

## A randomized controlled trial of family therapy and cognitive behavior therapy guided self-care for adolescents with bulimia nervosa and related disorders

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### Health technology

The study assessed the treatment of adolescents with bulimia nervosa using family therapy compared with cognitive behaviour therapy (CBT)-guided self-care. Family therapy consisted of up to 13 one-hour sessions with close others, and two individual sessions over a 6-month period. CBT-guided self-care consisted of 10 one-hour weekly sessions, three monthly follow-up sessions, and two optional sessions with a close other.

### Type of intervention

Treatment.

### Economic study type

Cost-effectiveness analysis.

### Study population

The study population comprised patients aged 13 to 20 years meeting the DSM-IV criteria for bulimia nervosa or eating disorder not otherwise specified, and with at least one "close other" to accompany them to family treatment. Patients with a body mass index below the 10th percentile for age and gender, poor knowledge of English, learning disability, severe mental illness, or substance abuse were excluded.

### Setting

The setting was outpatient care at a tertiary care level. The economic study was carried out in the UK.

### Dates to which data relate

It was reported that recruitment took place between September 2000 and May 2003. However, the dates during which the effectiveness and resource data were collected were not reported. The price year was not reported.

### Link between effectiveness and cost data

The costing was undertaken prospectively on the same patient sample that provided the effectiveness data

### Study sample

The authors reported that their study had an 80% power to detect abstinence from bingeing and vomiting at 6 months in 30% of the patients in the guided self-care group and in 60% of the patients on family therapy. The initial sample comprised 148 patients, of whom 63 (43%) were excluded. Reasons for exclusion were failure to meet the inclusion criteria (9), did not want a close other involved (15), did not have a close other willing to be involved (3), lack of time (4), treatment factors (5), lack of availability (3) and miscellaneous reasons (7). Ten patients did not give a reason, while 7 patients (4.7%) refused to participate in research. The remaining 85 patients were randomly assigned to a treatment group, 41 being allocated to family therapy and 44 to guided self-care. However, post randomisation, 6 patients in each group did not take up treatment, 2 refused family therapy and were given individual therapy instead, 29 attended the minimum adequate treatment (at least 4 sessions) of family therapy, and 31 attended at least 4 sessions of guided self-care. The authors noted that the proportion of patients attending 4 or more sessions was similar in the two treatment groups.

### Study design

The study was a multi-centre, randomised controlled trial that was carried out in four eating disorder services. Randomisation was conducted using permuted blocks of random sizes between 4 and 10. Randomisation was undertaken using a computerised randomisation database. Allocation was concealed until the interventions were assigned. Blinding of the patients and clinicians does not appear to have been possible. However, the research assistant performing the 6- and 12-month assessments was blind to treatment assignment. Recruitment to the trial took place between September 2000 and May 2003, and the patients were followed-up at 6 and 12 months. The proportion of patients who did not complete any of the 6- or 12-month follow-up measures was 4.9% in the family therapy group and 15.9% in the guided self-care group.

### Analysis of effectiveness

The primary outcome variables were abstinence rates from bingeing and vomiting over the previous month, assessed at 6 and 12 months on the EATATE interview. Bingeing and vomiting rates were defined as "abstinence" (behaviour absent during the previous 28 days), "subclinical" (behaviour present during previous 28 days less than twice per week), and "clinical" (behaviour present during previous 28 days two or more times per week). Other outcomes included the same abstinence rates assessed on the Short Evaluation of Eating Disorders, longitudinal assessment of bingeing and vomiting by interview at baseline and at 2, 4, 6, 8 and 10 months, and other eating disorder symptoms. The analysis was conducted on an intention to treat principle. The two groups of patients were comparable in terms of their baseline sociodemographic and clinical characteristics. The authors also analysed the results after adjusting for antidepressant use at baseline.

### Effectiveness results

It was reported that a significantly higher proportion of patients in the guided self-care group were abstinent from bingeing at 6 months compared with the family therapy group, 0.42 (95% confidence interval, CI: 0.26 to 0.59) versus 0.25 (95% CI: 0.13 to 0.42).

