

iCAHE JC Critical Appraisal Summary

Journal Club Details

Date of submission	2012
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JC Facilitator	Robyn Armstrong
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Article/Paper

Ismail K, Maissi E, Thomas S, Chalder T, Schmidt U, Bartlett J, Patel A, Dickens C, Creed F & Treasure J (2010) 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, *Health Technology Assessment*, 14(22):1-128.

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Article Methodology:	Randomised Controlled Trial
Returned JC on:	2012
By CAHE staff member:	Khushnum Pastakia



Ques No.	Yes	Can't Tell	No	Comments
1	✓			<p>Did the study ask a clearly-focused question?</p> <p>Yes. The main aims of this study were:</p> <ol style="list-style-type: none"> 1. To test the effectiveness and cost–utility of motivational enhancement therapy (MET) and cognitive behavioural therapy (CBT) compared with MET and compared with usual care in helping patients with type 1 diabetes improve their glycaemic control and quality- adjusted life-years (QALYs). 2. To identify cognitive, behavioural and biological predictors of glycaemic control. 3. To assess the effectiveness of MET + CBT compared with MET and with usual care in other secondary outcomes (depression, quality of life, diabetes cognitions and diabetes self care activities).
2	✓ ✓			<p>Was this a randomised controlled trial (RCT) and was it appropriately so?</p> <p>This study aimed to assess the effectiveness of different interventions and a RCT is a good study design to use to determine this. As this study assessed 3 different variations of interventions (MET + CBT, MET & usual care), they used a three arm parallel RCT as the gold standard design in order to test the effectiveness of psychological treatments.</p> <p>Is it worth continuing? YES</p>



3	✓		<p>Were participants appropriately allocated to intervention and control groups?</p> <p>The following information: clinic name and patient initials, hospital number, date of birth and sex, was given to the Clinical trials unit at the Institute of Psychiatry, King’s College, London.</p> <p>A randomisation list stratified according to centre using minimisation and blocks of random sizes (three, six, nine and twelve) was prepared in advance to ensure a roughly equal number of patients allocated in each of the three arms of the trial while avoiding possible predictability associated with blocks of fixed sizes.</p> <p>If the participant was randomised to either the MET or MET + CBT intervention, they was assigned to a nurse therapist depending on her availability.</p> <p>Allocation concealment was ensured as the Clinical Trials Unit held the randomisation list in a password-locked computer and a password-locked ACCESS program.</p> <p>Researchers contacted the participant by telephone to inform them of the group they were allocated to and a standard letter was sent to each participant with the dates of their 3-, 6-, 9- and 12-month follow-ups for the glycosylated haemoglobin (HbA_{1c}) blood tests.</p>
4		✓	<p>Were participants, staff and study personnel ‘blind’ to participants’ study group?</p> <p>The nature of the interventions such as talking therapy means that the participants and therapists can’t be blinded to the intervention. In addition all the psychological assessments were self report questionnaires, hence blinding of the participant was not possible.</p> <p>However all baseline measures collected were conducted by nurses and technicians who were blind to the participants group allocation.</p>



5	✓		<p>Were all of the participants who entered the trial accounted for at its conclusion?</p> <p>Participants dropped out of the study at the 3, 6, 9 and 12 month mark. The researchers report that participants who were unemployed were more likely to not complete their 12-month blood test than those in full- or part-time employment.</p> <p>Intention to treat analysis was used when conducting the statistical analysis in order to account for the participants that dropped out.</p>
6	✓		<p>Were the participants in all groups followed up and data collected in the same way?</p> <p>All participants had baseline and follow assessments done by a nurse or technician. The primary outcome measure of HbA_{1c} was analysed by technicians that were blind to the allocation. The self report psychological measures were assessed at baseline and 12 months follow up.</p> <p>Other assessment tools used were 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.</p>
7	✓		<p>Did the study have enough participants to minimise the play of chance?</p> <p>The researchers conducted a power analyses to ensure adequate number of participants were recruited. They calculated that at a power of 90%, a type 1 error rate of 0.05 (two-tailed), a randomisation ratio of 1:1:1 and a 20% drop-out rate, an estimated sample size of 339 participants ($n = 113$ in each group) was required.</p> <p>A total of 344 patients were recruited to the study, hence minimising any chance of play.</p>



8			<p>How are the results presented and what is the main result?</p> <p>The results are presented in terms of confidence intervals (CI), means, Standard deviations and p values. They are illustrated with tables and graphs.</p> <p>The main results are:</p> <ul style="list-style-type: none"> • The mean 12-month HbA_{1c} was 0.45% lower in those treated with MET + CBT than for usual care. • It was 0.16% lower in those treated with MET than for usual care • And it was 0.30% lower with MET + CBT than with MET • 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. • 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.
9			<p>How precise are these results?</p> <p>The results are presented in terms of CI's. The narrower the interval the more precise the result. In this study most of the intervals presented are fairly wide, which would imply that they aren't as precise as they could have been.</p> <p>Such as: The CI for the 12-month HbA_{1c} in those treated with MET + CBT than for usual care was = 95% (CI) 0.16% to 0.79%. Had this interval been 0.60-0.79% that would have implied a more precise result.</p>



10	✓		<p>Were all important outcomes considered so the results can be applied?</p> <p>Implications for practice that arise out of this study are:</p> <ul style="list-style-type: none"> • Diabetes professionals can be trained to deliver diabetes-specific MET and CBT competently in the context of concurrent supervision. • 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. • Adding these interventions to usual practice would result in an additional expense, however MET+CBT achieved additional HbA_{1c} improvements at a lower cost than MET.
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