

Adaptive Pharmacological and Behavioral Treatments for Children with ADHD: Sequencing, Combining, and Escalating Doses

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INTRODUCTION

ADHD is the most common mental health disorder of childhood, affecting 2% to 9% of the population, one of the most common problems in special education, and arguably the most common source of disruptive behavior in regular classroom settings. Nearly 5% of school-aged children in the U.S. are medicated daily for treatment of ADHD—primarily in school settings. The two evidence-based treatments for ADHD are pharmacotherapy with a CNS stimulant and behavior modification in the form of parent training, classroom intervention, and child treatment for peer problems (Fabiano et al., under review; Pelham et al., 1998; Pelham & Fabiano, 2008). Short-term studies have shown that combining these treatments often results in improved functioning relative to either alone. In a current project (R01 MH62946), we have shown that both behavior modification and medication have significant acute effects on children's behavior, and that response to each treatment varies as a function of the presence and dosage of the other treatment. We have found (a) that behavioral treatments can reduce the need for and dosage of medication in analogue classroom and regular classroom settings (e.g., Coles et al., 2004) and (b) that low doses of medication reduce the need for relatively more intensive and therefore more expensive behavioral treatments. Because medication—especially at high doses—has associated acute and long-term safety issues, discovering ways to minimize medication use and dose for classroom disruption—the primary justification for medication, is critical.

However, in the extant literature the two treatments are almost always implemented concurrently whether needed or not—no studies have addressed the important questions facing schools, practitioners, and families in making treatment decisions for individual children; that is, (a) whether it is better to initiate treatment with medication or behavior modification, (b) whether in a child with inadequate response it is better to escalate dosage of the current modality or add the other modality, and (c) what are the safety and cost-effectiveness tradeoffs associated with such answers? This IES-funded study is a controlled (random assignment) examination over 3 cohorts of treatment sequencing. It includes elements of an adaptive treatments design with multiple randomizations (Collins et al., 2004; Bierman et al., 2006). We present preliminary results for cohort 1. Specific aims:

- 1) How does a treatment strategy that includes either initial treatment with medication or initial behavior modification influence the rate of response to treatment and need for additional treatment?
- 2) When additional treatment is needed, what are the relative benefits of augmenting the dosage of the initial treatment versus adding the other treatment modality?
- 3) Is dosage in medication usage reduced as a function of treatment strategy?
- 4) Is intensity of behavior modification reduced as a function of treatment strategy?
- 5) Do these strategies differentially impact parent satisfaction with treatment and future use of treatments?
- 6) In what way do individual difference variables (e.g., severity of impairment, comorbid child psychopathology, prior medication history, parent and teacher treatment acceptability, parental characteristics, SES) influence the answers to questions addressed above?
- 7) What is the relative cost-effectiveness of these treatment strategies?

Baseline/Endpoint Measures

Child Behavior

Diagnostic Interview Schedule for Children (DISC) (Shaffer et al., 2000)
Disruptive Behavior Disorders (DBD) Rating Scale (Pelham et al., 1992)
IOWA Conners Rating Scale (Loney & Milich, 1982; Pelham et al., 1989)
Child Behavior Checklist (Achenbach & Rescorla, 2001)
Social Skills Rating System (SSRS; Gresham & Elliott, 1989)
Impairment Rating Scale (IRS, Fabiano et al., 2006)

IQ and Academic Achievement

Wechsler Intelligence Scale for Children—4th edition (WISC-IV; Wechsler, 2003)
Wechsler Individual Achievement Test—2nd edition (WIAT-II)

Treatment use and acceptability

Parents and teacher ratings of typical behavioral interventions (Fabiano et al., 2002)
Parents and teacher ratings of treatment acceptability (e.g., Kazdin, 1984)

Parental psychopathology and parenting

Maternal ADHD (CARS; Conners et al., 1999) and depression (BDI; Beck et al., 1961);
Negative/ineffective parenting styles (Hinshaw et al., 2000); Parenting Sense of Competence (Gibbard et al., 1978)

