TREATMENTS FOR HYPERKINETIC CHILDREN

TREATMENTS FOR HYPERKINETIC CHILDREN: A LITERATURE REVIEW AND A DESIGN FOR A TRIAL OF METHYLPHENIDATE AND BEHAVIOUR MODIFICATION

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ABSTRACT

Hyperkinetic children and their treatment are currently the subjects of heated discussions among medical persons, parents, teachers, government officials, the press and a concerned public. The focus of these discussions is often the appropriateness or inappropriateness of stimulant medications for hyperkinetic children.

The first part of this thesis contains a review of a substantial portion of the literature on hyperkinesis including : definitions and diagnosis of hyperkinesis, prevalence of hyperkinetic symptoms and of hyperkinesis, characteristics of children considered hyperkinetic, drug treatments for hyperkinesis, and non-drug treatments for hyperkinesis. The major purpose of the literature review is to examine all available studies of the effectiveness of methylphenidate for hyperkinesis and all available studies of the effectiveness of non-drug treatments for hyperkinesis. This review indicates that methylphenidate is the most effective drug treatment tested and that behaviour modification or operant conditioning is the best tested, effective non-drug treatment for hyperkinesis. The relative effectiveness of methylphenidate and behaviour modification alone or in combination for the treatment of hyperkinesis is not known.

In the literature review, Tables are provided which summarize information gleaned from an extensive selection of publications. These Tables include : A) Estimates of the Prevalence of Hyperkinetic Symptoms and of the Hyperkinetic Disorder in Children; B) Some Characteristics which Distinguish Children Diagnosed as Hyperkinetic from Normal Children; C) Some Characteristics which Distinguish Children Diagnosed as Hyperkinetic from Neurotic or Normal Children; D) A Summary of Studies of Methylphenidate for Hyperkinesis; E) The Effectiveness of Methylphenidate versus Placebo for Hyperkinesis : measures on which M and P have differed significantly in therapeutic effectiveness; F) The Effectiveness of Methylphenidate versus other Active Drugs for Hyperkinesis; G) A Summary of Studies of Non-Drug Treatments for Hyperkinesis; H) Evaluation of Miscellaneous Non-Drug Treatments for Hyperkinesis, and I) The Effectiveness of conditioning in the Treatment of Hyperkinesis.

The second part of this thesis is a research proposal which has been developed on the basis of the current state of knowledge pertaining to the treatment of hyperkinesis. The proposed research is designed to determine which of three very promising treatments for hyperkinesis has the greatest effectiveness and fewest side-effects: methylphenidate, behaviour modification, or methylphenidate plus behaviour modification. The protocol covers the following areas : Rationale for the study; Selection criteria for hyperkinetic

children; Collection of the sample of children; Sample size required; Pre-treatment assessments; Assignment to treatments; Methylphenidate treatment at .7mg/kg/day; Behaviour modification program including 8 sessions; Methylphenidate and behaviour modification in combination; Post-treatment assessments; Data analysis and budget for the study. This protocol could be adapted for use by other investigators interested in the area.

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Finally, I thank those who share responsibility for the treatment of hyperkinetic children. They appeared now and then in my imagination as potential readers who might use the information contained herein; and I therefore maintained hope that this thesis might eventually contribute in a small way to the improvement of treatments for hyperkinetic children.

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1. INTRODUCTION

"Hyperkinetic" is the label a child may receive if he or she is extremely active, has a short attention span, fidgets, is easily distracted, easily frustrated, volatile in mood, disturbing to other children and adults, and having problems with school work.

Depending upon who sees the child, this cluster of problems may instead, or in addition, be labeled minimal brain dysfunction, emotional disturbance, learning disability, or be given other appellations. Even when clinicians agree that a particular child is hyperkinetic, with or without attendant problems, they may disagree on the cause of the disorder and the treatment to be applied. Is the disorder a result of organic abnormalities or of environmental stresses? Should parents be advised to accept the child's behaviour as part of the spectrum of normal childhood behaviours, and ride out the storm? Should the child be treated with drugs, tutoring, behaviour modification? Should the parents and/or the child be given counselling? Or should all of these treatments be used simultaneously?

Confusion pervades the study and discussion of hyperkinesis. There is no widespread agreement on a definition for hyperkinesis. There is no consensus on how to diagnose hyperkinesis. We do not know what causes hyperkinesis. Its treatment is highly controversial; and the long term outcomes

for treated or untreated hyperkinetic children are poorly documented.

Not only do clinicians disagree, but parents, teachers, government officials, and the press have joined a debate whose major focus has been whether or not hyperkinetic children should be treated with stimulant drugs, particularly methylphenidate and dextroamphetamine. In 1970, an erroneous news report, that 5-10% of Omaha children were being treated with stimulant drugs, fomented a flurry of public debate ("Drugs," 1971, p. 531). In the midst of the debate a congressional hearing was held on "Federal Involvement in the use of Behaviour Modification Drugs on Grammar School Children on the Right to Privacy Inquiry" (1970). Later, an interdisciplinary panel of professionals working in areas related to this issue prepared a brief entitled "Report of the Conference on the use of Stimulant Drugs in the Treatment of Behaviourally Disturbed Young School Children" (1971).

A sample of opinions expressed in lay publications during this debate is provided below :

"Fight Racist Drugging:... Hyperactive kids aren't sick, they're just sad or frustrated. They're only a high risk to the school systems, which want to keep kids in line. Amphetamines help the school system by suppressing the child's unacceptable emotions " ("Drugs," 1971, p. 534).

"SDS Charges Profs. Help Drug Kids:... The Brown-Pembroke Chapter of Students of a Democratic Society is circulating a petition charging that Brown University is involved in an alleged government program for the distribution of amphetamines to unruly elementary school children. The petition referring to the program as 'a means of artificially controlling children's behaviour,' recommends 1) the cessation of advocation of this method by professors

of psychology and education, and 2) the elimination of any research on the subject being done presently at the university " ("Drugs," 1971, p. 532).

"Drug Use Upheld for Management of Hyperactivity:... Use of behaviour modification drugs has produced 'incredibly good results' in a group of about 40 initially hyperactive children who have been followed for as long as five years at the New York Hospital-Cornell Medical Center here. Children once branded as unmanageable at home and in school show remarkable improvement in behaviour and learning capacity said Dr. Lee Salk " ("Drugs," 1971, p. 533).

The spectrum of opinion published in professional journals and held among professionals who treat hyperkinetic children is also wide. The fact that some stimulant drugs, particularly amphetamines, are among the drugs used in high doses by "drug abusers" makes many clinicians wary of prescribing them for children. In addition the recent discovery (Safer, Allen and Barr, 1972; Safer & Allen 1973) that prescribed stimulant medication taken over several years is associated with suppression of children's percentile height and weight has aroused serious concern. Some reassurance is provided by the fact that low doses of the stimulant methylphenidate (less than 20 mg/day) are associated with relatively little suppression of percentile weight and height. (Percentile height and weight values indicate what percent of children of the same age and sex are shorter and weigh less respectively.)

Some clinicians are reluctant to use stimulants at any stage in the treatment of hyperkinesis because of their apparent effect on growth and the potential of other unknown side-effects including the possibility of encouraging drug

abuse.

Other clinicians prefer to use stimulants as a second course of action if drug-free interventions such as counselling of the family, and/or child, and/or school fail to bring about satisfactory improvement.

