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**Efficacy of Stimulant Medication Treatment
of
Attention Deficit Hyperactivity Disorder
in
Preschool-aged Children**

Dissertation
Submitted to the School of Graduate Studies
University of Ottawa

in Partial Fulfillment of the Requirements for
the Degree of Doctor of Philosophy

by

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Ottawa, Ontario
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1996



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In Memoriam

***Dr. Michael Hogben
(d. August 24, 1992)***

"Life only demands from you the strength you possess. Only one feat is possible - not to have run away." – Markings, Dag Hammarskjold

Acknowledgements

The present research was funded by the National Health Research and Development Program, Health and Welfare Canada, Project Number 6606-4979-63, the Ontario Mental Health Foundation and the Research Institute of the Children's Hospital of Eastern Ontario. Their support is gratefully acknowledged.

This project would not have been possible without the dedication and commitment of the parents and children who participated. I am indebted to them for giving their time and trusting me with their pain. More than that, I am changed, forever and irreversibly, by their stories of courage and determination. This dissertation contains the distilled numbers of their performance. Nowhere, but in these few words, does it contain the magnitude of the humanness and vulnerability that was each child.

Dr. Philip Firestone has served as primary supervisor. I extend my gratitude to him for his guidance in all matters of this clinical program. He has been an unfailing source of information, advice and support. I am particularly grateful for his ability to be neutral when necessary and to demonstrate care and concern for my rights when it was required.

Dr. Susan Pisterman has served as supervisor within the research/hospital venue. I extend my thanks for her support and the opportunity to learn from her experience. She has provided me graciously with the occasion to expand my knowledge to this clinical population.

Dr. Susan Bennett has served as the physician supervising the medication phase of this study. I have benefited from the many hours of consults and reassurance she has provided me in the care of each child who participated. Working with her has been an enriching experience and a positive lesson in inter-disciplinary cooperation.

I would like to extend my deepest gratitude to Dr. J. Goodman, Chief, Department of Psychology, and his staff at the Children's Hospital of Eastern Ontario. They have provided me with an invaluable set of experiences by permitting me to be a part of their daily functioning. Their insight, sharings and teachings have been a joy to experience.

A special thanks to the 'protocol kids', Julia, Dale and Antoine, who suffered through my halting early attempts to work out the bugs in the administration of this project.

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Dr. Ian Manion has provided me the support and guidance without which this project may well have grounded to a halt several times. I am grateful for the endless opportunities to present this research in safe and enhancing venues, all of which made conference presentations and finalizations of this work a positive experience.

Several Research Assistants have worked exceedingly hard in the administration of the research protocol, data entry and analyses. I extend my gratitude to Annie Youn, John Mercer and Brian Kauk for their grace in tolerating the long hours and interminable revisions to programs and processes.

Drs. Gail Crombie, Catherine Lee and Zul Merali, members of my dissertation committee, have provided me with the encouragement and faith that this project could be completed successfully.

Dr. Frank Musten has served as *ad hoc* research and clinical advisor. His influence was not through any diminishment of others but through his unswerving commitment to excellence in the science and art of Psychology. Being paced by the demanding standards he sets for himself leaves me with a secure knowledge that I will forever be learning and growing.



Professional acknowledgements are easy because behaviours are delineated and, for the most part, titles operationalize roles. Personal acknowledgements have no such boundaries. Thus, the following is an attempt to render into narrative a complex set of relationships. They reflect acts of grace and moments of salvation.

My daughter Alexandra who has been for me a neverending story. In her growing, she has been a living example of equanimity and gentleness. Through her I am able to feel the surprise in every day, astonishment in every thought and enlightenment in every connection. And, she makes good coffee.

My husband Frank who has been for me a tireless partner in the wrestle and the dance of Life. Were there ever tears which were not a deepening sense of Mystery? Have there been simple moments of quiet in which we have not touched the Spirit? In relationship we have built, planted, harvested and celebrated our transformation, becoming the dance of God.

My parents, Julia and Christopher Monteiro, who have been overwhelming examples of strength and forbearance in the face of

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unimaginable trials. The qualities of perserverance and hope are my legacy and touchstone heirlooms that have sustained me.



Friends have been the garden that surround the foundations and pillars of my life. Many of these have shared my Journey for several decades, some are new plantings who bring a brilliance of thought and compassion to my life.

Christine (and Jim) for all the talks, walks and laughter. The bad jokes, the good jokes, the great food, the nuturing and the fights that never annihilated but always enervated.

Pennie for the many, many years of sharing. The joy, pain, loss and gain are refractions through a relationship that has enriched and enveloped me for uncountable and unaccountable years.

Mary for the years of teaching and connecting. Growing from student to friend has given me a special perspective in meeting the challenges of being who we are.

Mary and Mike for the love and openness. Distance has never slowed relating, never been an obstacle to caring, always been a way of overcoming fears and rejoicing in courage.

Lise for containment of the joys, tears and silliness that made each day tolerable. Connecting comes from knowing without asking, feeling without smothering, rejoicing without diminishing.

Claude, Yolande, Wendy and David for all the teachings in the ways of the healers.

Susan for cherishing the special in me and being friend, colleague, supervisor and mentor.

Vicki, Glenn and those rowdy kids for keeping me grounded by always asking how many more years this was going to take; for always groaning when I said, "Two more."

Deputy Chief Randy Foster (his fiddle), the men of the Fighting Fourth, Station 4, and the volunteer recruit class of 1995, Cumberland Fire Department, for the opportunity to find my personal power, for never wanting me to be one of the guys, for expecting nothing but the best and always laughing when I can't deliver - yet.

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Mel for the stories we share, of hope and justice, of trust and freedom, of invitation and decision. For the song we write together whose lyrics are more than joyous, more than painful but rarely intolerable. For the single line that snakes through air, seeking to be healed in the waters of Spirit.

Dr. Brian Mills for the years of teaching and support in my quest for the perfect ride. His passing leaves a pause in my life and a drive to fulfill his vision of kindnesses performed with no thought of return.

Leslie for cajoling, criticizing and never surrendering to sloppy thinking and lousy analyses. For the love of elegant designs and eloquent statistics. For pushing me out of the cognitive ruts and popping the clutch on my thinking and whose threat of baked cookies was enough to get this work done on time.

Pat, Deano, Larry, Yves, Bud, Gary, Ray, George, Trudy, Ed, Mary, Ann, Jon and a raft full of crazy fisher people. Camelot was never so populated by such raucous, rowdy, bawdy, belligerent, brilliant subversives. I love you all and you have made the completion of this work a possibility by tying me to the computer with your silliness and insane tactics. Long lines, tight loops and hard strikes.

Linda for inspiration when needed most, for love and hugs when the well was dry, for all the editing hints and unfailing responses to unintelligible posts. Being the best is easy when I remember your teachings.

Alan for your presence on the path that seemed impossible without someone to hear my story, for the spiritual renewals, Miles, Johnny and vicariously living through the hussy archetype.

Finally, Michael Hogben. Friend, teacher and the person responsible for my ability to see the connectedness in all things. It is reported that Mike was shot by a crazed fellow-academic. In truth, he died as a result of the mistaken belief that we are solitary explorers of the universe with an entitlement to its riches, that we are the masters of the web rather than one of the strands. I miss him truly.

Abstract

Longitudinal information indicates children who present with 'hard-to-manage' or problematic behaviours at a very young age are at risk for on-going difficulties with parents, peers and in school. However, there are few interventions that have demonstrated effectiveness in ameliorating the symptoms that appear to be precursors of Attention Deficit Hyperactivity Disorder (ADHD).

Despite the use of methylphenidate (MPH) to treat Attention Deficit Hyperactivity Disorder in very young children, there is little information related to its efficacy within this age group. This study examined the effectiveness of medication on the cognitive, behavioural and interpersonal domains of young children who were diagnosed with ADHD. The children were assessed using cognitive measures, behavioural ratings scales and interactive measures assessing child compliance and attention.

Furthermore, the effect of the children's medication status on parental style, skills and stress also were assessed using behavioural observations of parent and child engaged in

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interactive tasks. Changes in parental style, skills and stress were evaluated.

Twenty-four children, aged 4 to 6 years, diagnosed with ADHD, participated in a double-blind, placebo-controlled study evaluating the efficacy of 0.3 mg/kg and 0.5 mg/kg methylphenidate BID. All treatments were randomized and administered for a minimum of 7 days.

Results indicated improvements related to medication were obtained on measures of cognitive tests of attention and as assessed by parent rating scales. Cognitive tests of impulsivity presented an equivocal picture of sensitivity to medication treatment. Attentional abilities in an interactive setting indicated a medication response from Baseline measures only and the degree to which this effect was augmented by Placebo treatment was unclear. That is, there was some evidence that parental expectancies played a role in these measures. No changes were obtained with respect to the children's tendency to comply with parental requests. Side effects were not significantly increased with medication treatment.

Parental skills appeared unaffected by the child's medication status. However, parental style appeared to become more positive

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especially following treatment with the higher dose. Although the stress reported to be experienced by the parent decreased following treatment, the response was non-specific, that is, not related to the medication status of the child.

Not surprisingly, clinical change analyses showed parent ratings were more effective than the cognitive task in picking up the number of children who had responded favourably to medication. Parents rated many children as having improved or normalized following treatment with both doses. Similar rates of positive change were obtained with respect to negative behaviours.

This investigation into the efficacy of MPH in the treatment of very young children diagnosed with ADHD indicated that it was effective in alleviating symptoms of inattention as assessed by laboratory tests and by parent rating scales. Although parents rated negative behaviours as having decreased as a function of medication, these behavioural changes were not detected during the interactive tasks. In general, parent-child tasks did not demonstrate the effectiveness of medication in changing the parents' behaviours or the parent-child dynamic.

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Introduction

Overview

Attention Deficit Hyperactivity Disorder (ADHD) occurs among 9.0% of boys and 3.3% of girls in Ontario between the ages of 4-16 years (Szatmari, Offord & Boyle, 1989). American studies report prevalence rates vary from 1% to 14% with most studies reporting 3-5% of children (Barkley, 1990) with the disorder. Among preschool children the prevalence rate is reported from 2% to 6% (Egeland, Kalkoske, Gottesman & Erickson, 1990; McGee, Partridge, Williams & Silva, 1991). The stability of the behaviours and the evidence of poor prognosis from longitudinal studies (Weiss & Hechtmann, 1993; Claude & Firestone, 1995) point to a need for examining the impact of early and more effective treatments.

Current investigations into the efficacy of methylphenidate treatment of preschool children with Attention Deficit Hyperactivity Disorder are scarce in comparison to the large body of research with older ADHD children (see Gadow, 1992, for a review). Difficulties with the diagnosis and the reluctance to use medical intervention in very young children have been some of the obstacles in assessing stimulant medication treatment of this age group. Nevertheless, 34% of pediatricians and 15% of family physicians report using stimulant medication to treat preschoolers diagnosed with ADHD (Wolraich, Lindgren, Stromquist,

Milich, Davis & Watson, 1990). This may be understandable for two reasons. First, it has been assumed conventionally that attentional difficulties may be amenable to chemical interventions (Mefford & Potter, 1989). Second, there are limited modalities of intervention currently available and, for this age group, medication may be one of the only direct interventions (Barkley, 1990).

Treatment studies, with ADHD children, have assessed stimulant medication effects on cognitive, behavioural and interpersonal changes in preschool- and school-aged subjects (Barkley, Fischer, Newby & Breen, 1988; Jacobvitz, Sroufe, Stewart & Leffert, 1990; see Barkley, 1990 for overview). However, there are too few comparable studies to allow firm conclusions about the efficacy of medication treatment of preschool ADHD children.

One point offered for drug treatment is that it provides an opportunity to investigate whether the problem behaviours are a result of child characteristics (Danforth, Barkley & Stokes, 1991), of ineffective parenting or some combination that results in a negative interactive cycle as proposed by the Reciprocal Model (Bell, 1968, 1971; Patterson, 1982). Second, given the possibility that behavioural treatment programs have a limited success for some children with ADHD, medication may provide an alternative or adjunctive mode of treatment. Finally, variables

related to the cognitive domain have been relatively unaffected by behavioural treatments but may be amenable to change via drug treatment (Pisterman et al., 1990).

In the current literature, seven studies have examined the effects of methylphenidate exclusively in the 4-6 year-old age range (Barkley, 1988a; Cohen et al., 1981; Conners, 1975; Cunningham & Barkley, 1978; Cunningham, Siegel & Offord, 1985; Mayes, Crites, Bixler, Humphrey & Mattison, 1994; Schliefer et al., 1975). However, clinical issues and methodological differences make it difficult to determine overall patterns of treatment efficacy with this age group.

Other studies have included preschool-aged children but the age ranges and reported results did not indicate specific responses of this age group (Barkley, Karlsson, Pollard and Murphy, 1985; Cunningham, Siegel & Offord, 1991). Similar difficulties arise with examinations of medication effects on age and gender that subsume very young children in a wide age range (Barkley, 1988b; Barkley, Karlsson, Strzelecki & Murphy, 1984; Pelham, Walker, Sturges & Hoza, 1989).

The factors contributing to the lack of medication efficacy information are summarized as follows. First, diagnosis of ADHD in younger children is problematic (Campbell, 1985). The

situational and individual variations as well as the transience of the core features of the disorder are considered the main contributors of difficulties (Campbell, 1990). Concerns related to the definition of the disorder and diagnostic accuracy in this age group must be considered in the selection of children appropriate for treatment for ADHD.

Second, although pharmacological management of hyperactivity in school-aged children appears widely accepted, the individual variation in patterns of drug responses suggest that continuing research is required even in this age group (Whalen & Henker, 1991). Significant areas of research continue to be the short- and long-term effects of stimulant medication, predictors of drug response and the side effects of drug treatment (Barkley, McMurray, Edelbrock & Robbins, 1990; Jacobvitz et al., 1990). However, equivocal findings in these areas have been interpreted as support for caution in the use of stimulant medication with very young children. In fact, stimulant medication is not recommended for children younger than six years because of the lack of information on its efficacy in this age group (CPS, 1990, 1995). Alternatively, compelling arguments supporting medication treatment have been made based on improved preschool child behaviour in parent-child interactions (Barkley, 1989).

Third, similar to studies involving school-aged children, research with preschool children suffers from a wide range of methodological problems. Inconsistencies in subject selection criteria, absence of age-appropriate measures, relevant control groups and varying medication doses have resulted in a lack of comparability among the studies. Although medication treatment has demonstrated equivocal results in this age group, other treatment modalities (eg., parent-training) have reported equally limited success in interpersonal domains and no improvement in cognitive functioning (Pisterman et al., 1990).

Summary. The prevalence, stability and poor prognosis for very young children with identified problem behaviours indicate a need for early intervention. Thus, the aim of the present study was to assess the efficacy of methylphenidate treatment of attention and behaviour problems in preschool children. To this end, current research pertaining to the assessment of ADHD in this age-group is reviewed. Studies of 4-6 year old children diagnosed with ADHD are presented and issues related to stability of the components of the disorder and prognosis are examined. Then, issues related to parent-child interpersonal behaviours are discussed. Finally, current information concerning the effectiveness of medication treatment with this age group is examined.

Behavioural and Attentional Factors of ADHD in Preschoolers

Definitional Issues

Stability of behaviours. The diagnosis of ADHD requires the identification of specific behaviours that comprise the syndrome. Among school-aged children, impulsivity, overactivity and inattention result in negative behaviours that typify children diagnosed with ADHD (Barkley, 1988b, 1990). These behaviours have been reported to be stable and predictive of problems in later ages (Loeber, 1982; Loeber & Dishion, 1983; Weiss & Hechtmann, 1993).

However, assessing behaviour disorders in very young children may be affected by many factors (see Campbell, 1995, for a review). Rapid changes of behaviour within this younger age group results in a behavioural transience that makes behaviour disorders difficult to diagnose at any one point in time. Despite such transience, the core features of hyperactivity are identifiable in groups of preschool children. Palfrey, Levine, Walker and Sullivan (1985) reported inattention is identifiable in at least 40% of preschool children and use of the three core features - inattention, overactivity and impulsivity - together classifies 11% to 20% of preschool children as "hyperactive" (Campbell, 1985; Campbell, Pierce, March, Ewing & Szumowski, 1994).

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Campbell and colleagues (Campbell, 1985, 1990; Campbell & Ewing, 1990) reported that among a subgroup of preschoolers these problem behaviours remit in 3 to 6 months. However, 10-50% of children with problems of inattention and overactivity that were of concern in the preschool years continue to have difficulties in later childhood and adolescence (Barkley, 1990; Fischer, Rolf, Hasazi & Cummings, 1984).

In a longitudinal study, Egeland et al. (1990) obtained a prevalence rate of 18% of preschool children with behaviour problems. However, their results must be interpreted cautiously because of small sample sizes. By the first and second grades, 33% of the 17 preschool children with identified acting out behaviours had improved; their behaviours were considered in the normal range. Conversely, of the children identified with acting out problems at age 4.5 years, the proportions with continuing behaviour problems in grades 1, 2 and 3 were 66%, 63% and 74%, respectively. This is supported by other researchers who have demonstrated a continuity of behaviour problems from preschool to early elementary school and adolescence (Campbell, 1994, 1995; Caspi, Henry, McGee, Moffit & Silva, 1995; Fischer, Barkley, Fletcher & Smallish, 1993a, 1993b; Olson & Hoza, 1993; Verhulst, Eussen, Berden, Sanders-Woudstra & Van der Ende, 1993).

Differentiation of inattention and hyperactivity/impulsivity from normal behaviours. The second issue in the identification of ADHD among preschool children is the differentiation of criterion problem behaviours from normal behaviours of preschool children (Campbell, 1985). Similar to older children, situational factors and multiple perspectives play a significant role in determining the specificity of inattention and impulsivity-hyperactivity to the disorder (August & Garfinkel, 1989; Barkley, DuPaul & McMurray, 1990).

Poor cognitive development and language functioning assessed at a very young age can be markers of later behaviour management problems (Miller and Scarr, 1989). However, many studies have noted difficulties in finding age-appropriate tasks or norms to measure preschool children's attention or impulsivity (Conners, 1975; Levy, 1980). Attention as measured by the rate of change in types of activity was shorter for preschool children who were identified as pervasively hyperactive than for a normal control group (Cohen & Minde, 1983). Pisterman et al. (1990) reported differences between preschool children diagnosed with ADHD and a normative group on age-appropriate measures of child attention (on-task behaviours) and productivity during parent-supervised and unsupervised tasks. Finally, Harper and Ottinger (1992) examined sustained attention on the Preschool Vigilance Task.

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Their results indicated hyperactive children made more errors of omission which indicated lapses in sustained attention.

McGee et al. (1991) reported differences between hyperactive three-year olds and non-hyperactive children on measures of vocabulary, comprehension and expression. However, this may not be directly related to aspects of inattention. Olson, Bates and Bayles (1990), for example, indicated cognitive competence is more likely related to the ability of the child to develop self-regulation.

With respect to the behavioural components of ADHD, difficulty in child management, demands for attention by the child and temper tantrums were the most common concerns of parents of 3- and 4-year old children (Jenkins, Bax & Hart, 1980). Crowther, Bond and Rolf (1981) reported high frequencies of externalizing behaviours among preschool children in a daycare and noted that the severity of the behaviour was the discriminating factor between normal early childhood behaviours and a behavioural disorder.

Campbell (1985, 1990, 1995) argued that a child's behaviour is often considered problematic in a structured environment such as preschool or elementary school. More specifically, the child's inability to regulate high levels of activity and to focus

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attention become sources of concern in the face of external demands for rule-governed behaviour. In effect, the child's behaviour problems become salient when a specific goal/end product is required in interpersonal contexts: between parent and child, teacher and child, peer and child.

In an epidemiological study of preschool children, Jenkins et al. (1980) reported that the focus of parental concerns changed as a function of their child's age. Sleeping and feeding were prominent concerns in infancy whereas child management and discipline concerns were prominent in early childhood. However, only about 50% of mothers and physicians in this study agreed with each other in their concern about the child's behaviour problem. These findings suggest that accurate determination of DSM-III-R target symptoms of ADHD in this age group will depend not only on the clarification of what constitutes age-inappropriate behaviours but also on the source of the referral (Campbell, 1990).

Campbell, Szumowski, Ewing, Gluck and Breaux (1982) demonstrated differences between a group of parent-referred 2- and 3-year olds and nonproblem control children on measures of activity, attention and management. As with school-aged ADHD children, the target symptoms of ADHD were identifiable and there was reported concordance between mother's and father's perceptions. These

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children were described as changing activities more often, being more aggressive and more noncompliant than the control group. On laboratory tasks they were off-task more often and less able to conform to adult demands to attend in structured task situations than were the control group.

Other studies have demonstrated the existence of differences between problem behaviour children and normal controls on measures of attention, impulsivity and overactivity (Campbell et al., 1982; Campbell, Breaux, Ewing & Szumowski, 1984; Campbell, Breaux, Ewing, Szumowski & Pierce, 1986). Using criteria that parallel the DSM-III definition of "attention deficit disorder with hyperactivity", their results indicated that, compared to normal controls during structured tasks, parent-identified problematic two- and three-year olds are more active, more impulsive on delay tasks, and less compliant with adult demands. They were also more likely to have social difficulties and were more inattentive in a variety of situations.

Supporting these results, Prior, Leonard and Wood (1983) reported that 3- to 5-year old children diagnosed by pediatricians as being hyperactive were discriminable from a normal control group on measures of overactivity and manageability. Using preschool teachers' ratings, Rubin and Clark (1983) demonstrated that children rated as Hyperactive-Distractible on the Preschool

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Behaviour Questionnaire (Behar & Stringfield, 1974) were viewed more negatively by their peers, engaged in more negative play and were considered behaviourally less mature.

However, defining "abnormal" behaviour may result in an over-diagnosis of ADHD among preschool children. Crowther et al. (1981) reported that among a normal daycare population the proportions showing extremes of externalizing behaviours was highest at ages 2 or 3 and decreased by ages 4 and 5 years. As well, at least 20% of their sample displayed high frequencies of a defined problem behaviour suggesting a high risk of false positives in assessing a behaviour disorder.

Despite this caveat, problematic behaviours in preschool-aged children have been associated with a constellation of behaviours associated with ADHD. Olson and Hoza (1993) reported high scores on conduct-problem scales were related to higher levels of aggressive responses to problem-solving and impulsivity on a Delay of Gratification Task among preschool-aged boys.

Noncompliance to parental requests (Kuczynski & Kochanska, 1990) and difficulty with peers (Ironsmith & Poteat, 1990; Levy-Shiff & Hoffman, 1989; Vitaro, Tremblay, Gagnon & Pelletier, 1994) have been associated with high scores on measures of hyperactivity.

Furthermore, biological and social contexts may also play a role in the developmental course of 'hard-to-manage' behaviours.

Adams, Hillman and Gaydos (1994) compared three groups of 2-4 year-olds classified as dual-risk (social and biological), social risk (low SES) and low risk (no congenital conditions). Social risk was identified as the primary predictor of later difficulties and may be a marker for development of problematic behaviours.

Summary. Despite difficulties in assessment, many studies have identified cognitive and interpersonal problem behaviours in preschool children (Crowther et al., 1981; Jenkins et al., 1980; Miller & Scarr, 1989). These findings of behavioural and cognitive difficulties suggest that a dysfunctional developmental course of early childhood behaviour may be discriminated from a normal course. However, the identification of behavioural differences between groups of children does not imply diagnosis of a behavioural disorder in general or ADHD specifically.

Diagnostic Issues

Standardized criteria. Although the Diagnostic and Statistical Manual - Revised (DSM-III-R; APA, 1987) provides the criteria to for diagnosis of ADHD, the fourteen descriptors include behaviours that can be found in a large number of very young children (Crowther et al., 1981). Thus, Barkley (1990) has

argued for increasing the cutoff score from 8 behaviours to 10 out of a possible 14 behaviours to reduce the likelihood of false positives among very young children. As well, he has recommended the inclusion of severity and situational pervasiveness ratings to address the concerns of age-appropriateness of the assessed behaviours. Optimally, as with school-aged children, using a multidimensional, multi-rater assessment approach to diagnosis may protect against the possibility of false positive diagnoses (DuPaul, 1991; DuPaul, Anastopoulos, Shelton, Guevremont & Metevia, 1992).

Comorbidity. The differentiation of ADHD from other disorders such as Oppositional Defiant Disorder, Conduct Disorder and Learning Disability (Barkley, DuPaul & McMurray, 1990) may be critical particularly with respect to the selection of appropriate treatments. Overlapping diagnostic criteria and the tendency for behavioural problems to cluster at certain ages suggest that differential diagnoses among very young children should be approached with caution (Barkley, 1990). In fact, Szatmari et al. (1989) reported a 40% comorbidity rate between ADHD and Conduct Disorder among 4-11 year old boys and girls.

Campbell et al. (1982) argued that differential diagnosis may be inappropriate and perhaps unnecessary. Analyses of one follow-up study (Campbell, Breaux, Ewing & Szumowski, 1986) indicated a

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high correlation between hyperactivity and aggression measures in three-year old parent-referred children. They concluded that because of the close association of these two behaviours, differential diagnoses may not be possible.

Summary. Accurate diagnosis necessitates differentiating ADHD from other childhood behavioural disorders. Among the preschool children who may qualify for a diagnosis of ADHD, similar to the school-aged group, there is a close association of criterion behaviours of ADHD with those of Oppositional Defiant Disorder. This makes differential diagnosis extremely difficult particularly in the face of the 40% comorbidity rate between these disorders reported by researchers (Szatmari et al., 1989). As well, high but unstable frequencies of certain ADHD-related behaviours and rapid developmental changes increase the potential for false positives among the preschool group.

In the main, earlier studies have avoided the diagnostic label, choosing instead to refer to parent- and teacher-identified "ADHD" preschool children as "hard-to-manage", "difficult", or "problem behaviour". Independent of the diagnostic label, these children present with a range of behavioural and cognitive difficulties that parallel those found in school-aged ADHD children. Thus, a diagnostic label may be less important in the determination of possible treatments of the problem behaviour

preschool child than a clear assessment of problem areas that may affect adjustment.

Long Term Outcomes of Preschool-aged Children with ADHD

Outcomes in early childhood. Results from follow-up studies indicate that the reported problem behaviours in some very young children are not temporary occurrences (Campbell et al., 1984; Campbell et al., 1986). Fischer et al. (1984) determined that the probability of retaining externalizing symptoms from age 2 to age 6 was three times higher for children identified with problem behaviours in preschool years. Egeland et al. (1990) determined that 80% of preschool-aged children classified as acting out continued to have behaviour problems in at least 2 out of 3 grades after school entry.

The stability of the problem behaviours has been assessed using behavioural, cognitive and interpersonal measures. Behaviour problem children differed from normal controls on behavioural observations of aggressive acts, hyperactivity-distractibility and off-task behaviours (Campbell, Endman & Bernfield, 1977). In their follow-up studies Campbell and colleagues demonstrated that these observed behavioural differences persist from intake at age 3 years through ages 4, 5 and 6 years (Campbell, 1994; Campbell

et al., 1982, 1984, 1986) and consistently discriminated problem children from controls.

The cognitive measures used by Campbell and her associates have not proven to be very sensitive in detecting between-group differences among preschool children (Campbell et al., 1986). Campbell et al. (1984) reported that only one cognitive measure of impulsivity discriminated problem children from normal controls at three years of age. Cognitive measures used by Campbell appear to be more sensitive in detecting within-group improvement over time for both problem children and controls (Campbell et al., 1984). In fact, Campbell's later publications do not discuss cognitive measures and focus on the interpersonal domain.

Maternal, teacher and interview ratings differentiated the problem behaviour group from a control group at intake and subsequently in the follow-up studies. Within the problem behaviour groups, maternal ratings of behaviour at age 3 were the strongest predictor of continuing behaviour difficulties at ages 6 (Campbell et al., 1986) and 9 years (Campbell & Ewing, 1990). Controlling for IQ and social adversity in a sample of kindergarten boys, Vitaro et al. (1994) reported teacher ratings of aggressive and hyperactive behaviours predicted later externalizing behaviours in grades 3 and 4.

Outcomes in middle childhood and adolescence. Preschool problem behaviours also predict difficulties into middle childhood. Child temperament and behavioural measures as well as maternal negative control variables were predictive of externalizing symptoms at age 9 years (Campbell & Ewing, 1990). Stabilities in noncompliance and family stress also support arguments for continuity between the preschool and middle childhood problems.

In a twelve-year follow-up of preschool children, McGee et al. (1991) identified "hyperactive" and "difficult to manage" children at age 3 years. Both groups evidenced problems in their cognitive and interpersonal behaviours at school entry (5 years) and through to adolescence (15 years). Differences in reading difficulties, parent- and teacher-reported behavioural difficulties that discriminated hyperactive from control groups at age 3 continued to be significant at ages 7, 9, 11 and 15 years. Among the adolescents, 50% of those identified as hyperactive at age 3 years also were diagnosed with an identified DSM-III disorder. These findings are consistent with Barkley, Fischer, Edelbrock and Smallish (1990) whose follow-up of 4- to 8-year old ADHD children indicated 60% had Oppositional or Conduct Disorder into adolescence. Furthermore, Fischer et al. (1993) followed 4-11 year old children over an 8-year period, noting childhood defiance was related to later difficulties with

the law. Negative parent-child interactions also persisted from early childhood through to adolescence (Barkley et al., 1991).

Summary. Longitudinal studies of difficulties identified in very early childhood appear to support the continuity hypothesis of childhood problem behaviours (see Campbell, 1990, 1995). Fischer et al. (1984) pinpoint ages 3 and 4 years as a "critical period" during which onset of aggressive behaviours are highly likely to result in long-term difficulties. Symptoms of inattention, overactivity and observation of aggression as well as negative maternal interactions appear to be potent predictors. Despite the 25-33% of hyperactive children who improved spontaneously, uncorrected problem behaviours in early childhood are more likely to result in externalizing disorders in later years. Thus, the behavioural and cognitive differences between normal control and problem behaviour children and the apparent "at risk" nature of the latter, intervention programmes focused on parent-identified behaviour problems in preschool children appear justifiable.

Interpersonal Behaviours of Preschool-aged ADHD Children

Parent-child interactions. Many interactions between ADHD children and their mothers are marked by negativity (Campbell, 1990; Campbell, March, Pierce, Ewing & Szumowski, 1991). Furthermore, the findings of controlling maternal behaviour and

child noncompliance among older children are amplified in the preschool ADHD child (Mash & Johnston, 1982). Conventionally, the type of behaviour that is initiated by mother or child and the type response made by mother or child are assessed across varying tasks (Barkley, 1990).

In both structured and unstructured settings, ADHD children of all ages have been observed to initiate more negative behaviours, be less independent and respond more often with noncompliance than normal controls (Barkley, Karlsson & Pollard, 1985; Cunningham & Barkley, 1979; Mash & Johnston, 1982, 1990). Mothers were observed in these studies to initiate fewer interactions with their children, give less praise and were more negative than mothers of normal control children. They also responded less frequently, less appropriately and tended to remain controlling and inappropriately directive when their child was compliant. In fact, compared to normal controls, the lack of responsiveness among mothers of preschool hyperactive children resulted in an exacerbation of negative behaviours among the children (Mash & Johnston, 1982).

Parenting stress. The parent's perceptions of the child and of the experience of parenting are affected by the negative relationship between the parent and the hard-to-manage preschooler (Barkley, 1990; Breen & Barkley, 1988). Although the

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reciprocal nature of negative mother-child interactions has been acknowledged (Crowell, Feldman & Ginsberg, 1988), there is evidence that the child's characteristics are a primary contributor to observed and reported stresses between parent and child (Mash & Johnston, 1990). These stresses in turn may contribute to exacerbating the child's problem behaviours and maintain the negative expectations of the parents in a recursive manner (Mash & Johnston, 1990).

Parenting stress is reported to be higher among parents of the ADHD child than among parents of non-ADHD children (Mash & Johnston, 1983). Specifically, maternal stress related to the child's characteristics discriminated mothers of hyperactive from mothers of normal children. In addition to child characteristics that contributed to parenting stress, parent characteristics of depression and self-blame were associated with high stress. Within the ADHD group, Mash and Johnston (1983) report parenting stress to be higher among parents of younger ADHD children than among parents of older ADHD children. Child distractibility and the negativity of the interactions contributed significantly to high maternal stress among mothers of 3- to 6-year old hyperactive children. Furthermore, Mash and Johnston (1990) indicated that these perceptions are congruent with independent observers.

Summary. Although most mothers of hyperactive children report experiencing negative interactions and high levels of stress in their relationships with their children, preschool problem behaviour children also present with greater negativity in interpersonal relationship and appear to contribute to greater parenting stress than do their normal peers. Despite the evidence that the child may be the source of the negative interchanges with and experiences of the parent (Fischer, 1990), the interactive nature of the parent-child relationship must be given greater weight in future investigations of preschool children.

Medication Treatment of Preschool-aged Children with ADHD

Treatment Designs

Individual treatment. The problem behaviours of preschool children, the consequent negative parent-child interactions and the poor prognosis for these children argue for early intervention. Whether that intervention is directed at child behaviour or parenting practices depends on which is perceived to be more amenable to change. Current investigations acknowledge the emergence of problematic behaviours in the preschool years with ages 3 to 4 years being a critical period (Fischer, 1984). However, parental characteristics and parenting style are also believed to contribute to and perpetuate negative cycles of

interchange. The initiator of the negative cycle, however, remains unclear.

Many treatment studies implicitly adopt one of two models: the child as the problem source or the parents as the problem source. The treatment models that propose the child as the greater source of difficulties implement and examine the impact of interventions that modify child behaviours (Baer & Neitzel, 1991; Gadow, 1991). Those proposing parenting practices as the greater source of difficulties use parent-training or education as the entry point to obtaining improved child behaviour (Pisterman et al., 1989; Pisterman et al., 1990; Pisterman et al., 1992; Strayhorn & Wiederman, 1989, 1991). Each approach has reported some success in improving behaviours, attention and parent-child interactions.

A third model incorporates parent and child behaviours and proposes that behavioural difficulties and unsupportive familial environment predict continuing problems (Lewis, Feiring, McGuffog & Jaskir, 1984). This transactional model is not necessarily directional and may give equal weight to the child's behavioural system and to the parental system (see Mash & Johnston, 1982, 1990 for discussions of a directional transactional model). Treatments motivated by this perspective would perforce be multimodal involving both child and parents, usually in simultaneous treatment.

