

Treating Oppositional Defiant Disorder in Primary Care: A Comparison of Three Models

John V. Lavigne,^{1,2,3} PhD, Susan A. LeBailly,^{1,3} PhD, Karen R. Gouze,^{1,2} PhD, Colleen Cicchetti,^{1,2} PhD, Jonathan Pochyly,^{1,2} PhD, Richard Arend,^{1,2} PhD, Bryn W. Jessup,² PhD, and Helen J. Binns,^{1,2,3} MD
¹Children's Memorial Hospital, ²Feinberg School of Medicine, Northwestern University, and ³Mary Ann and J. Milburn Smith, Child Health Research Program, Children's Memorial Research Center

Objective To determine if a nurse-led or psychologist-led parent-training program was more successful than a minimal intervention in treating early childhood Oppositional Defiant Disorder (ODD) in pediatric primary care. **Methods** Twenty-four practices were randomized to conditions in which parents of 117, 3- to 6.11-year-olds with ODD received the 12-session Webster-Stratton *Incredible Years* program led by primary care nurses or clinical psychologists, or to a minimal intervention group in which parents received only the companion book to the treatment program. **Results** There was improvement across posttreatment and 12-month follow-up for all groups, but no overall treatment group effects. There was a dose effect, with a reliable, clinically significant gain after seven sessions on the Eyberg intensity scale, and nine sessions on the Child Behavior Checklist externalizing scale. **Conclusions** There is little advantage to the therapist-led treatment over bibliotherapy unless parents attend a significant number of sessions.

Key words oppositional defiant disorder; parent training; primary care.

The most common psychiatric disorders among preschool children are disruptive behavior disorders, chiefly Oppositional Defiant Disorder (ODD), for which the prevalence in preschoolers is 4–16% (Egger & Arnold, 2006). Intraindividual stability in clinic (Campbell & Ewing, 1990) and community samples is substantial, with 65% of preschoolers with ODD in primary care remaining cases after 4 years (Lavigne et al., 1998a). Unfortunately, less than 20% of young children meeting criteria for psychiatric disorder as specified in the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV; American Psychiatric Association, 1994) are referred for mental health services (Horwitz, Leaf, Leventhal, Forsyth, & Speechley, 1992; Lavigne et al., 1998b). To reach more preschoolers with ODD, identification and treatment needs to be extended outside of the mental health services system (Kazdin, 1997). Promising school-based interventions (Gross et al., 2003; Reid, Webster-Stratton, & Hammond, 2003) may not be useful if ODD symptoms occur primarily at home,

and interventions and referrals originating in pediatric primary care offer certain advantages: (a) other than teachers, physicians have the most professional contact with the families of preschoolers; (b) pediatricians report that research on the role of the primary care provider in treating mental health problems is important to them (Chien et al., 2006); and (c) parents tend to trust physicians' opinions, and pediatricians' recommendations are the best predictor of help-seeking for preschoolers' behavior problems (Lavigne et al., 1993).

Although there are few studies of treatment for behavioral problems in primary care, studies conducted in the mental health service sector provide strong empirical support for the efficacy of behaviorally-oriented parent training for "oppositional" or "difficult to manage" preschoolers (for reviews, see Brestan & Eyberg, 1998; Kazdin, 1997; Serketich & Dumas, 1996; for more recent studies, see Gross et al., 2003; Shaw, Dishion, Supplee, Gardner, & Arnds, 2006; Webster-Stratton, Reid, & Hammond, 2004). Typically, these interventions have

All correspondence concerning this article should be addressed to John V. Lavigne, Department of Child and Adolescent Psychiatry (#10), Children's Memorial Hospital, 2300 Children's Plaza, Chicago, IL 60614.
E-mail: jlavigne@childrensmemorial.org.

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been moderately intensive, 8- to 12-session programs, and research designs establishing their efficacy compared active treatments to a wait-list control (WLC). With the efficacy of moderately intensive parent training well established, it now seems appropriate to determine if the moderately-intensive treatments are superior to briefer, less costly interventions, particularly because families frequently attend relatively few sessions, often five to eight or fewer (Armbruster & Kazdin, 1994; Kazdin & Wassel, 1998), well below the number recommended by these programs.

The few minimal intervention studies of children exhibiting ODD-related behavior problems either reduced therapist contact or involved self-directed treatment. A four-session intervention (Turner & Sanders, 2006) was superior to no treatment in reducing behavior problems immediately after treatment, while there was no difference between a treatment with reduced therapist contacts (five visits plus five phone calls) and a 12-session, therapist-led treatment (Nixon, Sweeney, Erickson, & Touyz, 2003). Morawska and Sanders (2006) found that a 10-session, self-directed intervention was superior to a wait-list control in reducing toddler's problem behaviors immediately after treatment, but not at 6-month follow-up. Webster-Stratton and colleagues (Webster-Stratton, Kolpacoff, & Hollinsworth, 1988; Webster-Stratton, Hollinsworth, & Kolpacoff, 1989; Webster-Stratton, 1990a,b, 1994) reported minimal differences between a program involving 10–12 weekly clinic visits to view instructional videotapes but no therapist contact, and a regular 12-session treatment program.

Certain characteristics of the minimal intervention studies, however, limit their use in treating ODD in primary care. First, minimal intervention studies either excluded children with diagnoses (Turner & Sanders, 2006) or did not confirm that a diagnosis was warranted (Morawska & Sanders, 2006; Nixon et al., 2003; Webster-Stratton et al., 1988). Second, with few exceptions (Shaw et al., 2006) most of the moderately intensive interventions (Cunningham, Bremner, & Boyle, 1995; Gross et al., 2003; Hood & Eyberg, 2003; Leung, Sanders, Leung, Mak, & Lau, 2003; Reid et al., 2003; Schuhmann, Foote, Eyberg, & Boggs, 1998; Webster-Stratton, 1981; Webster-Stratton & Hammond, 1997; Webster-Stratton et al., 2004) and only one study using a minimal intervention (Turner & Sanders, 2006) followed intent to treat procedures in data analysis. By including data from all children who enter treatment and not just “completers”, intent to treat analyses provide a more rigorous assessment of treatment efficacy.

