Brief Intervention, Physical Exercise and Cognitive Behavioral Group Therapy for patients with chronic low back pain (The CINS trial)

A. Harris, PhD[1]; T.F. Moe, MD[2]; H.R. Eriksen, PhD[3,5]; T. Tangen, PhD[6], S.A. Lie[3,4]; T.H. Tveito[3,9] & S. E. Reme, PhD[3,7,8*]

[1] Department of Psychosocial Science, Faculty of Psychology, University of Bergen, Norway
[2] Oslo University Hospital, Oslo, Norway
[3] Uni Research Health, Bergen, Norway
[4] Department of Clinical Dentistry, University of Bergen, Bergen, Norway
[5] Department of Sport and Physical Activity, Bergen University College, Norway
[6] Department of Clinical medicine, Section of psychiatry, Haukeland University Hospital,
[7] Department of Pain Management and Research, Oslo University Hospital
[8] Department of Psychology, Faculty of Social Sciences, University of Oslo
[9] Department of Health Promotion, University College of Southeast Norway, Horten, Norway

Corresponding author: Silje Endresen Reme
Department of Psychology, Faculty of Social Sciences,
University of Oslo, Norway
Tel: +47 22 84 52 36
Fax number: 23 02 74 02
E-mail address: silje.reme@psykologi.uio.no

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Conflicts of interest

The authors report no conflict of interest.

What does this study add?

Positive-outcome bias in publishing is a serious concern that has increased over last years. Our study demonstrates that treatments that previously have been found to be effective and are included in most treatment guidelines, such as group cognitive behavior therapy and exercise, were not effective in this given context compared to a brief, cognitive intervention. This implies that an optimized brief intervention is difficult to outperform in patients on sick leave due to low back pain.

Keywords: Brief Intervention; Cognitive Behavioral Therapy, group CBT; Sick leave; Supervised group exercise; chronic low back pain; Oswestry disability index; CATS, work disability

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Abstract

Background and objective: Cognitive-behavioral treatments (CBT) and physical group exercise (PE) have both shown promising effects in reducing disability and increasing work participation among chronic low back pain (CLBP) patients. A brief cognitive intervention (BI) has previously been demonstrated to reduce work disability in CLBP. The aim of this study was to test if the effect of BI could be further increased by adding either group CBT or group PE.

Methods: A total of 214 patients, all sick listed 2-10 months due to CLBP, were randomized to BI (n=99), BI + group CBT (n=55), or BI + group PE (n=60). Primary outcome was increased work participation at 12 months, whilst secondary outcomes included pain-related disability, subjective health complaints, anxiety, depression, coping, and fear-avoidance.

Results: There were no significant differences between the groups in work participation at 12 months follow-up ($\chi 2=1.15$, P=0.56). No significant differences were found on the secondary outcomes either, except for a statistically significant reduction (time by group) in one domain of subjective health complaints (sleep problems, tiredness, dizziness, anxiety, depression, palpitation, heat flushes) ($F_{2, 136}=3.109$, P=0.048) and anxiety ($F_{2, 143}=4.899$, P=0.009) for the groups BI + group CBT and BI + group PE, compared to BI alone. However, these differences were not significant in post hoc analyses (Scheffé adjusted).

Conclusion: There was no support for an effect of the added group CBT or group PE program to a brief cognitive intervention in this study of patients on sick leave due to low back pain.

Significance: Our study demonstrates that treatments that previously were found to be effective and are included in most treatment guidelines, such as group cognitive behavior therapy and exercise, were not effective in this given context compared to a brief, cognitive intervention. This implies that an optimized brief intervention is difficult to outperform in patients on sick leave due to low back pain.

Introduction

Chronic low back pain (CLBP) is a common condition with a lifetime prevalence of about 23% (Airaksinen *et al.*, 2006). In Norway, musculoskeletal pain account for about 40% of long-term sick leave, with low back pain (LBP) as the single most common diagnosis (NAV, 2014). The vast majority of people recover from an acute episode of back pain, while about 12% develop a disabling and chronic condition (Hoy *et al.*, 2012). Why some experience this unfortunate development is not fully understood, but psychological factors are important predictors of the transition from acute to chronic pain (Linton, 2000; Pincus *et al.*, 2002).

