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Allegiance Bias and Therapist Effects: Results of a Randomized Controlled Trial of Binge Eating Disorder

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Abstract

“Allegiance bias” has been hypothesized to compromise the findings of randomized controlled trials (RCTs). In contrast, our multi-site RCT involving the collaboration of investigators with different allegiances regarding interpersonal psychotherapy (IPT), guided self-help cognitive behavior therapy (CBTgsh), and behavioral weight loss therapy (BWL) for binge eating disorder showed no evidence of any differential site × treatment effects. The findings indicate that “allegiance bias” does not necessarily occur in well-controlled RCTS with appropriate therapist training. We also examined the role of individual therapist differences that have been alleged to be more important than treatment effects. No individual therapist effects emerged on any measure in either IPT or CBTgsh, both of which were significantly more effective than BWL at two-year follow-up.

Keywords

allegiance bias; therapist effects; randomized controlled trial; interpersonal psychotherapy; Binge Eating Disorder

“Allegiance bias” in psychotherapy outcome studies refers to the results being contaminated or distorted by the investigators’ theoretical or treatment preferences (Luborsky, Singer, & Luborsky, 1975). Some subsequent meta-analyses have shown a significant relationship between researchers’ therapeutic allegiances and the outcomes of the studies they conducted (e.g., Luborsky, Diguier, Seligman, Rosenthal, Krause, Johnson, et al., 1999; Robinson, Berman, & Neimeyer, 1990) although Gaffan, Tsaousis, and Kemp-Wheeler (1995) did not. As Leykin and DeRubeis (2009) acknowledge, if such a bias exists it could call into question the validity of randomized controlled trials (RCTs) of comparative treatment effects. Critics of RCTs have indeed cited the allegiance bias as further evidence of what

they charge is the fundamentally flawed nature of RCTs in psychotherapy research (e.g., Messer & Wampold, 2002).

Leykin and DeRubeis (2009) distinguished between “allegiance bias” and “allegiance association.” They make the case that proponents of the former have argued from correlation to cause and that alternative explanations of any detected allegiance association in a treatment outcome study need to be considered. An obvious possibility is that of reverse causality. Exposure to treatments that are inherently more effective than others leads investigators to develop an “allegiance” for such interventions (e.g., Weiss & Weisz, 1995).

Ruling out any unprofessional behavior, there are potential sources of bias that would need to be addressed (controlled for) in rigorously conducted RCTs. Thus Leykin and DeRubeis (2009) raise the possibility that an investigator’s enthusiasm for a favored therapy might result in better training and supervision of the therapists implementing that treatment as opposed to a less preferred comparative treatment. An alternative source of bias might be what Hollon (1999) called “honest differences” in expertise. It is plausible that greater experience and skill in a preferred treatment could, however inadvertently, result in better performance of this treatment over a non-preferred intervention.

Leykin and DeRubeis (2009) make several recommendations for methodologically improved research that would greatly reduce the likelihood of any allegiance bias in RCTs of psychological therapies. The most important is the need for studies that deliberately involve “collaborations between investigators who possess complementary areas of expertise, and correspondingly opposite allegiances” (p. 60). As Hollon (1999) put it, the solution “lies not in eliminating allegiances but in balancing them” (p.107). Leykin and DeRubeis (2009) note that most existing examples of this sort of scientific collaboration have involved a comparison of cognitive behavior therapy (CBT) with pharmacotherapy (e.g., Barlow et al., 2000; Walsh, Wilson, Loeb, Devlin, Pike, Roose, et al., 1997). Appropriately designed multi-site RCTs might provide the best means of testing for allegiance effects. For example, the different sites would be explicitly identified with experience and expertise in the alternative treatments evaluated in an RCT. It would be essential to ensure high quality methodology in completing such a study so that all therapists at the different sites would be deemed to have demonstrated sufficient levels of competence in the implementation of the treatments.

We report here the results of a multi-site RCT of binge eating disorder (BED) (Wilson, Wilfley, Agras, & Bryson, 2010) that incorporated Leykin and DeRubeis’s (2009) recommendations for more adequately evaluating the allegiance bias hypothesis. Two different treatment sites had identifiably contrasting allegiances to alternative forms of psychological treatment for binge eating disorder (BED). The allegiance bias hypothesis predicts site X treatment differences in line with a priori treatment allegiances. The absence of such an outcome would be inconsistent with the hypothesis. The allegiance of the “experimenter” or “investigator” has typically been used in reference to allegiance bias. It would also seem plausible that should such a bias exist it might be expressed by the therapists who implement comparative treatments in RCTs. Accordingly, we also evaluated the impact of any individual therapist effects across the different therapy conditions.

