NKR23 - PICO6 - Bulimia Nervosa: SSRI as add on to therapy

Characteristics of studies

Characteristics of included studies

Beumont 1997

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: 25.1 (5.8) ● *BMI (SD)*: 22 (2) ● *Sex (% female)*: 100 ● *BN/BN-like (% of sample (N))*: 100 (33) Psychotherapy + medication ● *Age (SD)*: 24.2 (4.5) ● *BMI (SD)*: 22 (2) ● *Sex (% female)*: 100 ● *BN/BN-like (% of sample (N))*: 100 (34) **Included criteria:** Inclusion criteria included: (i) women of at least 18 years of age; (ii) women who fulfilled DSM-111-Rcriteria for bulimia nervosa; and (iii) women whowere within the normal, healthy weight range with abody mass index (BMI) between 20 and 25. **Excluded criteria:** Specific exclusioncriteria were: (i) the use of an appetite suppressant ormonoamine oxidase inhibitor within 2 weeks of startingthe study, or of other psychotropic medicationwithin 1 week; (ii) presence of medical illness, psychosisor suicidal ideation; (iii) a history of drugabuse, bipolar depression, mania or hypomania; (iv)pregnancy, lactation or women of child-bearing agewho were not using medically acceptable means ofcontraception; (v) previous participation in any fluoxetinestudy or the use of fluoxetine within the previous5 weeks; and (vi) electrolyte levelssignificantly outside the normal range.
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: After an initial screening interview (week 1) witheither one of the consultant psychiatrists (PB, JR) orthe consultant clinical psychologist (ST), there was aplacebo 'wash-out' period of 7-10 days. Thereafter,patients were admitted to the trial and seen at weeklyinterviews (week 0, 'baseline', then weeks 1-44), untilactive treatment ceased. Follow-up assessments weremade 4 weeks after cessation of medication (week12), and again 8 weeks later (at week 20). ● *Content*: The dietitian provided nutritionalcounselling during the 8 weeks of active treatment. Patients were asked to keep a diary of their eating,bulimic episodes, and vomiting and purging behavioursduring the initial wash-out period, for eachweek of active treatment, and for the 12-weekfollow-up period.+placebo Psychotherapy + medication ● *Frequency*: After an initial screening interview (week 1) witheither one of the consultant psychiatrists (PB, JR) orthe consultant clinical psychologist (ST), there was aplacebo 'wash-out' period of 7-10 days. Thereafter,patients were admitted to the trial and seen at weeklyinterviews (week 0, 'baseline', then weeks 1-44), untilactive treatment ceased. Follow-up assessments weremade 4 weeks after cessation of medication (week12), and again 8 weeks later (at week 20). ● *Content*: The dietitian provided nutritionalcounselling during the 8 weeks of active treatment. Patients were asked to keep a diary of their eating,bulimic episodes, and vomiting and purging behavioursduring the initial wash-out period, for eachweek of active treatment, and for the 12-weekfollow-up period.+fluoxetine 3 x 20 mg per day
Outcomes	*Continuous*: ● Somatiske komplikationer ● Overspisninger/uge ● Livskvalitet ● Remission af SF ● Psyk. SF-symptomer ● Funktionsevne ● Opkastninger/uge ● Overspisninger (EDE) ● EDE eating concern ● EDE shape concern ● EDE weight concern *Dichotomous*: ● Dropout ● Remission af SF *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** Eli Lilly Australia **Country:** Australia **Setting:** outpatient **Comments:** **Authors name:** Pierre J.V. Beumont **Institution:** Department of Psychological Medicine, University of Sydney, **Email:** no info **Address:** no info
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	Low risk	

Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Fichter 1991

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: 24.6 ● *BMI (SD)*: no info ● *Sex (% female)*: no info ● *BN/BN-like (% of sample (N))*: 100 (20) Psychotherapy + medication ● *Age (SD)*: 26.5 ● *BMI (SD)*: no info ● *Sex (% female)*: no info ● *BN/BN-like (% of sample (N))*: 100 (20) **Included criteria:** Only patients undergoing intensive inpatient behavioral psychoterapy in addition to medication or placebo. **Excluded criteria:** PRegnant patients, serious suicidal risks, serious medical risks or disorders, schizophrenia, history of seizures or alcohol/drug addiction, pretreatment with long-acting neuroleptics.
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: placebo, 60 mg/day for 35 days+intensive broad-spectrum behavioral treatment program, ● *Content*: focus on the enhancement of proprio- and interoceptive perception, social skills, improvement of adequate expression of emotions, modification of abnormal eating behavior. Psychotherapy + medication ● *Frequency*: fluoxentine, 60 mg/day for 35 days. +intensive broad-spectrum behavioral treatment program ● *Content*: focus on the enhancement of proprio- and interoceptive perception, social skills, improvement of adequate expression of emotions, modification of abnormal eating behavior.
Outcomes	*Continuous*: ● Somatiske komplikationer ● Spiseforstyrrelsesadfærd ● Livskvalitet ● Remission af SF ● Psyk. SF-symptomer ● Funktionsevne ● Overspisning/uge *Dichotomous*: ● Dropout *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** not stated **Country:** Germany **Setting:** inpatients (Klinik Roseneck) **Comments:** **Authors name:** Manfred Fichter **Institution:** Klinik Roseneck, Hospital for Behavioral Medicine, Prien **Email:** none **Address:** Psychiatrische Universitätskinik, Nussbaumstrasse 7, 8000 München 2, Germany
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Louise Klokker Madsen* 39 of the 40 participants were women (not stated which group the single man was in) **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Louise Klokker Madsen* spiseforstyrrelsesadfærd = EDI Bulimia **Dichotomous outcomes:** **Adverse outcomes:** *Tine Pedersen* no difference in adverse events for the two groups.

