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Comparing family-based treatment with inpatient treatment in youth with anorexia nervosa eligible for hospitalization: A 12-month feasibility study

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Abstract

Objective: Family-based treatment (FBT) for youth with anorexia nervosa (AN), has not been compared to inpatient, multimodal treatment (IMT).

Method: Prospective, non-randomized pilot feasibility study of adolescents with AN receiving FBT ($n = 31$), and as a reference point for exploratory outcome comparisons IMT ($n = 31$), matched for baseline age and percent median BMI (%mBMI). Feasibility of FBT in youth fulfilling criteria for IMT was assessed via study recruitment and retention rates; acceptability via drop-out and caregiver strain; safety via adverse events; preliminary treatment effectiveness between groups was assessed via a change in %mBMI, AN psychopathology (Eating Disorder Examination-Questionnaire, EDE-Q), and hospital days, over 12 months with intent-to-treat, mixed models repeated measures analyses covering post-intervention usual care until 12 months.

Results: Taking into account that 8 FBT patients (25.8%) crossed over to IMT due to lack of weight gain or psychiatric concerns, FBT and IMT were similarly feasible,

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acceptable, and safe, apart from more physical antagonism toward others in FBT ($p = .010$). FBT lasted longer (median [interquartile range, IQR]; 33.6 [17.4, 49.9] vs. 17.3 [14.4, 24] weeks, $p < .001$), but required fewer hospital days than IMT (median, [IQR], FBT = 1 [0, 16] vs. IMT = 123 [101, 180], $p < .001$). Baseline comorbidity-adjusted changes over 12 months did not differ between groups in %mBMI (FBT = 12.6 ± 11.9 vs. IMT = 13.7 ± 9.1; $p = .702$) and EDE-Q global score (median, [IQR]; FBT = −1.2 [−2.3, 0.2] vs. IMT = −1.3 [−2.8, −0.4]; $p = .733$).

Discussion: Implementing FBT in this pilot study was feasible, acceptable, and safe for youth eligible for IMT according to German S3 guidelines. Non-inferiority of FBT versus IMT requires confirmation in a sufficiently large multicenter RCT.

Public Significance: This pilot study with 62 adolescent patients with anorexia nervosa demonstrated that for 2/3rd of patients eligible for a long hospitalization in the German health care system, outpatient, Family-based treatment (FBT) was a safe and feasible treatment alternative. Over 12 months, FBT lead to similar weight gain and reduction in eating disorder cognitions as inpatient treatment with fewer hospital days. This pilot study needs to be followed up by a larger, multicenter trial.

KEYWORDS

adolescents, eating disorders, evidence-based treatment, hospitalization, outpatient treatment

1 | INTRODUCTION

Anorexia nervosa (AN) is a mental disorder characterized by the restricted energy intake, underweight, fear of weight gain, and distorted body image. AN usually emerges during adolescence (Solmi et al., 2022) and involves multiple somatic, psychological, and behavioral consequences of starvation. While the German S3-guidelines recommend normalization of weight and eating behavior as key aims of treatment (Herpertz et al., 2019), treatment settings and strategies for youth with AN differ. Practice guidelines from the United States (Crone et al., 2023), and the United Kingdom (NICE guidelines, 2017) recommend family-based treatment (FBT) as first-line treatment, because evidence levels for FBT and Maudsley Family Therapy are higher than for cognitive behavioral, adolescent focused or family systems therapy (Zipfel et al., 2015). Meta-analyses investigating the effects of different forms of therapy have shown inconsistent results, that is, no superiority of a specific approach when analyzing adults and adolescents separately (Zeeck et al., 2018) versus FBT outperforming active control interventions (Monteleone et al., 2022).