Monthly Assessments on which Adaptive Modifications are based

Parents and teachers: DBD, IOWA Conners, IRS, CBCL, SSRS
Daily Idiographic Target Behavior Checklists (ITBC) as objective measures of classroom behavior
Naturalistic measures of performance and behavior including grades, homework, discipline
Treatment satisfaction

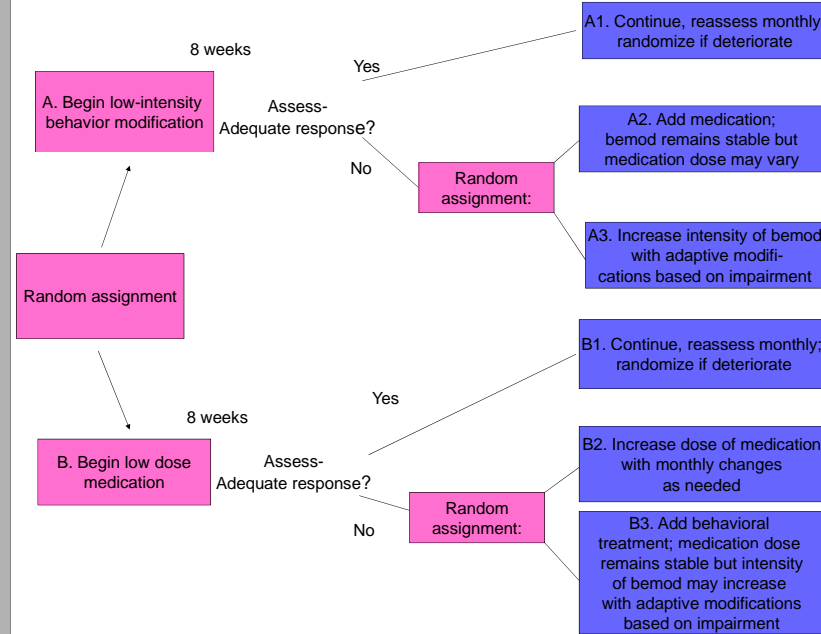
Parents: negative/ineffective parenting, the CAARS, the BDI, and the PSC

Indicator of need for additional treatment at 8-week and subsequent assessments:

- (1) Average school performance on the ITBC is less than 75% AND
- (2) Rating by parents or teachers as impaired (i.e., greater than 3) on the IRS in at least one domain.

Decisions are separate for school and home functioning. At each monthly assessment, treatment decisions are made (for the children who have gone through the second stage of randomization) regarding additional dose increases or adjustments to the behavioral treatment. These decisions are made based on the children's ITBC percentages and ratings on the IRS (using the same criteria as for initial response). For the children in augmented behavioral conditions, treatment decisions will be tailored to the specific domains of impairment rated on the IRS (e.g., a homework intervention or tutoring for children rated as impaired in the academic domain; a Saturday social skills group for impairment in the peer-relationship domain). All treatment decisions and the reasons for them are documented.

Poster and additional information available at <http://ccf.buffalo.edu>



Timeline	A. Behavioral Treatment First	B. Medication Treatment First
August	Begin parent training class (4 sessions); initial teacher consultation	Collect height and weight, determine initial dose; explain study procedures to teacher
September	Begin low-intensity procedures at school and home, including group parent training (4 sessions), monthly booster sessions, and school-based daily report card;	Begin medication at low dose (approx. .15 mg/kg, school-day dosing only)
End of October	<u>Assess functioning:</u>	<u>Assess functioning:</u>
	IF NEED ADDITIONAL TREATMENT, assign to (1) increase BMOD intensity or (2) add low dose of medication	IF NEED ADDITIONAL TREATMENT, assign to (1) increase medication dose or (2) add low intensity BMOD
Monthly	Assess functioning and (1) adjust BMOD components or (2) adjust medication dose as indicated by assessment (BMOD stays constant)	Assess functioning and (1) increase medication dose or (2) adjust BMOD components as indicated by assessment (Medication stays constant)
Monthly	Reassess responders from previous month; if need additional treatment randomize to group 1 or 2 for remainder of year	Reassess responders from previous month; if need additional treatment randomize to group 1 or 2 for remainder of year
May-June	End-point assessment	

