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Shorter communication

From efficacy to effectiveness: Comparing outcomes for youth with anorexia nervosa treated in research trials versus clinical care

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ABSTRACT

This study examined outcomes for 84 youth with anorexia nervosa (AN) who received family-based treatment (FBT) in a research trial (randomized trial care [RTC]: $n = 32$) compared to fee-for-service care (specialty clinical care [SCC]: $n = 52$) at an outpatient eating disorder clinic. Weight was collected up to 12 months post-baseline. Survival curves were used to examine time to weight restoration as predicted by type of care, baseline demographic and clinical characteristics, and their interaction. There was not a significant main effect for type of care, but its interaction with initial %EBW was significant ($p = .005$), indicating that weight restoration was achieved faster in RTC compared to SCC for youth with a lower initial %EBW (i.e., ≤81), while rates of weight restoration were comparable for those with a higher initial %EBW (i.e., >81). These data suggest that FBT is as effective as it is efficacious, except for youth with lower initial body weights. Therefore, clinicians may need to be particularly active in encouraging early weight gain for this subset of patients. Nevertheless, this study suggests that FBT is appropriate as a first-line treatment for youth with AN who present for clinical care.

Introduction

Identifying efficacious and effective treatments for children and adolescents with anorexia nervosa (AN) is essential to prevent severe and long-term consequences of this illness. However, only ten published randomized controlled trials have examined the efficacy of outpatient psychotherapies for youth with AN (Eisler et al., 2000: $N = 40$; Geist, Heinmaa, Stephens, Davis, & Katzman, 2000: $N = 25$; Gowers et al., 2007: $N = 167$; Herpertz-Dahlmann et al., 2014: $N = 176$; Le Grange, Eisler, Dare, & Russell, 1992: $N = 18$; Lock, Agras, Bryson, & Kraemer, 2005: $N = 86$; Lock et al., 2010: $N = 121$; Madden et al., in press: $N = 82$; Robin et al., 1999: $N = 37$; Russell, Szmukler, Dare, & Eisler, 1987: $N = 57$). Research suggests that family-based treatment (FBT)—a manualized treatment that emphasizes parental support of their child's eating-related behaviors—is an efficacious treatment for youth with AN (Lock et al., 2010). However, community-based clinicians who treat patients with eating disorders rarely use empirically supported treatments (ESTs) with adults (von Ranson & Robinson, 2006). Less is known about the use of ESTs with youth, but a recent study suggests that even when therapists utilize FBT, they make significant modifications in its implementation (Kosmerly, Waller, & Robinson, 2014) that may impact its effectiveness.

There are numerous factors contributing to the low use of ESTs in "usual care" settings (i.e., community-based non-research settings) (see Weisz, Weiss, & Donenberg, 1992 for a discussion). One reason is the lack of effectiveness studies, which provide evidence about a treatment's effect when delivered in routine practice settings by "usual" providers to "usual" patients. This gap is particularly pronounced in eating disorders treatment for youth. To date, five relatively small studies have examined the effectiveness of FBT for youth with AN (Couturier, Isserlin, & Lock, 2010: $N = 14$; Hughes et al., 2013: $Ns = 14$ and 21; Loeb et al., 2007: $N = 20$; Paulson-Karlsson, Engström, & Nevonen, 2008: $N = 32$; Turkiewicz, Pinzón, Lock, & Fleitlich-Bilyk, 2010: $N = 9$). While each utilized

Abbreviations: AN, anorexia nervosa; FBT, family-based treatment; EST, empirically supported treatment; RTC, randomized trial care; SCC, specialty clinical care; %EBW, percent of expected body weight.

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clinically-referred samples and practicing therapists, their generalizability to usual care is limited by the absence of a comparison condition, the provision of treatment at no cost (Couturier et al., 2010; Loeb et al., 2007; Turkiewicz et al., 2010) and the exclusion of boys (Couturier et al., 2010; Paulson-Karlsson et al., 2008; Turkiewicz et al., 2010). Another potential reason for the low use of ESTs in usual care is that these treatments perform more poorly in usual care than in research settings (Wampold et al., 2011; Weisz, Jensen-Doss, & Hawley, 2006). However, it is unclear which factors contribute to these diminished effects. Certainly, the process of being randomized to a particular condition and willingness to participate in a research trial is not reflective of how patients enter usual care, and therefore treatment effects from randomized comparisons may not generalize to a "real world" comparison of research and usual care settings. The relative lack of data examining FBT's effectiveness may contribute to therapist doubts about its appropriateness for youth with AN.