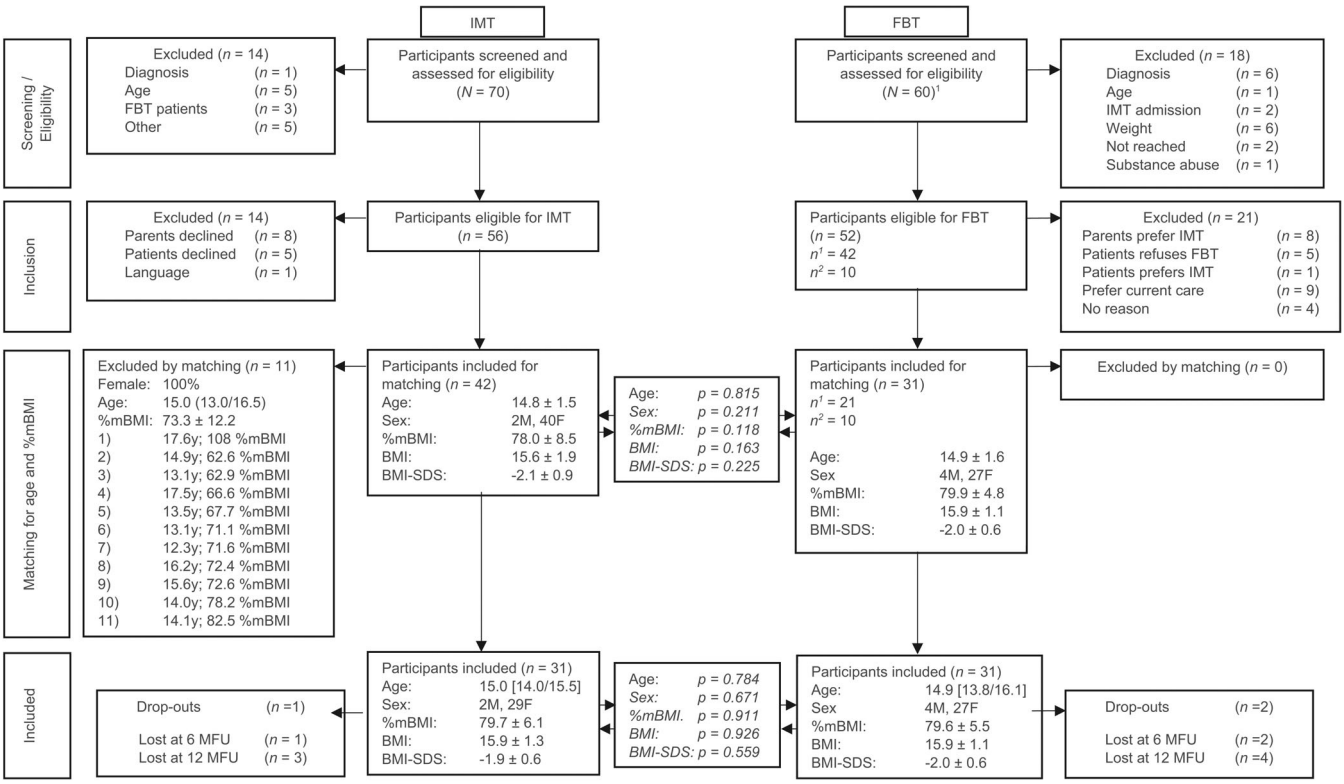
In the German S3-guidelines that are currently revised, treatments for youth with AN include individual cognitive behavioral and psychodynamic therapy as reimbursable in the German healthcare system (Herpertz et al., 2019). For severely ill patients, defined as (i) presenting with a BMI below the third age- and sex-adjusted percentile, or (ii) also at higher weight when presenting with a significant comorbid disorder, rapid weight loss or failure to gain weight after 3 months of outpatient care the German S3-guidelines (Herpertz et al., 2019) recommend inpatient, multimodal treatment (IMT) aiming at weight normalization and amelioration of eating disorder (ED) psychopathology in the hospital setting. As a consequence of these guidelines and the longstanding *modus operandi*, hospitalization of the above-defined patient group for 3–6 months is common in Germany (Focker et al., 2017). This approach culturally differs from many other countries where it is considered important to preferentially treat the disorder in the home environment as soon as possible. A wide variation in duration of hospitalization (e.g., a few weeks vs. many months) for youth with AN (Kan et al., 2021) that is not necessarily related to patient characteristics (Richard & B6, 2005) has been a long-standing debate (Madden et al., 2015). FBT is an evidence-based and manualized form of family therapy, which was developed for medically stable youth with EDs (Lock & Le Grange, 2013). So far, FBT has not been compared to IMT. A retrospective, literature-based comparison of aggregated weight trajectories in 7 RCTs using either FBT or IMT was limited due to differences in patient characteristics of the study cohorts, most notably higher baseline weight of the patients receiving FBT in the United States versus IMT in continental Europe (Haas et al., 2022). Therefore, FBT was compared with IMT using naturalistic patient data from two cohorts, one receiving FBT in the United States and the other receiving IMT in Germany (Nadler et al., 2022). This study demonstrated that outpatients receiving FBT in the United States started treatment at a higher body weight than inpatients receiving IMT in Germany and that in comparable subgroups of patients with respect to age and baseline percent median BMI (%mBMI), weight trajectories over 6 months were similar in the FBT and IMT subgroups. However, the time the FBT patients in the United States spent in hospital was unknown for most of the cohort, and ED psychopathology could not be compared. Given these preliminary findings and the desire to treat youth in the least restrictive setting, an RCT is needed comparing FBT and IMT in the same healthcare setting. Before an adequately powered,

multicenter RCT can be conducted, a pilot study is required to assess the feasibility of FBT in the target population, that is, patients eligible for IMT in Germany. Therefore, this pilot study aimed to: (i) assess the feasibility, acceptability, and safety of FBT in a German university clinic, and (ii) generate data on treatment characteristics and required sample size for a subsequent RCT. To be able to interpret the feasibility, acceptability, and safety data as well as preliminary effectiveness outcomes in FBT, we added an exploratory reference comparison group of IMT patients concurrently treated at the same university center, matched for baseline age and %mBMI. Based on the former indirect preliminary comparisons (Haas et al., 2022; Nadler et al., 2022), we hypothesized that for youth with AN eligible for IMT, FBT would be a feasible, acceptable, and safe treatment and that at 12 month exploratory effectiveness intent-to-treat follow-up, changes in %mBMI and AN psychopathology would be comparable between FBT and IMT, but achieved with less inpatient days in FBT.

2 | METHOD

2.1 | Study populations

Recruitment for FBT took place between January 06, 2020 and May 21, 2021 mainly from the waiting lists of two inpatient units in Berlin, Germany, specializing in the treatment of ED (Figure 1). These families had the choice to either start FBT or to remain on the waiting list for inpatient treatment but were not immediately offered the choice of IMT. Inclusion criteria were age 11–17 years, a diagnosis of AN (MINI International Neuropsychiatric Interview) of the subtypes restrictive and binge-purge AN, living within a distance to the study site that could be covered by car for face-to-face FBT sessions, and knowledge of the German language, so that the therapy could be delivered in German. All FBT patients fulfilled the criteria associated with a recommendation for inpatient treatment according to the German S3 guidelines (Herpertz et al., 2019) operationalized as BMI below the third Percentile OR BMI below the 10th BMI percentile AND the presence of a significant comorbid disorder OR rapid weight loss (>20% of body weight in the past 6 months) OR no weight gain despite 3 months of outpatient treatment. FBT patients were medically stable as defined by the Guidelines of the Society of Adolescent Health and Medicine (Golden et al., 2003), that is, a %mBMI >75, daytime heart rate > 50 bpm, blood pressure > 80/50 mmHg and body temperature > 35.6°C. When these criteria were not met, patients were medically stabilized either in the pediatric or the child and adolescent psychiatry (CAP) unit (counting these days to the total hospital days). If the second attempt of FBT did not achieve sufficient weight progress based on clinical judgment, a transfer to IMT was advised as recommended in the German S3 guidelines (Herpertz et al., 2019) to reduce the risk of a chronic course of AN.