References

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Participant Characteristics Cohort 1 and 2	
N	102
Gender	75% male
Age	8.6 years (1.7)
Family Composition	
Single parent	22%
2 parent	78%
Race	
81% Caucasian	
12% African-American	
7% Mixed race	
Family Income	
\$0-29999	14%
\$30000-59999	29%
\$60000-99999	38%
>\$100000	18%
Previously medicated	36%
Behavioral Ratings	
Parent	Teacher
Iowa I/O	10.1 (2.8) 9.9 (3.4)
Iowa O/D	7.4 (3.8) 5.2 (4.3)
DBD-Inattentive	2.0 (0.7) 1.9 (0.7)
DBD-Hyper/Impulsive	1.8 (0.6) 1.6 (0.8)
DBD-ODD	1.3 (0.6) 1.0 (0.7)
DBD-CP	0.2 (0.2) 0.3 (0.5)

Preliminary Results from Cohort 1 and 2

Participants:

102 children between the ages of 5 and 12 enrolled. Six families discontinued participation before (N=1) or during the study (N=5).

Treatment outcomes:

Of 51 participants assigned to receive medication first, 12% refused medication. Of 50 participants assigned to receive behavioral treatment first, no one refused behavioral treatment; 4% attended 2 or fewer of 8 assigned parent training sessions; 100% of children had the school intervention implemented.

78% of children in the Behavioral Treatment First group were rerandomized at the first 8-week assessment point.
77% of children in the Medication First group were rerandomized at the first 8-week assessment point.

By the end of the school year, 96% of the Behavioral Treatment First group and 88% of the Medication First group met criteria for rerandomization.

Impaired setting(s) that precipitated rerandomization by group	Home School Both		
	N=33	N=4	N=6
Medication First			
Behavior Modification First	N=13	N=10	N=23

Of 24 children rerandomized to receive medication after the initial course of BMOD, 25% refused medication.

Of 25 children rerandomized to receive BMOD after the initial course of medication, 68% of families attended 2 or fewer of 8 assigned group parent training sessions.

Medication Outcomes

Children who started with behavioral treatment and received additional medication (N = 23) ended with an average school dose of 17 mg Ritalin LA/Metadate CD and average home dose of 10 mg IR. 61% were medicated at school and 52% were medicated at home.

Children who started with medication and got additional medication (N = 19) ended with an average school dose of 19 mg Ritalin LA/Metadate CD and an average home dose of 6 mg IR. 89% were medicated at school and 68% were medicated at home.

Whereas 10 families refused medication when they were assigned to it, six families took medication when they were assigned to behavior modification (these families are **not** included in the above calculations but their doses are equivalent to the doses reported above.) Three behavioral treatment-behavioral treatment families took school medication and three medication to behavioral treatment families took home medication.

Discussion

- *This study is one of the first to investigate the sequencing of evidence-based treatments for children with ADHD in school settings.
- *This study also investigates dose of treatment (both modalities) in an innovative adaptive treatment design.
- *Cohort 1 and 2 results indicated that the majority of children with ADHD required intervention beyond a low dose of behavioral treatment (8 group PT sessions, a school-based DRC) or a low dose of medication (.15 mg/kg MPH at school); other end-of-year outcomes are currently being gathered.
- *Ending medication doses were comparable to doses in community practice and much lower than the MTA study medicated sample.
- *No families failed to attend parent training when behavioral treatment was first; nearly 70% failed to attend parent training when medication was first.
- *Future analyses with the complete study sample will investigate how sequencing and dose moderates treatment effectiveness and adherence. Effects of setting, individual differences, previous medication treatment, and fidelity of classroom behavioral treatments will be evaluated