Still other clinicians believe that the risks involved in using stimulant medication are small in comparison with the benefits, and that it is therefore unethical to withhold stimulant medication from the hyperkinetic child. This group might argue that the encouragement to drug abuse is negligible when stimulants are prescribed for children in such small doses and given under parental supervision. They might argue in addition that the effects of stimulant medication on height and weight can probably be mitigated somewhat by adjusting dose, timing of medication, and adding extra snacks for children on such medication. The probability of important side-effects from the medication, they would argue, is outweighed by the behavioural and cognitive benefits of stimulant drugs which have been demonstrated in numerous controlled clinical trials among hyperkinetic children. Of course not all hyperkinetic children respond well to stimulant drug therapy. However, because the response under adequate dosage is reported to be rapid and easily discernable, this group of clinicians might argue for a trial run of stimulant medication as the first form of treatment. If improvement is not satisfactory other therapies can be attempted.

A final variation in the clinical philosophy on this issue is that combined drug and non-drug treatments should be used to give hyperkinetic children maximum assistance. One group reports treating hyperkinetic children with pharmacotherapy, behaviour modification, family and teacher educational groups, curriculum counselling, and videotape feedback techniques (Feighner & Feighner, 1974).

While many studies have been done to compare active drugs with placebo in the treatment of hyperkinesis, there is very little known about the relative effectiveness of drug therapy versus non-drug therapy versus combined therapies for hyperkinetic children. Therefore clinicians are forced to select therapeutic programs for hyperkinetic children partly on the basis of their own clinical predilections.

If the various therapeutic modalities available were compared in controlled clinical trials then clinicians would be able to select from among them on the basis of demonstrated comparative effectiveness and side-effects rather than on the basis of presumed comparative effectiveness and side-effects.

The primary purposes of this thesis are to :

1) review selected portions of the literature on hyperkinesis with special attention to the literature on the treatment of hyperkinesis, and
2) set forth the design for a trial of drug, non-drug, and combined therapies for hyperkinesis.

2. LITERATURE REVIEW

2.1. OVERVIEW OF THE LITERATURE ON HYPERKINESIS

The etiology, diagnosis, prognosis, and treatment of hyperkinesis are subjects fraught with confusion and controversy. The literature in this area is substantial. More than 300 distinct articles are listed under "Hyperkinesis" in Index Medicus and in Psychological Abstracts since "Hyperkinesis" became a subject heading in these volumes in 1969 and 1973 respectively. Lipman's (1971) bibliography on Pharmacotherapy of Children, with a focus on hyperkinesis, lists more than 300 pre-1969 articles and numerous post-1969 articles as well. Further pertinent references can be found in the bibliographies of the 600-plus articles located through Index Medicus, Psychological Abstracts, and Lipman's bibliography.

In addition several complete volumes have recently been devoted to minimal brain dysfunction (MBD) which is a cluster of disorders including hyperkinesis. As explained in the next section on Terminology, some authors discuss children with MBD who are not hyperkinetic; however, a substantial proportion of the material in the following three volumes is pertinent to the study of hyperkinesis.

Minimal Brain Dysfunction published by Annals of the New York Academy of Science (Cruz, Fox & Roberts, Eds., 1973) is a compilation of articles in the following areas: historical overview, conceptual models;

experimental data; epidemiology; environment, heredity, and natural history; diagnosis and treatment, drug treatment; and non-drug treatment of MBD. Wender's book, Minimal Brain Dysfunction in Children, 1971, presents information gleaned from his review of the literature and his clinical experience on; characteristics; etiology, prevalence, diagnosis, prognosis, management, and the psychological basis of MBD. A third publication which provides current information pertaining to this area is the Psychopharmacology Bulletin, Special Issue, 1973. The first two sections of the publication provide a summary of past and present research, being supported by the Psychopharmacology Research Branch of the National Institute of Mental Health, on minimal brain dysfunction and other disorders of childhood. Much of the rest of this publication pertains to a battery of rating scales which has been put together to form a standard package for assessing children in research studies in order to facilitate comparison of results between studies.

The 600-plus articles and books related to hyperkinesis will not all be reviewed here. Fortunately, an interdisciplinary panel of 15, chaired by Dr. D.X. Freedman, did take on the responsibility of reviewing the available information in this area; and they have published a succinct report of what is known, what is believed, and what is not known about hyperkinesis. This panel was convened in 1971 by the Office

of Child Development and the Office of the Assistant Secretary for Health and Scientific Affairs in the United States in response to the public furor regarding stimulant drug treatment of hyperkinesis. Their publication is entitled "Report of the Conference on the Use of Stimulant Drugs in the Treatment of Behaviourally Disturbed Young School Children," (1971). Excerpts from that report are provided here so that the reader will have an overview of the available state of knowledge on hyperkinesis. Certain portions of the literature will then be discussed in greater detail.

Characteristics of Hyperkinesis

The panel reported that "Hyperkinetic Disorders" are best known by one of two names - minimal brain dysfunction or hyperkinetic behavioural disturbance. "The major symptoms are an increase of purposeless physical activity and a significantly impaired span of focused attention. The inability to control physical motion and attention may generate other consequences, such as disturbed mood and behaviour within the home, at play (with peers, and in the schoolroom" (p.24).

Prevalence

"A conservative estimate would be that moderate and severe disorders are found in about 3 out of 100 elementary school children..... More males than females are affected. A near majority are reported to have had behavioural problems since infancy..... Some of the children show hyperactivity and reduced attention which ranges in degree from mild to severe, with or without associated physical signs or special

learning impairments; some have complex behavioural and personality problems, as well as special learning and reading difficulties, along with the major hyperkinetic symptoms " (p.24).

Causes

"We know little about definitive causes. The disorder has been ascribed to biological, psychological, social or environmental factors, or a combination of these. There is speculation that the core set of symptoms - those affecting control of attention and motor activity - may have their origin in events taking place before the child is born or during the birth process, or they may be related to some infection or injury in early life. The neurological and psychological control of attention is an important but incompletely researched topic, as are the nutritional, perinatal, and developmental factors. Thus, in many instances, it is not yet possible even to speculate as to original causes " (pp.24-25).

Course

"Usually the excessive activity and attentional disturbances are less apparent after puberty. Specialists citing experience, and some fragmentary research data, believe that treatment enables many to lead productive lives as adults, while severely afflicted children who remain untreated may be significantly at risk for adult disorders. Extensive research is still required on these points " (p.25).

Diagnosis

"In diagnosing hyperkinetic behavioural disturbance it is important to note that similar behavioural symptoms may be due to other illnesses or to relatively simple causes. Essentially healthy children may have difficulty maintaining attention and motor control because of a period of stress in school or at home.... The diagnosis is clearly best made by a skilled observer. There unfortunately is no single diagnostic test " (p.25).

Treatment

"The fact that these dysfunctions range from mild to severe and have ill-understood causes and outcomes should *not* obscure the necessity for skilled and special interventions. Several approaches now appear [underline mine] helpful. Special classes and teachers can be directed to specific learning disabilities and thus restore the confidence of the child who experiences chronic failure. Modification of behaviour by systematic rewarding of desired actions has been reported to be useful in some children. Elimination of disturbing influences in the family or classroom through counselling may often tip the balance....

Stimulant medications are beneficial in only about one-half to two-thirds of the cases in which trials of the drugs are warranted. The stimulant medications are considered to be the first and least complicated of the medicines to be tried.... Response to stimulant medication cannot be predicted in advance. Fortunately, the issue can be resolved quickly. When stimulants are given in adequate doses, a favourable response - when it occurs - is fairly rapidly obtained.... Thus, if an adequate test of pharmacotherapy (a few days or weeks) produces only doubtful benefits or none at all, treatment can be promptly terminated.... When the medication is effective, the child can modulate and organize his activities in the direction he wishes. The stimulant does not slow down or surpress the hyperkinetic child in the exercise of his initiative. Nor does it "pep him up," make him feel high, overstimulated or out of touch with his environment. Rather, they appear to mobilize and to increase the child's abilities to focus on meaningful stimuli and to organise his bodily movements more purposefully. The hoped-for secondary consequences are better peer relationships, improved self-image and pleasure in acquiring competencies. Any coexisting dysfunctions - such as special perceptual and learning handicaps - must not

be left unattended, simply because pharmacotherapy is available and sometimes helpful. Similarly, personality and psychological problems, social and family problems, may require continued attention" (pp.25-26).

