Cost-effectiveness of nutritional counseling for obese patients and patients at risk of ischemic 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
The study examined nutritional counselling by a general practitioner (GP) or by a dietician to patients with obesity and dyslipidaemia, both risk factors for ischaemic heart disease (IHD). The intervention (both by a GP and by a dietician) comprised five counselling sections over a 12-month period.

The intervention delivered by the GP consisted of counselling in terms of general advice and the delivery of commercially available written information on healthy diet. The initial counselling session was approximately 30 minutes, while the following session was approximately 12 minutes.

The intervention delivered by the dietician consisted of individual counselling based on the indication for referral, dietary history and diet routines. The focus was on principles of good nutrition, advice on food shopping, cooking methods, meal planning and exercise. Recommendations included restriction of total dietary energy, reduction of the fat component, and/or a cholesterol lowering diet. The initial counselling session was approximately 1 hour, while the following session was approximately 30 minutes.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with obesity and a high risk of IHD. In particular, patients with a high body mass index (BMI; \( \geq 30 \) kg/m2), large waist circumference (men >102 cm; women >88 cm), dyslipidaemia, or Type 2 diabetes were included.

Setting
The setting was primary and secondary care. The economic study was carried out in Denmark.

Dates to which data relate
The effectiveness and resource use data were gathered from April 2000 to December 2001. The price year was 2001.

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

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

**Study sample**
Limited information on the primary HTA was reported as the study had already been published. A total of 60 GPs were initially identified and two possible groups were considered. GPs could either give nutritional counselling to their patients or refer patients to a dietician. Twenty-nine of the 30 GPs included in the dietician group participated, while 22 of the 30 GPs included in the GP group participated. Overall, 503 patients were involved in the study. There were 312 patients in the dietician group and 191 in the GP group. No information on patient demographics was given.

**Study design**
This was a prospective, randomised controlled trial that was presumably carried out at several centres. The participating GPs were randomised to either give nutritional counselling or to refer patients to a dietician for counselling (the study used two dieticians). The length of follow-up was not explicitly reported but the patients were followed until all counselling sessions were delivered (i.e. 12 months). Of the patients who were counselled by a dietician, 67.0% completed all six counselling sessions, while 68.1% of the patients who were counselled by a GP completed all the sessions.

**Analysis of effectiveness**
The analysis of the clinical study appears to have been restricted to those patients with complete data. The primary outcome measures were the life-years gained (LYG) and the LYG without IHD. Both measures were estimated using a Cox regression model with age as the time scale and with the following risk factors: gender, cholesterol (including high-density lipoprotein), systolic blood pressure, smoking, BMI, diabetes, familial predisposition and prior heart disease. The regression model had been validated using data from two Danish population studies with a 10-year follow-up to establish risk scores, and nine clinical trials to estimate the effect of the intervention. The baseline comparability of the study groups was not stated.

**Effectiveness results**
The LYG over no intervention were assessed for a sample of 401 patients with complete data. The LYG without IHD were estimated for a sample of 377 patients with complete data.

The total LYG over no intervention were 0.0528 (95% confidence interval, CI: 0.0317 - 0.0739) in the whole sample (both GP and dietician groups), 0.0274 (95% CI: 0.0013 - 0.0534) in the dietician group, and 0.0919 (95% CI: 0.0569 - 0.1269) in the GP group.

The effect was stronger among women when counselling was performed by a dietician, and stronger among men when counselling was performed by a GP. The average effect for men counselled by a dietician was insignificant.

The total LYG without IHD over no intervention were 0.1023 (95% CI: 0.0739 - 0.1306) in the whole sample, 0.0700 (95% CI: 0.0388 - 0.1011) in the dietician group, and 0.1608 (95% CI: 0.1054 - 0.2162) in the GP group.

The effect was greatest for the patients counselled by a GP, and was not significant for men counselled by a dietician.

**Clinical conclusions**
The effectiveness analysis showed that both interventions were significantly effective in comparison with no intervention. GP-delivered counselling was more effective than counselling by a dietician.

**Methods used to derive estimates of effectiveness**
The authors made an important assumption to estimate the LYG and the LYG without IHD.


**Estimates of effectiveness and key assumptions**
Life expectancy was assumed to be 80 years. It was also assumed that the LYG are gained at the end of life, that is, the LYG were discounted for a period equal to the remaining life expectancy.

**Measure of benefits used in the economic analysis**
The summary benefit measures used were the LYG and the LYG without IHD. Expected survival was discounted at an annual rate of 5%.

**Direct costs**
The analysis of the costs was carried out from a societal perspective. The direct costs included in the economic evaluation were intervention costs, which consisted of time spent by the GPs and dieticians. The costs associated with the changed consumption in medications were initially included in the analysis, but were then excluded because of their negligible impact on the total costs. The unit costs were not presented separately from the quantities of resources used. Resource consumption was estimated using data derived from the clinical trial. The cost of the time spent by the GPs and dieticians was derived from average hourly wages for dieticians and from paid salaries for GPs. Costs accrued because of changes in the use of prescribed medicine were estimated on the basis of individual but encrypted data on prescribed medicine from a central prescription register. Discounting was not relevant in the cost analysis and was not carried out. The price year was 2001.

