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Can adaptive treatment improve outcomes in family-based therapy for adolescents with anorexia nervosa? Feasibility and treatment effects of a multi-site treatment study☆

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ABSTRACT

Objective: Adolescents with Anorexia Nervosa (AN), treated with family-based treatment (FBT) who fail to gain 2.3 kg by the fourth week of treatment have a 40–50% lower chance of recovery than those who do. Because of the high risk of developing enduring AN, improving outcomes in this group of poor responders is essential. This study examines the feasibility and effects of a novel adaptive treatment (i.e., Intensive Parental Coaching-IPC) aimed at enhancing parental self-efficacy related to re-feeding skills in poor early responders to FBT.

Method: 45 adolescents (12–18 years of age) meeting *DSM TR IV* criteria for AN were randomized in an unbalanced design (10 to standard FBT; 35 to the adaptive arm). Attrition, suitability, expectancy rates, weight change, and psychopathology were compared between groups.

Outcomes: There were no differences in rates of attrition, suitability, expectancy ratings, or most clinical outcomes between randomized groups. However, the group of poor early responders that received IPC achieved full weight restoration (>95% of expected mean BMI) by EOT at similar rates as those who had responded early.

Conclusions: The results of this study suggest that it is feasible to use an adaptive design to study the treatment effect of IPC for those who do not gain adequate weight by session 4 of FBT. The results also suggest that using IPC for poor early responders significantly improves weight recovery rates to levels comparable to those who respond early. A sufficiently powered study is needed to confirm these promising findings.

Anorexia Nervosa (AN) is a life threatening disorder that usually onsets during adolescence. Studies suggest that AN in youth is responsive to early treatment (Le Grange, Accurso, Lock, Agras, & Bryson, 2014; Treasure & Russell, 2011), but becomes highly resistant to treatment once it has taken an enduring course (Touyz et al., 2013). Though treatment studies of AN remain limited, several randomized clinical trials support the effectiveness of a specific form of family therapy (Family-Based Treatment—FBT) for the disorder in adolescents (Lock, 2015). In these studies, FBT leads to recovery in between 35 and 50% of participants by the end of treatment (EOT). Follow-up studies suggest that once recovered, few relapse, but among those who do not recover, the majority (75%) were not recovered 3–5 years post treatment (Le Grange, Lock, et al., 2014; Lock, Couturier, & Agras, 2006).

To advance precision medicine by matching treatments to specific patient groups (McMahon & Insel, 2012), and because of the high risk of developing enduring AN and the associated poor prognosis, there is a need to develop and test novel interventions for those who are unlikely to recover with standard FBT. Previous studies of FBT found that a weight gain of less than 2.3 kg (4.8 lbs)

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by session 4 of treatment predicted poorer outcome, with about 75% not achieving weight restoration by EOT (Doyle, Le Grange, Loeb, Celio-Doyle, & Crosby, 2010; Le Grange, Accurso, et al., 2014; Madden et al., 2015). Thus, an alternative way to improve outcomes would be to address this group of poor early responders using a stepped care adaptive intervention for those that needed it. In the current study, we developed a novel 3 session intervention that is conceptually and procedurally compatible with FBT called Intensive Parental Coaching (IPC). IPC provides *in vivo* coaching that specifically targets parental self-efficacy related to re-feeding strategies (detailed below) so that their child starts to regain weight faster (Darcy et al., 2013; Doyle et al., 2010; White et al., 2015).

Because treatment research in AN is fraught with practical challenges related to recruitment, treatment acceptability, and attrition (Lock et al., 2012), our initial aim was to examine whether a multi-site randomized clinical trial (RCT) using an adaptive or stepped care approach was feasible and acceptable to families with an adolescent with AN. We hypothesized that data would support the feasibility and acceptability of the design by demonstrating similar recruitment, retention and suitability ratings in both treatment arms. Our second aim was to gather preliminary data on the treatment effect of IPC in the context of FBT for early poor responders. In addition, previous studies suggest that improving parental self-efficacy is a possible mechanism leading to successful re-feeding efforts by parents and weight gain in their child with AN (Byrne, Accurso, Arnow, Lock, & Le Grange, 2015; White et al., 2015). We therefore also examined changes in parental self-efficacy as a treatment target in FBT and FBT + IPC. This pilot study was not powered to examine treatment effects between the randomized groups, but we were able to compare the weight gain during treatment of early poor responders in this study to an independent historical sample of adolescents treated within another RCT who also did not respond early to FBT, but did not receive any additional parental coaching.