Concerns

"one should not confuse the effects of intravenous stimulants and the high dosages used by drug abusers with the effects or the risks of the low dosages used in medical therapy. In the dosage used for children, the questions of acute or chronic toxicity noted in the stimulant abuser are simply not a critical issue. Unwanted mental or physical effects do rarely appear in children; cessation of therapy or adjustment of dosage quite readily solves the problem. Thirty years of clinical experience and several scientific studies have failed to reveal an association between the medical use of stimulants in the pre-adolescent child and later drug abuse....

We doubt that prescriptions for the children who benefit from stimulants will require the manufacture of excessive and dangerously divertible supplies. With sensible precautions, there is at present no evidence justifying sensational alarm either, about the safety of the individual child who can benefit from therapy or about the safety of the general public" (pp. 26-27).

Conclusions

"In summary, there is a place for stimulant medications in the treatment of the hyperkinetic behavioural disturbance, but these medications are not the only form of effective treatment. Expanded programs of continuing education for those concerned with the health care of the young and also sustained research into their problems, are urgently needed" (p.29).

The report from which these previous excepts were

taken is in part a statement of clinical impressions and opinions and in part a summary of evidence collected from research. Unfortunately, references pertaining to the information given are not provided with the report, so it is impossible for a reader to know what evidence was included and what was overlooked in writing the report. In any case, these excerpts from the report are presented not as the gospel on hyperkinesis, but as an overview which will acquaint the reader with issues that are not covered in depth in this thesis. In particular, there are two important areas of the literature which are not reviewed in this thesis, and these are the etiology and the natural history of hyperkinesis. As the excerpts from the report indicate we are uncertain about the causes and the course of hyperkinesis, and further research is needed in these areas.

For a more thorough discussion of the available information pertaining to the etiology of hyperkinesis, see the second chapter of the previously noted book by Wender (1971). For further discussion pertaining to the natural history of hyperkinesis and the long term prognosis with treatment see the fourth chapter of Wender (1971) and also Lipman (1973, p.5).

Issues pertaining to hyperkinesis which are discussed further in this literature review are terminology, diagnosis, prevalence, characteristics, and treatment. The areas which are reviewed exhaustively herein are:

1) studies estimating the prevalence of the hyperkinetic disorder,
2) all studies of methylphenidate treatment for hyperkinesis which met specified criteria, and
3) all studies of non-drug treatment for hyperkinesis which met specified criteria.

2.2 TERMINOLOGY PERTAINING TO HYPERKINESIS

Hyperkinesis means overactivity. How much activity and what type of activity should be present before it is labelled hyperkinesis is debatable. Children who are considered disturbing and/or disturbed because of the extent and nature of their activity have been discussed in the psychiatric literature for decades. The labels applied to such children have varied with time and place. Some of the terms used in reference to such children are: overactive, hyperactive, hyperkinetic, hyperkinetic syndrome, hyperkinetic disorder of childhood, hyperkinetic impulse disorder, hyperkinetic behaviour disorder, hyperkinetic reaction of childhood, and other appellations easily recognized as deriviatives of the cognomen overactive.

Because no consensus has yet been reached on the definition of hyperkinesis, the children who are called hyperkinetic by one person may not be called hyperkinetic by another. Even when authors seem to be describing similar types of hyperkinetic children, they may label the disorder differently. It is easy for a reader to recognize the labels derived from the term overactive, such as hyperactive, hyperkinetic behaviour disorder, or hyperkinetic reaction of childhood. However, a reader may be confused by the fact that some authors refer to hyperkinesis as: minimal cerebral dysfunction, or minimal brain damage, or minimal brain dysfunction (MBD), or other variations of such terms. These

forbidding titles arose because some children who appeared at mental health clinics, with hyperactivity as the chief complaint, had other deficits such as poor coordination, a wide scatter in their IQ subtest scores, and abnormal EEG patterns, which suggested that some minimal central nervous system dysfunction might exist in the absence of any signs of gross brain damage.

Hyperkinetic children were among the first to whom the label MBD was applied, and they may constitute a major proportion of those children assessed as having MBD. This may explain why some authors use the terms hyperkinesis and minimal brain dysfunction interchangeably. However, most authors do not use the terms hyperkinesis and MBD interchangeably; and it is confusing to do so. Clements (1966, p.9) in a U.S. Health Education and Welfare Monograph, provided what now seems to be the most widely used definition of MBD.

> "The term 'minimal brain dysfunction syndrome' refers in this paper to children of near average, average, or above average intelligence with certain learning or behavioural disabilities ranging from mild to severe, which are associated with deviations of function of the central nervous system. These deviations may manifest themselves by various combinations of impairment in perception, conceptualization, language, memory, and control of attention, impulse, or motor function."

Within the MBD syndrome, Clements includes the hyperkinetic behaviour syndrome, the hypokinetic syndrome, learning disabilities, and other disorders. Thus MBD is a term applied to a broad range of children's problems including

hyperkinesis, and the definition of MBD is not very precise. Similarly, most of the definitions which have been offered for hyperkinesis are not very precise. That is, there could be substantial disagreement about whether a child fits the definition, as will be discussed in the section on Definitions and Diagnosis.

Throughout this thesis, for the sake of consistency, the terms hyperkinesis or hyperkinetic are used in referring to children described by various authors as having hyperactivity, the hyperkinetic syndrome, the hyperkinetic reaction of childhood, or other hyperactive or hyperkinetic disorders. At a few points in the thesis, where it seemed important for clarity in discussing the work of another author, the exact terms which that author used (e.g. overactive, or hyperactive) are repeated here. I have not assumed that children, described by any given author as having MBD, are hyperkinetic unless the author so indicated in his own description.

2.3. DEFINITIONS AND DIAGNOSIS OF HYPERKINESIS

2.3.1. Definitions of Hyperkinesis

Hyperkinesis is not listed in the World Health Organization (WHO) International Classification of Diseases, Eighth Revision (ICD-8), which was approved by WHO in 1966. However, at the Third WHO Seminar on Psychiatric Diagnosis Classification and Statistics in 1967, it was proposed that the hyperkinetic syndrome be included in the 1975 revision of the International Classification of Diseases which will be ICD-9. From this seminar, the first draft of a glossary of terms was developed for inclusion in ICD-9. The definition of hyperkinesis found under Specific Developmental Disorders in this glossary is as follows.

" Hyperkinetic Syndrome. This category should be used for disorders in which poorly organized and poorly regulated extreme overactivity, distractibility, short attention span, and impulsiveness, are the chief characteristics and in which the disorder is clearly *not* secondary to any other psychiatric syndrome. Marked mood fluctuations and aggression are also common symptoms of the disorder" (Rutter, Lebovici, Eisenberg, Sneznevskij, Sadoun, Brook, Lin, 1969, p.58)

One phrase in this definition poses a problem; this phrase is: "the disorder is clearly not secondary to any other psychiatric syndrome." Deciding whether hyperkinesis is secondary to other psychiatric syndromes is problematic. For example, if hyperkinesis and psychiatric problems in the family coexist, it is difficult to ascertain, especially at the time of assessment and diagnosis, if hyperkinesis is a secondary symptom or if two primary

conditions coexist. If the family problems are treated, and abated, and the hyperkinesis subsequently disappears then one may presume that the hyperkinesis was a secondary symptom to the family problems or to some other condition which cleared up at the same time. If the family problems are treated, and abated, and the hyperkinesis does not abate, then one may presume that the hyperkinesis is a primary condition or that it is a secondary symptom and will be affected by improved family function after a few months. If the family problems are treated but no improvement occurs in the family then one has no further information with which to decide if the hyperkinesis was secondary to the family problems.