Determining whether minimal interventions differ from standard interventions needs to be done within the intent to treat framework. In addition, when only “completers” are included, dose effects cannot be detected. Prior studies (Andrade, Lambert, & Bickman, 2000; Webster-Stratton et al., 1988; Werba, Eyberg, Boggs, & Algina, 2006) show inconsistent results for dose effects for child treatment in general, but dose effects have not been examined among children with ODD in primary care.

Third, previous minimal intervention studies have been efficacy-oriented, eliminating parents with problems that could interfere with treatment (Morawka & Sanders, 2006; Turner & Sanders, 2006) or children with organic pathology or history of trauma (Nixon et al., 2003). Fourth, only one study has been done in primary care (Turner & Sanders, 2006), and that study excluded children with psychiatric problems and did not include a long-term follow-up. Finally, all of the minimal interventions tested thus far required clinic attendance or therapist contact, limiting flexibility in providing services. Clarke, Lynch, Spofford, and DeBar (2006) see an increasingly important role for bibliotherapy in coming years, and an effectiveness-oriented intervention providing parents with self-instructional reading materials without therapist contact now needs to be tested with ODD in primary care.

This study examined the effectiveness of a moderately intensive, 12-session parent training program for ODD in young children suitable for implementation in primary care following two models for delivering mental health interventions within a primary health care setting (Morlock, 1989): (a) an office staff model with the provision of all services by individuals in the primary care setting, i.e., nurses; and (b) a mental health intervention model involving treatment within the practice by a mental health professional. The office staff and mental health referral models were compared to a third model, a minimal intervention treatment (MIT) using bibliotherapy. MIT using bibliotherapy was chosen as a comparison group because: (a) it seemed inappropriate to withhold treatment by assigning children to wait-list groups when the efficacy of moderately intensive parent training is well-established; (b) comparisons to alternative treatments provide stronger tests of treatment efficacy than do comparisons to untreated controls; and (c) WLC cause problems in assessing outcomes because WLCs generate a disproportionate number of dropouts that are difficult to address in “completer” analyses (Werba et al., 2006). Thus, studies seeking to improve available treatments might best be conducted by comparing the improved

treatments to the best available parenting intervention; studies seeking to determine if briefer interventions are effective should be compared to the standard treatments to see if there are significant reductions in effectiveness. Finally, efficacy and effectiveness studies fall along a continuum (Hoagwood, Hibbs, Brent, & Jensen, 1995); we consider the present study to be primarily an effectiveness trial because there were minimal exclusion criteria for participation, and because it was conducted in primary care pediatric offices with primary care health personnel providing treatment in one group.

Using planned comparisons to examine specific group differences, the study examined whether: (a) therapist-led interventions were superior to a MIT bibliotherapy group in treating ODD in pediatric primary care; (b) nurse-led training and psychologist-led treatments differed in effectiveness in treating ODD in pediatric primary care; and (c) there were dose effects associated with treatment.

Methods

Pediatric Practices

Patients were enrolled from 24 Chicago-area pediatric practices. Practices were stratified according to demographic characteristics (three clinics serving low-income families, 21 private practice groups) and randomly assigned to an intervention group.

Participants

Study participants were children ages 3.0–6.11 years and their parents. Eligible children (a) met DSM-IV criteria for ODD based on clinical consensus diagnoses; (b) exhibited receptive language at or above the 24-month level (lower levels of receptive language make participation in the intervention difficult); and (c) did not have a DSM-IV diagnosis that superseded the ODD diagnosis (e.g., autism). This study was approved by the medical center's Institutional Review Board.

Exclusions (see CONSORT flowchart, Fig. 1)

There were 4,233 age-eligible children screened by research assistants in the practices and an additional 50 children either referred to the study by their pediatrician or self-referred after reviewing brochures in the offices. Children were excluded if they screened low (externalizing scores below the 90th percentile, $n = 3,813$) on the Child Behavior Checklist (CBCL, Achenbach, 1991), were already in treatment or could not be scheduled for a pretreatment interview ($n = 39$), could not be reached

after screening ($n = 135$, including those who moved, lacked telephones, or passively refused participation), or refused further participation ($n = 92$).

Families of screen-high children (CBCL externalizing scores at or above the 90th percentile) participated in a second stage evaluation in which the pretreatment assessment battery was used to establish the ODD diagnosis. Children were excluded for not meeting diagnostic criteria for ODD ($n = 49$), failing the language screen ($n = 2$), refusing treatment ($n = 6$), being unavailable for treatment when pediatric offices were open ($n = 28$), or starting treatment after screening ($n = 2$). There were 117 children with ODD who started the study intervention.

Final Sample Characteristics

There were 49 children with ODD and their families enrolled in the nurse treatment group, 37 in the psychologist treatment group, and 31 in the MIT. Enrolled children included 62 (53%) males and 88 (75%) white children, with a mean Hollingshead score of 47.2 ($SD = 13.2$) (Hollingshead, 1975). The largest number were middle class families (Hollingshead-Redlich classes III and IV ($n = 66$, 60.0%), with both lower (class IV and V, $N = 11$, 10.0%) and upper classes (class I, $n = 33$, 30%) represented. This relatively large percentage of upper class children reflects the large number of well-educated, well-employed families available in a large, urban setting who seek care from private-practice physicians, the disparity in health care services making lower class residents less likely to have regular pediatricians and, perhaps, a tendency for practices serving patients of higher socioeconomic status to be willing to participate in research. The average age was 4.6 years ($SD = 1.0$). Within the treated sample, 65 (56%) had no comorbidities, while 52 (44.4%) had at least one comorbidity. The most common comorbid diagnosis was Attention Deficit Hyperactivity Disorder, occurring in 27.4% of the sample. Other comorbidities included anxiety disorders (not otherwise specified [NOS], separation anxiety, specific phobia; 5.1%), and depressive disorders NOS (6.0%).