1. Method

1.1. Participants

Participants for this two-site study were recruited by informing colleagues, organizations and other clinics treating eating disorders of our protocol. The study was also publicized on the Internet as well as in the local media. Potential participants could be included in the study if they were adolescents between 12 and 18 years of age living with their families and met DSM-IV criteria for AN, except for the amenorrhea requirement. Participants also had to be medically stable for outpatient treatment according to the recommended thresholds of the American Academy of Pediatrics and the Society of Adolescent Medicine (Golden et al., 2003). Potential participants taking a psychotropic medication for a co-morbid psychiatric condition (i.e., depression or anxiety), were entered into the study if they met all eligibility criteria while on stable dose of psychotropic medication for at least 8 weeks. Participants were excluded if they had an associated physical illness that necessitated hospitalization, psychotic illness/other mental illness requiring hospitalization, were dependent on drugs or alcohol or had physical conditions (e.g., diabetes mellitus, pregnancy) known to influence eating or weight. Participants were also excluded if they had previous FBT. Participants were withdrawn from the study if they were hospitalized for more than 30 days during the study or if they missed more than 4 consecutive therapy sessions.

Human subjects approvals were obtained from both participating institutional IRBs. After consent by parents and adolescents over the age of 18 years (and assent in adolescents under the age of 18 years), participants were randomized in a ratio of 3.5:1 to increase the number of participants in the experimental (adaptive care arm) to maximize data about feasibility, suitability, and treatment effects of the novel focused parental coaching (Efron, 1971). There were two planned assessments (baseline and end of treatment—EOT). In addition, weight and height were obtained at each session. Suitability and expectancy ratings by the participants and parents were conducted at the conclusion of sessions at 2, 4, 6, and 8. Parental self-efficacy was rated at the conclusions of sessions 2–8. Independent trained assessors conducted assessments blind to participant randomization. See Fig. 1 for our CONSORT chart.

1.2. Measures

The following measures were used to assess study outcomes:

1. Recruitment and attrition rates.
2. *Weight* and *height* were recorded at each time points on calibrated digital scales and stadiometer. Percentile body weight was calculated using an Excel program based on the CDC tables for height, weight, gender, age, and percent expected body weight (EBW).
3. *Therapy Suitability and Patient Expectancy (TSPE)*: Patients' and parental perceptions of the suitability of the treatment provided were rated on a visual analogue scale (0–10) at sessions 2, 4, 6, 8, and end of treatment.
4. *Eating Disorder Examination (EDE)* (Cooper & Fairburn, 1987): The EDE is a standardized investigator-based interview that measures the severity of the characteristic psychopathology of eating disorders.
5. Schedule for Affective Disorders and Schizophrenia for School-Aged Children (6–18 years) – Present and Lifetime Version (K-SADS-PL) (Kaufman et al., 1997): The KSADS-PL was adapted from the K-SADS-P that surveys additional disorders not assessed in the K-SADS, contains improved probes and anchor points, includes diagnosis specific impairment ratings and generates DSM-IV diagnoses.

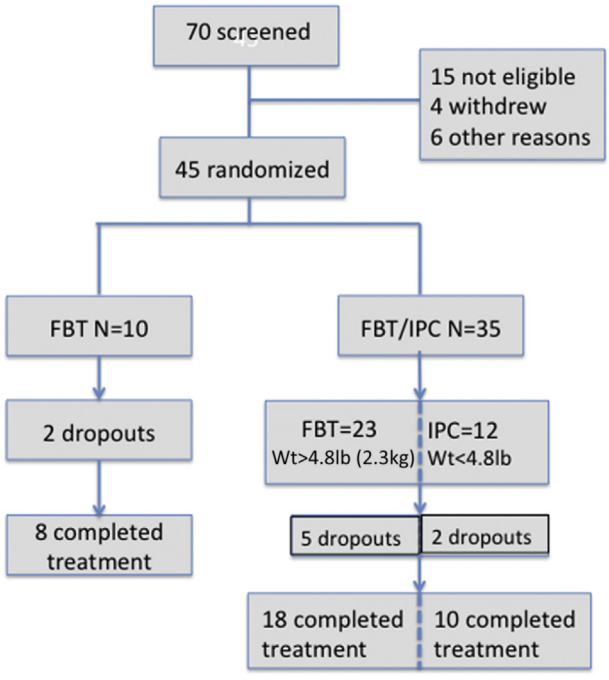

Fig. 1. Consort chart.