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A Preliminary Randomised Controlled Trial of the Efficacy and Acceptability of a New Emotional and Social Mind Group Training vs. Standard Cognitive Behavioural Group Therapy for Bulimia Nervosa

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Introduction

Bulimia nervosa (BN) is a common and disabling disorder, with a high burden on the individual, their families and society. Cognitive Behaviour Therapy (CBT) for BN has proved an effective treatment for many sufferers. Individual and group formats of this treatment have been tested, with comparable efficacy. However, although promising, only 30 to 40% of people are symptom free at the end of treatment with CBT. Thus, the need to develop more effective treatments for this condition remains.

Evidence from different sources suggests that negative self-evaluation, poor interpersonal skills, difficulties in understanding the minds of others (the 'social mind'), a propensity to attend to negative or threatening socio-emotional information and difficulties managing and tolerating emotions may be key factors in the maintenance of bulimic symptoms. Based on these ideas we have developed a new emotional and social mind group training programme for individuals with BN and related disorders. We believe that a group format may provide powerful opportunities to normalise experiences, learn from others and explore the 'minds' of others within a safe environment.

Hypotheses

We hypothesise that a treatment targeting these factors will lead to greater positive changes in self-evaluation, interpersonal functioning, and mood, and a greater reduction in bulimic symptoms than a group-based 'standard' CBT programme.

Methods

This was a two-arm randomised controlled trial designed to evaluate the efficacy of Emotional and Social Mind Training (ESM) compared to group CBT for adults with BN. The study was approved by the Joint South London and Maudsley Hospital NHS Foundation Trust (SLaM) and Institute of Psychiatry Research Ethics Committee, Study reference number 08/H0807/83.

Participants

Patients consecutively referred to the SLaM Eating Disorders Outpatient Service by their general practitioner were offered participation if they were (a) aged 18-60, and (b) fulfilled the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV) criteria for BN or EDNOS. Patients were excluded if they had insufficient knowledge of English or literacy levels to allow understanding of the intervention materials, active suicidality, current substance dependence, diabetes or pregnancy.

Interventions

In both arms patients received a 17-session treatment (4 individual sessions, 12 group sessions, 1 follow-up session). The follow-up session was a 'booster' for the group. Group sessions took place on a weekly basis. Individual sessions were 60 and group sessions 90 minutes in length. Group sessions included eight patients and were facilitated by two therapists. The ESM and CBT group timescales and group makeup were identical.

Emotional and social mind training (ESM):

We developed a manual for ESM that specified the content of each of the twelve sessions, divided into three stages, of the programme, which was designed to address the hypothesised maintaining factors outlined above. Unlike CBT, ESM is less symptom- and more emotion and interpersonally-focused. It targets the broader pathology associated with and hypothesised to underlie BN, including poor social functioning, low self-esteem and poor emotional regulation. It focuses more on group processes, particularly interactions between group members. It also uses some experiential techniques, for example therapeutic writing.

CBT: The intervention was based on the group CBT treatment for BN developed by Chen et al.(2003). We chose this programme as the comparison treatment as we wished to match the group format of our ESM intervention whilst comparing it to CBT.

Assessments

Patients in both groups met with a research worker to complete research assessments at baseline, four months (end of weekly treatment) and six months (follow-up). The research assessor was blind to the treatment condition.

Severity of bulimic symptoms was assessed using the Eating Disorder Examination (EDE), a widely used semi-structured clinical interview. The primary outcome was EDE Global score. Secondary outcomes included the EDE subscales, objective binge episodes and episodes of self-induced vomiting in the previous four weeks, comorbid depression and anxiety, quality of life and other psychopathology linked to the ESM model maintaining factors.

Sample size, Randomisation, Blinding and Protection against Bias

Because ESM was a novel intervention, power was calculated on the basis of Chen et al. (2003). A sample size of 30 in each arm would have 80% power to detect a difference in means of -0.850 on the EDE Global score, assuming that the common standard deviation is 1.15 using a two group t-test with a 0.05 two-sided significance level. Assuming a drop-out rate of 20%, the required sample size was 38 patients per group.

Once the assessing clinician ascertained a patient was suitable for the trial and consent had been obtained, she/he was introduced to the research assessor who completed the research assessment. The patient was then be randomised by a computerised system. Randomisation was stratified for diagnosis (BN or EDNOS).

Statistical analysis

Analyses were conducted using the intention to treat principle. Mixed models were used to simultaneously model multiple post treatment outcomes of a scale or subscale.

Results

74 patients were randomized, 37 to ESM and 37 to CBT. Two patients from each arm were excluded from analysis due to lack of baseline data. This was due to these participants accidentally being randomised prematurely when the clinician took consent before the baseline research assessment.

Patients allocated to ESM and CBT did not differ significantly in terms of any recorded baseline demographics or clinical characteristics.

We found no significant difference of the treatment effect on the primary and secondary outcomes between the two treatment groups.

Patients in both treatment groups significantly improved over time on primary and secondary outcome variables, which did not differ significantly between treatments. These gains were maintained at follow-up.

Discussion

This study investigated the efficacy of Emotional and Social Mind Training (ESM) a novel, group-based treatment for bulimia nervosa, compared to group-based CBT for bulimia. Both treatments performed well and patients in each group improved significantly, but contrary to our hypothesis no differences in primary or secondary outcomes were found between the two treatments at the end of treatment or at follow-up. This gives grounds for optimism that ESM may be a viable alternative to CBT for the treatment of some individuals with BN.

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