If instead the hyperkinesis is treated first (e.g. with stimulant drugs), and is improved without simultaneous amelioration of family problems, then one may presume that the hyperkinesis was a primary condition. However, it is conceivable that hyperkinesis, secondary to family problems, might be improved with stimulant medication, just as anxiety, secondary to family problems may be improved by antianxiety medication.

Thus using the definition of hyperkinesis proposed for inclusion in ICD-9, clinicians may have substantial difficulty and disagreement (especially at the time of initial diagnosis but also in post-treatment diagnosis) in deciding whether hyperkinesis is a primary condition or secondary to some other condition.

Another rather similar definition of hyperkinesis is already in use in the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders, Second Edition (DSM-II). This manual is an adaptation of ICD-8 for use in Psychiatry. In it hyperkinesis is included under ICD-8 classification 308 which is Behaviour Disorders of Childhood:

"308.0 Hyperkinetic reaction of childhood (or adolescence)
This disorder is characterized by overactivity, restlessness, distractibility, and short attention span, especially in young children; the behaviour usually diminishes in adolescence.
If this behaviour is caused by organic brain damage, it should be diagnosed under the appropriate non-psychotic organic brain syndrome (q.v.)" (DSM-II, p.49-50).

The definition in DSM-II reflects the fact that workers in this field generally describe but do not quantify the extent of the hyperkinetic disorder. Surely one would not consider a child hyperkinetic if on only a few occasions he was more active, restless, distractible, and short in attention span than others wanted him to be. However, what about children who exhibit these characteristics 25%, 50%, 75%, or 100% of the time? It is not clear with the DSM-II definition whether all or only some of such children should be considered to have the hyperkinetic reaction of childhood.

In addition, this definition poses the generally insoluable problem of deciding if particular behaviours are "caused" by organic brain damage. There are a number of things which may make one suspect that minor organic damage has occurred. These include a history of certain complications with birth, the presence of abnormal EEG's,poor motor

co-ordination or other soft neurological signs, and a wide scatter in IQ subtest scores. However, some of these can be environmentally induced characteristics, so their presence or absence does not tell one anything definitive about the origin of a hyperkinetic child's problems. Furthermore the same characteristics can also be found among otherwise normal children (though perhaps with less frequency). In short those who state that a child's hyperkinetic behaviour is or is not caused by organic brain damage are in most instances only guessing about etiology.

A third definition for hyperkinesis has been offered by Werry (1968a, p.583).

" Developmental hyperactivity will be defined as a level of daily motor activity which is clearly greater (ideally by more than two standard deviations from the mean) than that occurring in children of similar sex, mental age, socio-economic and cultural background and which is not accompanied by clear evidence of major central nervous system disorder or childhood psychosis and which has been present consistently since the earliest years of life."

There may be some disagreement about whether or not a particular child has a "major central nervous system disorder" (e.g. epilepsy, cerebral palsy), or a "childhood psychosis" (e.g. autism, schizophrenia), or what constitutes "the earliest years of life" (birth, age 2, or age 5). Nevertheless, there would probably be less disagreement over whether or not a child met this definition than there would be over whether or not a child met the proposed ICD-9 definition or the DSM-II definition.

Werry's definition is more precise about the severity of symptoms to be labelled hyperkinesis (two standard deviations from the mean), and Werry's definition requires no contentious inferences about etiology to be made.

Subsequent to the formulation of the proposed ICD-9 definition, the DSM-II definition and Werry's definition, a fourth definition of hyperkinesis was formulated from the deliberations of a sub-committee brought together by the Psychopharmacology Research Branch of the National Institute of Mental Health (NIMH). Werry (1973) has summarized the results of this sub-committee's deliberations. From these deliberations, a schema of mutually exclusive and exhaustive diagnostic categories were formulated for child psychiatry. In my view this is an important step towards order in psychiatric diagnosis. One of the diagnostic categories in this schema is the Hyperkinetic Reaction, and the following criteria are provided for diagnosis.

HYPERACTIVE REACTION (308.0)

"NECESSARY & SUFFICIENT SYMPTOMS

Hyperactivity - with a high and conspicuous level of gross motor activity (locomotion; or 'rump' hyperactivity when seated, i.e., squirming, changing position and getting up and down frequently; but not finger-hand-twisting, picking or other small muscle activity) occurring across environments in situations in which sedentary or quiet behaviour is appropriate for age.

and

Disorder of attention - with higher distractibility and shorter attention span than appropriate for chronological

age (not mental age) especially in school, or group situations.

SYMPTOMS COMMONLY ASSOCIATED BUT NOT SUFFICIENT FOR DIAGNOSIS

Poorly integrated and labile behaviour, which gives the impression of immaturity and of uneven but generally inadequate abilities.

Extremely variable relation to adults (including examiner), with rapid fluctuation from attempts at compliance to silly clowning, boisterous, mischievous or impertinent behaviour, clinging and demanding behaviour and/or angry or sullen negativism.

Labile affect. React with excessive irritability to any situation interpreted as rejecting demanding or restricting, with angry, suspicious, anxious, unhappy and silly clowning responses, often associated with gross motor discharge, tantrums, destructive or aggressive behaviour.

Speech is often sparse and unelaborated with a tendency to evade emotionally charged material.

Fantasy is usually expressed more clearly in play; concerned with movement and aggression, diffuse fears of retaliation and loss of love.

Motility usually variable, impulsive and poorly coordinated. Movements are relatively undifferentiated for age; having difficulty suppressing gross body movement when attempting isolated, finely coordinated finger-hand or arm movements. Body manipulation relatively uninhibited for age; chewing, sucking, nose picking, masturbation.

Unable to conform to demands of a group situation with peers; often become scapegoats and/or participate peripherally by provocative, silly, teasing, aggressive, quarrelsome behaviour; usually considered "babies" and "pests" by peers.

Adults usually consider them immature, demanding, difficult to manage. Have chronic and recurring difficulties in adapting to age-appropriate social and educational demands.

DISQUALIFIERS

Psychosis - If so permeated by autistic preoccupations or thought disorder, as defined under schizophrenia, as to necessitate a diagnosis of psychosis, then classify as Childhood Schizophrenia. Expressed preoccupation with anxiety and sadness which is pervasive, NOT, transient.

Unsocialized Aggressive Reaction with organized behaviour pattern. See discussion under 'Unsocialized Aggressive Reaction', 'Disqualifiers' (Werry, 1973, pp.139-140)."

I am impressed that this group managed to draw up mutually exclusive and exhaustive categories for diagnosis in child psychiatry, and that within each category they listed: necessary and sufficient symptoms for diagnosis, symptoms commonly associated but not sufficient for diagnosis, and disqualifiers for the diagnosis. However, this schema is not without its problems. First of all a diagnostician must decide whether "significant psychopathology" is present, and, if it is, the diagnostician goes on to decide which classification it falls into. There may be a substantial amount of disagreement over the first decision that a child has significant psychopathology or does not (normal). For example at what level of severity should symptoms of motor activity and short attention span be considered significant enough to warrant the initial classification of psychopathology (rather than normal) and the subsequent classification of hyperkinesis. It is not clear why the sub-committee did not provide

quantitative as well as qualitative guidelines for diagnosis as for example Werry (1968a, p.583) did in an earlier publication when he said "developmental hyperactivity will be defined as a level of daily motor activity which is clearly greater (ideally by more than two standard deviations from the mean) than that occurring in children of similar sex, mental age, socio-economic and cultural background."