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	Low risk	
Blinding of outcome assessment (detection bias)	Low risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Goldbloom 1997

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: ● *BMI (SD)*: ● *Sex (% female)*: 100 ● *BN/BN-like (% of sample (N))*: 100 (24) Psychotherapy + medication ● *Age (SD)*: ● *BMI (SD)*: ● *Sex (% female)*: 100 ● *BN/BN-like (% of sample (N))*: 100 (29) **Included criteria:** ages 18-45 yr, 85-125% matched population mean weight, DSMIII-R (American Psychiatric Association, 1987) diagnosis of BN on structured interview; bingeand vomit frequency of at least twice per week as defined by the Eating Disorder Examination;minimum 6-month duration of illness; ability and willingness to provide informed consent. **Excluded criteria:** Exclusion criteria included: ongoing pharmacotherapy or psychotherapy or use of MAO inhibitotswithin 2 weeks prior to the onset of the study treatment; immediate suicide risk or psychosis;medical contraindications to drug treatment; and previous exposure to the researchtreatments.
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: ● *Content*: Psychotherapy + medication ● *Frequency*: ● *Content*:
Outcomes	*Continuous*: ● Somatiske komplikationer ● Spiseforstyrrelsesadfærd ● Livskvalitet ● Remission af SF ● Psyk. SF-symptomer ● Funktionsevne ● Overspisninger/uge ● EDE shape concern ● EDE weight concern ● Overspisninger/måned ● Opkastninger/måned *Dichotomous*: ● Dropout ● Remission af SF *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** This study was supported by an operating grant from Eli Lilly Canada Inc. **Country:** Canada **Setting:** tertiary care program **Comments:** **Authors name:** David S. Goldbloom **Institution:** Clarke Institute of Psychiatry **Email:** no information **Address:** 250 College Street, Toronto, Ontario, Canada M5T 1R8
Notes	**Identification:** **Participants:** **Study design:** *Riitta Thrane* This study does not have a placebo group **Baseline characteristics:** *Riitta Thrane* At end of trial (after 14 weeks) the total sample had a mean age of 25.8 (5.5) and a BMI of 23.0(2.5) **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** *Riitta Thrane* Note: analysis made at 1 month post treatment **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	Unclear risk	no info
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Jacobi 2002

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**

Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: no info ● *BMI (SD)*: no info ● *Sex (% female)*: 100 (19) ● *BN/BN-like (% of sample (N))*: 100 (19) Psychotherapy + medication ● *Age (SD)*: no info ● *BMI (SD)*: no info ● *Sex (% female)*: 100 (18) ● *BN/BN-like (% of sample (N))*: 100 (18) **Included criteria:** Criteria for participation in the study included the following:(1) women aged 18 to 65 years who met DSM-III-R criteria for bulimianervosa; (2) a minimum of two episodes of binge eating and vomitingfor at least 6 months prior to the beginning of the study; (3) actual bodymass index between 17.5 and 25; (4) no other concurrent severepsychiatric disturbance (psychosis, depression with suicidal risk,alcohol or drug abuse); (5) no concurrent involvement in othertreatment, including medication; (6) no concurrent medical condition that would preclude the use of antidepressants; and (7) written andinformed consent to participate. **Excluded criteria:**
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: Cognitive-behaviour therapy involved 20 sessions over 16 weeks. Thesessions were 120 min in length and were held twice a week for the firstmonth and weekly for the remaining 3 months. ● *Content*: Cognitive-behaviour therapy involved 20 sessions over 16 weeks. Thesessions were 120 min in length and were held twice a week for the firstmonth and weekly for the remaining 3 months. The cognitivebehaviouraltreatment followed a detailed manual for each of the 20sessions. The therapists were two experienced clinical psychologists,one male and one female. The main goals and the structure of the threetreatment phases were based on the manuals by Fairburn (1985) andAgras (1987), and were supplemented by our own adaptation of CBT foranorexia and bulimia nervosa (Jacobi et al., 1996). The rationale fortreatment given to the patients was that bulimia nervosa develops on thebasis of low self-esteem, social pressures to be thin, subsequent dietaryrestraint and other weight control behaviours. Consequently, both theeating behaviour (dietary restraint, binge eating and purging) as wellas self-esteem and related problems were the target behaviours forchange. Psychotherapy + medication ● *Frequency*: Fluoxetine medication was startedat 20 mg/day for 2 weeks, increased to 40 mg/day for weeks 3 and 4,and was continued at 60 mg/day from week 5 to the end of the study.Medication was withdrawn completely after week 16.+CBT ● *Content*: Cognitive-behaviour therapy involved 20 sessions over 16 weeks. Thesessions were 120 min in length and were held twice a week for the firstmonth and weekly for the remaining 3 months. The cognitivebehaviouraltreatment followed a detailed manual for each of the 20sessions. The therapists were two experienced clinical psychologists,one male and one female. The main goals and the structure of the threetreatment phases were based on the manuals by Fairburn (1985) andAgras (1987), and were supplemented by our own adaptation of CBT foranorexia and bulimia nervosa (Jacobi et al., 1996). The rationale fortreatment given to the patients was that bulimia nervosa develops on thebasis of low self-esteem, social pressures to be thin, subsequent dietaryrestraint and other weight control behaviours. Consequently, both theeating behaviour (dietary restraint, binge eating and purging) as wellas self-esteem and related problems were the target behaviours forchange.+In the medication treatment condition, patients were seen weekly by thestudy physician during the first 5 weeks and then bi-weekly until posttreatmentto discuss possible side-effects and compliance. The studyphysicians were psychiatrists with 5 to 10 years of clinical experience.Sessions lasted about 10 min. No advice regarding eating behaviour,bingeing and purging was provided. Fluoxetine medication was startedat 20 mg/day for 2 weeks, increased to 40 mg/day for weeks 3 and 4,and was continued at 60 mg/day from week 5 to the end of the study.Medication was withdrawn completely after week 16.
Outcomes	*Continuous*: ● Somatiske komplikationer ● Spiseforstyrrelsesadfærd ● Livskvalitet ● Remission af SF ● Psyk. SF-symptomer ● Funktionsevne ● Overspisninger/uge ● Opkastninger/uge ● Overspisninger/måned ● Opkastninger/måned ● EDI drive for thinness ● EDI bulimia ● EDI body dissatisfaction *Dichotomous*: ● Dropout ● Remission af SF ● Remission af SF *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** This work was supported in part by Lilly Germany GmbH. **Country:** Germany **Setting:** Participants were recruited through local newspaper advertisements and professional referrals to the Department of Psychology at the University of Hamburg. **Comments:** **Authors name:** Corinna Jacobi **Institution:** Psychogical Institute III, University of Hamburg, Germany **Email:** corinna.jacobi@uni-hamburg.de **Address:** Dr Corinna Jacobi, Psychogisches Institut III, Universita¨ t Hamburg, VonMelle Park 5, D-20146 Hamburg, Germany
Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Louise Klokker Madsen* The mean age of the participants was 26.0 years (SD¼5.8 years).The participants' average past lowest body mass index (BMI) was 17.1(SD¼1.9) and their past highest BMI was 24.1 (SD¼3.0). Current meanBMI as measured at baseline was 20.6 (SD¼2.0). **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** *Tine Pedersen* They don't state how many subjects were assigned to the treatment arms. They only state dropouts among the subjects who agreed to their assigned treatment arm. **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Mitchell 2001

