

NKR23 - PICO4 - Bulimia Nervosa: FBT-BN

Characteristics of studies

Characteristics of included studies

leGrange 2007

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping:</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>FBT</p> <ul style="list-style-type: none"> ● Age (SD): 16.0 (1.7) ● BN/BN-like (% of sample (N)): 100 (41) ● Sex (% female of sample (N)): 98 (40) ● BMI (SD): 21.8 (2.5) <p>Individual therapy</p> <ul style="list-style-type: none"> ● Age (SD): 16.1 (1.6) ● BN/BN-like (% of sample (N)): 100 (39) ● Sex (% female of sample (N)): 97 (38) ● BMI (SD): 22.4 (3.4) <p>Included criteria: Participants, male or female, were eligible if they were aged 12 to 19 years, which represented the potential full range for precollege adolescents still living with their families or adult caregivers, and met the operational definition of the DSM-IV criteria for BN. Participants meeting the criteria for the "purging subtype" and the "nonpurging subtype" were included. In addition, participants who did not meet the DSM-IV binge and purge frequency criteria were included, provided they binged or purged at least once per week for 6 months and met all other DSM-IV criteria for BN (ie, the combined frequency of bulimic behaviors had to equal at least 24 episodes over the past 6 months, averaging about 1 episode per week).</p> <p>Excluded criteria: Participants were excluded if 1 of the following factors was present: associated physical or psychiatric disorder necessitating hospitalization; insufficient knowledge of English that would prohibit understanding treatment; current physical dependence on drugs or alcohol; current low body weight (body mass index [calculated as weight in kilograms divided by height in meters squared] 17.5), thereby excluding patients with an existing AN binge-and-purge subtype; current treatment for the eating disorder or current use of medication known to affect eating or weight; and physical conditions (eg, diabetes mellitus or pregnancy) or treatments known to influence eating or weight. Patients taking antidepressant medications were not excluded provided they were taking a stable dose for 4 weeks. However, given the established anti-bulimic effects of fluoxetine, 13 patients taking 50 mg or more were excluded.</p>
Interventions	<p>Intervention Characteristics</p> <p>FBT</p> <ul style="list-style-type: none"> ● Frequency: 20 sessions over 6 months. treatment sessions are weekly in phase 1 (2-3 months), every second week in phase 2, and monthly in phase 3. ● Content: Family-based treatment for BN was developed as an adaptation of FBT for AN. In the first phase, treatment aims at empowering parents to disrupt binge eating, purging, restrictive dieting, and any other pathological weight control behaviors. It also aims to externalize and separate the disordered behaviors from the affected adolescent to promote parental action and decrease adolescent resistance to their assistance. Once abstinence from disordered eating and related behaviors is approached, the second phase of treatment begins, during which parents transition control over eating issues back to the adolescent. The third phase is focused on the ways the family can help to address the effects of BN on adolescent developmental processes. <p>Individual therapy</p> <ul style="list-style-type: none"> ● Frequency: 20 sessions over 6 months. weekly sessions in phase 1 (2-3 months), every second week in phase 2, and monthly in phase 3. ● Content: Supportive psychotherapy for adolescent BN was an adaptation of the version of this treatment for adults with BN formulated by Walsh et al,¹³ which, in turn, was derived from the earlier work of Fairburn et al²⁵ for adults with BN. Manualized SPT was modified for use with adolescents with BN through on-site pilot testing and designed to provide a credible comparison treatment intended to represent the type of therapy that outpatients might typically receive from psychotherapists providing short-term treatment.¹³ Supportive psychotherapy contains no putative active therapeutic ingredients, such as stimulus control or problem-solving techniques, or instruction or implicit advice on changes in diet and eating patterns. Thereby, SPT is designed not to overlap with CBT, interpersonal therapy, or analytic therapy. Supportive psychotherapy is nondirective and consists of 3 phases,
Outcomes	<p>Continuous:</p> <ul style="list-style-type: none"> ● Objective binges per month ● Vomiting per month ● All compensatory behavior ● EDE Weight concern ● EDE Shape concern ● EDE Eating concern ● EDE Restraint ● Weight + shape concerns ● Food preoccupation <p>Dichotomous:</p> <ul style="list-style-type: none"> ● Remission of ED

	<ul style="list-style-type: none"> ● Dropout
Identification	<p>Sponsorship source: Financial Disclosure: Dr le Grange receives royalties from Guilford Press. Funding/Support: This study was supported by grant K23MH001923 from the National Institute of Mental Health (Dr le Grange).</p> <p>Country: USA</p> <p>Setting: outpatient</p> <p>Comments:</p> <p>Authors name: Daniel le Grange</p> <p>Institution: Departments of Psychiatry, The University of Chicago, Chicago, Illinois</p> <p>Email: legrange@uchicago.edu</p> <p>Address: Daniel le Grange, PhD, Department of Psychiatry, The University of Chicago, 5841 S Maryland Ave, MC3077, Chicago, IL 60637</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