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Combined treatment. Parent-training and medication, for example, have been administered to school-aged ADHD children and their parents at the same time with outcomes measured at the end of the longer treatment. With few exceptions, results, generally, have been disappointing with no statistically significant advantage found to combined treatment over medication alone (Firestone, Crowe, Goodman & McGrath, 1986; Horn et al., 1991; Ialongo, Horn, Pascoe, Greenberg, Packard et al., 1993). These studies did suggest that in limited instances results of their combined treatments while positive were not superior to medication alone.

Although combined treatments of school-aged ADHD children have been attempted with limited success, the lack of evidence for its superiority over medication alone may be attributable to conceptual and methodological difficulties (see Kendall & Lipmann, 1991, for discussion of comparative outcome research). One conceptual difficulty lies in the assumption that parent and child present as equivalent entry points for intervention.

It is possible that combined treatments are less powerful because two behavioural systems are changing concurrently creating a complex dynamic that may be difficult to assess. There may be insufficient time for parents to change their expectations of their child's behaviours despite concomitant changes in that behaviour. A more explicit transactional model may be required

to incorporate evidence offered by Mash and Johnston (1982, 1990) of the child's primary role in the negative interactions with significant others.

A directional transactional model may assert a child with problem behaviours who is lacking in consistent, effective parenting develops dysfunctionally in the behavioural, cognitive and interpersonal domains. Thus, ineffective parenting compounds already existing problematic behaviours in these preschool children. Interventions would require obtaining improvement in child behaviours prior to improving parent strategies. Improved child behaviours obtained through medication, for example, may accomplish two goals: first, the cognitive and behavioural improvement of the preschool child exhibiting problem behaviours; second, provide parents with an opportunity to teach and reinforce positive behaviours via appropriate parenting practices. In effect, the directional transactional model organizes the sequence of the treatments so that the impact of each treatment on different aspects of the disorder can be capitalized upon to increase the probability of positive change.

Medication Treatment

Current studies. There have been few interventions that have assessed medication treatment effects on preschool-aged children with problem behaviours. Although parent-training has been

investigated extensively by Pisterman and colleagues (Pisterman et al., 1989, 1990, 1992), studies using medication with this age group have been limited and produced equivocal results (Barkley, 1988a; Cohen et al., 1981; Conners, 1975; Cunningham & Barkley, 1978; Cunningham, Siegel & Offord, 1985; Mayes et al., 1994; Schliefer et al., 1975). None of the studies used a combined treatment (parent and child) although Cohen et al. (1981) compared medication alone to a combination of cognitive-behavioural therapy and medication.

In the existing studies, the efficacy of methylphenidate treatment as assessed by objective measures was inconclusive whereas ratings by parents and assessment of parent-child interactions indicated a reduction in problem behaviours. However, as outlined in Table 1 differences in sample recruitment, inclusion criteria, treatment doses and outcome measures limit comparisons.

Subject characteristics. Two of the seven studies (Barkley, 1988a; Schliefer et al., 1975) employed subjects with ages ranging from 2.5 to 4 years whereas Cohen et al. (1981) and Conners (1975) reported mean ages of 5.6 and 4.8 years, respectively. Cunningham and Barkley (1978) examined methylphenidate effects in a pair of 5 1/2-year old identical twin boys. Mayes et al. (1994) and Cunningham et al. (1985)

Table 1

Demographics, inclusion criteria and domains examined in previous research into methylphenidate effectiveness with preschool-aged ADHD children

Study	Age	N	Dose	Sample source	Inclusion criteria	Outcome Domains		
						Cognitive	Behaviour	Interpersonal
Barkley (1988)	2.5-4	27	.15-.5 mg/kg BID	Physician	Parent ratings; absence of neurological disorders	none	Off-task*; Aggression	Compliance*; Compliance duration*
Cohen et al. (1981)	5.6	8	10-30 mg/day (.5 mg/kg BID)	unknown	Parent/teacher ratings; WPPSI > 80; absence of neurological disorders	PMFFT Errors*; Etch-a-Sketch Errors*	Locus of Control; CPRS*; CTRS*	none
Conners (1975)	4.8	59	11.8 mg/day (.3 mg/kg BID)	Physician, school, parents	Parent ratings; absence of neurological disorders	MFFT; CPT; Copy design*	Physician ratings*	none
Cunningham et al. (1985)	4-6	42	.15 & .5 mg/kg	Physician	CPRS	drawing	none	controlling behaviour (w peers)*
Mayes et al. (1994)	1.8-5	14	titrated	Clinic, hospital	DSM-III-R psychiatrist ratings	none	CPRS*	none
Schliefer et al. (1975)	3.3-4.8	26	5.0 mg BID (.25 mg/kg BID)	Hospital	Parent complaints of overactivity, inattention, impulsivity	ECFFT errors; Draw-a-Line	Aggression; teacher ratings; Mother complaints*	none

a: Significant differences related to medication treatment.

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examined samples with broad age ranges but reported results for the subgroup of preschoolers. Although maturity as reflected by age differences between studies may have contributed to differing results (e.g., on cognitive tasks), it is more likely that differences in task demands played a more significant role.

Subjects were recruited from a variety of sources: pediatricians, parents and from referrals to a large hospital. Cohen et al. (1981) and Mayes et al. (1994) did not specify the source of subjects. Although there is no evidence at present that the source of referral results in a sample bias, it is conceivable that these subjects may differ from a sample of convenience in the presence of aggression or general severity. Among school-age children, Barkley, McMurray, Edelbrock and Robbins (1989) noted that aggressive ADHD children were rated higher than non-aggressive ADHD children on scales measuring Conduct Problems, Hyperactivity Index scores and general aggressive behaviours. Attentional and other cognitive symptoms did not differentiate the aggressive from the non-aggressive ADHD children. Although the aggressive group did not respond differently from the non-aggressive group to medication treatment on most measures, the latter group showed little medication-related improvement on ratings of Conduct Problems and Hyperactivity Index. Among the preschool studies, the lack of response to medication of negative

behaviours may be equally attributable to low baseline frequencies.

In general the inclusion criteria among the preschool studies are comparable. Barkley (1988a), Cohen et al. (1981), Cunningham and Barkley (1978) and Cunningham et al. (1985) utilized the Conners rating scales and parental reports of impulsive, inattentive and overactive behaviours. Conners (1975) and Schliefer et al. (1975) required parental or teacher reports of hyperactivity, impulsivity and inattention. Four studies excluded children with possibility of neurological problems. In contrast, Mayes et al. (1994) included children with learning disabilities and neurodevelopmental disorders in their sample. Although this latter study reported responses of the neurodevelopmental group separately, it is unclear how many of the preschool-aged group were in that category.

Only Barkley (1988a) stipulated a duration of 6 months for inclusion. The differences in the first two sets of studies reflect the historical changes in definition of the disorder and the greater availability of normative data for the ratings scales such as the Conners Parent and Teacher Rating Scales.

Medication design and dosage. No two studies were designed similarly. All studies used a within-subject design except

Conners (1975) who employed a between-subjects, double-blind design. Studies also differed in their comparison groups. Cohen et al. (1981) compared children treated with methylphenidate to baseline conditions whereas Barkley (1988a), Cunningham and Barkley (1978), Mayes et al. (1994) and Schliefer et al. (1975) compared subjects to placebo conditions. Cohen et al. (1981) also compared treated subjects to a normal control group. Three studies (Barkley, 1988a; Cunningham et al., 1985; Schliefer et al., 1975) reported using a double-blind crossover design. Although all studies provide information with respect to medication treatment, studies using a repeated measures design may have been more powerful in detecting changes.

Dosages varied across studies with two studies (Barkley, 1988a; Cunningham et al., 1985) testing two doses (0.15 mg/kg and 0.5 mg/kg methylphenidate). Four studies (Cohen et al., 1981; Conners, 1975; Cunningham & Barkley, 1978; Schliefer et al., 1975) reported average daily dosages of methylphenidate that ranged from 5 mg/day to 15 mg/day. Mayes et al. (1994) titrated the doses starting from 0.3 mg/kg methylphenidate and increasing by 2.5 mg until positive or negative response was obtained. These differences in dosages limit between-study comparisons and hamper interpretation and integration of their results. However, using average weights derived from weight tables and the reported average dosage, the mg/kg dosage can be inferred and may allow

for cautious comparisons of outcome variables. Table 1 lists the interpolated dosages in parentheses where possible.

Cognitive factors. Reflective impulsivity (i.e., the ability to plan), motor impulsivity and sustained attention were assessed in three studies (Cohen et al., 1981; Conners, 1975; Schliefer et al, 1975). The interpolated dosages for these studies were 0.5 mg/kg, 0.3 mg/kg and 0.25 mg/kg, respectively. Although the low and high doses effected a significant change in reflective impulsivity as measured by the Matching Familiar Figures Test (Kagan, 1964), the mid-range dose was non-significant. The different results reported by these three studies may be attributed to the difference in the test itself. Conners (1975) did not use the prechool version and reported that his subjects had considerable difficulty with the task.

Motor impulsivity was assessed in these same studies using a task that required drawing a line or lines slowly (Draw-a-Line slowly; Etch-a-Sketch). Only the high dose (Cohen et al., 1981) was effective in decreasing errors.

Sustained attention was assessed by Conners (1975) using a Continuous Performance Task. Neither errors of commission nor omission were significantly reduced. Based on Conners' descriptions of the task, the task did not appear to be age-

inappropriate however task parameters (rate of presentation, etc.) were not specified. In the same study, sustained attention improved significantly on a task requiring children to copy increasingly complex designs. However, this latter task has many features that Barkley (1990) noted will enhance performance in children with ADHD. It is possible that novelty, concrete outcomes and more immediate feedback inherent to this second task contributed to sustaining attention at this dosage (approximately 0.3 mg/kg) whereas higher dosages may be necessary to achieve the same result in the first task which was highly repetitive.

Behavioural factors. There are two methods of assessing behavioural changes: direct observation and behavioural ratings of the treated children by parents and teachers. Two studies used observation (Barkley, 1988a; Cunningham et al., 1985) and three used both (Cohen et al., 1981; Conners, 1975; Schliefer et al., 1975) to assess changes in behaviour. Mayes et al. (1994) used only the Conners Rating Scale as an outcome measure.

Directly observed behaviours included off-task, competing behaviours and aggression. Off-task behaviours were reported to decrease but only at the 0.5 mg/kg dosage in Barkley's study (1988a). It is unclear whether the off-task behaviours of the preschool-aged group responded to medication as assessed by Cunningham et al. (1985).

All studies differed in their inclusiveness of the term "aggression". Barkley (1988a) included several types of behaviours under the rubric of negative behaviours towards the mother including whining, tantrums, direct opposition, destructiveness and refusal to obey requests. Cohen et al. (1981) noted "disruptive behaviours" during class time whereas Schliefer et al. (1975) defined aggression as physical attacks against peers. The lack of interpretable effects of medication on aggression may be attributable to differences in what was being measured, different targets of the aggression (mothers, peers, teachers), differences in baseline levels of presenting aggression and dosage. It is conceivable that medication is effective only with high base rates of behaviours such as aggression.

Despite lack of changes in the child's observed behaviours, parents and teachers rated treated children as improved (Cohen et al., 1981; Mayes et al., 1994; Schliefer et al., 1975). Nursery school teachers reported decreases following medication treatment on a hyperactivity rating scale used by Schliefer et al. (1975). Decreases in Conners' Parent Rating Scale factors of impulsivity/hyperactivity following methylphenidate treatment were reported by Cohen et al. (1981) and Mayes et al. (1994). Teachers' ratings on the same scale indicated decreases on all factors. Although the treated children had improved relative to

their pre-treatment scores, their scores remained different from a normal control group in the former study. Mayes et al. (1994), however, reported an average change of 6 points between pre- and post-ratings. This suggested that statistical change, but neither clinical improvement nor normalization, had been achieved.

Interpersonal factors. Three studies assessed changes in the interpersonal domain. However, the results presented by Cunningham and Barkley (1978) did not indicate whether the differences obtained were statistically significant and therefore cannot be compared to other findings. Mother-initiated behaviours, child's responses, child-initiated behaviours and mother's responses were coded during free play and structured tasks (Barkley, 1988a; Cunningham & Barkley, 1978). Mothers questioned their children more during the low dose (0.15 mg/kg) and tended to be more rewarding when their child was on a high dose of methylphenidate. With respect to the child's responses, there were increases in duration and amount of compliance but only at the 0.5 mg/kg dose. Although none of the other studies formally assessed mother-child interactions, Schliefer et al. (1975) reported that mothers complained less about their child's behaviour following medication treatment. Cunningham et al. (1985) examined peer interactions and reported the 4-6 year-old group exhibited a reduced frequency of controlling responses

following treatment with 0.15 mg/kg and 0.5 mg/kg methylphenidate. It is of interest that their peers also exhibited a reduction in controlling responses.

Summary. The seven studies discussed differed in methodology making comparisons difficult. Despite this, some conclusions are possible. Cognitive tasks that are age-appropriate appear to be sensitive measures of medication effects but only at high doses (approximately 0.5 mg/kg) and if the tasks are not novel or immediately reinforcing (see Barkley, 1990).

Observed behaviours appeared to be poor indicators of medication effects although it is possible that longer treatment is necessary for changes to be apparent. One explanation is that medication may decrease the impulsivity and associated negative behaviours but appropriate or positive behaviours do not spontaneously occur in their absence. Thus programs which use medication to reduce noxious behaviours and which simultaneously assist the child to acquire alternative positive behaviours may be more successful (Firestone et al., 1986; Horn et al., 1991).

Parent and teacher rating scales were sensitive to medication effects. Although improvements on these scales may be augmented by parental expectations, changes in the parents' perception of the child's behaviour may have positive consequences for

interpersonal relationships (Mash & Johnston, 1990). Earlier suggestions that parents of ADHD children may be insensitive to their child's positive behaviours may be overstated. The amelioration of negative behaviour to the degree that parents and teachers can judge pre-post treatment differences suggests that care-givers are aware of changes in the child.

Changes in the preschool ADHD child's behaviour resulted in minimal changes in parenting behaviour however same-age peers appeared to have reciprocated the ADHD children's positive changes (Cunningham et al., 1985). Although the amount and duration of child's compliance increased, further studies are necessary to determine the impact of different doses and different tasks on interactions between preschool ADHD children and their parents. At present, changes in parenting behaviour as demonstrated by Pisterman et al. (1989) result in similar changes in child behaviour, suggesting that the three models of preschool ADHD (child's role, parent's role, parent-child interaction) require further investigation.

Given parents may in fact be sensitive to behaviour changes in their children and the child's cognitive abilities can be enhanced by medication, the interpersonal domain may be the ideal setting in which to explore the causative cycle of preschool ADHD. A directional transactional model hypothesis that the

negative interactive cycle originates in the child's behaviour can be effectively tested in a medication design. Insofar as rapid changes in the child's behaviour produce changes in parenting approach, the child's role in the negative interactive aspects of the disorder may be clarified (see Barkley, 1988a, for discussion).

Rationale for the study

The purpose of this study was to examine the efficacy of methylphenidate in the amelioration of behavioural, cognitive, and interpersonal difficulties of preschool-aged children diagnosed with Attention Deficit Hyperactivity Disorder. Treatment of this age group presents a challenge given a developmental stage marked by changes in behavioural, cognitive and interpersonal skills as well as individual variation in symptom presentation. At present, the lack of controlled studies into the behavioural, cognitive and interpersonal changes following stimulant medication treatment presents the major obstacle in the selection of appropriate treatments for preschool ADHD children. However, despite this lack of information, 34% of pediatricians and 15% of family physicians reported using this mode of untested treatment with preschoolers (Wolraich et al., 1990). Furthermore, evidence of poor outcome for children with problematic behaviours and the possibility that the biological

substrates of attention and impulsivity may be amenable to chemical intervention argue for medication as a viable treatment modality.

A second purpose of this study was to investigate the changes in the negative interactive cycle observed between the hard-to-manage child and his parent/caregiver. Social interactional theories (Bell, 1968, 1971; Patterson, 1982) propose that the behaviour of one member of the system changes systematically according to the behaviour of the other member of the system. Danforth et al. (1991) summarized results of studies that indicate the child's aversive behaviours may be what evokes negative parent behaviours.

Increased positive parenting behaviours and perceptions observed subsequently in parent-child interactions would support the theory that the child is a primary contributor to the negative cycle. Where parent behaviours remain unaffected by improvements in their child's behaviours and design issues such as length of treatment have been accounted for, the parents' contribution in the cycle can be addressed. Thus, the degree of the impact of the child's behaviour on the parent-child interaction will provide important information as to the broad-based effects of the medication and for the development of appropriate treatment plans (Fischer, 1990; Mash & Johnston, 1990).

An auxiliary purpose was to examine the degree of clinical change obtained with medication treatment. There have been recent studies with older children which directly assessed clinical change (DuPaul, Barkley & McMurray, 1994; Rapport, Denney, DuPaul & Gardner, 1994) however there are none in the preschool-aged group.

Thus, in the present study, a within-subjects, placebo-controlled design was implemented in order to determine the efficacy of MPH in ameliorating the symptoms of ADHD in the cognitive, behavioural and interpersonal domains. Whereas previous studies have examined MPH treatment in one or two of these domains, using the more powerful repeated measures design to examine changes in all three areas provides insight to the breadth of medication effects.

Hypotheses

Cognitive factors. Decreases in impulsivity have been associated with medical treatment of ADHD children (Barkley et al., 1988). Hypothesis 1 proposed that, consistent with studies of older children, the high dose condition would result in increased Number of Correct Responses to the GDS-Delay Task compared to the low dose condition. The low dose was predicted to be superior to the placebo condition. Furthermore, Efficiency Ratios would shift following the same pattern of response.

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Changes in sustained attention would be reflected in the Number of Correct Responses on the GDS-Vigilance Task across treatment conditions. Hypothesis 2 proposed that the Number of Correct Responses would increase across the treatment conditions with the greatest change at the high dose followed by low dose and placebo conditions. A similar pattern in the positive direction relative to medication was expected for the Errors of Commission.

Treatment effects on reflective impulsivity would be demonstrated on the Q score of the Porteus Mazes. Hypothesis 3 proposed that the scores would change positively with increasing dose relative to Placebo conditions.

Behavioural factors. Consistent with previous studies, the Conners Parent Rating Scale Hyperactivity Index was used as the primary measure of behaviour change. Hypothesis 4 proposed that, similar to medication treatments of school-age children, the high dose condition would result in a greater reduction in the Hyperactivity Index than the low dose condition. The low dose would be superior to the placebo and baseline conditions. In terms of aggression, Hypothesis 5 proposed that the number of aggressive acts performed by the child during free play will decrease in the order: High dose < Low dose < Placebo.

Interpersonal factors. As demonstrated by Barkley (1989), child behaviours during parent-child interactions improved during medication conditions. Hypothesis 6 proposed that child compliance on all measures would increase with medication doses with the highest level of compliance obtained during the high dose condition. The low dose condition was predicted to be associated with greater compliance than that obtained on placebo.

Although increases in other interpersonal measures were obtained, Pisterman et al. (1989) did not report changes in attention measures following parent-training. It is possible that these measures may only be sensitive to medication effects, that is, changes in cognitive processes may require intervention at a biological level. Hypothesis 7 proposed that sustained attention on supervised and unsupervised tasks would increase on all measures as a direct function of dosage of medication. The high dose condition would be associated with the greatest increase in Mean Time On-task and Productivity followed by the low dose and the placebo, respectively.

Hypothesis 8 proposed that treatment improvement, defined as a posttreatment minimum increase of 50% compliance from the pretreatment score, would increase in proportion to dose of

medication. The high dose would result in greater improvement compared to the low dose. The low dose would be superior to the placebo.

Parental factors. Observed parenting behaviours have been reported to improve when parents interact with ADHD preschool children who have been administered stimulant medication (Barkley, 1988a). Hypothesis 9 proposed that the high dose would be associated with the greatest increase in positive parenting skills compared to low dose conditions. The low dose would be superior to placebo. A reverse pattern was predicted for negative parenting behaviours. Hypothesis 10 proposed that the high dose would result in increased positive parenting style and decreased negative parenting style compared to the low dose. The low dose condition would be superior to the placebo condition. The percent of positive behaviours would increase in the order High Dose > Low Dose > Placebo; the percent of negative behaviours would decrease in the same order.

Consistent with the transactional model which indicated that parental stress is associated with negative child behaviours, Hypothesis 11 proposed that Parenting Stress would decrease as a function of the dose of medication. The high dose would result in greater decreases in reported parental stress compared to the low dose which would be superior to the placebo.

Method

Subjects

Sixty children between the ages of 4 and 6 years were recruited from two sources over a two-year period: (1) the Children's Hospital of Eastern Ontario, Department of Psychology list of children who had been referred by physicians for assessment and treatment of problem behaviours and (2) direct referrals to the study from family physicians, pediatricians, psychiatrists and psychologists. At initial contact, 14 families did not wish to take part in a research study. Of the 46 families who agreed to participate and completed the assessment, 36 children met diagnostic and research criteria based on the following:

1. Diagnostic and Statistical Manual of the Mental Disorders - Revised (DSM-III-R, 1987) criteria for the diagnosis of ADHD as reported by the parent in the Diagnostic Interview for Children and Adults - Parents (DICA-P; Herjanic & Reich, 1982; Reich, Herjanic, Welner & Gandhi, 1982; Appendix A) and the Swanson, Nolan and Pelham Checklist (SNAP; Johnston, Pelham & Murphy, 1985; Pelham & Bender, 1982; Appendix B). Items are included on the SNAP that reflect the DSM-III-R criteria. Criterion for inclusion was a score greater than 1, on 8 out of 14 DSM-III-R items.

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2. Standard score greater than or equal to 80 on the Peabody Picture Vocabulary Test (PPVT; Dunn & Dunn, 1981; Appendix C) if unilingual English, greater than or equal to 72 if bilingual.
3. A mean score equal to 1.5 SD above the age and sex mean on the Hyperactivity Index of the Conners Parent Rating Scale - Revised (CPRS-R; Conners, 1989; Appendix D) completed by the parent.
4. Attention score of less than 88 sec on the parent supervised attention task. This criterion is 1.5 SD above the mean for attention on the task performed by preschool ADHD children (Pisterman et al., 1989, 1990).
5. The children were not attending or entering Grade 1 at the time of assessment or for the duration of the study.
6. Parents and children were fluent in English.
7. The children did not have sensory or physical handicaps, developmental disorders (e.g., autism), neurological disease or obvious central nervous system dysfunction as assessed by a pediatrician.
8. Children who had been administered Ritalin were considered if they had been treated for less than six months and if the total dose was less than that specified for the research protocol. Medication was withdrawn for 48 hours prior to the screening assessment and only resumed if the child did not meet

inclusion criteria or the parents decided not to participate (N=2).

A final total of 30 children participated in the medication phase after parents received feedback and gave informed consent. Of these, 24 children completed the treatment regimen, 3 children withdrew from treatment and 3 children did not complete the assessment protocols following one or all of the treatment phases.

Procedure

Screening Procedure

Sessions 1, 2 and 3. There were three scheduled sessions during which screening assessments were conducted. Parents selected from the Department of Psychology referral list were contacted by telephone and were given information about the study. Direct referrals to the study were contacted by telephone following receipt of the referral in the Department of Psychology. Parents were informed that their child had been referred to the research project by their physician and the project was described to them over the phone. An appointment was made for participating parents to attend the initial interview without the child. All sessions were conducted in the same room

at the Research Institute in the Children's Hospital of Eastern Ontario.

During Session 1 the parents were informed of the details and purpose of the study as well as the full procedure involving medication treatment if the child met inclusion criteria. Parents were reassured that even if the child met inclusion criteria, participation in the treatment phase was voluntary. They were apprised of the amount of time required for assessment, treatment and feedback. Issues of confidentiality were presented and discussed especially as it related to the need to inform relevant personnel in cases of safety of the child. Parents were informed that although the assessments and final reports would become part of hospital records, the data acquired in the assessment and treatment phases would be used as aggregate data for statistical purposes. A written description of the study was given to parents outlining the sequence of the appointments (Appendix E). Prior to beginning the interview, parents signed a consent form that permitted screening procedures (Appendix F) and understood that additional consent forms would be required if their child proceeded to the treatment phase.

The primary care parent was usually the mother. Fathers were interviewed in cases where they were the primary care parent and,

in general, fathers were asked to attend the initial interview. Parents were interviewed using the semi-structured Diagnostic Interview for Children and Adolescents - Parent Interview and the Family Demographic Questionnaire (Appendix A and G). The DICA was administered using the computerised version of the DICA-R Computer Program (copyright (c) 1990, Washington University), by Multi-Health Systems Inc.

Session 2 involved the child and the target parent (i.e., parent who spends most time with the child). At this session, the Peabody Picture Vocabulary Test, Gordon Delay and Vigilance Tasks (GDS-Delay and GDS-Vigilance; Gordon, 1987; see Appendix H for standardized instructions and task parameters) and the Porteus Mazes Test (Porteus, 1955; Appendix I) were administered to the child while the parent completed the CPRS-R, the Parent Stress Index (PSI; Abidin, 1986; Appendix J) and the Side Effects Rating Scale (SERS; Barkley, 1990; Barkley et al., 1990; Appendix K).

During Session 3 the parent-child interactions were assessed using a pre-established behavioural assessment protocol and videotaped for later coding (Appendix L). The sequence and parameters of the parent-child interaction session are outlined in Appendix L. Parent-child interaction patterns were observed and coded for Aggression, Compliance and Attention exhibited by

the child. Parenting skills (Commands and Reinforcement) and style (Positives & Negatives) were also assessed from these sessions.

The parent and child were brought to the testing room where play materials and the standardized interaction materials were available. The parents were informed that they would be engaged in several tasks for a period of about an hour with a break about halfway through. They were instructed to deal with their child as they would in normal circumstances. The session began with a ten minute period of free play for the children and to acclimatize both individuals to the room. The parents were told that the focus was on how the children played by themselves. The children were told to play with any of the toys in the room while their parent read a magazine.

Following this, the first task, a Command Compliance Task, was administered. The parents were given a paper with 15 commands listed (Appendix M) and were instructed to ask their child as naturally as possible to comply to the requests. The list was to be completed in the order listed and no items were to be left out. The parents were told they had 20 minutes to complete the task. The interactions were videotaped for later coding. This was followed by a short break.

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After the break, the Attention Assessment Tasks, comprising one parent-supervised and one independent activity, were administered. In the parent-supervised paper-and-pencil task, the parent and child were given 18 pages of Dot-to-Dot designs ordered in progressively more complex patterns (Appendix N). There were three designs on the left-hand side of each page with unjoined dots on the corresponding right-hand side of the page. The object of the task was to reproduce on the right side of the page the design formed by joined dots on the left side. The children were given a pencil to complete the task. The parents were instructed that the task would last ten minutes and they could provide any assistance they felt the child needed.

In the following ten minutes the children were engaged in an unsupervised attention task. The parents were requested to read a magazine while the research assistant instructed their child on a paper-and-pencil Cancellation Task (Appendix O). The children were given two booklets comprised of rows of animals or geometric figures. The four-year old children were given the former; the five-year old children the latter. Pages were randomized in each package. The children were instructed to find and cross out the elephant (or circle) in each row. When it was clear that the instructions were understood, the children were told to try and

do as many pages as possible without seeking assistance from the parent. The task lasted ten minutes.

The session concluded with a 10 minute free play period during which the children were told to play with any of the toys in the room while their parent read a magazine.

Session 4. All participating families returned for feedback following the assessment. This session was usually scheduled one week after the assessment had been completed. A registered Psychologist was present at this session. Parents were informed whether the frequency, duration and intensity of symptoms as reported in the DICA-P were consistent with a diagnosis of Attention Deficit Hyperactivity Disorder. Clinical and research cut-off criteria were described and presented to explain the diagnosis and the inclusion/exclusion process. Children who did not meet clinical criteria were referred to appropriate facilities for additional assessment if necessary. Children who were diagnosed as ADHD but did not meet the cut-off scores on the research criteria were offered a referral to the Psychology Department for treatment.

Because of the sensitive nature of the information, feedback in the Fourth Session was devoted to discussion of the disorder and

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treatment possibilities. Written information related to medication treatment and the research project (Appendix P) was provided and parents were asked to volunteer. If necessary parents were offered some time and were called within the following week for their decision.

Treatment Procedure

Session 5. Children who participated were scheduled for a medical examination with a pediatrician in the hospital who conducted a complete physical examination and discussed medication issues with the parents. If there were no contraindications to medication treatment, the parents signed consent to treatment forms (Appendix Q) and received detailed written instructions for the administration of the medication (Appendix R). Included in the instructions were directions to give their child medication one-half hour prior to their appointment time on the day of assessment. Parents were informed that the pediatrician and the primary researcher were available (via pager) at all times for the duration of the treatment phase.

All participants received a minimum of 7 days of treatment for each of placebo, low dose and high dose. Dosage was determined by the weight of the child (0.3 mg/kg and 0.5 mg/kg) and the

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means for the two doses as administered were 0.30 mg/kg and 0.48 mg/kg, respectively. Treatment was presented in a fully randomized order prepared by the Pharmacy Department with all research and medical personnel kept blind to the order.

Sessions 6/7, 8/9 and 10/11. At the end of each treatment period, the child and parent attended two consecutive sessions. Similar to Sessions 2 and 3, the ratings scales, Gordon Diagnostic System and Porteus Mazes tasks were administered in one session with the parent-child interactive tasks administered in the other. The order of administration of sessions was randomized across children and treatment conditions. Treatment compliance was determined by counting the number of pills returned to the researcher at the end of each assessment week. All unused medication was returned to the Pharmacy Department for disposal.

Session 12. The treatment code was broken by the primary researcher after all tests were scored and interactions coded in order to provide medication response feedback to each participant's parents. This session occurred approximately five to six weeks after treatment was completed. Following the completion of the treatment protocol, parents were referred back to the primary physician who supervised any subsequent medication

treatment. Parents who requested auxiliary treatment (parent training, behavioural management) were referred to the appropriate facilities.

Scoring Procedure

Scoring of cognitive tests and rating scales. All assessment instruments were scored based on procedures outlined in manuals with scores converted where possible to standardized scores for 4-6 year old normative groups.

Coding of parent-child interactions. The parent-child interactions during the behavioural assessment were coded from videotape by a rater who remained uninformed about treatment conditions for the duration of the study. A list of the coded behaviours is presented in Appendix L. All identified behaviours were coded continuously in 30 second blocks of parental antecedent, child response and parental consequence sequences.

Interrater reliability was established by a second rater who was also uninformed about the treatment condition. A random selection of one eighth of the tapes with equal representation of the three assessments and behavioural tasks were coded. For child on-task behaviours and child sustained activities, reliability checks were based on identification of the beginning

and end of each period of sustained attention with 2 second margins of error. Kappa statistics have been obtained for each coded behaviour and range from .74 for Percent of negative statements made by parents to .97 for end of on-task behaviour in the Cancellation Task.

Medication

Two doses of methylphenidate (MPH) and lactose placebo were prepared by the pharmacy at the Children's Hospital of Eastern Ontario to the nearest 2.5 mg and placed in orange gelatin capsules (Size 16, Ely Lilly Company) to disguise the taste differences between placebo and the two doses. The two doses of MPH were .30 mg/kg and .50 mg/kg to be given twice daily (BID).

These doses were selected in accordance with earlier research outcomes of methylphenidate treatment of children. These studies (Barkley, 1988a, 1989; Barkley et al., 1984, 1985) demonstrated that, for children 4-6 years of age, significant behavioural changes occurred in children's compliance and parent's responses to ADHD children when doses ranged from a minimum of .35 mg/kg to .7 mg/kg BID. The effect of dose on measures of attention and impulsivity among preschool-aged children remains unclear.

Current researchers have administered doses that ranged from approximately .27 mg/kg to .77 mg/kg BID. In consideration of

the potential deleterious impact on the cognitive measures of any side effects (Barkley, 1990; Barkley et al., 1990), a conservative higher dose was selected. All medication was prescribed by a physician in the hospital who was available for consultation during the study.

Parents were given a bottle containing sufficient capsules for 7 to 10 days at the beginning of each drug condition. Each set of measures was assessed at the end of the treatment period which lasted at least 8 days and no longer than 10 days before cross-over to the next treatment condition. Unused capsules were counted as a measure of treatment compliance. Parents were called mid-week to assess compliance, progress, side effects and to remind them that the child should receive their medication one hour prior to each assessment session. In general, compliance was excellent.

Side Effects

Side effects related to the use of MPH in this study were assessed on a weekly basis. The Stimulant Drug Side Effects Rating Scale (SERS; Barkley, 1990; Barkley et al., 1990; Appendix K) was completed by the parent before each interactive session.

Design

All children participated in all treatment conditions in a double-blind, drug-placebo cross-over design using a placebo and two doses of MPH. In cases of prior administration of MPH, medication treatment was discontinued for 48 hours prior to initial assessment and the original dose was not resumed until parents had declined participation. Six possible blocks of treatment orders were presented with the order of treatment randomized within each block.

Screening Measures

Diagnostic Interview for Children and Adolescents - Parent version (DICA-P). The DICA-P is a structured diagnostic interview which gathers information about the children's relationships and social behaviours in the home, school and peer domains and allows a DSM-III-R diagnosis. Somatic and psychiatric symptoms are assessed as well. The interview questions are answered by "yes" or "no" with "yes" indicating the presence of the behaviour or symptom. Further questions assessed the frequency of occurrence of the symptoms. Herjanic and Reich (1982) reported strong agreement between mother and child reports for objective and concrete questions that can be externally validated (e.g., Do you take pills or medicine regularly? (kappa

= .70); have you played hookey from school? (.50); Do you wet the bed at night? (.54); Have you ever run away from home overnight or longer? (.54)). Questions related to antisocial behaviours had kappas in the high to medium range however several of the symptoms were reported more frequently by the children than by the mothers. Conversely, among the school behaviour problems, mothers reported more troublesome behaviours than did the children.

Swanson, Nolan and Pelham Rating Scale (SNAP). The SNAP is a 23-item rating scale that provides information on ADHD core behaviours based on DSM-III criteria (Barkley, 1990; Pelham & Bender, 1982). Additional items are included to reflect the DSM-III-R criteria (Rynard, 1991). The scale conventionally uses teachers as the primary raters (Johnston et al., 1985) although Pisterman et al. (1989, 1990, 1992) have used parents. Test-retest reliability (using teachers) has been reported at .69, .78, .92 and .66 for the Inattention, Hyperactivity, Impulsivity and Peer Problems factors, respectively. The scale provides normative data for children 6-11 years of age and Barkley (1990) has assessed the scale as being sensitive to treatment effects.

