NKR 29. PICO 6: Psykoterapi ved kronisk og svært behandlelig depression

Review information

Authors

Sundhedsstyrelsen (Danish Health Agency)[1]

[1][Empty affiliation]

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Characteristics of studies

Characteristics of included studies

Agosti 1997

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy Treatment as Usual **Included criteria:** **Excluded criteria:** **Pretreatment:**
Interventions	**Intervention Characteristics** Psychotherapy ● *Beskrivelse*: Interpersonel psykoterapi Treatment as Usual ● *Beskrivelse*: Placebo Case Management
Outcomes	*Frafald/All cause discontinuation* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Hospitalsindlæggelser* ● **Outcome type**: DichotomousOutcome ● **Reporting**: Fully reported ● **Direction**: Lower is better ● **Data value**: Endpoint *Hospitalsindlæggelser* ● **Outcome type**: ContinuousOutcome ● **Reporting**: Fully reported

- **Direction**: Lower is better
- **Data value**: Endpoint

Selvmordsadfærd

- **Outcome type**: DichotomousOutcome
- **Direction**: Lower is better
- **Data value**: Endpoint

Arbejdsfastholdelse

- **Outcome type**: DichotomousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

Skadevirkninger (farmakologisk)

- **Outcome type**: AdverseEvent
- **Reporting**: Fully reported
- **Direction**: Lower is better
- **Data value**: Endpoint

Funktionsevne (aktivitet og deltagelse)

- **Outcome type**: ContinuousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

Remissionsrate (kritisk outcome)

- **Outcome type**: DichotomousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

Livskvalitet (kritisk outcome)

- **Outcome type**: ContinuousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

Ham-d (respons rate), IPT

- **Outcome type**: DichotomousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

BDI (respons rate), IPT

- **Outcome type**: DichotomousOutcome
- **Reporting**: Fully reported
- **Direction**: Higher is better
- **Data value**: Endpoint

Ham-d (respons rate), CBT

- **Outcome type**: DichotomousOutcome
- **Direction**: Higher is better
- **Data value**: Endpoint

	BDI (respons rate), CBT ● **Outcome type**: DichotomousOutcome ● **Direction**: Higher is better ● **Data value**: Endpoint
Identification	**Sponsorship source:** No information **Country:** USA **Setting:** **Comments:** No information on funding. **Authors name:** Agostia & Ocepek-Weliksona, 1997 **Institution:** **Email:** **Address:** The Department of Psychiatry,Columbia University,New York,,USA
Notes	*Birgitte Holm Petersen* on 29/09/2015 07:33 **Select** Sammenlign ml. mono psykoterapi og farmakologisk beh alene kan uddrages at arbejdet. Men, "Forty percent (26/65) met criteria for Intermittent Depression" = eksklusionsgrund. *Stine MøLler* on 13/10/2015 20:34 **Population** earlyearly-onset chronic depression as an episode ofMajor Depression beginning before age twenty-oneDepression found that duration of depression ac- and lasting longer than two years. *Stine MøLler* on 13/10/2015 20:36 **Interventions** Imipraminepatients with and without early-onset chronic depres-Clinical Management (ICM), Cognitive Behaviorsion (N5204). Predictor variables were entered inTherapy (CBT) and Interpersonal Psychotherapythe following steps: (1) Baseline depression score;(IPT), with Placebo Case Management (PCM) *Stine MøLler* on 13/10/2015 20:45 **Interventions** IPT results were slighty poorer than CBT

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Unclear risk	Not described
Allocation concealment	Unclear risk	Not described
Blinding of participants and personnel	High risk	Not possible
Blinding of outcome assessors	High risk	Not possible
Incomplete outcome data	Low risk	Not detected

Selective outcome reporting	High risk	Not detMany rating scales are described in the 1985 protocol that turn out not to be reported.
Other sources of bias	High risk	1-2 week washout phase for psychotropic drugs prior to baseline.