The biopsychosocial model is commonly used to understand CLBP, where physical, psychological and social factors interact and produce pain disability. As a result, multidisciplinary biopsychosocial rehabilitation (MBR) programs, where all these factors are targeted simultaneously, have been developed and tested. A recent review supports the usefulness of such approaches; MBR is followed by less pain, disability, and to some degree, work disability, compared to usual care or physical treatment (Kamper *et al.*, 2014). Similar support has been found for pain rehabilitation programs in general, although questions still remain about dose and content aspects of such programs (Waterschoot *et al.*, 2014).

Brief Intervention (BI) programs have shown promising effects in sub-acute LBP patients when it comes to sick leave (Brox *et al.*, 2008). The BI consists of a thorough medical examination followed by information about back pain and an encouragement to stay physically active and return to work (Indahl *et al.*, 1995). The information is communicated with optimism and is believed to lower fear avoidance and increase the belief in recovery, which is in itself an important prognostic factor (Hildebrandt *et al.*, 1997; Reme *et al.*, 2009).

Since psychosocial factors have been recognized as important for understanding CLBP, CBT has become a common method to treat CLBP (Sveinsdottir *et al.*, 2012; Ehde *et al.*, 2014). The cognitive model asserts that CLBP is caused and maintained by biological, social and psychological factors mutually affecting each other. CBT targets the cognitive misinterpretations and unhelpful cognitions that are thought to be maintaining factors in the vicious circle of pain and disability (Moore *et al.*, 2000; Gatchel & Rollings, 2008).

Physical exercise has for decades been applied in the treatment of CLBP and is, together with CBT, one of the recommended treatments in the European guidelines (Airaksinen *et al.*, 2006). Based on the observation that CLBP patients often reduce their level of physical activity, it is correspondingly assumed that they will benefit from an increase in physical activity. However, there is a substantial lack of knowledge when it comes to how exercise intensity, frequency and duration of therapy sessions influence the outcome (Airaksinen *et al.*, 2006). Nevertheless, a Cochrane summary concludes that ”exercise therapy appears to be slightly more effective in decreasing pain and improving function in adults with chronic low-back pain compared to no treatment" (Hayden *et al.*, 2005).

The aim of this study was to test if BI and group CBT, or BI and group PE, were more effective than BI alone in increasing work participation and reducing disability and subjective health complaints in sick-listed CLBP patients.

Methods

Study design and participants

The study was part of a larger randomized controlled multicenter trial (The CINS trial = Cognitive Interventions and Nutritional Supplements) comparing different treatment strategies for CLBP in four different clinics (Reme *et al.*, 2011). In the CINS trial, BI was compared with BI and CBT or BI and nutritional supplements (seal oil and soy oil) in a 4-armed RCT. The results from the main trial did not show additional effects of either individual CBT or nutritional supplements (Reme *et al.*, 2016).

The participating centers (clinics) were given the opportunity to add one or two additional treatment arms to the study. Consequently, for the clinic where the data for the current study was drawn, patients were randomized to 6 treatments, the 4 in CINS + 2 unique for the current study (BI + group CBT; and BI + group PE). To increase statistical power, all participants randomized to BI from all participating clinics were used as a control comparison to the BI + group CBT and BI + group PE in the current study.

Patients on sick leave due to unspecific LBP between 2-10 months were invited to participate in the study by receiving a letter from the Norwegian Labor and Welfare

Administration (NAV). A total of 214 patients participated in the current study (Figure 1). The study was performed between 28.02.2008 and 24.06.2010.

---------- Insert figure 1 (flowchart) here ----------

Study context

The Norwegian public insurance system includes all lawful residents of Norway and provides health service benefits and pension benefits for all members of the National Insurance Scheme, administered by the government through the Norwegian Labour and Welfare Administration. The workers' compensation program provides 100% coverage for lost income due to a medically acknowledged sickness, disease or injury from day one until the person is able to work again, with an upper limit of 52 weeks. After that, long-term benefits provide approximately 66% coverage of former income. Sick leave can be full or partial, with the latter involving everything from 10% to 90%.