Peabody Picture Vocabulary Test-Revised (PPVT-R). The PPVT-R (Dunn & Dunn, 1981) is a test of receptive vocabulary. It was

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administered individually to all participants. The criterion of 80 (72 for bilingual children) has been conventionally adopted as a screening score to ensure exclusion of children with learning disabilities. Reported test-retest coefficients range from .52 to .90 and norms for this age group are available. The PPVT is reported to be highly correlated with other vocabulary tests and moderately correlated with measures of verbal intelligence and scholastic aptitude (Dunn & Dunn, 1981).

Outcome Measures - Rating Scales

Child behavioural ratings by parents. The Conners Parent Rating Scales - Revised (CPRS-R) is a well-documented measure of child behaviour and adjustment in the home (Conners, 1989; Goyette, Conners & Ulrich, 1978). The parents were required to rate their child on a three-point scale assessing various types of child behaviour problems.

The CPRS-R yields six factors obtained by summing the items related to each factor: Conduct Problems, Learning Problems, Psychosomatic, Impulsive-Hyperactive, Anxiety and the Hyperactivity Index (Goyette et al., 1978). Concurrent validity and reliability have been widely reported in many studies (Barkley, 1990; Edlebrock & Rancurello, 1985). Parent interrater reliability has been reported at .55 for the Hyperactivity Index.

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Parent-teacher correlations were reported at .49 for the same index (Goyette et al., 1978). Test-retest reliabilities are unavailable for the parents' scale. Clinical ranges are defined as T-scores greater than 60 (1 standard deviation above the standardized mean for each age group).

The Hyperactivity Index of the CPRS-R has been demonstrated to be sensitive to medication effects among school-aged children (Barkley, 1990; Barkley et al., 1988; 1989). Cohen et al. (1981) used the CPRS to measure the effectiveness of methylphenidate treatment of preschool-aged children. Although their results indicated a within-subject improvement on the Conners-total and the Impulsive-hyperactive factors following methylphenidate treatment, it is unclear from their discussion whether the Hyperactivity Index demonstrated a sensitivity to medication treatment. Compared to normal controls, the subjects' medication post-treatment scores for the learning problem, inattention and hyperactive factors remained significantly different as measured by the CPRS-R.

Because the Hyperactivity Index is a composite representation of the factors comprising ADHD, two additional subscales were examined in order to determine specific behavioural responses to medication treatment. The Conduct and Learning subscales were

used to determine changes in negative behaviours and attentional ability as assessed by parents' observations.

Outcome Measures - Cognitive Tasks

Impulsivity. The Preschool Delay Task in the Gordon Diagnostic System (Gordon, 1987) was used with standardized instructions as a measure of motor impulsivity. The Number of Correct Responses and the Efficiency Ratio (ER) were determined as indicated in the manual. The system is comprised of an LED visual display panel that remains blank until the child presses a button located below the display. The first press sets a timer and displays a numeral count in the display panel. In order to obtain additional points, the child must press the button after waiting a sufficient length of time. If the subject responds before waiting for the appropriate number of seconds, no point is earned and the task timer is reset. The time interval is not known to the child but is set at a standard 4 seconds. Thus, the Delay task measures the subject's ability to inhibit a motor response under conditions that are self-paced and with feedback.

Gordon (1987) reported threshold scores for 4-5 year old and for 6-7 year old subjects grouped in ranges labelled Abnormal, Borderline and Normal. Test-retest coefficients for normal

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children are reported at .68 for Number of Correct Responses and .60 for the Efficiency Ratio (Barkley et al., 1988).

Sustained attention. The Preschool Vigilance Task of Gordon Diagnostic System was used with standardized instructions as a measure of sustained attention. The Number of Correct Responses and Errors of Commission were calculated. In this task ("1" mode), different numbers flashed on the visual panel at a preset (standard) rate of one number every 2 seconds. The children were instructed to press the button only when the number "1" was displayed. Thus, the Vigilance task measured the children's ability to focus and maintain attention during a task that was machine-paced with the absence of immediate reward.

As with the Delay Task, threshold scores are available for the 4-5 year old and the 6-7 year old age range. Test-retest coefficients (Barkley et al., 1988) are reported at .66 for total Correct Responses, and .72 for Errors of Commission.

Reflective impulsivity. The Porteus Maze Test (PMT; Porteus, 1955) was used as a measure of planning and foresight. The qualitative or Q score is an index of how carefully or impulsively the child negotiates the mazes irrespective of correctly completing them. It has been reported to discriminate

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between normal and delinquent populations (Milich & Kramer, 1984) and to be negatively correlated with delay of gratification measures. Paulsen and Johnson (1980) administered the PMT to preschool-aged children (4.6 yrs) and reported significant negative correlations with IQ and latency scores for the Matching Familiar Figures Test (reflective impulsivity). However, neither validity nor test-retest reliabilities are available for this age group.

Observed child compliance. The Percent of Complied Commands was calculated by determining the number of commands to which the child complied relative to the total number of commands issued by the parent. Changes in Percent of Compliance could reflect a change in either one or a combination of the measure's two component behaviours: frequency of child compliance and frequency of parent's commands. Pisterman et al. (1990) inferred that higher scores on this measure reflect increased cooperation between parent and child. This measure has been demonstrated to discriminate children referred for problem behaviours from normal controls (Pisterman et al., 1990). Validity and test-retest reliabilities are not available for this measure and are used as criterion-referenced measures.

Observed child attention and productivity. The children's ability to sustain attention and their ability to improve their performance were assessed during the Dot-to-Dot and Cancellation Tasks. The first measure was the Mean Time On-task for each of the 10-minute Dot-to-Dot and Cancellation Tasks. The Mean Time On-task was calculated as the average duration of all periods of on-task behaviour. This particular measure has been demonstrated to discriminate clinic-referred children from normal controls (Pisterman et al., 1990). Validity and test-retest reliabilities are not available for this measure and are used as criterion-referenced measures.

The children's ability to improve their performance during the Dot-to-Dot and Cancellation Tasks were determined. Productivity was calculated from the Number of Patterns completed correctly in the Dot-to-Dot Task and the Number of Rows completed correctly in the Cancellation Task. Parent-supervised Productivity has been demonstrated to discriminate clinic-referred children from normal controls (Pisterman et al., 1990). Validity and test-retest reliabilities are not available for this measure and are used as criterion-referenced measures.

Aggression. The Number of Aggressive Acts performed by the child during the free play periods was coded and used as a

measure of level of aggressiveness. Behaviours that constitute aggression are described in Appendix K.

Outcome Measures - Parenting Behaviours

Observed parenting skills and style. Three measures of parenting skills were calculated from observed behaviours during each of the Command Compliance Task, the Dot-to-Dot Task and the Cancellation Task. The three measures, Percent of Commands, Percent of Reinforcement and Percent of Negative Feedback were obtained from each of the three tasks. The Percent of Commands was interpreted as an index of control attempted by the parent. The Percents of Reinforcement and Negative Feedback were used to determine how consistently the parent responded in a positive or negative manner to the child's compliance, respectively.

Two measures were used to determine overall changes in parents' style of interaction with their children. The Percent of parental behaviours that were Positive and the Percent that were Negative were determined as a function of total parent behaviours during each of the Command Compliance Task, the Dot-to-Dot Task and the Cancellation Task. Validity and test-retest reliabilities are not available for this measure and are used as criterion-referenced measures.

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Parental stress. The Parent Stress Index (PSI; Loyd & Abidin, 1985) is a 120-item scale which assesses the overall level of stress experienced by the parent. The PSI scores reflect stress that is related to the child's behavior and characteristics (Child Domain subscale) and to the parent's functioning (Parent Domain subscale). It was used to assess changes self-reported stress in each domain as a function of the child's medication treatment. The Child Domain subscale is comprised of 6 scales related to child characteristics such as adaptability, acceptability, demandingness, mood, distractibility /hyperactivity and reinforcing value to the parent. The Parent Domain is comprised of 7 scales which include unattached to child, feel incompetent in parental role, social isolation and health problems. The PSI has been normed with parents, the majority of whose children were under 5 years old. Barkley (1990) assessed its primary usefulness to be in determining parent stress among mothers of preschool children.

Loyd and Abidin (1985) reported internal reliabilities for the Child domain as .89, for the Parent domain as .93 and for the Total Stress score as .95. Test-retest reliabilities were .82 and .71 for the Child and Parent domain, respectively, over a 3-week interval.

Sample Size

Prior to beginning the study, sample size estimates were based on Barkley's (1988a) results of mother-child task interaction following medication treatment. The child compliance duration variable was chosen because it resulted in significant changes but smaller effect sizes relative to the behavioural rating scales or other compliance measures.

Following Cohen's (1977) recommendations for a within-subject comparison of means, the effect size d was calculated at .75 from Barkley's (1988) results. Thus, using Cohen's formula $n = [n_{.10}/100(d)^2] + 1$ and with power = .80 and alpha = .05, the sample required is 23 children.

A minority of children have been reported to experience no change or iatrogenic effects severe enough to require withdrawal from stimulant medication treatment. Barkley (1990) reported that rates range from 23% to 27% among school-age children and as many as 50% of preschool-age children in his stimulant medication study (Barkley, 1988a; personal communication, 1991) were taken off medication upon follow-up despite the reported gains in parent-child interactions. If null or negative effect responders can be considered at risk for attrition, a 40% rate would result

in requiring a total subject pool of at least 38 children in order to obtain the required final total of 23 children.

Statistical Analyses

The data were processed using the SPSS^R Professional Statistics and addressed two major questions. First, analyses to determine effects related to medication treatment were conducted. Multivariate Analyses of Variance (MANOVAs) for a repeated measures design were used to test conceptually grouped sets of variables for changes following administration of placebo and the two medication doses. Pillais' test of multivariate significance was adopted and *alpha* was set at .05 as the criterion. *A priori* comparisons were established using Helmert's contrasts which establishes three sets of contrasts thereby minimizing spurious significances (Stevens, 1992).

Univariate Analyses of Variance (ANOVAs) were conducted on comparisons that achieved significance with Bonferroni correction used to adjust the final *alpha* level (Tabachnik & Fidell, 1989). *Post hoc* all pairwise comparisons were conducted using Tukey's studentized range statistic (*q*). Experimenter error rate (EER) was controlled by setting *alpha* for each variable at .05 as recommended by Stevens (1992). Where the groupings of subscales

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of variables were moderately correlated and significant ($r^2 > .6$; $p < .001$), variables were prioritized and the Roy-Bargman Step-down F-tests of significance were used to determine the unique contributions of each variable to the overall effect.

A second line of inquiry was the determination of clinical significance. Variables that met the following two criteria were selected as indicators of clinical change (Steketee & Chambless, 1992): (1) A sensitivity to identifying medication effects, i.e., statistical significance had been demonstrated; (2) Established test-retest reliabilities or clinical cut-off scores were available to determine change in terms of clinical ranges. The Reliable Change Index (Jacobson, Follette & Revenstorf, 1984; Jacobson & Truax, 1991) was selected as the measure to determine the significance and stability of clinical change following medication treatment. The children's scores on each variable were coded in one of four categories: Normalized, Improved, No Change or Deteriorated. Nonparametric tests (Sign Test) were conducted to determine if the percent of children who responded to medication increased as a function of MPH treatment.

Auxiliary analyses were conducted with children who met the following criteria: (1) no response to Placebo condition, i.e., scores were clinically not different from baseline; and (2)

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responded to Placebo condition. Placebo Nonresponders and Placebo Responders were compared on baseline measures to ascertain whether there were group differences at inclusion between these groups. Second, the outcome measures of the Placebo Responders were subjected to the same analyses as the overall group to ascertain whether, having removed the "noise" from children who demonstrated a Placebo effect, additional treatment effects could be determined.

Results

Recruited Groups

Sample Selection

The children ($N = 46$) assessed for participation in the study were categorized as follows: children who (1) met the clinical and research criteria and participated in the medication phase ($n = 30$); (2) met both sets of criteria but did not wish to participate in the medication phase ($n = 6$); (3) did not meet clinical criteria ($n = 1$); (4) did not meet research criteria ($n = 4$); and, (5) did not complete the initial assessment ($n = 5$). Group 1 was further categorized into children who completed treatment ($n = 27$) and who withdrew from treatment ($n = 3$). Of the children who completed treatment, 3 subjects were excluded from analyses because of incompleting assessments in the treatment conditions leaving a sample of 24 children who completed treatment assessments.

Groups 1 and 2. Children in Groups 1 and 2 were compared using separate between-subjects MANOVAs with inclusion (Table 2), cognitive, rating scales and interactive measures as conceptually grouped dependent variables. Group differences were found on the number of symptoms of the DICA, $F(1, 28) = 20.47, p = .000$ and SNAP, $F(1, 28) = 7.93, p = .009$, and the Hyperactivity Index,

Table 2

Means and Standard Deviations of Inclusion Criteria for Children Accepting and Refusing Treatment with MPH

Inclusion Criteria	Treatment accepted (n = 24)		Treatment refused (n = 6)		<u>F</u>
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	
DICA symptoms (number)	12.15	1.48	9.17	1.17	20.47*
SNAP symptoms (number)	11.79	1.69	9.17	3.19	7.93*
PPVT (Standard Score)	97.42	13.96	103.00	16.83	.71
Conners Hyperactivity Index (T-score)	85.75	9.44	70.83	18.24	8.06*
Attention Task-Supervised (sec)	30.49	11.78	32.56	26.24	.09
Age	58.92	6.426	56.71	4.54	.71

*p < .01

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$F(1,28) = 8.06, p = .008$. Parents who had chosen medication as a treatment option rated their children as having a greater number of symptoms of ADHD and being more hyperactive than had parents who did not choose medication treatment. There were no differences in age between children who participated and those whose parents chose not to participate, $F(1, 28) = .710, p = .406$.

There were no group differences on Baseline cognitive measures (Gordon Delay and Vigilance Tasks and Porteus Q scores), behavioural rating scales (Conners Parent Rating Scales) or parent stress levels (Parent Stress Index). However, differences between the groups were found in the Percent of Positive statements made by the parent during the Compliance Task. Parents who chose medication treatment for their child expressed fewer positive statements when interacting with their child ($M = 11.85, SD = 6.38$) than did parents who did not chose medication treatment ($M = 21.52, SD = 8.16$), $F(1, 28) = 9.90, p = .01$.

Groups 3 and 4. One child did not meet clinical criteria for ADHD as reported by the mother in the DICA interview. Four children met clinical criteria but not research criteria. None of the parents of these children wished re-assessment and expressed ambivalence towards medication as a possible treatment.

Group 5. Three children began medication treatment but were withdrawn after parental reports of extreme moodiness, tics, rash and itchiness. Two children had been on the 0.3 mg/kg dose but the third child had been in the Placebo condition.

Description of Sample Receiving Treatment

Family demographics. Means and standard deviations of the family demographics of participants are presented in Table 3. The children who completed treatment were comprised of 21 boys and 3 girls. Family demographics indicated 21% of the children were in single parent homes, 25% were in blended families and 54% were in biological two-parent homes. All of the single parents were receiving social assistance at the time of the assessment and treatment. Fifty-five percent of the parents (13 mothers and 2 fathers) who participated were primary full-time caregivers. Means and standard deviations of the combined family income, age and education levels of both parents are presented in Table 3. Family income and parents' age were not correlated significantly with inclusion variables.

Comorbidity. All participants met clinical criteria for a diagnosis of ADHD based on the DICA - Parent Semi-Structured Interview. None of the children met criteria for diagnoses of

Table 3

Means and Standard Deviations of Family Demographics for Treatment Participants

Measure	<u>M</u>	<u>SD</u>
Mother's age (years)	31.04	4.66
Father's age (years)	33.54	5.27
Mother's education (years)	13.00	1.41
Father's education (years)	10.50	0.71
Combined family income (dollars)	27500	10607
Family classification		
Two-parent	54%	
Blended	25%	
Single parent	21%	

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Mood Disorders, Obsessive-Compulsive Disorders, Overanxious Disorder, Somatization Disorder or Psychotic symptoms.

Oppositional-Defiant Disorder and Conduct Disorder were diagnosed as present in 83% and 30% of the children with ADHD, respectively. A group of children also were reported to exhibit all the symptoms of Separation Anxiety Disorder (30%) but did not meet the criteria based on the duration of the symptoms. Four of the children diagnosed with ADHD (16.7%) were comorbid with ODD and CD as well as reported to exhibit sufficient symptoms of SAD except for the duration criterion.

Previous treatment. Two participants had received methylphenidate (MPH) as treatment for behaviour problems. Each boy had received 5 mg once a day; one child had been treated for six months and the other for two weeks prior to the initial assessment. Medication administration was stopped 48 hours prior to the assessment and not resumed. Two children had participated previously in behavioural/parent management treatment which was not conducted concurrent with participation in the medication study.

Data Evaluation

Assumptions of Linearity and Distribution

All variables were assessed with respect to linearity and the fit between their distributions and the assumptions of multivariate analyses to be conducted. Standardized scatterplots of residuals and the predicted residuals were symmetrical for all but one variable. The plot of the Percent of Negative Feedback expressed by the parent during the parent-child interactions suggested nonnormality. Skewness and kurtosis were evaluated using a cutoff value calculated from the standard error of skewness or kurtosis, respectively. All variables except one were determined to be reasonably normally distributed. The Percent of Negative Feedback expressed by the parent during parent-child interactions was assessed as seriously skewed in the positive direction across all tasks and treatment conditions. Given the violations of both linearity and distribution, this variable was excluded from all subsequent analyses.

Missing Data

Missing values which had occurred as a result of incompleting questionnaires or missed appointments for parent-child interactive tasks comprised less than 1% of the total data set. The means were substituted by mean shifts calculated as changes

from Baseline to Placebo or low to high dose as recommended by Tabachnick and Fidell (1989).

Outliers

The presence of univariate and multivariate outliers were assessed using a 3 standard deviation cutoff and Mahalanobis distance at $p < .001$. Adjustment of univariate outliers was sufficient and none of the multivariate outliers was assessed to be present or influential ($\chi^2 \geq 20.5$).

Order Effects

Treatment order effects were assessed for each conceptual set of variables. None exhibited significant effects related to the order of testing.

Correlations

Pearson product moment correlations were calculated for inclusion with outcome variables (Appendix S). Inclusion variables were moderately correlated with each other and exhibited low to moderate correlations with outcome variables. Because of the large number of correlations calculated, $r^2 > .80$ and $p < .01$ were adopted as criteria for considering inclusion variables sufficiently correlated to be considered as covariates of outcome measures.

Treatment Outcomes

Interpretation of Treatment Effects

Drug response and drug effect. Baseline, Placebo, 0.3 mg/kg MPH and 0.5 mg/kg MPH were compared in the analyses discussed below. There are several possible patterns of treatment response which reflect either a drug response and/or a drug effect (Ross & Buckalew, 1985). Statistical significances were interpreted as related clearly to medication components when MPH treatment differed from each of Baseline and Placebo conditions. This pattern reflects not only the placebo-augmented change from pre-treatment but also the extent to which the treatment surpasses placebo response. Although assignation of drug response solely to the constituent components of the medication requires that Baseline and Placebo do not differ statistically, a variation in this pattern of response would include differences among all four conditions. In this latter case, issues related to expectancies (child or parent) are examined as an integral part of the drug response.

Placebo effects. Analyses which indicate Placebo and MPH treatment differed from Baseline conditions, and not from each other, were viewed as a generalized response to the treatment process irrespective of the constituent content of medication

treatment. These situations were interpreted as reflecting non-specific treatment effects in which the expectancies and the medication effects were inseparable.

Deterioration effects. Patterns in which Placebo differed from Baseline and MPH treatment were treated as possible indication of a deterioration effect. That is, the decrement in the children's or parents' performance may have been a result of repeated testing without the presence of medication components to affect performance. In order to clarify patterns of decrement in performances, further analyses were conducted to assess order effects among groups which received Placebo in the first, second and third weeks of treatment. Interpretations focused on child and parental factors that may have resulted in the decrement.

Indeterminate effects. Baseline scores may differ from MPH treatment scores with neither differing from the Placebo condition. In other words, the Placebo conditions may occupy a position not differentiated from pretest and medication treatment. Whereas change may be assigned to medication effects, the possible augmentation of the response by a placebo effect could not be addressed. Other sources of variances were considered such as parent expectations, child behaviours and methodological issues.

A second possible pattern emerges with Baseline scores occupying an intermediate position between Placebo and MPH treatment conditions. Although drug response can be discussed with respect to placebo as the control, the absence of change from pretreatment levels requires examination. This pattern was not considered to be a deterioration effect and the relationship of Placebo means to Baseline means was examined in an attempt to ascertain the factors contributing to the variance. In other words, Baseline and Placebo conditions may be extensions of each other representing a general "no treatment" condition. Interpretations of a possible medication effect were considered and discussed in this context.

Medication Response and Effects Assessed by Child Response

Cognitive Tasks

Impulsivity. Two measures were used to assess changes in impulsivity following medication treatment. The Number of Correct Responses and the Efficiency Ratio obtained from the Gordon Diagnostic System Delay Task were analysed using a repeated measures MANOVA with dose as the within-subjects factor (Table 4; ANOVA summary tables are listed in Appendix T). Multivariate tests (Pillais') indicated an overall difference between groups, $F(6, 18) = 3.42, p = .020$. Univariate analyses

Table 4

Means and Standard Deviations of Cognitive Tests by Dose

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Gordon Delay					
No. Correct					
<u>M</u>	30.58	26.88	36.25	34.67	5.49**
<u>SD</u>	12.35	10.79	12.09	12.83	
P<L; P<H					
Efficiency Ratio					
<u>M</u>	.48	.54	.58	.59	1.68
<u>SD</u>	.21	.22	.22	.24	
Gordon Vigilance					
No. Correct					
<u>M</u>	15.88	15.67	19.67	20.42	4.84**
<u>SD</u>	7.52	9.20	7.65	8.78	
B<L; B<H; P<L; P<H					
Commission Errors					
<u>M</u>	34.96	14.71	18.33	18.71	6.40***
<u>SD</u>	27.03	13.17	18.31	21.43	
B>P; B>L; B>H					
Porteus Mazes					
Q-score					
<u>M</u>	62.29	63.42	72.83	67.79	2.13
<u>SD</u>	27.00	25.51	26.00	26.04	

p < .01; *p < .001

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indicated a significant difference in the Number of Correct Responses, $F(3, 69) = 5.49$, $p = .002$, but no differences in the Efficiency Ratio across treatment conditions, $F(3, 69) = 1.68$, $p = .179$.

Post hoc comparisons using the Tukey procedure and the studentized range statistic (Stevens, 1992) indicated the Number of Correct Responses during Placebo treatment was less than the Correct Responses with 0.3 mg/kg and 0.5 mg/kg, $p < .05$. There were no differences between Baseline and Placebo or between the two MPH conditions. There were no differences between Baseline and each of the two MPH doses. Examination of the means suggested that the change may have been related to the decrease in Correct Responses following Placebo treatment and not to an increase in Correct Responses following medication treatment.

It was hypothesized that accuracy may have decreased as a function of re-testing. If so, a comparison of Placebo treatment at each of the three time positions should reveal a decrement. An ANOVA was conducted comparing the scores of subjects administered Placebo as the first ($M = 26.78$, $SD = 11.45$), second ($M = 22.78$, $SD = 6.94$) and third ($M = 33.17$, $SD = 13.08$) treatment conditions. None of the comparisons achieved significance suggesting that there had been no decrement in

performance as a result of repeated testing, $F(2, 21) = 1.78$, $p = .193$. However, it must be noted that the smaller sample size in this analysis may have contributed to a loss of power to detect any changes.

Examination of the means and SDs of the Baseline and Placebo scores showed the latter were subsumed in the former. That is, the Placebo condition may reflect a lower range of a general "no treatment" condition. Thus, the difference between Placebo and the two MPH doses may reflect a medication effect that is potent enough to differentiate treatment scores from the lower range scores (Placebo condition) "no drug treatment" but not strong enough to differentiate from the higher range (Baseline) scores.

In summary, only tentative support was found for the improvement of impulsivity as a function of MPH treatment. Relative to Placebo, the children appeared to become better able to restrain their responding during the self-paced task but their performance did not improve beyond their pretreatment levels.

Attention. The Number of Correct Responses and the Errors of Commissions obtained from the Gordon Vigilance Task were used to assess medication-related changes in sustained attention and impulsivity under conditions of high arousal and low feedback

(Table 4). Overall multivariate tests indicated significant difference between treatment group, $F(6, 18) = 4.65, p = .005$.

Univariate analyses indicated differences among treatment conditions, $F(3, 69) = 4.84, p = .004$. Pairwise comparisons of the four conditions assessed by the Number of Correct Responses showed the changes were related to medication effects. Responses at Baseline were not different from those following Placebo administration. The means at Baseline and Placebo each were significantly different from means at 0.3 mg/kg and 0.5 mg/kg, $p < .05$. The absence of a Placebo effect (difference between Baseline and Placebo conditions) indicated that the increase in attentional levels is attributable primarily to medication administration. That is, the children's performance accuracy increased following administration of MPH. There were no differences observed between the two doses of MPH.

Univariate analyses of the Errors of Commission indicated differences among conditions, $F(3, 69) = 6.40, p = .001$. *Post hoc* pairwise comparisons localized the differences between Baseline and the remaining conditions, $p < .05$. Levels of impulsivity decreased from Baseline to all treatment conditions which themselves did not differ from each other. That is, decreases in levels of impulsivity appeared related to a non-

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specific treatment effect. This may reflect either a warm-up effect or the possibility that subjects learned the task demands following the initial exposure. Medication appeared ineffective in decreasing impulsivity below this level.

In summary, MPH treatment appeared to improve ability to sustain attention during the Vigilance task. However, the children appeared to have learned how to restrain their impulsivity during this task after the first administration and medication did not realize further gains.

Reflective impulsivity. The qualitative Q score from the Porteus Mazes Test was used to assess the ability of the children to improve their planning behaviour following medication treatment (Table 4). The univariate analysis of variance of the Q-score was not significant.

Behavioural Ratings

Parent ratings of inattention, conduct and hyperactivity. Three subscales of the Conners Parent Rating Scale - Revised were selected to assess the effectiveness of medication in decreasing parent ratings of negative behaviours (Table 5). The Learning subscale contains items relevant to the child's ability to attend; the Conduct subscale reflects the parent's assessment of

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negative behaviours such as aggression; and, the Hyperactivity Index is a composite measure of impulsivity, inattention and negative behaviours. The scales were entered in the analysis in the above order to determine if the Hyperactivity Index contributed unique information over and above the first two scales.

Multivariate analyses indicated significant differences related to treatment conditions, $F(9, 15) = 7.24, p = .000$. Univariate analyses revealed significant differences in each of the Learning, Conduct and Hyperactivity Index subscales, $F_s(3, 69) = 11.65, 15.03$ and $22.46, p = .000, .000$ and $.000$, respectively. Furthermore, Roy-Bargman Stepdown F-tests indicated each of the Learning, Conduct and Hyperactivity Index subscales contributed uniquely to the changes related to treatment, $F(3, 69) = 11.65, F(3, 68) = 4.14$, and $F(3, 67) = 4.79, p_s = .000, .009$ and $.004$, respectively.

Pairwise comparisons of the Learning subscale scores yielded no Placebo effect. The Baseline scores were significantly higher than 0.3 mg/kg and 0.5 mg/kg treatments, $p < .05$. Scores while in the Placebo condition were significantly higher than those in

Table 5

Means and Standard Deviations of Conners Parent Rating Scales by Dose

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Conners					
Learning					
<u>M</u>	85.21	79.38	74.96	65.96	11.65***
<u>SD</u>	10.26	16.24	16.15	16.25	
B>L; B>H; P>H; L>H					
Conduct					
<u>M</u>	79.92	74.75	66.83	60.58	15.03***
<u>SD</u>	15.38	17.90	16.80	14.45	
B>L; B>H; P>L; P>H; L>H					
Hyperactivity Index					
<u>M</u>	85.75	77.63	69.17	63.08	22.46***
<u>SD</u>	9.44	15.27	15.66	14.22	
B>P; B>L; B>H; P>L; P>H; L>H					

***p < .001

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the 0.5 mg/kg but not 0.3 mg/kg treatment, $p < .05$. There was a difference between doses with the scores when treated with 0.3 mg/kg being higher than that following 0.5 mg/kg, $p < .05$.

Thus, compared to initial conditions, children were rated by their parents as having less difficulty with attention. However, clear medication effects were noted by the parent only following treatment with the higher dose.

The scores obtained from the Conduct scale were analysed and pairwise comparisons yielded the following results. Baseline and Placebo conditions did not differ indicating no placebo effect. Baseline and Placebo scores each were significantly different from 0.3 mg/kg and 0.5 mg/kg treatments, $p < .05$. There was also a significant difference between the two doses, $p < .05$. The parents rated the negative behaviours itemized in the Conduct subscale as having decreased following treatment with both doses of MPH. Furthermore, the parents' ratings suggested that the higher dose was more effective than the lower dose in obtaining a reduction in parental assessment of these negative behaviours.

The Hyperactivity Index subscale was analysed in a similar manner with pairwise comparisons yielding significant differences between all pairs. A placebo effect was obtained suggesting

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parents responded to the treatment process independent of the effect of the constituent components of medication on the children. However, differences between the Placebo condition and 0.3 mg/kg and 0.5 mg/kg conditions also achieved significance, $p < .05$, indicating parental assessment was related to medication treatment of the child as well. Parents rated the behaviours associated with ADHD as decreasing following treatment with Placebo, the lower dose and higher dose of MPH.

In summary, parental ratings of the intensity of their child's negative behaviours, attention and impulsivity decreased as a function of medication. The higher dose was most consistent in being associated with decreases in levels of inattention, behaviour and impulsivity.

Child compliance. The Percent of Compliance obtained as a function of parent requests during each of the three interactive tasks was calculated (Table 6). Changes following medication treatment were assessed using separate ANOVAs for each of the Compliance, Dot-to-Dot and Cancellation Tasks. Compliance did not change significantly during any of the three tasks, univariate $F_s(3, 69) = 0.86, 0.87$ and $0.49, p_s = .468, .460$ and $.694$, respectively.

Table 6

Means and Standard Deviations of Observed Behaviours by Dose

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Child Compliance					
Compliance Task					
% Compliance					
<u>M</u>	36.66	32.49	31.60	32.66	0.86
<u>SD</u>	11.10	15.87	16.39	16.43	
Dot-to-dot Task					
% Compliance					
<u>M</u>	34.61	28.81	33.13	30.60	0.46
<u>SD</u>	16.62	21.39	17.04	19.06	
Cancellation Task					
% Compliance					
<u>M</u>	19.25	19.73	24.72	18.49	0.49
<u>SD</u>	16.21	14.03	27.22	20.40	
Time On-Task					
Dot-to-dot Task					
Mean time (sec)					
<u>M</u>	30.49	35.23	51.83	89.98	3.03*
<u>SD</u>	11.78	55.68	68.40	165.31	
B<H					
Cancellation Task					
Mean time (sec)					
<u>M</u>	36.64	17.38	33.79	53.64	4.81**
<u>SD</u>	32.38	16.99	28.91	58.89	
P<H					
Productivity					
Dot-to-dot Task					
Patterns Correct					
<u>M</u>	16.13	19.35	20.96	22.13	4.68**
<u>SD</u>	10.53	13.64	13.17	15.08	
B<P; B<L; B<H					
Cancellation Task					
Rows Correct					
<u>M</u>	63.08	54.07	70.69	83.17	1.61
<u>SD</u>	50.24	49.28	57.06	78.85	

*p < .05; **p < .01

Attention during interactive tasks. The Mean Time On-task (seconds) was obtained from each of the Dot-to-Dot and Cancellation Tasks (Table 6). These variables were used to determine changes in the ability of the children to sustain attention during the two tasks. Two separate ANOVAs were conducted to assess change related to medication treatment.

Univariate tests of the Mean Time On-task during the Dot-to-Dot Task indicated significant changes related to medication treatment conditions, $F(3, 69) = 3.03, p = .035$, that is, sustained attention increased over treatment conditions. Pairwise comparisons indicated the Mean Time On-task following treatment with 0.5 mg/kg MPH was higher than that at Baseline, $p < .05$.

Univariate analysis of the variables during the Cancellation Task indicated a similar pattern of differences. Mean Time On-task differed across treatment conditions, $F(3, 69) = 4.81, p = .004$. Pairwise comparisons of the four conditions indicated the Placebo condition differed from treatment with 0.5 mg/kg MPH, $p < .05$. To assess the presence of a deterioration effect related to re-testing, further analyses were conducted comparing order of Placebo administration presented first ($\underline{M} = 15.45, \underline{SD} = 13.81$), second ($\underline{M} = 19.21, \underline{SD} = 20.71$) and third ($\underline{M} = 17.32, \underline{SD} = 17.29$),

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$F(2, 21) = .103, p = .902$. No differences were found across the treatment weeks and in the absence of Baseline-Placebo differences no deterioration effect can be inferred.

In summary, tentative interpretations may be proposed for a medication effect in improving sustained attention during the Dot-to-Dot Task. However, the role of psychological factors in augmenting this response cannot be ruled out because of the absence of differences between the Placebo and other treatment conditions. The effect obtained during the Cancellation Task suggested the increase in sustained attention may be related primarily to the relative shift in position of the Placebo condition similar to that obtained for the Number of Correct Responses during the Gordon Delay Task. It is of interest to note nevertheless that the means increase in the predicted direction.

Productivity. The Number of Patterns completed correctly in the Dot-to-Dot Task and the Number of Rows correctly cancelled in the Cancellation Task were calculated (Table 6). These variables were used to assess the Productivity of the child during each task.

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The ANOVA assessing Productivity during the Dot-to-Dot Task was significant, $F(3, 69) = 4.68, p = .005$. *Post hoc* analysis indicated the difference was between Baseline and the remaining treatment conditions, $p < .05$, suggesting a non-specific treatment effect.

The ANOVA assessing the differences among Productivity means during the Cancellation Task was non-significant, $F(3, 21) = 1.42, p = .265$. Univariate analysis indicated no differences observed among treatment groups, $F(3, 69) = 1.61, p = .196$.

Thus, although the children responded with increased numbers of correctly completed Dot-to-Dot designs when working in a one-to-one situation, it could not be related to the medication alone. There was no effect of treatment on their ability to work efficiently and effectively on their own. It is noteworthy, however, that the means appear to increase in the direction expected for medication effects with the 0.5 mg/kg dose producing the highest patterns and rows completed correctly.