Of the children entering treatment, 70.1% completed assessment measures at all three time points (nurse-led group, $N = 30$, 61.2%; psychologist-led group, $N = 28$, 75.7%; MIT, $N = 24$, 77.4%). Values were moved forward to posttreatment for 21.4% overall (nurse-led group, $N = 16$, 32.7%; psychologist-led group, $N = 6$, 16.2%; MIT, $N = 3$, 9.7%). Values were moved forward to follow-up for 15.4% overall (nurse-led group, $N = 9$, 18.4%; psychologist-led group, $N = 4$, 10.8%; MIT, $N = 5$, 16.1%).

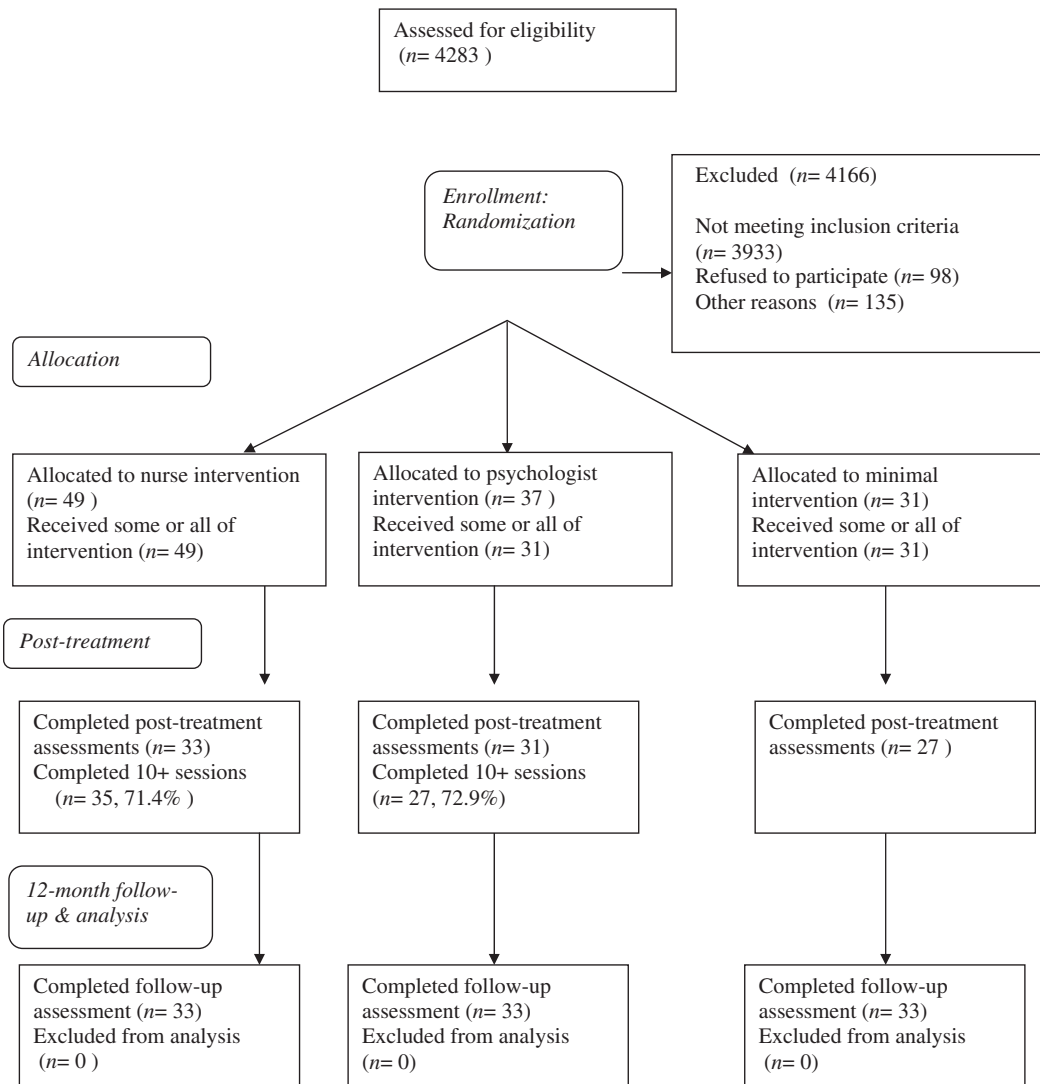


Figure 1. CONSORT flow chart.

Measures

Screening and Outcome Measures

Eyberg Child Behavior Inventory (ECBI). The intensity scale of the ECBI (Eyberg & Pincus, 1999) is a parent-reported measure of child oppositional behavior that has been widely used in studies of parent training for ODD symptoms. Scores range from 38 to 266; for preschoolers, $M = 99.2$, $SD = 33.8$.

Child Behavior Checklist. The CBCL (Achenbach, 1991) provides an estimate of the child's overall levels of behavioral symptoms, and indices of internalizing (i.e., anxiety, depression, and related problems), and externalizing symptom (e.g., noncompliance, temper tantrums, aggression, etc.). The T -score $M = 50$, $SD = 10$. With the Eyberg scale, the CBCL externalizing scale was one of the two primary measures of symptom change.

Family Background Questionnaire. At screening, parents completed a questionnaire to gather demographic information, including parental education and employment, which were coded for socioeconomic status (Hollingshead, 1975).

Peabody Picture Vocabulary Test (PPVT). The PPVT (Dunn & Dunn, 1981) is a widely used, individually administered, norm-referenced measure of single-word receptive language skills used as a language screening instrument.

Assignment of Diagnosis

Diagnoses were assigned on the basis of a semi-structured test battery for which reliability (Lavigne et al., 1994) and predictive validity were available (Lavigne et al., 1998). This assessment battery (Rochester Adaptive Behavior Inventory (RABI), observation of parent-child interaction,

Eyberg scale, CBCL) was the primary taxonomic assessment battery.