IMT, inpatient multimodal treatment; FBT, Familiy-Based Treatment; y, years old; %mBMI, percent median BMI; F, female; M, male; BMI-SDS, Body Mass Index Standard Deviation Score; MFU, months follow-up; [1]FBT offered by team, included: $n = 21$, Waiting list 2 CAP wards: $n = 17$, Pediatric ward: $n = 4$; [2]Parents actively sought FBT treatment, included: $n = 10$, parents self-help network: $n = 5$, Charité outpatient: $n = 1$, internet: $n = 4$.

FIGURE 1 Recruitment and matching.

IMT patients included in this study were recruited consecutively from the same two inpatient child and adolescent psychiatric wards between October 29, 2018 and March 10, 2021, as part of a separate study assessing the naturalistic outcomes of IMT offered of usual clinical care (EA2/051/18). These patients were not offered FBT. The IMT study was offered after admission which was scheduled based on the severity of the illness. When combining the data from the FBT and IMT studies, we oversampled IMT patients to allow for matching to the FBT patients without excluding any patient from the smaller FBT group. The only predefined exclusion criteria for both groups were acute psychosis and any medical condition in addition to AN, which might significantly affect weight outcome. All legal guardians provided written informed consent and participants provided written assent before participating in this study. The study was approved by the institutional ethics committee (EA2/133/19) and conducted in accordance with the Declaration of Helsinki on "Ethical Principles for Medical Research Involving Human Subjects."

2.2 | Outcome parameters

Key primary outcomes were the feasibility (study recruitment and retention), acceptability (treatment dropout and caregiver strain), and safety (adverse events). Secondary and preliminary outcomes were the change in %mBMI, patient-reported AN-related and further psychopathology, and hospital days over 12 months, the latter as a cost-effectiveness proxy.

2.3 | Assessments

All assessed parameters, assessment methods, and time points are presented in Table 1. Weight trajectories were assessed with a change in %mBMI. Additionally, BMI, BMI-Standard Deviation Score (SDS), and BMI percentiles are reported.

TABLE 1 Methodological overview of study assessments and timing of study visits.

	Measure	Timing
Feasibility		
Recruitment rate	Number of patients included into the study per month	Before baseline
Treatment acceptability		
Treatment drop-out	FBT: patients who received less than 10 FBT sessions IMT: discharged against medical advice	EOT
Caregiver strain	German translation of the caregiver strain questionnaire (Brannan, 1997)	0, 6, 12 M and EOT
Treatment safety		
Adverse events	Self-devised questionnaire (see Appendix 1)	FBT: 12 M IMT: retrospective chart review
Body weight metrics		
BMI	kg/m^2	0, 6, 12 M and EOT
BMI-SDS	https://adipositas-gesellschaft.de/aga/bmi4kids/	0, 6, 12 M and EOT
%mBMI	(Body weight in kg *100)/ lower margin of the 50th BMI-Percentile of the individual patient	0, 6, 12 M and EOT
BMI percentile	According to Kromeyer-Hauschildt (2001)	0, 6, 12 M and EOT
Psychopathology		
DSM-5 AN Diagnosis	MINI International Neuropsychiatric Interview (Sheehan et al., 1998)	Baseline
AN related psychopathology	Eating Disorder Examination Questionnaire (EDE-Q) (Hilbert, 2004)	0, 6, 12 M and EOT
Compulsive exercise	Compulsive Exercise Test (CET) (Schlegl, Vierl, Kolar, Dittmer, & Voderholzer, 2022)	0, 6, 12 M and EOT
Depression, stress, anxiety	Depression, Anxiety and Stress Scales (DASS-21) (Nilges 2021)	0, 6, 12 M and EOT
Clinical impairment	Clinical Impairment Assessment (CIA) (Bohn et al., 2008)	0, 6, 12 M and EOT
Socio-economic status (parents' education and profession)	Self-devised questionnaire based on Hollingshead and McMaster (Hoebel, Muters, Kuntz, Lange, & Lampert, 2015)	Baseline

Abbreviations: AN, anorexia nervosa; BMI, body mass index; DSM, diagnostic and statistical manual of disease; F/U, follow-up; M, months; SDS, Standard Deviation Score.

2.4 | Interventions

Manualized FBT (Lock & Le Grange, 2013) was offered by 9 clinicians (6 licensed CAP psychologists, 2 licensed child/adolescent psychiatrists, and one child/adolescent psychologist in training) who were trained in the foundation model of FBT by one of the senior authors (DLG) who has extensive experience in training clinicians in FBT. In FBT, the parents are closely involved from the beginning of treatment and are coached to support their child's weight restoration at home. In the first phase of treatment, the therapist guides the parents to take over the responsibility for all meals. In phase 2, this responsibility is handed back to the young patient step by step. The third phase of treatment focuses on the adolescent's topics. The clinicians worked in a treatment team including medical staff, a psychiatrist, and a dietician. If the clinical team perceived weight gain as not sufficient (not a standardized definition but judged on a case-by-case decision), FBT was ended and IMT recommended to the family. Regular conclusion of FBT occurred once the patient had completed the 3 treatment phases, with the therapist targeting this aim within about 20 sessions. In case the family or the therapist perceived the need for further, individual psychotherapy following FBT, the treating clinician supported the family to make this transfer. While a weight gain of about 1 kg/week is expected in FBT, concrete numbers are not communicated to the families.

