

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

K Ismail,^{1*} E Maissi,¹ S Thomas,²
T Chalder,¹ U Schmidt,¹ J Bartlett,³
A Patel,⁴ C Dickens,⁵ F Creed⁵
and J Treasure¹

¹Department of Psychological Medicine, Institute of Psychiatry, King's College London, London, UK

²Diabetes Centre, St Thomas' Hospital, London, UK

³Medical Statistics Unit, Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, London, UK

⁴Health Service and Population Research Department, Institute of Psychiatry, King's College London, London, UK

⁵Department of Psychiatry, University of Manchester, Manchester, UK

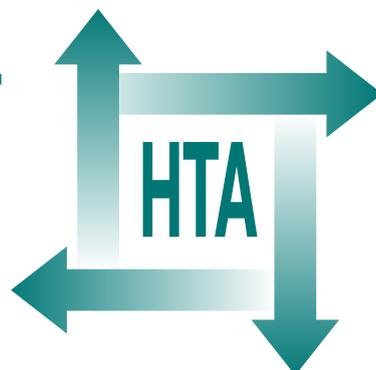
*Corresponding author



Executive summary

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Executive summary

Background

Sub-optimal glycaemic control in type 1 diabetes is common despite intensive insulin therapy and education. Psychological problems such as depression, eating problems and diabetes-specific problems (such as fear of hypoglycaemia, fear of self-injecting and testing, fear of complications) are also common and associated with sub-optimal glycaemic control, complications and mortality.

There is insufficient evidence from randomised controlled trials (RCTs) that psychological treatments are effective in improving glycaemic control in adults with type 1 diabetes. The training and effectiveness of diabetes professionals in delivering brief and focused psychological treatments to help people improve their diabetes self-care has received scant attention.

Two psychological treatments, motivational enhancement therapy (MET) and cognitive behaviour therapy (CBT), were selected for their time focused duration, brevity of training and ability to be translated into the clinical setting.

Motivational enhancement therapy is a brief counselling method for enhancing motivation to change problematic health behaviours by exploring and resolving ambivalence. It has been effective in reducing substance misuse but evidence for effectiveness in improving diabetes control is lacking. CBT aims to enable the patient to identify and modify unhelpful cognitions and behaviours and is effective in the treatment of a range of psychological problems, but limited evidence in improving glycaemic control. There is emerging evidence that adding CBT to MET helps to maintain behaviour changes.

Objectives

1. To determine whether (i) MET + CBT compared with usual care, (ii) or MET compared with usual care, (iii) or MET + CBT compared with MET was more effective in improving glycaemic control when delivered by general nurses with additional training in these techniques.

2. To examine the cost-effectiveness of MET + CBT compared with MET and compared with usual diabetes care, and MET compared with CBT, for improving glycaemic control.
3. To identify pre-randomisation moderators of the effectiveness of treatment.
4. To assess the effect of treatment on secondary outcomes including depression and quality of life.

Methods

Setting

The recruiting centres were diabetes clinics in seven acute trusts in south-east London and Greater Manchester.

Study population, case definition and study criteria

The target population was adults (18–65 years) registered having type 1 diabetes with one previous glycated or glycosylated haemoglobin (HbA_{1c}) value between 8.2% and 15%. The study population was those with a confirmed diagnosis of type 1 diabetes for a minimum duration of 2 years and a current HbA_{1c} value between 8.2% and 15%. Participants were excluded if they: were not fluent in English; were pregnant; had an antidepressant initiated less than 2 months ago; had a serious/acute medical illness defined by their treating physician; had advanced diabetes complications; had known haemoglobinopathy or severe mental disorder; were in psychotherapy or within 3 months of having completed a structured diabetes education programme; or were participating in another trial.

Baseline pre-randomisation measures

These were collected as follows: sociodemographic factors (age, gender, employment status, educational level, ethnicity, marital status); lifestyle factors (current smoking status and units of alcohol intake per week); physical health [blood pressure (mmHg), body mass index (weight/height²), total random cholesterol (mmol/l), duration of diabetes (years)]; and diabetes complication

status. We measured a range of psychological factors including depression, anxiety, eating disorders, quality of life, fear of hypoglycaemia and adherence to self-care activities.

Randomisation

A computer-generated randomisation list stratified according to centre using minimisation and blocks of random sizes was prepared in advance with allocation concealment.

Outcome measures

The primary outcome was HbA_{1c} at 12 months from randomisation. The HbA_{1c} was measured quarterly after randomisation to measure the rate of change in glycaemic control. The self-report psychological measures were repeated at 12 months. The HbA_{1c} was analysed by technicians blind to allocation.

Economic assessment: 1-year costs measured by the Client Service Receipt Inventory at baseline, 6 months and 12 months; quality of life-years [quality-adjusted life-years (QALYs)] measured by the SF-36 (Short Form-36 Health Survey Questionnaire) and EQ-5D (European Quality of Life-5 Dimensions) at baseline and 12 months.

Statistical analysis

The baseline characteristics were compared to assess the effectiveness of randomisation. We used an intention-to-treat analysis of covariance for the primary outcome of 12-month HbA_{1c} (and for quarterly HbA_{1c}), to estimate the differences in intervention group means, adjusting for the baseline HbA_{1c}. This was repeated for the secondary outcomes (depression, body mass index, fear of hypoglycaemia, diabetes self-care activities and quality of life). Effect modification of the interventions by baseline factors, such as age, education, depression, on 12-month HbA_{1c} was examined.

Interventions

Control. Usual diabetes care which varied between the hospitals but constituted at least three monthly appointments to diabetes clinic.
Usual care with MET. Participants were offered four individual sessions over a 2-month period based on a diabetes-specific patient workbook that included a standardised computerised self-assessment of diabetes relevant behaviours and rating of the

level of importance, confidence, and readiness to change, discussion of options for change, homework writing tasks, and the formulation of a collaboratively completed change plan.

