Comprehensive Treatment for ADHD:
Perspectives on Sequencing Treatments and Balancing Risks and Benefits of Medication and Behavioral Interventions

Max Hutt Lecture
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University of Michigan
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Disclosures
Past Consultant, scientific advisor, speaker, grant recipient:
McNeil/Alza (Concerta)
Abbott
Shire (Adderall, Adderall XR, guanfacine)
Noven (Daytrana)
Lilly (Strattera)
Cephalon (Sparlon)
MTA principal investigator
I don’t think that medications for ADHD are bad–just overused

Center for Children and Families
Departments of Psychology, Pediatrics, and Psychiatry
SUNY Buffalo

Collaborators:
Pittsburgh: Brooke Marlin, Tracey Wilson, Heidi Kipke, Oscar Bukstein, Carl Walker, Joanna Bethune, Kelle Saks, Vicki Krug, Jason Dink, Lila Souza, Tia Johnson, Vermont: Betsy Hoza
MTA Uncooperative Group (Pittsburgh, UC Berkeley/Irvine, Columbia, NYU, Duke) IES/CDC SACD Collaborative Group (Rochester, NYU, U. Md, UNC, Vanderbilt, UICC)
McMaster: Chuck Cunningham
UNC: Mike Foster, Patrick Curran
Chicago: Benjamin Lahey
Cincinnati: F. Randall Sallee; Rochester: Donna Palumbo
Current Funding Sources: NIMH (5), NIAAA, NIDA, NINDS, IES (3), CDC, Industry

ADHD: Importance to Professionals
Prevalence: 5% of population
Children dealt with by:
– Health Care Professionals
– Mental Health Professionals
– Allied Health Professionals
– Educators
Most common behavioral referral to health care professionals
Most common referral/diagnosis in special education
Most common behavior problem in regular education classrooms
Most common diagnosis in child mental health facilities
"All of the 'experts' at Jerome Horwitz Elementary School had their opinions about George and Harold. Their guidance counselor, Mr. Rected, thought the boys suffered from A.D.D. The school psychologist, Miss Labler, diagnosed them with A.D.H.D. And their mean old principal, Mr. Krupp, thought they were just plain old B.A.D!"

**Core Symptoms—Same Over Past 50 Years**

- Inattention
- Impulsivity
- Hyperactivity

*But are symptoms what we should focus on in diagnosis, treatment, and clinical trials?*

**Domains of Impairment in ADHD Children**

- Relationships with parents, teachers, and other adults
- Relationships with peers and siblings
- Academic achievement
- Behavioral functioning at school
- Family functioning at home
- Leisure activities
Central Role of Impairment in Treatment

- Impairment—that is, problems in daily life functioning that result from symptoms and deficits in adaptive skills—rather than symptoms themselves is
  - (1) why children are referred,
  - (2) what mediates long-term outcome, and therefore
  - (3) what should be targeted in treatment.
- Key domains are peer relationships, parenting/family, and academic achievement
- Assessment of impairment in daily life functioning and adaptive skills is the most fundamental aspect of
  - initial evaluation to determine targets of treatment
  - Ongoing assessment to evaluate treatment response.
- Normalization or minimization of impairment in daily life functioning and maximization of adaptive skills is the goal of treatment—not elimination of symptoms.

Use the Most Efficient Method of Diagnosis/Assessment

(Pelham, Fabiano & Massetti, JCCAP, 2005)

- Use Parent and Teacher Rating Scales
  - Either DSM-Based (e.g., SNAP, DBD, Vanderbilt, ADHDRS, Stony Brook)
  - Or Empically-derived (e.g., IOWA Conners, CAP, BASC)
- Focus on functional impairments (e.g., the IRS) rather than DSM symptoms or comorbid diagnoses (new AAP initiative)
- Use behavioral assessment and functional analysis of target behaviors based on clinical interview with caretakers
- Modify treatment based on ongoing assessment

Why Is it Important to Treat ADHD in Childhood?

Economic Impact of ADHD on Society--the Cost of Illness?

Pelham, Robb & Foster, in press
Reviewed for AAP, 7/05
## Total Annual Incremental Costs Per Child Across Sectors

<table>
<thead>
<tr>
<th>Sector</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Mental Health</td>
<td>$ 3,880</td>
</tr>
<tr>
<td>Education</td>
<td>$ 4,900</td>
</tr>
<tr>
<td>Crime and Delinquency</td>
<td>$ 3,789</td>
</tr>
<tr>
<td>Parental work loss</td>
<td>$ 800</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$13,316</strong></td>
</tr>
</tbody>
</table>

Range (lowest to highest ests.) $11,364--$17,904

## Annual Costs of Childhood/Adolescent ADHD

(Pelham, Foster, & Robb, in press)

<table>
<thead>
<tr>
<th>Sector</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health and Mental Health</td>
<td>$11.6 billion</td>
</tr>
<tr>
<td>Education</td>
<td>$14.7 billion</td>
</tr>
<tr>
<td>Crime and Delinquency</td>
<td>$11.4 billion</td>
</tr>
<tr>
<td>Parental work loss</td>
<td>$ 2.3 billion</td>
</tr>
<tr>
<td><strong>Total</strong> (low estimate based on incomplete data)</td>
<td><strong>$40 billion</strong></td>
</tr>
</tbody>
</table>

Range (lower to upper bounds based on currently available data) $34.1--$53.7

## Limitations and Extensions

**Major Limitation:** Very small literature
- Our estimates therefore preliminary
- Most domains assessed by single study
- Impossible to compute confidence intervals
- Many domains of cost not assessed
- Typically local samples—generalizability?
- Actual COI likely to be much higher

## Limitations and Extensions: Underestimated Costs

**Costs of treatment reflect dramatic underutilization of psychosocial treatments, including evidence-based behavioral treatments**
- Can money wasted on nonEBTs be shifted to behavioral EBTs?
- Medication costs higher for psychiatric prescriber?
- Little data on newer/long-acting medication costs

**Educational costs likely 50% higher than our estimates**
- 1992 OHI identification date
- 10 mins lost time for disciplinary infraction
- Staff time for suspension
- 504 plans not included in costs
- Nondiagnosed but impaired kids

**Work loss based on disability claims instead of records of productivity loss at work—~250% higher in case of depression in adults**

**Juvenile justice costs only for ages 12-15; these and victim costs based on self report only**
Limitations and Extensions:
Domains Not Assessed

<table>
<thead>
<tr>
<th>Domain</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Family functioning/quality of life</td>
<td>Not monetized</td>
</tr>
<tr>
<td>Family financial burden</td>
<td>Not assessed</td>
</tr>
<tr>
<td>Alcohol and drugs</td>
<td>No data</td>
</tr>
<tr>
<td>Work loss in ADHD probands</td>
<td>No data</td>
</tr>
<tr>
<td>Financial costs for ADHD probands</td>
<td>No data</td>
</tr>
<tr>
<td>Adult criminal activity</td>
<td>No data</td>
</tr>
<tr>
<td>Risky Sex/teen pregnancy</td>
<td>No data</td>
</tr>
<tr>
<td>Costs of ADHD in adulthood</td>
<td>?</td>
</tr>
</tbody>
</table>

Annual Cost of Other Disorders in U.S.

