
Design: Randomized clinical trial

Population/sample size/setting:
- 224 patients (123 women, 101 men, mean age 45) who completed a 3 months randomized trial after being referred by general practitioners to two rheumatological outpatient clinics in Denmark
- Inclusion criteria were current paid employment, age 17-63, willingness to accept a workplace visit, and concerns about ability to maintain current job independently of sick leave status
- Exclusion criteria were pregnancy, referral for low back surgery, and serious comorbidity

Main outcome measures:
- 300 patients were originally randomized to either counseling (n =150) or “usual care” as a control (n=150)
- Usual care typically consisted of brief instruction in exercises or referral back to a general practitioner for further physiotherapy or chiropractic treatment
- Counseling consisted of (1) an initial 45-60 minute session with an occupational physician (OP), (2) a workplace visit if required, (3) 6-week status interview, and (4) a 3 month concluding counseling session with the same OP
  - Initial counseling was to establish knowledge of the current work situation, to remove barriers for maintaining the current job, obtaining a moderate physical activity schedule, and establish an individual tailored plan for the individual based on the patient’s work and private life
    - Patients were asked about activities during a typical work week, and sometimes they were asked to simulate work tasks
    - Exercise goals were set at 3 sessions of 45 minutes of moderate intensity for the three months of the study
    - Patients were given advice about how to manage social problems such as workers’ compensation issues and job insecurity
    - Goals were set for gradual return to patient’s usual tasks, temporarily avoiding tasks which were strenuous to the lower back
  - Workplace visits occurred if the OP was not able to gain sufficient information from the initial interview; tasks were observed and solutions for barriers were discussed
    - Workplace visits occurred in only 26% of cases, mostly in blue-collar jobs, since it was easier for the OP to evaluate white collar job tasks in the initial office visit
The six week interim evaluation consisted of an interview with a research assistant, where compliance with the initial plan was discussed, and adherence to goals was evaluated.

The final follow-up counseling with the OP lasted 45-60 minutes, where final conclusions regarding levels of physical activity and occupational future were made.

- Primary outcomes were level of back pain on a scale of 0-10, function by the Roland Morris questionnaire, physical function and body pain subscales of the SF-36, and sick leave as assessed by self report and by the Danish National Register on Public Transfer Payments (DREAM), which captures sick leave periods of more than 2 consecutive weeks.

- Other outcomes included maximum oxygen uptake and fear avoidance assessed by the Fear Avoidance Beliefs Questionnaire.

- For pain on the numerical rating scale, there were no group differences in average pain improvements from baseline; the averages were 2.6 points in the counseling group and 1.9 points in the control group.
  - For the SF-36 body pain scale, the counseling group did improve more than the control group (13.5 points versus 7.3 points).

- For function, there were no statistically significant group differences on the Roland-Morris questionnaire with an average of 3.2 points of improvement in the counseling group and 2.2 points in the control group.
  - For the SF-36 physical function scale, the counseling group had more improvement than the control group (10.4 points vs. 4.8 points).

- Fear-avoidance beliefs for work did not differ between groups, but fear-avoidance beliefs for physical activity did improve in the counseling group compared to the control group.

- There was a statistically significant improvement in maximum oxygen consumption in the counseling group (2.8 ml/kg/min) compared to the control group (1.1 ml/kg/min).

- For sick leave, the duration was greater in the control group than in the counseling group; the cumulated number of sick leave days due to LBP was 406 in the counseling group and 1081 in the control group.

Authors’ conclusions:
- The group with two counseling sessions had greater improvement in the SF-36 body pain, the SF-36 physical function, and maximum oxygen consumption than the control group, and had fewer sick leave days as well.
- One limitation is lack of blinding of assessor and patient, but the randomization was successful.
- Occupational counseling with two sessions with an occupational physician has an effect on prognostic factors for low back pain in the workplace.

Comments:
- The counseling intervention is described in vague terms and could not be replicated without further information about its content.
- Even though attrition is approximately balanced between groups, it is fairly high, with less than 75% of patients completing the three month trial.
- The pain and function outcome differences are not very impressive; the numerical rating scale and Roland-Morris scales were not different between groups, leading the authors to emphasize the differences in the two SF-36 scales which were statistically significant.
- Maximum oxygen consumption, also emphasized in the authors’ discussion, has a statistically significant but a clinically trivial difference between groups (1.6 ml/kg/min).
  - The baseline VO2 max for the counseling group was 29.9 ml/kg/min and was 30.2 ml/kg/sec for the control group.
  - The data for the two sexes are averaged, even though there are sex differences in expected VO2 max for every age group.
- The self-reported sick leave due to LBP may indicate a favorable effect of counseling and workplace evaluation, but the effect sizes for the register-based sick leave are not significantly different between groups.

Assessment: Inadequate to provide evidence regarding the effects of counseling in low back pain (vague description of intervention, clinically unimpressive overall effects of counseling).