Keller 2000

Methods	**Study design:** Randomized controlled trial **Study grouping:** Parallel group **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy Treatment as Usual **Included criteria:** between the ages of 18 and 75 years; score of at least 20 on the 24-item Hamilton Rating Scale for Depression (HRSD) atscreening and, after a two-week drug-free period, at base line. Continuous illness of at least two years **Excluded criteria:** history of seizures, abnormal findings on electroencephalography,severe head trauma, or stroke; evidence suggestingthey were at high risk for suicide; a history of psychotic symptomsor schizophrenia; bipolar disorder, an eating disorder (if ithad not been in remission for at least one year), obsessive–compulsivedisorder, or dementia; antisocial, schizotypal, or severeborderline personality disorder; a principal diagnosis of panic, generalizedanxiety, social phobia, or post-traumatic stress disorders orany substance-related abuse or dependence disorder (except thoseinvolving nicotine) within six months before the study began; absenceof a response to a previous adequate trial of nefazodone ora cognitive behavioral-analysis system of psychotherapy; absenceof a response to three previous adequate trials of at least two differentclasses of antidepressants or electroconvulsive therapy or totwo previous adequate trials of empirical psychotherapy in thethree years preceding the study; a serious, unstable medical condition;or a positive urine screen for drugs of abuse. Women ofchildbearing potential had to agree to use adequate contraceptionduring the study. Patients were not allowed to take anxiolyticagents, sedatives, hypnotic agents, or any other types of sleep aids(pharmacologic or behavioral) during the study. **Pretreatment:**
Interventions	**Intervention Characteristics** Psychotherapy ● *Beskrivelse*: The cognitive behavioral-analysis system of psychotherapy also followed a manual specifying twice-weekly sessions during weeks 1 through 4 and weekly sessions during weeks 5 through 12. Twice-weekly sessions could be extended until week 8 if a patient wasnot adequately performing a learned social problem-solving pro-cedure according to the criteria. Treatment as Usual ● *Beskrivelse*: nefazodone monoterapi: Among the patients who received nefazodone, the initial dosewas 200 mg per day (100 mg twice a day) and was increased to300 mg per day during the second week. Thereafter, the dose wasincreased weekly in increments of 100 mg per day to a maximumof 600 mg per day, to maximize the efficacy of the drug

	withoutproducing intolerable side effects. To remain in the study, patientshad to be receiving a dose of at least 300 mg per day by week 3.Visits for medication were limited to 15 to 20 minutes.
Outcomes	*Frafald/All cause discontinuation* ● **Outcome type**: DichotomousOutcome *Hospitalsindlæggelser* ● **Outcome type**: DichotomousOutcome *Hospitalsindlæggelser* ● **Outcome type**: ContinuousOutcome *Selvmordsadfærd* ● **Outcome type**: DichotomousOutcome *Arbejdsfastholdelse* ● **Outcome type**: DichotomousOutcome *Skadevirkninger (farmakologisk)* ● **Outcome type**: AdverseEvent *Funktionsevne (kritisk outcome)* ● **Outcome type**: ContinuousOutcome *Remissionsrate (kritisk outcome)* ● **Outcome type**: DichotomousOutcome *Livskvalitet (kritisk outcome)* ● **Outcome type**: ContinuousOutcome *Ham-d (respons rate)* ● **Outcome type**: DichotomousOutcome ● **Direction**: Higher is better ● **Data value**: Endpoint ● **Notes**: A satisfactory therapeutic response was defined asa reduction in the HRSD score by at least 50 percent from baseline to week 10 and week 12, with a total score of 15 or less atthese times but of more than 8 at week 10, week 12, or both forthose who completed the study and at the time of departure forthose who did not complete the study. *BDI (respons rate)* ● **Outcome type**: DichotomousOutcome
Identification	**Sponsorship source:** Readers should know, however, that all but 1 (B.A.) ofthe 12 principal authors have had financial associations with Bris-tol-Myers Squibb — which also sponsored the study — and, inmost cases, with many other companies producing psychoactivepharmaceutical agents. **Country:** US **Setting:** outpatient **Comments:** **Authors name:** Keller et al, 2000 **Institution:** **Email:** **Address:**

Notes	*Jens Aaboe* on 08/10/2015 07:05 **Outcomes** Response rate for Ham-d: A satisfactory therapeutic response was defined as a reduction in the HRSD score by at least 50 percent from base line to week 10 and week 12, with a total score of 15 or less at these times but of more than 8 at week 10, week 12, or both for those who completed the study and at the time of departure for those who did not complete the study. *Stine MøLler* on 13/10/2015 23:08 **Population** chronic major depressive disorder (at least two years' duration),a current major depressive disorder superimposed on a preexistingdysthymic disorder, or a recurrent major depressive disorderwith incomplete remission between episodes in a patientwith a current major depressive disorder and a total duration ofcontinuous illness of at least two years

