DIGITAL ACCESS TO SCHOLARSHIP AT HARVARD
DASH.HARVARD.EDU

HARVARD LIBRARY
Office for Scholarly Communication

Testing Standard and Modular Designs for Psychotherapy Treating Depression, Anxiety, and Conduct Problems in Youth

The Harvard community has made this article openly available. **Please share** how this access benefits you. Your story matters

CONFIDENTIAL MANUSCRIPT, IN PRESS*

Testing Standard and Modular Designs for Psychotherapy with Youth Depression, Anxiety, and Conduct Problems: A Randomized Effectiveness Trial

John R. Weisz, Ph.D.[1,2]; Bruce F. Chorpita, Ph.D.[3]; Lawrence A. Palinkas, Ph.D.[4]; Sonja K. Schoenwald, Ph.D.[5]; Jeanne Miranda, Ph.D.; Sarah Kate Bearman, Ph.D.; Eric L. Daleiden, Ph.D.[6]; Ana M. Ugueto, Ph.D.; Anya Ho, Ph.D.; Jacqueline Martin, Ph.D.; Jane Gray, Ph.D.; Alisha Alleyne, Ph.D.; David A. Langer, Ph.D.; Michael A. Southam-Gerow, Ph.D.[7]; Robert D. Gibbons, Ph.D.[8]; and the Research Network on Youth Mental Health

Word Count: 4500

Corresponding Author: John R. Weisz, Ph.D., Department of Psychology, Harvard University, 33 Kirkland Street, Cambridge, MA 02138 (jweisz@jbcc.harvard.edu), Phone: 617-278-4299, Fax: 617-730-5440

Running head: Test of Modular Psychotherapy for Youth

*This manuscript has been accepted for publication at a journal that has a strict embargo policy. Until the article is published, the authors are not allowed to share the manuscript. However, I been given permission to share the manuscript with you, as a <u>confidential document</u>. I am allowed to tell you that is has been accepted for publication, but I am not allowed to indicate the name of the journal, *and* I am instructed to tell you that the information is embargoed until publication. John Weisz

[1] Harvard University, Department of Psychology, Cambridge, MA (Dr. Weisz)
[2] Judge Baker Children's Center, Harvard Medical School, Boston, MA (Drs. Weisz, Bearman, Ugueto, Ho, Martin, Gray, Alleyne, and Langer)
[3] University of California, Los Angeles, CA (Drs. Chorpita and Miranda)
[4] The University of Southern California, Los Angeles, CA (Dr. Palinkas)
[5] The Medical University of South Carolina, Charleston, SC (Dr. Schoenwald)
[6] Kismetrics, LLC, Satellite Beach, FL (Dr. Daleiden)
[7] Virginia Commonwealth University, Richmond, VA (Dr. Southam-Gerow)
[8] The University of Chicago, Chicago, IL (Dr. Gibbons)

Abstract

Context—Decades of randomized controlled trials have produced separate evidence-based treatments (EBTs) for youth depression, anxiety, and conduct problems, but these treatments are not often used in clinical practice, and they produce mixed results in trials with the comorbid, complex youths seen in practice. An integrative, modular redesign may help.

Objective—Standard/separate and modular/integrated arrangements of EBTs for youth depression, anxiety, and conduct problems were compared to usual clinical care, with the modular design permitting a multi-disorder focus and flexible application of treatment procedures.

Design, Setting, and Participants—84 community clinicians, randomized to 3 conditions, treated 174 clinically-referred youths (ages 7-13, 69.5% boys, 45.4% Caucasian). Study conducted 1/12/2005 – 5/08/2009.

Interventions—Standard manual treatment (59 youths [34% of sample]; cognitive-behavioral therapy [CBT] for depression, CBT for anxiety, and behavioral parent training for conduct problems); modular treatment (62 youths [36%]; integrating the procedures of the three separate treatments); and usual care (53 youths [30%]).

Main Outcome Measure(s)—Outcomes were assessed through weekly youth and parent assessments using a standardized Brief Problem Checklist (BPC) and a patient-generated Top Problems Assessment (TPA, severity ratings on the problems youths and parents had identified as most important), and through standardized diagnostic assessment at pre- and post-treatment.

Results—Mixed effects regression analyses showed that modular treatment produced significantly steeper trajectories of improvement than usual care and standard treatment on multiple BPC and TPA measures. Youths receiving modular treatment also had significantly

fewer diagnoses than usual care youths at post-treatment. In contrast, outcomes of standard manual treatment did not differ significantly from usual care.

Conclusions—The modular approach used here outperformed usual care and standard EBTs on multiple clinical outcome measures. The modular approach may be a promising way to build on the strengths of EBTs, improving their utility and effectiveness with referred youths in clinical practice settings.

Trial Registration—clinicaltrials.gov Identifier: NCT01178554

Testing Standard and Modular Designs for Psychotherapy with Youth Depression,

Anxiety, and Conduct Problems: A Randomized Effectiveness Trial

Youth depression, anxiety, and conduct-related disorders and problems are among the priority conditions identified by the World Health Organization,[1] which reports that mental health problems affect up to 20% of all youths worldwide. Fortunately, intervention researchers, across decades of randomized trials, have produced numerous manual-guided, evidence-based treatments (EBTs) for youth depression, anxiety, and conduct.[2] Unfortunately, these treatments have not been incorporated into most everyday clinical practice.[3-5] A common view is that the complexity and comorbidity of many clinically-referred youths, whose problems and treatment needs can shift during treatment, may pose problems for EBT protocols, which are typically designed for single or homogeneous clusters of disorders, developed and tested with recruited youths who differ from patients seen in everyday clinical practice, and involve a pre-determined sequence of prescribed session contents, limiting their flexibility.[3-8] Indeed, trials testing these protocols against usual care for young patients in clinical practice have produced quite mixed findings, with EBTs often failing to outperform usual care.[7,9]

The *Modular Approach to Therapy for Children with Anxiety, Depression, or Conduct Problems* (MATCH),[10] addresses these concerns through treatment redesign, informed by experience in clinical practice settings.[11-15] In MATCH, treatment procedures from EBTs for anxiety (CBT), depression (CBT), and disruptive conduct (BPT) are structured as free-standing modules—e.g., modules for self-calming, modifying negative cognitions, and increasing compliance with parents' instructions. The modules form a menu of options for clinicians. Decision flowcharts guide module selection and sequencing,[16] with a default module sequence suggested, but changes in the sequence specified to address treatment difficulties. For example,

the anxiety flowchart includes a core "practicing" module involving graduated exposure to feared situations; if youth motivation is low for "practicing," the therapist may use optional modules for "praise" and "reward," to boost motivation and thus increase practice.

