

Specialist treatment versus self-help for bulimia nervosa: a randomised controlled trial in general practice

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SUMMARY

Background: Little is known about general practice management of patients with eating disorders.

Aim: To compare the effectiveness of a general practice-based, self-help approach to the treatment of bulimia nervosa with that of specialist outpatient treatment.

Design of study: A prospective, parallel group, randomised controlled trial.

Setting: General practices and specialist eating disorder clinics in London.

Method: Patients were recruited from general practitioner (GP) referrals to specialist eating disorder clinics. Thirty-four patients were randomised to receive the self-help intervention in general practice and thirty-four were randomised to the clinic intervention. Patients randomised to the self-help arm of the trial worked through a manual based on cognitive behaviour principles, while keeping in contact with their GPs. Those randomised to receive specialist treatment were managed in the specialist clinic to which they had been referred. The main outcome measure was the Bulimic Investigatory Test Edinburgh score, assessed at baseline and at six and nine months. Secondary measures were eating pathology, depression, and social adjustment.

Results: A total of 74% and 80% of patients were followed up at six and nine months respectively. An intention-to-treat analysis revealed that, while bulimic symptoms declined in both groups over time, there was no significant difference in outcome between the two groups.

Conclusion: The findings lend support to the idea that patients with bulimia nervosa can be treated in general practice and that this approach warrants further investigation.

Keywords: bulimia nervosa; general practice; self-help; cognitive behaviour therapy.

Introduction

COGNITIVE behaviour therapy is an effective treatment for bulimia nervosa.¹⁻⁴ Recently, studies have reported improvements in patients using self-help handbooks based on cognitive behaviour principles.⁵⁻¹⁰ However, with the exception of studies examining the epidemiology of bulimia nervosa in general practice populations^{11,12} and a small pilot study,¹³ little attention has been paid to the possibility of treating patients with bulimia nervosa in general practice. Patients with eating disorders consult their family doctors more often than matched controls¹⁴ and the majority of referrals to specialist services come from general practitioners (GPs). GPs are well placed to support patients undertaking self-help treatment for bulimia nervosa. We compared, in a pragmatic randomised controlled trial, the effectiveness of a general practice-based, self-help approach to the treatment of bulimia nervosa with that of specialist outpatient treatment. We hypothesised that there would be no serious disadvantage in outcome for patients randomised to a self-help intervention in general practice, compared with those receiving specialist care.

Method

Participants

Participating patients were referred by their GPs in London to three specialist clinics for bulimia nervosa between January 1995 and June 1997 (Box 1).

Procedure

Approval for the trial was obtained from the following Local Research Ethics Committees: the Royal Free Hampstead National Health Service (NHS) Trust Ethics Subcommittee, the New River Health Authority Local Research Ethics Committee, and the Riverside Research Ethics Committee. After obtaining written consent, each of the patients was assessed at her GP's surgery. A stratified block randomisation was used to assign patients to each trial arm. Stratification was on the basis of scores on the Bulimic Investigatory Test Edinburgh (BITE)¹⁵ (low/high scores; high being a score of 35 or above). A random sequence of blocks of four for each of the strata was constructed by a statistician (two self-help and two specialist treatment in each block). Sealed envelopes were employed. The first author, who interviewed participants, was not blind to group allocation and resources did not allow for blind assessment at follow-up. However, the principal outcome of this study depended on participant self-report, thereby reducing interviewer bias.

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HOW THIS FITS IN

What do we know?

Recent research has shown improvements in patients suffering from bulimia nervosa treated with self-help manuals based on cognitive behaviour principles. However, little attention has been paid to managing patients in general practice.

What does this paper add?

The current study was designed to test the hypothesis that patients treated in general practice with a self-help intervention would not be disadvantaged, compared with those treated in specialist clinic. The results suggest that a self-help approach in general practice is worth considering when patients with bulimia nervosa present to their GP.