Perhaps a reference to "two standard deviations from the mean" was not included in the NIMH Committee's description of necessary and sufficient conditions for the diagnosis of hyperkinesis because it was felt that even children with less extreme symptoms warrant treatment. Nevertheless the committee could have suggested other quantitative cut-off points for use in diagnosis. Perhaps they did not include quantitative guidelines for the diagnosis of hyperkinesis because there were no available norms against which one could measure the extremeness of a child's motor activity and short attention span. However, norms for motor activity and attention span may be available in the near future; and in my view quantitative measures of these symptoms for an individual child, compared to the norm for children of the same age and sex, should be utilized in standardizing the diagnosis of hyperkinesis.

2.3.2. Diagnostic Tests for Hyperkinesis

In the previously discussed definitions of hyperkinesis, several symptoms were mentioned. These were as follows :

ICD-9 : overactivity, distractibility, short attention span, impulsiveness.

DSM-II : overactivity, distractibility, short attention span, restlessness.

Werry : motor activity.

NIMH : motor activity, distractibility, short attention span.

It would be useful to have standardized tests of each of the relevant characteristics so that these tests could be utilized in the diagnosis of hyperkinesis. That is, it would be useful to have testing instruments which measured the relevant characteristics in an individual child and for which norms were available to compare the child to other children of the same age, and sex.

Particular instruments which could be used to develop norms for motor activity in a defined situation are the pedometer, actometer, and stabilimetric seat cushion. Tests which could be used to develop norms for attention span include the Developmental Attention Test (Kassinove & Summers, 1968), and the Continuous Performance Test (Sykes, Douglas & Morgenstern, 1972). There are some behaviour checklists available which have been used to assess hyperkinesis and which include items on motor activity, and attention span, as

well as distractibility, and restlessness. Three such checklists are shown in Tables 1, 2, and 3 on pages 28 to 30.

On the Werry-Weiss-Peters Activity Scale (Table 1), a child can be rated by a parent or teacher, although it is possible that neither would have enough information on home and school behaviour to be able to rate all behaviours accurately. Total scores on this scale range from 0 (least active) to 62 (most active) and one could pick a cut-off point above which children could be considered hyperkinetic. There are no suggested cut-off scores for diagnosing hyperkinesis with the Werry-Weiss-Peters Activity Scale. However, there are suggested cut-off scores for use in diagnosing hyperkinesis with the behaviour rating scales shown in Tables 2 and 3.

Davids' Rating Scale (Table 2) is scored from 1 for much less than to 6 for much more than most children. Only the first six items are scored, so the total score ranges from 6 to 36. Davids (1971, p.37) states " in our work to date we have found that total scores of 24 or more suggest the presence of hyperkinesis in a child. Scores ranging from 19 to 23 are regarded as suspicious, and scores of 18 or less are viewed as indicating the absence of significant hyperkinesis in the child." (The seventh item is not included in the scoring system since some raters such as parents would not be able to complete this item accurately.)

Conners Parent-Teacher Questionnaire (Table 3) is scored from 0, "not at all", to 3, "very much" for each of 10 items, so the total score ranges from 0 to 30. It can be completed by either parents or teachers. Sleator and von Neuman (1974,p.21)

report that a score of 15 is two standard deviations above the normal mean, and they consider children scoring 15 or greater as potential subjects for drug treatment of hyperkinesis. They state that "the value of the scale as a diagnostic instrument was demonstrated by Sprague, Christensen and Werry [in press] with normative data collected at this center" (Sleator & von Neuman, 1974, p.20).

While both Davids' and Conners' Scales have suggested cut-off scores for diagnosing hyperkinesis, neither one has suggested age-specific cut-off scores. The same score could be used at all ages for diagnosing hyperkinesis with Davids' Scale since it automatically adjusts for age by asking the rater to rate the child in comparison with other children of the same age and sex. One could include similar instructions with Conners Parent-Teacher Questionnaire, or one could use age-specific scores for diagnosing hyperkinesis with the questionnaire since mean scores are likely to vary with age. Routh, Schroeder and O'Tuama (1974) demonstrated the variation of mean score with age for normal children being rated by their parents on the Werry-Weiss-Peters Activity Scale. A total of 140 children were rated on the 22 non-school items from the scale (possible scores 0 to 44). The 3 year olds showed a mean score of about 15, and this decreased fairly consistently with age to a mean score of about eight for the 9 year olds. It will be useful if the soon to be published normative data on the Conners Parent-Teacher Questionnaire (Sprague et al., in press) includes the mean and standard deviation of the scores for each year of age in the children sampled.

TABLE 1 : THE WERRY-WEISS-PETERS ACTIVITY SCALE

	NO	SOME	MUCH
During Meals			
Up and down at table	—	—	—
Interrupts without regard	—	—	—
Wriggling	—	—	—
Fiddles with things	—	—	—
Talks excessively	—	—	—
Television			
Gets up and down during program	—	—	—
Wriggles	—	—	—
Manipulates objects or body	—	—	—
Talks incessantly	—	—	—
Interrupts	—	—	—
Doing Home work			
Gets up and down	—	—	—
Wriggles	—	—	—
Manipulates objects or body	—	—	—
Talks incessantly	—	—	—
Requires adult supervision or attendance	—	—	—
Play			
Inability for quiet play	—	—	—
Constantly changing activity	—	—	—
Seeks parental attention	—	—	—
Talks excessively	—	—	—
Disrupts other's play	—	—	—
Sleep			
Difficulty settling down for sleep	—	—	—
Inadequate amount of sleep	—	—	—
Restless during sleep	—	—	—
Behavior Away From Home (except at school)			
Restlessness during travel	—	—	—
Restlessness during shopping (includes touching everything)	—	—	—
Restlessness during church/movies	—	—	—
Restlessness while vising friends, relatives, etc.	—	—	—
School Behavior			
Up and down	—	—	—
Fidgets, wriggles, touches	—	—	—
Interrupts teacher or other children excessively	—	—	—
Constantly seeks teacher's attention	—	—	—
Subtotal Score	× 0	× 1	× 2
Total score			

From Werry, 1968a, p.588

TABLE 2: DAVIDS RATING SCALE FOR HYPERKINESIS

Child's Name _____ Birth Date _____

Rater's Name _____ Date of Rating _____

Please rate the child on each of the characteristics (or behavior) listed on the following scales. Place a check mark at the point on the scale indicative of your estimate of the degree to which the child possesses the particular characteristic.

As you make each rating, judge the child in comparison with other children of the same sex and age. That is, the ratings should indicate your estimate of the child's behavior in comparison with the behavior displayed by other "normal children."

For each of the characteristics, which are defined below, place a check mark at one of the six points on the scales running from "much less than most children" to "much more than most children." Do not mark the midpoint on any of the scales. Even though it may sometimes be difficult to make a judgment, please make a rating on one or the other side of the scale.

1. *Hyperactivity* – Involuntary and constant overactivity, advanced motor development (throwing things, walking, running, etc.); always on the move, rather run than walk; rarely sits still.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

2. *Short Attention Span and Poor Powers of Concentration* – Concentration on a single activity is usually short, with frequent shifting from one activity to another, rarely sticks to a single task very long.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

3. *Variability* – Behavior is unpredictable, with wide fluctuations in performance, sometimes he (or she) is good and sometimes bad.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

4. *Impulsiveness and Inability to Delay Gratification* – Does things on the spur of the moment without thinking; seems unable to tolerate any delay in gratification of his (her) needs and demands; when wants anything, he (she) wants it immediately, does not look ahead or work toward future goals, thinks only of immediate present situation.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

5. *Irritability* – Frustration tolerance is low, frequently in an ugly mood, often unprovoked; easily upset if everything does not work out just the way he (she) desires.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

6. *Explosiveness* – Fits of anger are easily provoked, reactions are often almost volcanic in their intensity; shows explosive, temper-tantrum-type of emotional outbursts.