We designed a trial to test both modular and standard treatment approaches. We addressed some of the prior criticisms of EBT research by ensuring that (a) participants and study context were clinically representative, (b) there were no systematic differences in clinician competence across conditions (i.e., all clinicians were randomized), and (c) the sample would include the ethnic diversity critics have found insufficient in the RCT literature. [17-20] Accordingly, we sampled from outpatient treatment programs that served the general public across a broad demographic and income range, we included only youths whose families sought treatment (i.e., no recruiting or advertising), all treatment was provided by professional clinicians employed in the participating programs, and all treatment was provided in those programs (i.e., not in university lab clinics).

The sample had all sought outpatient care and had primary disorders or referral problems involving anxiety, depression, or disruptive conduct. The practitioners were randomized to three conditions: modular (i.e., MATCH), standard (i.e., the use of three established EBTs for anxiety, depression, and conduct problems), or usual care (UC). Measures included weekly problem assessments to measure change throughout treatment, plus diagnostic assessment at pre- and post-treatment. Analyses tested whether outcomes of usual care were improved upon by the use of standard EBT manuals, MATCH, or both.

Methods

All study procedures were approved by the IRB of Judge Baker Children's Center, Harvard Medical School and the University of Hawaii at Manoa, and all participants signed IRB-approved informed consent/assent documents.

Participants

Sample demographics. The 174 youths, aged 7-13 (mean age 10.59 years, SD=1.76); 70% were boys (*n*=121); 45% were Caucasian, 32% multiethnic, 9% African-American, 6% Latino/a, 4% Asian-American/Pacific Islander, and 2% other. Annual family income was below $40K for 55% of the sample, $40-79K for 28%, $80-119K for 12%, and $120K or higher for 6%; 53% lived in single-parent households.

Sample clinical characteristics. We sought youths with *Diagnostic and Statistical Manual of Mental Disorders, 4th edition* (DSM-IV)[21] disorders or clinically-elevated problem levels in the areas of anxiety, depression, and/or disruptive conduct. Diagnoses were obtained via the Children's Interview for Psychiatric Syndromes (ChIPS),[22,23] and elevated problem levels (i.e., T-scores of 65 or higher) were identified through relevant scales of the Child Behavior Checklist (CBCL) and Youth Self-Report (YSR).[24] Youths were excluded for mental retardation (*n*=1); pervasive developmental disorder or psychotic symptoms (N=1); primary bipolar disorder (*n*=2), or primary inattention or hyperactivity (*n*=3). Diagnoses, CBCL/YSR scale scores, and youth- and parent-identified top problems (see below) were used to identify the primary disorder and clinical problem in each case. Mean number of DSM-IV disorders was 2.74 (*SD* =1.52). Table 1 shows primary disorders and all disorders for the full sample. The three study conditions did not differ significantly in number of disorders (*p*=.76).

Therapists, service settings, experimental conditions. The study included 84 therapists who worked in ten different outpatient clinical service organizations in Massachusetts and Hawaii Therapists were 80% female and 56% Caucasian, 23% Asian-American, 6% African-American, and 6% Pacific Islander; mean age was 40.6 and mean years of clinical experience was 7.6; 40% were social workers, 24% psychologists, and 36% other (e.g., licensed mental health counselor). There were no significant differences across condition on any of the therapist characteristics. Therapists employed individual (not group) treatment in the study, with family members often included for parts of sessions (see below).

Measurement I. Outcome Trajectory Assessed Via Weekly Measures

Trajectories of change during treatment were tracked by blinded assessors using weekly measures selected to be sufficiently brief that youths and parents would complete them frequently, and to include (a) standardized measures reflecting widely recognized dimensions of youth psychopathology, and (b) assessment of the specific problems youths and parents identified as most important to them at the outset of treatment.

Brief Problem Checklist. The Brief Problem Checklist (BPC),[25] administered by phone, is a 12-item measure of internalizing (6 items; scores can range from 0-12) , externalizing (6 items; range 0-12), and total problems (12 items; range 0-24), developed through application of item response theory and factor analysis to data from the YSR and CBCL (two very widely-used youth symptom measures). Reliability and validity evidence is strong, and the BPC significantly predicts change in youth symptoms during treatment. In the original BPC clinical sample[25] (N=184), means (SDs) were 2.79 (2.62), 2.90 (2.40), and 5.68 (4.14) for youth-report internalizing, externalizing, and total, and 4.41 (3.11), 5.14 (3.04), and 9.55 (4.90) for parent-report internalizing, externalizing, and total, respectively.

Top Problems Assessment. The Top Problems Assessment (TPA),[26] also administered by phone, entails youth and parent severity ratings (on a scale of 0-10) of the top three problems the youth and parent independently identified as most important to them in separate structured pre-treatment interviews. Psychometric analyses have shown strong reliability, validity, and sensitivity to change during treatment. In the original TPA clinical sample[26] (N=178), the mean youth rating was 4.96 (SD=2.96) and the mean parent rating was 6.70 (SD=2.33).

Measurement II. Diagnosis

ChIPS Child and Parent Interviews (ChIPS, PChIPS). [22, 23] Blinded interviewers administered this structured interview to assess DSM-IV diagnoses. Reliability and validity are well-documented in studies of outpatient and inpatient samples,[27] and five psychometric studies have shown mean sensitivity of .66-.83, and mean specificity of .78-.88. [22, 23] Combined diagnoses were generated via the Silverman-Nelles[28] procedure for integrating youth and parent reports, in which all diagnoses generated by both informants are accepted, diagnoses generated by child report are accepted if internalizing (and thus potentially more evident to youths than adults--e.g., anxiety or depressive disorders) and diagnoses generated by parent report are accepted if externalizing (e.g., oppositional defiant disorder). See eMethods1 for interviewer training and diagnostic reliability. Because the study focused on youths across a broad spectrum (see Table 1)—not just a single target diagnosis, as in most RCTs—we used total number of diagnoses as an outcome measure, to reflect that spectrum.