The IMT group was treated in the same University department and under supervision by the same attending and chief of staff (CUC), using unified treatment approaches. The weight target was set at gaining at least 700 g/week. All meals were supervised by nursing staff, and if meals were not finished, liquid food was offered as meal replacement. In case of persistent food refusal over >2 days, a nasogastric tube was prescribed. Generally, the target weight for discharge was set at the 25th BMI percentile, yet individual variation due to lower or higher premorbid body weight was possible. The treatment paradigm included individual, patient-focused psychotherapy 2 × 45 min/week (cognitive behavioral or psychodynamic therapy), a 1 h family session every 2 weeks for 45–60 min to discuss the patient's progress, body-oriented therapy and nutritional counseling (both 1 h/week), and total of 6–8 h of group therapy (nutrition counseling, yoga, 0.5–2 h/week sports therapy adjusted for the underweight state, body-oriented therapy, relaxation, mindfulness, and skills training) by a multidisciplinary team experienced in the treatment of EDs. The patients attended the clinic school and along with re-alimentation and weight gain, became more independent in choosing food varieties or spending time outside the hospital. The required weight maintenance phase before discharge from the ward was usually ≥2 weeks. Generally, weekly ambulatory psychotherapy was recommended at discharge as post hospitalization care, which occurred in usual care outpatient settings. There were no standardized rehospitalization criteria in this observational study.

2.5 | Statistical analysis

To adjust for significant differences in baseline age and %mBMI, IMT patients were manually matched to the 31 patients who received FBT. Analyses were conducted using R version 4.0.3 (2020-10-10). All analyses were two-sided with alpha = .05. All continuous data are presented as mean ± standard deviation (SD) if normally distributed, otherwise as median and interquartile [IQR; 25th/75th percentile] range. Group differences were computed with either a *t*-test or Wilcoxon-test according to data distribution. Categorical data are reported with absolute frequency (relative frequency %) and were tested by Fisher's exact test. Longitudinal data reflecting changes over time were analyzed in the framework of linear mixed effect models when following a normal distribution, cumulative link mixed models for ordinal data, and generalized mixed effect models for categorical data. These methods make use of all available information, as they can handle missing values at one or more time points. Independent variables in these analyses were treatment, time, and interaction of treatment and time, testing if therapy-induced changes are comparable or different. They also allow adjustments to covariates as, for example, baseline traits as indicated later. Between-group comparisons were conducted with an intent-to-treat (ITT) approach assuming missing at random and were controlled for unmatched characteristics at baseline that could affect the outcome (e.g., comorbid disorders). All parameters that resulted in $p < .1$ in prior univariate analysis were included as covariates.

2.6 | Subgroup analysis

The ITT analysis was followed by a per-protocol analysis and exploratory comparison of patients who did vs did not cross over to IMT using the following classification:

Per protocol FBT subgroup (FBT^{PP}): patients who received FBT with/without IMT and who received IMT solely for stabilization before starting or returning to FBT.

Cross-over FBT to IMT subgroup ($FBT^{C/O}$): patients who changed from FBT to IMT and received inpatient treatment for other reasons than just targeted for medical stabilization (related to AN and/or severe psychiatric comorbidities).

Study drop-out: FBT: <10 FBT sessions in accordance with a prior FBT RCT (Le Grange et al., 2016).

3 | RESULTS

3.1 | Patient population

The patient recruitment flow chart is shown in Figure 1. Baseline clinical characteristics of the %mBMI and age-matched FBT and IMT samples are shown in Table 2. The overall sample ($N = 62$) were mostly female ($N = 56$, 90.3%) and aged 15.0 (13.9/16.1) years; 56 (90.3%) had restricting AN, 6 (9.7%) binge-purge AN. Before matching, the mean percent mBMI of all 42 IMT patients was 78.0% ± 8.5%. Excluding 11 IMT patients (Figure 1) with a %mBMI = 73.3% ± 12.2% resulted in equal %mBMI of the matched FBT and IMT subgroups (Figure 1, Tables S3, 2). Baseline demographic and clinical characteristics of included versus excluded IMT patients in comparison with the

TABLE 2 Patient baseline characteristics.