Inclusion and exclusion criteria

Inclusion criteria were at least 50% sick leave due to unspecific LBP, age between 20 and 60 years, being at least 50% employed, and having one of the following International Classification of Primary Care (ICPC) diagnoses for the current sick-leave episode: L02 (back symptom/complaint), L03 (low back symptom/complaint), L84 (back syndrome without radiating pain), or L86 (back syndrome with radiating pain). Exclusion criteria were pregnancy, haemophilia, osteoporosis (known osteoporotic fracture, or on anti-osteoporotic medication), currently being treated for cancer, recent back trauma, serious psychiatric disorders (on going psychosis, high suicide risk, and/or serious depression), assumed to be incompatible with participation in the trial, not fluent in Norwegian (assumed to be incompatible with CBT), debilitating cardiovascular disease, patients on anticoagulation treatment (e.g. warfarin), ongoing insurance issue, lawsuit, or pending legal action for LBP or related conditions.

All participants filled out questionnaires at the clinic immediately before BI. Follow-up was conducted at 3, 6, and 12 months after the first session of BI. During the clinical examination, a consultant physician screened the patients according to the selection criteria.

Primary outcome

The primary outcome was based on national registry data from the Norwegian Labor and Welfare Administration. Complete sick leave data was obtained for each month of follow-up, up until 12 months. Based on changes in the percentage of sick leave, change in work participation was calculated. *Increased work participation* was defined as change from full-time sick leave to partial sick leave or full return to work, or change from partial sick leave to a lower gradient of sick leave or full-time return to work.

Secondary outcomes

Secondary outcomes were pain-related disability, anxiety, depression, subjective health complaints, coping, and fear-avoidance. Disability, how activities of daily life were influenced by back pain, were assessed with The Oswestry Disability Index (ODI) (Fairbank *et al.*, 1980). ODI has been found to be both reliable and valid for Norwegian patients suffering from LBP (Grotle *et al.*, 2003). ODI consists of 10 items that deals with pain and how it influences activities of daily life. Each question has 6 different alternatives that the patient can rate from 1 (normal function) to 6 (very low function due to pain), which gives a maximum score of 60. A difference of at least 4 points between patient groups is suggested as the minimum clinical difference between groups (Meade *et al.*, 1986).

Anxiety and depression were assessed with the Hospitality Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983). The HADS consists of 14 self-reported items, each scored from 0 (not at all) to 3 (most of the time). Seven items measure anxiety and seven items measure depression, which gives a max score of 21 on each subscale. A cut off score equal to or larger than 8 indicates possible diagnosis of anxiety or depression, with an optimal balance between specificity and sensitivity (Bjelland *et al.*, 2002).

Subjective health complaints were measured with the Subjective Health Complaints Inventory (SHC) (Eriksen *et al.*, 1999). The inventory consists of 29 items measuring health complaints during the last 30 days. Each item is scored form 0 (no complaints) to 3 (severely bothered). SHC has been shown to have satisfactory validity and reliability (Eriksen *et al.*, 1999). A total score and sub-scores on the 5 subscales were calculated; musculoskeletal complaints, pseudoneurological complaints (sleep problems, tiredness, dizziness, anxiety, depression, palpitation, heat flushes), gastrointestinal complaints, allergy, and flu.

Coping was measured with a short, 22 items version of The Utrecht Coping List (UCL) (Schreurs *et al.*, 1988) from the Coping and Defense inventory (CODE) (Eriksen *et al.*, 1997). The items concerned how one generally would respond to problems, and an Instrumental Mastery-Orientated Coping (IMOC) style is measured. All items are scored on a 4-point scale. A high score on IMOC implies high scores on active problem solving and low scores on avoidance and passive expectancy, and depressive reaction pattern.