Measurement III. Medication Use

Services for Children and Adolescents—Parent Interview (SCAPI). The SCAPI has shown psychometric integrity, with particular strength in medication assessment, including start and end

dates, and dose (ICC=0.99).[29, 30] It was administered to parents at pretreatment and in weekly calls thereafter to assess psychotropic medication use.

Experimental Design and Random Assignment to Study Conditions

We used a cluster randomization design[31-33] with therapists assigned to condition (UC, standard, modular) using blocked randomization[33] stratified by therapist educational level (doctoral versus Masters). A computerized random number generator produced an unpredictable sequence of numbers representing condition, which were assigned to therapists. Block size was the entire cohort of therapists within each educational level within each site, and the allocation ratio for each block was 1:1:1. Allocation concealment was maintained through the use of therapist ID numbers. Youths and caregivers knew they were receiving treatment and that randomization was involved, but did not know the identity of the treatment they received.

Initial treatment focus for the modular and standard conditions was determined by using symptom and diagnostic information plus the TPA. For example, if the ChIPS and CBCL/YSR assessments (see above) identified both depression and conduct as relevant treatment foci, then the rank-ordering of client-identified problems on the TPA was used to determine whether treatment began with a focus on depression or conduct.

Treatment Procedures, Clinician Training, Treatment Duration

Usual Care (UC) Condition. Clinicians randomized to UC agreed to use the treatment procedures they used regularly and believed to be effective. Clinical supervision followed usual practices in their setting, and therapy continued until a normal client termination.

Standard Manual Treatment Condition. Clinicians randomized to the standard condition were trained to use three treatment protocols, with manualized instructions and prescribed order of treatment sessions:

1. *Coping Cat*[34,35] is a 16-20-session individual CBT protocol addressing anxiety through

    skills in identification and remediation of unrealistic fearful thoughts, relaxation, and

    graduated exposure to feared objects. Role plays and *in vivos* during the sessions are

    complemented by homework assignments requiring practice of the skills.

2. *Primary and Secondary Control Enhancement Training (PASCET)* [36-38] is a 10-15-session

    individual CBT protocol addressing youth depression through cognitive skills (e.g.,

    reframing) and behavioral skills (e.g., scheduling mood-boosting activities). The skills

    are practiced via in-session role plays, *in vivos*, and homework.

3. *Defiant Children*[39] is a ten-step BPT protocol addressing youth disruptive conduct and

    noncompliant behavior by helping parents build parenting skills such as differential

    attention and consequences to encourage appropriate youth behavior and discourage

    inappropriate behavior. Parents learn and role-play the skills during sessions and apply

    the skills at home with their children between sessions.

Modular treatment condition. Therapists in the modular condition used *MATCH*,[10] a

collection of 33 modules designed to correspond to the treatment procedures included in *Coping

Cat, PASCET, and Defiant Children*. MATCH prioritizes a focus on the initial problem area

identified as most important, based on the standardized measures and the patient priorities

identified in the TPA, as described above. The flowchart for the focus selected (e.g., depression)

specifies a default sequence of modules. If interference arises (e.g., a comorbid condition or

stressor impedes use of the default sequence), the sequence is altered, with other modules used

systematically to address the interference. For example, if treatment begins with a focus on

depression, but disruptive behavior interferes, the therapist may use modules from the conduct

section of the protocol to help parents manage the disruptive behavior, returning to depression treatment when the interference is resolved.

Clinicians randomized to standard and modular were trained together; all had two days of training on treatment for each problem area, for a total of six days. Subsequently both standard and modular clinicians received weekly consultation on study cases from project supervisors, who were informed by consultant-guided discussions of measurement feedback on client progress and practice history.[40] UC clinicians received usual supervision procedures in their settings, with no intervention from project personnel, to ensure that UC would not be altered.

Mean treatment duration was 275.49 days in UC, 196.24 days in standard, and 210.15 days in modular; a fixed-effects ANOVA showed that the groups were significantly different from each other, $F(2,171)=4.66$, $p=.011$. UC showed significantly longer duration than standard ($p=.011$) and modular ($p=.038$); standard and modular did not differ significantly. For total number of sessions, we have information only on the standard and modular conditions, due to total separation of study personnel from UC. Based on therapist report for this 70% of the sample, the mean number of treatment sessions was 16.17 (SD=9.95); 33.7% of sessions included the child alone, and 41.4% included the child plus one or more family members; and mean time between sessions was 11.96 days (SD=4.65).

We obtained therapist reports on session content to determine how often modular and standard cases included treatment procedures from multiple problem areas (e.g., including a depression procedure in a treatment episode for conduct problems, or having anxiety treatment followed by treatment for depression). Exactly half of the 62 modular cases met this criterion, whereas only 1.7% of the standard cases did so, $\chi^2 (1) = 36.26$, $p < .001$. Coding of a sample of 309 individual treatment *sessions* showed that 13% of modular treatment sessions used content

from more than one problem area protocol, whereas no standard sessions did so, $\chi^2(2) = 34.48$, p

<.001. Observational coding of recorded session content showed adherence to condition in all

three groups (see eMethods2 for details). In the standard condition, 92.75% of session content fit

the treatment elements of *Coping Cat*, *PASCET*, and *Defiant Children*. In the modular condition,

82.95% of session content fit the MATCH protocol. In UC only 8.47% of session content was

consistent with either the standard or modular manuals. The modular condition contained more

"other" (non-manual) content than the standard condition (means: 17% and 7%), $t = -3.54$, $df =$

307, $p < .001$. Thus, multiple measures suggested that treatment in the modular condition

entailed more use of treatment content from multiple problem domains (i.e., anxiety, depression,

conduct) and more flexibility than treatment in the standard condition.

Planned Analyses and Power Calculations

Because none of the three study conditions had fixed duration, and the UC condition had no

constraints on content or duration of treatment, comparison of groups at post-treatment-only

would have left condition confounded with treatment duration/dose. To address this concern, we

focused planned analyses on the question of whether there were treatment group differences in

trajectories of change across time on (a) mean BPC overall (youth and parent report included in

the same model, with informant [youth, parent] treated as a random effect), and (b) mean TPA

overall. For each outcome variable, we estimated mixed effects regression models with outcome

= a_0 (intercept) + a_1 (informant) + a_2 (treatment group) + a_3 (time) + a_4 (condition * time) with

intercept, informant, and time (log day) treated as random effects. To assess whether our cluster

randomized design was associated with substantial therapist-level variance, we evaluated three-

level models that included nesting of youths within therapists. The estimated therapist variances

were all near zero, and comparison of model fits between two-level (no therapist effect) and

three-level models were not statistically significant for any comparison. We also found no significant level-3 effects for models with organization (the ten outpatient programs) included as a third level of nesting. Tests of the condition by time interaction were virtually identical with and without nesting of youths within therapists or organizations.

