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REVIEW ARTICLE

Effects of cognitive therapy *versus* interpersonal psychotherapy in patients with major depressive disorder: a systematic review of randomized clinical trials with meta-analyses and trial sequential analyses

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Background. Major depressive disorder afflicts an estimated 17% of individuals during their lifetime at tremendous suffering and cost. Cognitive therapy and interpersonal psychotherapy are treatment options, but their effects have only been limitedly compared in systematic reviews.

Method. Using Cochrane systematic review methodology we compared the benefits and harm of cognitive therapy *versus* interpersonal psychotherapy for major depressive disorder. Trials were identified by searching the Cochrane Library's CENTRAL, Medline via PubMed, EMBASE, Psychlit, PsycInfo, and Science Citation Index Expanded until February 2010. Continuous outcome measures were assessed by mean difference and dichotomous outcomes by odds ratio. We conducted trial sequential analysis to control for random errors.

Results. We included seven trials randomizing 741 participants. All trials had high risk of bias. Meta-analysis of the four trials reporting data at cessation of treatment on the Hamilton Rating Scale for Depression showed no significant difference between the two interventions [mean difference −1.02, 95% confidence interval (CI) −2.35 to 0.32]. Meta-analysis of the five trials reporting data at cessation of treatment on the Beck Depression Inventory showed comparable results (mean difference −1.29, 95% CI −2.73 to 0.14). Trial sequential analysis indicated that more data are needed to definitively settle the question of a differential effect. None of the included trial reported on adverse events.

Conclusions. Randomized trials with low risk of bias and low risk of random errors are needed, although the effects of cognitive therapy and interpersonal psychotherapy do not seem to differ significantly regarding depressive symptoms. Future trials should report on adverse events.

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Key words: Cochrane, cognitive therapy, depression, interpersonal psychotherapy, meta-analysis.

Introduction

According to the World Health Organization, major depressive disorder is the second largest healthcare problem worldwide in terms of illness-induced disability (Levav & Rutz, 2002). Major depressive disorder afflicts an estimated 17% of individuals during their lifetime, at tremendous cost to the individual and society (Greenberg *et al*. 1993; Kessler *et al*. 1994). Roughly a third of all depressive disorders take a chronic course (Spijker *et al*. 2002; Arnow & Constantino, 2003). Compared with other medical disorders, depressive illness causes the most significant deterioration in individual quality of life (Bech, 1999). Approximately 15% of depressive patients will commit suicide over a 10- to 20-year period (Fawcett, 1993).

Antidepressant medication remains the mainstay in the treatment of depression (Cipriani *et al*. 2009). However, meta-analyses have shown that the new antidepressants only obtain beneficial effect in severely depressed patients, and that this effect seems to be clinically small (Kirsch *et al*. 2008; Turner *et al*.

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2008). Continuous use of antidepressants is, however, known to decrease the risk of relapse (Geddes *et al*. 2003). The therapeutic benefits of antidepressants seem to be limited and this raises the question of whether there are other effective treatments for this serious illness.

Cognitive therapy (or cognitive-behavioural therapy) and interpersonal psychotherapy are alternative interventions for major depressive disorder, but we did not identify any systematic reviews or meta-analyses using The Cochrane Collaboration methodology examining the effect of cognitive therapy *versus* interpersonal psychotherapy.

Method

We embarked on a systematic review using The Cochrane Collaboration methodology (Higgins & Green, 2008) involving meta-analyses (Higgins & Green, 2008) and trial sequential analyses (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009) to assess the effects of cognitive therapy *versus* interpersonal psychotherapy in the treatment of major depressive disorder (Higgins & Green, 2008). We used assessment of bias risk to reduce the risk of systematic errors (bias) (Higgins & Green, 2008), and trial sequential analysis to reduce the risk of random errors (play of chance) (Brok *et al*. 2008; Wetterslev *et al*. 2008).

For details regarding the methodology, please consult our protocol published on our website (http://www.ctu.dk) in February 2010 before we began the systematic literature searches in all relevant databases, data extraction and analyses (Jakobsen *et al*. 2010).

In short, we included all randomized clinical trials comparing the effect of cognitive therapy *versus* interpersonal psychotherapy – irrespective of language, publication status, publication year and publication type. We searched in The Cochrane Library's CENTRAL, MEDLINE via PubMed, EMBASE, Psychlit, PsycInfo, and Science Citation Index Expanded. The time-frame for the search was all trials published before August 2010.

To be included, participants had to be aged older than 17 years with a primary diagnosis of major depressive disorder. Trials were only included if the diagnosis of depression was based on one of the standardized criteria, such as International Statistical Classification of Diseases, tenth revision (ICD-10; WHO, 1992), Diagnostic and Statistical Manual of Mental Disorders, 3rd edition (DSM-III; APA, 1980), 3rd edition revised (DSM-III-R; APA, 1987), or 4th edition (DSM-IV; APA, 1994). Co-morbidity with other psychiatric diagnoses was not an exclusion criterion.

The following types of trials were excluded: (*a*) trials focusing on depressed participants with co-morbid serious somatic illness, e.g. myocardial infarction, multiple sclerosis, cerebral stroke, cancer, etc.; (*b*) trials focusing on 'late life' depression or depression in the elderly, most often participants over 65 years; (*c*) trials focusing on pregnancy-related depression, e.g. postpartum depression, postnatal depression, etc.; and (d) trials focusing on depression related to drug or alcohol abuse.

These exclusions were conducted because we expect participants in such trials to respond differently to standardized psychotherapy than other depressed patients, and these types of depressed patients are traditionally examined in separate trials (Howard *et al*. 2006; Wilkins *et al*. 2009; Davidson *et al*. 2010; Sofuoglu *et al*. 2010).

Interventions

Cognitive therapy

Cognitive therapy (or cognitive behavioural therapy) is a collective term for a range of different interventions, and it is difficult to find a simple definition that adequately describes this psychotherapeutic method. However, we considered the following criteria from Beck *et al*. (1979) as being necessary for the intervention to be classified as 'cognitive therapy' (Beck *et al*. 1979): (1) that the intervention sought to link thoughts, feelings, and behaviour – and related these to the depressive symptoms; (2) that the intervention sought to record and correct irrational thoughts or behavioural patterns, and related these to the depressive symptoms; (3) that the intervention sought to teach the patient alternative methods of thinking or behaving, and related these to the depressive symptoms; (4) that the intervention was undertaken face-to-face either individually or in a group.

