A 3-year prospective randomized controlled clinical trial of group care in type 1 diabetes

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 group care for the continuing education of patients with Type 1 diabetes (T1DM) compared with standard one-to-one care. The effects on quality of life, knowledge of diabetes, health behaviours and metabolic control were examined.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with T1DM, with onset of diabetes before age 30 years, who had insulin treatment started within 1 year of diagnosis. The patients were under 70 years of age and had attended the study clinic for at least 1 year.

Setting
The setting was not specified. The economic study was carried out in Italy.

Dates to which data relate
The dates to which the data referred were not specified. The price year was also not specified.

Source of effectiveness data
The effectiveness data were derived from a single study.

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

Study sample
Power calculations were not conducted to determine the sample size. Sixty-two people with T1DM were randomly selected by random table numbers from the patient population treated at the study centre. Of these, 31 were assigned to group therapy and 31 to the control, also by randomisation using random numbers. No patient refused to participate.

Study design
This was a 3-year, prospective, randomised controlled trial that was conducted in a single centre. Four patients were
lost to follow-up. One patient on group care and one in the control group moved to other cities because of work commitments, while two more in the control group declined to participate in the final visit and complete the questionnaires. There was no blinding other than that health operators were blinded to which patients in the general diabetes clinic served as controls. This could have helped to minimise performance bias.

**Analysis of effectiveness**

The analysis of the clinical study was conducted on the basis of treatment completers only. The main health outcomes were:

- quality of life, assessed using the original version of the diabetes quality of life (DQoL) questionnaire;
- knowledge of T1DM, assessed using a questionnaire produced by the Education Study Group of the Italian Society for Diabetes (GISED); and
- health behaviours, assessed with a purpose-designed 30-item questionnaire for T1DM.

Secondary end points were:

- body weight, fasting blood sugar, glycated haemoglobin (HbA1c), total and high-density lipoprotein cholesterol, triglycerides and the microalbuminurea/creatinine ratio, all assessed yearly in both groups; and
- episodes of hypoglycaemia, assessed retrospectively from clinic case notes.

The baseline comparability of the study groups was discussed. The authors noted that, in spite of randomisation, control patients had different schooling levels and higher HbA1c levels at baseline. The results were adjusted for schooling on multivariate analysis, to account for possible selection bias resulting from differences in schooling at baseline.

**Effectiveness results**

The authors reported that the DQoL improved from baseline for group care and that it worsened in the control group. However, the data provided suggested that the DQoL score decreased (-8.82, 95% confidence, CI: -12.51 to -5.14; p<0.001) with group care compared with controls, which increased (3.34, 95% CI: 2.38 to 430; p<0.001), (difference between groups p>0.001).

From the report it would appear that a typographic error might have resulted in the interchange of DQoL data in the two groups.

The GISED score increased by 3.10 (95% CI: 1.56 to 4.65; p<0.001) for group care compared with 0.24 (95% CI: -0.32 to 0.80) for controls, (difference between groups p>0.01).

The health behaviour score improved by 3.79 (95% CI: 2.61 to 4.98; p<0.001) for group care, whereas it decreased by -0.10 (95% CI: -0.41 to 0.21) for controls, (difference between groups p>0.001).

**Clinical conclusions**

The authors reported that, after 3 years, quality of life improved among patients on group care along with knowledge and health behaviours. Among controls, quality of life worsened whereas knowledge and behaviours remained unchanged.

**Measure of benefits used in the economic analysis**

The differential DQoL score between group care and individual care patients was used as a surrogate of utility, and this was the measure of benefit used in the economic analysis.
Direct costs
The costs to the INHS were evaluated. The quantities of resources used were estimated using data from the study, while resource costs were based on average salaries and costs to the INHS. The quantities and the costs were not reported separately. The costs of insulin, diagnostic materials and tests, and personnel time to update clinical records were not included because they did not differ between group care and controls. The costs were incurred during 3 years, but discounting was not carried out despite it being relevant. The dates when the quantities of resources were measured and the price year were not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
Cost to the patients in terms of transportation costs and opportunity cost of time spent in the clinic were evaluated from a questionnaire administered to 27 group care patients and 26 controls. The quantities and the costs were not reported separately. The costs were incurred during 3 years, but discounting was not carried out despite it being relevant. The dates when the quantities of resources were measured and the price year were not reported.

Currency
Euros (EUR).

Sensitivity analysis
A sensitivity analysis was performed by examining differential costs in terms of actual attendance in the two groups. Costs were also estimated on the assumption that care was undertaken with a smaller team of nurses and dieticians. The range tested was based on authors’ assumptions.

Estimated benefits used in the economic analysis
The differential DQoL score between group and individual care was 12.16.

The duration of follow-up was 3 years.

Cost results
The direct costs per patient were EUR 933.19 for group care and EUR 697.10 for one-to-one care.

Synthesis of costs and benefits
The cost-difference (EUR 236.09) divided by the differential DQoL score (12.16) between group and individual care resulted in a cost-utility ratio of EUR 19.42 spent over 3 years for each point gained in the quality of life scale.

Taking into account actual attendance rates, the cost of group care changed to EUR 907.88 and that of one-to-one visits decreased to EUR 574.31 per patient actually attending appointments, whilst the cost per point gained on the quality of life scale widened to EUR 27.43.

Using a smaller team of well trained nurses and dieticians reduced the extra cost spent per point gained in the quality of life scale to EUR 12.83.

Authors’ conclusions
Group care is feasible and cost-effective in Type 1 diabetes. It improves quality of life, knowledge and behaviours.
CRD COMMENTARY - Selection of comparators

Although no detailed justification was given for the choice of the comparator, it appears to have represented current clinical practice in the authors' setting. You should decide if the comparator represents current practice in your own setting.

Validity of estimate of measure of effectiveness

The analysis of effectiveness was based on an open randomised study, which was appropriate for the study question. Randomisation was carried out using random numbers. The study sample was representative of the study population. The groups were shown not to have been comparable at analysis (different schooling levels and higher baseline HbA1c levels) and an appropriate analysis was undertaken to account for this potential bias and other confounding factors. The validity of the effectiveness estimates should, therefore, be high.

Validity of estimate of measure of benefit

The estimation of benefits was obtained directly from the effectiveness analysis. The choice of estimate was justified on the grounds that translating the results into quality-adjusted life-years was not possible. The use of a standard DQoL scale helps facilitate comparison with the benefits of other health care interventions.

Validity of estimate of costs

All the categories of cost relevant to the perspectives adopted were included in the analysis. The costs and the quantities, however, were not reported separately. No statistical analysis of the quantities or prices was performed. Although the costs were incurred during a 3-year period, discounting was not undertaken. Charges were used to proxy prices, which limits the generalisability of the results. The date to which the prices referred was not reported. These factors will present difficulties when validating the study in other settings or in relflation exercises.

Other issues

The authors made appropriate comparisons of their findings with those from other studies. In particular, they made comparisons with their earlier study on Type 2 diabetics. The study was carried out in a single centre and the issue of generalisability to other settings was addressed. The authors did not present their results selectively.

Implications of the study

Group care may represent a model in which education merges with clinical care. Group dynamics and peer identification appear to lead to more active coping behaviours and improved quality of life. There were no recommendations for further research, but the authors suggested that alternative approaches should be negotiated with patients in order to achieve more impact on metabolic control.

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