Side effects. The Side Effects Rating Scale (SERS) was used to assess the symptoms usually associated with MPH treatment (Barkley, 1990). Symptoms ranged from somatic symptoms such as stomachaches and headaches to psychological symptoms such as

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anxiety and sadness. Two scores were derived from the 17 items (Table 7). The Number of Symptoms was used as an indication of changes in symptoms following treatment. The sum of the rating scale was used as an indication of the overall Severity of the symptoms endorsed.

Multivariate analyses of the Number of Symptoms and the overall Severity did not achieved significance, $F(6, 18) = 1.83, p = .150$. Furthermore, in testing the proposed hypothesis with Bonferroni correction, univariate analysis did not yield significant effects with respect to the Number of Symptoms reported across treatment conditions, $F(3, 69) = 2.92, p = .040$. Thus, neither the number of symptoms nor the severity of the side effects were noted to have increased during treatment.

Medication Response and Effects Assessed by Parent Behaviours

Effects of Child Medication Status on Parent Skills

Variables. The two variables that comprised parent skills were the Percent of Commands issued by parents as a function of total parent behaviours and the Percent of Reinforcements given by parents as a function of total child compliance. Percent Commands and Reinforcement were calculated for each of the Compliance, Dot-to-Dot and Cancellation Tasks (Table 8).

Table 7

Means and Standard Deviations of Side Effects by Dose

Variables	Dose				
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	<u>F</u>
Severity					
<u>M</u>	1.56	1.33	1.35	1.90	2.25
<u>SD</u>	1.09	0.82	0.96	1.12	
Number of Symptoms					
<u>M</u>	6.88	5.79	6.38	7.83	2.92
<u>SD</u>	4.05	3.28	3.99	3.24	

Table 8

Means and Standard Deviations of Parent Skills by Dose

Variables	Dose				
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	F
Compliance Task					
% Commands					
<u>M</u>	59.72	54.77	55.56	55.07	1.90
<u>SD</u>	12.33	10.47	12.79	12.34	
% Reinforcements					
<u>M</u>	13.79	14.73	13.16	12.55	0.17
<u>SD</u>	9.90	14.39	13.24	11.08	
Dot-to-dot Task					
% Commands ^a					
<u>M</u>	50.98	45.34	41.45	46.20	3.54*
<u>SD</u>	11.94	18.23	19.57	19.47	
% Reinforcements					
<u>M</u>	25.63	18.76	22.01	18.46	0.72
<u>SD</u>	18.19	17.76	24.27	16.67	
Cancellation Task					
% Commands					
<u>M</u>	54.10	57.56	45.88	42.92	3.90*
<u>SD</u>	28.07	17.94	21.14	26.90	
<u>P<H</u>					
% Reinforcements					
<u>M</u>	4.61	3.59	2.97	9.23	1.34
<u>SD</u>	12.08	7.56	10.52	19.53	

^aOnly univariate analysis is significant.

*p < .05

Compliance Task. Multivariate analysis indicated there were no changes in parent skills (Percent of Commands or Reinforcements) during the Compliance Task, $F(6, 18) = 0.85$, $p = .546$. In order to test the specific hypotheses, univariate analyses were conducted but were found to be nonsignificant for both Percent of Commands and Reinforcements, $F(3, 69) = 1.90$ and 0.17 , $p = .137$ and $.915$, respectively. Several characteristics of the task may have played a mitigating role. Unlike the Dot-to-Dot and Cancellation Tasks, the Compliance Task had no obvious outcome that was to be evaluated, i.e., no product. In the absence of assessment criteria obvious to the parent, the task may have been perceived to be relatively unstructured with low demands on both themselves and their child. Thus, parents may have responded by approaching the task in a manner that reduced the likelihood of confrontation or that was open-ended in terms of interactions with their child.

Dot-to-Dot Task. Multivariate test assessing changes in parent skills during the Dot-to-Dot Task was non-significant, $F(6, 18) = 2.09$, $p = .105$. In order to test the hypothesis, the univariate tests were examined and the Percent of Commands was noted to have achieved significance, $F(3, 69) = 3.54$, $p = .019$. The univariate analysis of variance of the Percent of Reinforcements was not significant, $F(3, 69) = 0.72$, $p = .541$.

Examination of the contrasts for the Percent of Commands revealed that the difference was between Baseline and 0.3 mg/kg MPH, $p < .05$. However, the absence of differences between Placebo and other treatment conditions mitigates an interpretation of unequivocal medication effects.

Cancellation Task. The multivariate analysis of Percent of Commands and Reinforcements measured during the Cancellation Task achieved significance, $F(6, 18) = 2.87, p = .038$. Univariate analysis indicated the Percent of Commands issued by parents were different across treatment conditions, $F(3, 69) = 3.90, p = .012$. Paired comparisons demonstrated the Percent of Commands issued by parents during the Placebo condition was higher than those issued during the treatment with 0.5 mg/kg MPH, $p < .05$. Relative to receiving a Placebo treatment, parents appeared to exert less control when their child had received treatment with 0.5 mg/kg MPH. However there was no change in behaviour compared to pretreatment. Similar to discussions above, if baseline and placebo can be considered extensions of a "no drug treatment" condition, then a tentative interpretation of a medication effect may be offered.

The univariate analysis of variance of the Percent of Reinforcements was not significant, $F(3, 69) = 1.34, p = .268$.

Thus, the assessment of parental skills across a variety of tasks appeared to have yielded no clear association with the child's MPH treatment.

Effects of Child Medication Status on Parent Style

Variables. The Percent of Positive and Negative statements made by parents was calculated as a function of the total parent verbal behaviours (Table 9). These two variables comprised parent's overall style of interaction. Separate MANOVAs were conducted for the Compliance, Dot-to-Dot and Cancellation Tasks yielding significant differences among means, $F_s(6, 18) = 2.83, 5.26, \text{ and } 4.17, p_s = .040, .003 \text{ and } .008, \text{ respectively.}$

Compliance Task. Univariate analysis of the Percent Positive, $F(3, 69) = 1.49, p = .224,$ and Negative statements, $F(3, 69) = 5.63, p = .002,$ measured during the Compliance Task indicated differences occurred between treatment conditions only for Percent of Negative statements. Pairwise comparisons localized the differences in Percent Negative statements as being between Placebo and the remaining three conditions, $p < .05.$ That is, parents appeared to use more negative statements when their children had received Placebo treatment than during the Baseline, 0.3 mg/kg and 0.5 mg/kg MPH. The difference between Baseline and Placebo suggests a possible deterioration effect on

Table 9

Means and Standard Deviations of Parent Style by Dose

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Compliance Task					
% Positives					
<u>M</u>	11.85	10.69	12.80	14.45	1.49
<u>SD</u>	6.38	5.64	9.89	10.83	
% Negatives					
<u>M</u>	8.34	13.41	8.72	8.34	5.63**
<u>SD</u>	4.98	8.60	7.52	5.49	
B<P; P>L; P>H					
Dot-to-dot Task					
% Positives					
<u>M</u>	14.94	23.35	26.59	26.65	6.89***
<u>SD</u>	11.40	19.57	19.76	22.33	
B<P; B<L; B<H					
% Negatives					
<u>M</u>	13.61	12.67	10.33	9.43	4.42**
<u>SD</u>	5.66	7.41	6.45	5.85	
B>H; P>H					
Cancellation Task					
% Positives					
<u>M</u>	9.25	6.81	14.75	22.71	4.04**
<u>SD</u>	12.27	10.05	19.44	25.60	
B<H; P<H					
% Negatives					
<u>M</u>	12.84	19.24	9.11	7.58	6.01***
<u>SD</u>	13.89	15.23	11.32	8.66	
P>L; P>H					

p < .01; *p < .001

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the part of the parent. That is, parental style as assessed by negative statements may get worse when the child is not medicated.

It was hypothesized that parental style may have become more negative as a function of re-testing. If so, a comparison of Placebo treatment at each of the three time positions should reveal a decrement. An ANOVA was conducted comparing the scores of subjects administered Placebo as the first ($\underline{M} = 12.79$, $\underline{SD} = 9.89$), second ($\underline{M} = 13.64$, $\underline{SD} = 8.65$) and third ($\underline{M} = 14.01$, $\underline{SD} = 7.92$) treatment conditions. None of the comparisons achieved significance suggesting that there had been no decrement in performance as a result of repeated testing, $\underline{F}(2, 21) = 0.04$, $\underline{p} = .963$. However, it must be noted that the smaller sample size in this analysis may have contributed to a loss of power to detect any changes.

The Placebo group is comprised of children who received Placebo before any active medication and those who received Placebo following active medication. In both groups parental negative statements may have increased from pretreatment to Placebo administration for the following reasons. If Placebo had been administered first, the increase in negativity may have been a result of the parents' premature expectations of positive outcome

from treatment. If Placebo had been received after active medication, the increase in negative statements may have been the result of a contrast to the children's behaviour during the active medication condition.

Dot-to-Dot Task. The Percent of Positives and Negatives expressed during the Dot-to-Dot Task were significantly different across treatment conditions, univariate $F_s(3, 69) = 6.89$ and 4.42 , $p_s = .000$ and $.007$, respectively. Pairwise comparisons of the Percent of Positive statements indicated Baseline differed significantly from Placebo, 0.3 mg/kg and 0.5 mg/kg MPH, $p < .05$, suggesting a non-specific treatment effect. However, the comparisons for the Percent of Negative statements showed Baseline and Placebo conditions differed from the treatment with 0.5 mg/kg, $p < .05$.

Whereas parents may have become more positive as a general response to receiving treatment, their negative expressions to their child was related to the dose received by the child. That is, during a task requiring intense interaction with their child, parents were less negative when their child had been treated with the higher dose.

Cancellation Task. During the Cancellation Task, both Percent of Positive and Negative statements were found to be significantly different across treatment conditions, univariate $F(3, 69) = 4.04$ and 6.01 , $p = .010$ and $.001$, respectively. Post hoc analyses showed Percent of Positive statements for each of Baseline and Placebo conditions differed from treatment with 0.5 mg/kg MPH, $p < .05$. Thus, during a task requiring minimal interaction with their child, parents appeared to become more positive as a function of medication treatment of their child.

The Percent of Negative statements expressed during Placebo differed from treatment with each of 0.3 mg/kg and 0.5 mg/kg MPH, $p < .05$. Although medication response may be inferred with respect to Placebo control, there were no changes in the parents' response to the child relative to pretreatment. Similar to previous situations, the absence of a Baseline-Placebo difference may be viewed as the two conditions forming a "no treatment" unit relative to which changes may be assessed. Thus, parental negative style may be said to have decreased as a function of the child's medicated state when compared to the child's non-medicated state.

In summary, during the Cancellation Task which requires the children to work on their own, parents' positive statements

increased as a function of medication. Although negative statements decreased, the change was relative to Placebo and was not different from pretreatment levels.

Effect of Child Medication Status on Parent Stress

Variables. The level of stress experienced by the parent with respect to child behaviours and the parents' own functioning were assessed using the Parent Stress Index (PSI) Child and Parent Domains (Table 10). Child and Parent Total scores were analysed using the repeated measures multivariate analysis of variance which achieved significance, $F(6, 18) = 4.08, p = .009$.

Child domain. Univariate analysis of variance indicated a significant difference between means in the Child Total score of the PSI, $F(3, 69) = 5.29, p = .002$. *Post hoc* analyses localized the differences between Baseline and the two methylphenidate treatment conditions, $p < .05$, suggesting a drug response to treatment. However, the absence of change from the Placebo conditions limits the assignation of drug effects totally to medication. Thus, the response must be viewed as indeterminate with respect to augmentation of response by parental expectancies.

Table 10

Means and Standard Deviations of Parent Reported Stress by Dose

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Child Domain					
<u>M</u>					
<u>SD</u>	144.08	135.25	128.04	126.92	5.29**
B>L; B>H	20.20	23.23	23.43	25.08	
Parent Domain^a					
<u>M</u>	133.54	126.29	123.04	119.71	5.51**
<u>SD</u>	25.08	29.42	28.10	30.08	

^aRoy-Bargman Step-Down F-tests indicates no unique contribution over Child Domain Score.

**p < .01

Parent domain. Univariate analyses conducted with the Parent Total score showed significant differences existed among the assessment conditions, $F(3, 69) = 5.51, p = .002$. However, because these scores were correlated with the Child Total scores, Roy-Bargman Step-down F-tests were interpreted, $F(3, 68) = 1.41, p = .248$. This latter analysis suggested there was no unique contribution by the Parent Total score to the change observed among treatment conditions.

In other words, the parents' level of stress appeared to decrease as a function of the children's medicated state but the role of their expectation of change cannot be separated from the overall decrease in stress they experienced. Although parents' stress levels related the parents' own functioning may have decreased in association with the child's medicated state, it was not independent of the stress levels related to the children's behaviour and characteristics.

Clinical Outcomes

Definition of Clinical Categories

The Reliable Change Index (RCI; Jacobson & Truax, 1991) was selected to determine clinical change using the Vigilance Task, Conners Learning scale and the Hyperactivity Index. Steketee and

Chambless (1992) recommended its use because it accounts for measurement error by using the test-retest reliability of the instrument or a clinical cutoff score. In effect, determination of positive change is based on the likelihood that the post-treatment score has moved reliably from the dysfunctional to within the functional population distribution.

RCI scores were calculated as described by Jacobson and Truax (1991). Using the Gordon Vigilance Task Number of Correct responses, children with an RCI ≥ 1.96 in the positive direction were classified as having Improved reliably. Children with scores greater than 19 and an RCI ≥ 1.96 were classified as Normalized. RCI scores ≤ 1.96 were defined as not improved and further classified as No change or Deteriorated depending on clinical cutoff scores. For measures such as the Conners Learning and Hyperactivity Index subscales, Jacobson and Truax (1991) recommended clinical cutoff scores that reflect a 1 SD change based on normative data. Thus, children who were categorized as Improved demonstrated a difference score ≥ 1 SD in the positive direction and Normalized scores were defined as a difference greater than or equal to 1 SD and final T-scores ≤ 60 . No Change category was defined as change less than 1 SD and deterioration was determined if the difference scores were greater than 1 SD in the negative direction.

Variables demonstrating statistical change, medication effects and high power ($\eta^2 \geq .80$) following medication treatment were assumed to be potentially potent indicators of clinical change. Thus, the Number of Correct Responses during the Vigilance Task, the Conners Learning subscale and the Conners Hyperactivity Index were selected to assess clinical change. The Sign Test (Conover, 1980) was used to determine significant differences in the direction of clinical change among treatment conditions. Matched pair-wise comparisons of the children's clinical change scores at Placebo, 0.3 mg/kg and 0.5 mg/kg MPH examined treatment differences in the overall direction of change. Thus, achieving significance with the Sign Test indicates one treatment condition positively affected more children than did the other. The percent of children are listed under the four clinical change categories representing the outcome of the treatment response in each condition (Table 11).

Direction of Clinical Change

Sustained attention. The Number of Correct Responses during the Vigilance Task assessed sustained attention. The Sign Test indicated there were no significant differences in the percent of children demonstrating clinical change between Placebo/0.3 mg/kg, Placebo/0.5 mg/kg or 0.3/0.5 mg/kg pairs of

Table 11

Percent of Children Demonstrating Clinical Change by Tasks and Dose

Measures	Clinical Change Category			
	Normalized	Improved	No Change	Deteriorated
Vigilance Task				
Placebo	16.67	4.17	62.50	16.67
Low	16.67	4.17	75.00	4.17
High	29.17	0.00	58.33	12.50
Learning (CPRS-R)				
Placebo	12.50	16.70	50.00	20.80
Low	12.50	29.20	54.20	4.20
High	41.70	25.00	33.30	0.00
Hyperactivity Index (CPRS-R)				
Placebo	12.50	20.80	58.30	8.30
Low	33.30	41.70	20.80	4.20
High	37.50	50.00	12.50	12.50

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doses, p s = .727, .754, and 1.00, respectively. Thus, despite statistically significant changes following MPH treatment, there was no increase in the number of children who improved their ability to sustain attention with increasing dose of MPH. Examination of the distribution of percentages in Table 11 reveals most children remained in the No Change category across doses.

Parent-rated attention. The Conners Learning subscale was used to assess the children's attention abilities as observed by their parents. Pair-wise comparisons of doses indicated significant differences in the percent of children reported as positively affected with increasing dose of MPH. Compared to Placebo and 0.3 mg/kg MPH, the 0.5 mg/kg dose MPH was associated with more children who were rated as having changed in the positive direction, p s = .001 and .013, respectively. There were no differences between Placebo and 0.3 mg/kg MPH in the distribution of children across clinical change categories, p = .227.

Examination of the percentages in Table 11 indicates 41.7% of the children had normalized their behaviours and 25% had improved following treatment with 0.5 mg/kg MPH. Treatment with Placebo and 0.3 mg/kg MPH left approximately 50% of the children

unaffected. Thus, it appears that the 0.5 mg/kg MPH dose was more effective than the lower dose for many of the children. None of the children had deteriorated in their behaviour following treatment with the higher dose.

Hyperactive behaviours. The Conners Hyperactivity Index subscale was used to assess parent-observed changes in behaviours associated with ADHD. Pair-wise comparisons of treatment conditions indicated significant differences in the numbers of children categorized as changing in the positive direction. When compared to Placebo, both 0.3 mg/kg and 0.5 mg/kg MPH were associated with increased number of children rated as having responded positively, $p_s = .001$ and $.002$, respectively. There was no difference between doses of MPH in the number of positive responders, $p = .424$.

Percentages in Table 11 indicate approximately one-third of the children normalized their behaviours following treatment with 0.3 mg/kg and 0.5 mg/kg MPH. Close to half the children were rated as having improved following the two MPH doses. Less than a quarter of the sample had failed to demonstrate any change or had deteriorated. Thus, it appears both doses were effective in

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producing positive changes in the majority of children. Furthermore, it would seem that the higher dose is no more effective than the lower for most of them.

Summary. The cognitive task did not emerge as a sensitive measure of positive change following MPH treatment. However, the Conners Learning and Hyperactivity Index subscales revealed interesting patterns of response among the children treated with the two doses of MPH. When assessing changes using the Learning subscale, the higher dose (0.5 mg/kg) of MPH appears to affect more children positively. However, with respect to behaviours assessed by the Hyperactivity Index, more children appear positively affected by the lower dose than by Placebo. Administration of the higher dose produced no further gains over the lower dose in the number of children who responded positively. It may be inferred that attentional abilities require higher dose treatment for many children whereas the negative behaviours may only require a lower-dose intervention. Nevertheless, it is important to note that almost 87% of children changed in the positive direction on the 0.5 mg/kg compared to 74% on the 0.3 mg/kg MPH dose.

Comparison of Medication Responders and Placebo Responders

Definition. Insofar as a response to Placebo conditions indicates the effects of expectancies or other moderating variables, a comparison was made between children who exhibited a positive or negative response to Placebo (Placebo Responders) and those who demonstrated no response to Placebo (Medication Responders). The response of this latter group was interpreted as representing a group with a clear medication effect. Using each of the Vigilance Task, Learning and Hyperactivity Index subscales, children who were categorized as No Change during Placebo administration were compared to a second group comprised of children categorized as Deteriorated, Improved or Normalized during Placebo conditions.

Medication Responders versus Placebo Responders. Separate MANOVAs indicated that the two groups did not differ on any baseline measures when medication response was classified using the Vigilance Task and the Learning subscale. Using the Hyperactivity Index to classify medication response yielded differences in the Number of Commission Errors, the Learning and the Impulsive-Hyperactive subscale of the CPRS-R, the Percent of Compliance during the Dot-to-Dot Task and the Percent of Reinforcement given by parents during the Dot-to-Dot Task, $F_s(1,$

22) = 10.07, 11.14, 7.38, 9.87 and 7.47, p s = .004, .003, .013, .005 and .012, respectively.

Table 12 summarizes the means, standard deviations and statistical significances of these variables. Specifically, the Medication Responders performed with fewer Errors of Commission, that is, were less impulsive, than the Placebo responders. They were rated as less problematic in their behaviours related to attention, impulsivity and hyperactivity, were more compliant to parental requests and parents were more reinforcing of these children's compliance.

In summary, it appeared that children who responded unequivocally to treatment with MPH were less severe in their presenting symptoms and whose parents were more skilled in acknowledging positive behaviours. Although regression to the mean may explain the response of the children who appeared to improve with Placebo treatment, it is also possible that the greater severity of these children is an indicator of complex familial and environmental difficulties. Thus, a non-specific treatment response in this case would reflect a potent response to receiving aid but which masks any possible gains made by medication administration.

Table 12

Means, Standard Deviations and Statistical Tests of Baseline Measures by Medication Responders and Placebo Responders

Variables	Medication Responders (n = 14)		Placebo Responders (n = 10)		<u>F</u>
	<u>M</u>	<u>SD</u>	<u>M</u>	<u>SD</u>	
Vigilance Task Commission Errors	22.43	14.89	52.50	31.00	62.49***
CPRS-R Learning	80.29	10.26	92.10	5.15	11.14**
CPRS-R Impulsive- Hyperactive	70.21	7.36	77.00	6.82	7.38*
Dot-to-Dot Task					
% Compliance	42.26	13.79	23.90	14.58	9.87**
% Reinforcement	33.20	18.27	15.03	12.21	7.47*

* $p < .05$; ** $p < .01$; *** $p < .001$

Assessment of Medication Effects of Medication Responders

Insofar as the absence of clinical response to Placebo is suggestive of a subgroup whose response is not moderated by expectancy factors, further analyses related to medication response were conducted. Children who demonstrated no clinical response to Placebo conditions as rated by the CPRS Hyperactivity Index were grouped and their response to treatment with MPH was assessed in a similar manner as the total sample. Tables 13 to 19 list the means, standard deviations and statistical significances by dose. Because of the number and the *post hoc* nature of the analyses conducted, only variables achieving omnibus multivariate significance were further assessed at the univariate level. Statistical tests in the tables indicating only univariate significance are qualified as such where appropriate.

Impulsivity. Multivariate analyses of variance of the Number of Correct Responses and the Efficiency Ratio of the Gordon Delay Task indicated a trend to significance, $F(6, 8) = 3.42$, $p = .056$ (Table 13). Nonsignificant findings were noted for the Porteus Mazes Q-score, univariate $F(3, 39) = 1.21$, $p = .320$.

Table 13

Means and Standard Deviations of Cognitive Tests by Dose for Medication Responders (n = 14)

Variables	Dose				
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	F
Gordon Delay					
No. Correct ^a					
<u>M</u>	27.36	26.36	35.36	34.36	3.54*
<u>SD</u>	11.94	12.91	12.53	16.71	
Efficiency Ratio					
<u>M</u>	.50	.56	.57	.61	.63
<u>SD</u>	.24	.26	.21	.26	
Gordon Vigilance					
No. Correct ^a					
<u>M</u>	14.14	14.64	19.36	18.00	3.00*
<u>SD</u>	8.48	10.14	8.78	9.29	
Commission Errors					
<u>M</u>	22.43	11.29	16.36	15.21	1.38
<u>SD</u>	14.89	10.50	16.03	22.31	
Porteus Mazes					
Q-score					
<u>M</u>	62.36	62.79	71.71	68.43	1.21
<u>SD</u>	29.46	26.31	24.22	27.25	

^aOnly univariate analyses significant.

*p < .05

Attention. Multivariate analysis of the Number of Correct Responses and the Commission Errors during the Vigilance Task were analysed. A trend towards significance was obtained, $F(6, 8) = 3.57$, $p = .051$ (Table 13).

Behavioural ratings. The MANOVA of the Learning, Conduct and Hyperactivity Index subscales of the CPRS-R was significant, $F(9, 5) = 5.02$, $p = .045$ (Table 14). Univariate analyses showed significant differences among doses for Learning, Conduct and Hyperactivity Index subscales, $F_s(3, 39) = 12.84, 8.85$ and 19.93 , $p_s = .000, .000$ and $.000$, respectively. However Roy-Bargman Step-down F-tests indicated only the Learning, $F(3, 39) = 12.84$, $p = .000$, and Hyperactivity Index, $F(3, 67) = 7.38$, $p = .001$, contributed uniquely to the treatment changes. *Post hoc* pair-wise comparisons using Tukey's Range Test localized the differences for the Learning scale to be between the Baseline and 0.5 mg/kg MPH dose, between Placebo and both doses and between the 0.3 mg/kg and 0.5 mg/kg doses, $p < .05$. Medication effects were in the direction of reducing negative behaviours with MPH treatment. Similar patterns of differences were obtained for the Hyperactivity Index. Baseline scores were significantly higher than both doses; scores obtained during Placebo conditions also were significantly higher than both doses, $p < .05$.

Table 14

Means and Standard Deviations of Conners Parent Rating Scales by Dose for Medication Responders (n = 14)

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Conners					
Learning					
<u>M</u>	80.29	83.14	71.93	61.79	12.84***
<u>SD</u>	10.26	10.14	14.90	11.37	
B>H; P>L; P>H; L>H					
Conduct ^a					
<u>M</u>	76.00	75.43	66.64	57.50	8.85***
<u>SD</u>	16.78	18.49	18.37	14.16	
Hyperactivity Index					
<u>M</u>	81.71	80.21	65.36	59.14	19.93***
<u>SD</u>	9.54	8.42	13.53	11.20	
B>L; B>H; P>L; P>H					

^aRoy-Bargman Step-Down F-test indicates no unique contribute over Learning and Hyperactivity Index subscales.

***p < .001

Compliance. The Percent of Compliance exhibited by the children was analysed for the Compliance, Dot-to-Dot and Cancellation Tasks (Table 15). The ANOVAs were not significant for any variables, $F_s(3, 69) = 0.17, 1.43$ and $0.72, p_s = .911, .293$ and $.548$, respectively.

Sustained attention. The Mean Time On-task during the Dot-to-Dot and Cancellation Tasks each was analysed for medication effects (Table 15). The ANOVAs of the Mean Time On-task for the Dot-to-Dot, but not the Cancellation Task, was significant, $F_s(3, 39) = 3.33$ and $1.38, p_s = .029$ and $.263$, respectively. Pair-wise comparisons indicated that the amount of time spent on-task during Baseline conditions was less than the time following treatment with 0.5 mg/kg MPH .

Productivity. There were no significant differences between conditions as assessed by the Number of Rows correctly cancelled during the Cancellation Task, univariate $F(3, 39) = 2.59, p = .066$. Analyses of the Number of Correct Designs completed during the Dot-to-Dot Task indicated significant differences related to medication treatment, univariate $F(3, 39) = 4.85, p = .006$. *Post hoc* analysis of pairwise comparisons revealed differences between Baseline and the three treatment conditions. That is, the results reflect a non-specific response to treatment.

Table 15

Means and Standard Deviations of Observed Behaviours by Dose for Medication Responders (n = 14)

Variables	Dose				
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	F
Child Compliance					
Compliance Task					
% Compliance					
<u>M</u>	36.71	34.74	37.13	37.29	0.17
<u>SD</u>	8.28	14.45	17.00	13.33	
Dot-to-dot Task					
% Compliance					
<u>M</u>	42.26	31.84	34.31	39.12	1.43
<u>SD</u>	13.79	23.00	20.47	19.91	
Cancellation Task					
% Compliance					
<u>M</u>	15.98	22.74	24.15	25.85	0.72
<u>SD</u>	16.49	14.58	23.77	23.53	
Time On-Task					
Dot-to-dot Task					
Mean time (sec)					
<u>M</u>	30.13	47.66	70.55	136.51	3.33*
<u>SD</u>	12.46	70.47	85.39	206.00	
B<H					
Cancellation Task					
Mean time (sec)					
<u>M</u>	32.84	23.61	33.68	45.97	1.38
<u>SD</u>	27.73	19.20	30.66	51.55	
Productivity					
Dot-to-dot Task					
Number Correct					
<u>M</u>	19.71	23.71	25.07	27.00	4.85**
<u>SD</u>	9.34	13.89	11.40	13.75	
B<P; B<L; B<H					
Cancellation Task					
Number Correct					
<u>M</u>	69.93	51.71	61.86	99.71	2.59
<u>SD</u>	62.11	56.56	53.07	90.23	

*p < .05; **p < .01

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Side effects. A MANOVA of the symptoms and severity of side effects indicated no significant changes occurred for either variable following treatment with MPH, $F(6, 8) = 1.19$, $p = .399$ (Table 16). Similar to the larger sample, there appeared to have been no significant difficulties for the children following either dose.

Parent skills. The Percent of Commands and Reinforcements emitted by parents during the Compliance, Dot-to-Dot and Cancellation Tasks were assessed (Table 17). The MANOVAs of the variables during Compliance and Cancellation Tasks indicated there were no differences in parent skills associated with MPH treatment, $F_s(6, 8) = 0.98$ and 1.21 , $p_s = .496$ and $.391$, respectively. However, the MANOVA of parent skills during the Dot-to-Dot Task indicated significant differences, $F(6, 8) = 3.61$, $p = .049$, in the Percent of Commands and Reinforcements. Univariate analyses revealed significant differences among doses for Percent of Commands and Reinforcements, $F_s(3, 39) = 3.88$ and 3.93 , $p_s = .016$ and $.015$, respectively.

Post hoc analyses indicated fewer commands issued by the parents in the 0.3 mg/kg MPH condition compared to those at Baseline, $p < .05$. However, with no differences obtained from Placebo conditions, an unequivocal interpretation of a medication effect

Table 16

Means and Standard Deviations of Side Effects by Dose for Medication Responders (n = 14)

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Severity					
<u>M</u>	1.81	1.40	1.58	1.64	0.55
<u>SD</u>	1.14	0.78	1.08	0.72	
Number of Symptoms					
<u>M</u>	8.00	6.00	7.43	7.93	1.57
<u>SD</u>	4.15	2.63	3.50	2.81	

Table 17

Means and Standard Deviations of Parent Skills by Dose for Medication Responders (n = 14)

Variables	Dose				
	Baseline	Placebo	Low	High	F
Compliance Task					
% Commands					
<u>M</u>	60.85	55.84	55.33	52.92	2.76
<u>SD</u>	12.09	11.22	10.44	13.10	
% Reinforcements					
<u>M</u>	15.63	11.84	9.77	11.20	1.84
<u>SD</u>	11.40	9.86	7.70	8.68	
Dot-to-dot Task					
% Commands					
<u>M</u>	50.12	47.14	39.63	41.17	3.88*
<u>SD</u>	15.12	21.05	22.54	22.20	
B > L					
% Reinforcements					
<u>M</u>	33.20	16.43	15.08	21.05	3.93*
<u>SD</u>	18.27	16.43	17.53	18.59	
B>P;B>L;B>H L<H					
Cancellation Task					
% Commands					
<u>M</u>	56.41	55.18	49.62	48.81	.91
<u>SD</u>	28.58	21.11	21.21	27.76	
P<H					
% Reinforcements					
<u>M</u>	2.55	3.72	2.47	12.24	2.21
<u>SD</u>	7.06	7.46	9.23	21.86	

*p < .05

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cannot be made. The Percent of Reinforcements provided by the parent indicated there was a non-specific treatment effect, that is, Baseline scores were higher than Placebo and 0.3 mg/kg MPH, $p < .05$. However, the direction of the change is in the opposite direction what might be expected.

Parent style. The Percent of Positive and Negative statements made by parents during the Compliance Task, Dot-to-Dot and Cancellation Tasks were analysed (Table 18). No differences were obtained for the variables during the Compliance Task, $F(6, 8) = 1.64$, $p = .252$.

The MANOVAs of the Dot-to-Dot and Cancellation Tasks indicated significant differences existed for both variables, $F_s(6, 8) = 6.44$ and 3.91 , $p_s = .010$ and $.040$, respectively. Univariate analyses of the Dot-to-Dot Task yielded significance for the Percent of Positive statements made by parents, $F(3, 39) = 6.95$, $p = .001$. Post hoc analysis indicated the Percent of Positive statements made during Baseline were less than those at 0.3 mg/kg and at 0.5 mg/kg MPH, $p < .05$. There were no treatment related differences in the Percent of Negative statements made by parents during this task, $F(3, 39) = 2.66$, $p = .061$.

Univariate analyses of the Cancellation Task yielded differences

Table 18

Means and Standard Deviations of Parent Style by Dose for Medication Responders (n = 14)

Variables	Dose				<u>F</u>
	Baseline	Placebo	Low	High	
Compliance Task					
% Positives ^a					
<u>M</u>	10.36	11.42	13.89	17.40	3.28*
<u>SD</u>	5.43	6.71	10.89	11.45	
% Negatives ^a					
<u>M</u>	8.30	13.09	8.17	6.75	6.10**
<u>SD</u>	4.73	8.93	6.17	3.39	
Dot-to-dot Task					
% Positives					
<u>M</u>	17.94	25.07	29.89	35.24	6.95**
<u>SD</u>	13.50	21.26	22.90	25.02	
B<L; B<H					
% Negatives					
<u>M</u>	12.32	11.80	11.01	7.94	2.66
<u>SD</u>	5.01	7.03	7.59	6.31	
B>H; P>H					
Cancellation Task					
% Positives					
<u>M</u>	6.86	6.80	10.32	22.33	3.62*
<u>SD</u>	10.78	10.24	16.84	24.19	
B>H; P>H					
% Negatives					
<u>M</u>	12.89	23.23	10.60	5.06	7.78***
<u>SD</u>	14.90	14.29	13.17	5.12	
B<P; P>L; P>H					

^aOnly univariate analysis significant.

*p < .05; **p < .01; ***p < .001

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in the Percent Positive and Negative statements made during this Task, $F_s(3, 39) = 3.62$ and 7.78 , $p_s = .021$ and $.000$, respectively. *Post hoc* comparisons were conducted for each variable. The Percent of Positive statements increased from Baseline and Placebo conditions to 0.5 mg/kg MPH, $p < .05$. Examination of the means showed the parents were more positive in their interactions when their children were receiving the higher dose of MPH. Percent of Negative statements decreased across treatment conditions with fewer negative statements made following treatment with both doses of MPH. However, the interpretation is indeterminate because the decrease was relative to Placebo conditions and did not reflect a change from pretreatment conditions.