Method

Participants

A detailed description of the multi-site treatment trial upon which provided the data for the present analyses has been reported elsewhere (Wilson et al., 2010). Two hundred of the original $n = 205$ participants were included in the analyses reported here. (Five were excluded because their therapists each treated fewer than the required number of five or more patients). The majority of patients were female (86%), Caucasian (82%), with a mean age of 48.3 and a mean body mass index (kg/m^2) of $36.4\text{kg}/\text{m}^2$ (range of 27.1 to $46.0\text{kg}/\text{m}^2$). Data were collected and analyzed at the coordinating center at Stanford University.

Design

Patients were randomly assigned to one of three treatment conditions: Interpersonal Psychotherapy, (IPT), Behavioral Weight Loss (BWL), or Guided Self-Help derived from cognitive behavior therapy (CBTgsh) with therapists nested within treatments. The IPT condition was based on the treatment as originally developed for depression (Klerman, Weissman, Rounsaville, & Chevron, 1984) and subsequently adapted for BED (Wilfley, Frank, Welch, Spurrell, & Rounsaville, 1998). The treatment, delivered by doctoral-level (PhD and PsyD) therapists, consisted of 19 individual sessions (the first of which was 2 hours) over a 6 month period. Dr Wilfley conducted training in IPT before the study began. Therapists received weekly supervision at their respective sites by the PIs (Wilfley and Wilson). In addition, joint supervision meetings twice a year and quarterly conference calls were held for both treatment sites throughout the study.

The BWL treatment followed the manual of the National Institute of Diabetes and Digestive and Kidney Diseases program for the Diabetes Prevention Program's Lifestyle Change Program (Gillis & Wing, 1996). Bonnie Gillis, MS, RD, conducted the initial training workshop and served as a consultant. The treatment, delivered by masters-level therapists in clinical psychology or nutrition, consisted of 20 individual sessions over a 6 month period. The therapists received local on-site supervision every other week. Quarterly joint supervisory meetings across sites were held throughout the study. CBTgsh was based on *Overcoming Binge Eating* (Fairburn, 1995). Patients received 10 sessions of CBTgsh, nine of which were only 25 minutes, over the 6 month period. The therapists at both sites were first- or second-year graduate students with no experience in CBTgsh or treating BED. Dr Fairburn conducted initial training in CBTgsh in a 3-hour workshop. The therapists did not receive regularly scheduled supervision but met with the PIs to discuss problems they encountered. Quarterly meetings across sites were held throughout the study.

All therapists were required to complete treatment of 2 pilot patients and to be approved before participating in the study proper. Treatment integrity was assessed at the Stanford site by auditing a 15% random sample of participants in each condition with 3 sessions from each participant sampled. The tapes were rated for adherence to the therapy protocol and quality of therapist-patient interaction on a 7-point scale. Mean ratings were as follows: IPT, 6.3 (SD, 0.7); BWL, 6.1 (SD, 0.8); and CBTgsh, 6.2 (SD, 0.7).

Assessment

Assessments were conducted pretreatment, at the end of treatment, and at 6-, 12-, 18-, and 24-month follow-ups. The primary outcome measure was the Eating Disorder Examination (EDE; version 14.3) (Fairburn & Cooper, 2000) which with the addition of a specific module (Wilfley, Schwartz, Spurrell, & Fairburn, 2000), was used to assign a diagnosis of DSM-IV BED. Assessors were blinded to treatment condition. Reliability of EDE ratings of binge eating was determined by having a randomly selected sample of 15% of the EDEs that were conducted at each treatment site rated by assessors at the other site. Inter-rater reliability coefficients were 0.97 for both episodes and days of binge eating. Questionnaires administered included the BDI (Beck & Steer, 1987) and the Self-Esteem Scale (Rosenberg, 1979).

The primary outcome variable was days of binge eating assessed during a 28-day period and weight. Analyses were by intent-to-treat and conducted separately for the treatment and follow-up periods. Change from posttreatment was used to examine maintenance at 2-year follow-up with an analysis of covariance (continuous measure) or logistic regression (categorical measure) with the posttreatment measure as a covariate. When data were missing at posttreatment, the baseline value was carried forward. During follow-up, if 2-year data were missing, 18-month scores were used. If no measures were available for a particular time, then the baseline value was used.