Based on the current dataset, we determined the effect size that would be required at one year to achieve 80% power assuming a sample size of n=58 subjects per group (n=174 total), with time measured in log days, Type I error rate of 5%, and a two-sided test. This effect size estimate was then translated back to the original score metric (i.e., difference in the original scale score units). Based on these assumptions, 80% power is achieved for an effect size (ES) of 0.56 SD units at one year for BPC total, 0.57 for BPC internalizing, 0.58 for BPC externalizing, and 0.51 for the TPA.

For these mixed effects regression analyses, we focused on BPC Total and TPA, but also examined BPC internalizing and externalizing, the two components of BPC Total. This provided the most complete look at the constructs, combining across informants. To explore whether we should also report parent- and youth-report measures separately, we fitted a model that included informant x time, informant x treatment, and informant x treatment x time interactions for these outcome measures; informant x treatment x time interactions were significant (all <.05), so we also reported parent- and youth-report measures separately. To reduce the risk of chance findings, we began with omnibus tests comparing the three treatment groups on overall BPC Total and TPA, applying a familywise Bonferroni to correct for the two tests. Omnibus effects that were significant after Bonferroni were followed up by conducting each possible two-group comparison among the standard, modular, and UC groups, again applying a familywise Bonferroni correction. For two-group comparisons that survived Bonferroni, we proceeded to

significance tests on the individual variables, including combined and separate youth- and parent-report measures.

A second set of planned analyses involved comparison of the treatment groups on number of diagnoses[22,23] at post-treatment, controlling for pretreatment. This included a test of the overall treatment group difference using a fixed-effects ANCOVA model applied to all youths for whom we had both pre- and post-treatment data, with analyses using type III sum of squares and controlling for number of pre-treatment diagnoses. Two-group comparisons were conducted if the overall treatment group effect was significant.

Statistical power was calculated for direct comparisons of treatment groups on the number of ChIPS diagnoses at post-treatment, controlling for pretreatment. This analysis assumed sample size of 58 per group and a Type 1 error rate of .05. We found power of .80 to detect an effect size of $f = 0.26$ (corresponding to d=.52), a medium effect.

In none of the planned analyses was power adequate for more fine-grained analyses, such as tests of moderation by gender or age.

Preliminary Tests: Baseline Measures and Medication Use

Analyses of baseline scores on the BPC internalizing, externalizing and total problem scores, on the TPA, and on number of CHIPS diagnoses showed no significant treatment group differences. Analyses of SCAPI data showed that prior to treatment 25.3% of study youths were taking some psychotropic medication, and there was no significant treatment group difference. During treatment 27.0% used some psychotropic(s) for at least one day. To determine whether effects of treatment condition were moderated by medication effects, a binary variable was added to the BPC and TPA analyses reported below, and medication use was controlled in the diagnostic analyses reported below. The significant findings reported below, involving treatment

group x time interactions on the BPC and TPA, and the significant difference between modular

and UC in post-treatment diagnoses, all remained statistically significant after adjusting for

medication usage.

Results

Trajectory of Change on BPC and TPA Measures: Sequence of Analyses, and Findings

For the mixed effects regression analyses, our planned analyses (see Methods section)

involved examining the overall scores of parents + youths combined, with informant included as

a random effect, and we focused on the BPC Total and TPA; these are shown in Table 2,

together with the component BPC internalizing and externalizing. As noted previously, we also

include parent- and youth-report measures separately in the table. Omnibus tests comparing the

three groups on the overall BPC Total and TPA were significant, even after Bonferroni (see

above), so we tested each possible two-group comparison among the standard, modular, and UC

groups, again with a focus on overall BPC Total and TPA. These tests were not significant for

Standard vs. UC following Bonferroni, so no further tests within the Standard vs. UC columns

are considered significant (although all the comparisons are shown in the table, for full

presentation of study data). In subsequent tests, comparing Modular to UC and Modular to

Standard, for any overall score that was significant, we tested the corresponding youth- and

parent-report measures separately for significance.

In the Modular vs. UC columns (Table 2), the group comparisons on overall BPC Total and

TPA were significant following Bonferroni, so we examined these effects further via tests on the

internalizing and externalizing subscales of the BPC, and parent- and youth-report on all

measures. The findings showed significantly steeper trajectories of improvement in modular than

UC on BPC Total overall and parent-report, TPA overall and parent report, BPC internalizing

overall (BPC internalizing parent-report was marginal), and BPC externalizing overall and parent report.

In the Modular vs. Standard columns, the group comparisons on overall BPC Total and TPA were significant following Bonferroni, so we examined these effects further via tests on the internalizing and externalizing subscales of the BPC, and of parent- and youth-report on all measures. The findings showed significantly steeper trajectories of improvement in modular than standard on BPC Total overall, youth-, and parent-report; TPA overall and youth-report; BPC internalizing overall and youth-report; and BPC externalizing overall, youth-, and parent-report.

In general, modular treatment outperformed UC on overall (p=.004 and .011, ES=.59 and .54, for BPC Total and TPA) and parent-report measures (p=.003 and .001, ES=.62 and .72, for BPC total and TPA); and modular outperformed standard treatment on overall (p=.001 and .012, ES=.71 and .61, for BPC Total and TPA) and youth-report measures (p=.014 and .009, ES=.50 and .53, for BPC total and TPA) as well as two parent-report measures. In all comparisons of the modular condition to UC and to standard treatment, the direction of the effects consistently indicated more rapid improvement in the modular group. In modular vs. UC, 7 of the 12 comparisons were statistically significant (one was marginal). In modular vs. standard, 10 of the 12 comparisons were significant.

Effect sizes (ESs) for log-linear rates of change are displayed in Table 2. These ESs are the ratio of the difference in estimated time trends divided by the square root of the estimated random time effect variance. Statistically significant condition by time interactions were associated with ESs ranging from 0.41 to 0.72.

