Treatment of Bulimia Nervosa in a Primary Care Setting

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Objective: The authors’ goal was to determine whether treatments known to be effective for bulimia nervosa in specialized treatment centers can be used successfully in primary health care settings. They examined the benefits of two treatments for bulimia: 1) fluoxetine, an antidepressant medication, and 2) guided self-help, an adaptation of cognitive behavior therapy.

Method: Ninety-one female patients in two primary care settings were randomly assigned to receive fluoxetine alone, placebo alone, fluoxetine plus guided self-help, or placebo and guided self-help.

Results: The majority of the patients did not complete the treatment trial; many patients found the treatment program too demanding, but others indicated it was not sufficiently intensive. Patients assigned to fluoxetine attended more physician visits, exhibited a greater reduction in binge eating and vomiting, and had a greater improvement in psychological symptoms than those assigned to placebo. There was no evidence of benefit from guided self-help.

Conclusions: The treatment of patients with bulimia nervosa in a primary care setting is hampered by a high dropout rate. Guided self-help, a psychological treatment based on cognitive behavior therapy, appears ineffective, but treatment with fluoxetine is associated with better retention and substantial symptomatic improvement.

In the last 15 years, effective treatment interventions for bulimia nervosa have been developed and validated in specialized treatment centers. Both cognitive behavior therapy and antidepressant medication have been established as useful interventions for this serious mental health problem (1, 2). Cognitive behavior therapy is an effective treatment approach for patients with bulimia, but there are limitations to its widespread implementation. Cognitive behavior therapy is ideally delivered by a specially trained mental health professional with an advanced degree (i.e., Ph.D. or M.D.), and there is a shortage of qualified therapists to provide treatment. Additionally, cognitive behavior therapy can be impracticable, with a recommended course of treatment of twenty 50-minute sessions over 4 to 5 months.

To make this approach more widely available, self-help programs based on cognitive behavior therapy principles have been developed and published in the form of books targeted at a lay audience. These books describe the cognitive behavior model of bulimia and encourage the reader to carry out cognitive exercises and to implement behavioral changes. A modification called “guided self-help” adds a limited number of brief visits (typically, four to eight) with a therapist whose primary role is to encourage the patient to follow the treatment program described in the book. Experience with the use of self-help and guided self-help, including five controlled trials, suggests that the results of self-help-based interventions for bulimia are superior to remaining on a waiting list and, in some reports, similar to those obtained with cognitive behavior therapy (3–7). The applicability of these results to a primary care setting is unclear because the controlled trials that evaluated self-help treatments were conducted in or supervised by specialized eating disorder programs.

The efficacy of the other major intervention for bulimia, the use of antidepressant medication, has been documented in more than a dozen randomized, placebo-controlled trials (2). The only selective serotonin reuptake inhibitor examined in these trials is fluoxetine, which received U.S. Food and Drug Administration approval for the treatment of bulimia in 1996. However, as in the case of cognitive behavior therapy and self-help, virtually all of the data on the use of fluoxetine for bulimia have come from trials conducted in specialty clinics.

Although effective treatments for bulimia have been developed, it is unclear whether they can be employed usefully in a primary care setting by nonspecialists. The current study was designed to address this question by evaluating the relative and combined benefits of fluoxetine and guided self-help in a primary care setting.

Method

Patient Selection

This study was designed to determine whether patients with the core symptoms of bulimia nervosa could be successfully treated in a primary care setting. In order to examine the utility of treatment for the broad range of patients who might receive treatment in a primary care setting, we slightly modified the DSM-IV criteria for bulimia nervosa as follows: 1) DSM-IV defines an episode of binge eating as the consumption of an amount of food
that is “definitely larger” than normal accompanied by a sense of loss of control over eating. We also included individuals who described the consumption of only moderate amounts of food during binges. 2) DSM-IV requires that binge eating and inappropriate compensatory behaviors, such as self-induced vomiting, occur on average at least twice a week for 3 months; we required a minimum frequency of at least once a week for 3 months.