Parent stress. The stress experienced by parents related to their child's behaviours and to their functioning as a parent were assessed for medication effects (Table 19). MANOVAs of the total scores for the Child and Parent Domains were significant, $F(6, 8) = 8.57$, $p = .004$ as were the univariate analyses, $F_s(3, 39) = 4.26$ and 5.66 , $p_s = .011$ and $.003$, respectively. However, Roy-Bargman Stepdown F-tests showed that Parent domain score did not contribute uniquely to the overall variance. All pairwise comparisons of the Child Domain score indicated Baseline scores were higher than those at both doses, $p < .05$. That is, stress

Table 19

Means and Standard Deviations of Parent Reported Stress by Dose for Medication Responders (n = 14)

Variables	Dose				<u>F</u>
	Baseline	Placebo	0.3 mg/kg	0.5 mg/kg	
Child Domain					
<u>M</u>					
<u>SD</u>	146.57	142.50	127.50	129.07	4.26**
B>L; B>H	20.68	18.18	25.86	23.25	
Parent Domain^a					
<u>M</u>	139.50	129.64	124.21	122.43	5.66**
<u>SD</u>	21.11	26.71	27.59	25.23	

^aRoy-Bargman Step-down F-tests indicates no unique contribution over Child Domain.
 **p < .01

related to the children's behaviours decreased as a function of treatment with MPH but without changes from the Placebo condition, the role of expectancies in the change cannot be evaluated.

Summary. It appears that the pattern of results obtained from the total sample was reproduced to a moderate extent in the analysis of 'clear' medication responders. The obtained trends for the cognitive tasks may reflect the smaller sample size and thus reduced power to detect changes. However, parent ratings reveal similar results as obtained previously with the total sample as did the measure of sustained attention during the Dot-to-Dot Task.

In general, the interactive variables assessing parent skills and style appear to parallel the results of the total sample. However, in some cases exclusion of children experiencing Placebo responses revealed a different pattern of behaviours exhibited by the parents. In contrast to the total sample, the exclusion of the Placebo Responders resulted in statistical significance for the Percent of Commands and Reinforcements expressed during the Dot-to-Dot Task. Similarly, the Percent of Positive statements during the Dot-to-Dot Task revealed a medication response however the role of the parents' expectancies could not be evaluated.

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In cases of variables not achieving significance, it may be assumed that the exclusion of the Placebo Responders resulted in decreased power to detect any patterns of results. Although it is possible that a different pattern may exist, this hypothesis could not be tested in the present design.

Finally, patterns of results for the assessments of parent stress and the children's side effects remained unchanged when compared to the total sample.

Discussion

Overview

The primary aim of the study was to assess the efficacy of methylphenidate in the treatment of preschool-aged children diagnosed with Attention Deficit Hyperactivity Disorder. Thirty children, following assessment and diagnosis of Attention Deficit Hyperactivity Disorder, participated with parental consent in the medication phase. Of these, 24 completed the medication treatment protocol which was comprised of Placebo, 0.3 mg/kg and 0.5 mg/kg, administered for a minimum of 7 days. Order of medication administration was known only to the dispensing Pharmacist.

Overall medication treatment showed its effectiveness in changing the behaviours of the preschoolers supporting a large body of research carried out with school-aged children. As might be expected some measures were more sensitive than others in detecting changes related to medication. In addition there was evidence of medication effects with some dependent measures showing responses to different doses of methylphenidate. Of particular interest is the fact that, in this regard, there was no evidence of increased side effects with the use of the higher dose of methylphenidate.

The integration of these results is presented in the context of the assessment of medication treatment. The child's responses to medication falls into three domains. First, useful to the concept of ADHD, measures of attention will be considered. Second, negative behaviours central to ADHD, consisting of impulsivity and hyperactivity, will be addressed. Third, the children's responses during parent-child interactions will be examined. Parental response to their children being treated with medication will be considered with respect to changes in skills, style and stress.

In addition, clinical responses to medication treatment in this study will be addressed. Finally, methodological and clinical issues pertinent to efficacy studies will be discussed and related to suggestions for future inquiries into the treatment of preschool-aged children with ADHD.

Assessment of Treatment Response to Methylphenidate

Diagnostic Issues

Several issues related to the diagnosis of these children require consideration. First, the mean number of symptoms endorsed by parents suggested that concerns raised with regard to using 10 symptoms as cutoff to avoid increased false positives was not a

consideration for this sample. Children who met the criteria were described as exhibiting an average of 12 out of 14 symptoms of ADHD (range: 10 to 14 symptoms) and were rated at least 3 SD above the mean for this age group on a composite scale of impulsive, inattentive and overactive behaviours. Thus, despite Barkley's (1990) concerns that DSM-II-R criteria may result in increasing false positives, these children appeared to represent a group with significant difficulties in impulsivity, inattention and overactivity (Lavigne et al., 1994).

Second, many of these children were diagnosed with comorbid disorders. Eighty-three percent of the sample were diagnosed as ADHD comorbid with Oppositional Defiant Disorder (ODD) and 30% with Conduct Disorder (CD). Some parents endorsed symptoms of Separation Anxiety Disorder (40%) although the children may not have received the diagnosis by failing to meet the duration criterion. With the exception of ODD, the proportions for CD and the presence of symptoms of anxiety appear to fall within the range of those reported in the literature (Plizka, 1992; Szatmari, Boyle & Offord, 1989).

Reported rates of comorbidity appear to vary as a function of the disorders that were examined. Szatmari et al. (1989) reported 42.2% of their sample of males (4-11 years old) were diagnosed

with ADHD comorbid with Conduct Disorder. However, Keller, Lavori, Beardslee et al. (1992) reported 17% and 39% of their sample (age 6 to 19 years) received a diagnosis of ADD with comorbid diagnoses of CD and ODD, respectively. Combining all three comorbid disorders, Steingard, Biederman, Doyle and Sprich-Buckminster (1992) described 48% of their sample as ADHD with a comorbid disorder of ODD, CD or Anxiety Disorder. Although 62% of their sample were young children (under the age of 8 years) it was not clear how many of these were represented in the ADHD + comorbid group. Consistent with the present study, Plizka (1992) noted 37% of his sample (aged 6-12) were reported to exhibit overanxious symptoms comorbid with ADHD.

The clustering of ADHD, ODD and CD in this sample may be in part a result of referral bias and/or overlapping diagnostic criteria (Caron & Rutter, 1991). That is, it is possible that these children represent those with a range of disruptive behaviours observed by parents and physicians (Frick, Lahey, Loeber et al., 1991). Caron and Rutter (1991) also suggested that the process of diagnosis which involves the use of high scores for inclusion may result in an oversight of children with less broad-based behavioural problems. In this study, only one referred child

failed to meet clinical criteria for ADHD, however, this does not preclude the fact that the inclusion criteria did not identify children with disruptive behaviours needing intervention.

The parent-endorsed anxiety-related symptoms focused on issues such as difficulty being away from parents, need for structure and routine. Parents noted that their children appeared to be less adaptable than they had expected a child to be and that this was a source of considerable stress. It is possible that the difficulties these children have attending to stimuli in their environment results in an experience of that environment as being unpredictable. This, in turn, may exacerbate the normal level of anxiety sometimes experienced by a very young child.

Third, children whose parents chose medication differed from those whose parents did not choose medication as a treatment option. The inequality of sample sizes may limit the generalizability of these results, however, the outcomes provide an indication of factors involved in treatment choice. Whereas both groups met the clinical criteria for ADHD, the participants of the medication phase were perceived as more impulsive, overactive and inattentive than the non-participants. Furthermore, they were less compliant to parental requests and elicited fewer positive statements in an interaction with their

parents. Thus, it appears that the treated group was more severe in their presentation and had more problematic interactions with their parents.

It is noteworthy that the two groups did not differ with respect to their attentional abilities as assessed by the cognitive tasks or interactional tasks. One conclusion, therefore, may be that the parents' impetus for selecting medication treatment may be less a function of their child's attentional difficulties and more a function of negative behaviours exhibited by their child as perceived by the parent.

Rostain, Power and Atkins (1993) reported that the intensity of child negative behaviours was not related but previous medication use and counselling were related to parents' willingness to use medication treatment for ADHD. Because of the above-mentioned unequal sample sizes, it is difficult to determine if the results presented by Rostain et al. (1993) are supported by this study. Further examination, using larger and equal sample sizes, of the factors related to choosing medication as a treatment option would clarify details of the decision-making process.

Children's Response to Medication

Summary of findings. Medication response to MPH treatment was apparent with cognitive tests, parent rating scales and parent-child interactive tasks. However, unequivocal medication effects were obtained only with the cognitive tests of attentional abilities and parent-rating scales, that is, significant differences of MPH doses from both Baseline and Placebo conditions.

Cognitive tests of impulsivity presented an equivocal picture of their sensitivity to medication treatment. Attentional abilities in an interactive setting indicated a medication response from Baseline measures only and the degree to which this effect was augmented by Placebo treatment was unclear. That is, there was some evidence that expectancies played a role in these measures. Finally, it is possible that the range of doses selected may not have been high enough to obtain a dosage effect.

In general, some measures showed greater sensitivity than others; that is, the cognitive tests and parent ratings of behaviours were more successful in detecting changes related to medication than were the interactive tasks. However, it is also possible that medication may not be effective in producing change in the latter domain.

Attention. Attention was assessed in three situations: cognitive tasks (Gordon Vigilance Task), parent-ratings (Learning subscale of the Conners Rating Scales) and time spent on-task during parent-child interactions (Dot-to-Dot and Cancellation Tasks). Unequivocal response to MPH treatment was obtained on cognitive measures of sustained attention and parental ratings of attention-related behaviours. Both perspectives of the children, strengthened by an absence of a placebo effect, indicated increased attention following treatment with MPH. The results showed specifically that both doses were successful in increasing the ability to sustain attention. Parents reported the higher dose was most successful in achieving increases in attention.

Two factors may contribute to this pattern of results. First, Sprague and Sleator (1976, 1977) noted a similar difference in dose response to cognitive tasks and teacher ratings leading them to suggest optimal doses may differ for attentional and behavioural changes. Although subsequent research apparently has not supported this finding (Rapport, Stoner, DuPaul, Birmingham & Tucker, 1985; see Barkley, 1990), the results of the present study appear to support the original proposals made by Sprague and colleagues. Second, it is possible that the difference in assessment settings contributed to this pattern. Parents were observing their children in a more socially diffuse situation

which may have placed greater demands on the ability of the medication to be effective. As well, parents may have had higher expectations of the medication in alleviating the symptomatology and, thus, may not have assessed behaviours as improving until definitive changes were noted. Finally, it should be noted that parent ratings may be subject to halo effects resulting in enhanced attention scores as a result of improved behaviours. This is not a problem with the cognitive tasks.

Parental influence is more evident in the equivocal response of sustained attention by the children in the interactive settings. The children's ability to sustain attention during an interactive, one-on-one task (Dot-to-Dot Task) with their parent indicated increased attention following medication but their response to medication treatment was not separable from an expectancy effect. Insofar as it is unlikely that very young children are cognizant of the treatment paradigm, this response may reflect components of parental expectations. That is, parental expectations may subtly alter the children's on-task behaviour via reinforcements or positive statements.

Examination of parental behaviours (Positive and Negative statements) during the same attention task indicated that overall they were less negative in their style of interactions with only

the higher dose producing significant changes in parental style. Positive statements emitted by the parents, on the other hand, indicated a non-specific response to treatment. Irrespective of the fact that the latter effect may be the result of anticipation and the former a true medication effect, the net result is one of a more encouraging style. Thus increased attention in the children, as a result of medication, may have been augmented in some form by treatment expectancies of the parents.

The absence of studies using these measures with preschool-aged children precludes comparisons of these results with previous studies. However, it is important to note that the efficacy of MPH in improving the attention abilities of the preschool-aged children in this study parallels that of the school-aged children described in the earlier literature (Barkley, DuPaul & McMurray, 1990, 1991; DuPaul et al., 1994). Previous investigations of interactive behaviours (Barkley et al., 1984) have reported medication-related positive changes in off-task behaviour of preschool-aged children however there are no estimates of the length of time spent on-task or its sensitivity to medication interventions.

In summary, it may be concluded that children's ability to sustain attention under optimal conditions increased as a

function of medication treatment and was maintained at the increased dose level. Parental assessment of attentional abilities also reflected a relation to medication treatment, however, only at the higher dose. The interactive setting presented equivocal results that may have been affected by parental behaviours or expectations.

Impulsivity-Hyperactivity. Impulsivity and hyperactivity were assessed using the cognitive tasks (Gordon Delay and Vigilance Task and Porteus Mazes) and parent ratings of negative behaviours (Conduct and Hyperactivity Index subscales). Changes obtained with respect to restraining behaviours during the Delay Task may have been a downward shift in means at one condition (Placebo) more than a specific treatment response. The Commission Errors reflected a non-specific treatment response. Planfulness as assessed by the Porteus Q-score was not affected by medication intervention.

Classification of the Number of Correct Responses during the Delay Task according to the threshold scores (Gordon, 1987) shows the children performed in the normal range across all conditions compared to their same-aged peers. A ceiling effect therefore may explain the failure of this variable to detect any medication effects.

In contrast, the Commission Errors were categorized as representing abnormal performance at Baseline with treatment scores improving to the borderline level. That is, all children initially performed in a manner indicative of having significant difficulties restraining behaviours. Upon entering treatment they appeared to have improved their performance. Examination of the testing sequence revealed a start-up practice effect from first to second presentations of the task with no subsequent changes. In other words, the children appeared to have mastered aspects of the task irrespective of treatment. This situation would suggest that, in future assessments using this variable, the task demands are selected to increase the cognitive load and thus tap aspects of impulsivity beyond the described effect. The fact that the means change in the direction of medication improvement of behaviour buttresses this argument.

Previous cognitive assessments of medication efficacy on improving impulsivity in preschool-aged ADHD children have been equivocal as well. Cohen et al. (1981) and Schliefer et al. (1975) indicated positive changes associated with medication treatment however Conners (1975) did not. On the other hand, parental ratings of changes in the behaviour of this age group have been reported to be sensitive to medication effects (Cohen et al., 1981; Conners, 1975; Schliefer et al., 1975).

Behaviourally, the children present a different picture as rated by their parents. Despite the apparent lack of efficacy of MPH in ameliorating impulsivity as assessed by cognitive tasks, parents reported a significant difference in the intensity of the negative behaviours expressed by their children. This effect parallels findings with school-aged children (Barkley, Fischer, Newby & Breen, 1988; Nolan & Gadow, 1994). On the Conners' Hyperactivity Index subscale, parents reported a decrease in behaviours associated with ADHD. Both doses were effective in reducing negative behaviours, whereas only the higher dose was effective in reducing inattentive behaviours. Thus it may be the differential dose response discussed earlier may also be an issue when parental ratings are considered. The ramifications of this pattern, important in the consideration of clinical effects and treatment choices, are discussed below.

Examinations of the means shows that parental expectations played a role (Baseline scores significantly greater than Placebo scores). Barkley (1990) and Fischer and Newby (1991) have reported sequential administrations of the Conners instrument can produce an apparent improvement in the child's scores however the absence of order effects in this study supports these findings. Thus, it may be suggested that the decrease obtained in Hyperactivity Index scores from Baseline to Placebo reflects

parental expectation to receiving intervention for their child or a change resulting from re-testing.

In summary, cognitive measures of impulsivity used in this study were not successful in detecting medication effects. Several reasons may be proposed for this. First, the children appeared to have performed within the level of non-ADHD peers and thus no apparent improvement was obtainable with medication treatment. Second, task parameters may not have been sufficiently demanding to compensate for the observed start-up practice effect.

With respect to impulsive/hyperactive behaviours associated with ADHD and as perceived by the parents, the findings are clear and congruent with the large number of studies with school-aged children. Parents reported a change in the positive direction with respect to their child's behaviours. Insofar as the Hyperactivity Index assesses a decrease in negative behaviours associated with ADHD, medication appeared effective in reducing the frequency of such behaviours. Differential dose response of attentional and behavioural factors were noted within parental rating subscales as they were between cognitive tasks and rating scales. The apparent lack of congruence between the cognitive tasks and the parent observations may be attributed to task dimensions. That is, cognitive tasks assess the ability to

increase positive responses whereas parents assess the reduction in negative responses. These may not represent converse or complementary behaviours.

Interactive behaviours. Medication effects on the child's response to the parent was assessed by determining the degree of compliance obtained by the parent during several tasks. In general, this measure proved to be insensitive to detecting medication effects. The children did not change in their level of compliance to parental requests.

Previous research with preschool-aged children has demonstrated medication effects on the percent of compliance (Barkley et al., 1984, 1985) and on the duration of compliance (Barkley, 1988a). However, the children in these studies represented a large age range (3 to 10 years old) and there is no clear indication of the medication responses of the very young children who participated.

Although parents reported observing positive changes in their children related to medication treatment, the children were not more likely to do the things asked of them in the various tasks. It is possible that the short-term nature of the treatment in the present study did not provide sufficient time for change in the parent-child relations.

Side effects. No changes were reported with respect to the number or intensity of symptoms usually noted as side effects of MPH treatment. It appears very young ADHD children are similar to older children in that they did not experience increases in the numbers and intensity of side effect symptoms following MPH treatment.

Results similar to the findings in this study have been reported in previous studies of side effects in children treated with MPH (Barkley et al., 1990; Fine & Johnston, 1993; Fischer & Newby, 1991; Pataki, Carlson, Kelly, Rapport & Biancaniello, 1993). However, none of these investigations noted the presence of these symptoms at pretreatment. This point is important particularly in view of the individual nature of response to medication treatment. Levy (1993) indicated that the reasons for variation in response may be the result both of individual variation and pharmacological action. Insofar as individual children may differ at the outset of the treatment in their susceptibility to side effects of MPH treatment, this may differentially impact the behavioural system under observation.

In addition, Ahmann, Waltonen, Olson et al. (1993) noted that high-baseline rates of the behaviours assumed to reflect side effects may be in fact behaviours associated with ADHD.

Furthermore, the pre-existing nature of these behaviours may be a function of parents actively seeking treatment by over-estimating the intensity of the difficulties at baseline. The treatment response in either case may be an over-estimate of the actual benefits of the medication.

Parental Response to Child Medication Status

Models of interaction. Reciprocity effects (Bell & Harper, 1977) are believed to underlie the observations of a negative cycle of parent-child interaction. In an extension of this theory, Patterson (1982) proposed a Coercion model of parent-child interaction in which negative behaviours on the part of one member of the system produced or exacerbated negative behaviours in the other. The assumption implicit in studies which examined the model was that changing one aspect of the system would produce changes in the corresponding unit (Barkley & Cunningham, 1980). That is, given the existing negative interactive cycle between parent and child, a change in the positive direction with respect to the child's behaviour may result in a corresponding change in the parent's behaviour. Thus, it was hypothesized that positive changes obtained in the children's behaviours via medication may result in changes in the parent's ability to interact with the child.

Parental skills. As assessed during the Compliance, Dot-to-Dot and Cancellation Tasks, the degree to which parents directed the child's behaviours (Percent of Commands) or responded to compliance (Percent Reinforcements) was not related to MPH treatment of the child. The single significant result that was obtained was ambiguous in clarifying this relation.

In contrast, previous research has indicated parental attempts at directing behaviours decreased following medication treatment (Barkley, 1988a; Barkley & Cunningham, 1979, 1980; Barkley et al., 1984, 1985). Specifically, in these studies mothers used fewer statements that constituted commands when their child was in the medication condition. It should be noted that there were no differences between the present study and others in the level of MPH dose; efficacy in the earlier studies was obtained using a range of 0.15 to 1.4 mg/kg MPH. However, other factors may address the apparent absence of agreement between previous and present investigations.

First, the children participating in the Barkley studies ranged in age from 3 to 10 years. The responses to medication treatment of 4 to 6 year old groups in these studies is not known.

However, Barkley et al. (1984) indicated Age X Dose interactions were not significant suggesting the changes reported for the

total sample collapsed across age was representative of each of the age groups.

Second, differences in the children's behaviour between studies may account for differences in the findings with regard to the parents' behaviour. The Barkley studies reported significant changes in the children's degree of compliance and off-task behaviours. The children in this study did not increase their degree of compliance to the parents' direction. It may be inferred from the tenets of the Reciprocity theory that increasingly positive behaviour on the child's part would accompany similarly positive behaviours on the parents' part. Thus, it is possible that in the present study the absence of changes in the child's compliance presented a situation that was inherently different from Barkley's studies. In this light, it is therefore noteworthy that the parents' behaviours remained unchanged, that is, did not become more directing, in the face of continued noncompliance by the children.

Finally, the analogue setting of the measurement of parent skills may present a truncated version of actual events. Parents, via rating scales, report medication-related changes in their children's behaviours. It is possible that parental skills may have been affected in the environment that was the focus of the

rating scales. In other words, changes in situations other than the laboratory setting were not obtained and may present a different picture of the changing relationship between parent skills and child behaviours. Furthermore, changes to a system such as parent-child relations may require longer term intervention than the short-term nature of medication treatment in this study.

Parent style. The overall response by parents to involvement in the treatment of their child was to use fewer negative and more positive statements in their interactions. However, these changes did not necessarily correspond to the child's medication status. Furthermore, parents' behaviours during the Dot-to-Dot and Cancellation Tasks appeared to differ in subtle ways.

In the Dot-to-Dot Task, the parent was asked to interact closely with the child. Whereas the parent's positive statements may reflect a non-specific treatment response, the frequency of negative statements were a function of changes in the child's behaviours. Examination of the child's behaviour during this task shows the higher dose produced relatively greater productivity and the longest time on-task for the Dot-to-Dot designs. It is therefore possible that parents had fewer

occasions to make comments focused on negative aspects of the child's behaviours.

Parents' behaviours provide a different picture when the children are expected to work on their own during the Cancellation Task. In general, parents appeared to engage in a more positive style during the task. Both positive and negative statements follow a similar pattern across doses. However, only the parent's positive style improved significantly and only when the child had been treated with the higher dose. Although not significant with respect to its relation to medication, the amount of time the child remained on-task and the accuracy of the output increased in the expected direction. Thus it is suggested that the parent may have had more occasion to respond positively.

Previous research with this age group is equivocal with regard to parental positive and negative behaviours. Barkley et al. (1984) indicated that maternal negative behaviours did change significantly following their children's treatment with 0.5 mg/kg dose MPH however a later study (Barkley et al., 1985) reported no changes.

One noteworthy and descriptive point during this task is the relatively lower amount of time spent on-task and productivity of

the children during the Placebo condition. This is paralleled by the decrease in positive and increase in negative statements made by the parent in this condition. It is possible that medication related changes in the children that were undetected are, ironically, only noticeable in comparison to the absence of the medication treatment.

Parent stress. The overall pattern of parent-reported stress decreased as a function of treatment of conditions. However, the change obtained cannot be attributed unequivocally to medication alone. The absence of difference between the medication conditions and Placebo does not allow a determination of the psychological components that may have augmented the treatment response. Nevertheless, parents report decreased stress related to their child's behaviours and characteristics. Whereas the stress related to factors associated with their parenting role also decreased, it was not independent of the factors related to the children. This suggests that the primary source of parental difficulties may lie in their perception and experience of the child's characteristics.

The medication-related reduction of stress associated with very young children's characteristics and their parents' functioning has not previously been examined. However, Mash and Johnston

(1983) reported negative child behaviours and distractibility were the primary contributors to parenting stress. Thus, it is understandable that the amelioration of these features of ADHD would have contributed to the decrease in the parents' stress levels.

Clinical Changes with Treatment

Positive Response to MPH Treatment

As suggested earlier, statistically significant changes were matched with the clinical picture of change. Not surprisingly, clinical change analyses showed the number of children responding reliably and positively varied with the instrument used to assess change. Compared to the cognitive tasks, the parent ratings picked up more children who had responded favourably to medication. Using the cognitive test of sustained attention (Gordon Vigilance Task) 60-75% of the children were categorized as not changed following treatment with both doses of MPH. Although some children were noted to have improved or normalized, the overall shift to the positive direction was not different between Placebo and MPH conditions.

Parent-ratings of the children's attention and negative behaviours, on the other hand, noted differences between

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treatments in the numbers of children who responded positively. With respect to the number of children who demonstrated attentional improvement with medication, the higher dose clearly affected more children than did the lower dose. Three-quarters of the group were noted to have improved or normalized with the higher dose whereas 41% of the children showed similar changes with the lower dose. With respect to negative behaviours, the lower dose appeared effective for 75% of the children with 87% rated as improved or normalized when treated with the higher dose.

Three points are noteworthy. First, many children were assessed as having normalized their behaviours. Both inattentive and negative behaviours responded to treatment with 0.5 mg/kg to a degree that the approximately 40% of the children were rated by their parents as not different from non-ADHD children. Second, the rate of deterioration as assessed by all measures was relatively low and statistically nonsignificant, ranging from 0 to 12% for the two MPH dose. Thus, it appears the treatment of very young children with MPH did not result in deleterious effects with respect to attentional abilities or exacerbation of negative behaviours.

Finally, this pattern of dose response is supported in the statistical changes as well. That is, unequivocal medication effects for attention were associated with the higher dose whereas behaviour changes were associated with both doses of MPH. This pattern of differences in doses for the attention and behavioural components of ADHD has been noted by Sprague and Sleator (1976, 1977) and alternative findings were discussed extensively in subsequent examinations of medication effects (Barkley, 1990; Conners & Wells, 1986). In the present study, the convergence of statistical and clinical information appears to suggest that for some children the two factors comprising ADHD may require different treatment doses. However, the absence of significant deterioration and side effects indicates the doses used may not have been sufficient to determine optimal or upper limits of medication efficacy.

Only two previously published studies using the Reliable Change Index for assessments of clinical change are available for comparison. DuPaul et al. (1994) reported approximately 60% normalized and approximately 20% of the school-aged children in their study improved in their ADHD-related behaviours. However, comparisons are restricted by the fact that they examined changes in a group of school-aged children assessed with differing degrees of internalization scores.

Rappoport et al. (1994) assessed MPH treatment of 76 school-aged children with ADHD. They reported 53% improved in academic functioning, 76% improved or normalized on attention measures and 94% improved or normalized as rated by their teachers.

Specifically, teachers' ratings showed the children treated with equivalent doses (5 mg and 10 mg) responded at approximately the same rates as reported in the present study.

These results imply that the assessment of optimal dose for treatment improvement may be dependent upon the aspect of ADHD chosen as the indicator of improvement. By inference it would be important to determine the sensitivity of the measure chosen to assess the attention or behavioural factor. Finally, the differences in dose response of many children suggests that pretreatment profiles may play a significant role in obtaining positive change at different doses. That is, children presenting predominantly as inattentive may require a different medication treatment regimen from those presenting as impulsive-hyperactive.

In summary, many of the children who were treated with MPH responded favourably with respect to the attentional and behavioural components of ADHD. Differences in the response rates between the two components are important considerations in treatment decision-making. Most of the children were noted by

their parents to exhibit improvements in attention only when treated with the higher dose. However, behavioural improvements were reported in most of the children with at least the lower dose. This suggests that the determination of treatment improvement may be dependent upon the aspect of ADHD chosen for examination, the measure chosen to determine improvement and the pretreatment profile of the child being treated. Nevertheless, it is important to note there were no increases in side effects with the higher dose and few children assessed as having deteriorated in their behaviours.

Clinical Change with Placebo Treatment

As assessed by the Hyperactivity Index, 42% of the children responded to treatment with a placebo. These children differed from those who did not demonstrate a placebo response in being more impulsive, less attentive, less compliant to parents and receiving of less reinforcement. The extreme nature of these baseline scores may impact on the accurate assessment of treatment outcome in many ways. First, they may indicate children with a different set of psychological and social factors that impinge on treatment progress. Second, there may be a 'regression to the mean' effect that overestimates or obscures the benefits of medication treatment (Lasgna, Mosteller, von

Felsinger & Beecher, 1954; Rosenzweig, Brohier & Zipfel, 1993; Shapiro, Struening & Shapiro, 1980).

Re-examination of the data using 58% of the sample who were placebo non-responders indicated the pattern of statistical responses obtained for the whole sample was stable. Despite the positive direction of change in the cognitive scores, none achieved significance. Support for medication responses may have been limited by the smaller sample size and loss of power to detect changes.

However, the effects as assessed by the parent-rating scales were reproduced. It is noteworthy that the placebo effect detected with the total sample using the Hyperactivity Index was not reproduced with the selected subsample. It is possible, therefore, that the placebo responders in this study may have attenuated the overall medication effects obtained with the total sample.

The patterns presented by parent-child interactive tasks were difficult to interpret and comparisons were not profitable. It is possible that the many subtle factors involved in these interactions do not allow for a simple dissection into placebo responders and nonresponders. Furthermore, given these tasks

assessed parent and not child behaviours, division of the sample on the basis of child behaviours may not be relevant to clarifying parent behaviours.

Methodological Issues in the Assessment of Medication Effects

Sampling Issues

Referral bias. There are several issues related to the type of sample obtained in this study. Some are related to the characteristics of the participating children and others may relate to the parents' need to seek immediate assistance. The participants were comprised of direct referrals to the study and to the Psychology Department. As such, these children may represent an extreme in behaviour and cognitive abilities than might be sampled from the general community. Additionally, few of these children had begun school. Thus the pervasiveness of their behaviours and the extent to which there were attentional difficulties in highly structured settings was not known. Finally, many of these children were referred because of disruptive behaviours and not specifically because of attentional difficulties as might be the case with school-based requests.

The limited availability of treatment options may also introduce a bias in the participating sample. In addition, the frequently

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stated association of family problems with ADHD (Rae-Grant, Thomas, Offord & Boyle, 1989) may provide impetus in families to seek a treatment modality that has the appearance of rapid amelioration of symptoms.

Referral to the study provided parents with the opportunity for assessment and possible treatment within a relatively short period of time. It is possible that parents who chose to participate were those whose children were experiencing significant difficulties. Although limited by unequal sample sizes this assumption is supported in the present study with parents who did not choose medication treatment reporting a lower intensity of child behavioural problems than those who chose medication treatment.

Thus, the generalizability of these results may be limited to the proportion of children who present with primarily disruptive behaviours within the home and family. Furthermore, parental needs may have dictated participation in the medication phase and thus, resulted in an indeterminable effect with respect to expectancies. As was noted in the results, however, exclusion of the behaviourally extreme group did not change the pattern of outcome measures.

Gender. The sample consisted primarily of boys (83%) with the ratio of boys to girls somewhat higher than usually reported (Szatmari et al., 1989). Consistent with the boys, the four girls were referred for treatment of behavioural difficulties and presented a similar diagnostic profile. The small number of girls in the sample precluded gender-related analyses and the effects of a mixed-gender sample could not be evaluated.

Although studies have proposed no differences between genders with respect to the risk for ADHD (Faraone, Biederman, Keenan & Tsuang, 1991), there have been suggestions that girls who meet the criteria for ADHD may present with a different profile (Horn, Wagner & Ialongo, 1989; Schachar, 1991; Szatmari et al., 1989). However, studies investigating the dimensionality of the disorder (Bauermeister, Alegria, Bird, Rubio-Stipec & Canino, 1992; Cantwell & Baker, 1992) did not include gender analyses. Thus, the possibility that attentional difficulties relate to gender remains unresolved.

However, gender comparisons have been addressed with respect to treatment outcome. Previous medication studies have examined changes in behaviours and interactions of girls and boys and reported no differences related to gender (Barkley, 1988a; Pelham, Walker, Stueges & Hoza, 1989). Although it may be

reasonable to assume a similar effect for this present study, such conclusions must be drawn with some caution pending further examination of potential diagnostic profile differences between genders.

Measurement Issues

Age-appropriate instruments. Despite the extensive number of available instruments measuring aspects of attention and impulsivity, there remains a limited number of well-calibrated and validated tools for the preschool-aged child. Previous studies have used impulsivity measures derived from tests such as the ECFFT (Schliefer et al., 1975) and the Cookie Delay Task (Campbell, 1990). However, these have either not been established as sensitive to detecting treatment effects or have not been validated with this age group.

The Porteus Mazes Test used in the present study represents such an instrument. Lacking normative data for this age group and a consistent pattern from previous use in medication studies, it is difficult to assess reasons for its inability to detect changes across treatment conditions. On the other hand, despite the availability of preschool normative data and established sensitivity of the Gordon Delay and Vigilance Task, the children's difficulty grasping the task instructions raises

questions of the relation between cognitive maturity and task success.

Re-testing. Practice effects due to the frequent testing required in medication studies is perhaps an unavoidable aspect of this paradigm. Whereas order effects were not detected, it is reasonable to assume that repeated exposure to tasks such as the Mazes and the Gordon Tasks increased familiarity with the task demands. The extent to which this enhanced performance cannot be fully determined beyond conducting order and practice effects analyses. However, in the context of dealing with children whose attention and impulsivity may be effected by re-exposure, this issue becomes critical.

The interactive tasks were particularly susceptible to the effects of re-testing. Despite the absence of order and practice effects, it was apparent from observation that with repeated exposure the children became attuned to aspects of the task and responded with a variety of behaviours ranging from statements of frustration at being asked again to anticipation of aspects of the task. Although these responses provide some clinical insight to the idiosyncratic repertoires of the children, it would be instructive to determine the impact of these reactions on the

ability of each task to tap into the dimensions of attention and impulsivity.

Dose selection. The use of different doses of medication in various studies limits direct comparisons and there is seldom a clear rationale for the dose selected. However, with both very young and older children effective treatment has been obtained with a variety of doses. Although there have been discussions of the relative merits of the fixed dose (i.e., 5 mg, 10 mg) and the weight-determined dose (0.3 mg/kg, 0.5 mg/kg), these represent singular treatment conditions. That is, it is unknown whether the specific dose selected is sufficiently potent for each child being treated.

An alternative method of determining the optimal treatment for a child is to use a titrated method of treatment in which the dose is increased until therapeutic effects or significant side effects are noted (Barkley, 1990). Assessment of change at the titrated dose levels may account for individual null or negative responses due to doses that may have been too low or too high. Furthermore, titration of the dose levels allows for a determination of optimal doses related to changes in attention and behaviour.

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The treatment conditions selected in this study represent a conservative estimate of the most effective doses based on previous studies with this age group. As such it may have resulted in a range of medication levels that were not sufficiently high or of large enough separation to achieve differential results between doses. The absence of significant side effects also suggests that a dose higher than the one selected might have been reasonable and safe to use.

Clinical Issues in the Use of Medication

Child-related Issues

Whalen and Henker (1980) have presented a compelling model of the direct and emanative effects of stimulant medication treatment of the child. Direct effects relate primarily to the child and subsume efficacy, side and iatrogenic effects. Clinical implications of the ethics of treatment selection, dose effects and conjunctive treatments available for the child also are discussed.