Number of Clinical Diagnoses at Pre- and Post-Treatment

At pre-treatment, there was no significant overall condition difference in number of diagnoses, $F(2,146)=0.541$, $p=.58$. At post-treatment, however, the overall condition difference was significant, $F(2,145)=3.49$, $p=.033$. After treatment, modular youths met criteria for significantly fewer diagnoses (mean = 1.23, $SD = 1.01$) than UC youths (mean = 1.86, $SD = 1.52$), $F(1, 96)=6.83$, $p = .01$; see Figure 2). No significant differences were found between standard youths (mean = 1.54, $SD = 1.30$) and UC youths, $F(1, 90) = 2.023$, $p = .16$ or between standard and modular youths, $F(1, 103) = 1.232$, $p = .27$.

Discussion

The findings support the effectiveness of a modular approach to youth treatment, an approach designed to address (a) the needs of clinicians who carry diagnostically diverse caseloads, and (b) the comorbidity and flux that are common among youths referred for mental health treatment. In our analyses of change trajectories measured via weekly assessments, and with initial Bonferroni correction applied, youths in modular treatment showed significantly faster improvement than youths in usual care, on overall and parent-report BPC Total and Top Problems measures, and modular also outperformed standard treatment on overall and youth-report BPC Total and Top Problems measures, as well as parent-report BPC Total. By contrast, with the same analytic procedures applied, outcomes in the standard manual condition did not differ significantly from outcomes in usual care.

Our analyses of diagnostic outcomes showed a similar pattern. Youths receiving modular treatment showed significantly fewer diagnoses at post-treatment than youths receiving usual care (with pre-treatment diagnoses controlled). By contrast, there was no significant difference between the standard condition and UC on number of disorders at post-treatment. Interestingly, we found superior outcomes of modular treatment relative to UC despite the fact that UC youths were in treatment a mean of 75 days longer than modular youths ($p<.008$).

Findings suggested that the modular design allowed a balanced flexibility: modular sessions included much more evidence-based content than did UC sessions (81% vs. 7%), but also contained more "other" content than standard sessions (18% vs. 8%). The results may reflect the greater flexibility of modular treatment, which may have facilitated coverage of more problems than standard treatment. Indeed, this was a key goal in designing the modular approach—i.e., to enhance the potency of standard evidence-based practices through a modular arrangement that supports flexible application of those practices.

Study limitations include constraints on level of analysis imposed by sample size. Although our sample provided adequate power to test the primary questions of the study, power was not adequate for tests of potential moderating effects of such variables as gender, age, and ethnicity, each of which would have been of interest. In addition, our emphasis on trajectories of change across the weekly assessments (BPC and TPA) as primary outcome measures of the study required that we exclude some youths who had been randomized but whose lack of participation in treatment made it impossible to calculate a trajectory. Finally, our interest in clinical representativeness led us to include only those who sought treatment on their own, to include a broad array of diagnoses (see Table 1), and to include substantial comorbidity; one effect is that the population to whom our findings apply is not so precisely defined as in an efficacy trial focused on a single disorder.

If the findings of this study are replicated in future work, implications for the use of evidence-based practice within clinical care settings could be significant. The modular approach might also fit well into pediatric primary care, the initial point of entry for many youths referred for anxiety, depression, and disruptive conduct. Our measurement model, too, may have potential value for multiple kinds of intervention—in mental health and other domains; for example, it

may be wise to learn the priorities of patients and their families and focus on these when developing and adjusting treatment plans. For youth mental health in particular, the findings suggest that intervention procedures developed and tested across decades of RCTs do have value for clinical practice, but that a systematic restructuring of those procedures may enhance their benefits for clinically-referred youths who are treated by practitioners in everyday treatment settings.

Acknowledgments

References

1. Saraceno B. Foreword. In: *Caring for children and adolescents with mental disorders*. Geneva: World Health Organization; 2003.
2. Weisz JR, Kazdin AE, eds. *Evidence-based psychotherapies for children and adolescents*. New York: Guilford Press; 2010.
3. Westen D, Novotny CM, Thompson-Brenner H. The empirical status of empirically supported psychotherapies: Assumptions, findings, and reporting in controlled clinical trials. *Psychol Bull*. 2004;130(4):631-663.
4. Westen D, Novotny CM, Thompson-Brenner H. The next generation of psychotherapy research: Reply to Ablon and Marci (2004), Goldfried and Eubanks-Carter (2004), and Haaga (2004). *Psychol Bull*. 2004;130(4):677-683.
5. Strupp HH, Anderson T. On the limitations of therapy manuals. *Clin Psychol*. 1997;4(1):76-82.
6. Hammen C, Rudolph K, Weisz J, Rao U, Burge D. The context of depression in clinic-referred youth: Neglected areas in treatment. *J Am Acad Child Adolesc Psychiatry*. 1999;38(1):64-71.
7. Weisz JR, Gray JS. Evidence-based psychotherapy for children and adolescents: Data from the present and a model for the future. *Child Adolesc Ment Health*. 2008;13(2):54-65.
8. Chorpita BF, Daleiden EL, Weisz JR. Modularity in the design and application of therapeutic interventions. *Applied Preventive Psychol*. 2005; 11: 141-156.
9. Weisz JR, Jensen-Doss A, Hawley KM. Evidence-based youth psychotherapies versus usual clinical care: A meta-analysis of direct comparisons. *Am Psychol*. 2006;61(7):671-689.
10. Chorpita BF, Weisz JR. *Modular approach to therapy for children with anxiety, depression, or conduct problems*. Honolulu and Boston: University of Hawaii at Manoa and Judge Baker Children's Center, Harvard Medical School; 2005.
11. Chorpita BF, Taylor AA, Francis SE, Moffitt, CE, Austin, AA. Efficacy of modular cognitive behavior therapy for childhood anxiety disorders. *Behav Ther*. 2004; *35*: 263-287.
12. Chorpita BF. *Modular cognitive-behavioral therapy for childhood anxiety disorders*. New York: Guilford Press; 2007.
13. Borntrager C, Chorpita BF, Higa-McMillan C, Weisz JR. Provider attitudes towards evidence-based practices: Are the concerns with the evidence or with the manuals? *Psychiatr Serv*. 2009;60(5):677-681.
14. Schoenwald SK, Kelleher, K, Weisz JR, Research Network on Youth Mental Health. Bulding bridges to evidence-based practice: The MacArthur Foundation Child System and Treatment Enhancement Projects (Child STEPs). *Adm Policy Ment Health*. 2008;35(1-2):66-72.
15. Weisz JR, Chu BC, Polo AJ. Treatment dissemination and evidence-based practice: Strengthening intervention through clinician-researcher collaboration. *Clin Psychol*. 2004;11(3):300-307.
16. Weisz JR, Chorpita BF. Mod squad for youth psychotherapy: Restructuring evidence-based treatment for clinical practice. In: Kendall PC, ed. *Child and adolescent therapy: Cognitive-behavioral procedures*. 4 ed. New York: Guilford; in press.
17. Bernal G, Scharró-del-Río MR. Are empirically supported treatments valid for ethnic minorities? Toward an alternative approach for treatment research. *Cultur Divers Ethnic Minor Psychol*. 2001;7(4):328-342.