Risk of bias table

Bias	Authors' judgement	Support for judgement
Sequence Generation	Low risk	Judgement Comment: "Central computerized randomization schedule, in a 1:1:1 ratio.." "Central computerized randomization schedule, in a 1:1:1 ratio.."
Allocation concealment	Unclear risk	Judgement Comment: Not described
Blinding of participants and personnel	High risk	Judgement Comment: Blinding not possible
Blinding of outcome assessors	Low risk	Quote: "At all sites the rater was located at a separate physical location so that he or she could not see pa- tients arriving for or departing from treatment sessions."
Incomplete outcome data	High risk	Judgement Comment: About 25% dropped out in each group.
Selective outcome reporting	Low risk	Judgement Comment: Not detected
Other sources of bias	High risk	Judgement Comment: Requirement for two-week drug free period prior to randomisation bias results against psychoterapy due to risk of confusion between treatment effect and alleviation of withdrawal symptoms. Also, previous non-responders were excluded, but we are not informed whether this predominantly led to exclusions for drug- or psychotherapy treated patients.

Footnotes

References to studies

Included studies

Agosti 1997

Agosti,V.; Ocepek-Welikson,K.. The efficacy of imipramine and psychotherapy in early-onset chronic depression: a reanalysis of the National Institute of Mental health Treatment of Depression Collaborative Research Program. Journal of affective disorders 1997;43(3):181-186. [DOI: S0165-0327(97)01428-6 [pii]]

Keller 2000

Keller,M. B.; McCullough,J. P.; Klein,D. N.; Arnow,B.; Dunner,D. L.; Gelenberg,A. J.; Markowitz,J. C.; Nemeroff,C. B.; Russell,J. M.; Thase,M. E.; Trivedi,M. H.; Zajecka,J.. A comparison of nefazodone, the cognitive behavioral-analysis system of psychotherapy, and their combination for the treatment of chronic depression. The New England journal of medicine 2000;342(20):1462-1470. [DOI: 10.1056/NEJM200005183422001 [doi]]