There were no statistically significant differences between the two groups in bingeing at 12 months and in vomiting at 6 and 12 months. The results did not change after adjusting for antidepressant use at baseline.

Outcomes on the Short Evaluation of Eating Disorders were comparable to those obtained through EATATE interview.

Longitudinal assessment showed significant improvement with time for bingeing, ( $F=6.96$ ,  $df=6$ ,  $p<0.0001$ ) and vomiting, ( $F=2.39$ ,  $df=6$ ,  $p<0.02$ ).

There were no other differences between the groups in other eating disorder outcomes.

### **Clinical conclusions**

The authors concluded that, compared with family therapy, CBT-guided self-care had the slight advantage of offering a more rapid reduction of bingeing.

### **Measure of benefits used in the economic analysis**

The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed. See 'Analysis of Effectiveness' for the clinical outcomes measured. The benefits were not discounted as the maximum follow-up duration was 12 months.

### **Direct costs**

The authors estimated the costs from the perspective of the public sector and patients and their family. They presented the direct mean cost of treatment (including supervision) for the two groups between the baseline and 6-month assessments. The study reported 3-month retrospective support costs identifying direct public sector costs and direct families and patients' out-of-pocket expenses. The costs included in the analysis of support costs were presented for three 3-month periods (baseline and 6- and 12-month assessments) and for each treatment group. The costs identified were for additional education, hospital services, primary care, specialist services, medication, social care, and families and patients' out-of-pocket expenses. The resource use data were collected alongside the clinical trial through the use of the Client Service Receipt Inventory. The authors presented the average costs. Neither resource use nor the unit costs was presented. However, the authors noted that the unit costs for each service were derived from national data (Curtis and Netten 2004, see 'Other Publication of Related Interest' below for bibliographic details), or were estimated using an equivalent methodology. The price year was not explicitly stated, although it might have been 2004. Discounting was not necessary as the time horizon for the estimation of the costs was one year.

### **Statistical analysis of costs**

Comparisons between the two groups were carried out using independent-sample t-tests with two-sided significance levels, while cost-differences between periods 1 and 3 were calculated using paired t-tests. The authors reported the use of bootstrap techniques for significant differences in costs between the two groups for the three 3-month periods. This was reported through bootstrapped 95% CIs.

### **Indirect Costs**

The authors reported the average costs of lost employment for the patients and the patient's carer and the carer's partner. The discussion with respect to unit costs, resource use, price year and discounting was similar to that presented above. (see 'Direct Costs').

### **Currency**

UK pounds sterling (£).

### **Sensitivity analysis**

The examination of uncertainty was restricted to the bootstrapping of the significant differences in costs. (see 'Statistical Analysis of Quantities/Costs').

### **Estimated benefits used in the economic analysis**

See the 'Effectiveness Results' section.

### **Cost results**

The mean cost of treatment was significantly lower for guided self-care than for family therapy between the baseline and the 6-month assessments. The costs were 245.63 (standard deviation,  $SD=176.69$ ) for guided self-care versus 409.35 ( $SD=288.81$ ) for family therapy, ( $p=0.003$ ), (bootstrapped 95% CI: 58.49 to 268.95).

There were no significant differences between the groups for any of the 3-month periods.

The total public sector costs were lower for period 3 than for period 1 (mean difference 441,  $p=0.001$ ,  $n=47$ , excluding a patient with high hospital costs in the guided self-care group).

It was reported that public sector savings were not significantly different between treatments and that these details could be obtained from the authors.

The mean cost of families' and patients' out-of-pocket expenses was lower for period 3 (mean difference 74,  $p=0.032$ ).

### **Synthesis of costs and benefits**

There was no synthesis of the costs and benefits as this was a cost-consequences study.

### **Authors' conclusions**

In adolescents with bulimia nervosa or eating disorder not otherwise specified, guided self-care had a slight advantage over family therapy in terms of acceptability, outcome and treatment cost. Overall, the "cost and outcome findings suggest a cost-effectiveness advantage to guided self-care".