18. Gray-Little B, Kaplan D. Race and ethnicity in psychotherapy research. In: Ingram CRSRE, ed. *Handbook of psychological change: Psychotherapy processes and practices for the 21st century*. New York: Wiley; 2000:591-613.

19. Hall GCN. Psychotherapy research with ethnic minorities: Empirical, ethical, and conceptual issues. *J Consult Clin Psychol*. 2001;69(3):502-510.

20. Sue S. In defense of cultural competency in psychotherapy and treatment. *Am Psychol*. 2003;58(11):964-970.

21. American Psychiatric Association. *Diagnostic and statistical manual of mental disorders, fourth edition, text revision*. Washington, DC: American Psychiatric Association; 2000.

22. Weller EB, Weller, R.A., Rooney, M.T., & Fristad, M.A. *CHIPS-Children's Interview for Psychiatric Syndromes*. Washington, DC: American Psychiatric Press; 1999.

23. Weller EB, Weller RA, Rooney MT, Fristad MA. *Children's Interview for Psychiatric Syndromes-Parent Version (P-ChIPS)*. Washington, DC US: American Psychiatric Association; 1999.

24. Achenbach TM, Rescorla LA. *Manual for the ASEBA School-Age Forms and Profiles*. Burlington, VT: University of Vermont, Center for Children, Youth and Families; 2001.

25. Chorpita BF, Reise S, Weisz JR, Grubbs K, Becker KD, Krull JL. Evaluation of the Brief Problem Checklist: Child and caregiver interviews to measure clinical progress. *J Consult Clin Psychol*. 2010;78(4):526-536.

26. Weisz JR, Chorpita BF, Frye A, Ng, MY, Bearman, SK, Ugueto, A, Hoagwood, K.. Youth top problems: Using idiographic, consumer-guided assessment to identify treatment needs and track change during psychotherapy. *J Consult Clin Psychol*. 2011; 79(3):369-380.

27. Fristad MA, Glickman AR, Verducci JS, Teare M, Weller EB, Weller RA. Study V: Children's Interview for Psychiatric Syndromes (ChIPS): Psychometrics in two community samples. *J Child Adolesc Psychopharmacol*. 1998;8(4):237-245.

28. Silverman WK, Nelles WB. The Anxiety Disorders Interview Schedule for Children. *J Am Acad Child Adolesc Psychiatry*. 1988;27(6):772-778.

29. Hoagwood KE, Jensen PS, Arnold LE, Roper, M, Severe, J, Odbert, C, Molina,BSG. Reliability of the services for children and adolescents-parent interview. *J Am Acad Child Adolesc Psychiatry*. 2004;43(11):1345-1354.

30. Jensen PS, Hoagwood KE, Roper M, Arnold, LE, Odbert, C, Crowe, M, Molina, BSG, Hechtman, L, Hinshaw, SP, Hoza, B, Newcorn, J, Swanson, J, Wells, K. The services for children and adolescents-parent interview: Development and performance characteristics. *J Am Acad Child Adolesc Psychiatry*. 2004;43(11):1334-1344.

31. Campbell MK, Elbourne, DR, Altman, DG. CONSORT statement: extension to cluster randomized trials. *BMJ*. 2004;328(7441):702-708.

32. Dohner A, Klar N. *Design and analysis of cluster randomization trials in health research*. London: Arnold; 2000.

33. Fayers PM, Jordhoy MS, Kaasa S. Cluster-randomized trials. *J Palliat Med*. 2002;26:69-70.

34. Kendall PC. Treating anxiety disorders in children: Results of a randomized clinical trial. *J Consult Clin Psychol*. 1994;62(1):100-110.

35. Kendall PC, Kane M, Howard B, & Siqueland L. *Cognitive-behavioral treatment of anxious children: Treatment manual*. Ardmore, PA: Workbook Publishing; 1990.

36. Weisz JR, Moore PS, Southam-Gerow MA, Weersing VR, Valeri SM, McCarty CA. *Therapist's Manual PASCET: Primary and secondary control enhancement training program*. 3 ed. Los Angeles: University of California; 2005.

37. Weisz JR, Thurber CA, Sweeney L, Proffitt VD, LeGagnoux GL. Brief treatment of mild-to-moderate child depression using primary and secondary control enhancement training. *J Consult Clin Psychol*. 1997;65(4):703-707.

38. Weisz JR, Southam-Gerow MA, Gordis EB, Conner-Smith, JK, Chu, BC, Langer, DA, McLeod, BD, Jenson-Doss, A, Updegraff, A, Weiss, B. Cognitive-behavioral therapy versus usual clinical care for youth depression: An initial test of transportability to community clinics and clinicians. *J Consult Clin Psychol*. 2009;77(3):383-396.

39. Barkley RA. *Defiant children: A clinician's manual for assessment and parent training*. 2 ed. New York: The Guilford Press; 1997.

40. Chorpita BF, Bernstein AD, Daleiden EL, Research Network on Youth Mental Health. Driving with roadmaps and dashboards: Using information resources to structure the decision models in service organizations. *Admin Policy Ment Health Ment Health Services Res.* 2008;35(1-2): 114-123.