We required all patients to meet the remaining DSM-IV criteria, which specify an overconcern with shape and weight and the absence of current anorexia nervosa. In addition, eligible patients were required to be women between the ages of 18 and 60, with a body mass index greater than 17.5 kg/m². We excluded patients who were pregnant, who had substantial medical illness, who were taking psychotropic medications or medications known to influence shape or weight, who had previously received a course of 60 mg/day of fluoxetine for 4 weeks or more or had received cognitive behavior therapy, who reported an adverse reaction to fluoxetine, who were in other psychological or psychiatric treatment, who reported substantial alcohol or substance abuse or dependence in the past 6 months, who described other serious psychiatric diagnoses requiring immediate treatment, or who were actively suicidal.

Patients were recruited primarily through newspaper advertisements and referrals. Two hundred twenty-seven patients contacted the clinic and, on the basis of a brief telephone interview, seemed to be eligible to participate. A research assistant spoke with these women by phone, describing the study in detail. One hundred one women who remained interested and eligible after the phone screening participated in an in-person evaluation with a research assistant. Ninety-one of these 101 women were found to be eligible, provided written informed consent to participate in the study, and were seen for the first treatment visit when random assignment to different treatments occurred. The most common reasons for attrition during the evaluation phase were failure to attend scheduled appointments and failure to meet entry criteria for the frequency of binge eating or compensatory behaviors.

Sites

The study was conducted at two primary care clinics, one in a suburban community in Connecticut 30 miles north of New York City and the other in midtown Manhattan. The Manhattan site was added after the study was under way in order to increase enrollment. Seventy-one of the patients were enrolled in the first center between March 1998 and September 2001 and 20 in the second between August 2000 and October 2001. Five physicians and six nurses provided treatment in Connecticut, and two physicians and two nurses in Manhattan. The study physicians were internists practicing general medicine with limited experience in treating patients with eating disorders; the nurses were members of the general office staff and had no specialized training or experience regarding eating disorders. Both the physicians and nurses received brief training (less than 2 hours) from two of us (B.T.W. and C.G.F.) in the clinical characteristics of bulimia nervosa and the use of guided self-help and fluoxetine in its treatment. Six pilot patients, five in Connecticut and one in Manhattan, were treated to familiarize the sites and personnel with the study procedures and treatment approach.

Assessment and Treatment

At the baseline visit, patients were assessed with an abbreviated Structured Clinical Interview for DSM-IV (8), an abbreviated version of the Eating Disorder Examination interview (9), and the following self-report measures: the Eating Disorder Examination questionnaire, the Beck Depression Inventory, and the 53-item version of the Symptom Check List (SCL-53). Patients completed an Eating Disorder Examination questionnaire on three occasions during the study to assess eating behavior during the previous month (28 days). At the last treatment visit, patients again completed these self-report measures and were reassessed with the abbreviated Eating Disorder Examination interview. Height was measured at the first treatment visit, and weight was measured at every physician visit.

All patients received medical management modeled on that used in a multisite study of depression (10). At the initial treatment visit, the physician obtained a brief history and performed a physical examination, described potential side effects of fluoxetine, and dispensed the medication. Patients were asked to return 2 weeks after the initial treatment visit for a brief evaluation of medication side effects. All patients were scheduled for four additional 15-minute visits with the physician, designed to occur at approximately monthly intervals.

Patients were randomly assigned to one of four treatment conditions: placebo alone, fluoxetine alone (pills-only conditions), placebo and guided self-help, or fluoxetine and guided self-help. Fluoxetine and placebo were packaged in identical 20-mg capsules, and patients were instructed to take three pills daily, beginning immediately after their first appointment with the study physician. The use of the fluoxetine dose of 60 mg/day was based on previous studies indicating that this dose is well tolerated and effective in the treatment of bulimia nervosa (2); the dose could be lowered to reduce side effects.

At the first visit with the physician, patients assigned to the guided self-help condition met with a nurse, who gave them a copy of the cognitive behavior self-help book used in this study (11) and instructed the patients to begin reading certain specified sections. In addition to their monthly physician visits, the patients assigned to the guided self-help condition were scheduled to see a nurse for six to eight sessions. The first four guided self-help visits were designed to occur weekly during the first month of the study, the fifth session in the second month, the sixth session in the third month, and two optional sessions in the third or fourth months. These sessions were approximately 30 minutes in length and focused on encouraging patients to progress through the self-help program.