Measures

As well as the outcome measures described below, the baseline assessment included the following measures devised by the authors:

- an interviewer-administered questionnaire on demographic characteristics and psychiatric, weight, and dietary history;
- a self-completion behavioural problems questionnaire, which included the CAGE screening questionnaire for alcohol problems;¹⁶
- a self-completion questionnaire concerning patients' perceptions of the severity of their eating problem, the importance of overcoming it, and the expected helpfulness of the two treatment interventions. Patients were asked to indicate which treatment they would choose.

The primary outcome measure was the BITE,¹⁵ which is a self-completed measure designed to assess the symptoms and severity of bulimia nervosa. Secondary outcome measures were: the Eating Disorders Examination-12 (EDE-12),¹⁷ which is a semi-structured interview for the assessment of eating pathology; the Beck Depression Inventory (BDI),¹⁸ and the Work, Leisure and Family Life questionnaire (WLFL),¹⁹ which is a self-report version of the Social Adjustment Scale (SAS).²⁰

Participants were reassessed at six and nine months using the instruments described above; in addition:

- a self-report 'satisfaction with treatment' questionnaire rated helpfulness of treatment at each follow-up by means of an 11-point visual analogue scale (0 = not at all helpful, to 10 = extremely helpful);
- participants rated the severity of their eating disorder at baseline and each follow-up (0 = not at all a problem, to 10 = an extremely severe problem).

Patients' general practice/clinic records were searched for data on attendance rates, prescribing of psychotropic medication, and interventions by staff. Where records were unavailable, patient or GP reports were used to calculate attendance rates. Patient self-reporting was employed to

Inclusion criteria

- General practitioner referral;
- Suffering from bulimia nervosa (DSM-IV bulimic symptoms assessed using the Eating Disorder Examination-12¹⁷);
- Aged 18 years or over;
- Female; and
- English-speaking.

Exclusion criteria

- Suffering from bulimia nervosa but requiring an urgent clinic assessment;
- Pregnancy;
- Medical disorders such as diabetes, which might have implications for eating;
- Substance or alcohol misuse problems; and
- Evidence of serious suicidal intent.

Withdrawal criteria for those randomised to self-help/general practice arm

Where general practitioners felt strongly that for medical or social reasons it was no longer appropriate that they continue in the self-help group or if patients expressed a strong wish to be withdrawn from this arm of the trial.

Box 1. Inclusion, exclusion and withdrawal criteria.

assess use of professional psychotherapeutic help beyond that provided in the study.

Patients who did not participate because they or their GP declined, but who subsequently attended the specialist clinics, were asked to complete the BITE questionnaire during their first clinic visit.

Postal surveys were conducted of the GPs who were supporting self-help patients, concerning the progress of their patients three months after commencement of treatment and at the end of the follow-up period. GPs were asked about patients' attendance for treatment, problems encountered, and their views of the general practice-based approach to treatment.

Interventions

General practice-based self-help. Patients in the self-help arm of the trial were given a copy of *Bulimia Nervosa: a guide to recovery*²¹ and advised to work through it while keeping in regular contact with their GP. As well as general information about bulimia nervosa, the manual contains a highly structured six-step, self-help programme based on the principles of cognitive behaviour therapy (Box 2). GPs supporting self-help patients received a copy of the manual and guidelines on providing support to patients. GPs could contact the clinic through the first author if they had any concerns about their patients.

Specialist clinic treatment. A consultant psychiatrist managed each clinic. Other staff included psychiatrists, psychologists, nurse specialists, and dieticians. Each clinic offered similar forms of therapy, including a combination of cognitive behaviour and interpersonal psychotherapy. Patients were seen on a weekly or fortnightly basis for as long as was deemed appropriate, in line with usual specialist care.

Analysis

An intention-to-treat analysis was conducted using SPSS-

Stage 1: Monitoring eating.
 Stage 2: Instituting a meal plan.
 Stage 3: Learning to intervene to prevent bingeing.
 Stage 4: Problem-solving.
 Stage 5: Eliminating dieting.
 Stage 6: Challenging beliefs about weight and shape.

Box 2. Stages in the self-help programme.