	Total ($N = 62$)	FBT ($N = 31$)	IMT ($N = 31$)	p-value, FBT versus IMT IMT
Female sex	56 (90.3%)	27 (87.1%)	29 (93.6%)	.671
Age (years)	15.0 [13.9, 16.1]	14.9 [13.8, 16.1]	15.0 [14.0, 15.5]	.784
Subtype				.390
Restricting AN	56 (90.3%)	29 (93.5%)	27 (87.1%)	1.000
Binge-purge AN	6 (9.7%)	2 (6.5%)	4 (12.9%)	.671
Duration of illness (months)	11.0 [7.0, 17.3]	9.5 [6.0, 15.1]	12.0 [8.2, 17.8]	.439
Previous hosp. adm. (years)		12 (38.7%)	15 (48.4%)	.698
0	34 (54.8%)	19 (61.3%)	16 (51.6%)	.609
1	16 (25.8%)	8 (25.8%)	8 (25.8%)	1.000
2	8 (12.9%)	2 (6.5%)	5 (16.1%)	.425
3	4 (6.5%)	2 (6.5%)	2 (6.5%)	1.000
Menstrual status				.647
Primary amenorrhea	14 (25.0%)	6 (22.2%)	8 (27.6%)	.761
Secondary amenorrhea	35 (62.5%)	19 (70.4%)	16 (55.2%)	.279
Menses intact	4 (7.1%)	1 (3.7%)	3 (10.3%)	.612
Contraceptives	3 (5.4%)	1 (3.7%)	2 (6.9%)	1.000
EDE-Q global score		3.36 [1.79, 4.32]	4.03 [1.72, 4.95]	.335
Restraint	3.20 [1.25, 4.80]	2.40 [1.20, 4.53]	3.40 [1.43, 4.80]	.148
Eating concern	2.60 [1.58, 4.00]	2.80 [1.60, 3.60]	2.60 [1.43, 4.17]	.756
Weight concern	3.40 [1.38, 5.02]	3.40 [1.40, 4.77]	3.60 [1.20, 5.20]	.682
Shape concern	4.45 [2.59, 5.63]	4.38 [2.67, 5.23]	4.63 [2.15, 5.73]	.811
BMI (kg/m^2)	15.9 ± 1.2	15.9 ± 1.1	15.9 ± 1.3	.926
BMI-SDS	−1.95 ± 0.61	−1.98 ± 0.60	−1.89 ± 0.61	.559
BMI Percentile	4.74 ± 6.24	4.32 ± 5.39	5.35 ± 7.00	.518
%mBMI	79.6 ± 5.5	79.9 ± 4.8	79.7 ± 6.1	.911
≥ 1 comorbid disorder (y)	37 (59.7%)	15 (48.4%)	23 (74.2%)	.067
Depression	24 (39.3%)	8 (26.7%)	17 (54.8%)	.037
OCD	14 (22.9%)	6 (20.0%)	8 (25.8%)	.762
Borderline personality traits	7 (11.5%)	0 (0%)	7 (22.6%)	.011
Intake ≥1 psych. med. (y)	12 (19.4%)	4 (12.9%)	7 (22.6%)	.508
SSRI	5 (8.1%)	1 (3.2%)	4 (12.9%)	.354
SNRI	1 (1.6%)	1 (3.2%)	0 (0%)	1.000
Antipsychotic med.	5 (8.1%)	1 (3.2%)	3 (9.7%)	.612
Suicidality (years)	28 (45.9%)	11 (36.7%)	17 (54.8%)	.202
Wish to be dead	13 (21.3%)	7 (23.3%)	5 (16.1%)	.534
Vague plans	8 (13.1%)	3 (10%)	6 (19.4%)	.473
Concrete plans	3 (4.9%)	1 (3.3%)	2 (6.5%)	1.000
Suicide attempt	4 (6.6%)	0 (0%)	4 (12.9%)	.113

Note: Values are means ± SD (range) or median [first quartile, third quartile].
Abbreviations: AN, anorexia nervosa; BMI, body mass index; EDE-Q, Eating Disorder Examination Questionnaire; FBT, family-based treatment; IMT, inpatient multimodal treatment; OCD, obsessive compulsive disorder; SSRI, selective serotonin reuptake inhibitors; SNRI, serotonin and norepinephrine reuptake inhibitors.

FBT patients are shown in Table S3. Despite matching, some differences remained: the IMT group had a higher proportion of comorbid depression ($p = .067$) and borderline traits ($p = .011$). The remaining baseline characteristics, including family status, patients' residence, and socioeconomic status (Table S2), were similar across treatment groups.

3.2 | Treatment characteristics

Treatment characteristics are shown in Table 3. FBT was delivered over 33.6 weeks [17.4, 49.9], while IMT was delivered over 17.3 weeks [14.4, 24], $p < .001$). FBT patients (missing data: $n = 2$) received 19 ± 5 FBT Sessions of 60–90 (average: 75) minutes, equaling 24 ± 7 h (0.8 ± 0.3 h/week) of therapy, while the IMT patients (missing data: $n = 13$) received 22 ± 7 h (1.4 ± 0.4 h/week) of individual psychotherapy ($p = .767$ and $p < .001$, respectively). After discharge from IMT, 26 of 31 (83.9%) of the IMT patients continued with individual outpatient psychotherapy sessions (19 patients with weekly sessions, 7 patients with 2 sessions per week). Uptake of psychotherapy between end of treatment (EOT) and 12 months was not assessed in the FBT group. In FBT, 60.3% of the sessions were delivered online due to the COVID-19 pandemic (data available for 25 patients). There was no linear association between percent online FBT delivery and change of %mBMI ($r = .262$, $p = .216$) or change of EDE-Q global score ($r = .183$, $p = .391$) between baseline and 12 months.

3.3 | Feasibility

Fifty-two patients were eligible for FBT and thirty-one FBT patients were included into the study in 17 months (1.8 patients/month, Figure 1). The major limiting recruitment factor was the shortage of bed capacity in the pediatric and CAP wards for medical evaluation and stabilization. For reasons of refusal to accept FBT see Figure 1. Forty-two IMT patients were recruited in 36 months (1.2 patients/month). At 12 months, study retention was 27/31 (87.1%) in FBT and 28/31 90.3% in IMT ($p = .688$).

3.4 | Acceptability

Two patients (6.4%) dropped out from FBT and 1 patient (3.2%) was discharged against medical advice in IMT after 7 days ($p = .554$). There were no significant differences in acceptability between FBT and IMT, measured via caregiver strain (Table 3).

TABLE 3 Treatment characteristics and outcomes.