Statistical Methods

The primary outcome measures were the frequencies of binge eating and vomiting at the end of treatment assessed by using the Eating Disorder Examination interview and Eating Disorder Examination questionnaire. The data were analyzed on an intent-to-treat basis with data from the last available assessment carried forward for patients who did not complete the full trial. Data from the Eating Disorder Examination interview and questionnaire, Beck Depression Inventory, and SCL-53 were analyzed by using analysis of covariance with the baseline value as the covariate. Square root transformations were performed on Eating Disorder Examination interview and questionnaire variables with skewed distributions (objective and subjective bulimic episodes and episodes of vomiting). The independent factors in the analyses of covariance were medication (fluoxetine versus placebo), guided self-help (guided self-help and pills versus pills only), and site (Connecticut versus Manhattan). Similar calculations were performed for patients who completed the full study. SPSS for Windows, version 10 (SPSS, Inc., Chicago), was used to perform statistical calculations.

The effect of randomization group on attrition was assessed by using a proportional odds polytomous logistic regression model. The dependent variable in this model was the last physician visit made by the patient. The PROC LOGIST procedure in SAS (SAS Institute, Cary, N.C.) was used to assess differences among medication group, guided self-help, and site.

This study was reviewed and approved by the New York State Psychiatric Institute/Columbia University Institutional Review Board. All patients provided written informed consent.
Results

Patient Characteristics

The mean age of the patients was 30.6 years (SD=7.8); their mean reported duration of bulimia was 12.0 years (SD=7.9). Seventy-six (83.5%) of the 91 patients met full DSM-IV criteria for bulimia nervosa. Twenty-eight (32.2%) of the 87 patients who provided this information had received previous treatment for eating disorder symptoms. Eighty-four (92.3%) of the 91 patients were Caucasian, five (5.5%) were Hispanic, one (1.1%) was Asian, and one (1.1%) was African American. There was substantial psychiatric comorbidity, the main disorders being major depressive disorder (N=30 [33.3%] of 90), past major depressive disorder (N=28 [31.1%]), and posttraumatic stress disorder (N=14 [15.6%]).

The levels of symptoms at baseline and at the end of treatment are shown in Table 1. There were no significant differences between the fluoxetine and placebo groups or between the pills-only and the pills-plus guided self-help groups at baseline in frequencies of binge eating, vomiting, or laxative abuse or any of the psychological measures. Similarly, there were no statistically significant differences between the two treatment sites.

Patient Attrition

Twenty-eight (30.8%) of the 91 patients completed the full course of treatment. Of the 63 patients who did not complete the full treatment course, 21 (33.3%) indicated that the treatment offered was either too demanding or not intensive enough; 13 (20.6%) gave no reason; 10 (15.9%) cited important life events that interfered with attendance; eight (12.7%), including one receiving placebo, cited difficulties with the medication; six (9.5%) felt their symptoms were not improving; and one (1.6%) felt she was “cured.” Four (6.3%) of the 63 patients were withdrawn by their physicians because of concern regarding their level of depression.

The proportions of patients completing the full study were similar for the self-help (14 [28.6%] of 49) and pills-only (14 [33.3%] of 42) conditions. A greater proportion of patients receiving fluoxetine (17 [38.6%] of 44) than placebo (11 [23.4%] of 47) completed the full study, but this difference was not statistically significant. The influence of treatment assignment on patient attrition was examined by using a proportional odds logistic regression model considering the outcome to be one of five possible ordinal variables, namely, whether the patient had attended zero, one, two, three, or four of the postrandomization physician visits intended to occur at monthly intervals. All patients who attended the third postrandomization physician visit also attended the fourth physician visit; therefore, only four categories were used in the analysis. Given that there were no site differences in attrition (p=0.86), data across sites were pooled and a single model was fit with indicators of randomized medication group and randomized guided self-help group as predictors. Significantly less attrition was noted for the fluoxetine group than the placebo group. The estimated odds ratio for attrition at any visit (placebo compared with fluoxetine) was