Interpersonal psychotherapy

Interpersonal psychotherapy is a structured form of psychotherapy that addresses interpersonal issues in depression (Cornes & Frank, 1994; Weissman *et al*. 2000; Levenson *et al*. 2002; Cutler *et al*. 2004). We selected the following criteria in order for the intervention to be classified as 'interpersonal psychotherapy': (1) that the intervention sought to intervene on interpersonal disputes, role transitions, grief, and interpersonal deficits (Cornes & Frank, 1994; Weissman *et al*. 2000; Levenson *et al*. 2002; Cutler *et al*. 2004); and (2) that the intervention was undertaken face-to-face either individually or in a group.

Psychodynamic-interpersonal therapy is a modified form of interpersonal psychotherapy (Wiser &

Goldfried, 1998), but due to its similar characteristics to interpersonal psychotherapy (Cornes & Frank, 1994; Wiser & Goldfried, 1998; Weissman *et al*. 2000; Levenson *et al*. 2002; Cutler *et al*. 2004), we chose also to include trials assessing the effects of psychodynamic-interpersonal therapy.

Regarding the interventions in general

We chose to include trials irrespective of the duration of therapy and trials assessing the effects of individual and group therapy. This was done as there is no evidence showing that short-term therapy *versus* long-term therapy or individual therapy *versus* group therapy leads to different effects. Furthermore, these inclusion criteria made it possible for us to conduct subgroup analyses examining if these factors influence the effects of the included interventions.

The trials had to present a treatment manual and had to document adherence to the treatment manual in order for the interventions to be classified as 'adequately defined'. All other trials that classified their interventions as 'cognitive' or 'cognitive-behavioural' *versus* 'interpersonal' or 'psychodynamic-interpersonal' were included, but these interventions were classified as 'not adequately defined'.

Trials comparing cognitive therapy *versus* interpersonal psychotherapy as add-on therapy to any co-intervention were included only if these co-interventions were described and administered similarly in the compared intervention groups.

Three of the review authors (J.C.J., S.S. and J.L.H.) independently selected relevant trials. If a trial was not identified by all three, it was discussed whether the trial should be included. Excluded trials were entered on a list, stating the reason for exclusion.

Trial selection and data extraction

Trials were selected and data were extracted independently by two authors (J.C.J. and J.L.H.). Disagreements were resolved by discussion (J.C.J. and J.L.H.) or through arbitration (C.G.). Data were extracted for trial design, bias risk and outcomes. We used the instructions in The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008) in our evaluation of the methodology and hence bias risk of the trials. We assessed the bias risk in respect to generation of the allocation sequence; allocation concealment; blinding; intention-to-treat analysis; drop-outs; reporting of outcome measures; economic bias; and academic bias. These components enable classification of the included trials into trials with 'low risk of bias' or with 'high risk of bias'. The trials were overall classified as 'high risk of bias' if one or more of the above components was categorized as 'unclear' or 'inadequate' (Kjaergaard *et al*. 2001; Gluud, 2006*a*,*b*; Higgins & Green, 2008; Wood *et al*. 2008). This classification is important because trials with 'high risk of bias' may overestimate benefits and underestimate harm (Kjaergaard *et al*. 2001; Gluud, 2006*b*; Higgins & Green, 2008; Wood *et al*. 2008).

Primary outcome measures

Depressive symptoms

Our primary outcome was the mean value of the Hamilton Rating Scale for Depression (HAMD; Hamilton, 1960) and the Beck Depression Inventory (BDI; Beck *et al*. 1961). We included data based on the total number of randomized patients (intention-to-treat analysis) (Anonymous, 1999; Higgins & Green, 2008) if these data were reported. We planned to estimate the therapeutic follow-up responses at two time points: (1) at cessation of treatment (the trial's original primary choice of completion date was used – this was the most important outcome measure time point in this review); and (2) at maximum follow-up.

Adverse events

We classified adverse events as serious or non-serious. Serious adverse events were defined as medical events that are life threatening; result in death, disability, or significant loss of function; that cause hospital admission or prolonged hospitalization; a hereditary anomaly; or fetal injury (International Conference on Harmonisation E9 Expert Working Group, 1997). All other adverse events (that is, events that have not necessarily had a causal relationship with the treatment, but that resulted in a change in or cessation of the treatment) were considered as non-serious events.

Quality of life

We included any measure of quality of life, noting each assessment measure.

Secondary outcome measures

Participants without remission

We calculated the proportion of participants not having achieved remission based on the total number of randomized participants (intention-to-treat analysis) (Anonymous, 1999; Higgins & Green, 2008) – if at all possible. If the results were not based on the total number of participants, we preformed an intention-to-treat analysis assuming that the participants not included in the results did not achieve remission

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(Anonymous, 1999; Higgins & Green, 2008). We pragmatically defined remission as a score on the HAMD of less than 8 or a BDI score less than 10, in that prioritized order (Hamilton, 1960; Beck *et al*. 1961).

Participants with suicidal inclination

Reports of suicide inclination, suicide attempts, or suicides were noted.

Statistical methods

This meta-analysis was undertaken according to the recommendations of The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). In analysing continuous outcomes with both fixed-effect and with random-effects models, we used the mean difference (MD) with a 95% confidence interval (CI). We did not use 'standardized MD', so each outcome measure was analysed separately. We did not adjust the outcome variables at follow-up according to the baseline values (Higgins & Green, 2008). We used the odds ratio (OR) with a 95% CI to estimate intervention effects on dichotomous outcomes with both fixed-effect and with random-effects models. We performed a 'test of interaction' (Altman & Bland, 2003) for all subgroup analyses. For statistical calculations we used RevMan version 5.0 (The Cochrane Collaboration, Denmark).

For the primary outcome measures, we also conducted trial sequential analyses (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009). In order to calculate the required information size and the cumulative Z curve's eventual breach of relevant trial sequential monitoring boundaries (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009), the trial sequential analysis was based on a type I error of 5%, a β of 20% (power of 80%), the variance of all the trials (as none of the trials had 'low risk of bias'), and a minimal relevant difference of 2 points on the HAMD or 4 points on the BDI.

Results

Search results

Our primary literature search identified 954 publications. Of these, 587 publications were excluded on the basis of the title or abstract, and a further 343 citable units were excluded on the basis of the full publication. These exclusions were done either because the publications did not relate to cognitive therapy, interpersonal psychotherapy, and major depressive disorder – or because they were not randomized trials comparing cognitive therapy *versus* interpersonal psychotherapy.