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

7. *Poor School Work* – Has difficulty participating successfully in school work, cannot concentrate on school work, has some specific learning difficulties or blocks (e.g., poor in arithmetic, poor in reading, etc.); poor visual-motor coordination (e.g., awkward gestures, irregular handwriting, poor in drawing, etc.).

Much Less Than Most Children	Less	Slightly Less	Slightly More	More	Much More Than Most Children

From Davids 1971, p.500

TABLE 3: CONNERS PARENT-TEACHER QUESTIONNAIRE

PATIENT INITIALS

A B C D E F G H I J
K L M N O P Q R S T
U V W X Y Z

FIRST INITIAL

A B C D E F G H I J
K L M N O P Q R S T
U V W X Y Z

SECOND INITIAL

FORM NO.

NUMBER MALES 001 TO 499, FEMALES 500 TO 998

0 1 2 3 4 5 6 7 8 9

PATIENT

0 1 2 3 4 5 6 7 8 9

RATER

0 1 2 3 4 5 6 7 8 9

PERIOD

0 1 2 3 4 5 6 7 8 9

M F

Hours 1 Days 2 Weeks 3 Months 4

PLEASE USE A NO 2 LEAD PENCIL BE SURE TO MAKE MARKS HEAVY AND DARK ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE

INSTRUCTIONS Listed below are items concerning children's behavior or the problems they sometimes have Read each item carefully and decide how much you think this child has been bothered by this problem *at this time* NOT AT ALL, JUST A LITTLE, PRETTY MUCH, or VERY MUCH Indicate your choice by filling in the space (▬) in the appropriate column to the right of each item

ANSWER ALL ITEMS

	Not at All	Just a Little	Pretty Much	Very Much
1. Restless (overactive)	0	1	2	3
2 Excitable, impulsive	0	1	2	3
3. Disturbs other children	0	1	2	3
4. Fails to finish things he starts (short attention span)	0	1	2	3
5 Fidgeting	0	1	2	3
6 Inattentive, distractable	0	1	2	3
7. Demands must be met immediately; frustrated	0	1	2	3
8 Cries	0	1	2	3
9. Mood changes quickly	0	1	2	3
10. Temper outbursts (explosive and unpredictable behavior)	0	1	2	3

	None	Minor	Moderate	Severe
How serious a problem do you think this child has at this time?	0	1	2	3

From Psychopharmacology Bulletin -- Special Issue, 1973, p.222

Thus one could select age-specific cut-off scores for use in diagnosing hyperkinesis with this questionnaire.

None of the three aforementioned scales by Conners, Davids or Werry-Weiss-Peters has available information on inter-rater reliability, test-retest reliability, or sensitivity, specificity, and predictive value for treatment response. Of course such information would be very valuable in choosing the best of the three as a diagnostic test. In the absence of such information, I am currently partial to the use of Conners Parent-Teacher Questionnaire over the Davids or the Werry-Weiss-Peters Scale, because the Conners Parent-Teacher Questionnaire seems to have the best possibility for widespread acceptance and usage as a standard diagnostic test for hyperkinesis. The Conners Parent-Teacher Questionnaire and/or two other questionnaires by Conners are currently used by many investigators studying hyperkinesis. The three questionnaires developed by Conners and entitled Conners Parent-Teacher Questionnaire, Conners Teacher Questionnaire (Appendix 1, p.217), and Conners Parent Questionnaire (Appendix 2, p .[218]), are all included in a battery of tests put together to facilitate uniform reporting of results of research among the pediatric population. This battery was developed with the support of the Psychopharmacology Research Branch of the National Institute of Mental Health in the United States, and evaluators using it can send their forms to the Biometric Laboratory Information Processing System at

George Washington University in Kensington, Maryland for statistical analysis and incorporation in a central data bank which hopefully will facilitate the advance of knowledge regarding treatments for childhood disorders (Psychopharmacology,1973, p.24).

An alternative to the use of one diagnostic test, such as Conners Parent-Teacher Questionnaire, is the use of results from several diagnostic tests which provide a profile of the child. Knights (1973) and Conners (1973 a) have both discussed a computer assisted formulation of a profile of test results for children under assessment for MBD. The profile may consist of scores from medical, psychological, neurological or other tests. When such profiles are paired with known responses to alternative treatments, we may be able to identify subgroups who respond differentially to the alternative treatments. The combination of scores in such a profile may be a better predictor of response to alternative treatments than would any single test score. Thus we may in the future be able to use such profiles to determine which treatment for the child under assessment has the highest probability of success.

One group of investigators (Satterfield, 1973; Satterfield, Lesser, Saul & Cantwell, 1973) has worked on the analysis of EEG's and neurological examinations to try to distinguish hyperkinetics and normals, and among the hyperkinetics the good and poor responders to stimulant drug

treatment. They have been fairly successful in both efforts. However, the combination of results from EEG's and neurological examinations would not make a particularly good diagnostic instrument as shown in Table 4, page 34, which is based on information extracted from Satterfield (1973, p.39).

If one decided on the basis of neurological examinations and EEG's which children assessed clinically as hyperkinetic should not receive methylphenidate (those with normal EEG's and normal neurological examinations) and which should receive methylphenidate (those with an abnormal EEG and/or an abnormal neurological examination), then one would withhold methylphenidate treatment from about 15 out of every 22 (68%) hyperkinetic children who would show a good response to such treatment (a good response in this case being 11% to 75% improvement on Conners Teacher Questionnaire). Given that a short period of methylphenidate treatment is fairly innocuous (unlike some surgical or radiation treatments in medicine), it seems reasonable to offer methylphenidate treatment to all children who are considered hyperkinetic by clinicians rather than add EEG's and neurological examinations to the diagnostic criteria.

In my opinion, Conners Parent-Teacher Questionnaire currently seems to be the most appropriate test for use in developing a standard criteria for the diagnosis of hyperkinesis. Using this questionnaire, we can find out how various cut-off scores affect the sensitivity, specificity,

TABLE 4 : THE USE OF EEG'S AND NEUROLOGICAL EXAMINATIONS IN THE DIAGNOSIS OF HYPERKINESIS

	Treatment Response: Good (+ 11% to +70%)	Poor (-40% to +10%)	Total
* Abnormal EEG and/or Abnormal Neurological	31	4	35
Normal EEG and Normal Neurological	15	7	22
Total	46	11	57

Sensitivity = 31 ÷ 46 = .67

Specificity = 7 ÷ 11 = .64

Positive Predictive Value = 31 ÷ 35 = .89

Negative Predictive Value = 7 ÷ 22 = .32

* Among children diagnosed clinically as having MBD with hyperactivity. Based on data in Satterfield, 1973.

and predictive value of this diagnostic test vis-à-vis treatment response. Of course if we should find in the future that another harmless, convenient and inexpensive test for hyperkinetic children (e.g. Davids Rating Scale or a standardized test of attention) has better sensitivity, specificity and predictive value in relation to treatment response (e.g. to methylphenidate) then it would be appropriate to use such a test in the diagnosis of hyperkinesis. Bear in mind that some children, who score very high (hyperkinetic) on Conners Parent-Teacher Questionnaire, may be rated as probable non-responders to methylphenidate on another diagnostic test, such as a standardized test of attention, and may in fact turn out to be non-responders to methylphenidate. However, such children still have serious hyperkinetic symptoms according to parents and/or teachers filling out the Conners Parent-Teacher Questionnaire, and this problem still needs some form of attention or treatment.