Measuring Allegiance

The major method that has been used to identify psychotherapy allegiance is analysis of investigators' prior publications (Leykin & DeRubeis, 2009). Applying this yardstick to the three principal investigators (PIs) in the Wilson et al. (2010) study yielded clearcut differences. Agras and Wilson have long-standing records of contributing to the development and evaluation of CBT treatment for different disorders, whereas Wilfley has a documented publication record of specialization in IPT. Leykin and DeRubeis (2009) underscore the potential importance of possible bias of clinical trial researchers having "authorship of the treatment under investigation" (p.57). Both Wilfley and Wilson have authored chapters on IPT and CBT respectively in authoritative handbooks on the treatment of eating disorders (e.g., Agras, 2010; Grilo & Mitchell, 2010). Another means of measurement of allegiance is self-report of investigators. The three PIs here would describe themselves as clinical scientists with a common commitment to studying empirically-supported psychological treatments albeit with different levels of past experience and expertise in IPT and CBT respectively. All three PIs had prior experience in conducting treatment outcome research on BWL.

Therapist Effects

Different therapists might well have contrasting prior experience and expertise in different forms of psychological therapies aside from any bias they might assume from the lead investigators in a trial. Therefore we analyzed individual therapist effects that have been shown to exert a significant effect on the outcome of psychological therapy in some studies (e.g., Okiishi, Lambert, Eggett, Nielsen, L., Dayton, & Vermeersch, 2006). To be included

in these analyses, therapists had to have treated a minimum of five patients; five IPT therapists, 4 BWL therapists, and 6 CBTgsh therapists.

Analyses of individual therapist effects on outcome were done separately by treatment. Logistic regression was used to analyze the effect of therapist on the binary abstinence outcomes controlling for baseline severity, assessed by baseline EDE and objective binge days. Continuous measures of global EDE, binge days, and BMI were analyzed for therapist effect using ANCOVA. Change from both baseline to posttreatment and posttreatment to 2 year follow-up were the dependent measure controlling for baseline and posttreatment values respectively. Therapist was modeled as a random effect.

Results

The main findings (see Wilson et al., 2010) can be summarized as follows: At posttreatment there were no differences among the three treatments in remission from binge eating, EDE subscale scores, BDI, or self-esteem. BWL was significantly more effective in reducing body mass index than IPT and CBTgsh. At 2-year follow-up, both IPT and CBTgsh resulted in greater remission from binge eating than BWL.

Site Effects

Of particular relevance to the present paper, no treatment X site differences were found on attrition rate or on measures of remission from binge eating, global EDE scores, or BDI at either posttreatment or 2-year follow-up.

Therapist Effects

In the IPT and CBTgsh conditions there were no significant therapist effects on attrition rate or on remission from binge eating, change in global EDE scores, or body mass index at either posttreatment or 2-year follow-up. In BWL, however, there was a significant therapist effect on remission from binge eating, $W(3) = 10.6, p = .01$, and reduction in binge days, $F(3,57)=2.9, p=.04$, at posttreatment. In addition changes on the global EDE score, $F(3,57) = 3.1, p = .03$, and binge days, $F(3,57) = 7.2, p = .001$, were significant at 2-year follow-up.

Discussion

As reported previously (Wilson et al., 2010), we found no evidence of any differential site effect or site \times treatment effects on any measure of clinical outcome. Here we expand upon the implications of this research and examine possible reasons for our findings.

The absence of any evidence of “allegiance bias” is noteworthy given that the circumstances of this multi-site study would seem optimally conducive to finding such an effect. First, there were obvious allegiance differences between the PIs at the two sites where the treatments were implemented. The PIs had different histories of expertise in IPT and CBTgsh respectively, but we did not assess their views of the alternative treatment. As noted above, all PIs favor empirically-supported treatments such as CBT and IPT. Thus the study did not test the possible effects of the investigators holding a negative view of one of the treatments in question.

Second, there were notable differences in experience and prior training between the two sets of therapists who treated the patients at the respective sites. Consider the IPT condition which of the three treatments might be considered the most likely to reflect allegiance effects. Although manual-based, it was the least structured of the three treatments and required continual therapist judgment about how to focus and pace individual sessions. The three therapists at the Rutgers University site had only recently received their doctoral degrees in clinical psychology. Two had graduated from the Rutgers Ph.D. and Psy.D programs that have been nationally recognized for their distinction in clinical training in CBT in general (e.g., recipients of the “Outstanding Training Program Award” from the Association for Advancement of Behavior Therapy, 1999). The third had a background in psychodynamic theory and therapy. By contrast, the two IPT therapists at the Washington University site were more senior and experienced in clinical practice. One was an expert in IPT and had participated in a previous outcome study documenting the efficacy of IPT (Wilfley et al., 2002). Differences also existed between the two sets of therapists who administered CBTgsh. The therapists at Rutgers University who treated the patients in this condition were graduate students who were mentored by the PI (Wilson) at Rutgers. The graduate student therapists at Washington University did not have this specialized focus on CBT in their clinical training. It should be noted that by nesting therapists within different treatments, the current study did not assess potential “therapist bias” in treatment outcome research in which the same therapists administer more than one form of therapy.

