Protocol

Protocol Title: Affect school as complementary treatment in eating disorders
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Principal Investigator: S. Petersson, PhD
Research Team: A. Birgegård, Associate professor; K-I Perseius, Associate professor; I. Wåhlin, PhD; L. Gullbing, MSc, & K. Årestedt, Professor.

Abstract

Background: Despite solid research there remains a large group of patients with eating disorders who do not recover. Emotion dysregulation has been shown to be a feature in the different eating disorders. A manualized group intervention developed in Sweden, the Affect School, aims to enhance emotional awareness and the ability to perceive and express emotions.

Aim: The three studies aimed to test the hypothesis that participation in the Affect School as a complement to ordinary eating disorder treatment would enhance awareness and regulation of emotions and reduce alexithymia and cognitive eating disorder symptoms in a sample of transdiagnostic sample of patients with eating disorders at a Swedish specialized outpatient clinic. Another aim was to explore patients' experiences of emotions and their experiences of attending the AS.

Design: A randomized clinical trial. Forty patients with various eating disorders were conductively randomized to either participation in the Affect School as a supplement to treatment as usual (TAU), or to a TAU control group. Participants were assessed with the Eating Disorder Examination Questionnaire, the Deficits in Emotion Regulation Scale-36, and the Toronto Alexithymia Scale-20 at start, end of intervention, and at the six- and 12-month follow-ups. Nine of the patients who attended the AS were interviewed about their thoughts on emotions and about their experiences of attending the ASW. The interviews were analyzed with Thematic Analysis.

I. Background and Significance/Preliminary Studies

Several theoretical accounts of ED contain emotion (dys)regulation as a central component, placing emphasis on ED behaviors as maladaptive forms of escaping from negative emotion, and in turn negatively reinforcing those behaviors. Wonderlich et al. (2010) emphasize ED symptoms as dysfunctional, temporary emotion regulation attempts, and the need for finding alternative coping strategies is a central part of the intervention. Further, the emotion dysregulation model of Gratz and Roemer (2004) has been applied to both AN and bulimia nervosa, (BN), noting pervasive problems in several respects, including lack of strategies, impulse inhibition, tolerance/acceptance, and clarity in relation to distressing emotional states (Lavender et al., 2025). All of these models maintain that a relative inability to tolerate, label, and accept emotion is central to ED risk and maintenance. Such difficulties in sorting and recognizing emotions, and lack of adequate skills to handle or express feelings, lead to problems making positive long-term decisions according to valued goals, complicate relationships, and reduce opportunities for greater well-being (Gross, 2015; Greenberg, 2009). For example, restriction of food intake has been suggested to prevent experiencing negative emotion, while bingeing and purging suppress negative emotion once activated (Cooper, Wells, & Todd, 2004).

With these studies we wanted to test the hypothesis that participation in the Affect School as a complement to ordinary eating disorder treatment would enhance awareness and regulation of emotions and reduce alexithymia and cognitive eating disorder symptoms in a sample of patients with eating disorders at a Swedish specialized outpatient clinic.

II. Study aims

The three studies aimed to test the hypothesis that participation in the Affect School as a complement to ordinary eating disorder treatment would enhance awareness and regulation of emotions and reduce alexithymia and cognitive eating disorder symptoms in a sample of transdiagnostic sample of patients with eating disorders at a Swedish specialized outpatient clinic. Another aim was to explore patients' experiences of emotions and their experiences of attending the AS.

III. Administrative Organization

The study was conducted at a youth/adult integrated psychiatric outpatient clinic in southern Sweden, specializing in the treatment of ED. At the time of the study the clinic received approximately 150 new patients yearly. Patients with different ED were treated at the clinic and patients were diagnosed by experienced psychologists or psychotherapists who classified according to the DSM-5 by adapting suggestions from the DSM-IV-based Structured Eating Disorder Interview (SEDI) [27] to the DSM-5 criteria for ED.

IV. Study Design

Experimental design of the study: A randomized clinical trial and a qualitative interview study with semi-structured questions.

Participants and procedure

a. **Study population general description:** *Inclusion criteria* were an ED diagnosis, ongoing treatment, ≥18 years of age, and Swedish speaking, *Exclusion criteria* were inability to participate meaningfully in AS due to BMI<15, psychosis, suicidal tendencies, or acute starvation. The criteria were evaluated by experienced staff at the clinic and in cases where there was doubt, there was access to a medical doctor for further evaluation.