Anxious beliefs and fear-avoidance behavior was measured with the Fear-Avoidance Beliefs Questionnaire (Waddell *et al.*, 1993). The FABQ has 16 statements. Each statement is scored on a 7-point Likert scale from 0 (totally agree) to 6 (strongly disagree). A high score indicates a high level of fear avoidance. The FABQ has two subscales. One applies to work and the other one to physical activity. The Norwegian version has been tested for reliability and validity and is recommended for assessing fear-avoidance in patients with acute or chronic low back pain (Grotle *et al.*, 2006).

Interventions

Brief Intervention (BI)

BI was given to all participants as two sessions over a period of 5 days, with the option of two booster sessions. The complete BI treatment comprised minimum two hours and maximum four hours. BI is a brief cognitive, clinical examination program based on a non-injury model addressing pain and fear-avoidance, where return to normal activity and work is the main goal. Specialists in physical medicine and rehabilitation conducted the first session, and a physiotherapist conducted the second session. The brief intervention starts with a thorough physical examination that includes diagnostic clarification, reassurance about normal findings, communication of recurrent back pain as troublesome but harmless and encouragement to engage in physical activity as normal as possible. The main purpose of the intervention was to provide the patients with coping skills to manage their back pain through evidence based information, practical advice and reassurance, and to motivate and encourage them to stay active, despite their pain. After the medical examination, the patients received a follow-up session with a physiotherapist, involving an educational and a behavioral part. The purpose of the educational component was to strengthen the message given in the medical examination. The purpose of the behavioral component was to help the patient turn the new insight into practical action.

Group Physical Exercise (Group PE)

The PE program followed a specific manual developed by the clinician at the rehabilitation clinic. To achieve a noticeable change in muscle hypotrophy and higher aerobic capacity, the group PE was administered three times a week over a period of three months. Each session lasted 90 minutes. The complete group PE treatment comprised of 54 hours. The PE was organized in groups of 10 patients and was led by a physiotherapist. Individual goals for the PE program were set to achieve functional improvement, especially focusing on work and activities of daily life. Based on the patients' unique symptoms and the goals set by each individual patient, the physiotherapist would adapt the PE program to meet the individual needs. Every session consisted of strength and endurance training and relaxation. The patients were exposed to physical activity they believed was harmful for their low back pain. The goal was to address fear avoidance and movement phobia, and help to re-establish normal movement patterns.

Each patient was discussed in weekly team meetings. If necessary, extra treatment from one of the team professionals (e.g. physiotherapist, psychologist or MD) was offered to ensure continued participation and enhance the effectiveness of the study. In addition, the patients could attend two sessions about chronic pain, coping strategies, and ergonomics at the clinic.

Group Cognitive Behavioral Therapy (Group CBT)

The CBT treatment manual for the Group CBT was adapted from the CBT treatment manual from the CINS trial (Reme *et al.*, 2011). The patients were offered seven group sessions administered over a period of 3 months. The treatment was flexible and adapted to the needs of the individual patient. The sessions were led by a psychiatrist with training in cognitive therapy and lasted 90 minutes. The complete group CBT treatment comprised of 10.5 hours. Focus for treatment was how to live with back pain. Between each session the patients had homework including exposure to pain provoking physical activity. The homework was discussed in the sessions. Specific challenges and problems were discussed among the patients. Through this, the patients had an opportunity to learn from each other and take active part in changing dysfunctional thoughts and establish alternative thoughts of other group participants. The therapists aimed to create an atmosphere of fellowship,

encouragement, and support in order to engage the patients in the work with cognitive techniques.

Randomization

After BI the patients were randomized to BI alone, BI + CBT, BI + Seal oil, BI + Soy oil, group CBT, or group PE, using concealed randomization and allocation procedures. Only data from BI alone, Group CBT and Group PE is used in this study. The randomization was done according to a computer-generated list at the research unit (Uni Research Health). The randomization was performed by block stratification. A research assistant, who was not involved in the treatments at the clinic, called the central research unit at Uni Research Health and got information on which treatment the patient was randomized to.