The evidence from this study shows that “allegiance bias” is not an inevitable feature of comparative treatment trials. The study complements those that have previously studied collaboration among researchers committed either to CBT or pharmacotherapy (e.g., Barlow et al., 2000; Heimberg et al., 1998) by showing that such bias need not occur in RCTs comparing different psychological treatments. Collectively these studies dispute the charge that RCTs of psychological therapies are inappropriate for evaluating the comparative effects of different psychotherapies (Luborsky et al., 1999; Messer & Wampold, 2002).

The findings support Leykin and DeRubeis’s (2009) conclusion that rigorously conducted studies can control for the operation of “allegiance bias.” In their review of therapist training in RCTs, Roth et al. (2010) emphasized the “major investment in training and supervision made by researchers in high-quality trials. Therapists are almost invariably carefully selected, trained in a specific and well-specified set of interventions, supervised intensively, and monitored closely, usually on the basis of audio-taped recordings” (p.296). Implementing protocols in high quality trials entails more than simply “following a treatment manual” (Roth et al., p. 296). In our study initial training and ongoing supervision of therapists, especially for IPT, exemplified the sort of commitment to treatment integrity noted by Roth et al. (2010). It was the Washington University investigators who successfully trained the relatively inexperienced Rutgers University therapists in IPT. The good news from this is that at least under certain conditions therapists from differing backgrounds and allegiances can, with suitably competent training, be trained to deliver high quality treatment that matches that of the experts themselves.

The evidence on individual therapist effects and their contribution to outcome compared with specific treatments is mixed (Crits-Christoph & Gallop, 2006). Some research has

shown large effects of individual therapists (e.g., Okiishi et al., 2006). Crits-Christoph and Mintz (1991), however, found that studies that implemented better “quality control procedures... (e.g., careful selection, training, and supervision of therapists and the use of treatment manuals)” (p.24) reduced if not eliminated therapist effects. In a large, well-controlled treatment study of bulimia nervosa, Loeb, Wilson, Labouvie, Pratt, Hayaki, Walsh, Agras, & Fairburn (2005) reported no individual therapist effects on outcome. The outcomes of the IPT and CBTgsh treatments in the current study are consistent with this previous research. Individual therapist effects were not found on any measure at any time in either IPT or CBTgsh.

In BWL, however, significant therapist differences were found on remission from binge eating at posttreatment, binge days, and changes in global EDE scores at 2-year follow-up. The differences occurred despite the highly structured nature of the BWL condition and are difficult to interpret. Of the BWL therapists, only one – the sole nutritionist – had prior experience in weight loss treatment although not in diagnosed cases of BED. No therapist differences were found for weight loss, the measure on which BWL was significantly superior to IPT and CBTgsh at posttreatment. Nor was there a pattern of one therapist being associated with poorer results across measures or assessment points. For example, the therapist with the most remission from binge eating at posttreatment also had the highest increase in number of binge days at 2-year follow-up. A different therapist with the least remission from binge eating at posttreatment nevertheless was linked with the biggest improvement in global EDE scores at 2-year follow-up.

Limitations of the current study should be noted. One was that the research was conducted in two specialty eating disorder clinics. Determining the generalizability of these findings requires research in routine clinical care. A major challenge in disseminating and implementing the findings of efficacy studies is to provide practical and economically feasible training in evidence-based treatments in routine clinical care (Herschell et al., 2010; McHugh & Barlow, 2010). A second limitation is the relatively small number of therapists who implemented the different treatments although the numbers are not unusual for large clinical trials comparing different psychological therapies. Analyses of therapist effects in larger samples of therapists in clinical trials are warranted. Finally, whether these findings would hold in other forms of psychotherapy (e.g., unstructured and not manual-based) remains to be determined.

In conclusion, the results suggest that investigator “allegiance bias” can be prevented in high quality treatment outcome research with manual-based treatments. Similarly, individual therapist differences will be less evident in rigorously conducted studies as Crits-Christoph and Mintz (1991) previously reported. A key feature of such studies, as Roth et al. (2010) make clear, is the intensive training and monitoring of therapists. It is a gross mischaracterization of therapists in high quality RCTs to dismiss them as “research assistant(s)” whose job is to “run subjects” (p. Westin et al., p.639). Nor is it entirely accurate to state that RCTs of empirically-supported treatments try to “minimize” the contribution of individual therapists (Okiishi et al., 2006, p.1167). It is more the case that the goal is to train all therapists to achieve a required level of competence in administering the

specific treatment. Optimal therapy requires competent therapists utilizing the most effective treatments (Shafran, Clark, Fairburn, Arntz, Barlow, Ehlers et al., 2009).

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