The effectiveness and cost effectiveness of a national lay-led self care support programme for patients with long-term conditions: a pragmatic randomised controlled trial

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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 lay-led generic course to improve patients' self-care skills. The course, the Chronic Disease Self Management Programme, had been adapted for use in England and was provided through the Expert Patients Programme (EPP). The comparator was current practice, which did not involve this programme.

Type of intervention
Other: Training patients in self-care.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients who characterised themselves as having a long-term condition. No other specific inclusion or exclusion criteria were used.

Setting
The interventions were provided in the community. The economic analysis was set in the UK.

Dates to which data relate
The patients were recruited between April 2003 and March 2005. As patients were followed up for 6 months, data on resource use can be assumed to pertain to the period from April 2003 up to September 2005. The price year was not reported.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.

Study sample
The authors reported that their study had 90% power to detect a standardised effect size of 0.25. Of the 1,260 potential participants identified, 629 took part in the study and were randomised. The authors stated that they attempted to recruit a patient population similar to that accessing EPP, but it was not possible for them to estimate the proportion of eligible patients who declined. A total of 313 were referred to the programme immediately and 316 were assigned to a waiting list as controls. The programme was attended by 232 patients, of which 184 attended more than 4 sessions and 104 attended all 6 sessions. Two hundred and forty-eight patients completed the 6-month follow-up. Of the controls, 273 completed the 6-month follow-up.
Study design
The study was a multi-centre, randomised controlled trial. Patient allocation was achieved using a computer programme. Blinding of the patients does not appear to have been possible, but efforts were made to conceal allocation from the researcher evaluating effectiveness. Follow-up was for 6 months.

Analysis of effectiveness
The primary clinical outcomes were self-efficacy, reported energy, and routine health service use at 6 months. The analysis was conducted on an intention to treat basis. Outcomes in all those available for follow-up at 6 months were compared, regardless of how many sessions of the programme they attended.

Effectiveness results
Self-efficacy scores in the intervention group were significantly better. The difference in scores between the groups was 8.9 (95% confidence interval, CI: 6.2 to 11.5; p=0.000). The energy score difference was 3.7 (95% CI: 1.2 to 6.3; p=0.004) in favour of the intervention. Health care visits were not significantly different at -0.20 (95% CI: -1.35 to 0.95; p=0.732).

Intervention patients reported considerably fewer social role limitations, better psychological well-being, lower health distress, more exercise and relaxation, and a greater partnership with clinicians. There were no differences between the groups in general health, pain, diet, use of complementary products or information seeking.

Clinical conclusions
Patients receiving immediate course access reported considerably greater self-efficacy and energy at the 6-month follow-up, but reported no statistically significant reduction in routine health services use over the same time period.

Measure of benefits used in the economic analysis
The measure of benefit was the quality-adjusted life-years (QALYs). The patients recorded their health-related quality of life using the EuroQoL instrument at baseline, and 6 and 12 months.

Direct costs
The study evaluated health service and patient costs. Resource use was recorded by patients and unit costs were applied to derive the total costs. The costs for all patients who were randomised to the course were included in the analysis, irrespective of attendance or loss to follow-up. The costs of inpatient days, medication, outpatient appointments, general practitioner visits, patient out-of-pocket expenses, day-case appointments and counsellor visits were calculated in both groups. Neither the source of the unit costs nor their values were reported. The costs were appropriately not discounted as the time horizon was 1 year. The price year was not reported.

Statistical analysis of costs
Differences in resource use between the intervention and control groups, along with 95% CIs, were reported.

Indirect Costs
Productivity costs were not considered.

Currency
UK pounds sterling (L).  

Sensitivity analysis  
Variability in the data was investigated in the sensitivity analysis. Three sensitivity analyses were conducted to assess the robustness of the results to the choice of covariates. Specifically, the addition of Strategic Health Authority to the model; the addition of variables to adjust for seasonal change and variable times between baseline and follow-up assessments; and an analysis unadjusted for any covariates other than the baseline value of the outcome.

Estimated benefits used in the economic analysis  
There was a difference in QALYs of 0.02 (95% CI: 0.007 to 0.034) in favour of the intervention group.

Cost results  
The authors reported that there was a cost-saving of 27. They also quoted a 95% CI of 368 to 422, which would appear to be an error; it is likely that it should be -368 to 422.

Synthesis of costs and benefits  
The intervention group was associated with a better QALY profile as well as a small reduction in costs. If decision-makers were willing to pay 20,000 per QALY, there would be a 70% probability that the intervention was cost-effective.

Authors' conclusions  
Lay-led self-care support groups are effective in improving self-efficacy and energy levels among patients with long-term conditions. They are likely to be cost-effective over 6 months at conventional values of a decision-maker’s willingness to pay.

CRD COMMENTARY - Selection of comparators  
Although no explicit justification was provided for the comparators used, it would appear that a newly introduced programme was compared with current practice. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness  
The analysis was based on a randomised controlled trial. Power calculations were performed to ensure that the size of the study sample was adequate. Internal validity was increased by randomisation, concealment of allocation, and the low attrition rate. No specific inclusion or exclusion criteria beyond a self-defined long-term condition were used, and recruitment was carried out in all Strategic Health Authorities in England. This helped improve the external validity of the study by ensuring a patient population similar to that accessing the EPP.

Validity of estimate of measure of benefit  
The measure of benefit used was the QALYs. The methods for deriving the QALYs were adequately reported.

Validity of estimate of costs  
The perspective of the analysis was not explicitly stated. However, health service costs and patient out-of-pocket costs were included. Neither the unit costs nor the source of the price information were reported. The authors stated that full details of the economic analysis would be presented elsewhere. These factors make it difficult to comment on the validity of the estimate of costs.
Other issues
No objective for the study was stated. The issue of generalisability of the findings was addressed. The authors drew attention to some shortcomings in their paper. In particular, those concerning the external validity of their study and related to the proportion of eligible patients who declined. The authors do not appear to have presented their results selectively.

Implications of the study
Self-care support may be a useful addition to current provision for long-term conditions. As the group approach may not be acceptable to some, the authors recommended further research into the benefits of other more individual interventions.

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