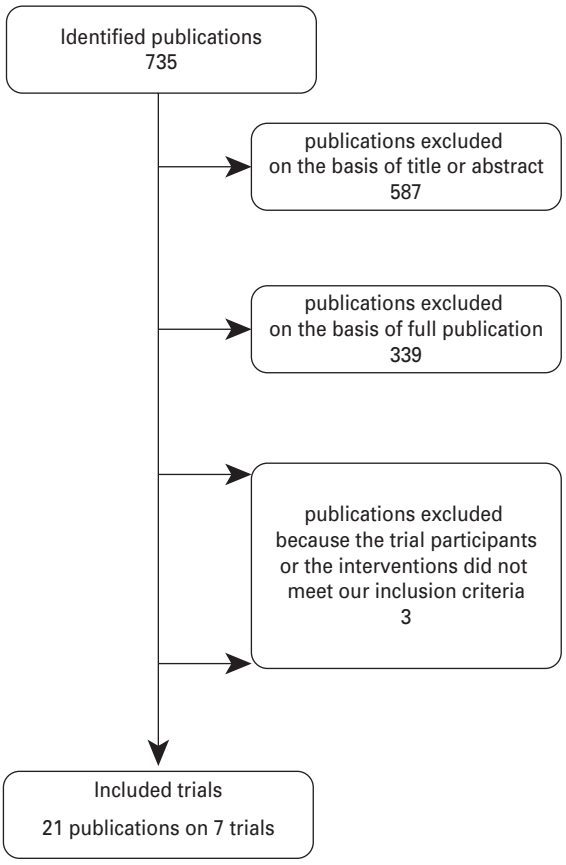

Fig. 1. Preferred reporting items for systematic reviews and meta-analyses (PRISMA) flowchart.

We excluded three publications (Hogg & Deffenbacher, 1988; Gallagher & Steffen, 1994; Kellet *et al*. 2007) because the trial participants or the interventions did not meet our inclusion criteria.

Included trials

We included 21 publications (Elkin *et al*. 1985, 1989; Covi & Lipman, 1987; Imber *et al*. 1990; Neimeyer & Feixas, 1990; Neimeyer & Weiss, 1990; Shapiro *et al*. 1990, 1994, 1995; Shea *et al*. 1990, 1992; Sotsky *et al*. 1991; Hardy *et al*. 1995; Barber & Muenz, 1996; Stewart *et al*. 1998; McBride *et al*. 2006; Bellino *et al*. 2007; Joyce *et al*. 2007; Luty *et al*. 2007; Marshall *et al*. 2008; Quilty *et al*. 2008) on seven randomized trials (Covi & Lipman, 1987; Elkin *et al*. 1989; Neimeyer & Weiss, 1990; Hardy *et al*. 1995; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008) randomizing a total of 741 participants [see Fig. 1 for a preferred reporting items for systematic reviews and meta-analyses (PRISMA) flowchart].

Of the trials, five compared the effect of cognitive therapy *versus* interpersonal therapy (Elkin *et al*. 1989; Neimeyer & Weiss, 1990; Bellino *et al*. 2007; Luty *et al*.

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2007; Quilty *et al*. 2008). Two trials compared cognitive therapy *versus* psychodynamic-interpersonal psychotherapy (Covi & Lipman, 1987; Hardy *et al*. 1995).

There were two trials that used group therapy in both intervention groups (Neimeyer & Weiss, 1990; Bellino *et al*. 2007). One trial used a combination of both individual and group therapy (Covi & Lipman, 1987). The remaining four trials used only individual therapy (Elkin *et al*. 1989; Hardy *et al*. 1995; Luty *et al*. 2007; Quilty *et al*. 2008).

The length of the intervention period varied from eight weekly sessions (Hardy *et al*. 1995) up to 24 weekly sessions (Bellino *et al*. 2007).

Both the cognitive and the interpersonal interventions were assessed as 'adequately defined' in three trials (Elkin *et al*. 1989; Hardy *et al*. 1995; Luty *et al*. 2007), and as 'not adequately defined' in the remaining four (Covi & Lipman, 1987; Neimeyer & Weiss, 1990; Bellino *et al*. 2007; Quilty *et al*. 2008). We classified the therapists' level of experience and/or education in one trial as 'low' (Luty *et al*. 2007), in three trials as 'intermediate' (Covi & Lipman, 1987; Hardy *et al*. 1995; Bellino *et al*. 2007), in one trial as 'high' (Elkin *et al*. 1989), and in two trials as 'unclear' (Neimeyer & Weiss, 1990; Quilty *et al*. 2008).

Bellino *et al*. (2007) used psychotherapy as add-on therapy to antidepressants (fluoxetine). The antidepressant medicine was delivered similarly in both intervention groups. All the participants in this trial had co-morbidity with borderline personality disorder. None of the other included trials used antidepressants as a part of the intervention.

Table 1 summarizes the characteristics of the seven included trials.

Bias risk

We assessed all seven trials (Covi & Lipman, 1987; Elkin *et al*. 1989; Neimeyer & Weiss, 1990; Hardy *et al*. 1995; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008) as having 'high risk of bias' due to unclear or inadequate components as described in Table 2.

Effects of cognitive therapy versus *interpersonal psychotherapy: primary outcome measures*

Depressive symptoms

Of the trials, four reported means and standard deviations on the HAMD at cessation of treatment (Elkin *et al*. 1989; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008). Five trials reported means and standard deviations on the BDI at cessation of treatment (Elkin *et al*. 1989; Hardy *et al*. 1995; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008).

Meta-analysis with the fixed-effect model on the HAMD data from the four trials (Elkin *et al*. 1989; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008) showed that the effect of cognitive therapy did not differ significantly compared with the effect of interpersonal psychotherapy (MD in favour of cognitive therapy −1.02 HAMD, 95% CI −2.35 to 0.32, $p=0.14$, $I^2=0$) (Fig. 2). Meta-analysis with the random-effects model gave an identical result.

Meta-analysis with the fixed-effect model on the BDI data from the five trials (Elkin *et al*. 1989; Hardy *et al*. 1995; Bellino *et al*. 2007; Luty *et al*. 2007; Quilty *et al*. 2008) also showed that the effect of cognitive therapy did not differ significantly compared with the effect of interpersonal psychotherapy (MD in favour of cognitive therapy −1.29 BDI, 95% CI −2.73 to 0.14, $p=0.08$, $I^2=0$) (Fig. 3). Meta-analysis with the random-effects model gave an identical result.