Ethics. The ethics of intervening with children who have not initiated their own treatment remains a complex, difficult and unresolved issue (Keith-Spiegel & Koocher, 1985). Preschool-aged children are categorized as one of many vulnerable study

populations requiring particular care in the decision to recruit for investigations or clinical treatment. Whereas older children have the capacity to reason and engage in treatment consent, the very young child may not be viewed as capable of such participation in treatment decision-making. As such, responses during all phases of assessment requires careful monitoring with respect to the children's ability to tolerate the sessions and any treatment effects.

The theoretical perspective of the researcher also falls within the context of the ethics of treating and conducting research with young children. Keith-Spiegel and Koocher (1985) argued that assumptions of poor outcome without treatment can result in a greater willingness of researchers to utilize treatments by rationalizing the apparent cost-benefit ratios.

The potential pitfall of this reasoning process becomes apparent when medication use is justified from longitudinal studies indicating poor outcome. For example, the reports of continuing difficulties among children diagnosed at a very young age (Fischer et al., 1984; Offord et al., 1992) has often been invoked as rationale for early intervention. Although such deductions may be logically accurate, they are incomplete and the proportion

of children whose difficulties abate must also be considered in any treatment decision-making conducted with parents.

Dose response. As a group, the children in the present study responded to the two doses of MPH in a manner similar to older children. However, individual responses were also apparent. First, as observed during assessments and from reports by parents, some children responded with irritability and increased whininess when administered the lower dose but improved with the higher dose. The reason for this response is not clear but it is apparent that idiosyncratic responses must be considered in the determination of dose levels for any child. Furthermore, rating scales and laboratory tests did not tap into these specific responses to medication treatment suggesting the necessity for close monitoring and examination of issues beyond treatment outcome data.

Side effects during each dose level did not appear to be deleterious to the positive effects of treatment. However, two children were withdrawn from treatment following the appearance of a rash and tics. Both children had received the higher dose as the initial MPH treatment. Rash as a side effect is a recent listing in the Compendium of Pharmaceuticals and Specialities (1995) and does not appear in the previous edition. Thus, little

is known about the origins of this response and it is not recorded in any recent studies. The tendency of MPH to exacerbate tics has been well-documented (Barkley, 1990; CPS, 1995) and this propensity was often cited as a contraindication of MPH in treating ADHD comorbid with Tourette's Syndrome. Both children's responses argue, therefore, for careful initial assessment with regard to histories of allergies and other syndromes that should be considered in the use of MPH.

Finally, in the context of history, preassessment is as necessary as obtaining placebo measures in the effective determination of dose response. As is evident with some of the outcome data presented here, the difference between baseline and placebo measures were crucial in determining the actual contribution of medication components to the final improvements. Fischer and Newby (1991) noted clearly that the presence of placebo effects provide a cautionary statement in any conclusions of medication efficacy. Further to this, the presence of placebo effects may also indicate the presence of other important clinical markers in the form of parental expectations that may require consideration.

Auxiliary and alternate treatments. The premise of medication treatment is the stimulation of excitatory and inhibitory sites providing more efficacious access to these

regulatory mechanisms (Tannock, Schachar, Carr, Chajczyk & Logan, 1989; Tannock, Schachar & Logan, 1993). However, it must be noted that neither process provides compensation for past missed opportunities to learn positive behaviours. In other words, enhanced ability to attend may not be synonymous with enhanced ability to make positive use of the now-attended information. Achieving this latter may therefore require auxiliary interventions with the child for whom medication performs a preparatory function.

However, there are few alternative treatments available to the ADHD preschool-aged child. Although Barkley (1991) noted several means of intervening with families and older children, he has suggested that medication treatment may remain the primary mode of intervention for very young children. Similarly, Weiss and Hechtman (1993) note there are very few systematic studies of treatment modalities thus limiting choices for alternative or adjunctive therapies. In fact, Whalen and Henker (1991) argued that stimulant medication treatment meets most of the criteria they propose in their incisive evaluation of different treatment approaches. On a more positive note, DuPaul and Stoner (1994) listed several methods to enhance preschoolers' attentional abilities in school situations but do not relate this to issues of medication treatment.

Nevertheless, the effects of non-medication interventions in the treatment of ADHD have not been studied as extensively as the effects of medication. Furthermore, there is little evidence with school-aged children that these interventions are more effective in the reduction of the correlates of ADHD (Firestone et al., 1981; Ialongo et al., 1993).

Parent-related Issues

Inter-relationships comprise Whalen and Henker's (1980) second level of influence and, in the context of the present study, this focuses on the clinical implications of medication treatment on the parent-child system. Changes in the parents' behaviour form one aspect of inter-relational issues. Lesser known and understood aspects include the process of decision-making in treatment selection and the meaning of the use of medication to the parents' understanding of their role.

Parent behaviours and stress. It is instructive that in this study the greatest number of indeterminate results were obtained during the parent-child interactive tasks. This may be due to the short-term nature of the intervention. However, the equivocal nature of the outcome data of this and other studies suggests that detecting changes in parental behaviours may require more careful thought and examination.

The premise of the Reciprocity Theory (Bell & Harper, 1977) is that each member of the unit is equally susceptible to change by the other. However, each unit may also be influenced by its own internal psychological (and perhaps, physical) components (Lahey, Russo, Walker & Piacentini, 1989). Mash and Johnston (1990) proposed a mediatory role of the parent's own characteristics in determining the parents' behaviour. Specifically, cognitions as they define parental roles may play a significant role in parent-child relationships.

To extend this proposal, insofar as the parental role includes concepts pertaining to responsibility for their child's behaviours, the use of medication may be viewed as an abrogation or an inability to fulfill that responsibility. These issues, as encountered in interviews with the parents, require further investigation with the intent of assisting parents in their treatment choice decision-making. Ultimately, careful assessment of the parents' expectancies, self-perceptions and sense of competence would be beneficial to understanding the recursive impact on their behaviours and may also enhance the probability of appropriate treatment selection for their child (Rostain et al., 1993).

A second factor relates to the generally high level of stress reported among families with an ADHD child (Fischer, 1990). This study may represent similar families in that half of the participants had experienced a disruption in the infrastructure by virtue of separation or divorce. The ADHD child therefore may represent only one of many stress-inducing factors in such a system. Thus, it may be unrealistic to expect changes produced in the child to generate changes in their parents. Living in demanding circumstances, these parents may require additional intervention that allows them to capitalize on the positive changes in their child.

Alternate and conjunctive interventions. The studies conducted by Pisterman and colleagues (1989, 1990, 1992) indicated parent-training was effective in changing parental skills and style. However, although Barkley (1990) discusses the benefits of parent-training/counselling interventions, it is not explicit that stimulant medication is concurrent with this type of intervention.

Most studies are comparative, examining differential effects of medication and parent-training (Firestone et al., 1981; Cohen et

al., 1981). It would be beneficial to determine not just the relative contributions of each modality but also any advantages to a particular sequence of treatment administration.

Specifically, the high level of disruptive of behaviours may require an initial administration of medication prior to attempting changes in parental behaviours. That is, it may be hypothesized that parent-training applied subsequent to may be more effective than if applied prior to or simultaneously with stimulant medication treatment of the child.

Future Directions

Assessment

Methodological issues discussed above indicate more research is required into the development of age-appropriate behavioural and attention measures. Cognitive tests conducted in an assessment situation present difficulties with respect to the absence of normative data, ability to discriminate clinical populations and, in many cases, separating impulsive from inattentive behaviours. Whereas it is acknowledged that some of these issues arise with measures used for older children, the availability of reliable and valid measures for the younger children remains an area in need of more investigation.

Interactive measures are perhaps in greatest need of validation as appropriate measures in the study of ADHD. At present, these measures serve primarily as laboratory assessments with only an inference of ecological validity. Again, the relation of behaviours observed in these limited situations to those in the home or school remains to be assessed.

The impact of the rapid developmental changes evidenced in very young children may present a challenge in determining the future usefulness and sensitivity of many measures. In the context of short-term assessments, this may not be an issue, however, long-term follow-up assessments will require instruments capable of discriminating labile from intractable behaviours.

Finally, the reported sensitivity of any one measure to detect clinical response can result in its acceptance as a measure of treatment outcome. However, treatment choice issues and clinical recommendations often are based on traditionally accepted measures and cut-off scores. There is currently little assurance of the stability of these outcome measures with respect to treatment response. Thus, the issues related to the selection of any one measure and the definition of what constitutes a reliable clinical change is imperative in studies of treatment efficacies.

Treatment

The options for treatment for the preschool-aged ADHD child are not as extensive as they are for older children. Direct interventions are focused on the use of medication whereas indirect methods rely on the parents as mediators of behaviour change. Within this context, several areas require closer investigation.

Further study into the range of MPH doses would provide useful information with respect to minimal and maximal doses required for clinical effectiveness on different aspects of ADHD. As well, concerns about cost-benefit ratios of effectiveness and negative effects can be addressed. Issues such as differential dose responses of cognitive and behavioural factors continue to require in-depth exploration. Although the present study reported a relatively high rate of responders, null and adverse responses to MPH require further investigation. In extension of this point, the pre-existing nature of some symptoms usually considered side effects of MPH and the possibility that they may reflect temperamental issues requires validation with a non-clinical sample.

Gender issues have not received much attention with respect to assessment and treatment of ADHD. Whether this is a result of

the lower proportion of girls diagnosed with ADHD or a deeper issue related to gender differences in the diagnostic process remains unclear. Insofar as girls may present with a different profile or experience a different development of the disorder, treatment options will be affected. Regardless, girls remain a seriously under-examined sub-group of children presenting with behavioural and attentional difficulties.

Whereas parent-training programmes have reported success in obtaining some changes, comparative studies would clarify whether they are preferred to the invasiveness of medication treatment. More importantly, it would be of greater value to determine whether and in what manner parent-training and medication can play an adjunctive role in treatment. It has been suggested above that a sequential treatment paradigm may provide more information on the parent-child dynamic and perhaps be more efficacious.

Summary

This investigation into the efficacy of MPH in the treatment of very young children diagnosed with ADHD has resolved some questions but raised many others. The results indicated that MPH was effective in alleviating symptoms of inattention as assessed by laboratory tests and parent rating scales. Although parents

rated negative behaviours as having decreased as a function of medication, these behaviour changes were not detected during the interactive tasks. In general, parent-child tasks were poor measures of the effectiveness of medication in changing the parents' behaviours or the parent-child dynamic.

Although dose responses changed in the expected direction, the only differences between doses were detected by the parents' ratings of their child's behaviours. This may have been related to the relatively conservative doses selected. In fact, the absence of notable side effects suggested the dose selection may have been conservative in balancing against negative effects.

In conclusion, the preschool-aged child with ADHD represents an under-examined population. This study has attempted to address some issues of the effectiveness of MPH and the areas within which medication is effective. Future research will require a focus on both methodological and clinical issues specific to this age group. Additional corroboration by other studies would provide a secure base of information for the recommendation of MPH in the treatment of preschool-aged children with ADHD.

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Appendix A

Diagnostic Interview for Children and Adolescents - Parent Version

- How old is your child?
- When is his/her birthday?
- What grade is (s)he in?
- Has (s)he ever failed a grade?
- What are his/her favorite subjects?
- Does (s)he play any sports?
- Does (s)he get along O.K. with his/her teacher(s)?

Attention Deficit Disorder

--In this section I will ask you questions about how your child gets along in school and at home. I'll be asking mostly about grade school. Some of these things may have happened in the past and not be happening any more. However, if they are still happening please let me know. O.K. are you ready? Y to continue

- Has your child ever had trouble in school because (s)he found it hard to stay in his/her seat?
- How often did that happen? That (s)he found it hard to stay in his/her seat?
- Is (s)he still like that?
- Has there ever been a time when people were always telling your child to sit still or to stop moving or squirming about?
SAMPLE ONLY
- How often did that happen? That your child had problems with moving or squirming about?
- Is (s)he still like that?
- Has there ever been a time when it was hard for your child to play quietly, either by him/herself or with other kids?
- Is (s)he still like that?
- Did people ever tell your child that (s)he talked ALL the time or that (s)he NEVER stopped talking?
- Is (s)he still like that?
- When (s)he worked in school or when (s)he was doing homework, did you often feel that (s)he was daydreaming or thinking about something else?
- When your child was playing alone or with other kids, would you say that (s)he would get restless pretty quickly and want to move on to something else?
- How often did that happen? That your child ended up wanting to move on to something else, even if the other kids weren't ready to stop?
- Is (s)he still like that?
- Did your child ever have problems in school because even after the teacher explained the lesson to the class, your child was still not sure what (s)he

was supposed to do?

--Was there a time when it was hard for your child to keep his/her mind on what (s)he was doing, when there were other things going on in the same room?

--Is (s)he still like that?

--Did the teacher or did other people complain that your child interrupted them or butted into their conversations or games?

--Is (s)he still like that?

--Has there ever been a time when you or the teacher felt that your child started answering questions before you finished asking them?

--Did your child find it hard waiting his\her turn when (s)he was playing with other children or waiting in line?

--Is (s)he still like that?

--Did people get upset with your child for doing dangerous things, like running out into the street without looking?

--How often did that happen? That people got upset with your child for doing dangerous things?

--Is (s)he still like that?

--Did your child get tired of doing one thing pretty easily? Then did (s)he move on to something else, even if (s)he hadn't finished what he/she was doing?

--Is (s)he still like that?

--Has there been a time when your child was always losing things things like pencils, notebooks, or papers from school?

--Has there been a time when you or the teachers often complained that (s)he was not really listening to them?

--Is (s)he still like that?

--You've told me about some problems your child has had. Do you remember if these problems started before his/her 7th birthday, or if they were happening in kindergarten? A..Before 7th birthday

--How old was your child the last time (s)he had these problems we've been talking about? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, press F4 to skip to grade box. Age:

--When your child was having these problems we've been taking about did they last for 12 months or longer. For example most of the school year?

--Would you say that these problems have interfered with how your child gets along at home or with his/her friends?

Medication: Preschool ADHD/211

--Has anyone ever take him/her to a doctor because of these problems you've been telling me about?

--Did the doctor give your child any medicine to help him/her with these problems?

Oppositional Disorder

--O.K! So far so good! Now we're ready for the second set of questions! Y to continue

--Does your child argue with you, his/her teachers or other adults a lot of the time?

--Does your child lose his/her temper with adults or with other kids a lot of the time?

--Does your child ever just refuse to do things that you, his/her teachers, or other adults have asked him/her to do?

--Do you, or other adults feel that (s)he does things on purpose to annoy or bug you/them?

--Do you, or other adults feel that your child is angry or crabby towards people a lot of the time?

--Does it seem as though people get on his/her nerves a lot of the time?
(Brothers and sisters don't count)

--When someone does something unfair to your child, does (s)he try to get back at them in some mean or spiteful way? For example, telling things about them that (s)he knew would get them into trouble or hurt their feelings?

--Does your child swear a lot or use what most people would say is bad language even in front of adults?

--Does your child tend to blame other people when (s)he makes a mistake, or when things goes wrong?

--In this section, we've been talking about things that seem as though they could be problems for your child. Do you remember how old your child was when these things FIRST started happening. Would you type in the age? Age:

--How old was your child the LAST time these problems happened? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Age:

--Did these problems last for six months or more? (For example most of the school year).

--Did these problems interfere with the way your child got along at home, at school or with his/her friends?

Conduct Disorder

--We're going to start the third set of questions! Y to start

Medication: Preschool ADHD/212

--Most kids do things that sometimes get them in trouble with their parents or teachers. I'm going to ask you about different ways that kids gets into trouble. O.K.? Y to continue

--Has your child ever been suspended from school?

--Has your child ever been expelled from school?

--Has your child ever skipped school? (Played hookey)?

--Has your child ever stolen anything like money from someone's purse, or shoplifted something at a store?

--What did (s)he steal?

--Has (s)he ever stolen anything else?

--Altogether, how many times has (s)he stolen things?

--How old was (s)he the FIRST time (s)he stole anything? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Age:

--How old was (s)he the LAST time (s)he stole anything? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Ag:

--Of course everybody tells lies or makes up stories to get out of trouble once in a while. I'd like to know if your child lies or makes up stories to get out of trouble A LOT of the time.

--Has your child ever set any fires (s)he wasn't supposed to set?

--Has your child ever run away from home overnight or longer?

--Has your child ever gotten into fights with other kids?

--Has your child ever mugged someone? Held someone up and robbed them?

--Has your child ever hurt a small animal like a cat or a dog, a gerbil or a hamster on purpose? Insects don't count. Neither does hunting.

--Has your child ever done anything on purpose to hurt another person or cause them pain?

--Has your child ever wrecked somebody's property?

--Has (s)he ever broken into a house, a building, or a car?

--Has your child ever forced anyone to do something sexual with him/her?

--Has your child ever been in trouble with the police or with juvenile court?

Separation Anxiety Disorder

--Some kids worry a lot about being away from their parents or away from home.

Medication: Preschool ADHD/213

I'm going to ask you some questions about how your child may have felt when (s)he was away from you or away from home. Some of these feelings may have happened when (s)he was younger, so be sure to think about his/her whole life. Y to continue

--Have there been times when your child was away from you, or other people (s)he loves, and (s)he worried a lot about something bad happening to them (like they might get sick or get hurt or die)?

--Have there been times when (s)he was afraid that you or another person (s)he loved would leave him/her and never come back?

--Have there been times when (s)he really worried that something bad might happen to YOU (like getting kidnapped or killed), so that (s)he couldn't see you or the other people that (s)he loved again?

--Have there been times when (s)he refused to go to school (or tried to stay home) because (s)he wanted to stay with you (or the other people that (s)he loved)?

--Have there been times when (s)he needed to have someone stay close to him/her at night so that (s)he could fall asleep?

--Have (s)he ever gone away from home for a few days, like visiting relatives and been so upset and worried that (s)he came back home right away?

--Has there ever been a time when (s)he was afraid to be by him/herself in a room at home?

--Have there been times when (s)he had bad dreams about being away from you, or other people that (s)he loved?

--Have there been times when (s)he had to leave for school or some place else and (s)he got headaches, or stomach aches, or felt sick to his/her stomach or even threw up?

--Have there been times when your child threw tantrums or cried and begged you to stay home when you had planned to go somewhere?

--Has your child ever had to be away from you or other people that (s)he loved and telephoned to make sure that nothing bad had happened to them?

--Did all these bad feelings of being away from you, or other people that (s)he loved, last only 1 or 2 days, or did they last longer - say on and off for about 2 weeks or longer.

--How old was (s)he the first time (s)he felt upset about being away from people that (s)he loved? If under 10, press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Age:

--When was the last time (s)he felt upset like that? Was it:

--How old was (s)he then? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Age:

Psychosocial Stressors

--Here is another set of questions. Y to continue

--Is there anything about your home or family that upsets your child a lot?

--Is there much fighting in the family? Lots of yelling and screaming?

--Have his/her parents separated or divorced?

--How old was (s)he when that happened? If under 10 press enter after the number. Also if you can't remember how old (s)he was, perhaps you can remember what grade (s)he was in. If you do, then press F4 to skip to grade box. Age:

--Are there big money worries like not having enough money for food or new clothes or to pay the rent?

--Does anyone at home drink too much?

--Does anyone from your home have problems with the police?

--Has anyone ever shoved your child or hit him/her or done anything to him/her that was really upsetting?

--Do you have any other big problems like we've been talking about?

Pregnancy/Birth

SAMPLE ONLY
---Now I'd like to ask you about the mother's pregnancy and the birth of this child. If you are not the child's biological mother, please tell me as much as you know. Y to continue

--When you (THE CHILD'S MOTHER) was pregnant with this child, did you have any problems with spotting or light bleeding?

--Did you (THE CHILD'S MOTHER) feel sick to your stomach or did you throw up a lot?

--Did being sick like that last longer than 3 months?

--Did you (THE CHILD'S MOTHER) gain a lot of weight (35 pounds or more) when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) lose any weight (10 pounds or more) when you were pregnant with this child?

--When you (THE CHILD'S MOTHER) was pregnant with this child, did you have any major illnesses for which you had to see a doctor?

--Did you (THE CHILD'S MOTHER) have any accidents for which you had to see a doctor, when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) have herpes or AIDS when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) take any medicine given to you by a doctor when you were pregnant with this child?

Medication: Preschool ADHD/215

--Did you (THE CHILD'S MOTHER) take any over-the-counter medicine like aspirin or cough syrup when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) have any emotional problems when you were pregnant with this child? For example, were you VERY depressed or VERY anxious? A lot more than is usual for you?

--Did you (THE CHILD'S MOTHER) smoke when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) drink any alcoholic beverages at all, when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) use marijuana at all when you were pregnant with this child?

--Did you (THE CHILD'S MOTHER) use any drugs like cocaine, crack, speed, acid or anything like that when you were pregnant with this child?

--Now I'd like to ask you some questions about the actual birth of this child. Y to continue

--Did you (THE CHILD'S MOTHER) have any problems at the delivery of this child?

--How long was your (THE CHILD'S MOTHER) labor? (code in hours)

--These next questions are about this child's first few months of life. Y to continue

--Was this child born prematurely?

--How much did the baby weigh?

--Did the baby have to stay in the hospital after you (THE CHILD'S MOTHER) went home?

Early Development

--Now I'd like to ask you some questions about this child's pre-school years.

If you are not the child's biological mother, please tell me as much as you know. Y to continue

--Was your child average when learning to sit up, crawl or walk?

--How about using words and sentences?

--Did you ever speak to the doctor because you were worried about your child's being slow at anything?

--Now I'm going to ask you about the pre-school years, when your child was under 5 years of age. Y to continue

--In the years when your child was under five, did you feel that (s)he was unusually difficult to raise?

--Was your child unusually active? Always on the go?

--Was your child very excitable, so that you dreaded taking him/her anywhere?

--Was your child very demanding and did his/her demands have to be met at

once?

--Was your child more clumsy than most of the other children? For example was (s)he slow to learn to run, jump, skip, or ride a bike?

--Did your child have temper tantrums after the age of 3½?

--Did your child have problems being away from you or other people who were taking care of him/her?

--Did your child tend to whine or cling?

--How did your child get on with other children?

--Did you have problems getting your child to sleep at night?

--Did (s)he wake up in the middle of the night?

--Did your child have a lot of nightmares?

--Has your child ever woken up at night and seemed to be absolutely terrified?

--Has your child ever had a problem with stuttering?

--During the pre-school years, did your child have any problems with his/her speech?

--Has there ever been a time when your child refused to speak, even though you know (s)he could speak? (Don't count it if your child wouldn't speak for a couple of hours because he/she was angry).

--Has your child ever eaten unusual things over a period of several weeks? Things like plaster, string, hair, pebbles, garbage or dirt?

--Has your child ever had lead poisoning?

--When your child was a pre-schooler, was (s)he an affectionate child? Did he/she like to cuddle up, hug or snuggle?

--Did your child have any problems looking at people when they tried to talk with him/her?

--Did it seem as though your child had a hard time understanding the difference between 'you' and 'I'. For example would (s)he say 'You want a cracker', when he/she should have been saying 'I want a cracker'?

--Did it seem as though your child wasn't very interested in other people and would just as soon play on his/her own?

--Did it seem as though your child didn't do very much pretending when (s)he was playing?

--Did your child spend time playing in unusual ways? For example, turning or spinning an object, making repeated hand motions, or flapping his arms as though they were wings?

--Did your child ever get upset if something was moved out of its usual place, or if you tried to go to the store by a different route?

--Was there anything unusual about your child's use of language? For example, instead of answering a question would (s)he just repeat some words over and over?

--Have you ever been told that your child was autistic or autistic like?

Appendix B

Swanson, Nolan and Pelham Questionnaire

SNAP

NO. SYMPTOMS: _____

COMPOSITE SCORE: _____

B #1 #2 #3

ID NO. : _____

Child's name: _____

Date: _____

Completed by: Mother _____

Father _____

OBSERVATION	Not at all	Just a little	Pretty much	Very much
SAMPLE ONLY				
A.				
1) Excessive running or climbing.	0	1	2	3
2) Difficulty sitting or excessive fidgeting.	0	1	2	3
3) Difficulty staying seated.	0	1	2	3
4) Motor restlessness during sleep. (Parents)	0	1	2	3
Motor restlessness. (Teachers)	0	1	2	3
5) Always on the go or acts as if "driven by a motor."	0	1	2	3
B.				
1) Often fails to finish things he or she starts.	0	1	2	3
2) Often doesn't seem to listen.	0	1	2	3
3) Easily distracted.	0	1	2	3
4) Difficulty sticking to a play activity.	0	1	2	3
5) Difficulty concentrating on school work or other tasks requiring sustained attention.	0	1	2	3
C.				
1) Often acts before thinking.	0	1	2	3
2) Excessive shifting from one activity to another.	0	1	2	3
3) Has difficulty organizing work -not due to cognitive impairment	0	1	2	3

OBSERVATION	Not at all	Just a little	Pretty much	Very much
4) Needs a lot of supervision.	0	1	2	3
5) Frequent calling out in class.	0	1	2	3
6) Difficulty waiting for turn in games or group situation.	0	1	2	3
D.				
1) Fights, hits punches, etc.	0	1	2	3
2) Is disliked by other children.	0	1	2	3
3) Frequently interrupts other children's activities.	0	1	2	3
4) Bossy, always talking other children what to do.	0	1	2	3
5) Teases or calls other children names.	0	1	2	3
6) Refuses to participate in group activities.	0	1	2	3
7) Loses temper often and easily.	0	1	2	3
E.				
1) Blurts out answers to questions before they have been completed.	0	1	2	3
2) Has difficulty playing quietly.	0	1	2	3
3) Talks excessively.	0	1	2	3
4) Loses things necessary for tasks or activities at school or at home e.g., toys, pencils, books, assignments.	0	1	2	3
5) Engages in physically dangerous activities without considering possible consequences (not for the purpose of thrill-seeking).	0	1	2	3

SAMPLE ONLY

OBSERVATION	Not at all	Just a little	Pretty much	Very much
F.				
1) Argues with adults.	0	1	2	3
2) Actively defies or refuses adult requests or rules.	0	1	2	3
3) Deliberately does things that annoy other people.	0	1	2	3
4) Blames others for his or her own mistakes.	0	1	2	3
5) Is often touchy or easily annoyed by others.	0	1	2	3
6) Is angry and resentful.	0	1	2	3
7) Is spiteful or vindictive.	0	1	2	3
8) Swears or uses obscene language.	0	1	2	3

SAMPLE ONLY

Appendix C

Peabody Picture Vocabulary Test - Form L

FORM L
TEST ITEMS AND ABBREVIATED INSTRUCTIONS

Administering the TRAINING ITEMS

For most subjects under age 8: Use Plates A, B, and C. Administer as many training item series as necessary to secure three consecutive correct responses. For most subjects age 8 and over: Use Plates D and E. Administer as many training item series as necessary to secure two consecutive correct responses.

ADDITIONAL PRACTICE WORDS & ACTS

Picture Name	Series 1	Series 2	Series 3	Series 4	Series 5
A	doll (1)	fork (1)	table (2)	car (3)	mouth (1)
B	men (2)	comb (3)	sock (4)	walking (1)	climbing (2)
C	swinging (3)	drinking (4)	roping (1)	rate (3)	royal (2)
D	wheel (4)	zipper (2)	ropes (1)	rate (3)	royal (2)
E	giant (1)	birds (3)	witch (4)	royal (2)	

(Complete directions are given in Part I of the Manual.)

Administering the TEST ITEMS

Best: Highest 8 consecutive correct responses
 Ceiling: Lowest 8 consecutive responses containing 8 errors
 Starting Point: For a subject assumed to be of average ability, find the person's age circled in the margin, and begin the test with that item. Otherwise consult Part I of the Manual for further instructions.
 Recording Responses and Errors: Record the subject's response (1, 2, 3, or 4) for each item administered. For each error, draw an oblique line either through the plate number of the item missed, or through the geometric figure, as illustrated below:

22 envelope (2) 4 or 32 envelope (2) 4 R
 Every eighth figure is identical to help determine the basal and ceiling.

NOTE:

Ages in circles refer to the lowest age in a 6- or 12-month interval. For example, item 1 is the starting item for ages 2-6 through 3-5, and item 30 for ages 5-0 through 5-5. Use item 110 for ages 16-0 and over.

Item	Picture	Age	Response	Item	Picture	Age	Response
10	lamp	(4)	△	44	dripping	(2)	□
11	drum	(3)	□	45	claw	(4)	□
12	knees	(4)	▽	46	decorated	(3)	□
13	helicopter	(2)	☆	47	frame	(1)	▽
14	elbow	(4)	◇	48	forest	(3)	☆
15	bandage	(4)	◇	49	faucet	(2)	◇
16	leather	(1)	□	50	group	(3)	○
17	empty	(3)	△	51	stem	(3)	□
18	fence	(4)	□	52	vase	(3)	△
19	accident	(2)	▽	53	pedal	(1)	□
20	net	(2)	☆	54	capsule	(2)	▽
21	fearing	(4)	◇	55	surprised	(4)	☆
22	sail	(1)	○	56	barfk	(2)	◇
23	measuring	(2)	□	57	mechanic	(2)	○
24	pecking	(3)	△	58	lambourne	(1)	□
25	cage	(1)	□	59	disappointment	(4)	△
26	fool	(4)	▽	60	awarding	(3)	□
27	square	(4)	☆	61	pitcher	(3)	▽
28	stretching	(1)	◇	62	reel	(1)	☆
29	arrow	(2)	○	63	signal	(1)	◇
30	tying	(2)	□	64	trunk	(2)	○
31	nest	(1)	△	65	human	(2)	□
32	envelope	(2)	□	66	nostril	(1)	△
33	hook	(3)	▽	67	disagreement	(1)	□
34	pasting	(4)	☆	68	exhausted	(2)	▽
35	patting	(1)	◇	69	vine	(4)	☆
36	penguin	(1)	□	70	ceremony	(4)	◇
37	sewing	(2)	□	71	casserole	(2)	○
38	delivering	(1)	△	72	vehicle	(4)	□
39	diving	(2)	□	73	globe	(3)	△
40	parachute	(3)	▽	74	filig	(3)	□
41	furry	(4)	☆	75	clamp	(2)	▽
42	vegetable	(4)	◇	76	replie	(2)	☆
43	shoulder	(3)	○	77	island	(1)	◇
78	spatula	(3)	□				
79	cooperation	(4)	□				
80	scalp	(4)	□				
81	twig	(2)	▽				
82	wessel	(2)	☆				
83	demolishing	(4)	◇				
84	balcony	(1)	○				
85	locket	(1)	□				
86	amazed	(3)	△				
87	tubular	(1)	□				
88	tusk	(1)	▽				
89	boil	(3)	☆				
90	communication	(4)	◇				
91	carpenter	(2)	○				
92	isolation	(1)	□				
93	inflated	(3)	△				
94	coast	(3)	□				
95	adjustable	(2)	▽				
96	fragile	(3)	☆				
97	essaulting	(1)	◇				
98	appliance	(1)	○				
99	pyramid	(4)	△				
100	blazing	(1)	□				
101	hoisting	(1)	□				
102	arch	(4)	▽				
103	lecturing	(4)	☆				
104	disappointed	(4)	◇				
105	contemplating	(2)	○				
106	carister	(1)	□				
107	dissecting	(3)	△				
108	link	(4)	□				
109	solemn	(3)	▽				
110	archery	(2)	☆				
111	transparent	(3)	○				

Appendix D

Conners Parent Rating Scale - Revised

Child Name: _____ Child Age: _____ Child Sex: _____ Parent Name: _____

Instructions: Read each item below carefully, and decide how much you think your child has been bothered by this problem during the past month.

Not at All	Just a Little	Pretty Much	Very Much	
0	1	2	3	1. Picks at things (nails, fingers, hair, clothing)
0	1	2	3	2. Sassy to grown-ups
0	1	2	3	3. Problems with making or keeping friends
0	1	2	3	4. Excitable, impulsive
0	1	2	3	5. Wants to run things
0	1	2	3	6. Sucks or chews (thumb, clothing, blankets)
0	1	2	3	7. Cries easily or often
0	1	2	3	8. Carries a chip on his/her shoulder
0	1	2	3	9. Daydreams
0	1	2	3	10. Difficulty in learning
0	1	2	3	11. Restless in the "squirmy" sense
0	1	2	3	12. Fearful (of new situations, new people or places, going to school)
0	1	2	3	13. Restless, always up and on the go
0	1	2	3	14. Destructive
0	1	2	3	15. Tells lies or stories that aren't true
0	1	2	3	16. Shy
0	1	2	3	17. Gets into more trouble than others same age
0	1	2	3	18. Speaks differently from others same age (baby talk, stuttering, hard to understand)
0	1	2	3	19. Makes mistakes or blames others
0	1	2	3	20. Quarrelsome
0	1	2	3	21. Pouts and sulks
0	1	2	3	22. Steals
0	1	2	3	23. Disobedient or obeys but resentfully
0	1	2	3	24. Worries more than others (about being alone, illness or death)
0	1	2	3	25. Fails to finish things
0	1	2	3	26. Feelings easily hurt
0	1	2	3	27. Bullies others
0	1	2	3	28. Unable to stop a repetitive activity
0	1	2	3	29. Cruel
0	1	2	3	30. Childish or immature (wants help s/he shouldn't need, clings, needs constant reassurance)
0	1	2	3	31. Distractibility or attention span a problem
0	1	2	3	32. Headaches
0	1	2	3	33. Mood changes quickly and drastically
0	1	2	3	34. Doesn't like or doesn't follow rules or restrictions
0	1	2	3	35. Fights constantly
0	1	2	3	36. Doesn't get along well with brothers or sisters
0	1	2	3	37. Easily frustrated in efforts
0	1	2	3	38. Disturbs other children
0	1	2	3	39. Basically an unhappy child
0	1	2	3	40. Problems with eating (poor appetite, up between bites)
0	1	2	3	41. Stomach aches
0	1	2	3	42. Problems with sleep (can't fall asleep, up too early, up in the night)
0	1	2	3	43. Other aches and pains
0	1	2	3	44. Vomiting or nausea
0	1	2	3	45. Feels cheated in family circle
0	1	2	3	46. Boasts and brags
0	1	2	3	47. Lets self be pushed around
0	1	2	3	48. Bowel problems (frequently loose, irregular habits, constipation)

SAMPLE ONLY

Appendix E

Information Sheet



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

THE PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT STUDY

THANK YOU FOR YOUR INTEREST IN OUR STUDY. We are hoping your child may be able to assist us in a study we are conducting on the medication treatment of child problem behaviour. The study will involve you and your child in the following way:

1. **APPOINTMENT #1:**
A screening interview which will give us information about your child.
2. **APPOINTMENT #2/#3:**
You and your child will participate in a set of tasks that will give us information about how he interacts with others.
3. **APPOINTMENT #4:**
We will meet to give feedback on our assessment for suitability. If YES, we will discuss the details of your continuing involvement. You will have some time to think about participating. We will call you in a couple of days for your answer.