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: 26.8 (6.9) ● *BMI (SD)*: no info ● *Sex (% female)*: 100 (22) ● *BN/BN-like (% of sample (N))*: 100 (22) Psychotherapy + medication ● *Age (SD)*: 29.3 (7.8) ● *BMI (SD)*: no info ● *Sex (% female)*: 100 (21) ● *BN/BN-like (% of sample (N))*: 100 (21) **Included criteria:** Inclusion criteria included the following: (1)female, (2) at least 18 years of age, (3) at least 85% ofideal body weight, (4) not currently receiving pharmacotherapyor psychotherapy, (5) satisfy DSM-III-R criteriafor BN with the additional criterion of binge eatingcoupled with self-induced vomiting three times a weekfor the last 6 months, (6) no current medical conditionthat would preclude safe outpatient treatment, (7) nohistory of hypersensitivity to fluoxetine, and (8) no priorexposure to fluoxetine in a total amount greater than140 mg (20 mg a day for 1 week) or within the preceding5 weeks before entering the study. **Excluded criteria:**
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: Subjects then were seen each week for the first 4 weeks and thenevery other week for 12 weeks by a research assistantand every other week by a study investigator. Therefore,they were maintained on medication for 16 weeks. ● *Content*: The manual incorporated a series of 14 reading andhomework assignments, assigned to be done over thecourse of an hour each evening. The manual includedmany elements used in the manual-based CBT programpreviously used in our research with BN.38 The initialpart of the manual focuses on meal planning and normalizingthe meal pattern. The manual progresses to anemphasis on behavioral strategies to avoid binge eating,cognitive restructuring, body image issues, and relapsepreventionstrategies. Psychotherapy + medication ● *Frequency*: Subjectsthen were seen each week for the first 4 weeks and thenevery other week for 12 weeks by a research assistantand every other week by a study investigator. Therefore,they were maintained on medication for 16 weeks.Active medication was 60 mg of fluoxetine administeredas a single dose in the morning. ● *Content*: The manual incorporated a series of 14 reading andhomework assignments, assigned to be done over thecourse of an hour each evening. The manual includedmany elements used in the manual-based CBT programpreviously used in our research with BN.38 The initialpart of the manual focuses on meal planning and normalizingthe meal pattern. The manual progresses to anemphasis on behavioral strategies to avoid binge eating,cognitive restructuring, body image issues, and relapsepreventionstrategies.
Outcomes	*Continuous*: ● Somatiske komplikationer ● Spiseforstyrrelsesadfærd ● Livskvalitet ● Remission af SF ● Psyk. SF-symptomer ● Funktionsevne ● EDE shape concern ● EDE weight concern ● Overspisninger/uge ● Opkastninger/uge ● EDE eating concern ● Overspisninger/måned ● Opkastninger/måned ● EDI drive for thinness ● EDI bulimia ● EDI body dissatisfaction ● Overspisn. (ændring i %) ● Opkastn. (ændring i %) *Dichotomous*: ● Dropout ● Remission af SF *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** This study was supported in part by a grant from Dista Pharmaceuticals,NIMH Grant MH R01 43296, and a center grant on Eating DisordersResearch from the McKnight Foundation. **Country:** USA **Setting:** self help **Comments:** **Authors name:** JAMES E. MITCHELL **Institution:** Neuropsychiatric Research Institute, Fargo; Department of Neuroscience, University of North Dakota School of Medicine, Fargo, North Dakota **Email:** mitchell@medicine.nodak.edu **Address:** James E. Mitchell, MD, NeuropsychiatricResearch Institute, 700 First Avenue South, P.O. Box 1415,Fargo, ND 58107
Notes	**Identification:** **Participants:** *Louise Klokker Madsen* All subjects who met admission criteria and gave writteninformed consent after the procedures and possibleside effects were explained to them were asked to selfmonitortheir eating behavior and to return 1 week later.Those who continued to meet admission criteria wereinitiated into a single-blind placebo phase of 2 weeks' duration.At the end of this 2-week period, subjects who reportedless than a 75% improvement in the number ofvomiting episodes

	relative to baseline were then randomlyassigned to receive active drug or placebo and toreceive or not to receive the self-help manual. **Study design:** **Baseline characteristics:** **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	Unclear risk	no info
Blinding of outcome assessment (detection bias)	Unclear risk	no info
Incomplete outcome data (attrition bias)	Unclear risk	no info
Selective reporting (reporting bias)	High risk	Quote: "0.15)."
Other bias	Low risk	