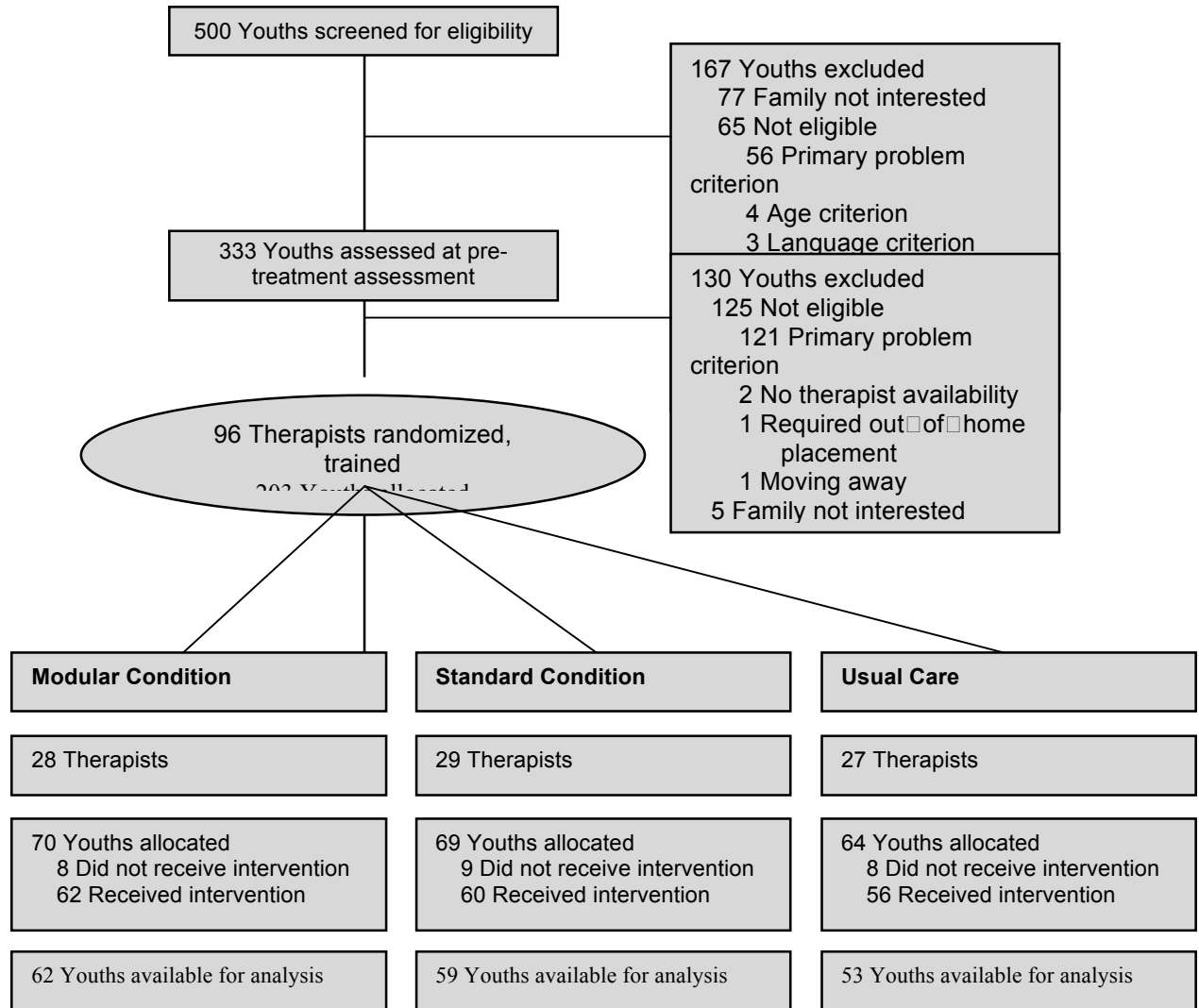**Figure 1.** CONSORT Chart showing sampling process and participant assignment

Figure 2. Diagnostic change from pre- to post-treatment by study condition.
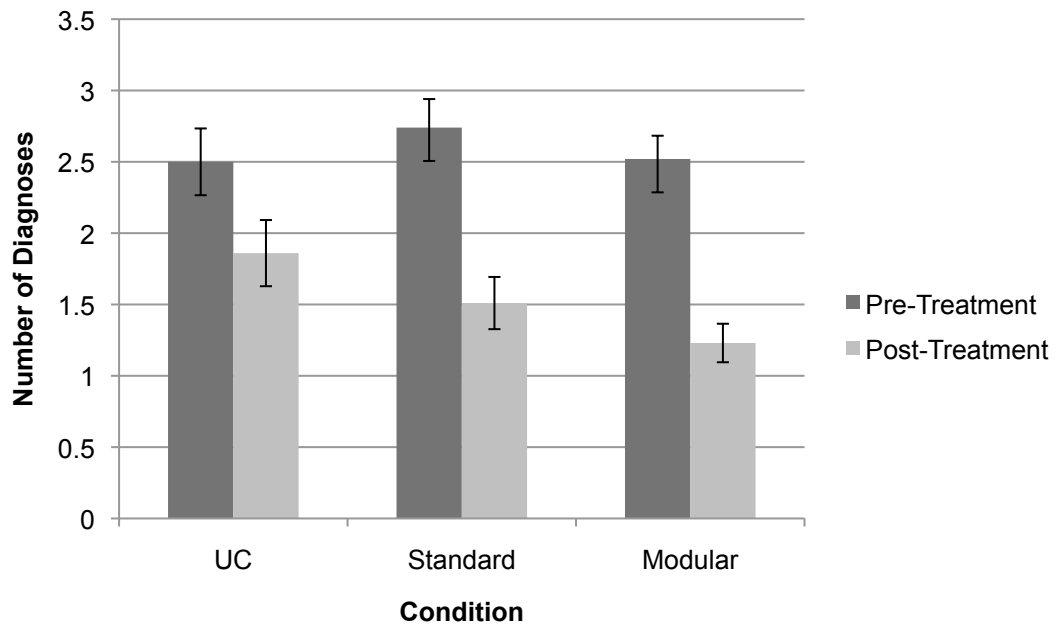
Table 1. Diagnostic Composition of Sample

