A prospective randomised controlled trial of nutritional supplementation in malnourished elderly in the community: clinical and health economic outcomes

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 provision of short-term nutritional support to elderly malnourished patients after discharge from hospital was examined. Supplement intakes of between 600 and 1,000 kcal/day were prescribed for 8 weeks. The aim was to increase the patients’ energy and macronutrient intake, and to help to improve compliance by minimising taste fatigue.

Type of intervention
Other: Supportive care.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients aged 65 years or older who were discharged from hospital with either:

a body mass index (BMI) of less than 20; or

a BMI of at least 20 but less than 25, with documented evidence of a loss in body weight of at least 10% in the last 6 months; or

a lost in body weight of at least 5% in the last 3 months.

All of the patients were required to score at least 7 on the Abbreviated Mental Test. Patients were excluded if they were incapable of taking supplemental nutrition to provide a minimum of 600 kcal/day in addition to usual food intake, if they could not stand to be weighed, or if they were intolerant to any of the ingredients in the supplements. Those with a history of diabetes, hyperglycaemia or chronic renal failure were excluded, as were those who required total parenteral nutrition or enteral feeds as their sole source of nutrition. Patients who had been prescribed supplements during the last week of their hospital stay were also excluded.

Setting
The setting was primary care and the community. The economic study was conducted in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from October 2000 to September 2001. The price year was likely to have been 2000.

Source of effectiveness data
The effectiveness evidence was derived from a single study.
Link between effectiveness and cost data

The costing was conducted prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample

Power calculations were based on a prior study. These calculations suggested that 48 patients per group were required to detect a statistically significant difference in mean change in body weight of 3 kg between study groups, with 90% power at a 5% significance level. A sample of 619 eligible patients was identified at the participating hospitals. However, 519 patients were excluded because they did not agree to participate (391), were too ill (30), were discharged before consent could be obtained (38), scored less than 7 on the Abbreviated Mental Test (56), were participating in another study (1), or died before informed consent could be obtained (3). Therefore, the final sample comprised 100 patients, 51 in the intervention group and 49 in the control group. The mean age in the intervention group was 76.8 (+/- 5.3) years and 22 of the patients were men. The mean age in the control group was 79.3 (+/- 8) years and 23 patients were men.

Study design

This was a prospective, randomised, open label trial that was conducted in four centres across the UK. The patients were randomised to either the intervention or control group using sealed envelopes. The length of follow-up was 24 weeks. The study dietician encouraged the intervention patients (via telephone contact) to take their supplements between visits, while control patients ate their usual meals. The supplements were delivered at the initial visit and then at weeks 1, 4 and 8 (if supplementation was required after week 8). Any visits from social services or health care professionals' service during the study were recorded in a diary card for both groups of patients. Compliance with supplements was recorded in an additional diary. The patients were visited at weeks 4, 8, 12 and 24. The overall loss to follow-up was 42 patients. Of these, 9 did not wish to continue, 6 experienced an adverse event, 13 withdrew due to excessive weight loss, one ineligible individual was entered and then withdrew, and 13 died.

Analysis of effectiveness

The analysis of the clinical study was conducted on an intention to treat basis. The outcome measures used were:

- the dietary intakes at 1 and 2 weeks;
- changes from baseline to week 24 in body weight, BMI, triceps skinfold thickness, mid-arm muscle circumference and handgrip strength;
- mortality; and
- quality of life, as measured using the EuroQol Questionnaire.

Mortality estimates were calculated using the Kaplan-Meier approach. The study groups appear to have been comparable in terms of their demographic characteristics, Abbreviated Mental Test scores and energy requirements.

Effectiveness results

At week 1, the mean dietary intakes were 1,936.1 (+/- 592.3) kcal in the intervention group and 1,797 (+/- 426.9) kcal in the control group. At 2 weeks, the mean dietary intakes were 2,025.2 (+/-414.8) kcal (intervention) and 1,679 (+/-634.8) kcal (control), respectively.

All differences between the intervention and control group were statistically significant, (p=0.041).

The mean change in body weight from baseline to 24 weeks was 1.85 (+/- 3.66) kg in the intervention group, (p=0.0076), and 1.33 (+/- 4.41) kg in the control group, (p>0.05).

The change in BMI was 0.72 (+/- 1.38) in the intervention group, (p=0.0058), and 0.50 (+/- 1.58) in the control group, (p>0.05).
The change in triceps skinfold thickness was 1.16 (+/- 2.88) mm in the intervention group, (p=0.0027), and -0.07 (+/- 2.53) mm in the control group, (p>0.05).

The change in mid arm muscle circumference was 0.31 (+/- 1.52) cm in the intervention group, (p>0.05), and 0.30 (+/- 1.13) cm in the control group, (p>0.05).

The differences between the groups were not statistically significant.

The median change in handgrip strength did not reach statistical significance between the groups, although there was a trend towards significance favouring the intervention group at week 8.

Seven intervention patients and 6 control patients died during the study period. A further 10 patients in the intervention group and 9 in the control group died during the 6-month follow-up period.