Walsh 2004

Methods	**Study design:** Randomized controlled trial **Study grouping:** **Open Label:** **Cluster RCT:**
Participants	**Baseline Characteristics** Psychotherapy/psychotherapy + placebo ● *Age (SD)*: no info ● *BMI (SD)*: 22.78 ● *Sex (% female)*: 100 (25) ● *BN/BN-like (% of sample (N))*: 100 (25) Psychotherapy + medication ● *Age (SD)*: no info ● *BMI (SD)*: 21.79 ● *Sex (% female)*: 100 (24) ● *BN/BN-like (% of sample (N))*: 100 (24) **Included criteria:** BN patients (modifyied DSM-IV criteria: also including individuals who described the comsumption of only moderate amounts of food during binges + including individualt with a minimum frequency of binge and compensating behavior of at least once a week for 3 months. Women, 18-60 years, BMI>17.5 **Excluded criteria:** pregnancy, substantial medical illness, psychotropic medications/medications known to influence weight or shape, previous use of fluoxentine (60 mg/day for 4 weeks or more), previous CBT, adverse reactions to fluoxentine, other psychologicel or psychiatric treatment, substantial alcohol/substance use in the past 6 months, serious psychiatric diagnoses requiring immediate treatment, suicial.
Interventions	**Intervention Characteristics** Psychotherapy/psychotherapy + placebo ● *Frequency*: Monthly physician visit for 15 minutes.Three tablets a day. Guided self-help see nurse for six to eight sessions. First four sessions were once weekly. 30 minutes in length. ● *Content*: cognitive behavior self-help book + nurse sessions + 20 mg of placebo 3 times a day Psychotherapy + medication ● *Frequency*: 60 mg fluoxetine/day. Monthly physician visit.Guided self-help see nurse for six to eight sessions. First four sessions were once weekly. 30 minutes in length. ● *Content*: cognitive behavior self-help book + nurse sessions + 20 mg of fluoxentine 3 times a day
Outcomes	*Continuous*: ● Spiseforstyrrelsesadfærd ● Remission af SF ● Somatiske komplikationer ● Psyk. SF-symptomer ● Funktionsevne ● Livskvalitet ● Overspisninger/uge ● Opkastninger/uge ● EDE shape concern ● EDE weight concern ● EDE eating concern ● Overspisninger/måned ● Opkastninger/måned ● EDI drive for thinness ● EDI bulimia ● EDI body dissatisfaction *Dichotomous*: ● Dropout ● Remission af SF *Adverse Events*: ● Kritiske med. bivirkninger ● Øvrige med. bivirkninger
Identification	**Sponsorship source:** National Institute of Diabetes and Digestive and Kidney Diseases grant DK-53635. Dr. Fairburn is supported by a Principal Research Fellowship from the Wellcome Trust (046386). Eli Lilly and Company provided medication and placebo. **Country:** USA **Setting:** Primary care **Comments:** **Authors name:** B. Timothy Walsh **Institution:** Dept. of Psychiatry, College of Physicians & Surgeons of Columbia Universtiy **Email:** btw1@columbia.edu **Address:** Dr. Walsh, M.D., Dept. of Psychiatry, College of Physicians & Surgeons of Columbia Universtiy, 1051 Riverside Dr., Unit 98, New York, NY 10032

Notes	**Identification:** **Participants:** **Study design:** **Baseline characteristics:** *Louise Klokker Madsen* mean age (across groups) 30.6 years (sd 7.8) **Intervention characteristics:** **Pretreatment:** **Continuous outcomes:** **Dichotomous outcomes:** *Tine Pedersen* Describes dropout as self-help versus pills only. **Adverse outcomes:**

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	no info
Allocation concealment (selection bias)	Unclear risk	no info
Blinding of participants and personnel (performance bias)	Low risk	
Blinding of outcome assessment (detection bias)	Unclear risk	no info
Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Footnotes

Characteristics of excluded studies

Agras 1994

Reason for exclusion	Wrong intervention

Brambilla 1995

Reason for exclusion	Wrong comparator

Fichter 1996

Reason for exclusion	Wrong intervention

Goldstein 1995

Reason for exclusion	Wrong intervention

Kotler 2003

Reason for exclusion	Wrong comparator

Leitenberg 1994

Reason for exclusion	Wrong intervention

Mitchell 2002

Reason for exclusion	Wrong intervention

Schmidt 2004

Reason for exclusion	Wrong intervention

StewartAgras 1992

Reason for exclusion	Wrong intervention

Walsh 1997

Reason for exclusion	Wrong intervention

Walsh 2000

Reason for exclusion	Wrong intervention

Wilson 1999

Reason for exclusion	Wrong study design

Footnotes

Characteristics of studies awaiting classification

Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

Beumont 1997

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Agras 1994

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Leitenberg,H.; Rosen,J. C.; Wolf,J.; Vara,L. S.; Detzer,M. J.; Srebnik,D.. Comparison of cognitive-behavior therapy and desipramine in the treatment of bulimia nervosa. Behaviour research and therapy 1994;32(1):37-45. [DOI:]