Trial sequential analysis

Trial sequential analysis on the HAMD data showed that insufficient data have been obtained to decide if cognitive therapy and interpersonal psychotherapy have different effects on this outcome (Fig. 4). Trial sequential analysis on the BDI data showed that the futility boundary was crossed. This indicates that there is no significant difference in effect between the two interventions and that no more trials may be needed regarding this outcome (Fig. 5*a*). However, we also performed trial sequential analysis on the BDI data with more strict presumptions (a power of 90% instead of 80%). This analysis showed that insufficient data have been obtained to decide if cognitive therapy and interpersonal psychotherapy have different effects on the BDI (Fig. 5*b*).

Follow-up

Only one of the trials included assessment data after the cessation of treatment (Hardy *et al*. 1995). Hardy *et al*. (1995) assessed the participants with the BDI 1 year after the beginning of treatment (36 weeks after cessation of treatment). There was no significant difference on the BDI between the two intervention groups (MD −0.13, 95% CI −2.94 to 3.21, $p=0.93$). None of the remaining trials included data after the cessation of treatment.

Adverse events

None of the included trials reported on adverse events.

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Table 1. *Characteristics of the included trials*

Trial	Inclusion criteria	Participants	Interventions	Outcomes and notes
Elkin *et al*. (1989)	Diagnosis of major depressive disorder (research diagnostic criteria) present for at least 2 weeks, and >13 on the HAMD	125 out-patients Characteristics at baseline (both groups): mean age 35 years; 63% women; HAMD 19.6	Cognitive therapy (individual, 16 weeks) *versus* interpersonal psychotherapy (individual, 16 weeks)	HAMD (17-item), BDI-I, remission (HAMD <7, BDI <10)
Hardy *et al*. (1995)	Diagnosis of major depressive disorder (DSM-III) and >15 on the BDI	114 out-patients Characteristics at baseline (both groups): mean age 40.25 years; 53% women; BDI 20.47/20.08	Cognitive therapy (individual, eight or 16 sessions) *versus* psychodynamic-interpersonal psychotherapy (individual, eight or 16 sessions)	BDI-I
Bellino *et al*. (2007)	Diagnoses of major depressive disorder and borderline personality disorder (DSM-IV-TR)	32 out-patients Characteristics at baseline (both groups): mean age 30.55 years; HAMD 19.7	Cognitive therapy (group, 24 weeks) plus 20–40 mg fluoxetine *versus* interpersonal psychotherapy (group, 24 weeks) plus 20–40 mg fluoxetine	HAMD (17-item), BDI-II, remission[a]. SAT-P participants have co-morbid borderline personality disorder
Luty *et al*. (2007)	Diagnosis of major depressive disorder (DSM-IV-TR), >17 years, and a medication-free period for a minimum of 2 weeks or five drug half-lives of any centrally acting drugs (except for the occasional hypnotic agent and the oral contraceptive pill)	177 out-patients Characteristics at baseline (both groups): Mean age 35.2 years; 69%/76% women; HAMD 16.7/16.0	Cognitive therapy (individual, 8–16 weeks) *versus* interpersonal psychotherapy (individual, 8–16 weeks)	HAMD (17-item), BDI-II, remission (HAMD <7, BDI <10)
Quilty *et al*. (2008)	Diagnosis of major depressive disorder (DSM-IV-TR), aged 18–60 years, free of antidepressant medication, had minimum 8 years education, were fluent in English, no electroconvulsive therapy in the past 6 months, and no concurrent medical illness	91 out-patients Characteristics at baseline (both groups): mean age 42.07/42.70 years; 65% women; HAMD 17.78/18.57	Cognitive therapy (individual, 16–20 weeks) *versus* interpersonal psychotherapy (individual, 16–20 weeks)	HAMD (17-item), BDI-II

HAMD, Hamilton Depression Rating Scale; BDI, Beck Depression Inventory; DSM-III, Diagnostic and Statistical Manual of Mental Disorders, 3rd edn; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, 4th edn, text revision; SAT-P, Satisfaction Profile.

[a] Bellino *et al*. (2007) used a combined measure of a decreased HAMD score of 40% or more, final HAMD score less than 9, and a score of 1 or 2 on the improvement item of the Clinical Global Impression Scale (Berk *et al*. 2008).

Table 2. *Risk of bias*

	Adequate allocation sequence generation?	Allocation concealment?	Intention-to-treat analysis?	Blinding?	Comparability of drop-outs in intervention groups?	Free of selective outcome measure reporting?	Free of economic bias?	Free of academic bias?	Overall bias assessment
Covi & Lipman (1987)	Unclear	Unclear	No	Yes	Yes	Unclear	Yes	Unclear	High risk of bias
Elkin *et al.* (1989)	Unclear	Unclear	No	Unclear	Yes	Yes	Unclear	Unclear	High risk of bias
Neimeyer & Weiss (1990)	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	High risk of bias
Hardy *et al.* (1995)	Unclear	No	No	Unclear	Yes	Unclear	Unclear	Unclear	High risk of bias
Quilty *et al.* (2008)	Yes	Unclear	No	Yes	Yes	Unclear	Yes	Unclear	High risk of bias
Bellino *et al.* (2007)	Unclear	Unclear	No	Unclear	Unclear	Unclear	Yes	Unclear	High risk of bias
Luty *et al.* (2007)	Yes	Yes	Yes	Yes	Yes	Unclear	Yes	Yes	High risk of bias

Quality of life

One trial (Bellino *et al*. 2006) assessed Satisfaction Profile (SAT-P) for quality of life (Majani *et al*. 2000). The results showed a significant change on two (psychological functioning and social functioning) of the five factors in favour of interpersonal psychotherapy. None of the remaining six trials assessed quality of life.

Effects of cognitive therapy versus *interpersonal psychotherapy: secondary outcome measures*

Participants without remission

Of the trials, four (Covi & Lipman, 1987; Elkin *et al*. 1989; Bellino *et al*. 2007; Luty *et al*. 2007) reported the proportion of participants without remission at cessation of treatment. We had planned to define remission as a HAMD score of less than 8 or a BDI score less than 10. However, these definitions were not used by all the trials, so we adopted the slightly different definitions of remission used by the four trials.

Elkin *et al*. (1989) defined remission in two different ways: HAMD less than 7 and BDI less than 10. Bellino *et al*. (2007) used a combined measure of a decreased HAMD score of 40% or more, a final HAMD score less than 9, and a score of 1 or 2 on the improvement item of the Clinical Global Impression Scale (Bellino *et al*. 2007; Berk *et al*. 2008). Covi & Lipman (1987) defined remission as a BDI score less than 10, and Luty *et al*. (2007) defined remission in two different ways: HAMD less than 7 and BDI less than 10.