Usual care with MET + CBT. Participants were offered four MET sessions over a 2-month period followed by eight CBT sessions for a further 4 months. We developed a range of diabetes-specific CBT techniques. A collaborative individualised programme was developed and structured around agenda setting, homework planning and feedback around diabetes-specific problems.

Training

Training of diabetes nurses involved workshops, self-directed learning, audiovisual feedback, weekly group meetings and individual supervision of a patient caseload. Therapy integrity was increased by use of manuals, and assessed quantitatively by trained clinical psychologists blind to allocation of a random sample of tapes. Weekly supervision continued throughout the study.

Results

One thousand six hundred and fifty-nine people with type 1 diabetes were screened and 344 were randomised to MET + CBT ($n = 106$), MET ($n = 117$) and to usual care ($n = 121$). The 12-month follow-up rate for HbA_{1c} was 88% ($n = 305$). The median age was 36 years [interquartile range (IQR) 28–44]; duration of diabetes was 18 years (IQR 11–25); and HbA_{1c} was 9.4% (IQR 8.8–10.2). The adjusted mean 12-month HbA_{1c} was 0.45% lower in those treated with MET + CBT [95% confidence interval (CI) 0.16% to 0.79%, $p = 0.008$] than for usual care; 0.16% lower in those treated with MET (95% CI 0.20% to 0.51%, $p = 0.38$) than for usual care; and 0.30% lower with MET + CBT than with MET (95% CI –0.07% to 0.66%, $p = 0.11$). This changed only slightly when imputed data were used for missing values. The higher the HbA_{1c}, and the younger the participant at baseline, the greater was the reduction in HbA_{1c}. The interventions had no effect on secondary outcomes such as depression and quality of life.

The six nurse therapists who delivered the interventions achieved acceptable competencies in most of the techniques in MET and CBT. Overall there was evidence of treatment integrity in that two technologies could be distinguished from each other, but there was evidence of overlap in some of the techniques.

Both interventions were associated with higher total health and social care costs than for usual care alone, largely as a result of the additional costs of the interventions which were not offset by reductions in other health-care use. There were no significant differences in societal costs. Only MET + CBT resulted in a significantly different outcome improvement (HbA_{1c}). MET + CBT had greater probabilities of cost-effectiveness compared with usual care than did MET, if value was placed on HbA_{1c} outcomes (over 0.7 at thresholds of £5000 per additional point improvement in HbA_{1c}); but MET had a greater chance of cost-effectiveness if value was placed on QALY outcomes, although at a threshold of £20,000 per additional QALY, probabilities only reached 0.31 (based on the SF-36). MET + CBT had a good probability of cost-effectiveness compared with MET based on HbA_{1c} outcomes but, based on QALYs, it was dominated by MET and had low probabilities of cost-effectiveness. These broad conclusions apply from both a health/social care and societal perspective.

Conclusions

Implications for health care

1. Diabetes professionals can be trained to deliver diabetes-specific MET and CBT competently in the context of concurrent supervision.
2. A combined MET and CBT approach may be useful in individuals with persistent sub-optimally controlled diabetes, but MET appeared less effective than usual diabetes practises and MET + CBT.
3. Compared with usual care, at a minimum of £48,636 per QALY gain (based on the EQ-5D), neither intervention fell within a notional policy-making threshold of cost-effectiveness. MET + CBT achieved additional HbA_{1c} improvements at a lower cost (£1756 per additional point improvement) than MET. MET + CBT had a high probability of cost-effectiveness than MET based on HbA_{1c} outcomes, but MET dominated on the basis of QALYs estimated from both the EQ-5D and the SF-36. Probabilities of cost-effectiveness are higher based on HbA_{1c} outcomes than on QALY outcomes. Therefore, decisions regarding the provision of such interventions depend on the relative importance of these two outcomes.
4. The interventions had no quality of life impacts over 1 year, as measured by the EQ-5D, SF-36 and diabetes quality of life. However, it is possible that any such effects would be more evident over a longer term, beyond the time horizon of this study, alongside any reductions in future complications for instance.

5. The younger the person with diabetes and the worse his or her diabetes control, the greater was the reduction in glycaemic control in the MET + CBT group only.
6. The treatments tested do not appear to improve other markers of psychological functioning.

Recommendations for research

1. To identify quantitatively and qualitatively the components of the complex intervention that was associated with improvement in glycaemic control in order to inform future generations of RCTs.
2. To examine whether the effects are sustained for longer than 12 months.
3. To compare variations of therapy such as whether additional sessions, group format, electronic formats or adding techniques for the treatment of depression are associated with additional effectiveness or cost-effectiveness to the intervention tested here.
4. To conduct a discrete choice experiment in order to understand how people with diabetes appraise the value of psychological treatments to help improve their diabetes control, taking account of any costs falling to themselves as a result of attending such time-intensive treatments.
5. To assess whether these techniques can be adjuncts to structured diabetes education programmes to enhance their effectiveness, such as DAFNE (Dose Adjustment For Normal Eating).
6. To assess whether the techniques can be modified for use in other diabetes groups, such as adolescents with type 1 diabetes, adults with type 2 diabetes and people from different ethnic backgrounds.
7. To explore impacts for decision-making when economic evidence is based on different methods of QALY estimation.

Trial registration

This trial is registered as ISRCTN77044517.

Publication

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The research reported in this issue of the journal was commissioned by the HTA programme as project number 01/17/05. The contractual start date was in February 2003. The draft report began editorial review in May 2008 and was accepted for publication in August 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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