



Title	A Randomized Controlled Trial of Cognitive Behavior Therapy and Motivational Interviewing for People with Type 1 Diabetes Mellitus With Persistent Sub-Optimal Glycaemic Control: A Diabetes and Psychological Therapies (Adapt) Study
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Aim

To determine whether 1) motivational enhancement therapy (MET)+cognitive behavior therapy (CBT) compared with usual care, 2) MET compared with usual care, 3) or MET+CBT compared with MET was more effective in improving glycemic control when delivered by general nurses with additional training in these techniques.

Conclusions and results

A combination of MET and CBT may be useful for patients with persistent suboptimal diabetic control. MET alone appears less effective than usual care. Economic evaluation was inconclusive. In people with type 1 diabetes, 1659 were screened and 344 were randomized 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 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). The higher the HbA_{1c}, and the younger the participant at baseline, the greater the reduction in HbA_{1c}. The interventions had no effect on secondary outcomes. The economic evaluation was inconclusive. Both interventions were associated with increased healthcare costs than for usual care alone. Social costs showed no significant difference. Cost effectiveness ratios, up to 1 year, varied widely according to whether QALY estimates were based on EQ-5D or SF-36 and whether imputed or complete data were used.

Recommendations

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 suboptimally controlled diabetes, but MET appeared less effective than usual diabetes practices and

MET+CBT. 3) Compared to usual care, at a minimum of 48 636 pounds sterling (GBP) per QALY gain, neither intervention fell within a notional policy-making threshold of cost effectiveness. MET+CBT achieved additional HbA_{1c} improvements at a lower cost (GBP 1756 per additional point improvement) than MET. MET+CBT had a higher probability of cost effectiveness than MET based on HbA_{1c} outcomes, but MET dominated on the basis of QALYs estimated from both EQ-5D and SF-36. Probabilities of cost effectiveness are higher based on HbA_{1c} outcomes than on QALY outcomes. Hence, decisions to provide such interventions depend on the relative importance of these two outcomes.

Methods

See Executive Summary link www.hta.ac.uk/project/1312.asp.

Further research/reviews required

1) To identify quantitatively and qualitatively the components of the complex intervention that was associated with improvement in glycemic control to inform future generations of RCTs. 2) To examine whether the effects are sustained >12 months. 3) To compare variations of therapy, eg, whether additional sessions, electronic formats, or treating depression are associated with additional effectiveness or cost effectiveness. 4) To conduct a discrete choice experiment to understand how people with diabetes appraise the value of psychological treatments to help improve diabetes control, taking account personal costs.