- Depression: $44 billion
- Stroke: $53.6 billion
- ADHD (child, adolescent, adult): $80 billion
- Alzheimer’s: $100 billion
- Alcohol abuse/dep: $180
- Drug abuse/dep: $180

Prognosis for ADHD Children

Chronic disorder extending into adolescence and adulthood

- One-third: **Tolerable outcome**: appear to have mild problems but must constantly work to adapt to their difficulties
- One-third: **Moderately poor outcome**: continue to have a variety of moderate to serious problems, including school difficulties (adolescents) or vocational adjustment difficulties (adults), interpersonal problems, general underachievement, problems with alcohol, etc.
- One-third: **Bad outcome**: severe dysfunction and/or psychopathology, including sociopathy, repeated criminal activity and resulting incarceration, alcoholism, drug use disorders

Pittsburgh ADHD Longitudinal Study (PALS) (Molina and Pelham)

- NIAAA/NIDA-funded
- N=365 ADHD and 240 Controls
- Half adolescents and half young adults
- ADHD subjects obtained in childhood (ages 5 to 14) from treatment clinic at WPIC
- Extensive childhood data available
- Follow up began an average of 8 years later (12-22)
- Annual assessments of substance abuse, psychopathology, criminal behavior, and multiple domains of individual and family functioning
- Lifetime histories of treatment, school functioning
% Reporting Weekly Binge Drinking (≥5 Drinks Per Occasion)

Percentage Smoking At Least 1/2 Pack a Day

Percentage Using Marijuana Daily

Pittsburgh ADHD Longitudinal Study

Findings:
- Higher rates of binge drinking
- Higher rates of daily marijuana use
- Higher rates of daily cigarette smoking
- Higher rates of other illicit drug use
- Earlier start of alcohol, cigarettes, and marijuana
- Higher rates of special education use
- Very high rates of disciplinary problems in school
- Very high rates of delinquency
- Continued severe impairment in multiple domains into young adulthood, including work, finances, romantic and family relationships, and legal difficulties

N = 201 ADHD and 109 control subjects who report ever smoking
N = 184 ADHD and 92 Control subjects who report ever using marijuana
What is Effective, Evidence-based Treatment for ADHD in Children?

Treatments That Are Commonly Used but Are Not Evidence-Based (i.e., are Not Effective)

(1) Traditional one-to-one therapy or counseling
(2) Cognitive therapy
(3) Office-based “Play therapy”
(4) Elimination diets
(5) Biofeedback/neural therapy/attention (EEG) training
(6) Allergy treatments
(7) Chiropractics
(8) Perceptual or motor training/sensory integration training
(9) Treatment for balance problems
(10) Pet therapy (including horse therapy)
(11) Dietary supplements (megavitamins, blue-green algae)
(12) Duct tape

Evidence-Based Short-term Treatments for ADHD

(1) Behavior modification
   - 48 classroom studies (N > 900)
   - 80 parent training studies (N > 5,000)
   (including prior to DX cat./ODD/CD)
(2) CNS stimulant medication
   > 250 studies (N > 5000)
(3) The combination of (1) and (2).
   > 25 studies (N > 800)

Most studies are crossover studies
AAP Clinical Practice Guideline: Treatment of the School-Aged Child with Attention-Deficit/Hyperactivity Disorder

**RECOMMENDATION 1**: Primary care clinicians should establish a management program that recognizes ADHD as a chronic condition.

**RECOMMENDATION 2**: The treating clinician, parents, and the child, in collaboration with school personnel, should specify appropriate target outcomes to guide management.

**RECOMMENDATION 3**: The clinician should recommend stimulant medication and/or behavior therapy as appropriate, to improve target outcomes in children with ADHD.

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Despite the Evidence, There is Controversy about which Treatments Should be Used for ADHD

The MTA Study has resulted in widespread agreement amongst psychiatric professionals, ADHD experts, pharmaceutical companies, media outlets, and advocacy groups that medication is the treatment of choice for ADHD.

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MTA Results in the Professional Community

- If one provides...medication...as the first line of treatment...many...children will not require...behavioral interventions. *MTA Cooperative Group, Archives of General Psychiatry, 1999*
- ...the MTA studies suggest that there’s very little benefit from any psychotherapeutic treatment. *David Shaffer, Cost and Therapeutics, 2000*

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MTA Results in the Professional Community

- There is not a consensus...that a comprehensive approach to treatment for ADHD is multimodal...stimulant treatment is easily available in the community and behavioral treatment is not...*Mina Dulcan, M.D., Editor, Journal of the American Academy of Child and Adolescent Psychiatry, 2002*
- The public health significance of this proposal is limited because the psychosocial interventions used in this study are rarely used in clinical practice...and are unlikely to be used broadly in the foreseeable future. *Anonymous [child psychiatrist] NIH grant reviewer, 2003*
MTA Results in the Media

- “Medication Makes the Difference in ADHD kids: Monitoring Medication is the Key”, “Psychosocial Treatments of No Benefit Even When Used with medication”…Clinical Psychiatry, Pediatric, Family Practice News
- Medication wins over behavioral treatments “hands down”…Jensen/NY Times
- We are wasting tons of money on psychosocial [behavioral] treatments that don’t work…Pelham, Clinical Psychiatry, Pediatric, Family Practice News

Comprehensive Psychosocial and Pharmacological Treatment for ADHD: The NIMH/USOE Multimodal Treatment Study

Randomized Clinical Trial of four treatments:
- Community Comparison Control
- Psychosocial Alone
- Pharmacological Alone
- Combined Psychosocial and Pharmacological

576 subjects, recruited from community, entered between January and May of three consecutive years across six sites
144 subjects per group overall; 24 per group per site Treatment for 14 months; follow up for 10 months
Extensive manualization and standardization of treatment:
- 1000+ pages of treatment manuals
- Coordinated staff training across sites
- Extensive measures of treatment fidelity for all components
- 10+ hours of weekly conference calls to standardize protocol

Summary of MTA Results at 14 Months

- All four groups improved dramatically with time
- Active Med (study: 39 mg MPH/day) was superior to faded Beh on ADHD symptom measures and some measures of impairment
- 75% of Beh group were maintained off medication
- Combined (31 mg MPH/day) was superior to Beh on all measures and to Med on most measures of impairment but not significantly on symptoms
- Comb (and sometimes Med) were superior to CC and Beh was equivalent (70% of CC medicated; 24 mg MPH/day)
- Combined produced more normalization at lower doses (and lower rates of increase in dose) than Med and was much preferred by parents
SNAP-ODD (Parent/Teacher): Treatment Group Outcomes across 24 Months

Composite Score Adjusted for Baseline

Change in Presenting Problems

- Declined/dropped out: Medmg 12%, Comb 4%, Beh 0%
- Worse/Unchanged: Medmg 6%, Comb 6%, Beh 5%
- Slightly improved: Medmg 22%, Comb 11%, Beh 22%
- Improved: Medmg 38%, Comb 37%, Beh 43%
- Much improved: Medmg 22%, Comb 41%, Beh 30%
Would Parent Recommend Treatment?
(Pelham & MTA Coop. Group, under review)

<table>
<thead>
<tr>
<th></th>
<th>Medmgt</th>
<th>Comb</th>
<th>Beh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declined/dropped out</td>
<td>12%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Not recommend</td>
<td>8%</td>
<td>3%</td>
<td>5%</td>
</tr>
<tr>
<td>Neutral</td>
<td>8%</td>
<td>1%</td>
<td>2%</td>
</tr>
<tr>
<td>Slightly Recommend</td>
<td>4%</td>
<td>2%</td>
<td>2%</td>
</tr>
<tr>
<td>Recommend</td>
<td>31%</td>
<td>15%</td>
<td>24%</td>
</tr>
<tr>
<td>Strongly recommend</td>
<td>38%</td>
<td>76%</td>
<td>67%</td>
</tr>
</tbody>
</table>

Overall Satisfaction with Treatment

<table>
<thead>
<tr>
<th></th>
<th>Medmgt</th>
<th>Comb</th>
<th>Beh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Declined/dropped out</td>
<td>12%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Dissatisfied</td>
<td>3%</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Neutral</td>
<td>6%</td>
<td>4%</td>
<td>1%</td>
</tr>
<tr>
<td>Slightly satisfied</td>
<td>5%</td>
<td>3%</td>
<td>4%</td>
</tr>
<tr>
<td>Satisfied</td>
<td>40%</td>
<td>18%</td>
<td>31%</td>
</tr>
<tr>
<td>Strongly satisfied</td>
<td>34%</td>
<td>70%</td>
<td>64%</td>
</tr>
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</table>

Program of Research: Background

Behavioral and pharmacological treatments both have a solid evidence base for the treatment of children with ADHD. There is debate about relative efficacy.