Diagnosis	Primary, No. (%)	Anywhere, No. (%)
ADHD (Any Type)	**8 (4.60)**	**101 (58.05)**
ADHD, combined type	3 (1.72)	50 (28.74)
ADHD, predominantly inattentive type	3 (1.72)	27 (15.52)
ADHD NOS[a]	2 (1.15)	23 (13.22)
ADHD, predominantly hyperactive-impulsive type	0 (0.00)	1 (0.57)
Adjustment Disorder (Any Type)	**2 (1.15)**	**4 (2.30)**
Adjustment disorder with mixed anxiety & depressed mood	1 (0.57)	2 (1.15)
Adjustment disorder with mixed disturbance of emotion	1 (0.57)	1 (0.57)
Adjustment disorder with depressed mood	0 (0.00)	1 (0.57)
Anxiety Disorder (Any Type)	**51 (29.31)**	**99 (56.90)**
Specific phobia	0 (0.00)	51 (29.31)
Separation anxiety disorder	22 (12.64)	47 (27.01)
Generalized anxiety disorder	19 (10.92)	40 (22.99)
Social phobia	6 (3.45)	21 (12.07)
Obsessive-compulsive disorder	4 (2.30)	7 (4.02)
Posttraumatic stress disorder	0 (0.00)	6 (3.45)
Panic disorder without agoraphobia	0 (0.00)	1 (0.57)
Conduct-Related Disorder (Any Type)	**74 (42.53)**	**115 (66.09)**
Oppositional defiant disorder	23 (13.22)	87 (50.00)
Conduct disorder	50 (28.74)	27 (15.52)
Disruptive behavior disorder NOS	1 (0.57)	1 (0.57)
Eating Disorder NOS[a]	**0 (0.00)**	**4 (2.30)**
Elimination Disorder	**0 (0.00)**	**1 (0.57)**
Mood Disorder (Any Type)	**29 (16.67)**	**76 (43.68)**
Major depressive disorder, single episode	12 (6.90)	34 (19.54)
Dysthymic disorder	6 (3.45)	22 (12.64)
Major depressive disorder, recurrent	5 (2.87)	8 (4.60)
Depressive disorder NOS[a]	4 (2.30)	8 (4.60)
Mood disorder NOS[a]	2 (1.15)	3 (1.72)
Bipolar disorder	0 (0.00)	1 (0.57)
Selective Mutism	**1 (0.57)**	**2 (1.15)**

[a] Not otherwise specified

Table 2. Coefficient Estimates for Condition by Time (log-day) for Overall, Youth, and Parent-Report Scores; N=174 for Each Analysis)

| | Standard vs. UC[a] | | | Modular vs. UC | | | Modular vs. Standard | | | Type-3[b] | |
	EST[c]	p[d]	ES[e]	EST	p	ES	EST	p	ES	F-value	p
BPC[f]											
Total											
Overall	0.070	.569	.12	-0.346	.004	.59	-0.416	.001	.71	7.03	.001
Youth	0.217	.161	.29	-0.242	.113	.32	-0.459	.002	.61	4.71	.009
Parent	-0.090	.609	.11	-0.441	.011	.54	-0.351	.039	.43	3.70	.025
BPC Internalizing											
Overall	0.014	.852	.04	-0.179	.014	.51	-0.193	.007	.55	4.53	.011
Youth	0.074	.420	.17	-0.148	.100	.3	-0.222	.012	.50	3.29	.037
Parent	-0.049	.663	.09	-0.205	.065	.38	-0.156	.152	.29	1.91	.148
BPC Externalizing											
Overall	0.059	.424	.17	-0.164	.023	.48	-0.223	.002	.65	5.36	.005
Youth	0.143	.093	.37	-0.092	.270	.24	-0.235	.004	.60	4.14	.016
Parent	-0.038	.718	.08	-0.234	.023	.50	-0.196	.053	.41	3.06	.047
Top Problems Assessment											
Overall	-0.043	.578	.12	-0.226	.003	.62	-0.183	.014	.50	5.16	.006
Youth	0.126	.230	.25	-0.138	.182	.28	-0.263	.009	.53	3.39	.034
Parent	-0.220	.027[g]	.47	-0.333	.001	.72	-0.113	.239	.24	5.94	.003

[a]All Standard vs. UC comparisons regarded as nonsignificant, following initial correction for multiple tests (see Results)

[b]Type-3 = Omnibus test of group by log day comparing the three treatment groups

[c]EST = estimate of the group by log_day interaction, adjusted for all other effects in the model. A negative interaction indicates that the treatment group to the left showed faster reduction in problem severity over time than the group to the right (e.g., in the Modular vs. UC column, a negative sign means that severity was reduced faster in Modular than in UC)

[d]p = probability value

[e]ES = effect size (i.e., magnitude of the difference in rates of change expressed in SD units) is the ratio of the difference in rates of change divided by the square root of the time trend variance. ES indicates the absolute value of the standardized magnitude of the effect

[f]BPC = Brief Problem Checklist

[g]Not statistically significant following Bonferroni correction

Table 3. Slopes and One-Year Change Estimates by Treatment Condition

Measure		Standard	Modular	UC
		Slope[a] (1 Year Change)[b]	Slope (1 Year Change)	Slope (1 Year Change)
Brief Problem Checklist (BPC)Total Score (Scale Range: 0 – 24)	Overall	-0.397 (-2.342)	-0.813 (-4.797)	-0.467 (-2.755)
	Youth	-0.226 (-1.333)	-0.685 (-4.042)	-0.443 (-2.614)
	Parent	-0.589 (-3.475)	-0.940 (-5.546)	-0.498 (2.938)
BPC Internalizing (Scale Range: 0 – 12)	Overall	-0.249 (-1.469)	-0.442 (-2.608)	-0.263 (-1.552)
	Youth	-0.166 (-0.979)	-0.387 (-2.283)	-0.239 (-1.410)
	Parent	-0.339 (-2.000)	-0.495 (-2.921)	-0.290 (-1.711)
BPC Externalizing (Scale Range: 0 – 12)	Overall	-0.148 (-0.873)	-0.371 (-2.189)	-0.206 (-1.215)
	Youth	-0.060 (-0.354)	-0.294 (-1.735)	-0.202 (-1.192)
	Parent	-0.251 (-1.481)	-0.447 (-2.637)	-0.213 (-1.257)
TPA Mean Rating on Top Three Problems (Scale Range: 0 – 10)	Overall	-0.435 (-2.567)	-0.619 (-3.652)	-0.392 (-2.313)
	Youth	-0.342 (-2.018)	-0.605 (-3.570)	-0.467 (-2.755)
	Parent	-0.537 (-3.168)	-0.650 (-3.835)	-0.317 (-1.870)

[a]Slope = Estimate of the change in scale score per log day
[b]One-Year Change = Estimate of the change in scale score one year after the initial assessment