

Lambeek LC, van Mechelen W, et al. Randomised controlled trial of integrated care to reduce disability from chronic low back pain in working and private life. *BMJ* 2010;340:c1035.

Design: Randomized clinical trial

Population/sample size/setting:

- 134 patients (78 men, 56 women, mean age 46) with chronic low back pain visiting outpatient clinics in hospitals in Amsterdam and Toronto
- Eligibility criteria were age 18-65 with low back pain for more than 12 weeks, in paid work for at least 8 hours per week, and absent or partially absent from work
- Exclusion criteria were absence from work for more than 2 years, specific low back pain due to tumor, infection, fracture, rheumatoid arthritis, osteoporosis, or inflammatory process; lumbar spine surgery in the past 6 weeks or scheduled for surgery or invasive examination within 3 months, serious psychiatric or cardiovascular illness, pregnancy, or litigation against an employer

Main outcome measures:

- Randomized to an integrated care program (n=66) or usual care (n=68)
- Integrated care was coordinated by an occupational physician, with a team including a medical specialist, an occupational therapist, and a physical therapist
- Overall aim of integrated care was to restore occupational functioning rather than pain reduction; it consisted of workplace intervention based on participatory ergonomics and a graded activity program based on cognitive behavioral principles, with a proposed date for full return to work in mutual agreement between the patients and the occupational physician
- Graded activity for integrated care group consisted of up to 26 sessions of graded activity over 12 weeks, teaching the patient that despite pain, moving is safe while increasing activity level
- Usual care consisted of continuing care by the patient's treating physician
- Primary outcome was return to work, defined as the number of calendar days from randomization until full return to work lasting at least 4 weeks without recurrence of absenteeism; also, the total duration of sick leave was calculated for the entire 12 month follow-up period (including days of absenteeism due to low back pain after return to work)
- Pain intensity was a secondary outcome, as were function assessed by the Roland disability questionnaire and the use of health care resources
- Although patients could not be blinded, the analysis of the data by the researcher was blinded, using a code by which data was entered into the computer
- The usual care group used more diagnostic tests, more analgesics, more psychological care, and more visits to manual therapy than the integrated care group

- Median calendar days from randomization until return to work in the integrated care group was 88 days; the median duration in the usual care was 208 days
- Median number of sick days in the 12 months of follow-up was 82 in the integrated care group and 175 in the usual care group
- Functional status and pain improved in both groups over time, but no statistically significant differences in pain improvement were found between the two groups (mean improvement of 1.64 points in the integrated care group and 1.85 points in the usual care group)
- Roland disability improvements were equal between groups at 3 and 6 months, but the integrated care group had greater improvement at 12 months (mean 7.16 points) than the usual care group (mean 4.43 points)

Authors' conclusions:

- Integrated care directed at the patients' workplace as well as at the low back pain had a beneficial effect on disability
- A placebo or Hawthorne effect cannot be excluded since the patients and therapists were not blinded
- The primary outcome was self-reported, but the data were checked with a database on sick leave from the occupational health services
- Compliance with integrated care was good and attrition was low (13%)
- Besides cognitive behavioral therapy for chronic low back disability, a visit to the workplace and adaptations at work are essential for return to work
- The lack of effectiveness on pain confirms the validity of the work disability paradigm, and may reduce the individual burden of low back pain

Comments:

- As the authors acknowledge, the trial compares usual care with the integrated care system, and cannot identify which components of the integrated care determined the outcome
- In addition to the comparison of median time to return to work between groups (using only the integrated care/usual care group for comparison), a Cox model was used to compare groups
- A Cox model is capable of adjusting the comparison between groups for other variables which may differ between groups (possible baseline imbalances), but it is not clear which variables were entered into the Cox model; however, the group comparison based only on treatment assignment is probably sufficient
- The cognitive content of the integrated care program is not described apart from teaching that moving is safe despite back pain during the graded activity sessions

Assessment: Adequate for evidence that an integrated care program consisting of workplace interventions and graded activity teaching that pain need not limit activity, is effective in returning patients with chronic low back pain to work, even with minimal reduction of pain