Risk of bias table

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	
Allocation concealment (selection bias)	Low risk	
Blinding of participants and personnel (performance bias)	High risk	
Blinding of outcome assessment (detection bias)	High risk	
Incomplete outcome data (attrition bias)	Low risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Schmidt 2007

Methods	<p>Study design: Randomized controlled trial</p> <p>Study grouping:</p> <p>Open Label:</p> <p>Cluster RCT:</p>
Participants	<p>Baseline Characteristics</p> <p>FBT</p> <ul style="list-style-type: none"> ● Age (SD): 17.9 (1.6) ● BN/BN-like (% of sample (N)): 100 (41) ● Sex (% female of sample (N)): 100 (41) ● BMI (SD): 21.1 (2.8) <p>Individual therapy</p> <ul style="list-style-type: none"> ● Age (SD): 17.4 (1.8) ● BN/BN-like (% of sample (N)): 100 (44) ● Sex (% female of sample (N)): 95.5 (42) ● BMI (SD): 21.1 (2.4) <p>Included criteria: Consecutively referred patients were invited to participate if they were 13–20 years of age, met DSM-IV criteria for bulimianervosa or eating disorder not otherwise specified, and had at least one "close other" to accompany them for "family treatment."</p> <p>Excluded criteria: We excluded patients with a body mass index below the 10th percentile for age and sex (5), patients whose knowledge of English was insufficient to understand the treatment, and patients with learning disability, severe mental illness, or substance dependence. We did not exclude patients taking antidepressants provided they had been on a stable dose for at least 4 weeks.</p>
Interventions	<p>Intervention Characteristics</p> <p>FBT</p> <ul style="list-style-type: none"> ● Frequency: Patients were offered up to 13 sessions with close others and two individual sessions over a 6-month period. ● Content: The family therapy used in this study was adapted from the Maudsley model of family therapy for anorexia nervosa (6, 7) and detailed in a manual. In this model, the family is seen as a key resource in the young person's recovery. An attempt is made to engage family members and show them that they are in the best position to help the adolescent. Treatment is problem oriented, emphasizing the role of the family in promoting restoration of normal eating and providing education about the effects of bulimia. <p>Individual therapy</p> <ul style="list-style-type: none"> ● Frequency: Patients had 10 weekly sessions, three monthly follow-up sessions, and two optional sessions with a close other. ● Content: We used a manual (8) that was previously tested with adults with bulimia nervosa (4). The Flesch-Kincaid Grade Level test suggests that the manual can be read by eighth graders (ages 13–14 years). Accompanying

	workbooks are available for patients and close others, as well as a guide for clinicians(9). The therapist's role is to motivate patients and guide them through the workbook to fit their needs.
Outcomes	<p><i>Continuous:</i></p> <ul style="list-style-type: none"> ● Objective binges per month ● Weight + shape concerns ● EDE Restraint ● EDE Eating concern ● All compensatory behavior ● EDE Shape concern ● Vomiting per month ● EDE Weight concern ● Food preoccupation <p><i>Dichotomous:</i></p> <ul style="list-style-type: none"> ● Remission of ED ● Dropout
Identification	<p>Sponsorship source: Dr. Treasure receives a consultancy fee from the Capio Hospital to provide carer workshops. All other authors report no competing interests. Supported by grant 1206/88 from the Health Foundation, U.K., to Drs. Schmidt, Eisler, Treasure, Beecham, and Rabe-Hesketh. The author thanks Dr. Rudolf Uher for helpful comments on the manuscript.</p> <p>Country: United Kingdom</p> <p>Setting: outpatient</p> <p>Comments:</p> <p>Authors name: Ulrike Schmidt</p> <p>Institution: Section of Eating Disorders, Clinical Trials Unit, Centre for the Economics of Mental Health, and the Section of Family Therapy, Institute of Psychiatry, London</p> <p>Email: u.schmidt@iop.kcl.ac.uk</p> <p>Address: Dr. Schmidt, Section of Eating Disorders (PO59), Institute of Psychiatry, De Crespigny Park, Denmark Hill, London SE5 8AF, UK</p>
Notes	<p>Identification:</p> <p>Participants:</p> <p>Study design:</p> <p>Baseline characteristics:</p> <p>Intervention characteristics:</p> <p>Pretreatment:</p> <p>Continuous outcomes:</p> <p>Dichotomous outcomes:</p> <p>Adverse outcomes:</p>

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Incomplete outcome data (attrition bias)	High risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Low risk	