<table>
<thead>
<tr>
<th>Measure</th>
<th>Fluoxetine (N=24)</th>
<th>Placebo (N=25)</th>
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<tbody>
<tr>
<td>Eating Disorder Examination interview</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulimic episodes/month</td>
<td>Objective: 27.42 (23.88)</td>
<td>27.80 (25.64)</td>
</tr>
<tr>
<td>Subjective: 17.58 (25.19)</td>
<td>15.84 (22.37)</td>
<td></td>
</tr>
<tr>
<td>Days of vomiting/month</td>
<td>20.29 (9.62)</td>
<td>20.12 (9.18)</td>
</tr>
<tr>
<td>Episodes of vomiting/month</td>
<td>38.04 (25.08)</td>
<td>44.16 (56.14)</td>
</tr>
<tr>
<td>Episodes of laxative use/month</td>
<td>2.54 (6.67)</td>
<td>3.64 (8.15)</td>
</tr>
<tr>
<td>Restraint rating for past month</td>
<td>5.00 (2.00)</td>
<td>5.16 (1.99)</td>
</tr>
<tr>
<td>Eating Disorder Examination questionnaire</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bulimic episodes/month</td>
<td>Objective: 20.70 (15.46)</td>
<td>17.92 (16.19)</td>
</tr>
<tr>
<td>Subjective: 10.19 (8.84)</td>
<td>10.45 (10.32)</td>
<td></td>
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<tr>
<td>Days of vomiting/month</td>
<td>20.74 (9.12)</td>
<td>19.32 (9.42)</td>
</tr>
<tr>
<td>Days of laxative use/month</td>
<td>2.70 (6.55)</td>
<td>4.32 (8.78)</td>
</tr>
<tr>
<td>Beck Depression Inventory score</td>
<td>19.74 (11.85)</td>
<td>19.56 (11.64)</td>
</tr>
<tr>
<td>SCL-53 general symptom index score</td>
<td>1.36 (0.80)</td>
<td>1.49 (0.93)</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>21.79 (3.40)</td>
<td>22.78 (4.33)</td>
</tr>
</tbody>
</table>

a ANCOVA of final value with baseline value as covariate. Main effects are guided self-help versus pills only, fluoxetine versus placebo, and Connecticut site versus Manhattan site.
b Eleven subjects completed the full study; data from the last assessment were used to determine end-of-treatment values for the 13 patients who did not complete the study.
c Three subjects completed the full study; data from the last assessment were used to determine end-of-treatment values for the 22 patients who did not complete the study.

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Eight (8.8%) of the 91 patients randomly assigned to different treatments achieved remission from binge eating and purging in the month before study termination (objective and subjective bulimic episodes, vomiting, and laxative abuse), as assessed by the Eating Disorder Examination interview. There were no significant differences in the number of patients remitted in the guided self-help (six [12.2%] of 49) or pills-only (four [9.5%] of 42) conditions, for patients receiving fluoxetine (seven [15.9%] of 44) or placebo (three [6.4%] of 47), or for the Manhattan (three [15.0%] of 20) and Connecticut (seven [9.9%] of 71) sites.

**Discussion**

The aim of this study was to assess the relative and combined effects of two treatments for bulimia nervosa, both of which are potentially suitable for use in primary care. The two treatments were fluoxetine, an antidepressant medication, and guided self-help, a simplified form of cognitive behavior therapy. The salient results of the study are that the rate of dropout was surprisingly high, that guided self-help had no discernible effect on either retention or symptomatic improvement, and that fluoxetine was clearly of benefit.

Approximately two-thirds of the patients who began treatment failed to complete it. Several interrelated factors, including the patient population, the treatment setting, and the treatments themselves, are likely contributors to the high dropout rate. The prevalence of bulimia nervosa in general medical practice is no more than 1% (12–14). Therefore, most patients were recruited for this study by means of advertisements. Patients with an established relationship with a primary care provider might have been less prone to end treatment prematurely, but recruitment of a sufficient number of such patients was

### Response to Treatment

Compared with placebo, fluoxetine was associated with a greater reduction in objective bulimic episodes per month as measured by the Eating Disorder Examination interview, episodes of vomiting per month assessed with the Eating Disorder Examination interview and questionnaire, days of vomiting per month and ratings of dietary restriction assessed with the Eating Disorder Examination interview, score on the Beck Depression Inventory, and the general symptom index score on the SCL-53 (Table 1). The only difference between the guided self-help and pills-only groups was that the patients in the pills-only condition exhibited a greater reduction in subjective bulimic episodes than did patients assigned to receive guided self-help.