b. Recruitment procedures

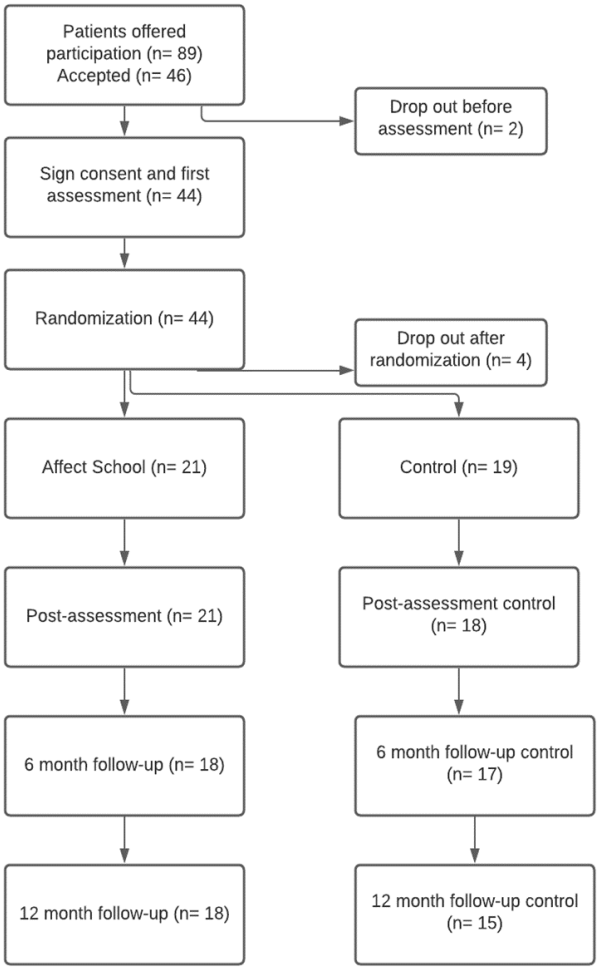

Figure 1. Flow chart of study process and participants.

Where the recruitment occurred: The study was conducted at a youth/adult integrated psychiatric outpatient clinic in southern Sweden, specializing in the treatment of ED. At the time of the study the clinic received approximately 150 new patients yearly. Patients with different ED were treated at the clinic and patients were diagnosed by experienced psychologists or psychotherapists who classified according to the DSM-5 by adapting suggestions from the DSM-IV-based Structured Eating Disorder Interview (SEDI) [27] to the DSM-5 criteria for ED.

Consent to participation was obtained by clinicians at the clinic and the interview participants were asked by the AS leaders after having finished the AS. Advertising was

only done in the clinic waiting room. The potential participants were provided written and verbal information about the AS and the study.

c. **Sample size determination and power analyses:** According to an a priori sample size calculation, the required sample size was 42 participants equally distributed between the AS group and the CG. The calculation was based on an expected a medium effect size ($f = 0.25$), $1-\beta = 0.8$, $\alpha = 0.05$, and $\rho = 0.1$.
d. **Study outcomes/endpoints:** Participants were assessed with the Eating Disorder Examination Questionnaire, the Deficits in Emotion Regulation Scale-36, and the Toronto Alexithymia Scale-20 at start, end of intervention, and at the six- and 12-month follow-ups.

V. Study Procedures

a. Screening tests/procedures are part of standard care: the EDEQ and the DERS-36. The TAS-20 was used for research purposes only.
b. **Randomization procedures:** block randomization; each block included two interventions and two controls in a random order (the process is illustrated in Figure 1.). The randomization was conducted in Stata 16.1 (StataCorp LLC, College Station, TX, USA) by an independent statistician.

Active intervention description: The Affect School, AS, originates from the Department of Psychology at Umeå University, Sweden. The initial aim was to develop a psychoeducational intervention to increase affect awareness for psychosomatic problems e.g. pain (Persson & Armelius, 2003). The method is based on the affect theories developed by Tomkins, Nathanson, and Ekman (Persson & Armelius, 2003. Since its inception the AS has been used within a number of areas in conjunction with pain treatment, e.g. stress-related problems, depression, and anxiety (Bergdahl, Armelius, & Armelius, 2020;

Bergdahl et al., 2005: Melin, Thulesius, & Svensson, 2020; Melin, Svensson, & Thulesius, 2018).

Control group: Parallel to the intervention both groups received treatment as usual which included individual psychotherapy (CBT) and in some cases also day care and/or physiotherapy. No dummy intervention was used.

VI. Safety Monitoring Plan

a. **Definition of adverse events, serious adverse events:** Suicidal tendencies, deterioration of eating disorder symptoms and/or psychological well-being.
b. **What procedures were used to monitor subject safety?:** The studies were conducted at a eating disorder unit with medical staff including nurses and medical doctors.
c. **Person responsible for identification, documentation, and reporting adverse events:** Suzanne Petersson
d. **Frequency for review of summarized safety information and who did perform the review:** These assessments were made continuously by therapists at the clinic.
e. **What stopping rules with regard to efficacy and safety were used:** Suicidal tendencies, deterioration of eating disorder symptoms and/or psychological well-being.

VII. Analysis Plan

Descriptive statistics were used to describe background characteristics and study variables. Independent sample *t*-test and Person chi-square test were used to compare differences in background characteristics between the AS group and the CG. Spearman Rank-Order Correlation was used for correlation analyses between the outcome measures at baseline. Mixed models with random intercepts were used to examine the intervention

effect on the outcome variables, one model for each outcome variable, i.e., EDE-Q (ED cognitions and behaviours), DERS-36 (emotion dysregulation), and TAS-20 (alexithymia). Group (0 = CG, 1 = AS), time (dummy-coded with the baseline assessment as reference category), and the multiplicative interaction term between them, i.e., group × time, were used as explanatory variables. The fixed effects included time, group, and group × time; the random effects included the subject level. The unstructured covariance matrix was used to model the correlations among the residuals. Due to the small sample size, restricted maximum likelihood (REML) was used to fit the models. Evaluated with histograms and normal probability plot of residuals and scatterplots of residuals versus predicted values respectively, no problems with non-normal distributed residuals or heteroscedasticity were detected. Statistical significance was set at $p < .05$. The statistical analyses were conducted in Stata 17.0 (StataCorp LLC, College Station, TX, USA) and Statistica 13.0 (StatSoft©, Tulsa, OK, USA).

VIII. Literature Cited

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