

**Jensen LD, Maribo T, et al. Counselling low-back-pain patients in secondary healthcare: a randomised trial addressing experienced workplace barriers and physical activity. Occup Environ Med 2011; doi:10.1136/oem.2010.064055.**

Design: Randomized clinical trial

Population/sample size/setting:

- 224 patients (123 women, 101 men, mean age 45) who completed a randomized trial which originally allocated 300 patients in an occupational medicine clinic in Denmark
- Eligibility criteria were age 17-63, Danish speaking, paid employment, willingness to accept a workplace visit, and concerns about ability to maintain current job independently of sick leave
- Exclusion criteria were referral for back surgery, pregnancy, disability pension, unemployment, and serious comorbidity

Main outcome measures:

- 300 patients were randomized to either usual care (n=150) or to the study intervention (n=150)
- Usual care consisted of brief instruction in exercises or readmission to a general practitioner for further consultation with a physiotherapist or chiropractor
- Study intervention consisted of an initial counseling session with an occupational physician (OP), a workplace visit if required, a 6-week status interview, and a 3 month follow-up counseling session with the OP
  - o Initial counseling session lasted between 45 minutes and one hour; it established an individual tailored plan based on patient's daily working and private life, and involved instruction in performing 45 minutes of moderate-intensity physical activity 3 times per week
  - o Workplace visit was arranged if the OP could not gain sufficient information about the work situation from the initial counseling session; the usual tasks were observed by the OP in the presence of the supervisor, and solutions for any barriers were discussed
  - o 6-week status interview with the OP, lasting about 45 minutes, monitored compliance and adherence to goals set at the first counseling session
  - o 3-month follow-up counseling with the OP, lasting 45-60 minutes, evaluated the experiences of the past 3 months, and decisions were made about the vocational future and level of physical activity in cooperation with the patient
- Primary outcomes were changes in back-specific and generic pain and function (from the SF-36) and sick leave at the time of follow-up
  - o Bodily pain on SF-36 was lower in the intervention group; the mean change was 13.5 points (vs. 7.3 in the control group)
  - o Mean SF-36 functional change was 10.4 in the intervention group and 4.8 in the control group

- Back-specific pain and function scores did not differ between groups
- A 30% or more improvement in pain was recorded in 49.5% of the intervention group and in 36.2% of the control group
- Sick leave (based on a central registry) exceeded 8 weeks in 11.3% of intervention group and in 19.3% of control group
- Secondary outcomes included maximum oxygen uptake, fear-avoidance beliefs questionnaire (FABQ) for physical activity, and FABQ for work
  - Oxygen uptake improved by 2.8 ml/kg/min in the intervention group and by 1.1 ml/kg/min in the control group (from baseline of 30)
  - FABQ-physical activity (scale 0-24) improved by 3.7 points in the intervention group and by 0.5 points in the control group
  - FABQ-work (scale 0-30) improved by 1.8 points in the intervention group and by 1.7 points in the control group
- Workplace visits by the OP were done in only 29 cases, mainly at blue-collar workplaces (most office workplace issues were addressed at the initial counseling session)

#### Authors' conclusions:

- Two counseling sessions by an OP addressing workplace barriers and encouraging physical activity was more effective than usual care in reducing SF-36 bodily pain, enhancing SF-36 physical function and maximal oxygen consumption, and reducing self-reported sick leave
- Although the assessments were not blinded, the effect of measurement bias on oxygen consumption should not be important
- In Denmark, sick leave is restricted to 52 weeks, and extrapolation to settings with different sick leave policies should be done with caution

#### Comments:

- Many of the effect sizes are small and did not differ significantly between the two groups; the percentage of patients with a 30% improvement in pain and function did not differ significantly, even though the mean SF-36 score differences were statistically significant
- The  $\text{VO}_2$  max improvement is less than 10% in the intervention group; this is also a fairly small amount if the participants were mostly untrained at the beginning of the study
- There is a large discrepancy between the sick leave in the per-protocol and the intention-to-treat analyses; the difference was large and significant for the per-protocol and was small and non-significant for the ITT analysis
- Most of the main results were done on only the participants who completed the program and follow-up; since overall attrition was 25% (from 300 at randomization to only 224 at follow-up), the lack of an intention-to-treat analysis for the SF-36 variables is likely to overestimate the effect of the interventions

Assessment: Inadequate for evidence about the counseling program's effect on pain and function (intention-to-treat should have been the main analysis, given the attrition rate; most differences are small between groups)