Though also effective, the combination of the two treatments has been understudied, particularly with respect to doses of treatment.

Most comparative studies (e.g., the MTA) have involved nonintensive or faded levels of behavior therapy, while medication has typically been implemented at high doses and has been sustained.

No-treatment controls have not been systematically included for behavioral treatments (problem of background rates of behavior modification).

Program of Research: Background

Thus, comparative and combined effects in extant studies have not considered dosing effects of the comparative/combined treatments and cannot be clearly interpreted without this information.

Although combined treatments are explicitly (e.g., CHADD) or implicitly (e.g., AAP, 2001) recommended by influential bodies in the ADHD field, no studies have addressed the question of how the components of combined treatments should be sequenced and whether sequencing influences need for combined treatment.
Recent Program of Research: Questions the MTA Did Not Answer
Should behavioral treatment begin before medication (parent preference) or vice versa (physician practice) or should they be implemented simultaneously (as in the MTA)?
What is the best “dose” of psychosocial and pharmacological treatment?
If one or the other modality is begun first, how long should it be conducted and at what dose before adding in the second modality?
What are the implications of different sequences for treatment dosing, benefit, and risk of side effects?
These are the questions that practitioners and parents face daily, but they have not been studied.

Why might it be important to use behavioral treatments first and then add medication only if it is needed?
FIRST DO NO HARM
Medication has short-term benefits but no long-term benefits and unknown long-term risks
Use of medication first may prevent effective use of psychosocial interventions at home and school and minimize long-term adherence
What would you do with your own child?

Components of Effective, Comprehensive Treatment for ADHD
Concurrent Psychostimulant Medication
Rarely should be used as first treatment implemented
Need determined following initiation of behavioral treatments; timing depends on severity and responsiveness
Individualized, school-based medication trial conducted to determine need and minimal dose to complement the behavioral intervention
Cycle through methylphenidate and amphetamine-based compounds before other drug classes
Need for t.i.d. or long-acting medication also determined during initial assessment based on child’s impairment across settings and times (do not assume 24/7 medication)
Use at minimal rather than maximal effective dose
Continue for as long as need exists (typically years–defined by annual trials to adjust dose and evaluate continued need)
Plan for possible emergent iatrogenic effects

Main Beneficial Short-term Effects
1. Decrease in classroom disruption
2. Improvement in teacher ratings of behavior
3. Improvement in compliance with adult requests and commands
4. Increase in on-task behavior and academic productivity and accuracy (but no long-term effect on academic achievement)
5. Improvement in peer interactions
6. Improvement in performance on laboratory measures of attention, impulsivity, and learning
Limitations of Pharmacological Interventions When Used Alone

1) Rarely sufficient to bring a child to the normal range of functioning
2) Works only as long as medication taken
3) Not effective for all children
4) Does not affect several important variables (e.g., academic achievement, concurrent family problems, peer relationships)
5) Poor Compliance in long-term use
6) Parents are not satisfied with medication alone
7) Removes incentive for parents and teachers/schools to work on other treatments
8) Uniform lack of evidence for beneficial long-term effects
9) Potential serious adverse effects in growth and substance use (data controversial)

Classroom Rule Violations

Academic Productivity

Negative Behavior During Board Games
Stimulant Prediction of Substance Use (Pelham et al, under review--PALS)

All regressions controlled for age, SES as measured by parental education level, ethnicity, child IQ, and current stimulant use.

Four models tested:
1. Controlling for childhood functioning measures
2. Controlling for intervening school problems
3. Controlling for concurrent adult functioning measures
4. Controlling for all measures at once

Stimulant Prediction of Substance Use

<table>
<thead>
<tr>
<th>Substance</th>
<th>Estimate</th>
<th>P</th>
<th>Odds Ratio</th>
<th>CI of Odds Ratio</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol</td>
<td>1.23</td>
<td>.05</td>
<td>3.00</td>
<td>1.02-13.20</td>
</tr>
<tr>
<td>Marijuana</td>
<td>1.37</td>
<td>.05</td>
<td>3.19</td>
<td>0.99-15.44</td>
</tr>
<tr>
<td>Cigarettes</td>
<td>1.34</td>
<td>.05</td>
<td>3.83</td>
<td>1.01-14.56</td>
</tr>
</tbody>
</table>
**Trends in Medication Use**

- **Before MTA, Concerta, and Adderall XR**
  - Meds for school hours only-184 days per year
  - Most children medicated 1-3 years
  - Modal total daily dose: 15-20 mg MPH; 10 mg Adderall
  - Lifetime dose: 5400 mg to 10,800 mg MPH
- **After MTA, Concerta, and Adderall XR**
  - Meds for school and home
  - Equivalent total daily doses: 36 mg Concerta; 20 mg Adderall XR
  - Weekends and summers medicated (so 365 days per year)
  - Current recommendations (e.g., MTA): start early and medicate for all 12 school years
  - Lifetime dose: 14,600 mg/year X 12 =175,000 mg MPH

**Components of Effective, Comprehensive Treatment for ADHD**

- Parent Training--Use always
- School Intervention--Use always
- Child Intervention--Use always
- Medication--Use when needed

**Why is it Important to Include Parent Training in Treatment?**

- Parents of ADHD children have significant stress, psychopathology, and poor parenting skills
- ADHD children contribute greatly to parental stress and disturbed parent-child relationships
- Parenting styles characteristic of ADHD parents predict long term negative outcomes
- These are transactional processes leading to ever greater dysfunction
- Parenting mediates most negative outcomes and needs to be the main focus of intervention
- No evidence that medicating the child affects these factors

**Do Your Children Cause You Stress?**
Health States from CSQ
(from PALS mothers)
- Computed health states using the CSQ analogous to those from HRQoL (EQ-5D Group)
- 29% of mothers of ADHD kids had lifetime health state scores (QALY) = -.67
- 31% had QALY = -.72
- Only 8.6% of control mothers had QALYs this low
- These scores are equivalent to scores for major depression, colitis, diabetes, asthma, migraine, ulcers, and stroke
- Only 2% said ADHD child did not interfere with daily life activities (vs. 50% of control mothers)

Components of Effective, Comprehensive Treatment for ADHD

Parent Training
Behavioral approach
Focus on parenting skills, child’s behavior, and family relationships
Parents learn skills and implement treatment with child, modifying interventions as necessary using ongoing functional analysis
Group-based, weekly sessions with therapist initially (8-16 sessions), then contact faded
Don’t expect instant changes—improvement (learning) often gradual
Continued support and contact as long as necessary (e.g., 2 or 3 years and/or when deterioration occurs)
Program for maintenance and relapse prevention (e.g., develop plans for dealing with concurrent cyclic parental problems, such as maternal depression, parental substance abuse, and divorce; make programs palatable and feasible)
Reestablish contact for major developmental transitions (e.g., adolescence)
Can be offered in MH, primary care, schools, churches, community centers by individuals with wide variety of training—very cost effective

Caregiver Strain Questionnaire
Assesses the impact on parents of having a child member with ADHD (Branna, Heflinger, & Bickman, 1997).
3 subscales:
Objective caregiver strain (e.g., loss of personal time, trouble in neighborhood, disruption of family relationships)
Internalized subjective caregiver strain (feelings internalized by caregiver; e.g., worry, guilt, tired)
Externalized subjective caregiver strain (negative feelings directed at the child; e.g., anger, embarrassment, resentful toward child)
Caregiver Strain Questionnaire (mother report lifetime-PALS)

<table>
<thead>
<tr>
<th></th>
<th>ADHD</th>
<th>Control</th>
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</thead>
<tbody>
<tr>
<td>Objective caregiver strain</td>
<td>28.1 (10.5)</td>
<td>14.1 (5.6)</td>
</tr>
<tr>
<td>Internalized subjective strain</td>
<td>19.7 (5.4)</td>
<td>10.4 (5.5)</td>
</tr>
<tr>
<td>Externalized subjective strain</td>
<td>10.3 (2.7)</td>
<td>8.4 (2.3)</td>
</tr>
</tbody>
</table>

Significant group differences ($p < .01$) on all scales

Why is it important to also treat in school settings?