**Statistical analysis of costs**
The costs were treated deterministically in the base-case.

**Indirect Costs**
The indirect costs associated with time spent to attend nutritional counselling were included since a societal perspective was adopted. However, the indirect costs were not included in the base-case analysis but in the sensitivity analysis. The unit costs were not reported separately from the quantities of resources used. Resource consumption was derived from the clinical trial and authors’ assumptions. The costs were estimated on the basis of gender- and age-specific hourly wages (gross) for the private sector. Calculations were adjusted for work force participation. No discounting was applied. The price year was 2001.

**Currency**
Danish kroner (Dkr).

**Sensitivity analysis**
Univariate sensitivity analyses were carried out to address the issue of the robustness of the base-case results to variations in the cost data. Indirect costs (patients’ time) were included in the first sensitivity analysis, while alternative cost estimates were used in the second sensitivity analysis. In particular, two alternative cost calculations were used in which the costs were calculated based on either the estimated use of GP time (identical time estimates for dieticians and GPs) or the registered use of dietician time (identical time estimates for dieticians and GPs). Finally, a probabilistic sensitivity analysis was carried out using the non-parametric bootstrap method (10,000 iterations) to generate CIs for the cost-effectiveness ratios.

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

**Cost results**
The direct costs (including only intervention costs) were Dkr 1,642 (range: 720 - 3,240) in the dietician group and...
Dkr755 (range: 416 - 818) in the GP group.

**Synthesis of costs and benefits**
Incremental cost-effectiveness ratios were calculated to combine the costs and benefits of the alternative counselling strategies.

In comparison with no intervention, the additional cost per extra LYG Dkr 8,213 (95% CI: 5,910 - 12,850) with GP counselling and Dkr 59,987 (95% CI: 30,545 - 996,368) with dietician counselling. The intervention was most cost-effective among men counselled by a GP.

In comparison with no intervention, the additional cost per extra LYG without IHD was Dkr 4,670 (95% CI: 3,480 - 6,905) with GP counselling and Dkr 23,469 (95% CI: 16,223 - 41,912) with dietician counselling.

The sensitivity analysis showed that, regardless of the cost calculation method or the inclusion of the indirect costs, GP counselling remained more cost-effective than dietician counselling. However, the inclusion of the indirect costs increased the incremental cost-effectiveness ratios for both groups relative to no intervention.

The use of acceptability curves suggested that if the maximum willingness to pay for a LYG was Dkr 25,000, then counselling by a GP would have been accepted with certainty, whereas counselling by a dietician would not have been accepted.

**Authors' conclusions**
Nutritional counselling by a general practitioner (GP) was the most cost-effective strategy for the treatment of patients with obesity and a high risk of ischaemic heart disease (IHD). However, it was stated that nutritional counselling by dieticians was also cost-effective.

**CRD COMMENTARY - Selection of comparators**
The selection of the comparators reflected the two possible types of nutritional counselling for obese patients. Both options were compared with no intervention, which might be a relevant strategy in some settings. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness data came from a clinical trial, which was appropriate for the study question. However, limited information on the design and other characteristics of the trial were reported because the study had been published already (in Danish). The method used to select the sample was described, but the patients' demographics were not reported. Similarly, the baseline comparability of the study groups was not commented on. Randomisation was based on the GP to which the patients belonged. The multi-centre design enhances the validity of the analysis.

**Validity of estimate of measure of benefit**
Both a generic and a disease-specific summary benefit measure were used in the analysis. Survival is comparable with the benefits of other health care interventions. Discounting was applied. A validated instrument (Cox regression model) was used to estimate the expected survival.

**Validity of estimate of costs**
A societal perspective was adopted in the study, although the indirect costs were included only in the sensitivity analysis. The costs associated with the change in prescribed medications were not considered since their impact on the total costs was negligible. The authors did not present the unit costs or quantities of resources used, which limits the possibility of replicating the cost analysis in other settings. The sources of the economic data were reported. The impact of alternative cost estimates was investigated in the sensitivity analysis. The costs were treated deterministically in the
base-case analysis, but a probabilistic approach was used in the sensitivity analysis. The price year was reported, which aids reflation exercises in other settings.

**Other issues**
The authors stated that the effects of both interventions on survival were of moderate magnitude. However, similar modest results were achieved in published studies evaluating other interventions. It was also noted that counselling is the only available health care strategy for some obese patients since surgery is usually restricted to patients with a BMI in excess of 40. The authors noted that the greater effect that was observed in the GP group might have been due to further advice on other lifestyle changes suggested by GPs. The issue of the generalisability of the study results to other settings was not explicitly addressed, and few sensitivity analyses were performed.

**Implications of the study**
The study results supported nutritional counselling by GPs for patients with obesity and a high risk of IHD. However, the authors noted that other health professionals, such as dieticians, might deliver cost-effective nutritional counselling.

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**Other publications of related interest**


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