further, participants are informed that the physical exercise will be tailored according to their painful body regions, and that they can participate in the selective attention training to prevent development of stress (if stress levels are low) or reduce stress (if stress levels are high). In case of contraindications for high-intensity physical training (e.g., carpal tunnel syndrome), participants are informed that they can participate in the physical training sessions, but the exercises will be adjusted and not include strength training.

**Weekly intervention schedule**

To make training easily accessible to the participants at the worksite, a weekly training structure of 20 min. supervised physical/cognitive training is available four times per week (Monday, Tuesday, Thursday and Friday) with 3 session possibilities daily (10.00am, 10.30am and 11.00am). Selective attention training is made available once weekly (Wednesday) on two separate occasions (10.00am and 11.00am). All instructors are available for consultation and support via email throughout the intervention weeks and participants are encouraged to train and practice selective attention during leisure time. Instructors take attendance to strength and mobility classes as well as selective attention training and monitors non-participation rates for each participant.
The organisation of the four intervention elements (1. strength training, 2. motor control and mobility training, 3. selective attention training and 4. cognitive behavioural training) are grouped together in two blocks to save time and make it easily accessible for the participants during their working day. Finally, if they want, participants are allowed to attend sessions in both blocks, regardless of our recommendation. Figure 3 shows the grouping of the intervention elements.

**Adjusting the strength training element**

In case of acute worsening of pain or other contraindications during the time of physical training, the training instructor applies the following 4-stage model, previously described by our research team [53], to adjust the specific exercise.

- **Stage 1**: Reduce loading intensity. A reduction in load (e.g. resistance of elastic tubing) should be implemented in the specific exercise that causes an increase in acute pain in the back, neck, shoulder, elbow or hand. A load reduction of up to 100% can be necessary, i.e. performing the movement without external resistance.

- **Stage 2**: Reduced movement velocity. If a reduction in load fails to address the problem, the movement velocity should be reduced.

- **Stage 3**: Reduced range of motion (ROM). As a final action to solve the problem, the ROM should be reduced the point where pain is not worsened.

- **Stage 4**: Exercise termination. If none of the above stages resolves the problem, the specific exercise will be terminated and replaced by a targeted joint mobility or motor control exercise.

Progression in strength and motor control training is done in reverse, i.e. increasing ROM, increasing movement velocity and increasing the load by applying external resistance. The progression, as well as the regression is supervised and controlled by the instructor present.

**Reference group (group R)**

The participants of group R receive an email with encouragements to participate in the company’s on-going initiatives, e.g. weekly elastic band group training sessions (only available in some departments) and are encouraged to continue to take “exercise breaks” whenever needed. As this is part of the existing and on-going program at the company, it can be considered “usual care”. No new interventions were added in this group.

**Co-interventions**
The company’s own health and safety professionals are available to provide ergonomic education in accordance with the standard company policy, which consists of ergonomic worksite observations by trained professionals and subsequent individualized recommendations on changing task-specific positions and adjusting ergonomic aids to fit each department structure. Each individual department management is responsible for prioritizing and utilizing the option of ergonomic support.

Outcome measures

All outcome measures will be collected by trained clinical examiners and by questionnaire survey at baseline and after the 10-week intervention period.

Primary outcome measure

Our primary outcome measure is average value of (back, neck, shoulder, elbow and hand) perceived musculoskeletal pain intensity of the last week by questionnaire (scale 0-10) from baseline to week 10. The regions of the body will be defined by drawings from the Nordic Questionnaire [54].

Secondary outcome measure

Stress

Stress is measured from baseline to week 10 by Cohen’s perceived stress scale which is based on the answers of 10 questions each scored with the following categories: i) Never, ii) Almost never, iii) Sometimes, iv) Fairly often and v) Very often. Examples of questions include: “In the past month, how often have you found that you could not cope with all the things you had to do?” and “In the past month, how often have you been able to control irritations in your life?” [55].

Other outcome measures

Work ability

Work ability is assessed by Work Ability Index questionnaire [56, 57] from baseline to 10 week follow-up and cognitive performance is assessed by CNS Vital Signs [58] at baseline and follow-up. Electroencephalography (EEG) will be used to sample brain activity during the CNS Vital Signs test.