The rest of this section is devoted to a discussion of Conners Parent-Teacher Questionnaire, Conners Teacher Questionnaire and Conners Parent Questionnaire with particular attention to the factor analyses of the latter two. As previously discussed, a clinician can decide on the basis of the 10 item Conners Parent-Teacher Questionnaire which children warrant treatment for hyperkinesis. For example

a clinician might decide that when both parent(s) and teacher(s) rate a child higher than 15 on the Questionnaire, that such a child warrants treatment for hyperkinesis. (Hopefully age-specific norms for this Questionnaire will soon be available to facilitate the development of age-adjusted cut-off scores.) A clinician can then move on to a more thorough assessment with the 39 item Conners Teacher Questionnaire (Appendix 1, p217) and the 93 item Conners Parent Questionnaire (Appendix 2, p.218) each of which includes the 10 items on the abbreviated form. In the Parent Questionnaire, parents are asked to rate their child on 93 items and to circle those which they are most concerned about. Thus a fairly broad profile of the child's behaviour can be provided with notation of areas which particularly need attention. All three questionnaires can be used pre-treatment to assess the nature and severity of the behavioural disorder, and post-treatment to assess improvement.

When Conners (1969) factor analyzed the Teacher Questionnaire, five factors emerged and one of them was labelled hyperactivity. Inter-rater reliability values for the factors are not available. However an indication of the test-retest reliability of the factors is provided by data showing that under placebo treatment the five pre-post factor score correlations ranged from .72 to .91. (Under drug treatment each of the five pre-post factor score correlations was lower.) Conners (1973b, p.26) also reports that Sprague et al. (in press) compared normal children to children diagnosed as hyperkinetic

and found that all five factors significantly discriminated between the groups.

Conners (1970; 1973 b, p.30) has also factor analyzed the Parent Questionnaire using two different approaches. In the earlier publication (1970) the scores of 24 groups of symptoms were factor analyzed for 316 clinic patients and 367 normal controls, producing six factors -- none of which was labelled hyperactivity. However the children who were considered hyperkinetic scored significantly higher than the neurotic children on factor I labelled Aggressive-Conduct disorder (Conners 1970, p.677). In the same study "discriminant function analysis showed that 83 percent of controls and 70 percent of clinic patients could be correctly identified from factor scores. Neurotic and hyperkinetic children were also correctly identified in 77 and 74 percent of the cases respectively. Mother-father agreement (inter-rater reliability) averaged .85 on total scores" (Conners 1973b, p.24).

In Conners later publication (1973 b) the scores of the 93 individual symptom items for the 683 subjects were factor analyzed, producing eight factors -- one of which was labelled Impulsive-Hyperactive. Of course the names picked for factors which emerge from a factor analysis are somewhat arbitrary in that one looks at the items loading on a particular factor and picks a title which seems to generally describe those items. One should not assume that the factor

analyses in which a factor is labelled Hyperactivity or Impulsive-Hyperactive has magically identified the real qualities of hyperkinesis which will always appear with the disorder.

A factor analysis can identify groups of items, for example behavioural symptoms which, in the sample studied, appear together or are correlated with each other (a factor) while being independent of other groups of items (factors). A given item will often "load" or appear, in part, on more than one factor, but be most heavily loaded on a single factor. Each item may be identified as belonging to the group of items or factor which it most heavily "loads on" (though to keep the factors strictly orthogonal one must retain the actual factor loadings for each item). A factor is given a name which seems to best describe the type of items included in it.

Thus a factor analysis of a symptom checklist identifies groups of symptoms which tend to appear together. Such an analysis can confirm informal observations that children who have one symptom, say aggressiveness tend to have other specific symptoms, while children who are passive for example, tend to have a different group of accompanying symptoms. One should bear in mind that it is impossible for a trait to appear on a factor if it is not measured, and that traits which cluster together in one sample which is atypical may not cluster together in the population at large.

It is interesting to compare Conners 10-item Parent-Teacher Questionnaire, which reportedly has the key items for diagnosing hyperkinesis, with the items which appear on the factor labelled "Hyperactivity" from the Teacher Questionnaire, and the items which appear on the factor labelled "Impulsive-Hyperactive" on the Parent Questionnaire. This is done in Table 5, pp.41-42.

Of the 10 items which appear on the Parent- Teacher Questionnaire, seven are also included on Conners (1969) Teacher Questionnaire. Four of these loaded on the Hyperactivity factor and three did not. Of the 10 items on the Parent-Teacher Questionnaire, all 10 appeared on the Parent Questionnaire. Only two are listed as part of the Impulsive-Hyperactive factor (Conners 1973b, p.55), however these two were not even included in the actual factor analysis (Conners 1973b, p.32) so it is unclear how it was decided which factor they should be listed with. An additional two of the 10 items have factor loadings high enough to be included among those items on the Impulsive-Hyperactive factor but they are not so included. No rationale is provided for these inconsistencies.

In any event this underscores the earlier point that a group of items labelled Hyperactivity as a result of the magic of factor analysis is not necessarily "the unveiled essence of the hyperkinetic disorder."

These caveats on factor analysis notwithstanding, all three of Conners questionnaires are useful in assessing behavioural symptoms. Conners Parent-Teacher Questionnaire in particular is herein recommended as an instrument for current use in diagnosing hyperkinesis.

TABLE 5: SYMPTOMS INCLUDED ON THE HYPERACTIVITY FACTORS OF CONNERS QUESTIONNAIRES

Parent-Teacher[a]		Teacher[b] Hyperactivity factor includes underlined items		Parent[c] Impulsive-Hyperactive factor includes underlined items	
Item #	Symptom	Item #	factor loading	Item #	factor loading
1)	restless or overactive	5)	80	52)	-34
2)	excitable, impulsive	6)	62	53)	-39
3)	disturbs other children	14)	66	49)	-15
4)	fails to finish things he starts, short attention span	8)	27[d]	54)	-26
5)	constantly fidgeting	1)	52[d]	80)	not factor analyzed
6)	inattentive, easily distracted	7)	35	79)	not factor analyzed
7)	demands must be met immediately - easily frustrated	3)[e]		85)	-56[f]
8)	cries often and easily	13)[e]		88)	-32
9)	mood changes quickly and drastically	16)[e]		91)	-48[f]
10)	temper outbursts, explosive and unpredictable behaviour	21)	33	55)	-15

a Conners 1973b, p.60
b Conners 1969; 1973b, pp.35-37
c Conners 1973b, p.30 and pp. 55-59
d Factor loading for 1969 item with slightly different wording than 1973 form
e Does not appear in 1969 factor analyzed form
Does appear in Teacher form in 1973b.
f Factor loading suggests this item should appear on this factor
x Does not appear on questionnaire

TABLE 5 continued :

Parent-Teacher[a]		Teacher[b] Hyperactivity factor includes underlined items		Parent[c] Impulsive-Hyperactive factor includes underlined items	
Item #	Symptom	Item #	factor loading	Item #	factor loading
x		2) hums and makes other odd noises 64		x	
x		29) teases other children or interfers with their activities 56		51) -10 rewarded	
x		35) excessive demands for teacher's attention 68[f]		x	
x		x		81) cannot be left alone -52	
x		x		82) always climbing -55	
x		x		83) a very early riser -32	
x		x		84) will run around between mouthfuls at meals -57	
x		x		89) unable to stop a repetitive activity -56	
x		x		90) acts as if driven by a motor -68	
x		x		86) cannot stand too much excitement -52[f]	
x		x		92) poorly aware of surroundings -47[f]	

a - x : for key see previous page of Table 5.

2.4 PREVALENCE OF HYPERKINETIC SYMPTOMS AND OF HYPERKINESIS

Only a few studies have attempted to produce estimates of the prevalence rates of hyperkinetic symptoms in children or of the prevalence rates of a condition severe enough to be termed a hyperkinetic disorder. One study in the former category, and five studies in the latter category are discussed in this section.