Dropout

Eleven patients dropped out of the study after randomization. Two because they preferred treatment at another clinic, 2 because they went back to school and did not have time to participate, 5 did not want CBT, and 2 did not give any reason. After 12 months, 140 responded and returned the questionnaires (see figure 1).

Statistics

Return to work was based on crude rates of participants with increased work participation in the three groups. Differences between groups were measured with chi-square tests for each of the 12 months. For secondary outcomes, we performed a mixed between–within subject analyses of variance with one between group factor (BI, BI + group CBT, Bi + group PE) and with one within subjects/repeated measures factor (baseline and 12 months follow-up). The effect of time and the interaction effect (Time x Group) are reported, and when significant, the interaction effects indicate different time courses for the three interventions. For group comparison, effect sizes are reported with partial eta squared. For post hoc analyses effect sizes are reported with Cohens d_{ppc2} as suggested by Morris (2008). Analyses adhered to the "intention-to treat" principle. Stata version 14.0 for MS-Windows (TX USA) was used for the primary analyses and SPSS version 23.0 (IBM Corporation, Armonk NY, USA) for Apple was used for the secondary analysis. Degrees of freedom vary somewhat because of missing values on single items. Significance level was set at < 0.05.

Ethics

The principles in the Helsinki declaration were followed and the study was approved by the Ethical Committee and the Norwegian Social Science National Register of Data. Each participant signed informed consent and the right to withdraw from the study at any time without any explanation was emphasized.

Results

The study population consisted of 50.5% women with an average age of 44.8 years (SD 9.8). Average duration of back pain was 10 years. Further baseline characteristics of the participants are presented in Table 1.

----------Insert table 1 here----------

Primary outcome

There were no significant differences in return to work between intervention groups at 12 months follow-up, with 60% in the BI group, 55% in the BI + group CBT, and 52% in the BI + group PE showing increased work participation (Table 2). The results showed differences between the intervention groups in the first four months of follow-up (figure 2). However, pairwise comparison showed that this was in favor of the BI group compared to the other interventions. Subgroup analyses showed that it was particularly the healthiest participants, with low scores on anxiety, depression, subjective health complaints, disability, and fear avoidance, that benefit most from the BI in the first four months (see Table A-E in supplementary files for detailed information). Furthermore, subgroup analyses showed that a higher proportion of the participants with high scores on HADS-depression scale (≥8) showed increased returned to work after 9 and 10 months.

---------- Insert table 2 and figure 2 here ----------

Secondary outcomes

There was no significant interaction effect (time by group) for disability (ODI), indicating that the three intervention groups did not show different trajectories over time (Table 3). However, the results showed an overall effect of time, indicating an overall improvement in disability during the intervention period. There was a significant interaction effect (time by group) for

pseudoneurological complaints (sleep problems, tiredness, dizziness, anxiety, depression, palpitation, heat flushes) measured with SHC and anxiety measured with HADS, indicating different time course for the three interventions on these secondary outcomes. However, post hoc analyses (Scheffé adjusted) revealed no significant differences between the groups: SHC-pseudoneurological complaints (BI and BI + group CBT: mean difference=-0.623, p=0.61, d_{ppc2}=0.276, BI and BI + group PE: mean difference=-0.418, p=0.79, d_{ppc2}=0.427, BI + group CBT and BI + group PE: mean difference=0.205, p=0.95, d_{ppc2}=0.010), HADS-anxiety (BI and BI + group CBT: mean differences=-0.553, p=0.76, d_{ppc2}=0.429, BI and BI + group PE: mean difference=-0.097, p=0.99, d_{ppc2}=0.311, BI + group CBT and BI + group PE; mean difference=-0.456, p=0.85, d_{ppc2}=0.014). For the other secondary outcomes there were no significant interaction effects, indicating that the groups did not differ over time.

---------- Insert table 2 here ----------

There was an overall effect of time for SHC-musculoskeletal complaints, SHC-pseudoneurological complaints, SHC-total score, HADS-Anxiety, HADS-depression, coping, fear avoidance beliefs applied to general physical activity and fear avoidance beliefs to work associated strain, indicating an overall improvement in these secondary outcomes during the intervention period.