PC software (versions 6 and 9). Where self-help patients were seen in the specialist clinic, they were retained in the self-help trial arm in the analysis. Where patients could not be followed up, or where follow-up data were missing, the last observed value was carried forward for inclusion in the analysis. A repeated-measures multivariate analysis of variance and covariance was conducted on mean BITE scores¹⁵ for the two groups, using baseline BDI scores,¹⁸ age, and length of illness as covariates, as these are potential clinical predictors of outcome. The covariates were included individually and then together. BDI scores at baseline and the two follow-up points were included as time-varying covariates in a separate analysis. Also, individual repeated-measures analyses were conducted, to examine differences in mean scores on the BDI, EDE,¹⁷ and WLFL¹⁹ questionnaires between the two groups (using last observation carried forward where data were missing). Significance test results from the repeated measures analysis are reported using the *F* ratio equivalent of the multivariate tests (Wilks' λ) for within-subjects and between-subjects effects. Patients' ratings of the helpfulness of their treatment and the severity of their eating disorder were analysed using Wilcoxon signed ranks tests and Mann-Whitney *U* tests as appropriate. Change scores for 'objective bulimic episodes' and vomiting on the EDE¹⁷ (the 28 days prior to each follow-up) were calculated, using last observations carried forward data, and analysed for group differences using Mann-Whitney *U* tests.

The power calculation for the study was based on the development of the BITE,¹⁵ in which mean scores were 33.8 (standard deviation [SD] = 6.0) for patients with bulimia nervosa entering specialist treatment and 8.3 (SD = 6.0) at the end of treatment. We aimed to assess whether self-help would be no less effective than specialist treatment by two-thirds of a standard deviation (moderate treatment effect). In order to detect outcome scores on the BITE at least 0.66 of a standard deviation higher in the self-help arm, it was estimated that, at a significance level of 0.05 and a power of 0.8, 36 patients would be required in each arm of the trial.

Results

Participants

Sixty-eight patients were recruited (Figure 1). The first clinic provided 113 referrals, of which 43 (38%) were recruited; the second clinic provided 69 referrals, of which 19 (28%) were recruited; and the third clinic provided 27 referrals, of which six (22%) were recruited. GPs' reasons for refusing to participate included being too busy, insisting upon specialist intervention, not knowing the patient well, and having already undertaken self-help work with the patient. Although patients were not obliged to say why they declined to take part, rea-

sons given included feeling that their problem was too serious for supported self-help, having already undertaken a self-help approach, and not getting on with their GP. Thirty-two GPs provided support to self-help patients (two GPs saw two patients each). Three self-help patients were seen at the clinic after their doctors requested it — one after several weeks and the other two after several months. In addition, two self-help patients requested clinic appointments, one of whom was seen only once.

Participants in the two groups were balanced at baseline on demographic and clinical characteristics (Table 1). Similar percentages of both groups expressed preferences for the self-help/GP treatment and the specialist service treatment.

BITE scores were measured for 47 of the patients who did not participate in the study but who attended the clinics. Three of those for whom data were collected would have been excluded from the study on the basis of their BITE scores being too low, and seven questionnaires were incomplete. The mean score for the remaining 37 non-participants was 37.9 (SD = 7.4), which was significantly higher than participants in the trial (mean difference = -4.02, standard error (SE) = 1.34, 3.01, degrees of freedom (df) = 103, *P* = 0.003).

Attendance for treatment

Over the time of the trial, patients in the self-help arm saw their family doctors a mean of 4.9 times (SD = 5.6; range = 0 to 28; *n* = 31), while those in the specialist intervention arm saw a specialist 4.8 times (SD = 6.0; range = 0 to 25; *n* = 34). Participants in the specialist intervention group consulted their GP on average 1.9 times (SD = 2.7; range = 0 to 13; *n* = 29). Three self-help and four clinic patients (out of 48) reported seeing counsellors, while four clinic and one self-help patient (out of 47) reported seeing a therapist during the study period. Of 23 self-help patients for whom data were available at the second follow-up, 18 (78%) reported undertaking at least the first step of the self-help programme.