### **CRD COMMENTARY - Selection of comparators**

A justification was provided for the technologies compared. Family-based treatment seems to have been standard practice for adolescents with bulimia nervosa in the authors' setting. The authors noted that CBT-guided self-care could be as effective as therapist-delivered CBT, which was considered common practice for adults with bulimia nervosa. The merit of CBT-guided self-care relative to family therapy in adolescents was unknown. You should decide if these represent valid comparators in your own setting.

### **Validity of estimate of measure of effectiveness**

The analysis was based on a randomised controlled trial. The study sample was representative of the study population. The fact that the study was carried out in eating disorder services, which are the main service providers for the populations, may provide the reader with some reassurance that the sample

was typical of the study population. In addition, the patient groups were shown to be comparable at analysis. The method of randomisation, length of study and loss to follow-up were all reported, which suggests that the internal validity of the study is likely to be good. Given the nature of the intervention, blinding was only possible for the research assistants responsible for the assessments. Appropriate statistical analyses were undertaken to take account of potential biases (intention to treat, CIs and p-values reported) and confounding factors (adjustment for antidepressant use at baseline). Power calculations were reported to ensure that the size of the study sample was adequate.

#### **Validity of estimate of measure of benefit**

The authors did not derive a summary measure of benefit. In effect, a cost-consequences analysis was performed.

#### **Validity of estimate of costs**

The authors did not explicitly state the perspective of their study, but it appears to have been societal. All the relevant categories of costs and costs within each category seem to have been included in the analysis. The resource quantities were collected alongside the trial but were not presented. The source of the unit costs was presented (national data) but not the unit costs themselves, as the authors presented only average costs. Discounting was not necessary given that the time horizon for the estimation of the costs was one year. The authors evaluated uncertainty in the cost data by bootstrapping the significant differences in costs between the two treatment groups. The cost data were not reported adequately, as there was no reference to the price year or resource dates and the unit costs and resource quantities were not reported separately. There was no sensitivity analysis to address variation in the unit costs or service provision for different settings. The fact that the cost data were poorly reported may have implications for the generalisability of the study beyond the study setting

#### **Other issues**

The authors acknowledged the small sample size and the absence of a placebo control group or waiting list as the two main limitations of their study. The results were compared with the costs and outcomes of other studies conducted on adults with bulimia nervosa. This comparison showed the results to be in agreement. The authors also commented on the generalisability of their findings, stating that the study was conducted in a catchment area-based setting, where all-comers were taken. The results do not appear to have been presented selectively and the authors appear to have provided a balanced discussion. The study enrolled adolescents with bulimia nervosa and related disorders, and this was reflected in the authors' conclusions.

#### **Implications of the study**

The authors stated that, for adolescents with bulimia nervosa, guided self-care is of value as an early intervention that can be delivered in non-specialist settings. The authors made recommendation for future research, pointing out that mechanisms of change should be addressed, that the questions of whether different groups of adolescents respond differently to the two treatments should be analysed, and whether different ways of involving the family in treatment might be more beneficial and should also be studied.

#### **Source of funding**

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#### **Bibliographic details**

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#### **PubMedID**

[17403972](#)

#### **Other publications of related interest**

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Curtis L, Netten A. *The Unit Costs of Health and Social Care 2004*. Canterbury: University of Kent, Personal Social Services Research Unit; 2004.

#### **Indexing Status**

Subject indexing assigned by NLM

#### **MeSH**

Adolescent; Bulimia /diagnosis /psychology /therapy; Bulimia Nervosa /diagnosis /psychology /therapy; Cognitive Therapy /methods; Eating Disorders /diagnosis /psychology /therapy; Family Therapy /economics; Female; Follow-Up Studies; Great Britain; Health Care Costs; Humans; Longitudinal Studies; Male; Patient Dropouts; Retrospective Studies; Self Care /economics /methods; Treatment Outcome

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