Steven J. Linton, Katja Boersma, Markus Jansson, Lennar Svard, Marianne Botvalde. The Effects of Cognitive-Behavioral and Physical Therapy Preventive Interventions on Pain-Related Sick Leave: A Randomized Control Trial. Clin J Pain 2005; 21(2):109-119.

Design: Randomized clinical trial

Reviewed (10-10-16): No changes to conclusions

Population /sample size/setting/interventions:

- 185 participants at risk for developing long-term disability were recruited from local primary care facilities in Sweden. All participants were randomized to one of three interventions; 1) Minimal Treatment Group, 2) Cognitive-Behavioral Treatment Group (CBT), or 3) Cognitive-Behavioral Treatment +Preventative Physical Therapy Group (CBT+PT).
- Minimal Treatment Group intervention consisted of a medical exam, advice on remaining active, and a booklet on managing pain.
- The CBT group intervention was aimed at preventing future problems. It included the minimal treatment and a 6-session, 2 hours each, structured group program over 6 weeks teaching strategies for obtaining behavioral changes and improving coping skills.
- The CBT+PT intervention included the minimal treatment, the CBT group interventions, and preventative physical therapy aimed at preventing future problems. It included advice about continuing activities, functional training, and a personalized exercise program.
- Eligibility criteria included 1) employed, 2) all adults aged 20 to 60 years of age, 3) report of nonspecific back or neck pain, 4) < 4 months of sick leave taken during the past year for spinal pain, and 5) no physical therapy during the past year.
- Exclusion criteria included history of disc disease or the lack of fluency in Swedish.

Main outcome measures:

- Primary outcome variables were sick leave from work and health-care utilization. Secondary outcome measures were Outcome Evaluation Questionnaire (pain perception and medication use), Hospital Anxiety and Depression Scale (14-item instrument), Pain Catastrophizing Scale, Tampa Scale of Kinesophobia, Fear Avoidance Behavior Questionnaire, Roland and Morris Disability Questionnaire (RMDQ), questions on function of ADLs from Orebro Musculoskeletal Pain Screening Questionnaire.
- Outcome measures were taken at baseline and 12 months after the intervention using completed postal questionnaires.
- Intention to treat approach was used.
- 85% or 158 participants completed the pre- and 1-year follow-up assessments. Of the 27 who failed to complete the follow-up assessment, 4 (8.5%) were in the Minimal Treatment Group, 15 (21.7%) were in the CBT group, and 8 (11.6%) were in the CBT+PT group.
- The 27 people that dropped out of the study differed from the other participants in that they were significantly older, more often male, and tended to take less sick leave. They did not differ in regards to health care consumption, function, and employment status.

- Primary outcomes:
    - Health care utilization was lower in both the CBT group and the CBT+PT group (statistically significant p=0.003) than in the Minimal Treatment group.
    - Sick leave was also lower in the CBT and CBT+PT groups than in the Minimal Treatment group. At the 1-year follow-up, the Minimal Treatment group had the highest percentage of participants on sick leave (9-14%), the CBT group had 6-8% on sick leave, and the CBT+PT group had the lowest percent on sick leave at 2-5%.
    - Percentage of participants on long-term sick leave ($\geq$ 15 days) before the intervention was compared to the rates at the 1-year follow-up for each of the 3 groups. The percentages increased only slightly between pretest and the 1-year follow-up for both the CBT and CBT+PT groups. The Minimal Treatment group showed a large increase from 4.8% to 16.3%.
    - Risk for developing long-term sick leave disability ($\geq$ 15 days) was assessed. The Minimal Treatment group had a 5 fold higher risk of being on long-term sick leave compared to the CBT and CBT+PT groups combined, a 6 fold higher risk compared to the CBT group alone, and over a 4 fold higher risk compared to the CBT+PT group alone.
- Secondary outcomes:
    - Between-group differences for all the secondary outcomes were small and not significant.
    - All three groups experienced improvements from pretest to follow-up on their ratings of pain and physical functioning, but no significant between-group differences were noted.
    - Outcome measures on the psychologic aspects of pain showed little change between pretest and follow-up for all 3 groups.
- A best case, worst case, and intermediate case analysis was conducted to assess how the 27 people who failed to complete the 1-year follow-up assessment might have affected the results. The analyses indicated that the nonresponders probably do not significantly alter the outcome results.

Authors' conclusions:

- The addition of cognitive-behavioral treatment with or without physical therapy to the standard minimal treatment for patients with nonspecific back or neck pain decreases the risk for future disability by more than 5 fold.
- The addition of cognitive-behavioral treatment with or without physical therapy to the standard minimal treatment for patients with nonspecific back or neck pain reduced future health care utilization and the risk for being on long-term sick leave.
- There were no large or significant differences between the two treatment groups, CBT and CBT+PT, in any of the primary outcome measures or any of the secondary outcome measures.
- All three groups experienced improvements from pretest to follow-up on their ratings of pain and physical functioning, as is to be expected in the natural course of acute back pain, but the CBT and CBT+PT groups produced the best results on the primary outcome variables of sick leave and reduced health care utilization.

Comments:

- This is a well-designed and documented study.
- Both the CBT and CBT+PT interventions did show improvement at the 1-year follow-up, but the improvements were similar for both interventions. The magnitude of the group differences do appear to be small and not significant between these 2 groups.
- Even though blinding was not feasible, the study is probably adequate because health care utilization and sick leave are acceptable outcomes for a workers' compensation population, and both the CBT and CBT+PT groups had less sick leave and less health care utilization than the minimal treatment group.
- The measured outcomes are acceptable indicators of functional disability.
- There is not enough information to indicate that the CBT plus PT program was superior to the CBT program.
- The authors recognized the unequal drop-out rates between the groups and the potential bias this could introduce, and so they performed the best case, worst case, and intermediate case analyses. The best case, worst case, and intermediate case analyses suggest that although the worst case scenario would greatly reduce the results and obliterate the positive significant differences reported between the groups, the authors concluded that this scenario is highly unlikely. However, if this worst case scenario were true, the evidence from this trial would be deemed inadequate. Essentially, there would be no evidence.
- The difference in the drop-out rates between the groups might be related to demographics rather that the treatment or the experienced results of the interventions. The CBT group had slightly older and more male participants as did the participants who dropped out. This might explain the high drop-out rate in the CBT group.
- The sample size for this trial is probably too small to detect preventive effects. Because only a small minority of patients with an acute problem actually develops long-term disability, the power to observe actual differences is greatly reduced.
- The reliability and validity of the self-report data used in this trial for measuring health care utilization and sick leave may be affected by measurement error (bias), since self-reported data is influenced by memory and other factors.

Assessment:

This study is adequate for some evidence that a 6-week program of cognitive-behavioral group intervention with or without physical therapy can reduce sick leave, health care utilization, and the risk for developing long-term sick leave disability ($\geq$ 15 days) in workers with nonspecific low back or neck pain compared with simple verbal instruction by a physician.