Academic Functioning

- 33% of ADHD have academic problems (special ed., academic probation, dropped out, or held back) every year, vs. 2% of controls
- 48% of ADHD children have at least one year of special education placement vs. 3% of controls (bulk of cost)
- 12% of ADHD vs. 5% of controls have been held back a grade
- 9% of ADHD adolescents drop out of school vs. 1% of controls
- ADHD adolescents a full letter grade lower than controls, with twice the rate of absences
### School Discipline Problems

**Discipline Problems (sent to principal, serious warnings, detention, suspension, expulsion) per Year:**

<table>
<thead>
<tr>
<th></th>
<th>ADHD</th>
<th>Control</th>
</tr>
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<tbody>
<tr>
<td>None</td>
<td>20%</td>
<td>41%</td>
</tr>
<tr>
<td>&lt; Quarterly</td>
<td>34%</td>
<td>51%</td>
</tr>
<tr>
<td>Quarterly</td>
<td>17%</td>
<td>7%</td>
</tr>
<tr>
<td>Monthly</td>
<td>19%</td>
<td>1%</td>
</tr>
<tr>
<td>Weekly</td>
<td>10%</td>
<td>0%</td>
</tr>
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</table>

### Components of Effective, Comprehensive Treatment for ADHD

**School Intervention**

- Behavioral approach—teachers are trained and implement treatment with the child, modifying interventions as necessary using ongoing functional analysis.
- Focus on classroom behavior, academic performance, and peer relationships.
- Widely available in schools.
- Teacher training: (1) in service training and follow up or (2) consultant model—initial weekly sessions, then contact faded.
- Don’t expect instant changes—improvement (learning) often gradual.
- Continued support and contact for as long as necessary—typically multiple years and/or if deterioration.
- Program for maintenance and relapse prevention (e.g., school-wide programs, train all school staff, including administrators; eventually train parent to implement and monitor).
- Reestablish contact for major developmental transitions (e.g., adolescence).

### Daily Report Card (Downloadable)

- An integral part of all of our school interventions with ADHD children.
- Serves as a means of identifying, monitoring, and changing the child’s classroom problems.
- Doubles as an avenue of regular communication between the parents and the teacher.
- Costs little, takes little teacher time, and is highly motivating to the children if parents have selected the right rewards for home back-up.
- Effectiveness documented in numerous studies.
- Can be used to titrate medication dose.

### Daily Report Card: Good Example

<table>
<thead>
<tr>
<th></th>
<th>Special</th>
<th>LA/Art/Reading</th>
<th>SS/Sci.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Follows class rules with no more than 2 rule violations per period</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Completes homework within the designated time</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Completes homework at 80% accuracy</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Follows lunch rules (&lt; 3 violations)</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Follows recess rules (&lt;2 violations)</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>

**Total Number of Yesses/Noses:**

- Teacher’s Initials: [Blank]
- Comments: [Blank]
Components of Effective, Comprehensive Treatment for ADHD

Child Intervention
- Behavioral and developmental approach
- Focus on teaching academic, recreational, and social/behavioral competencies, decreasing aggression, increasing compliance, developing close friendships, improving relationships with adults, and building self-efficacy
- Paraprofessional implemented (for cost reasons)
- Intensive treatments such as summer treatment programs (9 hours daily for 8 weeks), and/or school-year, after-school, and Saturday (6 hours) sessions
- Don’t expect instant changes—improvement (learning) often gradual
- Continued support and contact as long as necessary—multiple years or if deterioration occurs
- Program for generalization and relapse prevention (e.g., integrate with school and parent treatments—link all through home/school report card systems)
- Reestablish contact for major developmental transitions (e.g., adolescence)

Why is it Important to Use Psychosocial Treatments for ADHD Peer Relationships?
- We have long known that impaired peer relationships in children are the best predictors of negative adult outcomes
- ADHD children have seriously impaired peer relationships
- ADHD children have the negative adult outcomes that are predicted by disturbances in peer relations
- Peer relationships arguably mediate ADHD children’s adult outcomes
- Medication does not normalize this domain

Why Treat ADHD in a Summer Setting?
- Work on peer relationships in an ecologically valid setting (e.g., playing common games in peer group settings)
- Teach sports skills and knowledge and team cooperation
- Build friendships with other ADHD children
- Minimize summer learning loss that characterizes low achieving children
- Teach compliance skills to child and parents
- Teach daily report card concept to child and parents

Hypothetical Changes in Achievement over Time for Low Achieving Children as a Function of Summer School
(Adapted from Cooper et al, SRCD Monograph 2000)
Comprehensive and Intensive Treatment for ADHD: Summer Treatment Program

Named in 1993 as one of the country’s model service delivery program for children and adolescents by the Section on Clinical Child Psychology of the American Psychological Association.

Used successfully in clinical trials at NIMH, CMHS, and NIDA

Innovative Program of the Year, 2003, CHADD

SAMHSA list of Evidence Based Practices (NREP), 2005

Summer Treatment Program Overview

- Eight-week program, 9 hours daily
- Children grouped by age into groups of 12
- Groups stay together throughout the day
- 5 counselors work with each group all day outside of the classroom
- One teacher and an aide staff the classroom for each group
- Treatment implemented in context of recreational and academic activities

Typical STP Schedule

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:30-8:00</td>
<td>Arrivals</td>
</tr>
<tr>
<td>8:00-8:15</td>
<td>Social Skills Training</td>
</tr>
<tr>
<td>8:15-9:00</td>
<td>Soccer Skills Training</td>
</tr>
<tr>
<td>9:15-10:15</td>
<td>Soccer Game</td>
</tr>
<tr>
<td>10:30-11:30</td>
<td>Art Class</td>
</tr>
<tr>
<td>11:45-12:00</td>
<td>Lunch</td>
</tr>
<tr>
<td>12:00-12:15</td>
<td>Recess</td>
</tr>
<tr>
<td>12:15-2:15</td>
<td>Academic/computer class</td>
</tr>
<tr>
<td>2:30-3:30</td>
<td>Softball Game</td>
</tr>
<tr>
<td>3:30-4:30</td>
<td>Swimming</td>
</tr>
<tr>
<td>4:45-5:00</td>
<td>Recess</td>
</tr>
<tr>
<td>5:00-5:30</td>
<td>Departures</td>
</tr>
</tbody>
</table>

Summer Treatment Program Overview

Treatment Components:
- Point System
- Social Skills Training, Cooperative Tasks, Team Membership, and Close Friendships
- Group Problem Solving
- Time out
- Daily Report Cards
- Sports Skills Training and Recreation
Summer Treatment Program Overview

Treatment Components:
- Positive Reinforcement & Appropriate Commands
- Classrooms--Regular, Peer Tutoring, Computer, and Art
- Individualized Programs
- Parent Training
- Medication Assessments
- Adolescent Program
Daily Report Card

Name: Robert G
Date: March 8, 2001

Tapped 4 or less times a day

Yes No

Reads more than 4 sentences a day in all assignments in group discussion

Yes No

Passion the test 3 times or more in a nonacademic period

Yes No

Verbally abusive 10 times or less a day

Yes No

Interrupts 5 times or fewer a day

Yes No

Learning Center

Completed 8 assignments at 80% accuracy or better

Yes No

Respects others with 1 or fewer rule violations a day

Yes No

Wears quietly with 2 or fewer rule violations

Yes No

Comments:

**STP Parent Training**

Parents attend weekly, group sessions designed to transfer gains children make in the STP to home settings. Child care provided for siblings and ADHD children to encourage attendance.

