The effects of cognitive therapy versus 'treatment as usual' in patients with major depressive disorder

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CRD summary
The authors concluded that cognitive therapy might not be an effective treatment for patients with major depressive disorder compared with treatment as usual. The authors’ conclusions reflect the evidence presented and are likely to be reliable, although the high risk of bias in the included studies should be borne in mind

Authors’ objectives
To examine the effects of cognitive therapy versus treatment as usual in patients with major depressive disorder.

Searching
PubMed, EMBASE, PsycLIT, PsycINFO, Cochrane Central Register of Controlled Trials (CENTRAL) and Science Citation Index Expanded were searched to February 2010 with no limitations on language and publication status.

Study selection
Randomised controlled trials (RCTs) that compared the effects of cognitive therapy to those from treatment as usual for major depressive disorder were eligible for inclusion. Treatment as usual could include standard care or clinical management and had to include some kind of non-specific supportive treatment. Cognitive therapy and treatment as usual could be conducted as monotherapy or in combination with any cointervention administered equally in both intervention groups. Eligible studies had to include participants aged 17 years or older with a primary diagnosis of major depressive disorder based on standardised criteria such as International Classification of Diseases, Diagnostic and Statistical Manual of Mental Disorders (DSM) III, DSM III-R and DSM IV. Studies that evaluated depressed participants with comorbid serious somatic illness, depression in elderly participants and depression related to pregnancy, drug or alcohol were excluded. Primary outcomes of interest were change in depressive symptoms, adverse events and quality of life. Secondary outcomes of interest were participants without remission or with suicidal inclination.

Interventions included group and individual cognitive therapy. The number of sessions varied between studies from eight weekly group sessions to 20 weekly individual sessions. The content of the treatment-as-usual control group varied between studies. Some studies included cointerventions of pharmacological therapy. Most of the included studies reported outcomes using the Hamilton Rating Scale for Depression (HDRS) observer dependent interview. Other studies reported outcomes using the Beck Depression Inventory (BDI) self report questionnaire. Some studies used both.

Three reviewers independently selected studies for inclusion. Disagreements were resolved through discussion.

Assessment of study quality
Quality was assessed using Cochrane criteria to assess generation of allocation sequence, allocation concealment, blinding, intention-to-treat analysis, drop-outs, reporting of outcome measures, economic bias and academic bias. Studies were classified as high risk of bias if one or more criteria were graded as uncertain or high risk of bias.

Two reviewers independently assessed quality. Disagreements were resolved through discussion or with reference to a third reviewer.

Data extraction
Data were extracted to enable reporting of odds ratios (ORs) for dichotomous outcomes and mean difference (MD) for continuous outcomes, together with 95% confidence intervals (CIs). Study authors were contacted for additional information where necessary. Studies that lacked data on means and standard deviations were excluded from the meta analysis.
Data were extracted independently by two reviewers; disagreements were resolved through discussion or with reference to a third reviewer.

**Methods of synthesis**
Data were pooled using both fixed-effect and random-effects models. A test for interaction was undertaken for all subgroup analyses. Trial sequential analyses were undertaken for primary outcome measures. Heterogeneity was assessed using the $I^2$ statistic. Subgroup analyses were conducted on type of therapy and therapists' level of education and experience.

**Results of the review**
Eight RCTs (719 participants, range 25 to 179) were included in the review. The authors reported that all RCTs had a high risk of bias: allocation sequence generation was reported in three RCTs, allocation concealment in three RCTs, intention-to-treat analysis in three RCTs and blinding in three RCTs; none of the studies reported on all the measures. One study was considered to be free of selective outcome measure reporting.

**Depressive symptoms at cessation of treatment (five RCTs):** Trials that used the Hamilton Rating Scale for Depression reported a significant reduction for depressive symptoms for cognitive therapy compared with treatment as usual at the end of therapy ($MD\ -2.15,\ 95\%\ CI\ -3.70\ to\ -0.60$; four RCTs, one RCT contributed two data sets, fixed-effects model). There was no evidence of statistical heterogeneity ($I^2=0\%$) and overall results did not differ when the random-effects model was used. However overall results using Beck Depression Inventory found no significant difference between cognitive therapy and care as usual at the end of therapy ($MD\ -4.85,\ 95\%\ CI\ -12.08\ to\ 2.39$; four RCTs, random-effects model). There was significant evidence of statistical heterogeneity for this analysis ($I^2=89\%$). Sensitivity analysis that removed one trial removed statistical heterogeneity ($I^2=0\%$), but the result was still not significant with random-effects and with fixed-effect models ($MD\ -1.57,\ 95\%\ CI\ -4.30\ to\ 1.16$; three trials). Trial sequential analysis reported that insufficient data had been obtained to decide whether cognitive therapy was superior to treatment as usual.

**Follow-up (two RCTs):** One study reported an increased probability of remission at 12 months compared to community care. One RCT found no significant differences between groups.

**Adverse events (one RCT):** Two participants dropped out of the control group.

**Quality of life (one RCT):** There was no significant difference between groups at cessation of treatment.

**Participants without remission (two RCTs):** There were no significant differences between groups for risk of no remission.

Results of subgroup analyses were reported.

**Authors' conclusions**
Cognitive therapy might not be an effective treatment for major depressive disorder compared with treatment as usual.

**CRD commentary**
The review question was clear. Inclusion criteria were defined. Several relevant sources were searched without restrictions on language and publication status. Study quality was assessed and results were reported for individual studies. Appropriate methods to reduce reviewer error and bias were used throughout the review process. The methods of analysis appeared appropriate. Relevant study details were reported.

The authors' conclusions reflect the evidence presented and are likely to be reliable, although the high risk of bias in the included studies should be borne in mind.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that further robust RCTs (with a low risk of bias and larger sample sizes) with broader more clinically relevant outcomes were required. Future trials should report adverse events, suicide inclination/Attempts and number and the content of treatment as usual.
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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.