Outcome measures

Primary outcome. For BITE scores,¹⁵ there was a significant main effect for time (*F* = 18.00; df = 2,65; *P* < 0.001) but not for intervention group by time (*F* = 0.16; df = 2,65; *P* = 0.85) (Table 2). Both groups improved significantly over time, with no difference between them. When BDI¹⁸ baseline scores, age, and duration of illness were assessed individually as covariates, only the BDI baseline scores reached significance (*F* = 11.60; df = 1,65; *P* = 0.001). The results were confirmed when all three covariates were entered into the analysis together (*F* = 4.32; df = 1,63; *P* = 0.008). BDI scores were also incorporated in the analysis as varying covariates (baseline, six months, and nine months). The results confirmed the relationship between BDI and BITE scores throughout the course of the study (*F* = 30.06; df = 1,65; *P* < 0.001). As BITE scores decreased over time, so did BDI scores.

Analysing only participants with full data produced the same results (main effect of time but no difference between treatment groups over time). Baseline BDI scores on their

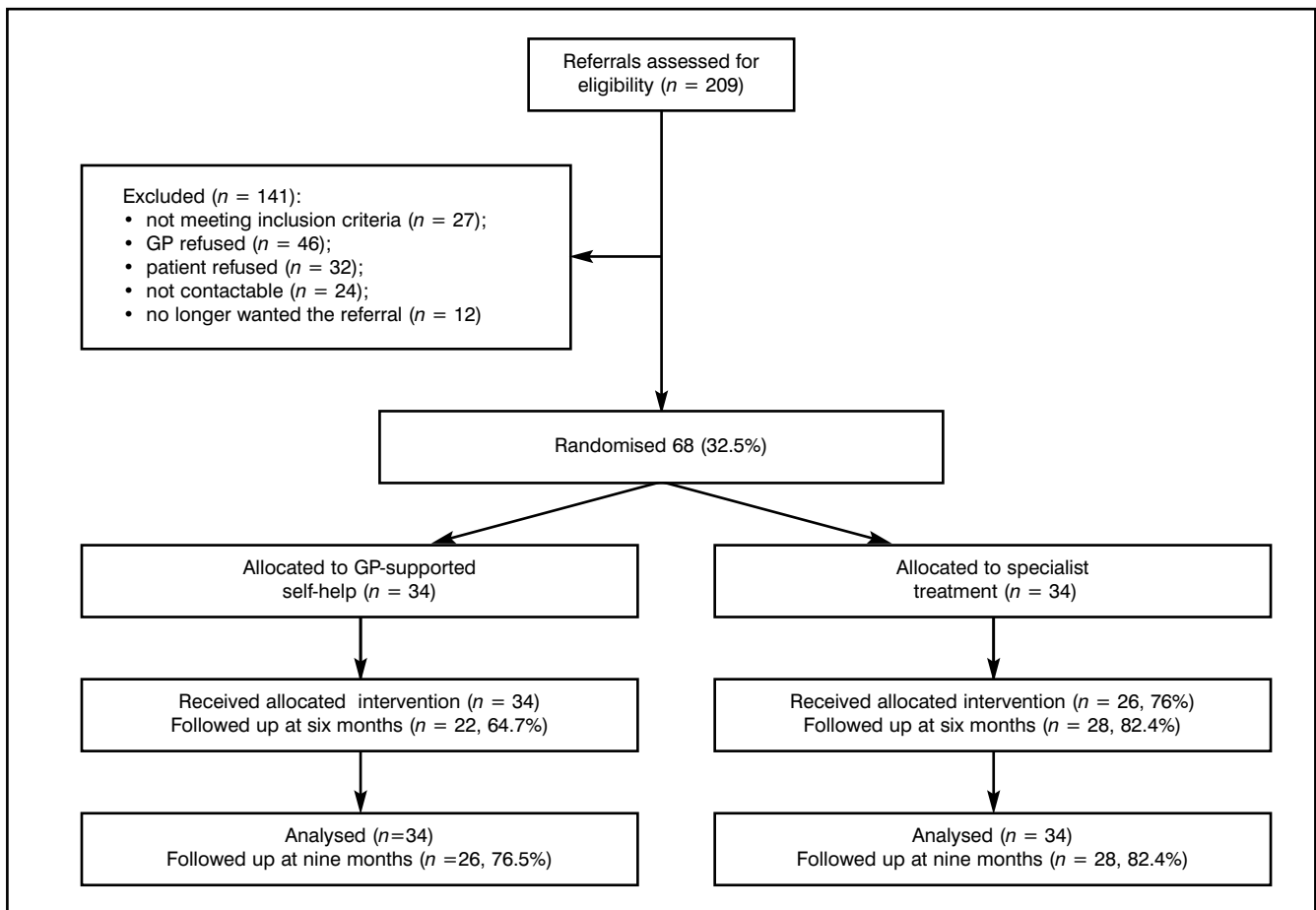


Figure 1. Trial flow diagram.

own almost reached significance and BDI scores (included as varying covariates) were significant, indicating a similar pattern of results to the intention-to-treat analysis. Baseline BDI scores, age, and duration of illness had no significant effect as covariates.

Secondary outcomes. Analysis of BDI scores revealed a main effect for time ($F = 14.81$; $df = 2,65$; $P < 0.001$), but not for treatment group by time ($F = 0.13$; $df = 2,65$; $P = 0.88$). Analysis of EDE¹⁷ global scores and SAS²⁰ scores (WFLFL questionnaire¹⁹) also revealed a main effect for time ($F = 18.92$; $df = 2,65$; $P < 0.001$ and $F = 8.66$; $df = 2,65$ $P < 0.001$, respectively), but again there was no significant time-by-treatment-group effect.