Data and analyses

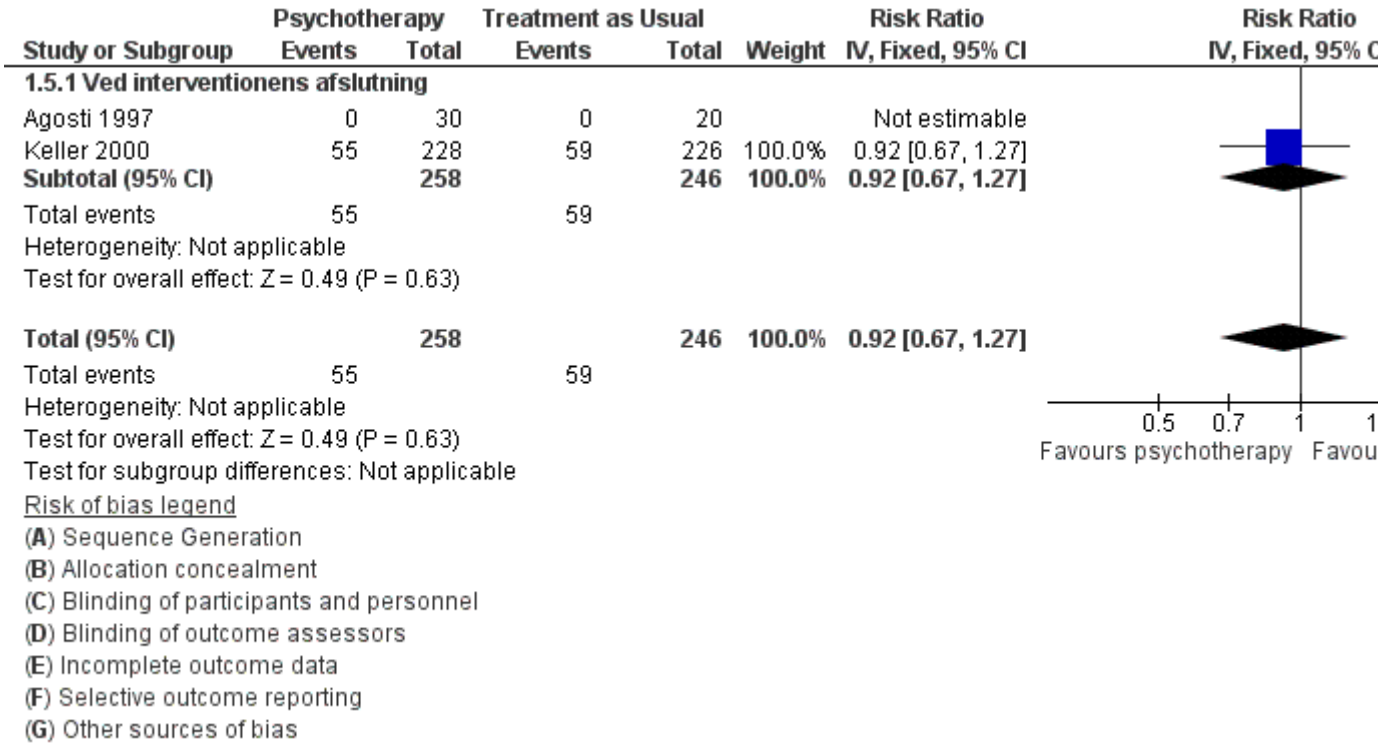
1 Psychotherapy vs Treatment as Usual

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 Hospitalsindlæggelser	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.2 Funktionsevne (aktivitet og deltagelse)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.3 Livskvalitet (kritisk outcome)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.4 Funktionsevne (kritisk outcome)	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.5 Frafald/All cause discontinuation	2	504	Risk Ratio (IV, Fixed, 95% CI)	0.92 [0.67, 1.27]
1.5.1 Ved interventionens afslutning	2	504	Risk Ratio (IV, Fixed, 95% CI)	0.92 [0.67, 1.27]
1.6 Hospitalsindlæggelser	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.7 Selvmordsadfærd	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.8 Arbejdsfastholdelse	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.9 Remissionsrate (kritisk outcome)	1	454	Risk Ratio (IV, Fixed, 95% CI)	1.12 [0.84, 1.48]
1.9.1 Efter endt behandling	1	454	Risk Ratio (IV, Fixed, 95% CI)	1.12 [0.84, 1.48]

1.10 Ham-d (respons rate), IPT	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.10.1 Efter endt behandling, IPT som interventionsgruppe	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.11 BDI (respons rate), IPT	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.11.1 Efter endt behandling, IPT som interventionsgruppe	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.12 Ham-d (respons rate), CBT	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.12.1 Efter endt behandling, CBT som interventionsgruppe	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.13 BDI (respons rate), CBT	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.13.1 Efter endt behandling, CBT som interventionsgruppe	1		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.14 Ham-d (respons rate)	2	504	Risk Ratio (IV, Random, 95% CI)	0.96 [0.79, 1.16]
1.14.1 Efter endt behandling	2	504	Risk Ratio (IV, Random, 95% CI)	0.96 [0.79, 1.16]
1.15 BDI (respons rate)	0		Risk Ratio (IV, Fixed, 95% CI)	No totals
1.16 Adverse events	1	454	Odds Ratio (M-H, Fixed, 95% CI)	0.08 [0.03, 0.28]