Footnotes

Characteristics of excluded studies

Footnotes

Characteristics of studies awaiting classification

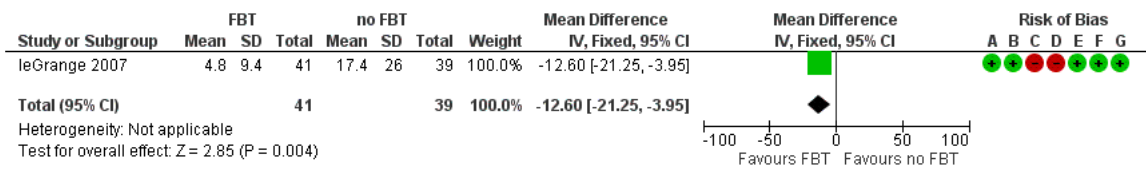
Footnotes

Characteristics of ongoing studies

Footnotes

References to studies

Included studies

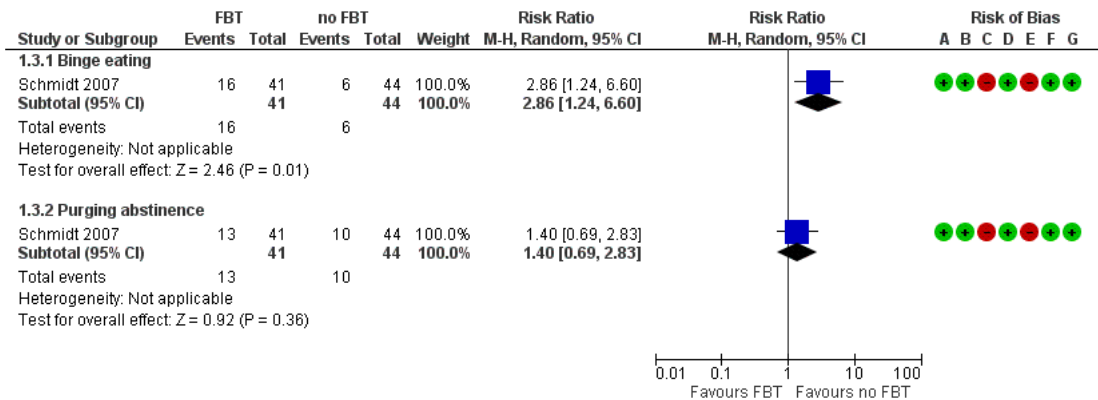


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.2 ED behaviour, Vomiting per month, end of treatment.

Figure 3 (Analysis 1.3)

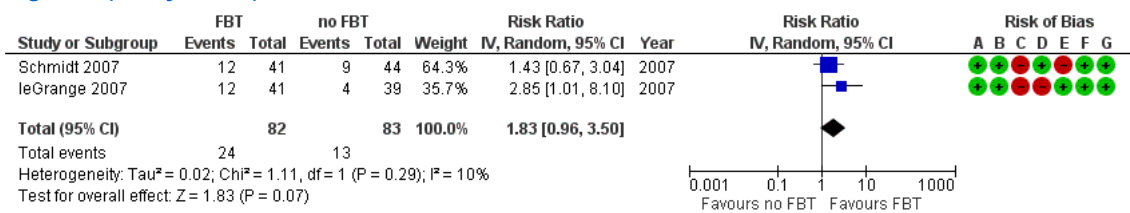


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.3 ED behaviour, end of treatment.

Figure 4 (Analysis 1.4)

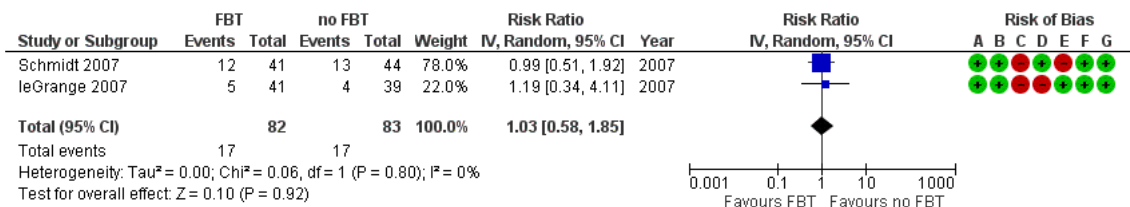


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.4 Remission of ED, longest FU.

Figure 5 (Analysis 1.5)

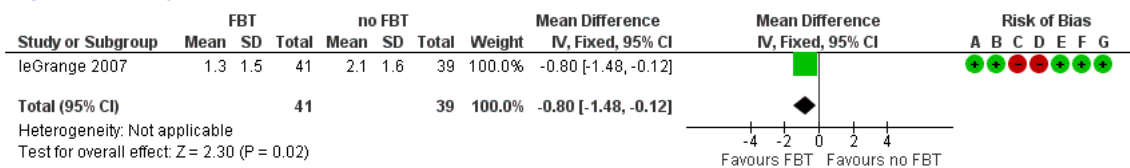


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.5 Dropout, end of treatment.