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Data and analyses

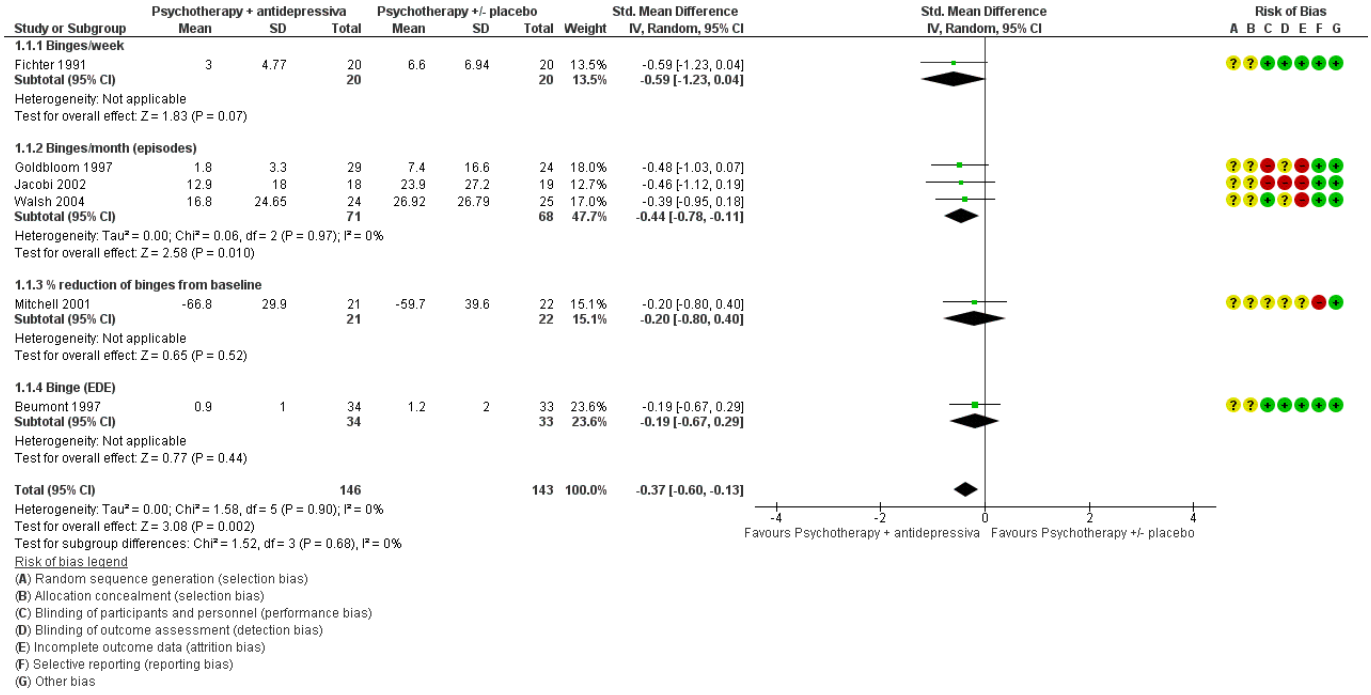
1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo

Outcome or Subgroup	Studies	Participants	Statistical Method	Effect Estimate
1.1 ED behaviour, end of treatment	6	289	Std. Mean Difference (IV, Random, 95% CI)	-0.37 [-0.60, -0.13]
1.1.1 Binges/week	1	40	Std. Mean Difference (IV, Random, 95% CI)	-0.59 [-1.23, 0.04]
1.1.2 Binges/month (episodes)	3	139	Std. Mean Difference (IV, Random, 95% CI)	-0.44 [-0.78, -0.11]
1.1.3 % reduction of binges from baseline	1	43	Std. Mean Difference (IV, Random, 95% CI)	-0.20 [-0.80, 0.40]
1.1.4 Binge (EDE)	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.19 [-0.67, 0.29]
1.2 ED behaviour, end of treatment	5	249	Std. Mean Difference (IV, Random, 95% CI)	-0.41 [-0.66, -0.15]
1.2.1 Vomiting/week	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.35 [-0.83, 0.14]
1.2.2 Vomiting/month (episodes)	3	139	Std. Mean Difference (IV, Random, 95% CI)	-0.45 [-0.79, -0.11]
1.2.3 % reduction of vomiting from baseline	1	43	Std. Mean Difference (IV, Random, 95% CI)	-0.36 [-0.96, 0.24]
1.3 Remission of ED, longest FU	3	157	Risk Ratio (IV, Random, 95% CI)	0.56 [0.36, 0.87]
1.4 Serious side effects of medication, end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.36, 4.13]

1.5 Dropout, end of trial	4	197	Risk Ratio (IV, Random, 95% CI)	1.32 [0.86, 2.05]
1.6 Psych. ED-symptoms, end of treatment	4		Std. Mean Difference (IV, Random, 95% CI)	Subtotals only
1.6.2 EDE weight concern	2	120	Std. Mean Difference (IV, Random, 95% CI)	-0.48 [-1.40, 0.45]
1.6.3 EDE shape concer	2	120	Std. Mean Difference (IV, Random, 95% CI)	-0.33 [-0.95, 0.29]
1.6.4 EDE eating concer	1	67	Std. Mean Difference (IV, Random, 95% CI)	-0.25 [-0.73, 0.23]
1.6.5 EDI drive for thinness	1	37	Std. Mean Difference (IV, Random, 95% CI)	0.16 [-0.49, 0.80]
1.6.6 EDI bulimia	2	77	Std. Mean Difference (IV, Random, 95% CI)	-0.11 [-0.56, 0.34]
1.6.7 EDI body dissatisfaction	1	37	Std. Mean Difference (IV, Random, 95% CI)	0.04 [-0.61, 0.68]
1.7 Other side effects of medication (insomnia), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	1.59 [0.89, 2.83]
1.8 Other side effects of medication (nausea), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	3.11 [1.28, 7.51]
1.9 Other side effects of medication (shakiness), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	7.76 [1.03, 58.70]
1.10 Other side effects of medication (depression), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	0.39 [0.14, 1.12]
1.11 Other side effects of medication (headache), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.35, 2.71]
1.12 Other side effects of medication (tiredness), end of trial	1	67	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.35, 2.71]
1.13 Somatic complikations, end of treatment	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.14 Quality of Life, longest FU	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable
1.15 Level of Functioning, longest FU	0	0	Mean Difference (IV, Fixed, 95% CI)	Not estimable