Rochester Adaptive Behavior Inventory. The RABI (Jones, 1977) a semi-structured parent-completed interview includes items on anxiety, mood, and disruptive disorders. Interviewers record parental responses for review by clinicians.

Observations of Parent-child Interaction. Following Forehand and McMahon's (1981) procedures, children and mothers were videotaped for 15 min engaging in child-chosen and parent-chosen activities, and a clean-up period. Observers rated child compliance in 15 s intervals to two types of parental commands: (a) compliance to specifically stated maternal "alpha" commands (e.g., "Put your shoes in your closet"); (b) compliance to less specifically stated "beta" commands [Would you put it away (when "it" is not clear)?]. κ are affected by base rates of observed behaviors, but were substantial (0.60–0.80; Landis & Koch, 1977) for alpha commands (0.61) and moderate to substantial for compliance to alpha commands, 0.59. Because agreement was only fair (0.35) for compliance to beta commands, that measure was eliminated. Alpha command compliance was expressed as the ratio of number of complies to number of commands ($M = 0.85$; $SD = 0.21$; Range, 0–1.0).

Outside Service Use. At follow-up, parents were asked whether they had sought treatment from community mental health professionals during the study period.

Knowledge Test. At follow-up, all parents completed a 35-item test of our devising to examine their knowledge of parenting practices.

Procedure

At screening, parents completed a demographic questionnaire and CBCL. Those screening high and agreeing to participate were administered the pretreatment assessment battery and PPVT. Subsequently, two doctoral-level psychologists independently reviewed the diagnostic battery results, viewed the videotaped observation, and assigned diagnoses following DSM-IV criteria. When a disagreement occurred, they met to assign a consensus diagnosis. The intervention was then conducted, followed by administration of questionnaires and the assessment battery posttreatment and at 12-month follow-up.

Intervention

Therapist-led Treatment Groups. The parenting program (Webster-Stratton, 1997) provided instruction and videotaped modeling of key parenting activities including appropriate play, and use of parental attention, praise,

consequences, and appropriate discipline techniques, including time out. Videotaped vignettes demonstrated the principles involved; therapists used a manual to guide discussion and gave homework.

Because the present study was designed to be an effectiveness trial and prior studies noted earlier showed that attrition before 12 sessions from child treatment is common in actual clinical settings, parents were given the choice of attending 6 two-hour meetings each of which covered two sessions or the standard 12 one-hour session procedure. The number of identified patients in any particular practice was too small to form groups without an undue waiting period, so treatment was provided either to individual parents or to small parent groups (two to three parents). All parents enrolled in the therapist-led interventions were given a copy of Webster-Stratton's book, *The Incredible Years* (Webster-Stratton, 1992), which served as a companion work to the intervention.

Intervention Leaders. Treatment for the nurse-led group was provided by seven licensed registered nurses with experience in primary care either employed by individual practices ($n = 2$) or provided by the study ($n = 5$). While all practices expressed an interest in having practice nurses learn and use the parenting programs if the study results warranted, study-provided nurses were used when practices lacked adequate staff to temporarily reassign clinical responsibilities. Five doctoral-level clinical child psychologists provided treatment in the psychologist-led group. Study-provided nurses and psychologists rotated between offices to provide treatment. All therapists were trained in the Webster-Stratton intervention by attending a 6-hr training seminar. Subsequently, two trainers with extensive experience in parent training for ODD supervised each therapist for two cases.

Minimal Intervention Treatment Group. Parents in the MIT condition were given *The Incredible Years* but did not participate in any treatment sessions; otherwise, they received the same care that would typically be provided in the pediatric setting.

Treatment Integrity. To ensure treatment integrity, therapists: (a) received training prior to beginning the intervention, as described above; (b) followed a treatment manual; (c) completed weekly checklists of principles covered in each session; and (d) provided audiotapes of sessions for review at regular supervisory meetings. Audiotapes were reviewed by a master trainer for each therapist for one full case, and a randomly selected 10% of tapes were reviewed by both of the master raters. In assessing interrater agreement, the master raters examined whether the major goals of the session were met and

whether information inconsistent with the treatment was introduced by the trainer. Agreement on these major categories was 88% for meeting goals ($\kappa=0.64$, $p=0.001$), with all goals met in 94% of the sessions; agreement was 100% that no information incompatible with the goals was introduced by the trainers.

Statistical Analyses

For continuous measures, linear mixed model analyses were used to assess pretreatment group differences with pediatric practices treated as random effects because clustering could occur within pediatric practices. χ^2 analyses were used to compare pretreatment categorical variables across groups. Linear mixed modeling procedures were also used to assess treatment-related changes over time, with treatment group, trials, and the group by trials interactions treated as a fixed effect and pediatric practice as a random effect. In assessing changes over time, the combined therapist-led treatments were compared with the MIT group, and the two therapist-led groups were compared with one another. Linear mixed modeling procedures were appropriate because of the hierarchical nature of the data, with trials nested within participants, and participants within practices. Analyses followed an intent to treat model including data from all participants receiving any treatment, with scores “moved forward” from one assessment period to the next if the family did not participate in that assessment period.

Results

Pretreatment Comparisons

There were no treatment group differences for child's age, gender, race, parent's marital status, social class, maternal or paternal education, or child's receptive vocabulary (PPVT). There were no differences between treatment groups on the number of children exhibiting comorbidity (any diagnosis vs. no comorbidity). The mean CBCL externalizing score for the sample was 70.7 ($SD=5.96$, Range=63–87); internalizing $M=60.74$, $SD=10.20$, Range=34–91; total problem scores $M=68.87$, $SD=7.37$, Range=52–90; Eyberg intensity scores $M=155.44$, $SD=27.41$, Range=74–219; alpha command compliance $M=0.85$, $SD=21$, Range=0–1.0.