An analysis of the number of baseline episodes of 'objective bulimic episodes' and of change scores at each of the follow-ups revealed no difference in the two groups at any time point. Similarly, there were no differences in the number of baseline episodes of vomiting or change scores at either follow-up between patients in the two arms of the trial.

Using last-observation-carried-forward data, ten self-help (29.4%) and nine clinic (26.5%) patients had a total score of less than 20 on the BITE at final follow-up, suggesting that they no longer met full clinical criteria for bulimia nervosa. There were no significant differences between self-help and specialist clinic patients in terms of their ratings of the severity of their eating disorder at baseline or at either of the two

follow-ups. However, both self-help (Wilcoxon signed rank $Z = -3.262$; $P = 0.001$) and specialist clinic patients (Wilcoxon signed rank $Z = -3.571$; $P < 0.001$) rated their eating disorder as less severe by the time of the final follow-up. There was no difference in perceived helpfulness of treatment between patients for whom data were available, in the two trial arms at either follow-up.

GPs' attitudes

Twenty-nine of the GPs supporting self-help patients responded to the first survey and 24 to the second (in each case one GP responded about two patients in his/her care). Eighteen GPs reported finding the manual useful in increasing their understanding of bulimia nervosa. Perceived patient benefits of the approach included continuity of care, and perceived outcomes included improved general wellbeing, reduced symptoms, and increased insight. Seven GPs would have liked more specialist input, while the main difficulty reported was lack of time. Eleven GPs said they would be willing to use the approach again, or were already doing so with other patients. However, six said that they would not be able to because of time constraints or other demands.

Patients' attitudes

When asked, at the second follow-up, which parts of the self-help programme they had found most helpful, seven

Table 1. Baseline characteristics.