Meta-analysis on the data from all four trials (Covi and Lipman, 1987; Elkin *et al*. 1989; Bellino *et al*. 2007; Luty *et al*. 2007), prioritizing the results from the HAMD (see 'Discussion'), showed no significant difference between the effect of cognitive therapy and interpersonal psychotherapy on risk of 'no remission' (OR in favour of cognitive therapy of no remission 0.74, 95% CI 0.49–1.13, $p=0.16$, $I^2=67\%$) (Fig. 6).

Meta-analysis on the BDI data from the three trials reporting on the BDI (Elkin *et al*. 1989; Bellino *et al*. 2007; Luty *et al*. 2007) showed no significant difference between the effect of cognitive therapy and interpersonal psychotherapy on risk of 'no remission' (OR in favour of cognitive therapy of 'no remission' 0.70, 95% CI 0.46–1.08, $p=0.11$, $I^2=77\%$) (Fig. 7).

Suicide inclination, suicide attempts, or suicides

Quilty *et al*. (2008) reported that two participants dropped out from the trial due to risk of suicide. Both participants were in the interpersonal psychotherapy group. None of the other trials reported on suicide inclination, suicide attempts, or suicides.

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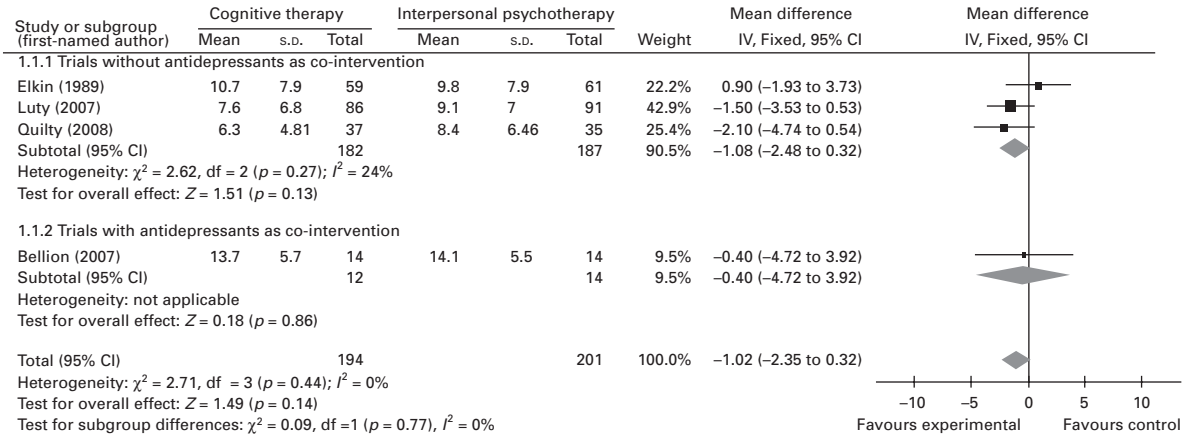

Fig. 2. Effect of cognitive therapy *versus* interpersonal psychotherapy at cessation of treatment on the Hamilton Rating Scale for Depression. S.D., Standard deviation; IV, inverse variance; CI, confidence interval; df, degrees of freedom.

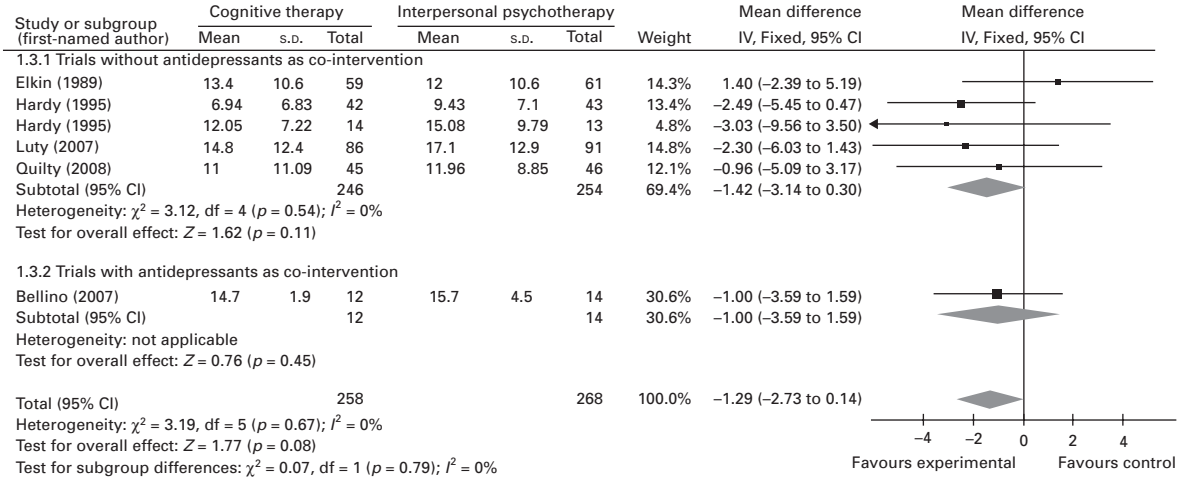

Fig. 3. The effect of cognitive therapy *versus* interpersonal psychotherapy at cessation of treatment on the Beck Depression Inventory. S.D., Standard deviation; IV, inverse variance; CI, confidence interval; df, degrees of freedom. The results from Hardy *et al*. (1995) are reported as two subgroups because the means and S.D. were reported for participants with and without co-morbid personality disorder.

Sensitivity analysis and 'test of interaction'

One trial (Bellino *et al*. 2006) differed from the rest of the trials because it was the only trial including antidepressants as co-intervention, it had a relatively long trial period (24 weeks), and all of the included depressed participants had co-morbidity with borderline personality disorder. A 'test of interaction' (Altman & Bland, 2003) showed no significant difference between this trial and the rest of the included trials (p = 0.77) (Fig. 2). We also conducted a sensitivity analysis excluding this trial from the meta-analysis on the HAMD data, and found results similar to the meta-analysis including the results from the trial by Bellino *et al*. (2006) (MD in favour of cognitive therapy −1.08, 95% CI −2.48 to 0.32, p = 0.13, I^2 = 24%).

Results from trials not included in the meta-analyses

Covi & Lipman (1987) reported that cognitive therapy significantly reduced depressive symptoms measured on the HAMD compared with interpersonal psychotherapy, but the authors did not report means and standard deviations.

Neimeyer & Weiss (1990) reported no significant difference on the mean value on the HAMD and BDI between the participants receiving cognitive therapy and interpersonal psychotherapy. However, the authors did not report means and standard deviations.