There were no significant interactions between the medication and self-help conditions or between treatment site and either treatment condition. Analysis of data from the 28 patients who completed the full course of treatment showed a similar pattern of findings (data not shown).

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### Table 1

<table>
<thead>
<tr>
<th></th>
<th>Pills Only</th>
<th>Placebo</th>
<th>Analysis of Covariance (ANCOVA)*</th>
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<tr>
<td></td>
<td>Fluoxetine (N=20)d</td>
<td>Placebo (N=22)e</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Baseline Mean</td>
<td>SD</td>
<td>Mean</td>
</tr>
<tr>
<td>Treatment Baseline</td>
<td>24.20</td>
<td>22.60</td>
<td>17.25</td>
</tr>
<tr>
<td>End of Treatment</td>
<td>16.25</td>
<td>16.06</td>
<td>3.70</td>
</tr>
<tr>
<td></td>
<td>18.80</td>
<td>9.36</td>
<td>11.55</td>
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<tr>
<td></td>
<td>34.30</td>
<td>29.34</td>
<td>19.85</td>
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<tr>
<td></td>
<td>4.70</td>
<td>10.20</td>
<td>3.90</td>
</tr>
<tr>
<td></td>
<td>5.20</td>
<td>1.67</td>
<td>3.90</td>
</tr>
</tbody>
</table>

*Six subjects completed the full study; data from the last assessment were used to determine end-of-treatment values for the 14 patients who did not complete the study.

Eight subjects completed the full study; data from the last assessment were used to determine end-of-treatment values for the 14 patients who did not complete the study.

Square root transformation used in ANCOVA.

Significant difference in body mass index by analysis of variance between guided self-help and pills-only groups (F=4.34, df=1, 89, p=0.04).

*p<0.05.

2.83 (95% confidence interval=1.18–6.77, p=0.02). There was no difference in attrition between the guided self-help and pills-only groups (p=0.99).

### Discussion

The aim of this study was to assess the relative and combined effects of two treatments for bulimia nervosa, both of which are potentially suitable for use in primary care. The two treatments were fluoxetine, an antidepressant medication, and guided self-help, a simplified form of cognitive behavior therapy. The salient results of the study are that the rate of dropout was surprisingly high, that guided self-help had no discernible effect on either retention or symptomatic improvement, and that fluoxetine was clearly of benefit. Approximately two-thirds of the patients who began treatment failed to complete it. Several interrelated factors, including the patient population, the treatment setting, and the treatments themselves, are likely contributors to the high dropout rate. The prevalence of bulimia nervosa in general medical practice is no more than 1% (12–14). Therefore, most patients were recruited for this study by means of advertisements. Patients with an established relationship with a primary care provider might have been less prone to end treatment prematurely, but recruitment of a sufficient number of such patients was...
not feasible. The average patient had been ill for more than a decade, and one-third had previously sought treatment for their eating disorder.

Information obtained from patients indicated that the primary reason for dropping out was a discrepancy between their expectations and the treatment provided. The physicians and nurses who provided the treatment were unfamiliar with eating disorders, and it is possible that their inexperience, the general medical setting, and the low intensity of treatment undermined the confidence of some patients in the treatments and led to poor compliance. On the other hand, patients receiving fluoxetine attended more sessions than did patients receiving placebo. The fact that fluoxetine was clearly more beneficial than placebo suggests that an important contributor to patient retention was whether the treatment was helpful.

The rate of dropout in this study is substantially greater than the 20%–35% rate of dropout of patients with bulimia in comparable trials conducted in specialty clinics (4, 5, 7, 15). However, trials conducted in specialty clinics have generally required patients to complete a more demanding series of assessments before random assignment to treatment, which may serve to reduce the number of patients not able or not sufficiently motivated to comply with the demands of treatment.

