

Study Protocol with SAP

Date: 21.1.2023

Effects of family-based treatment on adolescent outpatients treated for anorexia nervosa in the Eating Disorder Unit of Helsinki University Hospital

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Study design

The study was conducted at the outpatient department of the Eating Disorder Unit, which is a tertiary health care unit at Helsinki University Hospital's Psychiatry Department. The unit provides specialized assessment and treatment for adolescents and adults with severe eating disorders in the Helsinki region, with around 1.6 million inhabitants. At the unit, most treatment is provided at an outpatient level, but day patient and inpatient treatments are also available.

The study plan was approved by the Ethics Committee of Helsinki University Hospital before the beginning of the data collection. Patients and their guardians received information about the study both orally and in a cover letter. The participants were assured of the confidentiality and anonymity of the data and of the voluntary nature of participation. The patients and their guardians gave written confirmation of their consent.

Data for the study was gathered from the medical records of the patients at the end of treatment.

Participants

The participants and their parents were recruited from June 1, 2013, through December 31, 2017. All outpatients aged 13–18 years meeting the diagnostic criteria for Anorexia nervosa (AN) and admitted to the Family based treatment (FBT) at the Eating Disorder Unit of Helsinki University Hospital were invited to participate in the study. During the study period, 428 adolescent patients started outpatient treatment at the Eating Disorder Unit. Of those, 52 female patients diagnosed with AN, with a mean age of 14.50 ($SD = 1.31$) years, were admitted to FBT, and all of them participated in the study. The mean BMI at the beginning of treatment was 16.42 ($SD = 1.48$). On average, the participants had suffered from eating disorder symptoms for 13.29 ($SD = 8.15$) months before FBT started.

Intervention

On the patient's first visit to the unit, the attending psychiatrist usually makes a clinical decision of whether FBT is suitable for the patient. The decision is based on an assessment of the patient's medical and mental state, compliance to treatment, and family functioning. At the unit, FBT is carried out by a family therapist who has received FBT training. The duration of FBT is commonly 6–12 months, in most cases comprising 10–20 sessions. At the beginning of treatment, there are weekly sessions; later in treatment, the sessions are less frequent. The patient and their family meet their psychiatrist every four to six weeks, and the family therapist also takes part in these meetings. The treatment is implemented in accordance with the FBT treatment manual, but in a few cases, the FBT protocol was modified to have an increased number of sessions and longer duration due to the patient's clinical condition.

Treatment characteristics

The number of FBT treatment sessions ranged from 5 to 40 (*Mean* = 15.3, *SD* = 7.34). In 11 cases (21.2%), the treatment demanded more than 20 sessions. The treatment lasted up to 23 months, with an average duration of 10.25 (*SD* = 5.0) months. In all cases but one, FBT was finished in accordance with the clinical situation and treatment plan, and only one family dropped out of treatment. This withdrawal happened after session 10 of FBT when the family decided to continue the treatment at a private clinic. As the participant had participated in half of the planned FBT sessions before dropping out and had achieved change in weight and eating disorder symptoms, we did not exclude her from the study.

Assessments

Pre-treatment information about the patients' growth and health before eating disorder onset, as well as diagnostic evaluations of comorbid psychiatric disorders, was gathered from their medical records. Assessment at baseline and at the end of treatment (EOT) included weight, height, eating

disorder symptoms, and psychopathology. According to FBT protocol, weight was assessed before every treatment session. The participants were weighed in their underwear on a balance beam scale that was regularly re-calibrated. According to the World Health Organization's (WHO) definitions, normal body weight was defined as a BMI ≥ 18.5 .

The attending psychiatrists' assessments of eating disorder symptoms and psychopathology at baseline and at EOT were used. The participants' caregivers, as well as their therapist, had a chance to express their opinion regarding whether the patient benefited from FBT or not.

Statistics

The statistical analyses were performed using IBM SPSS Statistics 25. First, the data was analyzed for descriptive parameters and incidence rates of all the variables. According to skewness and kurtosis, the data was mostly normally distributed. To assess treatment outcomes, the change in BMI was tested using a two-way analysis of variance for repeated measures, and the McNemar chi-square test was used to analyze the change in the incidence rates of symptoms. Further, for comparing groups of patients at EOT, Student's *t*-test and chi-square tests were used. All analyses were two-tailed. The alpha level was set at $p \leq 0.05$. We also calculated Cohen's *d* to estimate the effect sizes of statistically significant differences in the *t*-test, interpreting an effect size of 0.2 to 0.5 as small, 0.5 to 0.8 as medium, and over 0.8 as large. For the chi-square test, the phi (ϕ) coefficient was a measure for the effect size. A value of 0.1 was considered a small effect, 0.3 a medium effect, and 0.5 a large effect.

Results

At EOT, a majority (73.1%) had achieved a normal body weight [body mass index (BMI) ≥ 18.5]. Participants with a BMI ≥ 18.5 at EOT had a significantly higher pre-treatment BMI than those with BMI < 18.5 at EOT. Participants with a BMI ≥ 18.5 at EOT showed significantly higher total weight gain during the treatment period, a significantly higher rate of regular menstrual period at EOT,

significantly lower rates of dietary restrictions, and less cognitive or behavioral symptoms of the eating disorder overall, compared to participants who did not achieve a normal body weight. In 22 cases (42.3%), there was no need for further treatment at the end of FBT. Participants who needed further treatment after FBT, compared to those who did not, showed significantly higher rates of psychiatric comorbidity, history of mental health treatment, and need for psychopharmacological treatment.

Competing interests

The authors declare no conflict of interest

List of abbreviations

AN = Anorexia nervosa

BMI = body mass index

EOT = end of treatment

FBT = Family-based treatment

WHO = World Health Organization