Effectiveness of a back pain prevention program: a cluster randomized controlled trial in an occupational setting
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined a prevention programme for low-back pain (LBP). The programme consisted of an integrated approach comprising three measures:

first, combining individually tailored education and training in work techniques;
second, immediate treatment of (sub)acute LBP through an in-company physical therapy service; and
third, advice on ergonomic adjustment of the workplace.

Each of the three components was described in detail. The programme was compared with usual care, which was delivered by the general practitioner or occupational physician according to national guidelines. It consisted mainly of drug prescriptions (analgesics or non-steroidal anti-inflammatory drugs) and physical therapy.

Type of intervention
Primary and secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised workers in physically demanding jobs.

Setting
The setting was the workplace. The economic study was carried out in the Netherlands.

Dates to which data relate
The dates during which the effectiveness and resource use data were gathered were not reported. All data were obtained over a 1-year time period. The price year was not stated.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the analysis of effectiveness.

Study sample
Power calculations were performed in the preliminary phase of the study. These suggested that a sample of 350 workers with complete questionnaires in each group would be sufficient to detect a difference of 10% in prevalence of LBP.
episodes between groups (80% power and level of significance of 0.05). Occupational sites were chosen from among those that were likely to be able to provide two clusters of workers with approximately the same estimated demanding jobs. Overall, of 590 workers assessed for eligibility in 18 clusters, 101 were initially excluded (87 were not interested and 14 did not meet the inclusion criteria. Thus, the final study sample included 489 workers. The intervention group (9 clusters) comprised 258 individuals (2% women) with a mean age of 41.3 (+/- 9.6) years. The control group (9 clusters) comprised 231 individuals (4% women) with a mean age of 41.3 (+/- 9.8) years. The average cluster size was 29 in the intervention group and 26 in the control group.

**Study design**
This was a prospective, cluster RCT, which was carried out in nine large companies (more than 500 workers). The workers included order pickers and operators in two warehouses, maintenance workers in a stevedoring company and a petrochemical plant, railway workers, and groups of operators in four chemical plants. Randomisation was based on a computer-generated table of random numbers. The unit of randomisation was the work unit. The length of follow-up was one year. The loss to follow-up over 12 months was 73 workers in the intervention group and 56 workers in the control group. Reasons for loss to follow-up were reported (manly loss of interest or time). Investigators evaluating the clinical end points were blinded to group allocation, but it was not possible to blind the participants. Physical therapists could not be blinded to treatment allocation but were not involved in the assessment of outcome measurements.

**Analysis of effectiveness**
The clinical end points were:

- the occurrence and duration of LBP, and subsequent sickness absence,
- pain intensity and functional limitations due to LBP,
- the presence of upper extremity complaints (UECs) and related sickness absence,
- productivity losses at work due to LBP and UEC,
- general health status (evaluated using the SF-12), and
- health-related quality of life (evaluated using the EQ-5D).

The presence of musculoskeletal symptoms was evaluated using the standardised Nordic questionnaire. Chronic complaints were defined as pain that was present almost every day in the preceding 12 months with a minimal presence for at least 3 months. Data on sick leave were collected using a validated questionnaire. Functional limitations were assessed using the Roland Morris Disability Questionnaire. All clinical outcomes were collected at 6 and 12 months.

The analysis of the clinical study was conducted on an intention to treat basis. At baseline, study groups were comparable with respect to clinical and demographic factors. Clinical data were adjusted for baseline factors, when necessary. Mixed-effects models were used.

**Effectiveness results**
The effectiveness analysis showed that there was generally no statistically significant difference in any of the clinical end points between groups. The exception was sickness absence related to UEC, which was 3.2% in the intervention group and 7.4% in the control group at the end of follow-up (difference 4.2%, range: 0.9 to 7.5; p<0.05).

None of the other differences in clinical outcomes reached statistical significance.

The quality of life scores at 6 and 12 months were also similar between groups.