Descriptor	Self-help/GP	Specialist clinic
Age (mean, SD), <i>n</i> = 68	28.3 (6.5)	24.5 (5.2)
Civil status, <i>n</i> = 68		
Single	24 (71%)	24 (71%)
Married/cohabiting	5 (15%)	9 (26%)
Other	5 (15%)	1 (3%)
Ethnicity, <i>n</i> = 68		
White	29 (85%)	30 (88%)
Black	3 (9%)	3 (9%)
Other	1 (3%)	1 (3%)
Missing data	1 (3%)	0 (0%)
Duration of eating problem (mean years, SD), <i>n</i> = 68	7.7 (4.6)	5.9 (3.9)
Previous diagnosis, <i>n</i> = 68		
None	23 (68%)	25 (74%)
Bulimia nervosa	9 (27%)	8 (24%)
Other eating disorders	2 (6%)	1 (3%)
Previous referral for eating disorders, <i>n</i> = 68	18 (53%)	13 (38%)
Taking antidepressants, <i>n</i> = 68	7 (21%)	9 (27%)
Expectations of effectiveness, <i>n</i> = 68 (mean and SD on 11-point scale)		
Self-help manual	5.7 (2.6)	5.9 (2.9)
GP	5.9 (2.7)	6.0 (2.8)
Specialist clinic	7.3 (2.2)	6.9 (2.2)
Treatment preference, <i>n</i> = 63		
Self-help	7 (21%)	8 (24%)
Specialist clinic	12 (35%)	14 (41%)
No preference	13 (38%)	9 (27%)
Missing	2 (6%)	3 (9%)

patients mentioned the behaviourally-focused early stages. Four others found having a structure to follow or someone to talk to useful. The later stages of the programme were beneficial to others. However, five patients found none of the steps particularly helpful. Six experienced difficulties associated with the time and discipline involved. While GPs were generally helpful, seven patients mentioned perceived time constraints that affected their GP's ability to help them. Sixteen patients made suggestions about improving the self-help programme, including longer or set appointments, GP training, the involvement of other professionals, and meeting other patients with similar problems. Twelve of the patients who attended the clinic reported that having someone to talk to was the most helpful aspect of that treatment approach. Six patients reported that they had had difficulty attending the clinic because of work or other commitments. When asked about how the clinic treatment might be improved, four patients suggested more active participation on the part of therapists, while five suggested more frequent/longer appointments. Others suggested more contact with other patients.

Discussion

Main finding

To our knowledge, this is the first clinical trial in general practice of a self-help package for patients with bulimia nervosa in which GPs provided added support. There was no major difference in clinical outcome for patients receiving self-help or specialist care.

Strengths and limitations

The trial was pragmatic in nature and mirrored as closely as

possible usual care in the specialist clinics for eating disorders. There are, however, a number of limitations to the findings. First, recruitment was difficult because of the need for agreement by the GP and patient. Although there is incomplete evidence that patients with milder conditions were successfully recruited to the trial, this is not an argument against the findings as they stand. If such a service were implemented in general practice, only doctors and patients prepared to consider self-help would participate. Second, our principal outcome was limited to scores on a self-report scale of symptoms and behaviour for bulimia nervosa. Although less satisfactory than a full clinical assessment, we used this scale in order to reduce bias, as our research assessments of outcome were not conducted blinded to treatment group. However, even our assessment with a structured clinical tool revealed no differences between the groups in our secondary analyses. This was also true of other outcomes, such as depressive symptoms, social adjustment, and perceived helpfulness of treatment. Third, although only an equivalence trial would definitely address the question of no difference between treatment arms, it would require very large numbers of participants. We sought only to investigate whether there was a serious clinical disadvantage for patients receiving general practice-based self-help. McAlister and Sackett²² have recently proposed criteria to judge clinical trials; the aim there has been to demonstrate that the new intervention is not inferior to an established control, in this case specialist treatment. The criteria that apply to our study are:

- there is already evidence for effectiveness of the established treatment¹⁵ and therefore it cannot be claimed

Table 2. Outcomes at six and nine months. Data shown are based on last observation carried forward (n = 68).