Treatment Effects

Eyberg Scale

For the Eyberg intensity scale, the group comparison was not significant, $F(2, 12.26)=0.40$, $p=0.68$, but the trials effect was significant, $F(2, 305.94)=25.52$, $p=0.001$, indicating improvement across all three

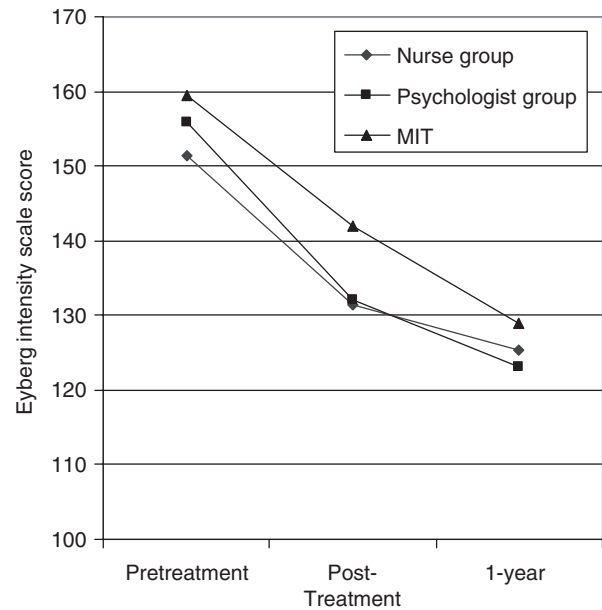


Figure 2. Eyberg intensity scale scores at pretreatment, posttreatment, and follow-up for all three treatment groups.

groups over time (Fig. 2). The group \times trials interaction was not significant, $F(4, 205.94)=0.26$, $p=0.92$, reflecting no overall differences between treatments over time. The group effect was not significant for the combined therapist-led groups versus MIT, $F(1, 13.59)=0.92$, $p=0.35$, but the trials effect was significant, $F(2, 307.01)=22.22$, $p=0.001$, while the treatment by trials interaction was not significant, $F(4, 307.01)=17$, $p=0.86$. In addition, the two therapist-led groups showed a nonsignificant group effect, $F(1, 3.87)=0.04$, $p=0.85$ and a significant trials effect, $F(2, 219.93)=19.04$, $p=0.001$, but did not differ from one another over trials, $F(2, 219.92)=0.26$, $p=0.77$.

CBCL Externalizing Scale

Group differences for the CBCL externalizing scale were not significant, $F(2, 12.43)=1.23$, $p=0.33$, the trials effect was significant, $F(2, 321.60)=53.55$, $p=0.001$ (Fig. 3), and the group \times trials interaction was not significant, $F(4, 321.69)=0.827$, $p=0.52$. In the combined therapist-led versus MIT comparison, the group effect was not significant, $F(1, 14.33)=1.60$, $p=0.23$, the trials effect was significant, $F(2, 323.040)=44.47$, $p=0.001$, but the treatment group by trials interaction was not significant, $F(2, 323.04)=0.61$, $p=0.54$. The two therapist-led groups showed no group difference, $F(1, 6.73)=1.44$, $p=0.27$, a significant trials effect, $F(2, 239.05)=37.66$,

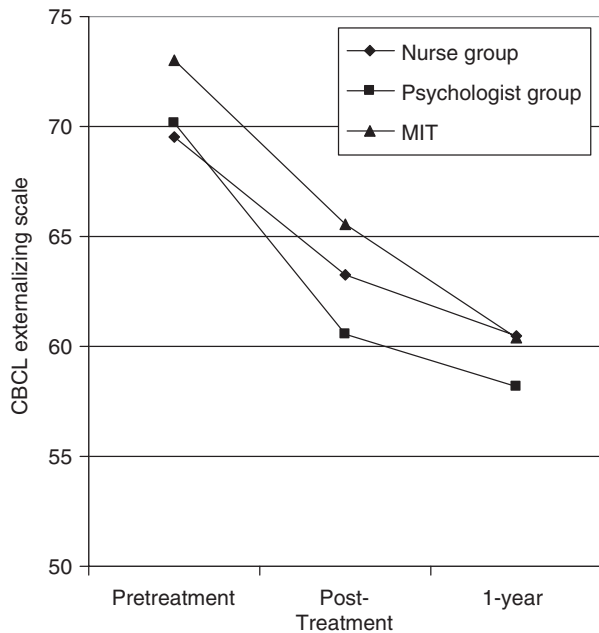


Figure 3. CBCL externalizing scale at pretreatment, posttreatment, and follow-up for all three treatment groups.

$p = 0.001$, but a nonsignificant group \times trials interaction, $F(2, 239.05) = 1.05$, $p = 0.35$.

Alpha Command Compliance

Group differences in the alpha compliance ratio were not significant, $F(2, 15.57) = 0.29$, $p = 0.76$, and neither the trials effect, $F(2, 306.96) = 0.47$, $p = 0.62$, nor the group \times trials interaction were significant $F(4, 306.97) = 0.34$, $p = 0.85$. Neither planned comparison was significant for group (therapist led vs. MIT), $F(1, 18.29) = 0.46$, $p = 0.51$, trials, $F(2, 309.07) = 0.51$, $p = 0.60$, or group \times trials, $F(2, 309.07) = 0.02$, $p = 0.98$; for nurse versus psychologist, group $F(1, 9.25) = 0.045$, $p = 0.79$; trials, $F(2, 223.04) = 0.21$, $p = 0.81$; or group \times trials, $F(2, 223.04) = 0.58$, $p = 0.56$. Ceiling effects seem to have contributed to the lack of change over time, with most children complying at relatively high rates during the observation period at baseline (85.4%).