	FBT ($N = 31$)	IMT ($N = 31$)	p-value, FBT versus IMT
Duration (weeks)	33.6 [17.4, 49.9]	17.3 [14.4, 24]	<.001
Psychotherapy during AI (total hours)	24 ± 7 (13–38)[a]	25 ± 7 (18–40)[b]	.767
Psychotherapy during AI (h/week)	0.8 ± 0.3[a]	1.4 ± 0.4[b]	<.001
Total hospital days 0–12 months	1 [0, 16] (0–78)	123 [101, 180] (7–232)	<.001
Caregiver strain father			
Baseline	9.2 [8.2, 10.0]	8.9 [8.2, 10.3]	.891
End of treatment IMT		8.16 [6.33, 9.35]	.392
6 months	8.45 [6.42, 9.76]	7.89 [6.06, 9.39]	.648
End of treatment FBT	7.23 [5.39, 9.43]		.392
12 months	7.48 [5.63, 9.06]	7.90 [6.38, 9.53]	.397
Caregiver strain mother			
Baseline	9.3 [7.7, 10.6]	9.5 [8.4, 10.5]	.912
End of treatment IMT		8.14 [6.91, 9.60]	.705
6 months	8.25 [6.37, 9.73]	8.42 [6.08, 9.43]	.840
End of treatment FBT	7.86 [5.18, 9.66]		.705
12 months	7.86 [6.86, 9.19]	6.65 (5.74, 8.64)	.154
Adverse events ($N = 28$ for FBT and IMT), N (%)	16 (55.2%)	11 (39.3%)	.292
Suicidal thoughts and comments	11 (37.9%)	11 (39.3%)	1.000
Suicidal behavior	1 (3.4%)	2 (7.1%)	.611
Light self-injurious behavior	8 (27.6%)	8 (28.6%)	1.000
Severe self-injurious behavior	0	2 (7.1%)	.237
Aggressive behavior	7 (24.1%)	0	.010
Light physical aggression	7 (24.1%)	0	.010
Severe physical aggression	3 (10.3%)	0	.237
Serious adverse events, N (%)	1 (3.4%)	1 (3.6%)	1.000

Note: Values are means ± SD (range) or median [first quartile, third quartile].
Abbreviations: AI, assigned intervention; ED, eating disorder; EOT, end of treatment; FBT, family-based treatment; IMT, inpatient multimodal treatment. 0–12 M, between baseline and 12 months follow-up. For Chi^2-tests, $n = 0$ was changed to $n = 1$. 6 M, 6 months; 12 M, 12 months.
[a]Excluding $N = 2$ study drop-outs.
[b]Data available for 18 IMT patients.

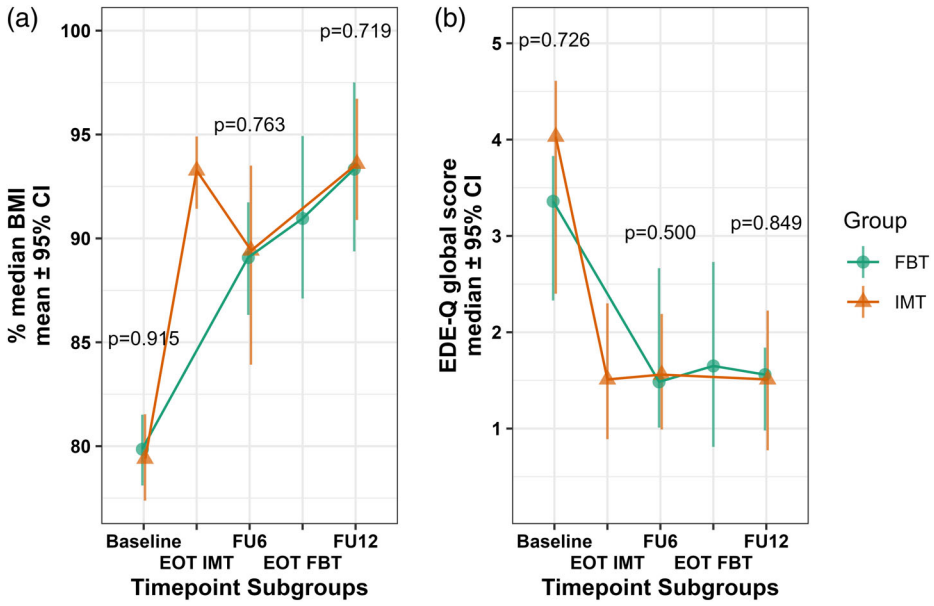


FIGURE 2 (a)–(b): Changes in percent median BMI (%mBM; a), and EDE-Q global score (b) over 12 months analyzed with linear mixed effect models in an intent-to-treat approach and corrected for differences in baseline depression and borderline traits by multiple linear regression analysis ($N = 31$ per group).

3.5 | Safety

In each group, one serious adverse event was reported: one patient in FBT attempted suicide and one patient in IMT engaged in serious self-harm (cutting) requiring surgical attention. The occurrence of specific adverse events (measured with a standardized questionnaire, Appendix 1) was comparable between treatments with one exception: in FBT, physical antagonism toward others occurred more often than in IMT ($p = .010$, Table 3).

3.6 | Preliminary treatment outcomes

From baseline to 12-months, controlling for unmatched baseline characteristics (depression and borderline traits), %mBMI and EDE-Q global score improvement did not differ between groups (Figure 2, Table S1). Nonparametric effect sizes despite normally distributed change in %mBMI for comparison with non-normally distributed change in EDE-Q global scores yielded 0.78 (FBT) and 0.76 (IMT) for %mBMI and for EDE-Q global score 0.64 (FBT) and 0.69 (IMT). Time was a significant predictor of change (%mBMI, $p < .0001$; EDE-Q global score, $p = .001$), while treatment group was not a significant predictor of change (%mBMI, $p = .914$; EDE-Q global score, $p = .726$). The interaction between group and time was not a significant predictor (%mBMI, $p = .544$; EDE-Q global score, $p = .543$). In the first 4 months, the increase in %mBMI was steeper in IMT, yet, due to a decrease in %mBMI after discharge from IMT, the increase over 6 months was similar in both groups (Figure 2, Table S1). Further patient-reported outcomes, that is, the EDE-Q subscales (restraint; eating, weight, and shape concern), compulsive exercise, clinical impairment, depression, stress and anxiety, and BMI-SDS did not differ at baseline or at the following study visits between groups (Table S4).