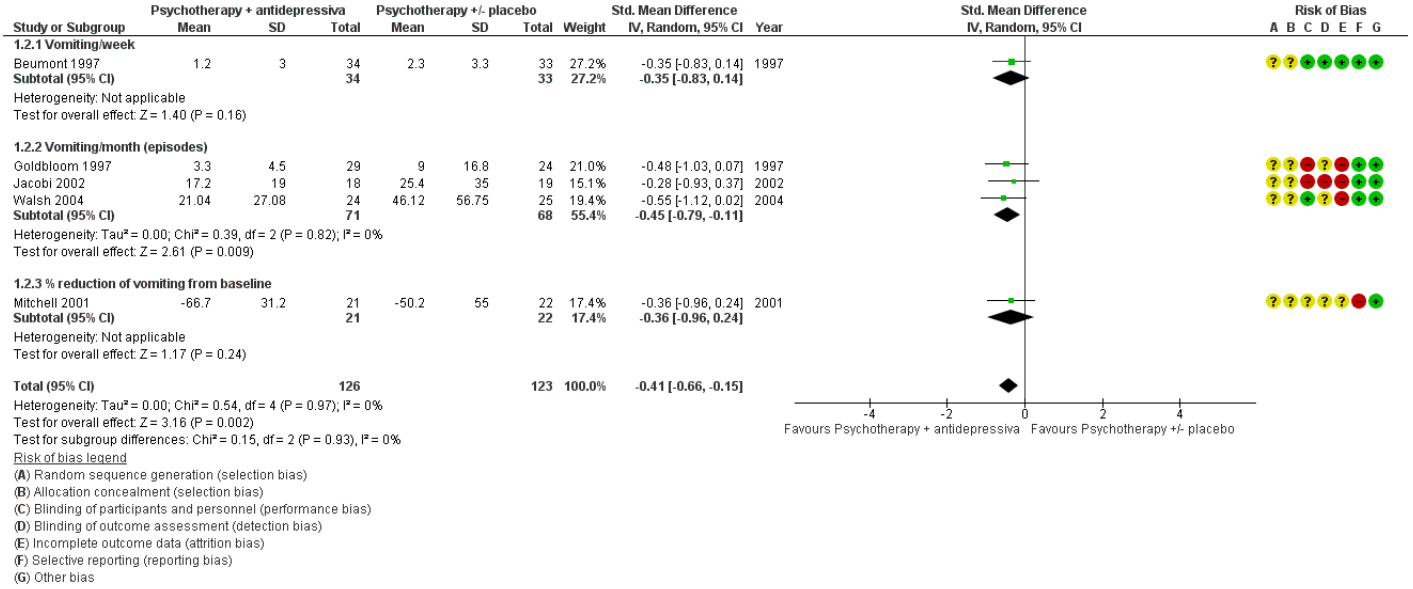
Figures

Figure 1 (Analysis 1.1)



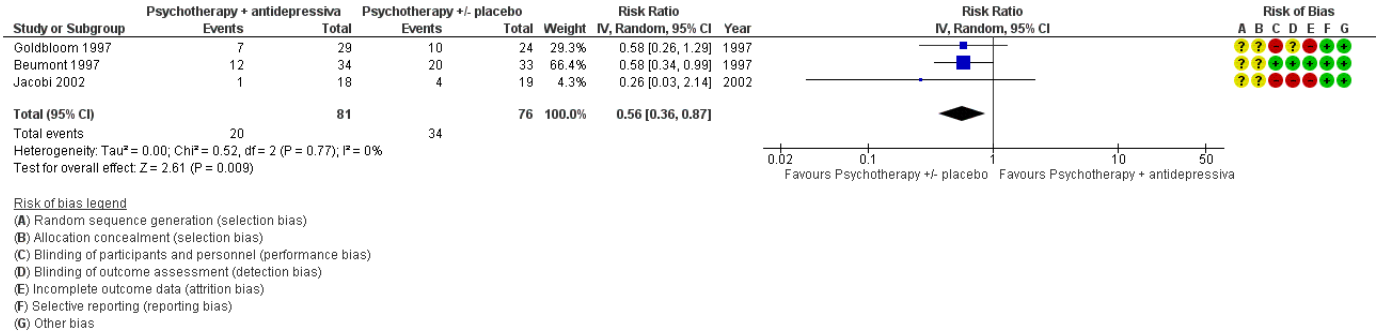
Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.1 ED behaviour, end of treatment.

Figure 2 (Analysis 1.2)



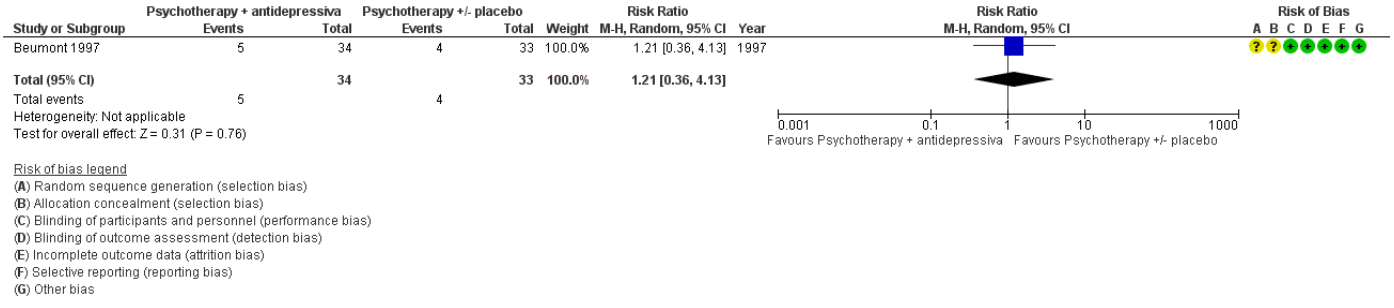
Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.2 ED behaviour, end of treatment.