Figures

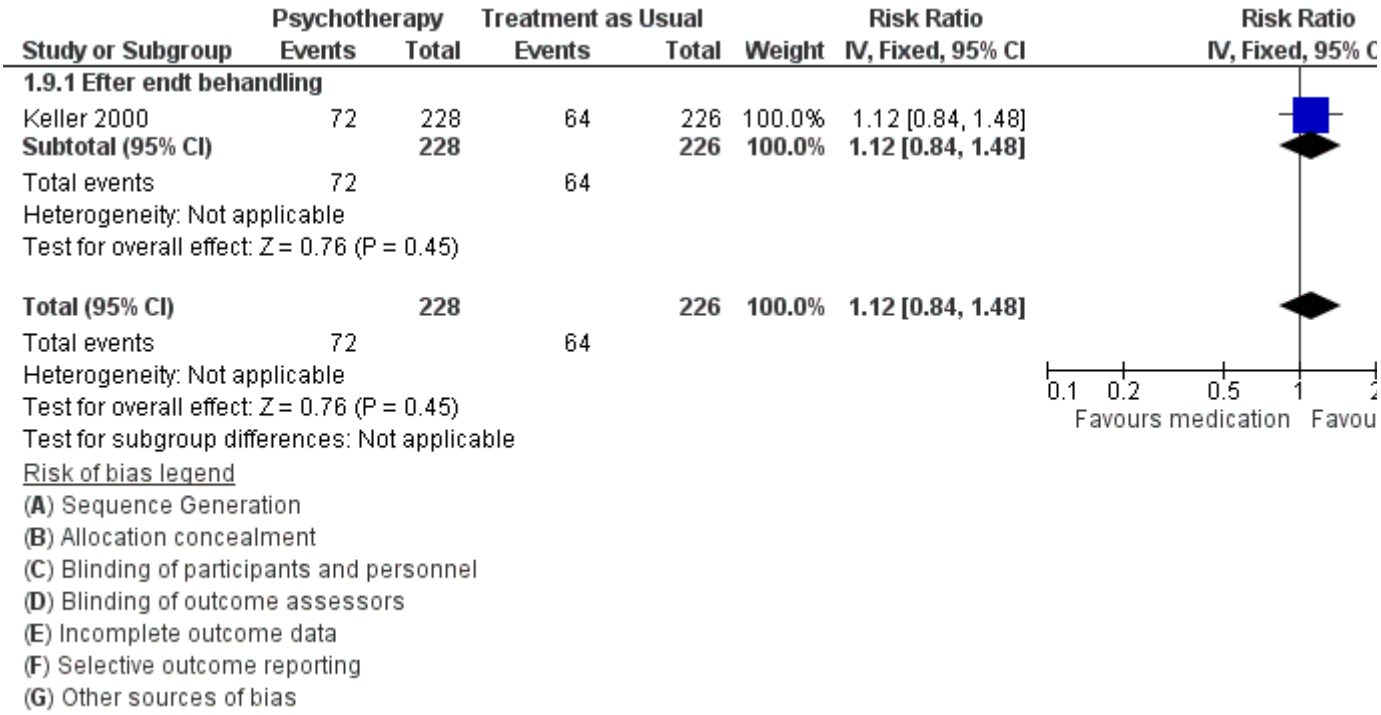
Figure 1 (Analysis 1.5)



Risk of bias legend
(A) Sequence Generation
(B) Allocation concealment
(C) Blinding of participants and personnel
(D) Blinding of outcome assessors
(E) Incomplete outcome data
(F) Selective outcome reporting
(G) Other sources of bias

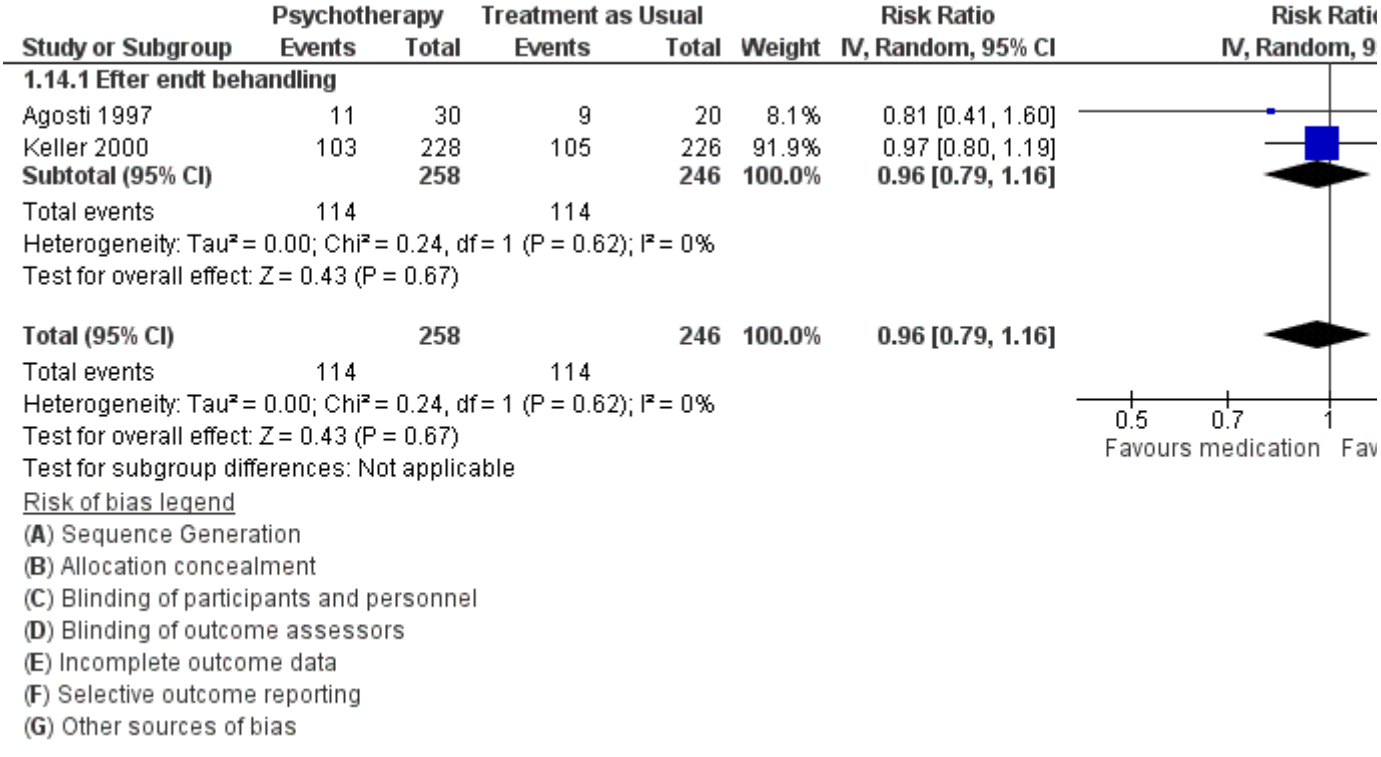
Forest plot of comparison: 1 Psychotherapy vs Treatment as Usual, outcome: 1.5 Frafald/All cause discontinuation.