If NO, you will be informed of the results of our assessment and given our recommendations.
4. **APPOINTMENT #5:**
A medical examination will be scheduled for your child. We will meet to sign the consent forms and answer any questions you may have. The medication will be prepared for your child and you will receive instructions on how to give the medication daily. We will call mid-week to check on your child's progress.
5. **APPOINTMENT #6/7, 8/9, 10/11:**
You and your child will participate in tasks to assess the medication. The second round of medication will be given to you for the next week.
6. **SUMMARY FEEDBACK:**
You will be given feedback on how your child has responded to the medication and our recommendations for treatment possibilities.

THERE IS NO CHARGE FOR ANY VISITS OR THE MEDICATION. IT IS VERY IMPORTANT THAT YOU PARTICIPATE IN ALL STAGES OF THIS STUDY.

CONTACT: LYNETTE MUSTEN (738-3279; 737-2492) OR DR. SUSAN PISTERMAN (737-2492).

Appendix F

Consent for Assessment



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT RESEARCH PROJECT

CONSENT FOR SCREENING

I agree to participate in the SCREENING phase of the Preschool Hyperactivity Medication Treatment Research Project as it has been explained to me; I understand that

1. my child will participate in various tasks designed to assess whether he meets the criteria for inclusion in this project;
2. as well, my interview information given to the researchers will be used to determine whether he meets the criteria for inclusion in this project;
3. I am not obligated to participate even if my child meets the inclusion criteria.
4. if he does not qualify for this project, it will not effect my child's position on the waiting list for assessment and/or treatment nor will it effect the type or quality of treatment available for him.

SAMPLE ONLY

Name (child): _____ Name (parent): _____

Parent signature: _____

Date: _____

Appendix G

Family Demographic and Composition Questionnaire

FAMILY DEMOGRAPHICS AND COMPOSITION

Subject name: _____ Birthdate: _____ ID# (1-3) _____
 Subject I.D. #: _____ Date: _____
 Parent(s) names _____ Age at intake _____ age (4-5) _____
 mother: _____
 father: _____
 Is your child currently in day care or kindergarden? _____
 (if yes, circle appropriate program) (Yes/No)

I. CURRENT MANAGEMENT

1. Mother
 How do you discipline? What do you try first when your
 child is disobedient?
 What do you try if that doesn't work?

SAMPLE ONLY

Do you ever?	0 = no	1 = yes		
Method		Use now	3 most effective = 1	Most Use Effect
a) spank (physical punishment)	—	—	1a)	(1) (2)
b) yell or threaten	—	—	b)	(3) (4)
c) remove priveleges (toys, T.V., dessert)	—	—	c)	(5) (6)
d) time-out or remove from situation	—	—	d)	(7) (8)
e) reason and explain	—	—	e)	(9) (10)
f) give praise or treats for good behaviour	—	—	f)	(11) (12)
g) ignore, leave room	—	—	g)	(13) (14)
h) redirect interest in something else	—	—	h)	(15) (16)
i) other _____	—	—	i)	(17) (18)

2. Father

How do you discipline? What do you try first when your child is disobedient?
 What do you try if that doesn't work?

Do you ever?	0 = no	1 = yes		
Method		Use now	3 most effective = 1	Most Use Effect
a) spank (physical punishment)	—	—	2a)	<u> </u> (19) <u> </u> (20)
b) yell or threaten	—	—	b)	<u> </u> (21) <u> </u> (22)
c) remove priveleges (toys, T.V., dessert)	—	—	c)	<u> </u> (23) <u> </u> (24)
d) time-out or remove from situation	—	—	d)	<u> </u> (25) <u> </u> (26)
e) reason and explain	—	—	e)	<u> </u> (27) <u> </u> (28)
f) give praise or treats for good behaviour	—	—	f)	<u> </u> (29) <u> </u> (30)
g) ignore, leave room	—	—	g)	<u> </u> (31) <u> </u> (32)
h) redirect interest in something else	—	—	h)	<u> </u> (33) <u> </u> (34)
i) other _____	—	—	i)	<u> </u> (35) <u> </u> (36)

SAMPLE ONLY

3. What does your child do when (s)he doesn't get his/her own way?

	no=0	yes=1	two most frequent=1		Most Use Effect
a) cries	—	—	3a)	<u> </u> (37) <u> </u> (38)	
b) has tantrum (yells, kicks, bites)	—	—	b)	<u> </u> (39) <u> </u> (40)	
c) pouts	—	—	c)	<u> </u> (41) <u> </u> (42)	

	no=0	yes=1	two most frequent=1		Most Use	Effect
d) nags or argues	—	—	—	3d)	<u> </u>	<u> </u>
					(43)	(44)
e) complies	—	—	—	e)	<u> </u>	<u> </u>
					(45)	(46)
f) goes to another activity	—	—	—	f)	<u> </u>	<u> </u>
					(47)	(48)
g) other _____	—	—	—	g)	<u> </u>	<u> </u>
					(49)	(50)

If younger sibling, ask: How did (s)he react to the birth of the baby? Did you consider this a problem? (0,1,2,3: none/mild/moderate/severe)

 sibling (51)

Is your child currently attending kindergarten? (0,1,2: no, half-days, full days)

SAMPLE ONLY

 kg (52)

Is your child currently attending daycare? (0,1,2: no, half-days, full days)

 daycare (53)

Does your child currently spend days with a babysitter? (0,1,2: no, half-days, full days)

 babysitter(54)

Does (s)he like going? _____
0=yes, no problem 1=doesn't like it, problem

 like (55)

How long has your child been attending? (months)

 months (56-57)

Does (s)he play well with the other children there? (0,1,2,3: none/mild/moderate/severe)

 play (58)

How did (s)he initially react to being away from you? _____

0,1,2,3: none/mild/moderate/severe

 separation(59)

II. PROFESSIONAL CONTACT

- a) Has (s)he ever had any serious medical problems or serious illness? (e.g. requiring hospitalization or frequent non-routine visits to physician. (0=no 1=yes) a) _____(1)
- b) Has your physician ever indicated to you that there might be a developmental or behavioural problem? (0=no 1=yes) if yes, elaborate: _____
_____ b) _____(2)
- c) Have you ever sought professional help (other than family physician's) before for concerns regarding your child? (0=no 1=yes) If yes, for how long? _____(4-5) months sought c) _____(3)
- d) Are you currently seeing a professional (other than family physician) for concerns regarding your child? (0=no 1=yes) If yes, for how long? _____(7-8) months sought d) _____(6)
- e) Is your child currently taking stimulant medication? (0=no 1=yes) If yes, for how long? _____(10-11) months e) _____(9)
- f) In the past, has your child taken stimulant medication? (0=no 1=yes) If yes, for how long? _____(13-14) medication f) _____(12)
- g) Is your child currently taking allergy medication? (0=no 1=yes) If yes, for how long? _____(16-17) months allergy g) _____(15)
- h) In the past, has your child taken allergy medication? (0=no 1=yes) If yes, for how long? _____(19-20) months h) _____(18)

SAMPLE ONLY

- i) Is your child currently taking other medication? (0=no 1=yes) If yes, for how long? _____ (months) i) _____ (21) medication
 _____ (22-23) months
- j) In the past, has your child taken other medication? (0=no 1=yes) If yes, for how long? _____ (months) What medication? _____ j) _____ (24) medication
 _____ (25-26) months

II. FAMILY DEMOGRAPHICS AND COMPOSITION

Now we'd like to learn more about the kind of family your child lives in.

1. Mother
- a) age (months) _____ 1a) _____ (27-28)
- b) occupation _____ b) _____ (29-30)
- c) education (years) _____ c) _____ (31-32)
- d) occupational status (0,1,2: unemployed/part-time/full-time) _____ d) _____ (33)
- e) medical problems _____ Total number _____ e) _____ (34)
- f) psychological problems _____ Total number cited _____ f) _____ (35)
- g) school related learning difficulties (0=no 1=yes) _____ g) _____ (36)
- h) school related behavioural difficulties (0=no 1=yes) _____ h) _____ (37)
- i) school related difficulties (0=no 1=yes) _____ i) _____ (38)
- j) behaviour problems - hyperactivity related _____ Total number cited _____ j) _____ (39)
- k) behaviour problems - other _____ Total number cited _____ k) _____ (40)

SAMPLE ONLY

2. Father

- a) age (months) 1a) ____ (41-42)
- b) occupation -- Blishen SEI _____ b) ____ (43-44)
- c) education (years) c) ____ (45-46)
- d) occupational status (0,1,2: unemployed/part-time/full-time) d) ____ (47)
- e) medical problems _____ Total number _____ e) ____ (48)
- f) psychological problems _____ Total number cited _____ f) ____ (49)
- g) school related learning difficulties (0=no 1=yes) _____ g) ____ (50)
- h) school related behavioural difficulties (0=no 1=yes) _____ h) ____ (51)
- SAMPLE ONLY**
- i) school related difficulties (0=no 1=yes) _____ i) ____ (52)
- j) behaviour problems - hyperactivity related _____ Total number cited _____ j) ____ (53)
- k) behaviour problems - other _____ Total number cited _____ k) ____ (54)

3. Family Status

- a) marital (0=never 1=divorced/separated/widowed, 2=married) 3a) ____ (1)
- b) how long married? ____ (years) b) ____ (2-3)
- c) how long separated/divorced/widowed? ____ (years) c) ____ (4-5)
- d) parental status: check one
- two parent family (both biological) (1)
 - natural mother is single parent (2)
 - natural mother/stepfather or reverse (3)
 - adoptive parents (4)
 - adoptive mother-headed household (5)
- d) ____ (6)

If single parent, ask appropriate questions about father's involvement. If divorced/separated ask:

Sometimes children become upset when a parent leaves. Did you have any sign that your child was upset? For example, did (s)he become more difficult to handle or show changes in sleeping patterns? _____

For all single parents, ask:

What kinds of visiting arrangements, if any, do you have with the child's father? _____

How does the child react to visits? _____

SAMPLE ONLY

If step-parents

How old was the child when you married your husband/wife _____ (months)? How did the child react to your marriage? _____

Does your husband/wife have children? _____no _____yes
If yes, do they live with you? _____no _____yes
If yes, do they visit? _____no _____yes

How does _____ behave with them? _____

If adopted:

At what age was the child adopted? _____ (months)? _____ (7-8)

How did (s)he behave then? _____

Where was (s)he living before the adoption? _____

What do you know about the child's early history? _____

Other children in the family (age, sex, school, grade)

1 _____
2 _____
3 _____

Any history in your child's immediate extended family i.e.:

parents	of	mental illness
grandparents		depression
uncles/aunts		addiction
siblings		learning disabilities
		hyperactivity
		conflicts with the law
		phobias

Total number _____ (9)

During the previous year have there been any noticeable changes in the family due to separation, deaths, births; changes in occupational or financial status, changes in residence or day care.

Total number _____ severity (0-3) _____ (10)
total

_____ (11)
severity

SAMPLE ONLY

Appendix H

Gordon Diagnostic System Instructions and Data Sheets

Delay Task

Examiner: We're going to play a game. You get a chance to win a lot of points. See this Light (point to a small RED light)? Every time you make this light go on you'll earn a point. This counter tells how many you've won. At the end of the game we'll see how many points you've won. To make the light go on all you have to do is push this BLUE button (POINT) and wait a little while before pressing it again. BUT if you press it TOO SOON the light won't go on and you won't get a point. But if you push the button, WAIT A WHILE then push it again you'll get a point.

Vigilance Task - "1" MODE

We're going to play a game. You need to know what the number "1" looks like. Can you show me a "1"? (Show care with LED-style numbers). Can you show me a "7"? Show me a "1" again? (Establish child know difference between a "1" and a "7". If child cannot pick out a "1" then task cannot be administered.)

After the trail:

Now we're going to play this game for a longer time. I want you to press the BLUE button only when you see a "1" Only press the blue button if you see a "1". I'll sit here and wait until you're done. You'll know when the game is over when the GREEN light comes on and you hear a BEEP. If you have any questions or want to talk, wait until the game is over.

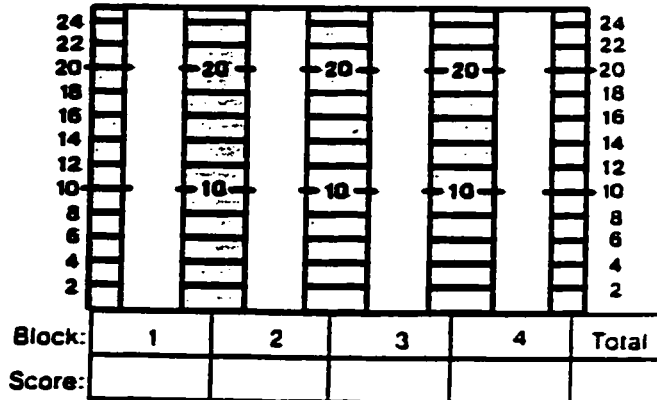
SAMPLE ONLY

DELAY TASKS

TASK PARAMETERS

<input type="checkbox"/> Standard 6" Delay 120" Blocks	<input type="checkbox"/> Preschool 4" Delay 90" Blocks	<input type="checkbox"/> Sound 6" Delay 120" Blocks		
<input type="checkbox"/> Variable Parameters				
Block	1	2	3	4
Delay Interval	_____	_____	_____	_____
Block Length	_____	_____	_____	_____

CORRECT

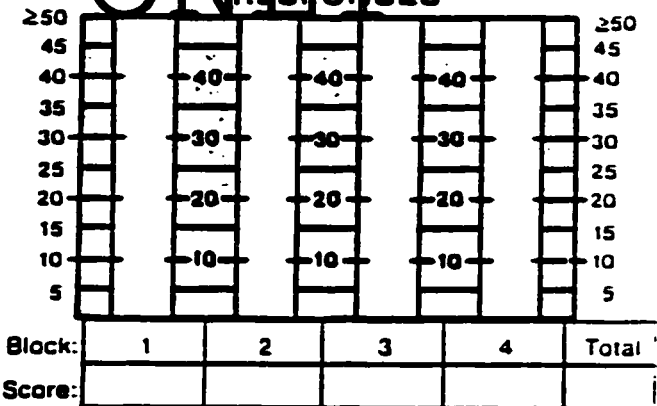


RESULTS

SUMMARY DATA	Sel. Pos.	TRACKING DATA
Total Correct	0	0.99
Total Responses	1	1.99
Block 1 Correct	3	2 - 2.99
Responses	4	3 - 3.99
Block 2 Correct	5	4 - 4.99
Responses	6	5 - 5.99
Block 3 Correct	7	6 - 6.99
Responses	8	7 - 8.99
Block 4 Correct	9	9 - 17.99
Responses	10	2 - 18.00

SAMPLE

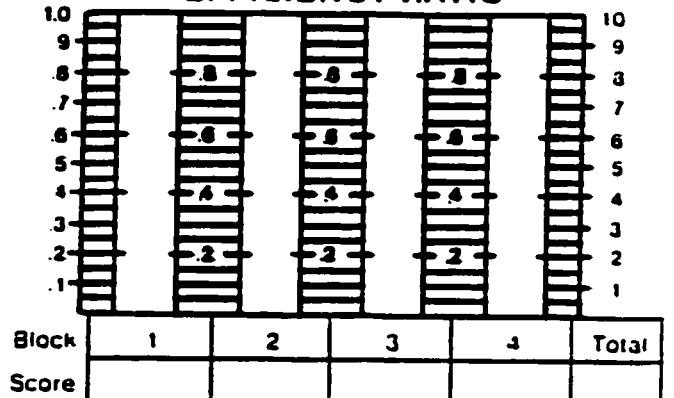
ONLY



SUMMARY STATISTICS

	Score	Normal Bord./Abnl.
Total ER		
ER Block Variability		
Slope Score		
Total Responses		
Total Correct		

EFFICIENCY RATIO



STRATEGIES/COMMENTS:

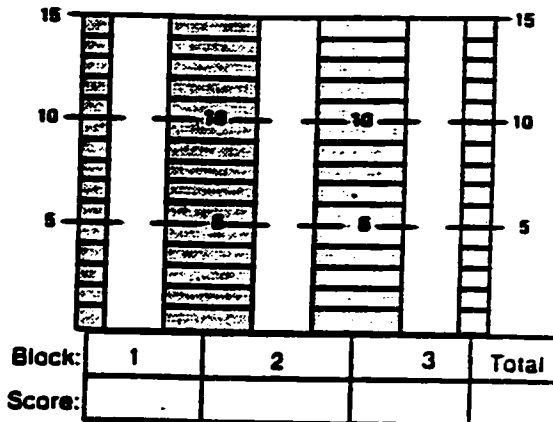
Peak ER YES / NO Valley ER YES / NO

VIGILANCE TASKS

TASK PARAMETERS

<input type="checkbox"/> Standard	<input type="checkbox"/> Parallel	<input type="checkbox"/> Preschool	<input type="checkbox"/> Preschool
1/9 1" Interval 180" Blocks	3/5	1 Mode 2" Interval 120" Blocks	0 Mode
<input type="checkbox"/> Other Parameters			
	Block	1	2
Presentation Interval	_____		
Block Length	_____		

CORRECT



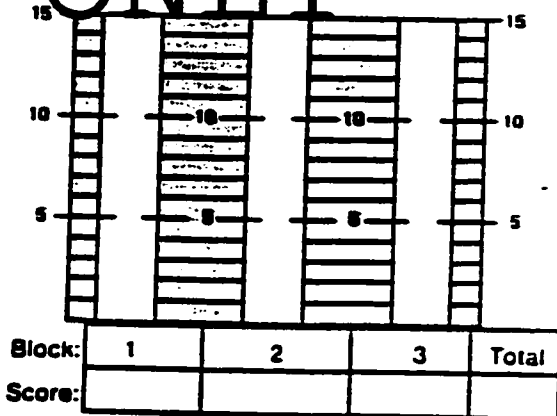
RESULTS

SUMMARY DATA	Sel. Pos.	TRACKING DATA
Total Correct	1	XX
Block 1 Correct	2	XX Error
Omission	3	XX1 of
Commission	4	X1X Commission
Block 2 Correct	5	X9X
Omission	6	XXX
Commission	7	Block 1
Block 3 Correct	8	Block 2 Latency
Omission	9	Block 3 (0.1 sec.)
Commission	10	Total

SAMPLE

Peak Score: YES / NO Valley Score: YES / NO

ONLY COMMISSIONS

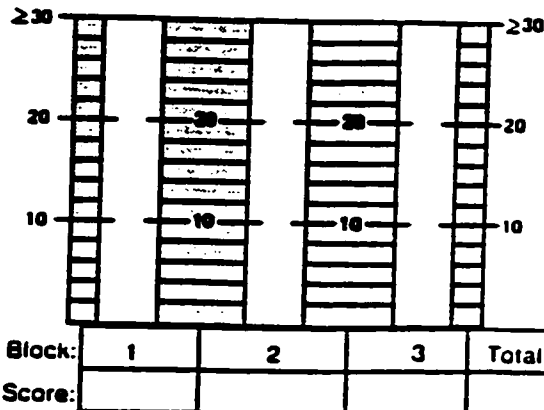


SUMMARY STATISTICS

	Score	Normal Bord./Abnl.
Total Commissions		
Commissions Block Variability		
Total Correct		

STRATEGIES/COMMENTS:

COMMISSIONS



Peak Score: YES / NO Valley Score: YES / NO

Appendix I

Porteus Mazes Test Instructions and Form

YEAR III: The examiner says:

I want to see whether you can draw all around between these lines without crossing or touching them with the pencil. You draw just like this. (The examiner demonstrates a slow and careful drawing performance between the guidelines, beginning at the arrow and proceeding just around the first angle. He then places a new blank design on the table and hands the pencil to the child.)

YEAR IV: The examiner says:

Do this the same way. Begin here (indicating starting arrow) and draw right around without crossing any of the printed lines.

YEAR V: The examiner says:

This is what is called a maze and you must draw with your pencil like this (draws about 1.5 inches of the course from the starting arrow near the rat to around the first turn). These lines are all supposed to be walls and this rat went in here (indicating arrow) to try and get some cheese. (Point to cheese at end of maze.) Now I want you to draw a line showing me where the rat went to find the cheese. But you must be very careful not to cross any lines or to go into any place that is blocked at the other end. If you go into any blocked place, you cannot turn around and come out. You must start all over again with a new maze. One more thing you must remember - you can stop anywhere and look as long as you like, but try not to lift your pencil off the paper until you have drawn right to the end of the maze.

YEAR VI: The examiner says:

This is another maze. Begin here and show me where the rat went to get the cheese. But do not cross any lines or go into any blocked places.

YEAR VII: The examiner says:

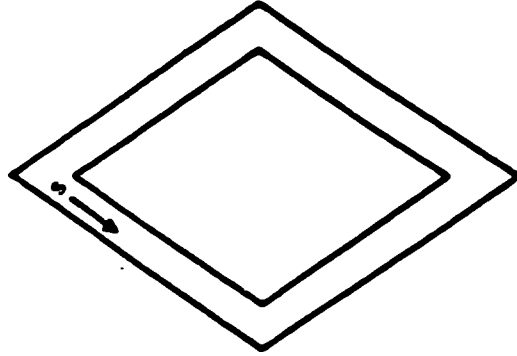
I want you to suppose that this maze is in the form of a street map. All the lines are stone walls. You can imagine, if you like, that you are walking or driving a car in here (examiner points to starting point marked S) and you have to find your way out here (examiner points to exit arrow). But you must be very careful not to bump into any of the walls nor go into any blocked street, because if you do so you cannot turn around or back out. So if you go into a blind street, you must start all over again. This is not a speed test. You can stop anywhere as long as you like while you decide which way to go, but try not to lift the pencil off the paper until you are right outside the maze, and don't bump into any walls. Start as soon as you are ready.

YEARS VIII, IX, X. The examiner says:

Begin here and find your way out. (Examiner points to the starting arrow, but not to the exit.)

YEAR XI, XII, XIV, ADULT. The examiner says:

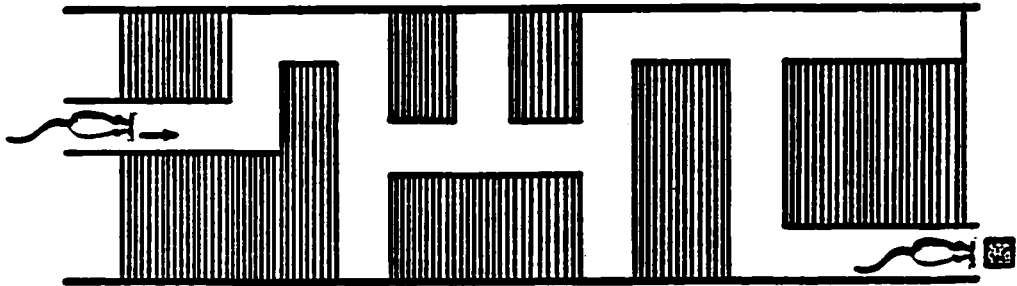
Begin here in the center and find your way out.



PORTeus TESTS — VINELAND REVISION YEAR 10

The Psychological Corporation
Personnel Group Assessment, Inc.
New York, New York 10017
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SAMPLE ONLY



PORTeus TESTS — VINELAND REVISION

YEAR 7

See Series Form "The Maze Test and Mental Subtests," Copyright 1988,
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Published by The Psychological Corporation, New York

Printed in U.S.A.

88-1187 (2/88)

Appendix J

Parent Stress Index Questionnaires and Forms

PARENTING STRESS INDEX (PSI)

Administration Booklet

Richard R. Abidin
Institute of Clinical Psychology
University of Virginia

Directions:

In answering the following questions, please think about the child you are most concerned about.

SAMPLE ONLY *See this answer sheet*

The questions on the following pages ask you to mark an answer which best describes your feelings. While you may not find an answer which exactly states your feelings, please mark the answer which comes closest to describing how you feel. **YOUR FIRST REACTION TO EACH QUESTION SHOULD BE YOUR ANSWER.**

Please mark the degree to which you agree or disagree with the following statements by filling in the number which best matches how you feel. If you are not sure, please fill in #3.

1	2	3	4	5
Strongly Agree	Agree	Not Sure	Disagree	Strongly Disagree

Example: (1) ● (3) (4) (5)

I enjoy going to the movies. (If you sometimes enjoy going to the movies, you would fill in #2.)

1. When my child wants something, my child usually keeps trying to get it.
2. My child is so active that it exhausts me.
3. My child appears disorganized and is easily distracted.
4. Compared to most, my child has more difficulty concentrating and paying attention.
5. My child will often stay occupied with a toy for more than 10 minutes.
6. My child wanders away much more than I expected.
7. My child is much more active than I expected.
8. My child squirms and kicks a great deal when being dressed or bathed.
9. My child can be easily distracted from wanting something.
10. My child rarely does things for me that make me feel good.
11. Most times I feel that my child likes me and wants to be close to me.
12. Sometimes I feel my child doesn't like me and doesn't want to be close to me.
13. My child smiles at me much less than I expected.
14. When I do things for my child I get the feeling that my efforts are not appreciated very much.
15. Which statement best describes your child?
 1. almost always likes to play with me,
 2. sometimes likes to play with me,
 4. usually doesn't like to play with me,
 5. almost never likes to play with me.
16. My child cries and fusses:
 1. much less than I had expected,
 2. less than I expected,
 3. about as much as I expected,
 4. much more than I expected,
 5. it seems almost constant.
17. My child seems to cry or fuss more often than most children.
18. When playing, my child doesn't often giggle or laugh.
19. My child generally wakes up in a bad mood.
20. I feel that my child is very moody and easily upset.
21. My child looks a little different than I expected and it bothers me at times.
22. In some areas my child seems to have forgotten past learnings and has gone back to doing things characteristic of younger children.

23. My child doesn't seem to learn as quickly as most children.
24. My child doesn't seem to smile as much as most children.
25. My child does a few things which bother me a great deal.
26. My child is not able to do as much as I expected.
27. My child does not like to be cuddled or touched very much.
28. When my child came home from the hospital, I had doubtful feelings about my ability to handle being a parent.
29. Being a parent is harder than I thought it would be.
30. I feel capable and on top of things when I am caring for my child.
31. Compared to the average child, my child has a great deal of difficulty in getting used to changes in schedules or changes around the house.
32. My child reacts very strongly when something happens that my child doesn't like.
33. Leaving my child with a babysitter is usually a problem.
34. My child gets upset easily over the smallest thing.
35. My child easily notices and overreacts to loud sounds and bright lights.
36. My child's sleeping or eating schedule was much harder to establish than I expected.
37. My child usually avoids a new toy for a while before beginning to play with it.
38. It takes a long time and it is very hard for my child to get used to new things.
39. My child doesn't seem comfortable when meeting strangers.
40. When upset, my child is:
1. easy to calm down,
 2. harder to calm down than I expected,
 4. very difficult to calm down,
 5. nothing I do helps to calm my child.
41. I have found that getting my child to do something or stop doing something is:
1. much harder than I expected,
 2. somewhat harder than I expected,
 3. about as hard as I expected,
 4. somewhat easier than I expected,
 5. much easier than I expected.

42. Think carefully and count the number of things which your child does that bothers you. For example: dawdles, refuses to listen, overactive, cries, interrupts, fights, whines, etc. Please fill in the number which includes the number of things you counted.
1. 1-3
 2. 4-5
 3. 6-7
 4. 8-9
 5. 10+
43. When my child cries it usually lasts:
1. less than 2 minutes,
 2. 2-5 minutes,
 3. 5-10 minutes,
 4. 10-15 minutes,
 5. more than 15 minutes.
44. There are some things my child does that really bother me a lot.
45. My child has had more health problems than I expected.
46. As my child has grown older and become more independent, I find myself more worried that my child will get hurt or into trouble.
47. My child turned out to be more of a problem than I had expected.
48. My child seems to be much harder to care for than most.
49. My child is always hanging on me.
50. My child makes more demands on me than most children.
51. I can't make decisions without help.
52. I have had many more problems raising children than I expected.
53. I enjoy being a parent.
54. I feel that I am successful most of the time when I try to get my child to do or not do something.
55. Since I brought my last child home from the hospital, I find that I am not able to take care of this child as well as I thought I could. I need help.
56. I often have the feeling that I cannot handle things very well.
57. When I think about myself as a parent I believe:
1. I can handle anything that happens,
 2. I can handle most things pretty well,
 3. sometimes I have doubts, but find that I handle most things without any problems,
 4. I have some doubts about being able to handle things,
 5. I don't think I handle things very well at all.

SAMPLE ONLY

58. I feel that I am:

1. a very good parent,
2. a better than average parent,
3. an average parent,
4. a person who has some trouble being a parent,
5. not very good at being a parent.

59. What were the highest levels in school or college you and the child's father/mother have completed?

Mother:

1. 1-8th grade
2. 9-12th grade
3. Vocational or some college
4. College graduate
5. Graduate or professional school

60. Father:

1. 1-8th grade
2. 9-12th grade
3. Vocational or some college
4. College graduate
5. Graduate or professional school

SAMPLE ONLY

61. How easy is it for you to understand what your child wants or needs?

1. very easy,
2. easy,
3. somewhat difficult,
4. it is very hard,
5. I usually can't figure out what the problem is.

62. It takes a long time for parents to develop close, warm feelings for their children.

63. I expected to have closer and warmer feelings for my child than I do and this bothers me.

64. Sometimes my child does things that bother me just to be mean.

65. When I was young, I never felt comfortable holding or taking care of children.

66. My child knows I am his or her parent and wants me more than other people.

67. The number of children that I have now is too many.

68. Most of my life is spent doing things for my child.

69. I find myself giving up more of my life to meet my children's needs than I ever expected.

70. I feel trapped by my responsibilities as a parent.

71. I often feel that my child's needs control my life.

72. Since having this child I have been unable to do new and different things.

73. Since having a child I feel that I am almost never able to do things that I like to do.
74. It is hard to find a place in our home where I can go to be by myself.
75. When I think about the kind of parent I am, I often feel guilty or bad about myself.
76. I am unhappy with the last purchase of clothing I made for myself.
77. When my child misbehaves or fusses too much I feel responsible, as if I didn't do something right.
78. I feel everytime my child does something wrong it is really my fault.
79. I often feel guilty about the way I feel towards my child.
80. There are quite a few things that bother me about my life.
81. I felt sadder and more depressed than I expected after leaving the hospital with my baby.
82. I wind up feeling guilty when I get angry at my child and this bothers me.
83. After my child had been home from the hospital for about a month, I noticed that I was feeling more sad and depressed than I had expected.
84. Since having my child, my spouse (male/female friend) has not given me as much help and support as I expected.
85. Having a child has caused more problems than I expected in my relationship with my spouse (male/female friend).
86. Since having a child my spouse (or male/female friend) and I don't do as many things together.
87. Since having my child, my spouse (or male/female friend) and I don't spend as much time together as a family as I had expected.
88. Since having my last child, I have had less interest in sex.
89. Having a child seems to have increased the number of problems we have with in-laws and relatives.
90. Having children has been much more expensive than I had expected.
91. I feel alone and without friends.
92. When I go to a party I usually expect not to enjoy myself.
93. I am not as interested in people as I used to be.
94. I often have the feeling that other people my own age don't particularly like my company.
95. When I run into a problem taking care of my children I have a lot of people to whom I can talk to get help or advice.

- 96. Since having children I have a lot fewer chances to see my friends and to make new friends.
- 97. During the past six months I have been sicker than usual or have had more aches and pains than I normally do.
- 98. Physically, I feel good most of the time.
- 99. Having a child has caused changes in the way I sleep.
- 100. I don't enjoy things as I used to.
- 101. Since I've had my child:
 - 1. I have been sick a great deal,
 - 2. I haven't felt as good,
 - 4. I haven't noticed any change in my health,
 - 5. I have been healthier.

During the last 12 months, have any of the following events occurred in your immediate family? Please check on the answer sheet any that have happened.

- 102. Divorce
- 103. Marital reconciliation
- 104. Marriage
- 105. Separation
- 106. Pregnancy
- 107. Other relative moved into household
- 108. Income increased substantially (20% or more)
- 109. Went deeply into debt
- 110. Moved to new location
- 111. Promotion at work
- 112. Income decreased substantially
- 113. Alcohol or drug problem
- 114. Death of close family friend
- 115. Began new job
- 116. Entered new school
- 117. Trouble with superiors at work
- 118. Trouble with teachers at school
- 119. Legal problems
- 120. Death of immediate family member

SAMPLE ONLY

Parenting Stress Index

Profile Sheet and Norms-Form 6
R.R. Abidin-University of Virginia

Parents Name _____ Parents Sex _____ Parents Date of Birth _____ Date _____
 Childs Name _____ Childs Sex _____ Childs Date of Birth _____ Age _____

Norms
N=2633

X	S.D.
222.8	36.6

Percentile Ranks																					
1	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	99+	
131	159	170	180	188	195	201	208	214	217	222	224	228	234	239	244	252	258	267	294	320	

Raw Score

TOTAL STRESS SCORE

CHILD DOMAIN SCORE

- Adaptability
- Acceptability
- Demandingness
- Mood
- Distract./hyper.
- Reinforces Parent

50	66	75	78	82	87	89	93	95	97	99	100	102	105	108	111	114	116	122	130	145
7	15	17	19	20	21		22	23		24	25	26	27		28	30	31	33	38	
4	6	7	8	9		10		11		12	13	14		15	16	17	18	21		
8	10	12	13	14	15	16	17		18	19	20	21		22	24	25	31			
3	5	6	7		8		9		10		11		12	13	14	18				
12	16	18	19	20	21	22	23		24	25	26		27	28	29	31	33	36		
5		6			7		8		9	10			11	12	14	15	18			

99.7	18.8
24.9	5.7
12.6	3.5
18.3	4.6
9.7	2.9
24.7	4.8
9.4	2.9

PARENT DOMAIN SCORE

- Depression
- Attachment
- Restric. of Role
- Sense of Competence
- Social Isolation
- Relat. Spouse
- Parent Health

69	82	92	99	102	107	110	112	115	118	121	123	126	129	132	137	142	148	153	169	188
8	12	13	15	16		17	18		19	20		21		22	23	24	26	27	30	36
6	7	8	9		10		11		12		13		14	15	16	17	18	22		
8	11	12	13	14	15	16		17	18		19	20	21	22	23	24	26	29	32	
15	18	21	22	23	24	25	26	27	28		29	30	31	32	33	34	35	37	40	45
6	7	8	9		10		11		12	13		14	15	16	17	18	20	22		
6	8	10	11	12	13		14	15		16	17	18	19	20	21	22	23	26	28	
5	7	8		9		10		11		12	13	14	15	16	17	19	21			

123.1	24.4
20.3	5.5
12.7	3.2
18.9	5.3
29.1	6.0
12.6	3.7
16.9	5.1
11.7	3.4

LIFE STRESS (Optional Scale)

Percentile Ranks																					
1	5	10	15	20	25	30	35	40	45	50	55	60	65	70	75	80	85	90	95	99+	

Raw Score

7.8	6.2
-----	-----

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To profile: Circle the raw score in the row to the right of the scale

Appendix K

Side Effects Rating Scale

baseline #1 #2 #3

SERS

Name: _____

Date _____

Person completing form: Mother

Father

Instructions

Please rate each behavior from 0 (absent) to 9 (serious). Circle only on number beside each item. A zero means that you have not seen the behavior in this child during the past week, and a 9 means that you have noticed it and believe it to be either very serious or too occur very frequently.