Figure 3 (Analysis 1.3)



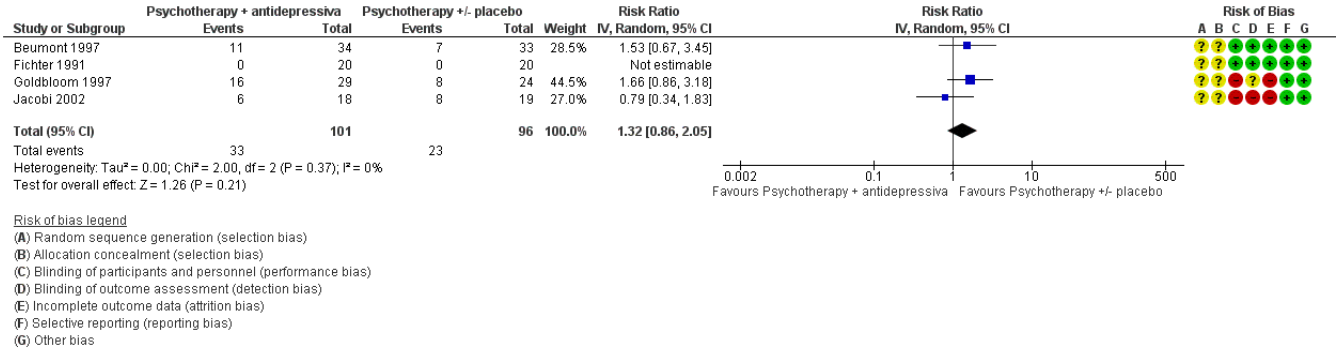
Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.3 Remission of ED, longest FU.

Figure 4 (Analysis 1.4)



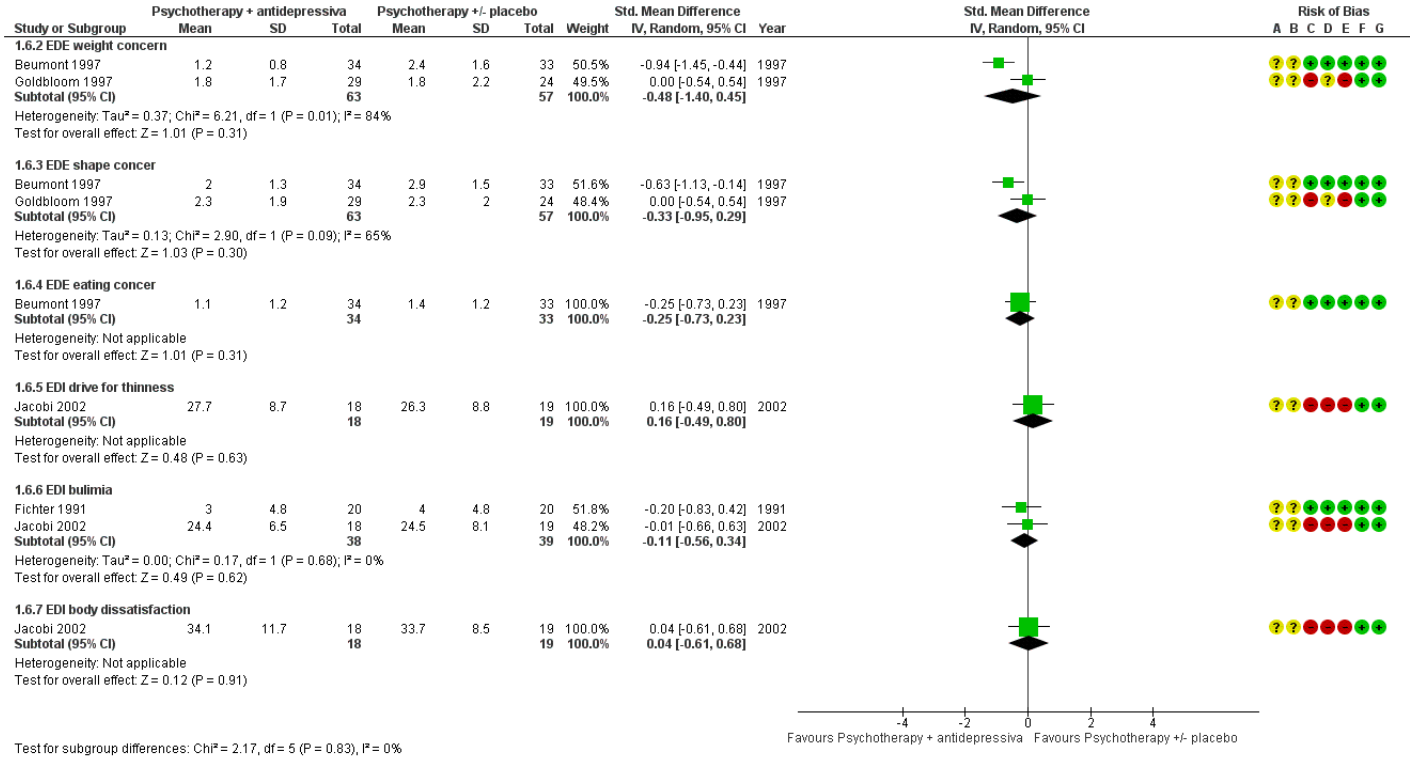
Forest plot of comparison: 1 Psychotherapy +/- placebo versus Psychotherapy + medication, outcome: 1.4 Serious side effects of medication, end of trial.

Figure 5 (Analysis 1.5)



Forest plot of comparison: 1 Psychotherapy +/- placebo versus Psychotherapy + medication, outcome: 1.5 Dropout, end of trial.

Figure 6 (Analysis 1.6)

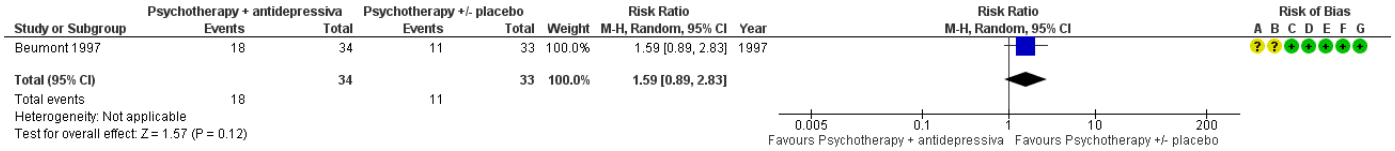


Test for subgroup differences: Chi² = 2.17, df = 5 (P = 0.83), I² = 0%

Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.6 Psych. ED-symptoms, end of treatment.