Figure 6 (Analysis 1.6)

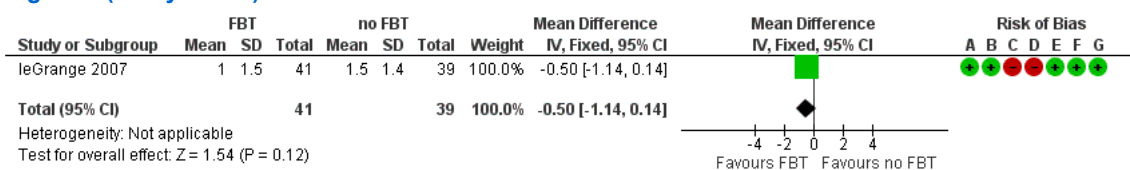


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.6 Psychological ED symptoms, EDE Restraint, end of treatment.

Figure 7 (Analysis 1.7)

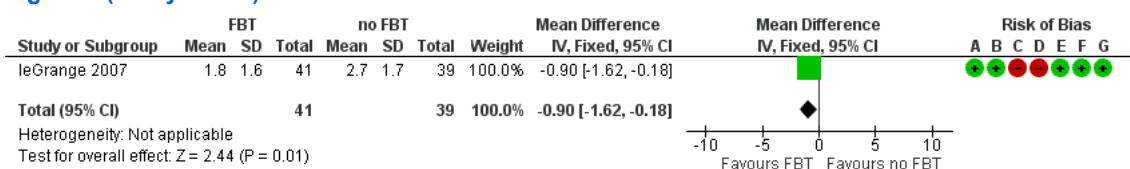


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.7 Psychological ED symptoms, EDE Eating concern, end of treatment.

Figure 8 (Analysis 1.8)

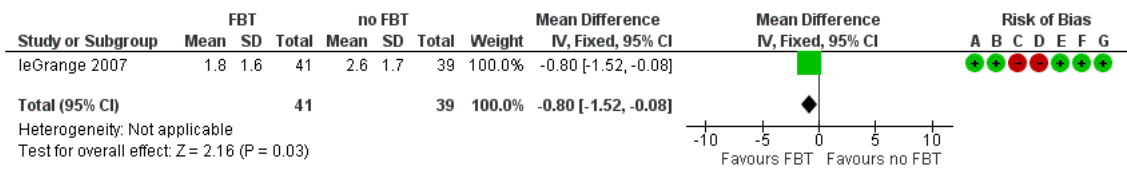


Risk of bias legend

- (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)
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- (F) Selective reporting (reporting bias)
- (G) Other bias

Forest plot of comparison: 1 FBT vs no FBT, outcome: 1.8 Psychological ED symptoms, EDE Shape concern, end of treatment.

Figure 9 (Analysis 1.9)

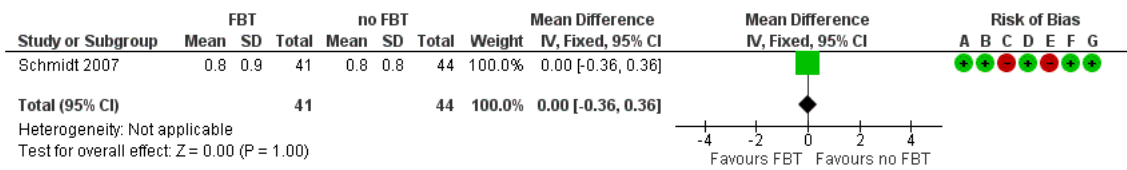


Risk of bias legend

- (A) Random sequence generation (selection bias)
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- (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 FBT vs no FBT, outcome: 1.9 Psychological ED symptoms, EDE Weight concern, end of treatment.

Figure 10 (Analysis 1.10)

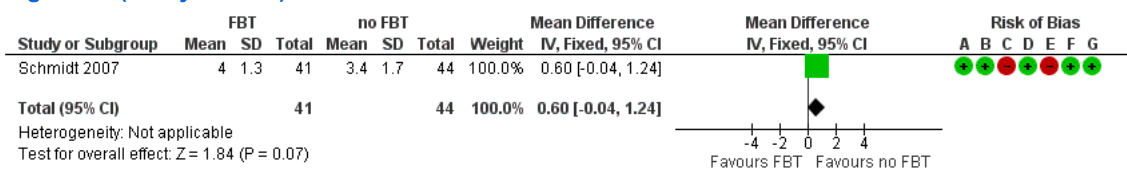


Risk of bias legend

- (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 FBT vs no FBT, outcome: 1.10 Psychological ED symptoms, Food preoccupation, end of treatment.

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 FBT vs no FBT, outcome: 1.11 Psychological ED symptoms, Weight + shape concerns, end of treatment.