<u>Behavior</u>	<u>Absent</u>										<u>Serious</u>									
Insomnia or trouble sleeping	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Nightmares	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Stares a lot or daydreams	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Talks less with others	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Uninterested in others	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Decreased appetite	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Irritable	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Stomachaches	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Headaches	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Drowsiness	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Sad/unhappy	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Prone to crying	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Anxious	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Bites fingernails	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Euphoric/unusually happy	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Dizziness	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9
Tics or nervous movements	0	1	2	3	4	5	6	7	8	9	0	1	2	3	4	5	6	7	8	9

SAMPLE ONLY

Appendix I

Parent-child Interaction Tasks: Sequence, Instructions and Coding Protocol

Tasks were administered as follows:

Free play - 10 minutes
Compliance Task - 20 minutes
Dot-to-Dot Task - 10 minutes
Cancellation Task - 10 minutes
Free Play - 10 minutes

Behavioural Observation Protocol

1. Set up play room - toys, chalk, chair, dol, drapes open.
Set up VCR videotape, time marking tape, clip boards, task materials and checklists.
2. Collect completed questionnaires from parent and scan them to ensure completedness.
3. Suggest child void before session begins.
4. Explain rationale for assessment while getting settled in playroom.
5. Mixer and camera power on.
VCR on RECORD.
Time-marking Tape on.
Return to playroom to give instructions.

SAMPLE ONLY

- a) To parent: This session will take about an hour. First there will be a 10 minute free play time. Then there will be a 20 minute period of tasks. Following that we will take a short break. After the break there will be another 20 minute period of tasks and free play again at the end. I will be giving you instructions as we go along.

To parent: I am going to leave the room now. For the next 10 minutes, we want to see how your child plays with the toys on his own. Let the child choose whatever he wants to play with and don't worry about tidying up. Please step in if you feel there is some danger. But other than that, while he is playing, please spend your time reading this magazine.

To child: _____, play with any of these toys you want to while Mom is busy reading this magazine. I'll be back in 10 minutes.

--- 10 minutes unstructured play ---

(bring clipboard, pencil, checklist, tracing materials)

- b) To parent: Here is a list of 15 things I would like your child to do during the next 20 minutes. Tell him to do all of these things in this exact order and check them off the list when they are done. Try to act as naturally as you can. Read the list now so that I can answer any questions you may have before I go. I'll be back in 20 minutes.

--- 20 minutes compliance task ---

VCR off
Mixer off

Now we'll have a break for 10 minutes. It might be a good idea if _____ went to the washroom and had a drink of water. I'll meet you back here inside the playroom at _____.

--- 10 minute break ---

Mixer on
VCR on RECORD
Time-marking tape on

(bring clipboard, pencil, checklist and dot-to-dot materials)

- c) To parent: Here is the first activity I would like the two of you to do during the next 10 minutes. This booklet has pages lettered from A-S. Starting with A, have _____ draw the design on the boxes on the right just the way it is in the boxes on the left. When it is done correctly, check it off on the list and move on to B. Please try to have your child complete as many pages as possible and help him in whatever way you feel is best. Make sure you don't skip any pages. Any questions? I will be back in 10 minutes.

--- 10 minutes supervised attention task ---
SAMPLE ONLY

(bring 2 packages of continuous performance materials)
(collect dot-to-dot materials)

- d) To parent: this is the second activity I would like _____ to do. For this activity I would like to see how _____ works on his own. I will show him how to do it and then ask him to continue working on it by himself after I leave the room. Please sit here and read the magazine again.

Use Elephants for age 4-4.11
Use Circles for age 5-6.0

- Row 1 - Model cancellation of figures in row shaping toward child performing with prompts and questions.
- Row 2 - Child attempts row with Research Assistant (RA) shaping toward independence.
- If 100% correct - RA leaves.
- Row 3 - If child is unsuccessful in Row 2, RA models again as in Row 1.
- Row 4 - Child attempts row with prompts and shaping as in Row 2.
- Row 5 - Child does last row too.
- If 2 of 3 circles in rows 4 & 5 are correctly saved or crossed, child goes to next page.
- If 2 of 3 are not correct, model again to criterion.

If child is completely non-compliant, and does not attempt initially-presented

task, RA models line 2 and presents task with the information that this is the last game. RA models line 2 again if child does not comply. RA then leaves room after giving instructions to child to continue working while Mom reads, and to go to next page when he finishes each one and not to skip any pages.

To parent: Any questions: I'll be back in 10 minutes.

--- 10 minute unsupervised attention task ---

(collect continuous performance materials)

- e) To parent: Now you will have 10 minutes again for free play. As before, _____ can play with any of the toys he wishes on his own while you read the magazine. Again, let him choose whatever he wants to play with and don't worry about cleaning up.

To child: You can play with the toys again for awhile while Mom reads her magazine.

To parent: Any questions? I'll be back in 10 minutes.

--- 10 minutes free play ---

VCR OFF and rewind video tape
Time-marking tape off and rewind
Mixer and camera power off

SAMPLE ONLY

6. Return to playroom to thank parent and child for their hard work. Ask whether the child's behaviour today was about the same as it is at home or was it different in any way. Record parent's response. Inform parent that this video tape will aid in the assessment of the family's eligibility for medication treatment. Because children's behaviour changes from one day to the next, it may be necessary but unlikely to repeat this session. Inform the parent that we'll have a look at this tape and will call them after the tape has been viewed to let them know what the next step is.

For treatment conditions:

Inform parent of necessity to maintain regularity of medication. Give new medication set. Arrange next treatment assessment time. Inquire if there are any concerns about side effects or questions about medication.

Time on activity

Ranking of activities (code highest ranking activity):

- 1) educational verbal or combination of parent-initiated verbal interaction combined to the ongoing activity
- 2) request for parental involvement
- 3) physical and eye contact with a play object/physical activity
- 4) eye contact alone
- 5) physical contact alone or physical activity with eye contact disturbance
- 6) shaping and teaching
- 7) brief reply/recognition of parental verbalization

Types of activities:

- Pa/Pp Play things in focus of attention
- Co/Op Objects in the room as focus of attention
- Ma/My Activity-involvement verbal interaction
- Pa/Pr Parental involvement
- Co/Op Continuous physical activity
- Ma/My Involvement activities

ATS Time on Task

On-task requirements:

- 1) appropriate body position, i.e. within reach of and oriented toward the task material
- 2) eye contact with the task material (eye contact with relevant instruction is accepted)

Sequence of child's on-task behaviours:

- 1) Turns the page of the booklet to the appropriate page. May not be fully on the edge of the page.
- 2) Holds a pencil.
- 3) Focuses on the design to work on.
- 4) Draws lines between dots in the right square to copy the model length but square.
- 5) May do the square on a page in any order unless the parent gives a specific direction.
- 6) May follow the model with a finger or describe it.
- 7) May look at the parent for feedback.
- 8) May evaluate teacher over performance.
- 9) May adjust the body position as long as the material on the table remains within teacher reach.
- 10) May look at the checklist without comments or questions while parent is working on it.

Types of off-task behaviours:

- BP Loss of appropriate body position
- EC Loss of eye contact with task material
- Ma/My Task-involvement instructions
- IA Inappropriate use of task material
- ED
 - a) verbally refuses or argues
 - b) verbal incapability combined with other task-involvement behaviours of refusal
 - c) refuses to listen
 - d) behaves aggressively toward the parent
- R
 - a) refused to remain on task
 - b) when any of the off-task behaviours listed under ED occurs within parental direction
 - c) leaving job of the pencil or offering it to the parent
- F1 Parent-supposed off task period

SAMPLE ONLY

ATU Time on Task

On-task requirements:

- 1) appropriate body position, i.e. torso positioned so that booklet is within easy reach
 - 2) eye contact with the task material (eye contact with parent is still accepted)
- Mark with P directly under (1) if parent looked downward or upward direction to get the child back on task during the preceding off-task period. Observe mark with C directly under (1).

Sequence of child's on-task behaviours:

- 1) Turns the page of the booklet to the appropriate page. May comment briefly on the letter on either the completed or new page.
- 2) Holds a pencil.
- 3) Examines task shape and either puts a mark on it or leaves it blank.
- 4) May follow any pattern of scanning to go over all the shapes on a page.
- 5) May evaluate teacher over performance.
- 6) May adjust the body within the requirements of the body position requirements above.

Types of off-task behaviours:

- BP Loss of appropriate body position
 - torso straggle from ATU; any major deviation from normal drawing position of torso
- EC Loss of eye contact with task material
 - eye contact with parent is still accepted
- Ma/My Task-involvement instructions
- IA Inappropriate use of task material
- R
 - refused to remain on task
 - stated refusal to remain on task accompanied by another behaviour indicative of refusal

Appendix M

Compliance Task List

B 1 2 3

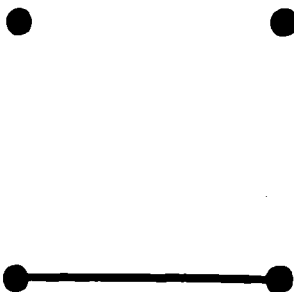
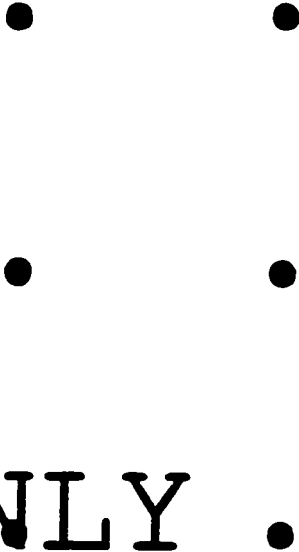
Name: _____ Date: _____

CHECKLIST FOR FIFTEEN THINGS TO DO.

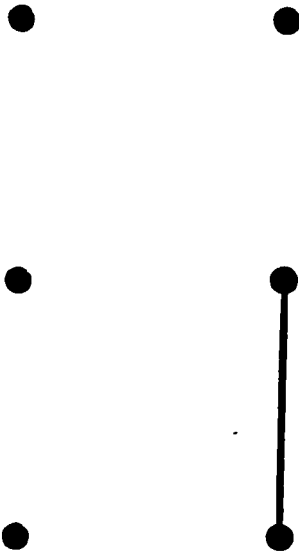
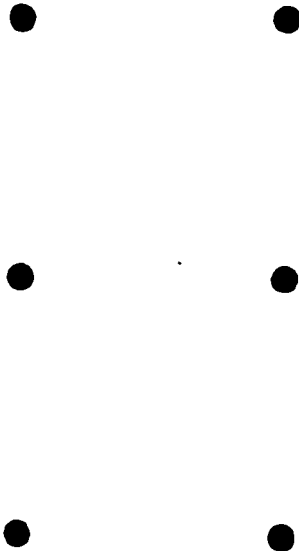
- ___ 1. Come here and let me fix your hair.
 - ___ 2. Get me the small doll with the pink dress on (to mother: examine the doll).
 - ___ 3. Put the doll back in its spot.
 - ___ 4. Sing me a song (or say a nursery rhyme you like).
 - ___ 5. Put all the toys and things back in their spots.
 - ___ 6. Get me the box beside the door.
 - ___ 7. Set eight base on the floor (to mother: stick should be at your feet between the couch and table).
 - ___ 8. Take a piece of paper and a pencil out of the box.
 - ___ 9. Take the red bear out of the box and trace all the way around it with the pencil to draw its shape.
 - ___ 10. Take the yellow pig out of the box and trace its shape the same way.
 - ___ 11. Do the same with the blue pony.
 - ___ 12. Do the same with the white monkey.
 - ___ 13. Put the paper, the pencil and the animal shapes in the box.
 - ___ 14. Draw a circle on the blackboard.
 - ___ 15. Get me a magazine from the table (to mother: please look at the first 2 pages).
-

Appendix N

Dot-to-Dot Task

 <p>SAMPLE</p>	 <p>ONLY</p>
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F

	
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Appendix O

Cancellation Task

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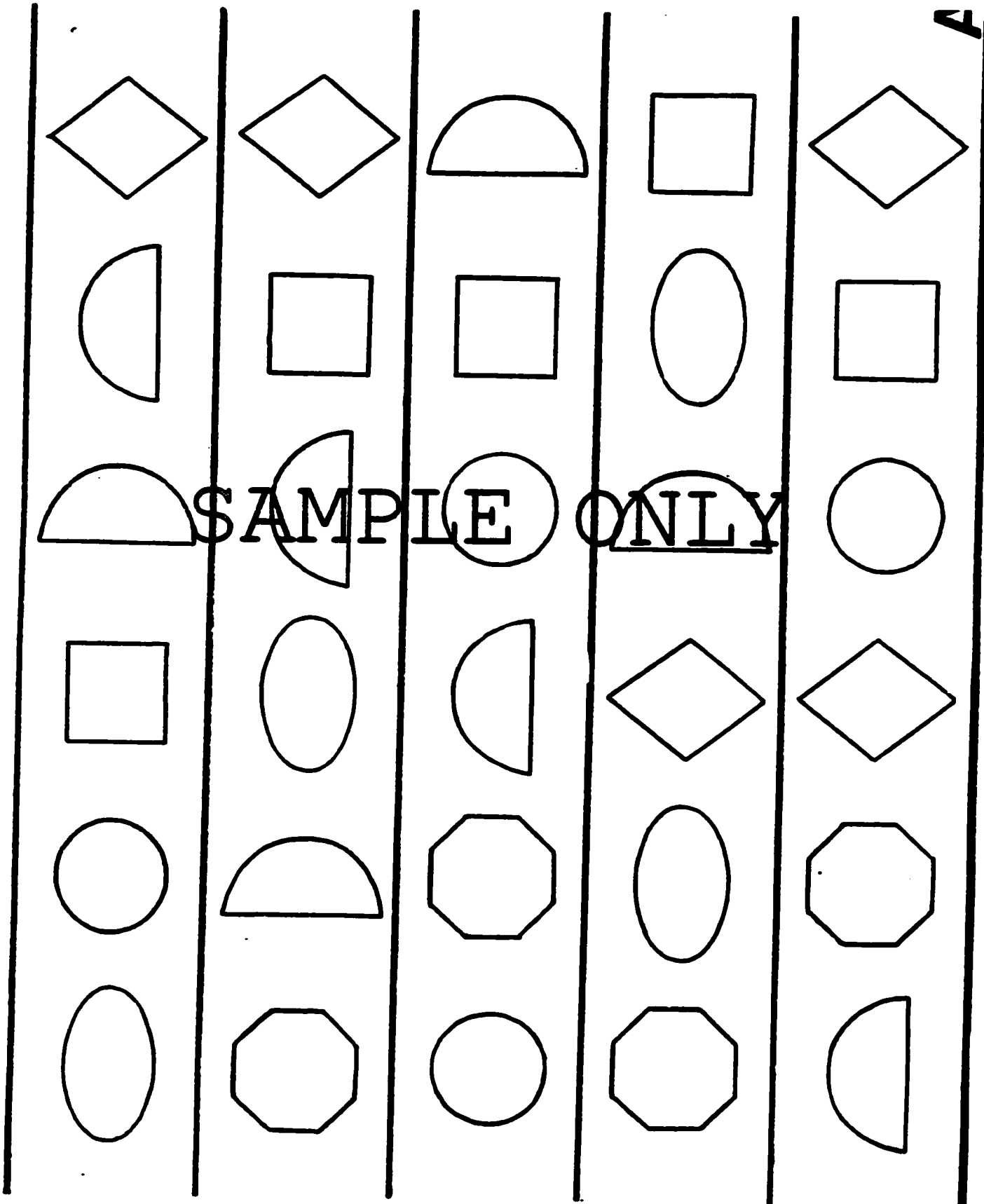
↑

↑

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Dog	Lion	Giraffe	Elephant	Tiger
Dog	Lion	Giraffe	Elephant	Tiger
Dog	Lion	Giraffe	Elephant	Tiger
Dog	Lion	Giraffe	Elephant	Tiger
Dog	Lion	Giraffe	Elephant	Tiger



Appendix P

Feedback Information Sheet



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT RESEARCH PROJECT

Dr. S. Pisterman, C. Psych.
Ms. L. Monteiro Musten, M.Sc., M.A.
Dr. P. Firestone, C. Psych.
Dr. S. Bennett, M.D.

Attention Deficit Hyperactivity Disorder (ADHD) or hyperactivity occurs in 4-10% of school-aged children. It also occurs among preschoolers. The symptoms are lack of attention, overactivity and impulsivity. Although many very young children will display these behaviours, the ADHD preschooler's behaviours will be far more intense than the average child.

One form of therapy is the use of stimulant medication to help your child interact more positively with you, their friends and caregivers. Ritalin is the primary medication and has been demonstrated to have positive effects when used with school-aged children. Many of the behaviours that cause problems between the child and others can be reduced when treated with Ritalin. **The Preschool Hyperactivity Medication Treatment Research Project** has been designed to investigate the benefits of using stimulant medication treatment with preschool children who are diagnosed ADHD.

Steps of the PHM Treatment Research Project

1. Participation in the study requires involvement in all phases of the project. Your child will be placed in **THREE MEDICATION PERIODS** that are within the normal range of medication used with preschoolers. One period will consist of a neutral lactose (called a placebo) for a baseline measure; the other two will consist of .3 mg/kg and .5 mg/kg doses of Ritalin.

Each period will last one week. At the beginning of the medication period you will be given the prescribed amounts of Ritalin for that week. It is important that your child take his medication exactly as prescribed. Neither you nor the persons administering the assessments will know whether your child is on a placebo or medication cycle. At the end of each medication period, you and your child will be requested to come to the hospital for assessment.





Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

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Steps of the PHM Treatment Research Project, continued

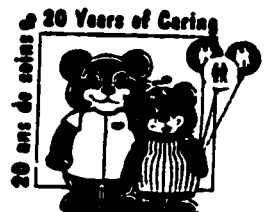
2. There will be **SEVEN VISITS** (two for each medication period and one feedback session) to the hospital during which time (1) parents will be asked to fill out questionnaires related to their child's behaviour, their parenting approaches and experiences; (2) your child will be asked to take part in various tasks with and without your involvement. The **TOTAL TIME** required from you will be **TWO** consecutive morning visits every 7-10 days.

3. If your child is attending a preschool or daycare facility or is cared for during the day by a babysitter, s/he will be asked to complete a questionnaire (similar to yours) related to your child's daily behaviours.

SAMPLE ONLY

4. Side effects are possible. However, other studies have reported only mild side effects in some preschool children who have taken Ritalin. The symptoms of side effects may include stomachaches, headaches, dizziness, tremors/tics or insomnia. The side effects can be lessened by reducing the dosage and cease when the medication is stopped. All children participating will be monitored for these side effects and if they are assessed to be severe, alternatives to the program will be discussed with you.

PLEASE FEEL FREE TO CONTACT THE RESEARCHERS FOR ANY INFORMATION YOU NEED. LYNETTE MONTEIRO MUSTEN (738-3279; 737-2492) OR DR. SUSAN PISTERMAN, PSYCHOLOGIST (737-2492).



Appendix Q

Treatment Consent Forms



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT RESEARCH PROJECT
INFORMED CONSENT

I have read the information package describing the research project and fully understand the nature of the study. Furthermore, I understand that

1. my child meets the criteria for a diagnosis of Attention Deficity Hyperactivity Disorder;
2. stimulant medication treatment is available and the medication benefits and side effects have been explained to me by Dr. Bennett; a physical examination of my child will be required and conducted by Dr. Bennett or my family physician with results forwarded to the project principals;
3. the treatment program as outlined in the information package will require: six visits to the research laboratory at the Children's Hospital of Eastern Ontario and one feedback session at the end of the project (at CHEO);
4. my child's treatment will include a period of time on a placebo and a period of time on two doses of stimulant medication (0.3 mg/kg and 0.5 mg/kg); any problems with side effects can be discussed with the researcher and alternatives considered;
5. I will be answering questions related to my child's behaviour, my parenting approaches and experiences and my child will be assessed on a variety of tasks; where applicable my child's daily caregiver will be asked to answer question related to his everyday behaviours;
6. I may withdraw from the project at any time and my withdrawal will not jeopardize the type nor quality of treatment that my child will receive;
7. Dr. Bennett will be available for the duration of the project to address my concerns about the treatment procedure, side effects, etc., or I may call Ms. Lynette Musten (738-3279);
8. all information will be maintained in the strictest of confidence and will be used only in the context of this research project.

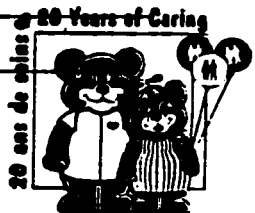
SAMPLE ONLY

Name (child): _____

Name (parent): _____

Parent signature: _____

Date: _____





Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT RESEARCH PROJECT

Researcher's Acknowledgement of Provision of Information

I have explained the nature of this study to _____
and believe he/she has understood it.

Name: _____

Signature: _____

Position: _____

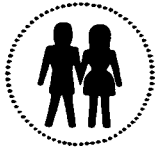
Date: _____

SAMPLE ONLY



Appendix R

Medication Information and Instructions



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

TO: DR. S. BENNETT, PEDIATRICS

CLIENT NAME: _____

DOB: _____

MOTHER NAME: _____

FATHER NAME: _____

DATE ASSESSED: _____

MEDICAL APPOINTMENT SCHEDULED FOR: _____

SAMPLE ONLY

INCLUSION CRITERIA FOR STUDY CONFIRMED WITH PARENTS.

INCLUSION PENDING MEDICAL REPORT.

TO: MS. LYNETTE MONTEIRO MUSTEN, M.A.
PRESCHOOL HYPERACTIVITY MEDICATION TREATMENT PROJECT

CHILD'S WEIGHT: _____ KG HEIGHT: _____

MEDICATION TREATMENT: RECOMMENDED _____

NOT RECOMMENDED _____

Comments (if necessary): _____

PLEASE RETURN THIS FORM TO THE PARENTS WHO WILL BRING IT TO THEIR APPOINTMENT AT THE RESEARCH INSTITUTE (PSYCHOLOGY).





Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

TO: PHARMACY

FROM: PRESCHOOL MEDICATION TREATMENT PROJECT
Lynette Monteiro Musten, M.Sc., M.A. (738-3279)

SUBJECT NUMBER: _____

CLIENT NAME: _____

DOB: _____

MOTHER NAME: _____

FATHER NAME: _____

DATE ASSESSED: _____

SAMPLE ONLY

MEDICAL APPOINTMENT / MEDICATION PICK UP SCHEDULED FOR:

_____ 8:30 9:15

CHILD'S LOW DOSE: 2.5 5.0 7.5 MG

CHILD'S HIGH DOSE: 5.0 7.5 10.0 MG

SUFFICIENT CAPS REQUIRED FOR 10 DAYS.

NEXT SCHEDULED MEDICATION PICK UP



Children's Hospital of Eastern Ontario
Hôpital pour enfants de l'est de l'Ontario

401 SMYTH, OTTAWA, ONT. K1H 8L1 TELEPHONE (613) 737-7600

MEDICATION INSTRUCTIONS

You have been given sufficient medication for _____. There is enough for 7 to 10 days of treatment.

START THE MEDICATION ON _____.

YOUR NEXT APPOINTMENT IS ON _____.

The medication must be given to your child **TWICE A DAY** - once at breakfast and once at lunch (or one hour before school/daycare and once at noon).

SAMPLE ONLY

PLEASE MAKE SURE YOUR CHILD RECEIVES HIS MEDICATION REGULARLY.

DO NOT DOUBLE ANY DOSES IF S/HE MISSES A DOSE.

THIS MEDICATION HAS BEEN SPECIALLY PREPARED FOR YOUR CHILD ONLY.
DO NOT GIVE IT TO ANY OTHER PERSON.

RETURN THE VIAL TO THE RESEARCHER WHEN YOU COME BACK FOR YOUR NEXT APPOINTMENT.

ON THE DAY OF YOUR NEXT APPOINTMENT

- GIVE THE MORNING DOSE AT LEAST ONE-HALF HOUR BEFORE HIS ASSESSMENT.

If you have any questions please call Lynette Monteiro Musten at 738-3279 and, if necessary Dr. Bennett will be contacted.



January 1995



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Appendix S

Pearson Product Moment Correlations of Inclusion Criteria with Baseline Measures

Measures	DICA symptoms	SNAP symptoms	PPVT SS	H-Index	DTD Mean time on-task
CPRS Conduct	.004	.216	-.277	.673***	.137
CPRS Learning	.224	.395	-.095	.629***	-.049
CPRS H-Index	.025	.293	-.153	1.00	-.077
Delay Correct	.186	.123	.058	.415	-.031
Delay ER	-.070	-.204	-.331	-.155	-.092
Vigilance Correct	.352	.206	.379	.152	.528**
Vigilance Commission	-.138	-.097	-.054	.513**	-.131
Porteus Q	.000	.508	-.005	.101	-.383
DTD Mean time	.152	.003	.176	-.077	1.00
CANC Mean time	.216	-.207	.021	-.162	.670**
Patterns correct	.325	.026	.129	-.177	.460
Rows correct	.333	.146	.188	-.035	.446
CT compliance	-.172	-.031	-.001	.038	-.324
DTD compliance	-.048	.113	-.117	-.271	.362
CANC compliance	.275	-.076	.214	-.186	.148
SERS symptoms	.046	.155	-.448	.105	.014
SERS severity	-.016	.098	-.420	.249	.014
CT Commands	-.178	-.333	-.303	-.199	-.093
CT Reinforcement	.125	-.212	.051	-.252	.026
CT Positive	.170	.191	.358	.349	.180
CT Negative	-.045	.021	.176	.145	-.312
DTD Commands	-.216	.147	-.381	.271	-.402
DTD Reinforcement	.098	.181	.438	-.451	-.220
DTD Positive	.074	-.279	.128	-.307	.302
DTD Negative	-.178	-.335	-.194	.028	-.503
CANC Commands	-.481	-.418	-.334	-.374	.020
CANC Reinforcement	.404	-.130	.263	.169	-.434
CANC Positive	.420	.072	.228	.192	-.126
CANC Negative	.328	.284	-.163	.040	-.056
PSI Child	.283	.692	-.108	.351	.161
PSI Parent	-.023	.176	-.127	.089	.294

** p < .01; *** p < .001

Appendix T

ANOVA Summary Table for Cognitive Tasks

Number of Correct Responses (Delay Task)					
Source	SS	df	MS	F	Sig of F
Dose	1281.86	3	427.29	5.49	.002
Within + Residual	5373.89	69	77.88		

Efficiency Ratio (Delay Task)					
Source	SS	df	MS	F	Sig of F
Dose	0.17	3	0.06	1.68	.179
Within + Residual	2.44	69	0.04		

Number of Correct Responses (Vigilance Task)					
Source	SS	df	MS	F	Sig of F
Dose	445.03	3	148.34	4.84	.004
Within + Residual	2115.72	69	30.66		

Number of Commission Errors (Vigilance Task)					
Source	SS	df	MS	F	Sig of F
Dose	5878.78	3	1959.59	6.40	.001
Within + Residual	21119.47	69	306.08		

Appendix T, continued

ANOVA Summary Table of Conners Parent Rating Scales

Learning					
Source	SS	df	MS	F	Sig of F
Dose	4741.00	3	1580.33	11.65	.000
Within + Residual	9356.50	69	135.60		

Conduct					
Source	SS	df	MS	F	Sig of F
Dose	5244.46	3	335.02	4.14	.009
Within + Residual	8024.04	68	80.96		

Hyperactivity Index					
Source	SS	df	MS	F	Sig of F
Dose	7048.86	3	110.28	4.76	.004
Within + Residual	7217.39	67	23.00		

Appendix T, continued

ANOVA Summary Table of Observed Child Behaviours

Percent Compliance (Compliance Task)					
Source	SS	df	MS	F	Sig of F
Dose	365.70	3	121.90	0.86	.468
Within + Residual	9817.44	69	142.28		

Percent Compliance (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	481.32	3	160.44	0.87	.460
Within + Residual	12686.32	69	183.86		

Percent Compliance (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	575.30	3	191.77	0.49	.694
Within + Residual	27276.14	69	395.31		

Appendix T, continued

ANOVA Summary Table of Observed Child Behaviours, continued

Mean Time On-Task (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	52477.47	3	17492.49	3.03	.035
Within + Residual	398591.04	69	5776.68		

Mean Time On-Task (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	15920.24	3	5306.75	4.81	.004
Within + Residual	76060.53	69	1102.33		

Number of Correct Patterns (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	488.53	3	162.84	4.68	.005
Within + Residual	2399.86	69	34.78		

Number of Correct Figures (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	10929.30	3	3643.10	1.61	.196
Within + Residual	156611.88	69	2269.74		

ANOVA Summary Tables for Side Effects

Number of Symptoms					
Source	SS	df	MS	F	Sig of F
Dose	53.86	3	17.95	2.92	.040
Within + Residual	424.39	69	6.15		

Severity of Symptoms					
Source	SS	df	MS	F	Sig of F
Dose	5.03	3	17.68	2.24	.091
Within + Residual	51.55	69	6.15		

ANOVA Summary Tables for Parent Skills

Percent Commands (Compliance Task)					
Source	SS	df	MS	F	Sig of F
Dose	387.07	3	129.02	1.90	.137
Within + Residual	4675.89	69	67.77		

Percent Commands (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	1102.77	3	367.59	3.54	.019
Within + Residual	7160.88	69	103.78		

Appendix T, continued

ANOVA Summary Tables for Parent Skills, continued

Percent Commands (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	3386.392	3	1128.80	3.90	.012
Within + Residual	19993.82	69	289.77		

Percent Reinforcement (Compliance Task)					
Source	SS	df	MS	F	Sig of F
Dose	62.29	3	20.76	0.17	.915
Within + Residual	8343.20	69	120.92		

Percent Reinforcement (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	810.38	3	270.13	0.72	.541
Within + Residual	25718.32	69	372.73		

Percent Reinforcement (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	577.90	3	192.63	1.34	.268
Within + Residual	9895.20	69	143.41		

Appendix T, continued

ANOVA Summary Tables for Parent Style

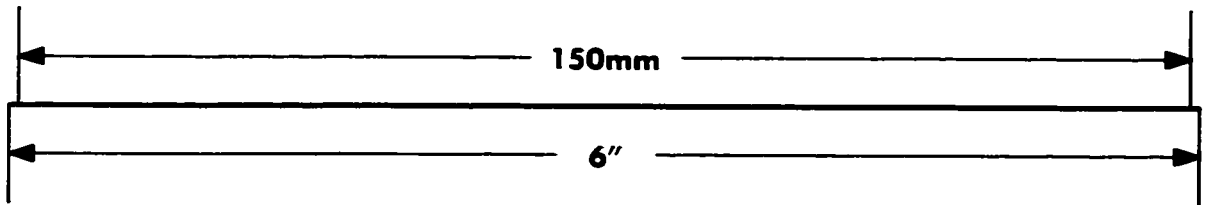
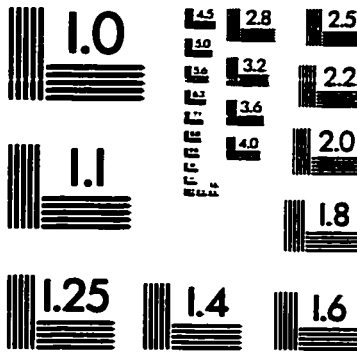
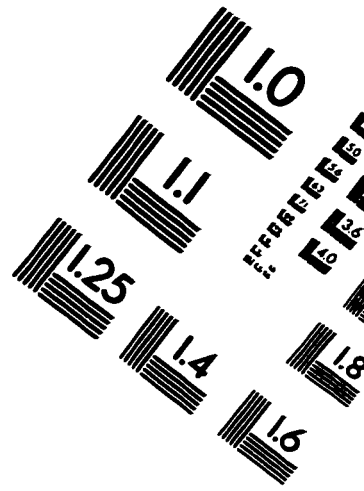
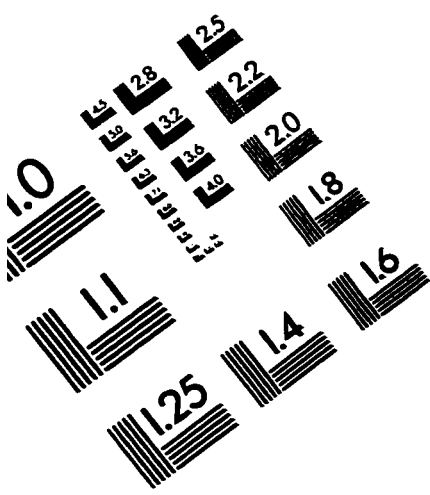
Percent Positive (Compliance Task)					
Source	SS	df	MS	F	Sig of F
Dose	181.43	3	60.48	1.49	.224
Within + Residual	2797.18	69	40.54		

Percent Positive (Dot-to-Dot Task)					
Source	SS	df	MS	F	Sig of F
Dose	2188.45	3	729.48	6.89	.000
Within + Residual	7303.99	69	105.85		

Percent Positive (Cancellation Task)					
Source	SS	df	MS	F	Sig of F
Dose	3583.15	3	1194.38	4.04	.010
Within + Residual	20385.49	69	295.44		

Percent Negative (Compliance Task)					
Source	SS	df	MS	F	Sig of F
Dose	442.94	3	147.65	5.63	.002
Within + Residual	2797.18	69	26.22		

IMAGE EVALUATION TEST TARGET (QA-3)



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