We have written to the authors from both trials requesting the necessary data but we have received no answer. Therefore we have not been able to include the results from these two trials in our analysis.

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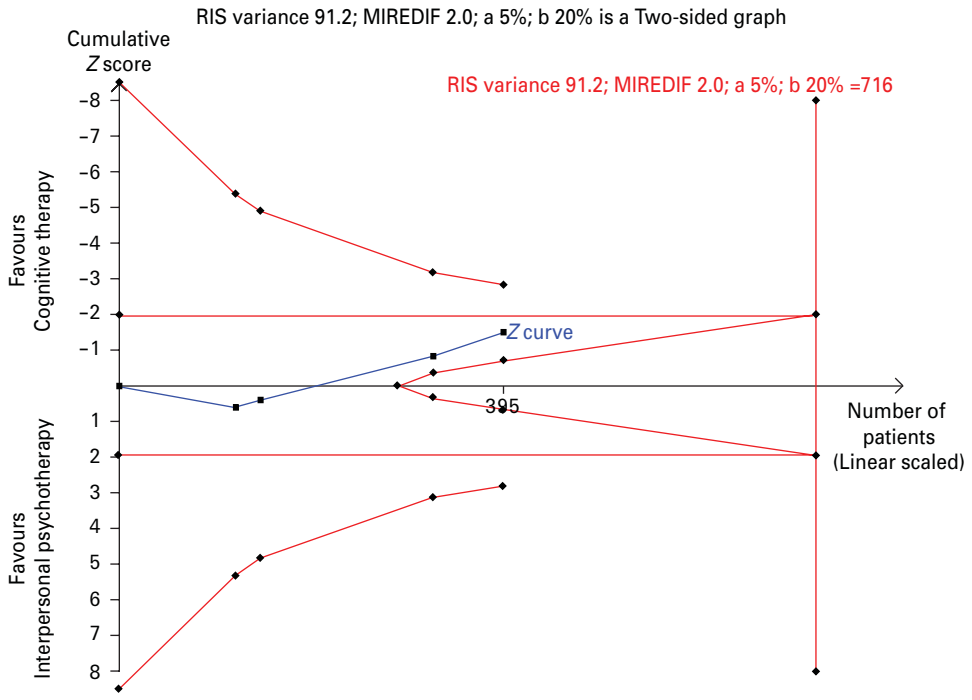

Fig. 4. Trial sequential analysis of the cumulative meta-analysis of the effect of cognitive therapy *versus* interpersonal psychotherapy for major depressive disorder. The required information size of 716 participants is calculated based on an intervention effect compared with interpersonal psychotherapy of 2 points on the Hamilton Rating Scale for Depression, a variance of 91.2, a risk of type I error of 5% and a power of 80%. With these presumptions, the cumulated *Z* curve (blue curve) does not cross the trial sequential monitoring boundaries (red inner sloping lines), implying that there is no firm evidence for a beneficial effect of cognitive therapy compared with interpersonal psychotherapy.

Subgroup analyses

In subgroup analyses stratified according to the type of therapy (group compared with individual therapy and interpersonal psychotherapy compared with psychodynamic-interpersonal) and according to the therapists' level of education and experience ('high' and 'intermediate' compared with 'low' and 'unclear'), a 'test of interaction' (Altman & Bland, 2003) on the HAMD data showed no significant differences in treatment effect between these subgroups. Furthermore, we found no heterogeneity in our meta-analysis result on the HAMD data. This indicates that these factors do not seem to influence the effect of cognitive therapy measured on the HAMD.

We had also planned a subgroup analysis according to risk of bias (Jakobsen *et al*. 2010). However, as all trials were classified as 'high risk of bias', it was not possible to conduct this analysis.

Discussion

The results of our systematic review with meta-analyses show that cognitive therapy and interpersonal psychotherapy do not seem to differ significantly regarding depressive symptoms in patients with major depressive disorder, but randomized trials with low risk of bias and low risk of random errors are needed. Future trials should include assessment of quality of life and report on adverse events.

One of our trial sequential analyses on the BDI data showed that the futility boundary was crossed. The results from the two other trial sequential analyses further underline the lack of firm evidence on the intervention effects of cognitive therapy *versus* interpersonal psychotherapy for major depressive disorder. The trial sequential analyses results also indicate that in order to detect or reject an intervention effect with a minimal relevant difference of 2 points on the HAMD, an information size of 716 participants may be needed. Trial sequential analysis is a statistical analysis that is adjusted for multiple testing on accumulating data and, therefore, is a more robust analysis than a traditional cumulative meta-analysis (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009).

The BDI is a self-report questionnaire. The HAMD is an observer-dependent interview that enables a more objective and blinded assessment of the degree of depressive symptoms. We therefore emphasize the HAMD results more than the BDI results (Wood *et al*. 2008).