**Clinical conclusions**
The effectiveness analysis showed that the prevention programme had no additional positive effect in comparison with usual care, although sickness absence related to UEC was significantly lower.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

Direct costs
The analysis of the costs was carried out from a societal perspective. It included the direct costs associated with the prevention programme (both fixed and variable costs were included), general practitioner visits, occupational physician visits, physical therapist visits and other outpatient visits. The unit costs and the resource quantities were presented separately for most items. Resource use was derived prospectively from actual consumption of resources in the sample of workers included in the RCT. The costs were mainly derived from in-company sources and national tariffs or charges. Discounting was not relevant as 1-year costs were evaluated. The price year was not reported.

Statistical analysis of costs
A two-sided Mann-Whitney U test was used to test for statistical differences between the groups in costs and resources.

Indirect Costs
Productivity costs (i.e. sickness absence and productivity losses) were included, which was appropriate given the adoption of a societal perspective. The unit costs and the resource quantities were presented separately. Estimated days of sick leave were derived directly from the clinical trial. The costs were obtained from average wages of the Dutch population according to age and gender. As in the analysis of the direct costs, the price year was not reported and discounting was not relevant.

Currency
Euros (EUR). The conversion rate from euros to US dollars ($) and UK pounds sterling (£) was EUR 1 = $0.90 = 0.60.

Sensitivity analysis
A sensitivity analysis was carried out to evaluate whether the results of the analysis were affected by the choice of the randomisation unit (the patient rather than the working unit), when adjusting for the cluster effect, or when the analysis was replicated in specific sub-groups.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total mean costs per patient of the programme over 12 months were EUR 231 (range: 155 to 600).

The total mean direct costs per patient due to medical consumption over the 12-month period were EUR 101 (range: 0 to 1,604) in the intervention group and EUR 165 (range: 0 to 3,110) in the control group (difference -EUR 64).

The total mean indirect costs per patient over the 12-month period were EUR 1,673 (range: 0 to 49,865) in the intervention group and EUR 1,993 (range: 0 to 54,412) in the control group (difference -EUR 220).

The total mean societal costs per patient over the 12-month period were EUR 2,118 (range: 155 to 50,096) in the intervention group and EUR 2,200 (range: 0 to 56,655) in the control group (difference -EUR 82).
None of the cost-differences reached statistical significance.

The indirect costs accounted for 85% of the total costs (54% caused by sickness absence and 46% by productivity losses).

The sensitivity analysis did not alter the conclusions of the analysis.

**Synthesis of costs and benefits**
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

**Authors' conclusions**
Compared with usual care, there was no evidence of a positive effect of the prevention programme for low-back pain (LBP) in terms of either the clinical or economic outcomes.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparators was clear in that the prevention programme was compared with usual care, which was defined according to patterns of care recommended in national guidelines. Comprehensive details of the intervention were given. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The clinical analysis was based on an RCT, which was appropriate for the study question. The choice of using a cluster trial was appropriately justified, as the authors attempted to minimise the potential bias due to contamination. The use of randomisation and blinding represent two strong features of the analysis. Further, the multi-centre design and the use of a power calculation enhance the internal validity of the analysis. Extensive information on sample selection, inclusion and exclusion of patients, refusal rates, and loss to follow-up was provided. An adjusted analysis was performed to account for potential confounding factors, although the two groups of patients were generally comparable at baseline.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the economic analysis as a cost-consequences analysis was performed.

**Validity of estimate of costs**
The analysis of the costs was consistent with the authors' stated perspective, both direct and indirect costs being included. Extensive information on the unit costs and quantities of resources used was provided, which enhances the possibility of replicating the analysis in other settings. The authors noted the skewed distribution of costs and appropriate statistical analyses were carried out. However, the cost estimates were specific to the study setting and the use of alternative cost estimates was not investigated. The price year was not stated, which will limit the possibility of carrying out reflaction exercises in other time periods. The sources of the costs were reported.

**Other issues**
The authors did not compare their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses on the costs were not performed, which limits the external validity of the study results. The authors discussed extensively the possible explanations for lack of statistical significance between groups with respect to both clinical and economic outcomes, such as methodological limitations (inadequate sample size, high drop-out rate, possible inaccuracy in outcome measurement) or poor implementation of the prevention programme.

**Implications of the study**
The study results do not support the implementation of a prevention programme for LBP. Other analyses performed in different settings are needed to provide a more definitive conclusion concerning the effectiveness of the programme.

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Other publications of related interest
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