In the current study, 101 patients were seen for a single, relatively brief assessment visit before beginning treatment, and 91 of these patients were randomly assigned to different treatments. In a trial of comparable length conducted in a specialty clinic, also involving random assignment to medication and psychotherapy (15), patients were required to attend two evaluation appointments and to remain symptomatic during 7–10 days of placebo treatment before being randomly assigned. In this trial, 229 patients were seen for the initial screening assessment, 149 returned for the single-blind placebo phase, and 120 were randomly assigned; the most common reason for attrition during the evaluation phase was simply failure to return for the subsequent appointment. The fractions of patients initially evaluated who completed the full study are similar to ours: 41 (17.9%) of 229 in the specialty clinic study and 28 (27.7%) of 101 in our current study. These data suggest that across different treatment settings, only a small fraction of patients with bulimia who express interest in participating in a treatment study actually complete it.

Compliance with mental health treatments provided in a primary care setting is also problematic for other psychiatric disorders. For example, within the first month of treatment, approximately one-third of depressed adults in primary care cease to comply with antidepressant treatment (16). Thus, while the high rate of dropout is a major challenge to the treatment of patients with bulimia and a major limitation of the current study, the high dropout rate observed in this study likely reflects difficulties providing mental health treatment in a primary care setting as well as characteristics of patients with bulimia nervosa.

On virtually every measure, fluoxetine was superior to placebo, and the magnitude of the response appears comparable to that observed in multicenter trials of fluoxetine conducted in specialty clinics (17, 18). Two large studies (17, 18) reported only the rates of remission from binge eating and from vomiting, not the rate of remission from both behaviors. In those studies, the rates of remission from vomiting, respectively, for patients receiving fluoxetine were 19% and 23%, and the rates of remission from binge eating were 18.3% and 26%; these rates are virtually identical to the rates of 22.7% and 20.5% observed in our current study. On the other hand, treatment with fluoxetine was associated with remission of both binge eating and vomiting in only about 15% of our patients, compared with remission rates of 30%–50% achieved with cognitive behavior treatment in specialty clinics (19). These data highlight that full remission is difficult to achieve in any treatment setting but appears more difficult in a primary care setting.

The current study extends evidence on efficacy of fluoxetine in bulimia from a specialty to a primary care setting and suggests that fluoxetine may be a useful intervention for bulimia available to physicians in primary care settings but will rarely produce symptomatic remission.

We were unable to detect any significant benefits from guided self-help. This result is surprising in the light of positive reports of the utility of guided self-help in bulimia and binge eating disorder (20–24). There are several possible explanations. Most previous studies have compared guided self-help with a waiting-list condition, which provides little benefit. In the current study, the effect of guided self-help was assessed by comparing guided self-help plus medication management with medication management alone, a more demanding standard. One study using a design identical to that of the current study but conducted in a specialty clinic (6) also failed to detect statistically significant benefit from guided self-help.

A second possible explanation for the lack of efficacy of guided self-help is the setting, since previous controlled studies of guided self-help for bulimia nervosa have not assessed its utility in primary care. In the current study, the nurses who guided patients in the self-help program had little or no previous experience with patients with eating disorders and were in an unfamiliar therapeutic role. This fact, coupled with the high level of symptoms of most of the patients, may have decreased compliance and diminished the impact of guided self-help.

Finally, the low rate of study completion and the modest number of subjects limited the statistical power of this study to detect differences between the guided self-help and pills-only conditions. We estimate that the power was about 0.5 to detect a 50% difference between conditions in reduction in binge eating and vomiting frequencies.

In summary, the current study demonstrated benefits of fluoxetine provided by nonpsychiatrists in a primary care setting and detected no utility of a guided self-help pro-
gram. Fluoxetine, at a dose of 60 mg/day, appears to be a potentially useful treatment option available to primary care physicians for the treatment of bulimia but will rarely produce complete symptomatic remission. A major obstacle to the successful implementation of such treatment is the high rate of treatment noncompliance. Noncompliance is a substantial problem in the treatment of other psychiatric disorders in primary care, such as major depression. Efforts to increase compliance that appear effective for patients with major depression, such as systematic telephone follow-up (16, 25), might also be useful for patients with bulimia. The problems of noncompliance, the lack of evidence for utility of guided self-help, and the limited impact of fluoxetine also suggest that early referral to a specialty clinic should be strongly considered for patients with bulimia seen in primary care settings.

References