A randomised controlled trial of cognitive behaviour therapy and motivational interviewing for people with type 1 diabetes mellitus with persistent sub-optimal glycaemic control: A Diabetes and Psychological Therapies (ADaPT) study


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.

CRD summary
This was an economic evaluation carried out alongside a clinical trial of motivational enhancement therapy (MET) with or without cognitive behavioural therapy (CBT), compared with usual care, for patients with type 1 diabetes mellitus and persistent suboptimal glycaemic control. The authors concluded that neither MET nor MET plus CBT was indisputably cost-effective, compared with usual care alone, in the short term. The methods were valid and appropriate and the study was extensively described, making the authors’ conclusions robust.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
This was an economic evaluation carried out alongside a clinical trial of motivational enhancement therapy (MET) with or without cognitive-behavioural therapy (CBT), compared with the usual care, for patients with type 1 diabetes mellitus, with persistent suboptimal glycaemic control, which was defined as a blood haemoglobin (Hb) A1c level between 8.2% and 15%. It was a Health Technology Assessment study.

Interventions
Three interventions were examined: MET plus usual care; MET and CBT plus usual care; and usual care alone. Usual care consisted of at least three monthly appointments at a diabetes clinic. MET consisted of four individual sessions over a two-month period. The sessions covered computerised self-assessment of diabetes-relevant behaviour and rating of the level of importance, confidence, and readiness to change; discussion of options for change; homework writing tasks; and formulation of a collaboratively completed change plan. MET and CBT consisted of the four MET sessions over two months, followed by eight CBT sessions over four months.

Location/setting
UK/diabetes clinics.

Methods
Analytical approach:
The analysis was based on a single study with a one-year time horizon. The authors stated that the perspectives of the health system and society were adopted.

Effectiveness data:
The clinical analysis was based on a three-arm, parallel, randomised controlled trial, which included 344 patients, with 106 in the MET plus CBT arm, 117 in the MET arm, and 121 in the usual care arm. The median age of these patients was 36 years. Randomisation was by a computer-generated list stratified according to centre. The length of follow-up was one year and 88% of patients provided clinical data at the end of follow-up. The impact of baseline characteristics on the clinical outcomes was considered, using regression analysis. The change in HbA1c level from baseline to one-year assessment was the key endpoint and this was assessed by technicians, who were blinded to the group allocation.

Monetary benefit and utility valuations:
The utility values were estimated at patient level, using two instruments, namely the Short Form (SF)-36 Health Survey.
and the European Quality of Life (EQ-5D) questionnaire at baseline and at 12 months.

Measure of benefit:
The change in HbA1c level and quality-adjusted life-years (QALYs) were the summary benefit measures and both were derived from the clinical trial.

Cost data:
The economic analysis considered the following health and social care costs: hospital in-patient and out-patient services, primary care services, other community-based services, social services, medications, insulin-related equipment, other equipment and adaptations, and implementation of the interventions. The societal costs also included informal care, out-of-pocket expenses incurred by the patients and their families (travel to the intervention sessions), lost productivity due to absence from work, and lost productivity, leisure time, and pay due to attending the intervention sessions. The resource use data were gathered alongside the clinical trial, using the Client Service Receipt Inventory at baseline, six months, and 12 months. Only patients who provided data at all time points were included. The unit costs were from official NHS data, such as the Department of Health and NHS reference costs. Published studies were used for a few estimates. All costs were in UK pounds sterling (£) for the fiscal year 2005 to 2006.

Analysis of uncertainty:
The uncertainty was investigated by means of cost-effectiveness acceptability curves, for various levels of willingness-to-pay for a unit of outcome. A nonparametric bootstrap method was used because the economic data were not normally distributed.

Results
For QALYs, no statistically significant differences were observed for any comparison (MET plus CBT versus usual care; MET versus usual care; and MET plus CBT versus MET). For example, QALYs based on the SF-36 improved by 0.004 (95% CI -0.01 to 0.02) with MET versus usual care. For HbA1c improvement, only the difference between MET plus CBT and usual care was statistically significant, with a mean difference of 0.45 (95% CI 0.11 to 0.80).

The total costs were not significantly different between the two intervention groups, but both were significantly higher than usual care. For example, the adjusted mean differences in societal costs were £643 (95% CI -414 to 1,549) with MET versus usual care, £814 (95% CI -176 to 1,586) with MET plus CBT versus usual care, and £144 (95% CI -581 to 894) with MET versus MET plus CBT.

When the costs and benefits were compared, the only significant comparison was the incremental cost per additional unit of HbA1c improvement with MET plus CBT over usual care, which was £1,756. MET was dominant (better clinical and economic outcomes) compared with MET plus CBT, when QALYs were used as the benefit measure. The incremental cost for MET plus CBT versus usual care was extremely high (over £270,000) for both perspectives, using either the SF-36 or the EQ-5D. Similarly, the incremental cost per QALY for MET versus usual care was very high (over £130,000), except for the health care perspective, using the EQ-5D (£48,636), but high variability was found due to the similar QALY results.

The cost-effectiveness acceptability curves showed that, at a threshold of £20,000 per additional QALY, the probabilities of cost-effectiveness for MET versus usual care were 0.08 (EQ-5D) and 0.03 (SF-36) from the health and social care perspective; from the societal perspective the probabilities were higher, but still low. At the same threshold, MET plus CBT had no probability of cost-effectiveness versus usual care from the health and social care perspective, and 0.06 (EQ-5D) and 0.11 (SF-36) probability of cost-effectiveness from the societal perspective.

Authors’ conclusions
The authors concluded that neither MET nor MET plus CBT was likely to be cost-effective, compared with usual care alone, in the short term, but the probability of cost-effectiveness was greater with HbA1c as the measure than with QALYs and quality of life impacts might be greater in the long term.

CRD commentary
Interventions:
The selection of the comparators was appropriate given the available and widely practised therapies for this patient population. A description of the three approaches was given and the authors acknowledged the variability in therapies for usual care.

**Effectiveness/benefits:**
A randomised controlled trial was a valid source of evidence because of its rigorous methods. The trial was extensively described, enhancing the transparency and reliability of the clinical data. The inclusion and exclusion criteria were clearly presented and the characteristics of the patient population were appropriately defined. An intention-to-treat analysis was used to assess the clinical outcomes. The sample size was valid as it was based on power calculations. Statistical analyses were carried out and the impact of missing data was considered in an alternative analysis. Appropriate benefit measures were used to examine the impact of the interventions on a patient's health and two instruments were used to capture the effects on health-related quality of life. QALYs allow comparisons with the benefits of other health care interventions.

**Costs:**
The economic analysis was satisfactorily carried out and was well presented. The use of two perspectives showed the variability in the results. The unit costs and resource quantities were clearly presented. The authors provided extensive information on the data sources in an appendix. The price year was stated. Statistical analyses of costs were carried out, using nonparametric bootstrapping. The Client Service Receipt Inventory data included a detailed list of resource use, but some recall bias might be present. The analysis was based on a subsample of patients who provided full data for all time periods and an alternative scenario, in which all patients were included, was considered without substantially altering the results.

**Analysis and results:**
The results were clearly presented and the costs and benefits were appropriately combined, in an incremental analysis, and the methods were reported. The cost-effectiveness acceptability curves highlighted the uncertainty in the results. The authors acknowledged some potential limitations of their analysis, such as the short time horizon and the relatively high number of missing values in the economic data, which did not change the cost-effectiveness results. These results appear to be specific to the UK context and cannot be easily transferred to other settings.

**Concluding remarks:**
The methods were valid and appropriate and the study was extensively described, making the authors’ conclusions robust.

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