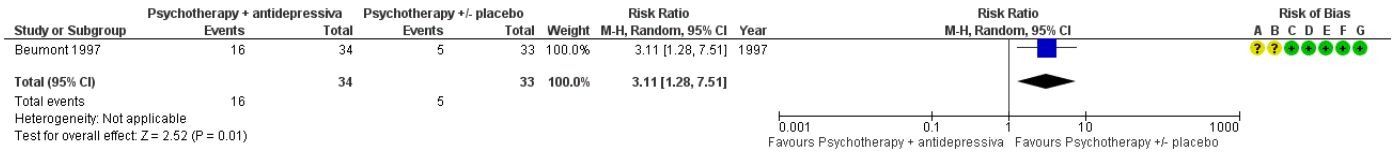
Figure 7 (Analysis 1.7)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.7 Other side effects of medication (insomnia), end of trial.

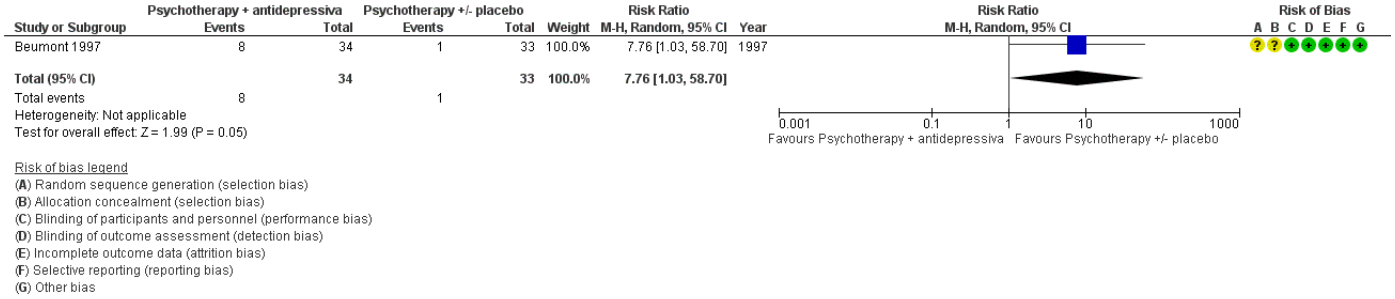
Figure 8 (Analysis 1.8)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.8 Other side effects of medication (nausea), end of trial.

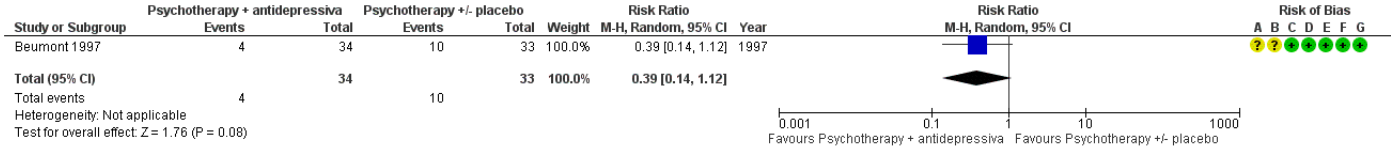
Figure 9 (Analysis 1.9)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.9 Other side effects of medication (shakiness), end of trial.

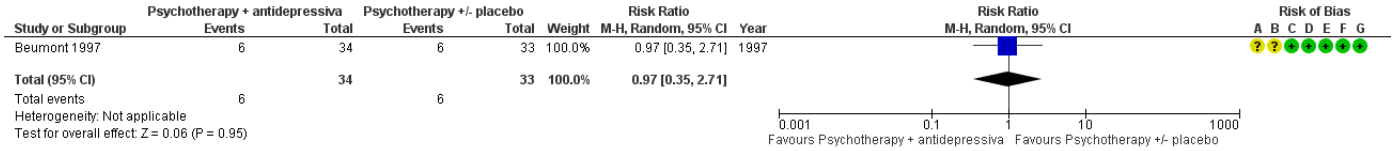
Figure 10 (Analysis 1.10)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.10 Other side effects of medication (depression), end of trial.

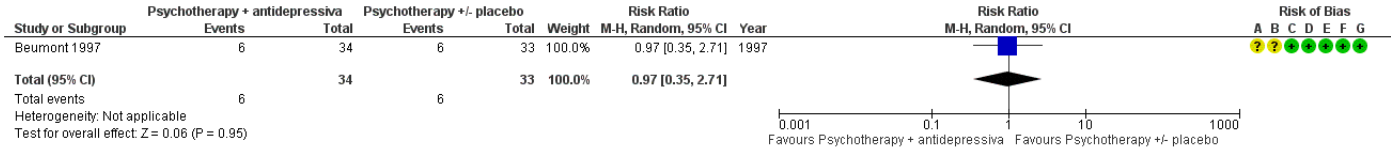
Figure 11 (Analysis 1.11)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.11 Other side effects of medication (headache), end of trial.

Figure 12 (Analysis 1.12)



Risk of bias legend
(A) Random sequence generation (selection bias)
(B) Allocation concealment (selection bias)
(C) Blinding of participants and personnel (performance bias)
(D) Blinding of outcome assessment (detection bias)
(E) Incomplete outcome data (attrition bias)
(F) Selective reporting (reporting bias)
(G) Other bias

Forest plot of comparison: 1 Psychotherapy + antidepressiva vs. Psychotherapy +/- placebo, outcome: 1.12 Other side effects of medication (tiredness), end of trial.