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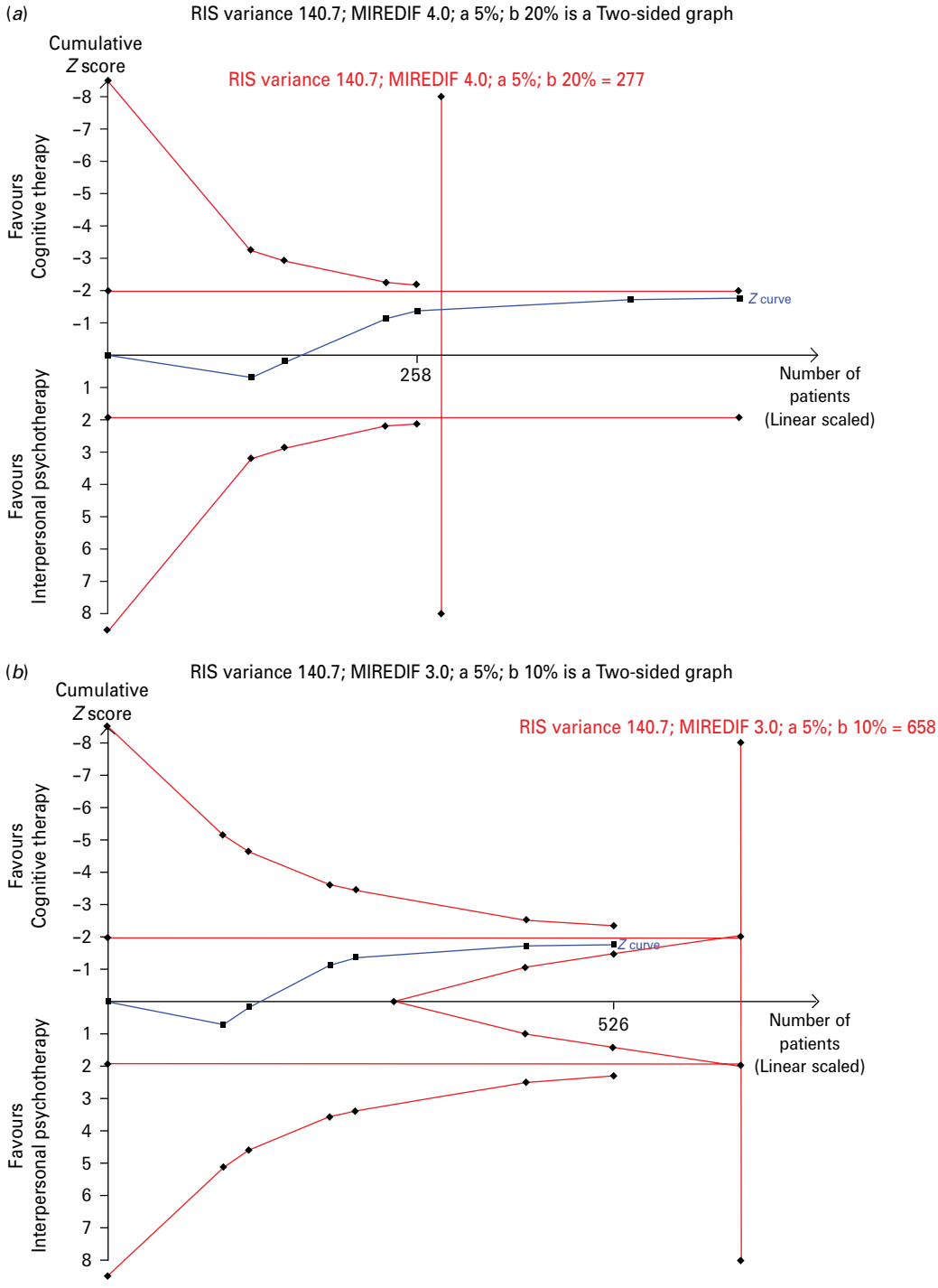

Fig. 5. Trial sequential analysis of the cumulative meta-analysis of the effect of cognitive therapy *versus* interpersonal psychotherapy for major depressive disorder. (*a*) The required information size of 277 participants is calculated based on an intervention effect compared with interpersonal psychotherapy of 4 points on the Beck Depression Inventory (BDI), a standard deviation of 10, a risk of type I error of 5% and a power of 80%. With these presumptions, the cumulated *Z* curve (blue curve) does cross the futility boundary, implying that there are no significant differences in effect between the two interventions and no more trials are needed. (*b*) The required information size of 658 participants is calculated based on an intervention effect compared with interpersonal psychotherapy of 3 points on the BDI, a variance of 140.7, a risk of type I error of 5% and a power of 90%. With these presumptions, the cumulated *Z* curve (blue curve) does not cross the trial sequential monitoring boundaries (red inner sloping lines), implying that there is no firm evidence for a beneficial effect of cognitive therapy compared with interpersonal psychotherapy.

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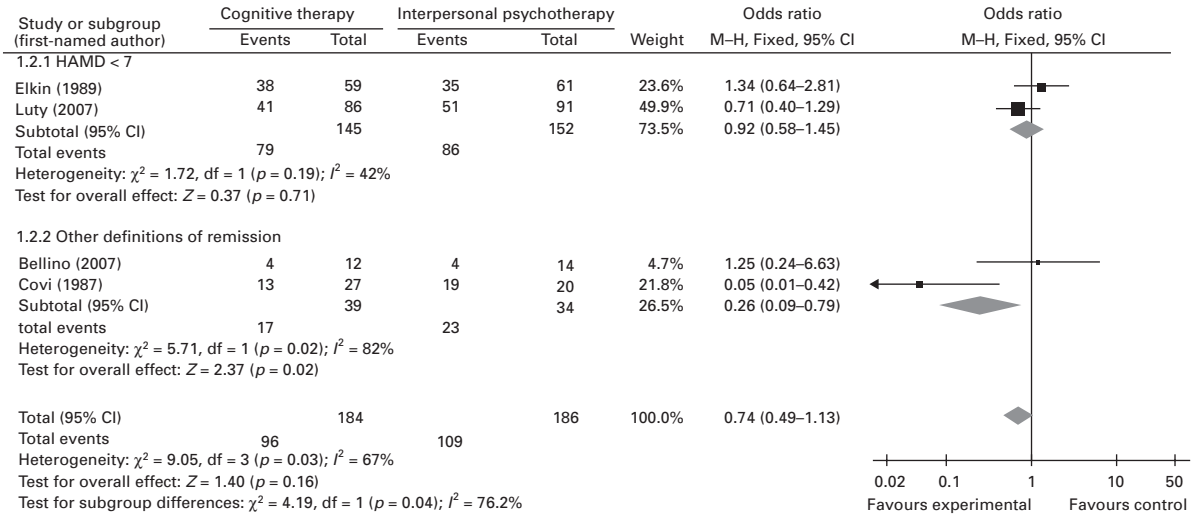

Fig. 6. Effect of cognitive therapy *versus* interpersonal psychotherapy on 'no remission' at cessation of treatment. MH, Mantel–Haenszel; CI, confidence interval; HADS, Hamilton Rating Scale for Depression.

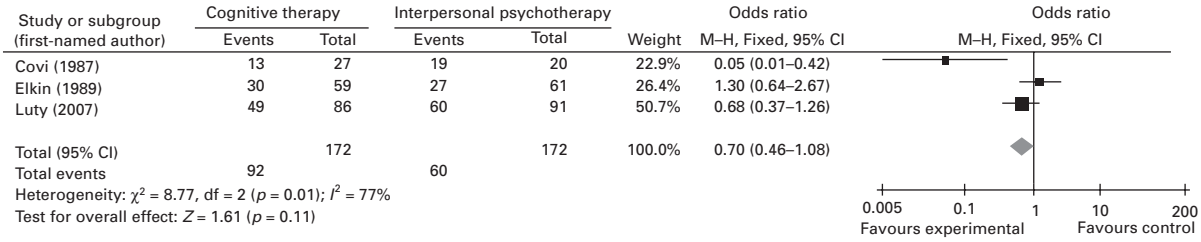

Fig. 7. Effect of cognitive therapy *versus* interpersonal psychotherapy on 'no remission' at cessation of treatment (Beck Depression Inventory). MH, Mantel–Haenszel; CI, confidence interval.

