Clinical trial of an Internet-based case management system for secondary prevention of heart disease

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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
An Internet-based programme that allowed nurse case managers to provide risk factor management support, education and monitoring services to patients suffering from cardiovascular disease (CVD) was studied. The advantage of using the Internet was that it allowed the patients to access the programme from their own home, at the time they chose. A case manager, who was the same person the patient used to see on routine visits, remained in contact with the patient electronically using a format similar to e-mails. Moreover, the patients had the chance to develop online discussion groups with other CVD patients and their families. They were also able to access online assessments, interactive education modules and dynamic self-monitoring tools, and contact other health care providers such as patients’ physicians, dieticians and psychologists.

Type of intervention
Secondary prevention and rehabilitation.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with diagnosed coronary heart disease and/or congestive heart failure. The patients were required to have the approval of their primary care physician and/or their cardiologist, and to have access to the Internet.

Setting
The clinical setting was the patients' own homes, primary care and the hospital. The economic study was carried out in the USA.

Dates to which data relate
There was no information about when the resource use and effectiveness data were gathered. The price year was not explicitly reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was performed, probably prospectively, on the same sample of patients as that used for the effectiveness analysis.
Study sample
Power calculations, if performed, were not reported. Among all patients who expressed an interest in the study, 8 were excluded from the analysis due to a diagnosis other than CVD, failure to complete the necessary tests, relocation to another state, or the lack of continued interest. Of the 104 patients included in the final sample, 53 were randomised to the Internet special intervention (ISI) and 51 were randomised to usual care (UC). The average age of all the patients was 62.3 years and 25% were females. The majority of the patients had a past medical history of myocardial infarction (57.7%), and 59.6% had undergone a coronary artery bypass graft.

Study design
This was a randomised controlled trial that was performed in several centres. The patients were stratified on the basis of minority status, participation in cardiac rehabilitation and acute status. They were randomly assigned to the two study groups on the basis of a computer-generated random number. The patients were followed up for a maximum of 6 months. The average follow-up was 190 days in the UC group and 186 days in the ISI group. Four patients in the ISI were lost to follow-up due to different dietary intervention (n=1), psychiatric condition (n=1), relocation out of state (n=1) and general loss of interest in the study (n=1). No blinding methods were used for the outcome assessment.

Analysis of effectiveness
The analysis of effectiveness was conducted on the basis of treatment completers only. The primary health outcomes used in the study were:

- functional status, assessed using the Duke Activity Status Index;
- angina grade, according to the Canadian Cardiovascular Society Angina grading system;
- the level of depression (Beck Depression Inventory);
- dietary conditions (MEDFICTS);
- the change in weight;
- the change in body mass index (BMI);
- systolic and diastolic blood pressure;
- total cholesterol, triglycerides, and low- and high-density lipoprotein; and
- amount of weekly exercise.

All of these outcomes were calculated at baseline (entry visit) and at the end of the study period (exit visit). In addition, the number of patients experiencing major cardiovascular events in the two groups was estimated. At baseline, the two groups were comparable in terms of their demographics, clinical and economic characteristics, and past medical history.

Effectiveness results
At the exit visit there were statistically significant differences between the ISI and UC groups in terms of body weight loss and body weight, (p=0.003). The patients in the ISI group had lost 3.6 pounds and showed a reduction of 0.6 in the BMI. The patients in the UC group had gained 0.47 pounds and showed an increase of 0.1 in the BMI.

Eight patients in the UC group suffered a major cardiovascular-related event versus 2 patients in the ISI group, (p=0.053).

Although there was a trend in favour of ISI in the majority of the other clinical outcomes assessed (in particular, amount of weekly exercise, activity status and MEDFICTS score), none of these differences reached statistical significance.
Clinical conclusions
The authors concluded that the use of the Internet-based rehabilitation programme had a beneficial effect on cardiac risk factors, underlined by the reduction in weight, the increase in weekly exercise, and the reduction in cardiovascular-related major events.

Measure of benefits used in the economic analysis
No summary benefit measure was used. A cost-consequences analysis was therefore carried out.

Direct costs
Discounting was not carried out given the short time during which the costing was undertaken. The quantities of resource use and the unit costs were not presented separately. The unit costs were only reported for some items. The quantity/cost boundary was unclear, but it may have been that of the national health system. The categories of costs in the analysis were those related to the Internet programme and hospitalisations. The Internet-related costs included the salaries of case managers and nurses, overheads and the 6-month subscription to the programme. The resource use quantities were derived using actual data obtained from the sample of patients included in the effectiveness study. The unit costs and resource use were obtained from hospital records and (for only one patient hospitalised) from the AHRQ Healthcare Cost and Utilization Project using ICD-9 codes and the 1999 National Dataset. The dates when the resource use data were collected were not stated. The price year was also not reported.

Statistical analysis of costs
No statistical analysis of the costs was carried out.

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analyses were conducted.

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

Cost results
The average hospitalisation costs per patient were $2,053 in the UC group and $635 in the ISI group.

The cost per patient for the ISI programme was $453.

The total saving per patient with the ISI programme was, therefore, $965.

Synthesis of costs and benefits
Not relevant because a cost-consequences analysis was performed.
Authors’ conclusions
The use of an Internet-based rehabilitation programme for patients with cardiovascular disease (CVD) not only showed a beneficial effect in terms of a reduction in risk factors, but also led to health care cost-savings with a return estimated at 213%.

CRD COMMENTARY - Selection of comparators
The authors justified the choice of the comparator. The new Internet-based rehabilitation programme was compared with the standard programme used for patients suffering from CVD. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a randomised controlled trial that was appropriate for the study question. The authors performed a statistical analysis to compare the patients at baseline and found no difference in any characteristic. The internal validity of the study appears to have been high. However, as the authors acknowledged, the lack of blinding methods in the outcome assessment may have biased the results reported for some outcomes (e.g. blood pressure). The authors described in detail the characteristics of the Internet-based rehabilitation programme and patient participation. It was unclear whether the study sample was representative of the study population. However, the effectiveness results were based on treatment completers only and only patients randomised to the ISI group were lost to follow-up. These issues tend to limit the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The study was therefore categorised as a cost-consequences analysis.

Validity of estimate of costs
The perspective of the cost analysis appears to have been that of the health care system. If this was the case, then the categories of costs included were appropriate. However, only the total costs were presented and a breakdown of the cost categories was only partially reported. Also, the quantities of resources used were not presented separately from the unit costs, thus limiting the reproducibility of the analysis. The unit costs were presented for a few items only. No sensitivity or statistical analyses were carried out and no details on when the resource use data were collected were reported. The cost estimates were specific to the study setting.

Other issues
The authors did not compare their results with those of other published articles, because they stated that this was the first clinical trial examining the effectiveness of an Internet-based rehabilitation programme for patients with CVD. The lack of a sensitivity analysis and the scant information on the resources used and unit costs reduce the external validity of the study. The authors stated that the fact that only the differences in weight between the two groups were statistically significant might reflect the patients’ chosen main goals for the programme (reduction in weight and increase in exercise). However, the small change across risk factors, together with the significant reduction in weight, might explain the difference in the two groups in terms of cardiac-related major events. Finally, the authors stated that the self-reported instruments used to assess exercise and dietary habits might have been a limitation of the study.

Implications of the study
This programme could be used in physician services as an alternative to standard cardiac rehabilitation programmes, to increase participation in the 80% of heart patients who do not choose to participate in cardiac rehabilitation.

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