STP parent training in our Buffalo program is conducted using the large-group, Community Parent Education (COPE) Program (Cunningham, Bremner, & Secord-Gilbert, 1995). Other parent training programs could also be used. Booster parent training sessions and school consultations in Fall included in package to facilitate maintenance; parents taught to establish DRC with teacher using summer DRC as model.

---

**Major Benefits of the STP**

- 360 hours of treatment (equivalent to seven years worth of weekly social skills training sessions) in an 8-week period
- Teaches skills (e.g., sports) not taught in other interventions and provides on-line practice
- Parents have daily contact with therapist
- Extremely low dropout rate (3%) compared with up to 50% in other studies
- High parent attendance at parent training meetings
- Supportive “community” environment for child and family
- Stress-relief for parents and child provided by an 8-week daily treatment program
- Unusually high level of parent and child satisfaction with treatment—critical for long-term palatability and implementation
- Maintains academic gains/prevents summer loss
STP Documentation

STP Manual: 429 pages, describes procedures and treatment components in detail
Child Binder: Provides clinical data tracking forms to monitor each child's progress in key areas and individualized target behavior graphs
Group Binder: Provides group-based tracking forms and materials used in treatment

Learning Center Binder: Provides academic productivity/accuracy tracking forms and individualized target behavior graphs
Supervisor Binder: Provides treatment integrity materials and instructions and other managerial materials
All data recording forms are provided

Treatment Fidelity/Integrity

A comprehensive set of materials has been developed to measure treatment integrity. Materials include procedural checklists and qualitative ratings that supervisors complete during regular observations. Supervisors provide feedback to staff members based on completed integrity materials. Supervisors assign remedial activities any time staff performance falls below predetermined levels of accuracy or quality (e.g., fewer than 80% of procedures completed; inferior quality ratings.)
Treatment Integrity and Fidelity
Staff read manual, memorize operational definitions, and take test to mastery prior to training
Six days of intensive training, including extensive practice and feedback
During program, point system and learning center reliability (checks on the accuracy of staff members’ reporting and classifying behaviors)
Weekly reliability quizzes for counselors and learning center staff members
Supervisors complete frequent observations using TIF forms (see below) and provide daily feedback and remediation as necessary for staff members

Treatment Integrity/Fidelity Forms
Social Skills Training: Communication, Cooperation, Participation, Validation, Teasing Module
Group Problem-Solving/Reparation Discussion Discussion
Time Out
Command Sequence
Point Check, Transition, and Bathroom Break
Social Reinforcement
Honor Roll
Recreational Activities: Soccer, Softball, Kickball, Basketball
Skill Drills
Swimming
Academic Learning Center: Seatwork, Peer Tutoring, Computer
Art Learning Center
Parent Training Fidelity Checklist
Parental and child report on daily home reward delivery

Dissemination
• All STP materials on one CD ($249 US)
• Training available annually in Latrobe PA and Buffalo NY (very low cost)
• Trainers available to come to your site
• After first summer, maintained by your staff
• Adapted for many settings/uses (e.g., after school (UCLA, Cleveland Clinic), summer school (Buffalo), city recreation departments (Chicago)

STP Sites
• Buffalo (UB and BPS)
• New York City (NYU)
• Cleveland, OH (Cleveland Clinic)
• Irvine, CA (UCI)
• Erie, Johnstown, Indiana, and Butler, PA (4 Community Agencies with 9 different sites)
• SC, WVA, NJ, and WA community agencies/professionals
• Birmingham AL (UAB)
• Chicago (IUCC/community parks)
• Kurume, Japan
• Planning stages: Cincinnati Children’s Hospital; community MH agencies in NYC, WI, and IO; Atlanta, Paris, France; Sapporo and Osaka, Japan
• Smaller, shorter camps in many U.S. cities that use parts of STP
• Why none in Ann Arbor or Detroit?
World Wide Web Page

Information and applications for staff and children (as well as downloadable information for parents, teachers, and other professionals), as well as information about setting up an STP in your community are available on the WWW at:

http://wings.buffalo.edu/adhd

Summary:
Components of Effective, Evidence-based, Comprehensive Treatment

- Parent Training—Use always
- School Intervention—Use always
- Child Intervention—Use always
- Medication—Use when needed

How Should These Two Treatments be Combined or Sequenced?

- Begin medication first (physician practice)?
- Begin behavior therapy first (parent preference)?
- Begin them simultaneously (MTA procedure)?

Program of Research

Four studies funded by NIMH and IES that examine dose effects and sequencing effects:

1. Controlled examination of 3 levels of behavior modification (none, low intensity, high intensity) crossed with 4 doses of medication in a summer program setting and at home
2. Follow up to (1): School-year evaluation of effectiveness and need for medication after beginning the year on one of 3 behavior modification levels (none, low intensity, high intensity)
3. Evaluation of effectiveness and need for medication in young ADHD children beginning treatment (home, school, peers, academic) with one of the same behavior modification levels as above (with adaptive components) and continuing without fading for 3 years (to pass peak period for medication use)
4. SMART (sequential, multiple, adaptive, randomized trial) design to examine whether to begin treatment with medication or behavior therapy and, when nonresponse, whether to add the other modality or increase the intensity of initial modality
Which Outcomes to Measure?

Our studies always focus on functional outcomes rather than DSM symptoms.

This is true for making decisions about need for medication, deciding about adaptive components, and measuring endpoint functioning.

Dose-Response Effects of Behavior Modification, Medication, and their Combination in ADHD Children in a Summer Setting


Study 1 Design

48-52 ADHD children per summer for 3 summers

4 Medication conditions: placebo and 3 doses of methylphenidate (.15mg/kg, .3 mg/kg, .6 mg/kg, t.i.d.), with order varying daily within child for 9 weeks

3 Behavioral Modification conditions: No behavioral treatment (NBM), low-intensity (LBM) treatment, and high-intensity (HBM) treatment (BM), varying triweekly in random order by treatment group

3-4 days per medication X Bmod condition.
NonADHD comparison group (24/summer).

Comparative and Combined Treatments for ADHD

3, 3-week Behavior Modification conditions assigned randomly:

- High Intensity BMod
- Low Intensity BMod
- No BMod

Daily Crossover of 4 Med conditions:
Placebo
.15 mg/kg MPH
.3 mg/kg MPH
.6 mg/kg MPH

Daily Crossover of 4 Med conditions:
Placebo
.15 mg/kg MPH
.3 mg/kg MPH
.6 mg/kg MPH

Daily Crossover of 4 Med conditions:
Placebo
.15 mg/kg MPH
.3 mg/kg MPH
.6 mg/kg MPH
High Intensity Condition

All standard STP behavioral treatments with individualized programs as needed:

**Point system.** Comprehensive point system with both reward and cost components in recreational and classroom settings.

**Activity rules.** Standard activity rules, reviewed at the beginning of the activity; children lost points for breaking rules.

**Social skills and problem solving.** Daily social skills training, incorporated into all daily activities and the point system. Problem-solving sessions as necessary to resolve problems in group functioning.