There was no statistically significant difference in quality of life at 24 weeks, although the intervention patients performed better in the mobility domain. More specifically, 32.4% of the intervention group versus 7.7% of the control group had no mobility problem, while 67.6% of the intervention group versus 92.3% of the control group had some mobility problems, (p=0.022).

Clinical conclusions
The effectiveness study showed that nutritional support had a negligible impact on quality of life and clinical outcomes in comparison with no support. However, differences in BMI, body weight and triceps skinfold thickness between baseline and week 24 were significant for the intervention group, but did not reach statistical significance in the control group. A trend favouring the intervention group was observed for change in handgrip and a quality of life domain.

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 conducted.

Direct costs
Discounting was not relevant since the costs per patient were incurred during a 6-month timeframe. The unit costs were not reported, but the quantities of resources used were. The health services considered in the economic evaluation were general practitioner consultations (at the surgery and at home), prescriptions, visits from a district nurse, hospital admissions, outpatient appointments and other social services. The cost/resource boundary of the NHS was adopted. The costs were estimated from published NHS data (Personal Social Service Research Unit). The main cost comparison referred to the 24-week study period. However, the resources required during the 24 weeks prior to the study were also compared with estimates for the 24-week study period. The resources used were estimated for the same sample of patients as that used in the effectiveness study. The price year was not reported, but it was likely to have been 2000.

Statistical analysis of costs
The costs were compared using t-tests.

Indirect Costs
The indirect costs were not considered in the economic evaluation.

Currency
UK pounds sterling (£).
Sensitivity analysis
Sensitivity analyses were not performed.

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

Cost results
There were no statistically significant differences between the groups in terms of the individuals' requirements for health care professionals' services and social services.

During the 24-week period, the mean total costs in the whole sample of patients were 2,989.17 (+/- 4,418.22) in the intervention group and 2,146.19 (+/- 2,238.26) in the control group. The difference in costs did not reach statistical significance.

Similar results were obtained for both groups when patients living alone were compared with patients who did not live alone. However, there was a trend for patients living alone to require more services than those who did not live alone.

When costs in the 24 weeks before the study were compared with costs in the 24-week study period, only the change in hospitalisation costs was statistically significant between the groups, (p=0.0001). The difference in costs, -326.94 (+/- 4,620.1) in the intervention group versus -2,703.90 (+/- 4,380.20) in the control group, favoured the control patients.

Synthesis of costs and benefits
The costs and benefits were not combined because a cost-consequences analysis was performed.

Authors' conclusions
The short-term nutritional support programme for malnourished elderly patients was ineffective in improving quality of life and clinical indicators and in reducing health care costs.

CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparator (no nutritional support) appears to have been appropriate for reflecting standard care. You should decide whether it represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence came from a prospective randomised trial, which was appropriate for the study question. The methods of randomisation and sample selection were reported. In particular, details of the reasons for patient exclusions and withdrawal were described. It would have been interesting had the authors investigated whether those who refused to participate were comparable with those who remained in the study, as a high number of patients declined the invitation to participate in the study. The authors noted that, due to the inclusion of a heterogeneous group, it was not possible to control for disease severity, which could have been a confounding factor.

Power calculations were conducted in the preliminary phase of the study. Therefore, the number of patients enrolled appears to have been adequate to detect statistically significant differences in the main outcome measure. The patients were enrolled from four hospitals. Since all eligible individuals were considered, the study sample was likely to have been representative of the study population. The study groups were comparable at baseline and the basis of the analysis was intention to treat, which enhanced the internal validity of the study.

Validity of estimate of measure of benefit
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted.
Validity of estimate of costs
The authors implicitly reported the perspective adopted in the economic evaluation. It appears that all the relevant categories of cost have been included in the study. The quantities of resources used were presented. Both the costs and resources were estimated from actual data, the sources of which were reported. The price was provided, which makes reflation exercises in other settings possible. Statistical tests were conducted when the estimated costs were compared. Highly skewed distributions of costs were observed. The cost estimates were specific to the study setting and no sensitivity analyses were conducted. A sub-group analysis, to account for variations in resource consumption in patients who lived alone, was performed. The authors noted that significantly more resources were consumed by patients living alone. This implies that some resources, which were not recorded in patients who did not live alone, were borne by family members who were not calling on social services for assistance.

Other issues
The authors compared their findings with those from a published study that found that the provision of nutritional supplements to frail elderly people did not result in functional improvements. The authors did not address the issue of the generalisability of the study results to other settings and did not perform any sensitivity analysis. Therefore, the external validity of the analysis was low. The study referred to elderly malnourished patients discharged from hospitals and this was reflected in the authors' conclusions.

Implications of the study
The study results suggested that, in already malnourished individuals with serious underlying disorders, the implementation of a short-term nutritional support intervention did not lead to improvements in function or quality of life, nor reductions in costs. It is unclear whether a longer intervention could have achieved more encouraging results. Future studies should assess the cost-effectiveness of nutritional support programmes in patients where a single, major disease condition is present. The prevention of malnutrition would appear to be the sole effective instrument in reducing costs and improving quality of life.

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