Clinically Significant Change

Because there were large trials effect for both the Eyberg and CBCL externalizing scales, we examined whether participants achieved: (a) a statistically reliable level of change; and (b) whether the changes returned the child to a normal level of function by surpassing a cutoff score showing that the child's posttreatment or follow-up score was closer to the mean of the normal population than to the mean of the dysfunctional patients (Jacobson

& Truax, 1991). The cutoff scores (CBCL externalizing scale cutoff = 62.85; Eyberg intensity scale cutoff = 129.66) were based upon the mean and *SD* from the standardization samples and the pretreatment mean and *SD* for the diagnosed children enrolled in the present study. On the Eyberg scale, 16.7% had both achieved a reliable change and returned to the normal range at posttreatment, while this was achieved by 23.1% at the 1-year follow-up; on the CBCL externalizing scale, it was 35.0 and 47.9%, respectively. Thus, a substantial portion of the children in the study showed a clinically significant level of improvement. Reliable change indices were not calculated for the observational data because data from normative samples were unavailable.

Testing Treatment Equivalence

While the finding of "no difference" in traditional hypothesis testing does not mean that two treatments are equivalent, equivalence testing can establish that two treatments are essentially equivalent in producing an outcome. Equivalence testing is particularly important in determining whether a lower cost or more convenient treatment is as effective as a more costly or less convenient intervention (Rogers, Howard, & Vessey, 1993). We examined the equivalence of the interventions for the two measures that did not show ceiling effects, the Eyberg intensity, and CBCL externalizing scales, following the confidence interval (CI) approach in which the CI for a difference between the means of two groups is considered significant only if the CI did not include zero (Rogers et al., 1993). We chose an equivalence interval of 10%, i.e., groups were considered equivalent if they differed by less than 10% following treatment.

The MIT group was equivalent to the combined therapist-led groups at the 10% level on the CBCL externalizing scale both posttreatment (CI = -0.639 to 7.44) and at follow-up (CI = -2.94 to 4.82), and on the Eyberg scale at both posttreatment (CI = -3.94 to 23.48) and at follow-up (CI = -11.33 to 14.81). The nurse-led and psychologist-led groups were equivalent at the 10% level on the CBCL externalizing scale both posttreatment (CI = -1.43 to 2.12) and follow-up (CI = -1.52 to 6.14), and on the Eyberg scale at both posttreatment (CI = -16.08 to 13.42) and at follow-up (CI = -8.15 to 19.49).

Dose Effects

While there was little evidence for overall treatment group differences, it was possible that there were treatment dose effects, with the MIT and therapist-led groups differing

only when parents attended a relatively large number of treatment sessions. In examining dose effects, each session of material reviewed with a therapist was treated as one dose of treatment, and participants in the MIT group were treated as receiving no dose of treatment. Because nurse-led and psychologist-led groups did not differ in the number of meetings attended or the number of sessions of material covered [meetings attended, $F(1, 10.35) = 1.8, p = 0.20$; sessions covered, $F(1, 11.66) = 1.47, p = 0.25$; session $M = 9.95, SD = 3.45$], the two therapist-led groups were combined in comparisons with the MIT group. Because the number of sessions and number of meetings correlated highly ($r = 0.71$), only results for sessions are presented.

Eyberg intensity scales showed a significant dose effect [trial \times sessions, $F(3, 72.02) = 4.68, p = 0.005$], with greater improvement for those attending more sessions. Scores showed a large improvement between no therapist-led sessions and one or more sessions at posttest, but at follow-up the difference between attending no therapist-led sessions and one or more is smaller than at posttest results. This pattern should not be interpreted to mean that attending a single session made the largest difference because the one session reflects the minimum number attended (1 or more, 2 or more, etc.) and most parents attending one session continued on to receive more. After the first session, there was a smaller improvement associated with an increase in the number of sessions at both posttreatment and 12-month follow-up.

Externalizing scores showed a similar pattern. For the externalizing scores, however, convergence could not be achieved with the random effect for practices, so it was conducted without practice as a random effect. The treatment \times trials interaction was significant, [$F(3, 44.05) = 6.05, p = 0.001$]. Alpha compliance, [$F(3, 47.63) = 1.03, p = 0.38$] did not show a significant dose effect.

We then examined whether there was a critical dose level at which significant gains could be detected. This was done with a series of linear mixed model analyses comparing participants with no dose and those with N or more doses. Patients may have left treatment because they felt it was not beneficial, but others may have terminated treatment because they felt they had benefited as much as they needed. When trying to identify a critical number of sessions, the differences in the reasons for leaving treatment may produce inconsistent trends, i.e., if enough patients benefiting from treatment left at four sessions, and others making less progress remained for an

Table I. Dose Effects

Sessions	Measure			
	Eyberg Scale		CBCL Externalizing Scale	
	<i>F</i>	<i>p</i>	<i>F</i>	<i>p</i>
≥ 1	1.78 (3, 53.9)	NS	2.10 (3, 61.8)	NS
≥ 2	2.14 (3, 50.1)	NS	1.98 (3, 60.9)	NS
≥ 3	2.68 (3, 52.0)	NS	2.82 (3, 47.8)	.05
≥ 4	2.85 (3, 53.1)	.05	3.02 (3, 44.5)	.04
≥ 5	2.45 (3, 54.6)	NS	2.86 (3, 45.7)	.05
≥ 6	2.18 (3, 56.1)	NS	1.08 (3, 48.6)	NS
≥ 7	3.34 (3, 56.0)	.03	2.92 (3, 56.0)	.04
≥ 8	2.81 (3, 52.1)	.05	2.46 (3, 49.2)	NS
≥ 9	2.95 (3, 50.1)	.04	2.90 (3, 46.0)	.05
≥ 10	3.25 (3, 51.2)	.03	3.32 (3, 44.4)	.03

additional session, attending four or more sessions might be significantly better than none, but five or more sessions might not. As a result, we sought to determine if there was a critical dose beyond which treatment was consistently better than no treatment.

For the Eyberg scale (Table I), attending three or fewer therapist-led sessions did not differ from attending no sessions. Between four and six sessions, results were inconsistent, with four sessions differing from no sessions but not five or six sessions. In contrast, attending seven or more sessions was consistently better than no treatment. For the CBCL externalizing scale (Table I), attending two or fewer therapist-led sessions did not differ from attending none, and results were inconsistent between three and eight sessions. Attending nine or more sessions was consistently better than no sessions.