Discussion

The results showed that adding group CBT or group physical exercise (PE) to a brief intervention (BI) for chronic low back (CLBP) was not superior to BI alone in reducing sick leave, pain-related disability and subjective health complaints. All patients reported increased work participation from baseline to follow-up, but there were no significant differences between the groups at 12 months follow-up. On the secondary outcomes, the two active treatment groups (group CBT and group PE) showed larger improvements on both anxiety and pseudoneurological complaints compared to BI alone, but these differences were not significant in post hoc analyses.

All three treatment modalities in the study have previously been shown to have an effect on CLBP and are all recommended in the European guidelines. However, there is little

knowledge about the effect of group CBT, or which elements of the treatments that work, to which intensity it should be given, and which patients that could potentially benefit from what. The picture becomes even more complicated by the existence of a substantial degree of psychiatric and somatic comorbidity and health complaints. In the current study, all patients received BI. BI has earlier been proven to be an effective treatment for LBP patients on sick leave for a shorter period of time (8-12 weeks) (Indahl *et al.*, 1995). Despite a longer sick leave period in the current study (2-10 months), it was still hypothesized that participants would benefit from the BI, which the results indicated. The main aim of the study, however, was to investigate if adding a group CBT and a group PE program to the BI would result in additional effects, but this was not supported by the results. One exception was found in the subgroup analyses, were patients with high score on depression who received group CBT showed an increase in work participation after 9-10 months. This result may suggest that CLBP patients with comorbid depression may benefit from group CBT in addition to the BI.

BI lasted for approximately three hours, while the group CBT and the PE sessions lasted 1.5 hours and were given frequently over a period of three months. Similar treatments have previously been shown effective when given alone both in a primary care setting (Lamb *et al.*, 2010) and in a specialist health care setting (Nicholas *et al.*, 1992). The group CBT in our study was administered in 7 sessions while the PE involved 36 sessions. The extent of treatment should have been sufficient to impact the outcome, if the issues addressed in the treatments were crucial for the patients' reported disability. Some caution should, however, be added here since dose aspects in general are largely unknown in pain rehabilitation programs (Waterschoot *et al.*, 2014). The lack of significant additional effects could nevertheless imply that the psychological and physiological elements already had been sufficiently addressed in the BI, and that further treatment therefore had little impact on the outcome.

Another explanation might be that chronic pain cannot be fully understood within the framework of a disease model and that the understanding of pain should be expanded to include motivation and interference with other goals in life (Crombez *et al.*, 2012). Both PE and CBT are based on a pathology model and addresses biological factors described as physical de-conditioning syndrome or psychological factors like cognitive misinterpretations. They may therefore not be able to reach the right topics if socio-cultural

factors such as specific life goals or more general "meaning of life" issues are crucial to the patient, as these will only marginally be discussed in CBT and PE group sessions. Focusing too much on pathology in the form of aberrant physiological or psychological elements may be a too narrow therapeutic approach, and may be a reason for the lack of additional effects of the interventions.

Patients were invited to the study by receiving a letter from the Norwegian Labor and Welfare Administration (NAV). Although it was voluntary, patients may have experienced a certain pressure because they depend on NAV for financial support. They may thus have been incentivized to accept the study invitation in order to demonstrate a willingness to get back to work, despite conflicted intentions. Underlying factors, such as labor disputes or a desire for permanent disability pension, could in these cases be acting as barriers for return to work.

The patients had a moderate score on ODI. Mean score at baseline was 28.7, which were surprisingly low for patients being sick listed for 2-10 months due to LBP. In a review article, the Oswestry score from pooled data for various categories of patients showed a mean score of 43.3 for patients with CLBP (Fairbank & Pynsent, 2000). The fact that the patients in this study had significantly better function than the average CLBP patient may have affected the result and made it more difficult to demonstrate differences between groups (i.e. ceiling effect). It further indicates that the study population may not be representative of CLBP patients per se, possibly due to the recruitment procedure described above.