Fear avoidance

Fear avoidance is evaluated by the Fear Avoidance Beliefs questionnaire [59] and objectively quantified as the strength and rate of force development deficit during the physical examination isometric strength tests.
Muscle function

Muscle strength, function and tenderness of the shoulder, arm, wrist/hand is assessed by maximal isometric voluntary contractions in a custom-built dynamometer (Bofors Elektronik, Karlskoga, Sweden) setting and by pressure-pain threshold testing (PPT) [60]. Also rate of force development (RFD), force steadiness (FS), force precision (FP) and fatigue (F) are measured. The strength tests are a part of an extensive physical examination by trained medical professionals at baseline and follow-up. Muscle activation level is measured by electromyography (EMG) (Nexus Mark 10, Mindmedia, Netherlands) and EEG (Nexus Mark 10, Mindmedia, Netherlands) will measure brain activity during pre- and post testing.

Sample size and power

A priori power analysis based on previous measurements reveals that 27 participants of each group for 95% power, SD of 1.5 and a minimal relevant difference in pain intensity of 1.5 is sufficient to test the null-hypothesis of equality (alpha = 0.05, beta = 0.95). With an estimate of a 10% dropout during the intervention period, the minimal group size should be 30 (i.e. a total of 60 participants). However, to increase generalizability of the findings we aim to include 100 participants.

Statistical analysis

All statistical analyses will be performed using the SAS statistical software for Windows (SAS Institute, Cary, NC). The change in perceived pain (0–10 scale) will be evaluated using a repeated-measures two-way analysis of variance (ANOVA) with group, time and group by time as independent variables. Subject is entered as a random effect. Analyses will be adjusted for baseline values. We will perform all statistical analyses in accordance with the intention-to-treat principle using the Proc Mixed procedure of SAS, which inherently accounts for missing values. An alpha level of 0.05 will be accepted as significant. Outcomes will be reported as between-group, least mean square differences and 95% confidence intervals from baseline to follow-up.

DISCUSSION

We aim to investigate the change in perceived pain intensity of the back, neck, shoulder, elbow and hand. Furthermore, we will investigate the occurrence and possible changes in psychological stress following an intervention period. Finally, the effect of the experimental training on work ability will be evaluated. We prioritize a cost-efficient training program design with easy-to-use exercises and a minimal amount of necessary equipment based on the assumption that work site post-intervention implementation will have a higher success rate if the program design, including exercises, is transparent, inexpensive and easily integrated.
Ergonomic counselling aiming at reducing physical exposure to compromising body positions are considered the standard prescription/conventional approach on prevention and treatment of musculoskeletal disorders in various work environments. However, increasing employee physical and mental capacity by means of individualized strength-, mobility/motor control- and cognitive training at the work site may represent a useful approach for reducing chronic pain, stress and work disability in laboratory technicians.

The present study will provide documentation to better guide workplace initiatives to reduce chronic musculoskeletal pain among employees with repetitive and monotonous movement tasks of the shoulders, arms and hands, while shedding light on the association between pain, work disability and stress.
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Figure 1: Figure 1 shows the three primary elastic tubing exercises used during the intervention. Exercise a shows shoulder external rotation start (a1) and end (a2) and exercise b shows shoulder squeeze start (b1) and end (b2). Finally, exercise c shows lateral raise start (c1) and end (c2) and exercise d shows wrist extension start (d1) and end (d2).

Figure 2: Figure 2 shows the seven primary mobility and motor control exercises used during the intervention. Exercise e and f shows axillary mobilization start (e1) and end (e2) and cervical mobilization start (f1) and end (f2), respectively. Exercises g, h and l show shoulder camshaft mobilization start (g1), ¼ of the way (g2), ¾ of the way (g3) and end (g4), brachial external rotation mobilization start (h1) and end (h2) and shoulder internal/external distraction mobilization start (i1) and end (i2), respectively. Exercise j show brachial internal rotation mobilization start (j1), ¼ of the way (j2), ¾ of the way (j3) and end (j4). Finally exercise k shows hip circular motor control and mobilization start (k1), ¼ of the way (k2), ¾ of the way (k3) and end (k4).

Figure 3: Figure 3 shows the elements of the experimental group intervention. Based on the screening questionnaire participants of the intervention group (EX) are recommended to attend training in one or both blocks.
Experimental group
participant recommendations

- Strength/mobility/motor control
- Cognitive behavioral training; focusing on fear avoidance beliefs and education about the positive effects of exercise and movement

- Selective attention training
- Cognitive behavioral training; focusing on pain-decatastrophizing and education about stress