Dose Effects in Therapist-led Groups Only

We then examined if there were dose effects only for those receiving therapist-led treatment. Eyberg intensity scales showed a significant dose effects for number of sessions, trial \times sessions $F(3, 186.29) = 3.814, p = 0.011$, with greater improvement for those attending more sessions. Externalizing scores showed a similar pattern, trials \times sessions $F(3, 329.00) = 4.169, p = 0.007$. Alpha compliance showed no significant dose effects, $F(2, 214.30) = 0.487, p = 0.615$.

Comparison of Results to Untreated Controls in Other Studies

For heuristic purposes, we compared the results of this study to those of three studies by Webster-Stratton and colleagues (Webster-Stratton, 1982; Webster-Stratton & Hammond, 1997; Webster-Stratton et al., 1988) using one of the same outcome measures, the Eyberg

intensity scale. In those studies, the percent of change from pretreatment to immediate posttreatment for groups receiving parent training ranged from 9.9 to 30.1%; the percent change at posttreatment for the present study fell within that range (nurse-led treatment, 13.1%; psychologist-led treatment, 15.3%). One study by Webster-Stratton (1982) using parent-training and the Eyberg scale included a 1-year follow-up, for which the percent change was 28.9%; in the present study, it was 17.2% for nurse-led groups and 28.6% for psychologist-led groups. In the one study (Webster-Stratton et al., 1988) in which self-directed treatment was conducted, the percent change at posttreatment was 19.2%; for the present study it was 11.0%. Webster-Stratton did not include a 1-year follow-up for the self-directed treatment; in the present study the 1-year percent change for the MIT group was 19.1%. These results can be compared to percent changes for Webster-Stratton et al.'s wait-list groups, which were 4.9 and 6.1% at posttreatment. No 12-month follow-up data were available. Overall, treatment results for this study seem comparable to those conducted by Webster-Stratton.

Child-rearing Knowledge at Follow-up

The three groups did not differ in their scores on the postfollow-up knowledge test, [$F(2, 13.89) = 0.034, p = 0.97$].

Use of Other Mental Health Services

At the follow-up assessment, parents were asked if they had seen a mental health professional for treatment of the participating child during the study year. The groups did not differ on outside mental health service use, $\chi^2(2) = 1.47, p = 0.48$ (nurse-led group, $N = 8, 16.3%$; psychologist-led group, $N = 10, 27.0%$; MIT, $N = 7, 22.5%$).

Discussion

A key problem for improving the provision of mental health services in primary care is the development and testing of efficacious treatments suitable for such settings (Kelleher & Rickert, 1994). The present study compared three models of intervention: an office model, with primary care nurses providing a moderately intensive parent training program; a referral model, with clinical child psychologists providing the same parent training, and a minimal intervention treatment without therapist contact. The Webster-Stratton parent training program we used has considerable empirical support and its videotape-based program seemed suitable for use by

nonmental health professionals. In the MIT group, parents were given Webster-Stratton's *The Incredible Years*, which covers the concepts used in the fuller parent training program. We compared the therapist-led treatments to the MIT condition rather than a wait-list control because: (a) the superiority of parent training over wait-list controls seemed well-established and there appeared to be little additional benefit from conducting another comparison of parent training with a wait-list group; and (b) families receiving mental health care often come for too few sessions to complete a 12-session treatment program such as those often used in manual-driven, empirically-supported treatments. Thus, for some families a less demanding, minimal intervention treatment regimen may have been appropriate. Only if behavior change was greater in the intensive interventions than the minimal intervention treatment would the costs of the more intensive treatments be worthwhile.

There was a significant improvement over time on parent-reported measures of symptoms for all three treatment groups, but there were no significant treatment differences across trials. Overall gains were substantial on the Eyberg and CBCL externalizing scales at posttreatment and follow-up, with 23.1% returning to normal function on the Eyberg scale and 47.9% on the CBCL externalizing scale at follow-up. Improvement was not noted on the play observation compliance measure due to ceiling effects, with most children complying during the observation period at high rates. Equivalence tests showed the MIT group to be equivalent to the therapist-led groups at posttreatment and follow-up, with less than a 10% difference between groups at either time.

While overall treatment group differences over trials did not emerge, there were significant dose effects, with greater improvement on both the Eyberg and CBCL externalizing scales for those receiving more treatment sessions. A consistent pattern of improvement was noted on the Eyberg scale if participants attended at least seven therapist-led sessions and, for the externalizing scale, at least nine sessions.

The few prior studies using abbreviated interventions with children exhibiting ODD-related behavior problems provide some support for the efficacy of briefer interventions, at least at posttreatment. The present study extends this work by demonstrating that an even less intensive treatment than studied previously, involving neither therapist contact nor office visits, provides similar outcomes to therapist-led treatment overall, and that there is a dose effect requiring a fairly high level of

attendance before therapist-led treatment is superior to a minimal intervention. The present study was also conducted with children with confirmed ODD diagnoses following a rigorous intent to treat design rather than a “completer” analysis.