Strengths

This review has a number of strengths. Our protocol (Jakobsen *et al*. 2010) was published before we began the systematic literature search in all relevant databases, data extraction and data analyses. Data were extracted by two independent authors minimizing the risk of inaccurate data extraction, and we assessed the risk of bias in all trials according to The Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2008). We meta-analysed data both with the fixed-effect model and the random-effects models. Furthermore, we performed trial sequential analysis to control for random errors (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009).

We chose both to include interventions classified as 'interpersonal psychotherapy' and 'psychodynamic-interpersonal psychotherapy'. The extent and form of the compared interventions varied, and one of the trials used antidepressants as co-intervention in both intervention groups (Table 1). We did not, however, find any heterogeneity in our analyses on the primary outcomes. This indicates that there might be a comparable treatment effect between the different types of interventions regardless of the use of antidepressants as co-intervention and regardless of the form of interpersonal psychotherapy. This may make our results more generally applicable.

Limitations

Our systematic review has a number of limitations. Our results are based on only seven trials with a limited number of participants. Cognitive therapy, or interpersonal psychotherapy, might have a superior effect on major depressive disorder, but we need more randomized trials to show this difference in effect. Apart from one trial (Elkin *et al*. 1989), none of the included trials was assessed as being free of 'selective outcome measure reporting bias' (Higgins & Green, 2008). There is, therefore, a risk of within-study selective outcome reporting in the seven included trials. All of the included trials had an overall assessment as 'high risk of bias' – so we cannot exclude that our results may be biased. Moreover, trial sequential analysis showed that we could not exclude the risk of random errors (Brok *et al*. 2008; Wetterslev *et al*. 2008; Thorlund *et al*. 2009).

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As mentioned under 'strengths', we found no heterogeneity in the majority of our results, and this indicates that the different interventions assessed in the included trials have comparable effects. On the other hand, few trials with few participants were included and this decreases our power to detect any differences. Furthermore, in order to thoroughly examine a difference in effect between interventions, head-to-head comparisons are needed.

Only one of the included trials included assessments after the cessation of treatment. The evidence for long-term effects of cognitive therapy *versus* interpersonal psychotherapy seems to be lacking.

Only one of the trials reported measures of quality of life. Outcome measures of quality of life are generally not standardized and thoroughly validated (Higginson & Carr, 2001). The use of standardized outcome measures for quality of life in research has been limited by difficulties in administering and scoring quality of life (Higginson & Carr, 2001), but quality of life can be used as a valid outcome measure (Higginson & Carr, 2001; Gluud, 2006*a*). The effect of cognitive therapy *versus* interpersonal psychotherapy on quality of life is, therefore, unclear.

Only one of the trials reported on risk of suicide (Quilty *et al*. 2008). None of the remaining trials reported on adverse events or on suicide inclination, suicide attempts, or suicides. Typically, adverse events are not reported as thoroughly as beneficial outcome measures (Hopewell *et al*. 2008), and psychological interventions might have harmful effects. Psychological debriefing for preventing post-traumatic stress disorder is one example (Rose *et al*. 2002). Debriefing has in some clinical trials showed to have a harmful effect (Rose *et al*. 2002). Possible harmful effects of these two interventions have therefore not been adequately examined.

A number of subgroups of depressed patients (e.g. in-patients) were not included in the trials of this review. These subgroups may react differently to psychotherapy and our results cannot be generalized to other than the included patient groups. These aspects might make our results less generally applicable.

Only three of the included trials (Elkin *et al*. 1989; Hardy *et al*. 1995; Luty *et al*. 2007) used an intervention that we classified as 'adequately defined', i.e. using and documenting the use of therapeutic manuals. And although we did not find any heterogeneity on our primary outcomes indicating that this classification may not influence the effect of the psychotherapeutic interventions, it is imperative in clinical trials that the interventions are adequately defined and described (Boutron *et al*. 2008). Factors such as personal style, communication skills and personality of the therapist evidently will influence the way psychotherapy is delivered (Walwyn & Roberts, 2010). It is difficult to describe and control for these subjective factors, and this makes it even more important to relate the therapy to a treatment manual. Otherwise, it is unclear what kind of intervention the participants were receiving and it is difficult to apply any result in clinical practice.

Implications

Our results indicate that there is no major difference in effect between the two interventions, and if there is a difference it presumably only amounts to a few points on the HAMD or the BDI. From a clinical point of view it could be argued that this possible difference in effect is not clinically relevant, and that the two interventions in practice are equally effective. On the other hand, our results also show that we may need more data on the comparative effects.

The included trials used the HAMD and BDI as outcome measures. However, the HAMD and the BDI might not be useful instruments to quantify the effect of interventions for depression. Other assessment methods could demonstrate a more or less substantial effect of any given intervention for depression. Furthermore, severity of depression as measured by the total HAMD score has failed to predict suicide attempts (Chakraborty & Chatterjee, 2007), and some publications have questioned the usefulness of the HAMD and concluded that the scale is psychometrically and conceptually flawed (Bagby *et al*. 2004). The BDI probably corresponds with the HAMD (Fitzgibbon *et al*. 1988; Heo *et al*. 2007). From the patient's point of view, a score on the HAMD or BDI is not necessarily a relevant measure of the degree of suffering. The HAMD has during 40 years been the 'gold standard' to quantify depressive symptoms in clinical trials (Bagby *et al*. 2004). There is a need for trials assessing and reporting more clinically relevant outcome measures. We believe such assessment methods should include more thorough reporting of adverse events and outcome measures based on the patient's point of view. To our knowledge, the evidence on such clinically relevant assessment methods is lacking.

Future research should focus on comparing the effect of cognitive therapy *versus* interpersonal psychotherapy for major depressive disorder. First and foremost, such trials should be conducted with longer follow-up, low risk of bias (systematic errors) and low risk of random errors (play of chance) (Keus *et al*. 2010). Such trials should report on adverse events, suicide inclination, suicide attempts and numbers of suicides. There may be a need for a new 'gold standard' assessment method other than the HAMD to assess depressive symptoms.

Conclusions

Randomized trials with low risk of bias and low risk of random errors are needed, although the effects of cognitive therapy and interpersonal psychotherapy do not seem to differ significantly regarding depressive symptoms. Future trials should include assessment of quality of life and report on patient-relevant outcomes including adverse events.

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Ethical approval was not required for this review.

Declaration of Interest

None.

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