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Feasibility Study Comparing Standard FBT and Guided Self-Help FBT for Adolescent Anorexia Nervosa

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Study Protocol and Statistic Analysis Plan

While Family Based Treatment (FBT) is an evidenced based therapy for adolescents with Anorexia Nervosa (AN; Lock and Le Grange 2013; Lock 2018), patients struggle to access the treatment. A preliminary case series implementing a parent's only guided self-help version of FBT (GSH-FBT) aimed to address this gap in care (Lock J, Darcy A et al. 2017). This study expands on the previous data to determine the feasibility of GSH-FBT by piloting a randomized controlled trial of GSH-FBT as opposed to virtual FBT (FBT-V). Specifically, the pilot study aims to compare GSH-FBT to FBT-V through (1) recruitment and retention rates, (2) weight change and eating disorder symptoms, (3) parental self-efficacy of refeeding, and (4) efficiency (therapist time over participant outcomes).

This study recruited 40 families with an adolescent between the age of 12 to 18 diagnosed with DSM-V criteria for AN. Recruited occurred at two sites: Stanford University and McMaster University. Families were randomized to either GSH-FBT or FBT-V. GSH-FBT used an online platform with lectures, readings, and home-work assignments. Over the course of 4-6 months, parents were instructed to complete online modules and attend twelve 20 to minute coaching sessions with a trained therapist "coach." The coach would direct parents to specific content, answer questions about the material, and assign homework. FBT-V included fifteen 60 minutes sessions of FBT conducted by a trained therapist over a secure online video conferencing system. As is standard for FBT, the entire family would attend session in FBT-V.

Data was collected on participants from participants at three major time points, baseline (BL), end of treatment (EOT), and 3-month follow-up. Weight data was also collected for each session (as is in-line with FBT). Expected Mean Body Weight (EBW) was used to assess weight restoration. Online surveys were administered after sessions 1 through 8 and all major time points. Surveys would consist of the measures—Parents versus Anorexia Nervosa Scale (Rhodes, Baillie, Brown, & Madden, 2005), Therapy Suitability and Patient Expectancy, Beck Anxiety Inventory (Beck and Steer 1993), Beck Depression Inventory-11 (Beck, Steer et al. 1996), and the Helping Alliance Questionnaire (deWeert-Van Oene, de Jong et al. 1999). All major assessment timepoints would include the Eating Disorder Examination (EDE; Cooper and Fairburn 1987, Fairburn, Cooper et al. 2008) conducted by assessor unaware of treatment condition.

Analysis was conducted on SPSS Version 27. A descriptive analysis was used to examine within and between group effects at the major time points and bi-weekly mediator assessments during the first 8 weeks of treatment. As the study is not adequately powered, descriptive statistics and effect size are reported. Correlations were used to assess the bi-weekly mediator assessment. In line with intent to treat principles, percentages are based on a denominator of the total N per arm barring investigator withdrawals. Efficiency was calculated through average therapist time per participant over the EDE outcome and EBW.