**Sports skills.** Skill drill periods, immediate feedback regarding skills and sport rule violations during games, and game-awareness questions during games.

High Intensity Condition

**Time out.** Time-out procedures with escalation for inappropriate behavior, time reductions for appropriate behavior, and contingent release components.

**Social reinforcement and social honors.** Praise and social reinforcement, daily social rewards & privileges for high point totals and improvements.

**Daily Report Cards.** Individualized target behaviors in recreational, classroom, and home settings. Daily and weekly rewards at STP and home.

**Recess and field trips.** Two free-play recess periods daily based on DRC; weekly field trips for meeting both individualized point goals and DRC goals.

Classroom. Classroom rules with response-cost, public posting and feedback, Premack contingency (5-min free-play period) for behavior and productivity.

Low Intensity Condition

**Point system.** Children received feedback about their behavior only, without earning or losing points.

**Activity rules.** Activity rules were reviewed at the beginning of the activity, but children did not lose points.

**Social skills and problem solving.** Weekly social skills training sessions with children during parent training sessions.

**Sports skills.** Counselors provided coaching and instruction, and asked game-awareness questions; but children did not earn points for attention or lose points for violating rules.

Low Intensity Condition

**Time out.** Fixed-length sit-outs without a contingent release component.

**Social reinforcement and social honors.** Praise and social reinforcement, daily social rewards (buttons, but without accompanying privileges) for high point totals and improvements.

**Daily Report Cards.** Children received STP and home-based DRCs. Parents provided rewards on a weekly basis rather than daily.

**Recess and field trips.** Two free-play recess periods based on DRC performance; weekly field trips for meeting DRC performance goals (no points goal).

Classroom. Classroom rules, public feedback, noncontingent free-play period.
No Behavior Modification Condition

Point system: Children received feedback about their behavior only, without earning or losing points.

Activity rules: Activity rules were not reviewed at the beginning of the activity.

Social skills and problem solving: None.

Sports skills: Counselors provided skills training during skills periods but no coaching and instruction during games, no game-awareness questions.

Time out: None; children were "suspended" for dangerous behavior only.

Social reinforcement and social honors: Praise and social reinforcement; noncontingent social rewards.

Daily Report Cards: None.

Recess and field trips: Children earned recess and field trips noncontingently.

Classroom: No rules, public posting or feedback; noncontingent free-play period.

Participants

Data available on 154 ADHD subjects (130 boys and 24 girls) and 72 controls, ages 5-12.

Controls matched to ADHD subjects by gender, ethnicity, and age (no medication—otherwise same participation).

All participants had full-scale IQ ≥ 80; ADHD children were DSM IV-diagnosed using the DISC parent interview and parent and teacher ratings.

Control subjects could not meet ADHD diagnostic criteria on the same measures.

Dependent Measures

Counselor-Recorded Daily Behavior

Following Activity Rules
Noncompliance
Interrupting
Complaining
Conduct problems
Negative verbalizations

Classroom Behavior

Seatwork productivity and accuracy
Staff and parent behavior ratings
Staff and parent ratings of treatment effectiveness and distress
Data Analysis

For all measures, 4 (Drug) x 2 (Behavioral Treatment) MANOVAs (SPSS GLM) were conducted. Significant interactions were followed by examining simple effects of each treatment component.

Results

On all behavioral measures, both medication and BMOD produced significant main effects. The two treatments interacted such that the dose-response curve was flattened in the presence of behavioral treatment compared to medication alone. The majority of the medication effect occurred at the lowest dose in the LBM and HBM conditions. A more linear dose-response relationship was found for the NBM condition.
Performance on Home Target Behaviors

Between-Group Comparison of First Behavioral Condition

Effect Sizes for Behavior Modification at the Third Week of Treatment

<table>
<thead>
<tr>
<th>Measure</th>
<th>Low Intensity</th>
<th>High Intensity</th>
<th>High vs. Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rule Violations</td>
<td>0.40</td>
<td>0.65</td>
<td>0.30</td>
</tr>
<tr>
<td>Noncompliance</td>
<td>0.42</td>
<td>0.71</td>
<td>0.29</td>
</tr>
<tr>
<td>Interruption</td>
<td>0.35</td>
<td>0.52</td>
<td>0.17</td>
</tr>
<tr>
<td>Neg. Verbalizations</td>
<td>0.26</td>
<td>0.58</td>
<td>0.32</td>
</tr>
<tr>
<td>0.15 mg/kg</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Rule Violations</td>
<td>0.66</td>
<td>0.88</td>
<td>0.22</td>
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<tr>
<td>Noncompliance</td>
<td>0.49</td>
<td>0.58</td>
<td>0.09</td>
</tr>
<tr>
<td>Interruption</td>
<td>0.46</td>
<td>0.69</td>
<td>0.23</td>
</tr>
<tr>
<td>Neg. Verbalizations</td>
<td>0.32</td>
<td>0.57</td>
<td>0.25</td>
</tr>
</tbody>
</table>
Effect Sizes for Behavior Modification at the Third Week of Treatment

<table>
<thead>
<tr>
<th>Measure</th>
<th>Low Intensity</th>
<th>High Intensity</th>
<th>High vs. Low</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.3 mg/kg</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Rule Violations</td>
<td>0.60</td>
<td>0.85</td>
<td>0.23</td>
</tr>
<tr>
<td>Noncompliance</td>
<td>0.48</td>
<td>0.81</td>
<td>0.38</td>
</tr>
<tr>
<td>Interruption</td>
<td>0.33</td>
<td>0.54</td>
<td>0.23</td>
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<tr>
<td>Neg. Verbalizations</td>
<td>0.25</td>
<td>0.61</td>
<td>0.36</td>
</tr>
<tr>
<td>0.6 mg/kg</td>
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<tr>
<td>Rule Violations</td>
<td>0.73</td>
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<tr>
<td>Noncompliance</td>
<td>0.45</td>
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<td>0.11</td>
</tr>
<tr>
<td>Interruption</td>
<td>0.44</td>
<td>0.57</td>
<td>0.14</td>
</tr>
<tr>
<td>Neg. Verbalizations</td>
<td>0.32</td>
<td>0.64</td>
<td>0.35</td>
</tr>
</tbody>
</table>

Normalization Rates

Means and standard deviations were computed for the control sample.
Percentages of ADHD children whose behavior means fell within 2 SDs of the control mean were computed for each treatment condition.
Normalization Rates
In the NBM condition few children were normalized without medication and approximately equal numbers were normalized with each dose.
In the LBM and HBM conditions, many more children were normalized with behavior modification alone and an approximately equal number normalized at the .15 dose of MPH.
Relative to LBM, HBM was not needed for most children but was helpful for a small number.
The lowest medication dose—.15 mg/kg—normalized the largest number of children in the presence of behavior modification.

Parent Evaluations
At the end of the STP, parents evaluated all treatment conditions, including questions about treatment effectiveness, ease of implementation, & whether they would use the treatment again in the future
Increasing the intensity of behavior modification increased parents' effectiveness ratings, and parents gave the highest ratings to the two combined treatments (4.6 and 5.6 out of 6, respectively, compared with 3.5 for medication only, 2.7 for LBM and 3.8 for HBM).

Parent Evaluations
Parents also rank-ordered the conditions they would most like their child to receive (1) over the following year and (2) over the rest of childhood and adolescence.
High-intensity behavioral treatment, alone or in combination with medication, was overwhelmingly picked as parents' first choice.
Only 1% of the parents ranked medication alone as their preferred treatment.
58% of parents chose behavior modification as the more important of the two treatments.
Conclusions

Thus study is the second largest, between-groups analysis of BMOD for ADHD, following only the MTA Study. In the crossover analysis, it is the largest study of comparative and combined treatment for ADHD. Both medication and behavioral treatment produced large, significant, and generally comparable effects on nearly all measures in the recreational and classroom settings. On most measures, the low dose of medication produced as much and sometimes more change in conjunction with the BM conditions than did the four-times higher doses of medication in the NBM condition.