The pseudoneurological complaints subscale consists of seven items; i.e. extra heartbeats, heat flushes, sleep problems, tiredness, dizziness, anxiety, and sadness/depression. Patients receiving longer lasting treatment had fewer complaints. Why patients with CLBP have complex symptoms and a pronounced degree of comorbidity is understandable within the framework of the bio-psycho-social model. An attempt to link mental and physical symptoms together is done in the Cognitive Activation Theory of Stress (CATS) (Ursin & Eriksen, 2004). In this theory, sensitization has been proposed as the crucial factor explaining the individual cluster of symptoms. Sensitization is believed to be a multilevel phenomenon seen on the biological level at the neuronal synapses as well as on the psychological level. Whether a stressor, like LBP, will result in a chronic, disabling

condition or not, depends in part of the individual patient's expectations (positive or negative) and the ability to cope with the situation. Stress is considered a normal reaction to an unpleasant stimulus, such as LBP, but can, if sustained, cause illness and disease according to CATS. Sensitization of the central nervous system is further an increasingly recognized feature in many patients with CLBP (Roussel *et al.*, 2013), in which an amplification of neural signaling elicits pain hypersensitivity (Woolf, 2011). Top-down approaches, such as CBT and exercise therapy, are implied for patients with central sensitization, and would as such be expected to decrease pain and disability. For the group of CLBP, however, the evidence of central sensitization is somewhat conflicting, which could contribute to the understanding of the current study findings.

Secondary outcome measures showed significant improvements in almost all areas from pre to post intervention, regardless of treatment group. Based on the assumption that CLBP has a multidimensional nature with detectable symptoms in biological, psychological and social areas where the symptoms are interconnected and have the ability to influence each other, this result was expected. However, we cannot be certain that the actual treatments were responsible for the result. It may reflect a regression towards the mean or an expression of natural fluctuations. Patients often make contact with the health care system when they are at their worst, which implies that the majority will experience an improvement regardless of the treatment they receive. Another factor that may have contributed to the few significant between-group-differences is limitations related to the relatively small sample size. The data for this study was collected at one of the four participating centers. To increase statistical power, all participants allocated to the BI group regardless of center were compared to the BI + group CBT and BI + group physical exercise groups. By doing this the strict requirements for a randomized controlled trial was broken. However, none of the results changed as a result of adding BI data from the other centers.

Conclusion

We found no support for an effect of the added group CBT or group physical exercise (PE) interventions to a brief cognitive intervention on sick leave, pain-related disability or subjective health complaints.

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Author Contributions

The first and second author (AH and TFM) conducted the analyses and drafted the manuscript with substantial input from the remaining authors. SA conducted the analyses of the primary outcome. HRE designed the study, and THT and SER were the trial coordinators. All authors have been involved in drafting or revising the manuscript and have read and approved the final version to be published.

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Table 1. Baseline characteristics of participants (N=214)

	Brief Intervention (n=99)	**CBT** (n=55)	**Physical Exercise** (n=60)
Continuous variables	Mean (SD)	Mean (SD)	Mean (SD)
Age (years)	44.8 (9.7)	45.5 (9.1)	44.2 (10.6)
Duration of back pain (years)	12.5 (11.3)	9.6 (10.9)	11.51 (10.6)
Back pain during activity (0-10)	6.1 (1.9)	5.6 (2.4)	5.8 (2.0)
Pain while resting (0-10)	4.1 (2.3)	4.0 (2.2)	3.7 (2.0)
Pain during the night (0-10)	3.8 (2.4)	3.6 (2.7)	3.7 (2.5)
Categorical variables	n (%)	n (%)	n (%)
Men	43 (43.4)	31 (56.4)	32 (53.3)
Civil status			
Married/cohabitant	71 (77.2)	38 (70.4)	40 (67.8)
Single/widow/divorced	21 (22.8)	16 (29.6)	19 (32.2)
Education			
Primary school (1-12 years)	60 (63.2)	36 (65.5)	31 (51.7)
University/college	29 (30.5)	14 (25.4)	24 (40.0)
Other	6 (6.3)	5 (9.1)	5 (8.3)