Therefore, the main goal of this study was to compare outcomes achieved in a research trial compared to those achieved in clinical care. Time to weight restoration, defined as reaching ≥95% of expected body weight (EBW) (based on age, gender, and height) was compared for youth with AN who received FBT in the context of a randomized trial versus a fee-for-service clinic, controlling for baseline patient differences. We were interested in how differences inherent to research and clinical service settings (e.g., treatment schedule, supervision, flexibility in implementation) impacted patient outcome. Although this analysis was unable to directly examine how outcomes were influenced by specific differences in settings, it provides a comparison of patient outcomes in light of these contextual differences. We hypothesized that patients would do well in both types of care but that those who received care within a research trial would achieve more rapid weight restoration, given generally better outcomes of ESTs when delivered within research settings (Wampold et al., 2011). We also examined other baseline predictors of outcome, as well as their interaction with type of care, in order to identify which patients benefit most from treatment, and whether this depended on type of care.

Method

Participants included 84 youth who 1) met DSM-5 criteria for AN, 2) were medically stable for outpatient treatment, and 3) engaged in FBT at The University of Chicago Eating Disorders Program between 1999 and 2011. Participants provided informed assent/consent, and all protocols were approved by The University of Chicago Institutional Review Board. All therapists had specialized training in FBT and were supervised by one of the treatment developers (DLG) in their delivery of randomized trial care (RTC: $n = 32$) (i.e., research trial treatment) or specialty clinical care (SCC: n = 52) (i.e., fee-for-service not-for-profit clinical treatment). Compared to patients in RTC, patients in SCC had to pay for treatment (versus no cost treatment), had limited contact with the research staff (versus frequent contact), and received non-randomized treatment (versus randomization to FBT) that was implemented with greater flexibility (versus stricter adherence with a fixed dose) (see Table 1 for a summary of differences between types of care).

Randomized Trial Care (RTC)

The RTC sample ($n = 32$) was drawn from a sample of youth ages 12–18 who were evaluated in the Chicago research clinic between 2005 and 2007 as part of a two-site clinical trial and randomized to FBT (provided by three psychologists) (Lock et al., 2010). Exclusion criteria included new or unstable psychotropic medication dosage (<8 weeks), current psychosis, alcohol or drug dependence, current physical condition known to influence eating or weight (e.g., diabetes mellitus, pregnancy), or previous receipt of either FBT or adolescent-focused therapy.

Specialty Clinical Care (SCC)

The SCC sample ($n = 52$) was drawn from youth who were evaluated in the fee-for-service clinic between 1999 and 2011. Of those who agreed to participate in an observational study (83.3%, $n = 363$), 124 (ages 9–18) met criteria for AN. Of these, 71 (57.3%)

Table 1
Differences in types of care by setting, treatment, therapists, supervision, and patients.

		Specialty Clinical Care (SCC)	Randomized Trial Care (RTC)
Setting	*Location*	Highly specialized eating disorders program located in an academic medical center	
	Medical/psychiatric care	Provided by the team pediatrician and (if indicated) psychiatrist	
	Payment	Fee-for-service with insurance (private or public) or self-pay	No-cost treatment
	Waitlist	Longer (typically six weeks)	Shorter (less than one week)
	Contact and assessments with research staff	Limited (usually only at baseline)	Frequent contact and assessments throughout treatment
	"Observation"	Sessions not recorded	Sessions audio/videotaped
Treatment	*Implementation*	Manualized FBT Greater flexibility allowed in implementation	High adherence required in implementation
	Assignment	Clinical recommendation to receive FBT	Random assignment to FBT
	Dose	No defined endpoint	Fixed dose (24 sessions)
Therapists	*Degree*	Doctorate (psychology)	Master's (social work, psychology) and doctorate (psychology and psychiatry)
Training & Supervision	*Training/supervision*	Structured training/supervision in FBT provided by treatment developer (DLG), with cases discussed in clinical team rounds	
	Oversight	Less intensive supervision with less oversight of treatment adherence	More intensive supervision with greater oversight of treatment adherence
Patients	*Referral route*	Clinical and personal referrals	
	%EBW	<90	<87
	Age	Up to 18	12–18
	Medication	No medication exclusion criteria	Stable dose of medication