We have long argued that a benefit of combining treatment modalities is to produce equivalent improvement using lower doses of medication. The lowest dose used in this study was equivalent to less than 5 mg IR MPH t.i.d—a very low dose that is only 40% of that utilized in the MTA study. There were no side effects at this dose and many side effects at the highest dose. The highest dose was twice that utilized in the MTA combined treatment group and 50% greater than the Medmt group, suggesting that optimal doses of medication in the absence of all behavioral treatments requires very high doses. Notably, at the high dose levels of either condition, there were little incremental benefits of adding the other intervention. This explains why the MTA study found that combined treatment was only marginally better than medication and better than BT.

The effect of treatment is much larger after 3 weeks than after one week, because of worsening in NBM. Behavioral conditions in earlier studies (Carlson et al., 1992; Pelham et al., 1993; Chronis et al., 2004; Pelham et al., 2005) lasted only several days to a week, thus minimizing the impact of BMOD vs. medication compared to the current study. A major effect of BMOD was to prevent deterioration in behavior over time. Similar patterns of effect have been observed within days for medication effects (Pelham et al., 2001). Interestingly, BMOD also completely prevented deviancy training (Dishion et al, 1999), which also worsened over weeks in NBM, while medication only partially prevented it.

Analyses of individual differences/predictors of response currently ongoing

Effect sizes for BMOD were medium to large for most measures when measured after 3 weeks, and as large as the effects of medication. As the figures make clear, this result was obtained because a true NBM condition was employed—analogous to the placebo condition for medication. This explains why the BMOD effect in the MTA was comparable to and not greater than the CC group, where much behavioral treatment was used by parents and teachers. Thus, treatment doses, timing of assessments, and control conditions are critical factors in evaluations of combined treatment effects. Finally, parents strongly preferred psychosocial approaches or combined approaches, never medication alone.

Limitation: Analogue setting and treatments were implemented simultaneously. What would have happened in natural setting and if BM were implemented first?
What would happen with different behavioral doses in a regular school setting?

Would some children do so well with behavioral treatments that medication is not necessary?

Three Doses of School-based Behavioral Interventions Following a Summer Treatment Program for Children with ADHD: Impact on Need for Medication

(NIMH 2003-2006)

Study 2 Design

128 participants from the Study 1 were randomly assigned to one of three groups for follow-up treatment:

- High behavior modification consultation (HBC; N=44)
- Low behavior modification consultation (LBC; N=43)
- No behavior modification consultation (NBC; N=41)

School Year Follow-Up

- Begin behavioral intervention
- Weekly evaluations
- Begin or no additional treatment
- Need for medication?
- Yes—medication assessment (separate for home and school) and add medication as recommended
- Continue as needed
Procedures

LBC and HBC: teachers received three initial consultation visits at the beginning of the school year aimed to improve existing classroom behavior modification programs and to institute a daily report card. Parents also received monthly group booster parent training meetings.

LBC group: both teachers and parents eligible to receive three additional individual meetings if behavior ratings indicated impairment or as otherwise needed.

HBC group: parents and teachers eligible to receive nine additional individual meetings if behavior ratings indicate impairment or as otherwise needed.

NBC group: received no consultation from the study staff.

Procedures

Teachers and parents in both groups completed weekly ratings of ADHD symptoms and impairment.

If ratings indicated the need for additional treatment or special services for two weeks in a row, and both parents and teachers agreed that medication was indicated, a double-blind, placebo-controlled, school-based medication assessment (Pelham, 1993) was conducted to select the optimal dose and children subsequently began a medication regimen.

Medication was introduced in a step-wise manner. That is, medication was introduced in the school first. Only after a medication regimen was established in school could a medication trial be initiated in the home.

Procedures

Mean numbers of individual teacher consultation sessions actually received ranged from 0.83 to 1.23 across settings and conditions, indicating that very few of the teachers in either behavioral condition took advantage of the additional possible individual consultations after the initial three.

Mean parent training booster groups attended was 2.5 (out of 9 over 10 months), with no difference across the low and high behavioral conditions.

Results

Survival analyses were conducted separately for school and home settings to evaluate whether continued BMOD reduced the need for medication.
Results

A survival analysis conducted for the school-based medication was significant, Breslow statistic = 7.22, $p = .03$. Children in the NBC group began medication at an average of 12.6 weeks, compared with 18.6 weeks for LBC and 19.7 weeks for HBC.

Results

For the home setting, the survival analysis also showed a significant group difference, Breslow statistic (2) = 9.91, $p < .01$; children began medication after an average of 27 weeks (NBC), 37.6 weeks (LBC), or 32.1 weeks (HBC).
Previous Medication Status

Survival results were examined with previous medication status as a covariate in the model. Previous medication was a significant factor in both home- and school-based need for medication.

School Survival Curves

Home Survival Curves
**Results**

During the Fall, nearly twice as many children were maintained off medication in the behavioral consultation groups—60% vs 30%.

With only one additional teacher consultation being used per group, it is not surprising that more children were medicated as the school year progressed—approximately 60% and 80% of the BM and NBM groups.

Notably, the majority of children who received either behavioral consultation condition (booster group parent sessions for both groups)—approximately 80%—remained off medication in the home setting, and 50% of those who received summer behavioral parent training without further follow-up remained medication-free at home.

The vast majority of these children were medicated prior to enrollment in the summer study, and survival was affected as would be expected by prior medication.

**Limitations**

All children had received both medication and behavior modification in the summer (Study 1); Medication use prior to STP (and during STP?) strongly predicted later medication use at school and home (as in the MTA).

As discussed above, behavioral consultations at school in this study were driven (after the first few sessions) by teacher/parent request rather than therapist determined. Both consultation groups ended up receiving the same, low intensity treatment.

Because children were randomly assigned to the three groups, there were children in the HBC group who did not require high-intensity treatments and there were children in the LBC group who may have had better outcomes with HBC procedures.

Could these strategies prevent need for and use of medication over a long time period and is more flexibility needed in the behavioral strategies?

**Dosage of Behavioral Interventions and Long-term Treatment with Young ADHD Children: Can Medication use Be Prevented and at What Cost?**

William E. Pelham, Jr., Lisa Burrows-MacLean, James Waxmonsky, Greta Massetti, Daniel Waschbusch, Gregory Fabiano, Martin Hoffman, E. Michael Foster, Elizabeth Gnagy (NIMH 2005-2010)

**Study Aims**

To expand findings from the STP study to regular classroom settings with young (K and first grade) treatment-naïve ADHD children.

To evaluate whether medication need and dose can be minimized by beginning treatment with behavioral intervention and continuing treatment over the long term.

To determine the dose of behavioral treatment necessary to minimize medication usage and associated cost-benefit tradeoffs.
Design

- Young (k or 1 grade), medication naïve, ADHD children, N=150
- As in previous study, randomly assigned to
  - (1) Treatment as usual (no intervention from study)
  - (2) Standard clinical behavioral intervention school and home and peers
  - (3) Enhanced behavioral intervention school and home and peers
- Treat for 3 years
- Weekly assessments, as in previous study
- As in previous study, continue treatment if success, add medication if need exists
- Behavioral treatment includes multiple components that differ across dose (e.g., STP, academic intervention) and are tailored to the child.

