Telecare in a structured therapeutic education programme addressed to patients with type 1 diabetes and poor metabolic control

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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 assessed the use of telecare appointments, integrated into a structured therapeutic education programme (TEP), in helping patients with Type 1 diabetes and bad metabolic control to improve their metabolic control and self-management. The comparator was conventional face-to-face outpatient appointments.

Type of intervention
Disease management.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients (with poor metabolic control) attending routine clinical outpatient appointments. The inclusion criteria specified patients aged from 18 to 50 years with Type 1 diabetes for at least 2 years, who had been treated with at least three doses of insulin per day and had a glycosylated haemoglobin (HbA1c) value greater than 8%. The exclusion criteria included patients beginning continuous subcutaneous insulin infusion, patients planning to become pregnant or who were pregnant, patients with psychiatric disorders, and lack of appointment compliance (50%).

Setting
The setting was the home and outpatient care. The economic study was carried out in Barcelona, Spain.

Dates to which data relate
The effectiveness and resource use data were obtained between 2001 and 2003. The price year was not reported.

Link between effectiveness and cost data
The costing appears to have been undertaken prospectively on the same sample of patients that provided the effectiveness data.

Study sample
No details of the sample size required to power the study were provided. Fifty patients were invited to participate in the study, of which 40 accepted and were assessed and randomised. There were 20 patients in the telecare group (TG) and 20 in the conventional group (CG).

Study design
The study was a single-centred, randomised controlled trial. The patients were randomised using a random variable generator. The authors stated that 19 patients in the TG and 16 patients in the CG were included in the intention to treat analysis. This did not match up with the reported exclusion data. The duration of follow-up was 1 year.

### Analysis of effectiveness

The primary health outcomes used in the analysis were metabolic control, self-management (of diabetes) and quality of life. Metabolic control related to achieving normal values of HbA1c and the occurrence of hypoglycaemic episodes. Self-management involved compliance records. Quality of life was evaluated by the Spanish Diabetes Quality of Life (DQOL) test and the SF-12 Health Survey.

The primary analysis was carried out on an intention to treat basis. Both groups were shown to be relatively comparable at baseline. However, patients in the CG were younger, on average, and there was a higher proportion of males than in the TG.

### Effectiveness results

Improvements in metabolic control were similar in both groups at 6 months.

In the TG, the HbA1c value fell from 8.4% (+/- 1.2) at the outset to 7.5% (+/- 1.4) at 6 months and 7.6% (+/- 0.9) at 12 months, (p=0.008). The corresponding figures for the CG were 8.9% (+/- 1.3) at the outset, 7.7% (+/-0.9) at 6 months and 7.6% (+/-0.7) at 12 months, (p=0.001).

In the TG, the proportion of patients reporting 3 or more mild hypoglycaemia episodes a week decreased from 75% at the outset to 10% at 6 months and 6% at 12 months, (p=0.001). The corresponding figures for the CG were 79% at the outset, 12% at 6 months and 15% at 12 months, (p=0.001).

There were improvements in both groups in the DQOL score (assessed by satisfaction, impact, social worry and diabetes worry), although only the impact component in the CG was significant.

The general health status SF12 test did not change during the study in either group.

In both groups, there was a significant increase in the diabetes knowledge test DQK2 scores. The score in the TG (out of a maximum of 35) was 27 (+/- 4) at baseline, 29 (+/- 3) at 6 months and 30 (+/- 3) at 12 months, (p=0.05). The score in the CG was 26 (+/- 4) at baseline, 29 (+/- 4) at 6 months and 29 (+/- 3) at 12 months, (p=0.05).

There was a significant increase in the proportion of patients who readjusted insulin doses considering self-monitoring of capillary blood glucose after three or more daily controls. For the TG, this was 40% of patients at baseline, 82% at 6 months and 80% at 12 months, (p=0.001). The corresponding figures in the CG were 25% at baseline, 88% at 6 months and 92% at 12 months, (p=0.001).

### Clinical conclusions

The authors concluded that intensive telematic follow-up achieved similar results to those of intensive face-to-face follow-up in patients with Type 1 diabetes.

### Measure of benefits used in the economic analysis

The authors demonstrated therapeutic equivalence and only the costs were analysed in the economic analysis.

### Direct costs

The direct costs included in the analysis were those of the patient and family, and medical team. The patient and family costs were the cost per telematic or hospital appointment (including the length and expenses, transportation and GlucoBeep device), and the total cost per type of follow-up (the authors did not explicitly define these costs). These costs were obtained from a questionnaire administered during the clinical or telematic appointment. The medical team
costs included the time and expenses spent on both types of appointment, and the total cost per type of follow-up. The source of these costs was not reported, but they can be assumed to have been the costs to the institution in which the study took place. The price year was not reported. The costs and the quantities were reported separately in some cases, but not all.

**Statistical analysis of costs**
No statistical analysis of the costs was performed.

**Indirect Costs**
The authors reported that the daily activities, which the patients could not perform because of the appointments, and the number of school or workdays missed, were included as a cost. However, no further details of this were provided.

**Currency**
Euros (EUR).

**Sensitivity analysis**
There was no attempt to allow for uncertainty.

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

**Cost results**
The total cost of the TEP follow-up was lower in the TG (with and without technical problems) than the CG.

The total cost for the TG was EUR 347 without technical problems and EUR 421 with technical problems. The total cost for the CG was EUR 696.

**Synthesis of costs and benefits**
The costs and benefits were not combined.

**Authors' conclusions**
Telematic follow-up provided similar results to those of face-to-face follow-up as part of a therapeutic education programme (TEP), but with lower patient costs.

**CRD COMMENTARY - Selection of comparators**
The rationale for the choice of the comparator was clear. The authors chose the comparator as it represented current practice in their setting. You should decide if this represents a valid comparator in your own setting.

**Validity of estimate of measure of effectiveness**
The study was based on a randomised controlled trial, which was appropriate for the study question. The study sample appears to have been representative of the study population. However, differences between the two groups at baseline (most importantly, the higher proportion of males in the CG) were not accounted for and might have biased the results if, for example, males were less likely to respond to the education programme than females. The method of randomisation, length of study and loss to follow-up were all reported, suggesting that the internal validity of the study is likely to be good. No power calculations were reported, thus it is not possible to ascertain whether the results obtained
were due to the intervention or to chance.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

**Validity of estimate of costs**
The perspective of the analysis was not reported. However, the authors included the costs of both the family and health service, as well as recording the time lost due to keeping appointments, which might be consistent with a societal perspective. No discounting was performed, but it was not necessary given that the length of follow-up was 12 months. The source of many of the unit cost data and the price year were not reported.

**Other issues**
The authors did not compare their findings with those from other studies, so the extent to which their results agree with those from other published studies cannot be determined. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively. The authors noted a number of additional limitations to their study, such as the high number of drop-outs and problems with the GlucoBeep system.

**Implications of the study**
The authors concluded that the use of an interactive telematic system as part of a TEP achieves similar improvements in metabolic control, quality of life and self-management to the conventional face-to-face consultation, but with lower patient costs. However, they also noted that there is a need for improvements in the communication facilities.

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**Other publications of related interest**
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**Indexing Status**
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