Figure 2 (Analysis 1.9)



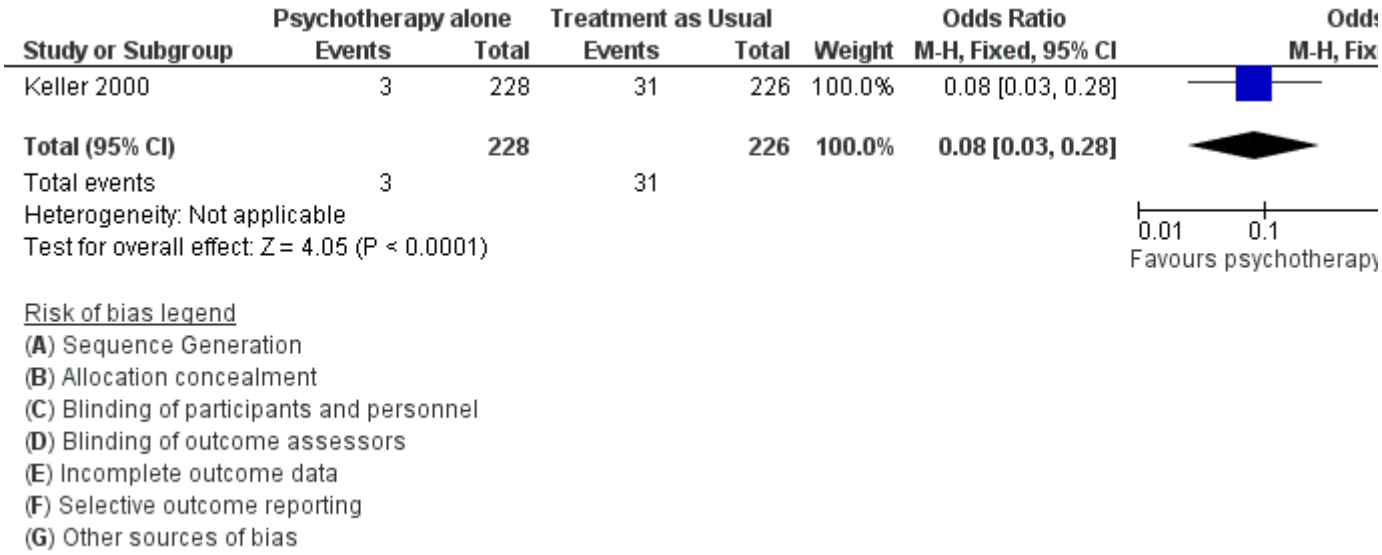
Forest plot of comparison: 1 Psychotherapy vs Treatment as Usual, outcome: 1.9 Remissionsrate (kritisk outcome).

Figure 3 (Analysis 1.14)



Forest plot of comparison: 1 Psychotherapy vs Treatment as Usual, outcome: 1.14 Ham-d (respons rate).

Figure 4 (Analysis 1.16)



Forest plot of comparison: 1 Psychotherapy vs Treatment as Usual, outcome: 1.16 Adverse events.