Behavior Modification

Enhanced:
- 16 sessions of group behavioral parent training (COPE/COPE+) followed by 8 sessions of father-child training and monthly booster sessions and phone calls over 3 years
- Up to 8 individual parent sessions per year, initiated when problems arise
- School intervention including daily report card and classroom management practices analogous to the HBM procedures in the STP (response-cost, Premack contingencies, time out).
- 6 initial meetings with teacher to establish program + up to 8 individual sessions per year
- Paraprofessional aides available temporarily to assist with high-intensity procedure initiation (e.g., RECESS)
- 7-week summer treatment program including intensive peer-group social skills and sports skills training, and academic supplement with phonological awareness training component

Standard:
- 12 sessions of group parent training (COPE) followed by bimonthly group booster training for 3 years
- Up to 4 individual parent sessions per year, initiated when problems arise
- School intervention including daily report card and lower-intensity procedures (classroom rules, sit-outs, commands)
- 3 initial meetings with teacher to establish program + up to 4 individual sessions per year
- Weekly group social skills training conducted along with initial 12 parent training sessions.
Indicator of Need for Additional Treatment at weekly Assessments:

(1) Average performance on the ITB 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.

Treatment decisions regarding content will be tailored to the specific domains of impairment rated on the IRS.

Mediators and Moderators

Family SES and ethnicity
Parenting effectiveness and feelings of self efficacy in the parenting role (PSOC), maternal ADHD (CAARS) and depression (BDI), and treatment acceptability (Kazdin, 1984).
Child severity and comorbidity (parent and teacher DBD ODD and CD scores, CBCL affective problems, child IQ and achievement)
Baseline attitudes toward medication
Baseline measures of behavioral treatment use
Treatment fidelity and cumulative behavioral treatment

Analysis and Specific Aims

- Survival to medication is main DV
- Functional outcomes secondary measures
- Main questions:
  - Can medication use be prevented in young ADHD children over the entire period of peak medication risk?
  - What dose of behavioral treatment is necessary to do this (a) in school, (b) at home, and (c) with peers?
  - What are individual differences in outcome?
  - Is medication dose lowered if needed in behavioral conditions and does this reduce SE (e.g., growth retardation)?
  - What are cost-benefit tradeoffs?
  - Do clinical social skills training and/or STP affect the peer domain
- Limitation: This and previous studies do not address whether it might be more prudent to begin treatment with medication at low dose levels

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

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(IES 2006-2010)
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?

Monthly Assessments on which Adaptive Modifications are Based

Parents and teachers: DBD, IOWA Conners, IRS, CBCL, SSRS
Daily Idiographic Target Behavior Lists 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 performance on the ITB 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.

Treatment decisions and content will be tailored to the specific domains of impairment rated on the IRS.
Study Design

A. Begin low-intensity behavior modification
8 weeks
Assess Adequate response?
Yes
No
B. Begin low dose medication
8 weeks
Assess Adequate response?
Yes
No
B1. Continue, reassess monthly; randomize if deteriorate
B2. Increase dose of medication with monthly changes as needed
Random assignment:
B3. Add behavioral treatment; medication dose remains stable but intensity of meditation may increase with adaptive modifications based on impairment

Conclusions

- **Dose** of treatment is important in comparative and combined studies of treatment for ADHD; study results (e.g., the MTA) cannot be understood without understanding dose effects.
- **Sequencing** of treatments is a critical decision but has not been studied systematically with the exception of our follow up study, which shows that providing behavioral treatment reduces need for medication, a result shown naturalistically in the MTA.
- **Parents strongly prefer** psychosocial approaches—alone or in combination with medication. Preference is important in part because it affects compliance.
- **Dose and sequencing questions utilizing adaptive designs** (e.g., SMART designs) mimic the questions that face practitioners daily and are the next wave of treatment outcome research in ADHD.

Summary of Treatment Literature for ADHD

- Behavioral and pharmacological interventions are the only two evidence-based treatments for ADHD.
- Behavioral treatments teach skills and maintain after fading; medication must be continued for long term change.
- Parents prefer behavioral treatments to medication.
- If behavioral treatments are started first and continued, 50-75% of ADHD children do not need medication (lower at school and more at home) and doses are dramatically (75%) lower in those who do need medication.
- For children who need them, multimodal (Beh and Pharm) interventions produce (1) better effects acutely, especially in impairment, with lower doses, (2) lasting behavioral effects if medication is withdrawn, and (3) are strongly preferred by parents and teachers to medication alone and thus more likely to be utilized in the long run.
- There are large individual differences in response to behavioral (and stimulant) treatments.
- There are few studies of dose effects and sequencing effects.

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...the decision about which treatment to use first [should] be guided by the balance between anticipated benefits and possible harms of treatment choices...which should be the most favorable to the child. By this we mean, the safest treatments with demonstrated efficacy should be considered first before considering other treatments with less favorable profiles.

For most of the disorders reviewed herein, there are psychosocial treatments that are solidly grounded in empirical support as stand alone treatments.

Moreover, the preponderance of available evidence indicates that psychosocial treatments are safer than psychoactive medications.

Thus, it is our recommendation that in most cases psychosocial interventions be considered first.
Clinical Recommendations for ADHD

- Focus on impairment in daily life functioning rather than symptoms and monitor impairment to monitor treatment effects.
- Depending on severity, start with behavioral treatment and add medication when impairment is not minimized and parents prefer medication or resources limit more intensive behavioral treatments.
- Dose meds low (not optimally) so as not to remove need for behavioral and educational treatments.
- Minimize lifetime dose of medication.
- Treat for settings and domains of impairment.
- Use 6 to 8 hour stimulant to avoid in-school dosing.
- Use 12-hr evening and weekend meds only when necessary.
- Try all children on both common forms of stimulant.
- Stay in regular contact with family to monitor both behavioral treatments and medication—chronic condition model of treatment.
- Effective treatment will ill require systems redesign (e.g., collaboration with schools, mental health clinics, primary care).

Buffalo Treatment Algorithm for ADHD

- Explain risks and benefits of treatment, develop management plan with family, and begin evidence-based behavioral treatment focusing on domains identified as impaired:
  - Family/Parenting: 8-week group-based behavioral parent training course.
  - School: School-based Daily Report Card established by parent.
  - Peer: 8-week group-based child social skills training (concurrent with parent training).
- Add limited number of individual, problem-focused behavioral parent-training sessions and/or teacher consultations to deal with continued impairment in key domains (family/parents, school, peers).
- Discuss with family risks and benefits of additional treatments to develop management plan; consider parental preference, family resources (e.g., insurance coverage, teacher cooperativeness, socioeconomic factors), and risk:benefit ratios.
- Increase intensity of behavioral interventions according to continued impairment; add parent training sessions, summer program, school consultation (for special education), as needed.
- Conduct ongoing, brief, idiographic assessments of functioning (e.g., IRS, ITBE) in home, school, and peer domains throughout treatment.
- Provide information about ADHD; assess using EBA (e.g., brief P and T rating scales, FBA); focus assessment on key functional domains:
  - Family/parenting skills/parent-child relationship
  - Academic progress/school behavior
  - Relationships with peers

Downloadable Materials (Free) on our Websites

- Instruments:
  - Impairment Rating Scales (Parent and Teacher)
  - Disruptive Behavior Disorder Symptom Rating Scale (Parent and Teacher)
  - Pittsburgh Scale Effect Rating Scales
  - DBD Structured Interview
  - Parent Application Packet and Clinical Intake Outline
  - Initial Teacher Interview
- Information:
  - What Parents and Teachers Should Know about ADHD
  - Medication Fact Sheet for Parents and Teachers
  - Psychosocial Treatment Fact Sheet for Parents and Teachers
  - All of our reprints
- How to Establish a School-Based Daily Report Card
- How to Conduct a School-based Medication Assessment
- How to Establish a Home-Based Daily Report Card
- How to Begin a Summer Treatment Program
- http://wings.buffalo.edu/adhd/
- http://summau.com
Thank you!