These results differ from prior studies, which generally find strong support for therapist-led parent training as an effective treatment of ODD-related symptoms. There are several reasons for this: (a) therapist-led, moderately intensive treatments provide more impressive outcomes when compared to wait-list controls than minimally intensive interventions. (b) most prior studies of parent training have conducted “completer” rather than intent to treat analyses. As this study shows, when the “dose” is large enough, parent training seems more effective than when data from all participants are used in an intent to treat analysis; (c) the present study provided a more rigorous test than most prior studies by only admitting children to treatment who met DSM-IV criteria for ODD; and, perhaps most importantly, (d) this study was designed as an effectiveness trial, while most prior studies were efficacy-oriented. Efficacy trials concentrate on maintaining the internal validity of the study to demonstrate treatment effects and emphasis is often placed on reducing conditions that might prevent treatment effects from emerging by eliminating more complex subjects (e.g., excluding those exhibiting comorbidity), eliminating more complex families that might not be able to complete or carry out treatment, or including children exhibiting high symptom levels but not meeting diagnostic criteria for the disorder under study. While this is appropriate when treatment effects are being examined initially, it can restrict the external validity of the results, i.e., how well results can be extended to the patients in clinic situations. In the present study, exclusion criteria were minimal. As a result, children were not excluded if comorbid conditions were present and many families had complex social situations. We also sought to maintain treatment conditions as close as possible to those that could be sustained in clinical practice, employing nurses with training and experience in primary care rather than psychiatric nursing, deciding not to provide transportation or incentives for attending sessions as sometimes occurs in efficacy trials. These decisions may have led therapist-led treatment to be less effective in this study than in prior trials, but the procedures are more representative of parent training in clinic settings.

Possibly the results of this study may be specific to characteristics of primary care participants that differ from

those participants in prior studies seen outside of primary care, in mental health service settings. Such participant differences have not been well-delineated as yet. Families of children with ODD in primary care may not have sought services in the mental health system either publicly or privately, and may not have brought their concerns to the pediatrician’s attention so that intervention can take place. While the differences have not been well-delineated, one study suggests that preschoolers not receiving referrals were less impaired, and came from families experiencing less conflict (Lavigne et al., 1998b). If so, these children could be particularly responsive to minimal interventions and not require the more intensive, therapist-led treatment.

In the present study, children from all social classes were represented but many families came from the highest two Hollingshead-Redlich social classes. This social class distribution may not be unusual in private practice primary care pediatric settings, but the results could be different if the study were conducted primarily in less well-educated or socially disadvantaged samples.

The results indicate that the intensive, therapist-led intervention developed by Webster-Stratton et al. can be implemented in primary care using either the nurse-led or psychologist-led linkage models. Since moderately intensive, therapist-led treatment was not found to be more effective in primary care than a minimal intervention, the study does not provide support for the use of therapist-led interventions as the first-line of treatment at this time, even for children meeting criteria for ODD in primary care. Similar treatment gains can be achieved with a minimal intervention. Unless families attend a relatively large number of sessions, bibliotherapy may provide the best initial intervention. Possibly, more intensive treatment would be appropriate as a second stage intervention, or with specific families if predictors for better response to therapist-led interventions than bibliotherapy can be identified in future studies. Possibly, however, families receiving bibliotherapy could be less likely to attend treatment sessions if that treatment was unsuccessful and they became discouraged; this is an empirical question that warrants further study.

While this study design allows us to conclude that, overall, the therapist-led intervention was not more successful than minimal treatment, and was only better if parents attended a large proportion of treatment sessions, the present study cannot conclusively determine how much better the minimal intervention bibliotherapy is than no intervention at all. Regression to the mean, for example, could account for the improvements across

trials seen for all treatment groups; this is unlikely to be the sole cause of improvement, however, because dose effects would not have occurred if regression to the mean was the sole reason for improvement. Furthermore, when the results of this study are compared to existing studies, it seems unlikely that the bibliotherapy had no effect since (a) several prior studies show minimal gains for wait-list groups in a year and prior research in this age group suggests ODD is reasonably stable; and (b) prior studies show that parent training is superior to no treatment and this minimal intervention group showed similar results overall to the therapist-led interventions. Further research, however, would be needed to determine if a period of “watchful waiting” without reading at all would be as successful as reading *The Incredible Years*. The study also differed from prior work in allowing the intervention to be administered in fewer meetings and in an individual format. These changes, designed to make the interventions more suitable for the primary care setting and clientele, did not seem to be significant changes from prior research since the “dose” findings in this study are similar to the “completer” findings of prior research, and because prior studies of less intensive interventions involving therapist contact also show similar effects for less intensive treatments.

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Appendix

The following are the individuals who worked closely with the research team: Barry Abrams, M.D., Advocate Oak Park Pediatrics, Oak Park, IL; Barbara Bayldon, M.D., Winfield-Moody Health Center, Near North Health Service Corporation, Chicago, IL; Richard Burnstine, M.D., North Suburban Pediatrics, Evanston, IL; Joseph O’Neil, M.D., Child and Adolescent Center, Evanston Northwestern Health Care, Evanston, IL; Marvin Cooper, M.D., North Shore Pediatrics, Chicago, IL; David Dobkin, M.D.,

North Arlington Pediatrics, Arlington Heights, IL; Lisa Gadek, M.D., Lake Forest Pediatrics, Lake Forest, IL; H. Garry Gardner, M.D., Du Page Pediatrics, Darien, IL; Karen Haught, M.D., M.P.H., Children’s Memorial Pediatrics—Uptown, Chicago, IL; Inyang Isong, M.D., Lawndale Christian Health Center, Chicago, IL; John Kahler, M.D., Advocate Hyde Park Pediatrics, Chicago, IL; Bennett Kaye, M.D., Children’s Health Care Associates, Chicago, IL; Peter Liber, M.D., Wheaton Pediatrics, Wheaton, IL; Fatima Moghadam, M.D., Dr Moghadam and Associates, Naperville, IL; John Poncher, M.D., Associated Pediatrics, Portage, IN; William D. Rutenberg, M.D., Grove Pediatrics, Long Grove, IL; Jaye Schrier, M.D., Child Life Center, Homewood, IL; Davila Sen, M.D., Evanston, IL; Norman Segal, M.D., Pediatric Healthcare Associates, Arlington Heights, IL; Joyce Smith, M.D., Circle Family Care, Chicago, IL; Timothy Wall, M.D., Pediatric Health Associates, Naperville, IL; Lori Weiss, M.D., Ad-Park Pediatrics, Oak Park, IL; Lori Walsh, M.D., Glenview Pediatrics, Glenview, IL; Amy Becker Manion, C.P.N.E., Northwestern Children’s Primary Care, Chicago, IL.

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