3.7 | Exploratory subgroup analysis: FBT per protocol versus cross-over to IMT patients

Twenty-two patients (70.9% of the FBT group) received FBT with no or only brief inpatient medical stabilization (FBT^{PP}) and 8 FBT patients (25.8%) crossed over to IMT ($FBT^{C/O}$), 2 patients (6.5%) dropped out of FBT, with one being a cross-over patient at the same time. The baseline characteristics of the subgroups are shown in Table S5. While %mBMI, comorbid diagnoses, and intake of medication did not differ between groups, the cross-over patients had more previous hospital admissions and their baseline psychopathology was significantly higher when compared with FBT^{PP} patients and showed less decrease over time (Figure S1). Baseline depression, stress, and anxiety were similar in both groups but also showed less decrease over time in $FBT^{C/O}$ (Figure S1).

3.8 | Preliminary cost-effectiveness: Cumulative hospital days

With a median of 2 [0, 76] days, FBT required significantly less hospital time than IMT (median = 128 [100, 182] days, $p < .001$; Table 3). For details about the timing, duration, and reasons for (re)hospitalizations, see eResults.

4 | DISCUSSION

In this non-randomized pilot study in youth with AN eligible for IMT, FBT was a feasible and acceptable treatment alternative to IMT in a German treatment setting for the majority of participants/families and without difference versus the IMT group. The latter was included as a reference point for exploratory outcome comparisons. Although

8 FBT patients (25.8%) needed to cross over from FBT to IMT due to insufficient weight progress or psychiatric concerns, FBT could be implemented with similar safety compared to a matched IMT group, apart from more physical antagonism toward caregivers occurring in the FBT group. Exploratory outcome analyses suggested that FBT yielded similar weight and psychopathology improvement over 12 months with considerably less hospital days for youth scheduled for long, inpatient treatment.

In the United Kingdom, where manualized Family Therapy for AN has been practiced since the 1980s, a major government investment has orchestrated a shift from inpatient to outpatient treatment, based on research evidence, to reduce treatment costs while at the same time improving clinical outcomes for youth with AN (Eisler et al., 2022). Additionally, an economic evaluation indicated FBT to be more cost-effective compared to adolescent-focused therapy (Le et al., 2017). Currently, data supporting such a shift is still scarce in the German healthcare setting.

In a German pilot study, home treatment, delivered by health care teams visiting patients and families in their home, has been shown to reduce hospital days for youth with AN from 17 to 8 weeks and treatment costs from 56.000€ to 41.000€ per patient (Herpertz-Dahlmann et al., 2020). In this pilot study, hospital days served as a proxy of treatment costs, as the actual costs were not assessed. While both FBT and home treatment aim for minimizing hospitalization time, the therapeutic approach of home treatment has not been described in detail and future studies delivering FBT or home treatment in the German health system should add a careful cost-economic evaluation to enable a comparison of cost-effectiveness of these two approaches. The question may arise regarding the rationale to compare hospital days between an outpatient and an inpatient pathway of care in this study. While less inpatient days in the outpatient treatment are expected, this will only hold true if FBT is sufficiently effective for patients who otherwise warrant inpatient care as per German S3 guidelines or if current practice was not to lead to frequent/lengthy inpatient medical stabilization or early/frequent cross-over into IMT.

In this pilot study, physical antagonism toward caregivers occurred with greater frequency in FBT when compared to IMT. Although we did not assess the reasons behind this aggression, we learned from the families that this was mainly due to the child/adolescent pushing or hitting the parents in the meal situation as an expression of the high-stress levels induced by eating a meal and the reinforced realimentation rules by the parents. We assume that most patients would feel stressed at mealtimes in hospital, too, but would feel too intimidated to hit or push the nursing staff. Our findings highlight that in FBT, a continuous, professional assessment of potential physical aggression at home exerted by the patient toward the caregivers particularly around mealtimes is crucial and if judged by the clinician and/or family members to cross the boundaries of tolerability, a transfer to IMT should be considered. Although in this pilot study, at a group level, FBT and IMT had similar core outcomes, future studies should aim to identify subgroup characteristics of youth who can benefit from FBT the most and of those who require IMT. Our exploratory subgroup analysis identified higher baseline ED psychopathology and more previous hospital admissions, but not lower baseline %mBMI, the presence of comorbid disorders, AN illness duration, or age as correlates of the 8 FBT patients who needed to be transferred to IMT. However, despite IMT leading to an increase in weight, this subgroup of FBT patients crossing over to IMT was characterized by a distinct lack of psychological recovery in different domains at 12 months compared to the patients receiving either IMT or FBT per protocol. These findings are helpful to inform future treatment outcome moderator analyses yet in the current study these preliminary data are difficult to interpret, as the cross-over occurred at different times, both soon after the start, in the middle of FBT, and after having concluded FBT. Thus, the cross-over between treatments can for now only mark a subgroup that could not benefit regarding AN psychopathology from either treatment. The worse outcome of the cross-over subgroup (Figures S1, S2) can serve to justify the conservative ITT approach guarding against an otherwise false overestimation of positive treatment results in the FBT group. A sufficiently large study is needed to help with a better initial identification and interpretation of moderators and mediators of treatment outcomes in both FBT and IMT.