Table 2. Differences in proportions between the three treatment groups in work participation (increased RTW) at each month until 12 months follow-up

	BI	BI + group CBT	BI + group PE			
ITT:	n (%)	n (%)	n (%)	χ^2	df	*p*-value
0-1 months	36 (36)	14 (25.5)	8 (13.3)	9.87	2	0.007
0-2 months	49 (49)	22 (40.0)	6 (10.0)	25.38	2	<.001
0-3 months	60 (60)	26 (47.3)	7 (11.7)	36.18	2	<.001
0-4 months	64 (64)	25 (45.5)	16 (26.7)	21.26	2	<.001
0-5 months	63 (63)	31 (56.4)	29 (48.3)	3.32	2	0.190
0-6 months	61 (61)	33 (60.0)	31 (51.7)	1.45	2	0.485
0-7 months	58 (58)	30 (54.6)	32 (53.3)	0.38	2	0.827
0-8 months	58 (58)	33 (60.0)	33 (55.0)	0.30	2	0.860
0-9 months	53 (53)	33 (60.0)	32 (53.3)	0.78	2	0.676
0-10 months	57 (57)	33 (60.0)	31 (51.7)	0.85	2	0.654
0-11 months	59 (59)	32 (58.2)	33 (55.0)	0.25	2	0.881
0-12 months	60 (60)	30 (54.6)	31 (51.7)	1.15	2	0.563

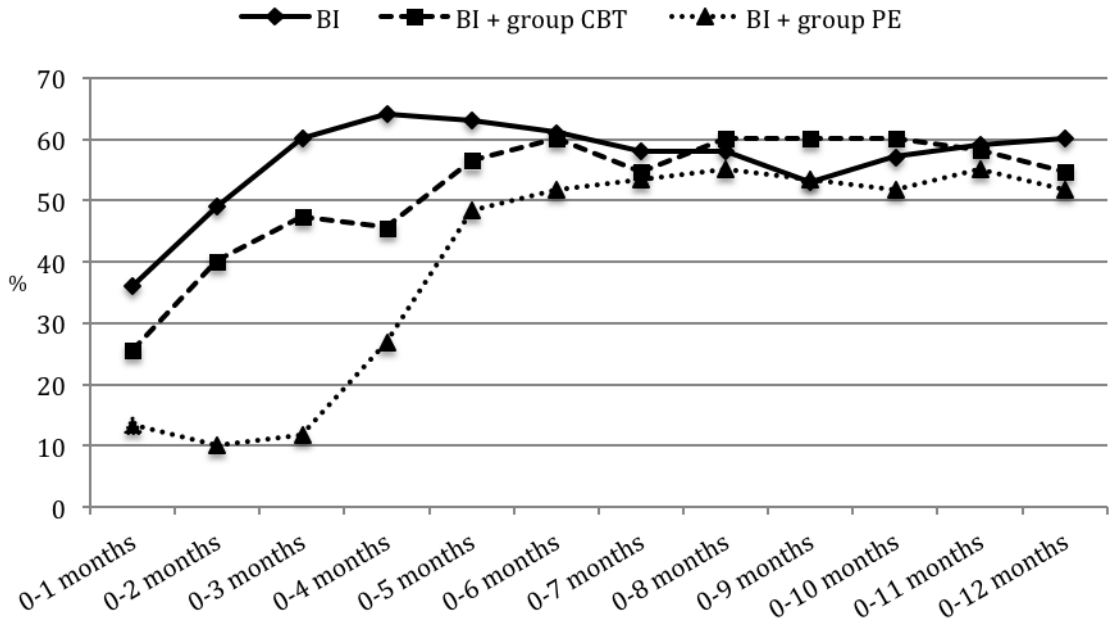

Figure 2. Illustration of the differences in proportions between the three treatment groups in work participation (increased RTW) at each month until 12 months follow-up