Outcome measure (mean and SD)	Self-help in general practice	Specialist clinic
Bulimic Investigatory Test Edinburgh¹⁵		
Baseline	34.1 (6.3)	33.7 (5.9)
6 months	28.9 (11.3)	28.2 (9.9)
9 months	26.2 (12.4)	26.6 (11.4)
Beck Depression Inventory¹⁸		
Baseline	21.7 (9.7)	21.4 (10.7)
6 months	17.8 (11.7)	18.1 (10.6)
9 months	16.2 (9.9)	15.5 (10.8)
Patient-rated severity		
Baseline	7.6 (2.2)	7.1 (2.6)
6 months	6.6 (3.2)	6.1 (3.0)
9 months	5.8 (3.1)	4.8 (2.8)
Social adjustment (WLFL)¹⁹		
Baseline	2.4 (0.4)	2.5 (0.5)
6 months	2.3 (0.5)	2.3 (0.5)
9 months	2.2 (0.4)	2.2 (0.6)
Objective bulimic episodes (in previous 28 days)		
Baseline	19.0 (15.2)	20.4 (19.6)
6 months	16.4 (17.4)	12.6 (14.2)
9 months	15.0 (17.4)	14.9 (18.9)
Episodes of vomiting^a (in previous 28 days)		
Baseline	35.1 (31.0)	37.8 (33.9)
6 months	25.0 (25.6)	16.5 (18.7)
9 months	20.3 (27.0)	20.5 (23.9)
Eating Disorder Examination¹⁷		
Eating restraint		
Baseline	3.3 (1.0)	3.4 (0.8)
6 months	2.8 (1.3)	2.6 (1.4)
9 months	2.4 (1.4)	2.8 (1.1)
Eating concern		
Baseline	2.4 (1.2)	2.5 (1.0)
6 months	2.0 (1.3)	2.1 (1.3)
9 months	1.8 (1.3)	1.9 (1.2)
Weight concern		
Baseline	3.1 (1.3)	3.4 (1.3)
6 months	2.6 (1.4)	3.0 (1.2)
9 months	2.5 (1.5)	2.9 (1.3)
Shape concern		
Baseline	3.4 (1.2)	3.9 (1.1)
6 months	2.9 (1.3)	3.3 (1.2)
9 months	2.9 (1.3)	3.0 (1.3)
Global score		
Baseline	3.0 (1.0)	3.3 (0.8)
6 months	2.6 (1.2)	2.8 (1.0)
9 months	2.4 (1.2)	2.6 (1.0)

^an = 48, based on the number of patients who reported vomiting at baseline (28 self-help, 20 specialist clinic).

that both GP and specialist care are ineffective;

- patients involved were typical of those seen normally in the established service;
- we specified *a priori* the magnitude of difference we would accept before GP-supported, self-help was regarded as inferior.

Our trial is weakest on size of the sample and the magnitude of the difference we could detect in order to define GP care as disadvantageous. However, further support for our conclusions comes from the lack of serious difficulty encountered by self-help patients and the low numbers of patients withdrawing to seek specialist attention during the trial.

What the trial means

The trial endorses other reports that non-specialists can play a role in the management of patients with bulimia nervosa in non-specialist settings.^{7,13} The advantages of self-help for bulimia nervosa are reported to include lower costs, an alternative for patients who do not wish to attend specialist clinics, and easier access than traditional interventions.⁹

It could be argued that a primary care intervention might have greater success were it to occur earlier in the course of the eating disorder, before the requirement for specialist treatment. However, GPs do not readily recognise these disorders in their sub-clinical stages and require education in their management.^{11,12} Thus, we decided that a pragmatic trial would require inclusion of patients at the point they are

recognised by GPs and in most instances this is at the point of referral. However, this means that patients will have already received some primary care input and may expect a specialist intervention.

Studies of psychotherapeutic interventions for bulimia nervosa (including self-help) have reported quite varied results in terms of recovery and remission rates in participants.¹⁻¹⁰ Psychotherapy trials are often conducted under highly experimental conditions and therefore their findings may not be applicable to routine settings.²³ Our pragmatic trial reflected the realities of treating patients in busy clinics and general practices, and thus our findings indicate how these treatments would work in actual clinical practice.

The Royal College of Psychiatrists²⁴ advocated a stepped approach to the treatment of bulimia nervosa, with the least intensive taking place in non-specialist setting. Its recent report²⁵ also advocates a role for primary care services in the detection of cases of eating disorders and in the treatment of less severe cases. The advent of primary care trusts may mean that interested GPs could potentially undergo brief training and offer services on a trust-wide basis, resulting in a coordinated general practice-based approach to patient care.

In conclusion, our results indicate that a self-help approach in general practice is worth considering when patients first present to GPs with bulimia nervosa.

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