In the present study, improvement of weight and AN psychopathology did not differ whether FBT was delivered in person or via telemedicine, dictated by the COVID-19 pandemic-related restrictions. These results are consistent with prior pilot studies in the United States (Anderson et al., 2015; Hambleton et al., 2020), expanding access of FBT to those in more remote geographical areas or without an adequate number of trained FBT therapists. However, although FBT was delivered via telemedicine, in this pilot study, medical monitoring and care were not provided in the community, but in presence by the FBT team that was closely linked to inpatient facilities.

The results of this study need to be interpreted within its limitations that all should be considered in a future and adequately powered multisite RCT and/or future studies when comparing FBT with IMT. First, for matching, we had excluded 11 patients from the IMT group, so that the matched IMT subgroup was not representative of all patients who had received IMT. Consequently, in a future RCT, a higher rate of cross-over (FBT to IMT) may be expected. However, even if a smaller subgroup than 70.9% of patients scheduled for IMT can be successfully treated with FBT, this finding would still have crucial implications. Second, this was not a randomized trial. However, patient care in FBT or IMT occurred at around the same time and by research as well as clinical staff employed, trained, and supervised in the same department. Third, the number of 62 families in this pilot study was small. Fourth, the statistical approach chosen for longitudinal analysis, LMEM, assumes a random distribution of missing data due to study drop-outs. This assumption could not be tested due to the small number of participants not available at follow-ups. Nevertheless, since only 8.1% (%mBMI), 14% (EDE-Q), and 0% (days in hospital) of patients had missing data for the primary and secondary analyses, we consider the potential effect of non-random missingness of the data less relevant for the

interpretation of the results. The pathway of care aiming at brief medical stabilization for FBT patients was feasible but needs to be further developed and refined so that it can be routinely applied in the German healthcare system. Sixth, the assessment of adverse events was not conducted in the same manner in the two groups, that is, at EOT by the therapist in FBT and by retrospective data extraction by study staff in IMT and uptake of individual psychotherapy between EOT and 12 months was not assessed in the FBT group. Seventh, while IMT in this pilot study closely represented guideline-concordant care for youth with AN in Germany, IMT elements may vary from site to site. Therefore, the findings of our study may not be fully generalizable to other treatment sites in Germany or in other countries. To test the generalizability of the results to the German treatment environment a multicenter trial is needed to replicate the findings. Finally, there was no study assessment scheduled at the time cross-over from FBT to IMT occurred and ethnicity of the participants was not assessed.

5 | OUTLOOK

A stepped-care model needs to be developed and evaluated to (i) facilitate timely intensified FBT in case of insufficient success with FBT as well as (ii), if needed, a timely transfer between FBT and IMT in a standardized manner that can be applied using clear, medical cut-off criteria that can be adhered to in the German healthcare system. These same criteria can be used to guide the length and aims of brief inpatient admissions for stabilization before the patients can return to FBT. In a future RCT with a sample size calculated based on the present pilot study, particular attention should be paid to (i) potential differences in socio-economic status of the families, (ii) the possibility of a greater likelihood of physical antagonism of FBT patients toward their caregivers, and (iii) the potential financial strain arising for parents taking part in FBT when accompanying all meals of their child at home for an extended period of time.

6 | CONCLUSIONS

In this first non-randomized pilot study comparing indirectly FBT with IMT in a matched group of patients, FBT was as feasible, acceptable, and safe as IMT, apart from more physical antagonism occurring toward others in FBT. While our findings are preliminary, FBT appeared to be similarly effective at 12 months follow-up as IMT while at the same time using fewer inpatient days. Future RCTs should follow up on these promising findings.

AUTHOR CONTRIBUTIONS

Verena Haas: Conceptualization; data curation; formal analysis; funding acquisition; investigation; methodology; project administration; writing – original draft. **Katja Wechsung:** Data curation; writing – review and editing. **Vivien Kaiser:** Data curation; writing – review and editing. **Janine Schmidt:** Data curation; writing – review and editing. **Klemens Raile:** Conceptualization; writing – review and editing. **Andreas Busjahn**: statistical analyses, review and editing; **Daniel Le Grange:** Conceptualization; funding acquisition; methodology; project administration; supervision; writing – review and editing. **Christoph U. Correll:** Conceptualization; funding acquisition; investigation; methodology; project administration; resources; supervision; writing – review and editing.

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CONFLICT OF INTEREST STATEMENT

Dr. Correll has been a consultant and/or advisor to or has received honoraria from: AbbVie, Acadia, Alkermes, Allergan, Angelini, Aristo, Biogen, Boehringer-Ingelheim, Cardio Diagnostics, Cerevel, CNX Therapeutics, Compass Pathways, Darnitsa, Denovo, Gedeon Richter, Hikma, Holmusk, IntraCellular Therapies, Janssen/J&J, Karuna, LB Pharma, Lundbeck, MedAvante-ProPhase, MedInCell, Merck, Mindpax, Mitsubishi Tanabe Pharma, Mylan, Neurocrine, Neurelis, Newron, Noven, Novo Nordisk, Otsuka, Pharmabrain, PPD Biotech, Recordati, Relmada, Reviva, Rovi, Seqirus, SK Life Science, Sunovion, Sun Pharma, Supernus, Takeda, Teva, and Viatris. He provided expert testimony for Janssen and Otsuka. He served on a Data Safety Monitoring Board for Compass Pathways, Denovo, Lundbeck, Relmada, Reviva, Rovi, Sage, Supernus, Tolmar, and Teva. He has received grant support from Janssen and Takeda. He received royalties from UpToDate and is also a stock option holder of Cardio Diagnostics, Mindpax, LB Pharma, PsiloSterics, and Quantic. Dr. Le Grange receives royalties from Guilford Press and Routledge, is co-director of the Training Institute for Child and Adolescent Eating Disorders, LLC, and a member of the Clinical Advisory Board for Equip Health. The other authors declared no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data will be available on author request.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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