In one study by Werry and Quay (1971), teachers for kindergarten through grade two in the Urbana, Illinois public school system were asked to rate each of the children in their class on the Quay-Peterson problem checklist, which consists of 55 behaviour symptoms commonly found in child-guidance clinic populations. Ratings were made on 926 boys and on 827 girls (97.2%, and 95.7% respectively of those enrolled). The prevalence of many symptoms was high in this sample of public school children as shown in Table 6, on page 44.

You may recall a previous quote (p. 19) from DSM-II indicating that the hyperkinetic reaction of childhood is characterized by overactivity, restlessness, distractibility and short attention span. These same symptoms were present in 30.3%, 49.7%, 48.2% and 43.5% of boys in early public school grades respectively. The latter three symptoms were in fact the most common symptoms in boys. It seems likely that it is not the presence of these particular symptoms, but

TABLE 6: PREVALENCE OF BEHAVIOUR SYMPTOMS IN GRADES K, 1, & 2.

Symptoms from the 55 rated in Werry and Quay's study are cited here if :

*1) they are considered characteristic of hyperkinesis in DSM-II (see 2.1 Terminology)

2) they were among the 5 most common symptoms in public school boys in the study

3) they were among the 5 most common symptoms in public school girls in the study

	Boys (N=926)		Girls (N=827)	
	Percent Prevalence	Symptom Rank	Percent Prevalence	Symptom Rank
*2. Restlessness, inability to sit still	49.7	1	27.8	6
*45. Distractibility	48.2	2	28.3	5
8. Disruptiveness, tendency to annoy others	46.3	3	22.3	11
*20. Short attention span	43.5	4-5	25.8	8
22. Inattentiveness to what others say	43.5	4-5	25.0	9
*44. Hyperactivity; "always on the go"	30.3	15	13.8	23
30. Hypersensitivity; feelings easily hurt	26.9	18	31.8	4
21. Lack of self confidence	39.8	6	32.9	3
6. Self-consciousness; easily embarrassed	38.5	7	39.3	2
14. Shyness, bashfulness	33.3	10	41.4	1
NUMBER OF SYMPTOMS PER CHILD (55 POSSIBLE) MEAN:	11.4		7.6	
S.D	9.4		7.9	

Adapted from Werry and Quay 1971, p.138.

the total number of symptoms or the severity of symptoms which distinguishes children who are considered disturbing (disturbed). When parents take their disturbing children to mental health clinics or to pediatricians, school psychologists etc., the parents are asked to describe their child's behaviour. The parents are likely to cite the most common behavioural symptoms, and if the child is male the most common symptoms are likely to include restlessness, distractibility, short attention span and hyperactivity. It is not surprising that the literature on disturbing children includes descriptions of children with these symptoms. The name applied to such children's disturbing symptomatology is again not surprising - hyperactivity or hyperkinesis.

Note, according to Table 6, that girls in early public school grades are less likely than boys to exhibit restlessness, distractibility, short attention span, and hyperactivity, but more likely than boys to exhibit hypersensitivity, self-consciousness, and shyness. It is conceivable that this is a result of the differences in our socialization processes for girls and boys. At any rate, given such differences in common behavioural symptoms, it is not surprising that far fewer girls than boys are diagnosed as hyperkinetic by clinicians.

While 30.3% of boys and 13.8% of girls exhibited some degree of hyperactivity in this study, Werry and Quay by no means suggested that these large proportions of children had a hyperkinetic disorder requiring special

medical, behavioural, or educational attention. It is probably those children who exhibit severe forms of these symptoms or moderate forms of these symptoms plus additional troublesome traits who are likely to be considered in need of treatment for hyperkinesis.

We turn now to studies which have provided estimates of the prevalence of a condition severe enough to warrant labelling it a hyperkinetic disorder. In the "Report of the Conference on the Use of Stimulant Drugs in the Treatment of Behaviourally Disturbed Young School Children" (1971, p.24), the following statement is made about the prevalence of the hyperkinetic behavioural disturbance: "A conservative estimate would be that moderate and severe disorders are found in about 3 out of 100 elementary school children." Unfortunately no data or references are provided to substantiate this estimate.

In a study by Stewart, Pitts, Craig, and Dieurf (1966), a minimal amount of data was available for their estimate of the prevalence of hyperkinesis. They reported that 3 children from a total of two first grade classrooms had to be excluded from a normal control group they were selecting because these children had previously been diagnosed as hyperactive. From this they concluded that the prevalence of hyperactivity in children is approximately 4%. Since treatments for hyperkinetic children have been in the news quite a bit since 1966, it is possible that clinicians are

now more aware of the term hyperkinesis and thus more likely to render it as a diagnosis. For a condition which is as ill defined as hyperkinesis, the popularity of its diagnosis is probably a poor estimate of the actual prevalence of the disorder.

In fact Krager and Safer (1974) have collected survey data showing that in Baltimore County Public Elementary Schools the percent of children known by school nurses to be taking medication for hyperactivity went from 1.07% to 1.73% in the two years between spring 1971 and 1973. It is of course possible that the nurses' awareness of those taking such medication increased, but it seems unlikely that this would account for the large increase (62%), since in both years school nurses were responsible for maintaining a health record on every child including notation of medications taken. It seems more likely that the prevalence of the diagnosis of hyperkinesis increased and/or the practice of prescribing medications for this diagnosis increased over these years. Some additional results have been abstracted from Krager and Safer's study (1974, p.1119) and presented in Table 7 on page 48.

TABLE 7 : PERCENT OF BALTIMORE COUNTY CHILDREN ON MEDICATION FOR HYPERACTIVITY

	1971	1973
Districts with family income:		
greater than median--	1.22%	1.81%
less than median--	.93%	1.64%
Total County	1.07%	1.73%
N =	35,941	33,201

Adapted from Krager and Safer 1974, p.1119.

Given that a greater proportion of children in the higher income districts seem to be taking medications for hyperactivity, one could speculate that the prevalence of the disorder is higher in this group, or alternatively that the condition is being overdiagnosed and overtreated in the wealthier areas, or perhaps the condition is being underdiagnosed and undertreated in the poorer areas. It is difficult to make reasonable statements about the appropriateness of certain percentages of children being given medications for hyperkinesis without having an independent, valid estimate of the prevalence of this disorder among children.

The last two studies to be discussed in this section appear to have arrived at a definition of hyperkinesis and to have made estimates of the percentage of children in a sample surveyed who met this definition. Huessy (1967, p.131) says "we surveyed over 300 children in the second year of school by another questionnaire and found that 10% of

the children seemed to meet the definition of hyperkinesis, and that these were the children that the school was having the most difficulty with. The distribution was along the usual bell-shaped curve." Unfortunately Huessy did not include information on the questionnaire used, or the definition of hyperkinesis used so it is impossible for a reader to assess whether the criteria are too liberal or too restrictive and thus whether the estimate of prevalence is high, low or appropriate.

A final estimate of the prevalence of hyperkinesis comes from a prospective cohort study of live births on the island of Kauai, Hawaii (Werner, Bierman, French, Simonian, Conner, Smith, Campbell, 1968). A cohort of children born in 1955-56 were followed to 1965-66 when a panel reviewed information from medical sources, educational sources, the home, and standard tests in order to assess emotional, intellectual and physical status of each child. In this study hyperkinetic symptoms were defined as "extremely hyperactive, unable to sit still; marked inability to concentrate, distractable; extremely irritable" (Werner et al. 1968,p.116). Among the sample of 90% of children born in 1955 (N=750): 8.7% of the boys and 3.2% of the girls were reported to have hyperkinetic symptoms in 1965-66. The estimated prevalence of hyperkinetic symptoms among both sexes at about age 10 was thus 5.9%. Unfortunately the mass of information presented in this publication precluded the reporting of

details on how judgements were made about the "extremeness" of the hyperactivity, and what judgements were made if only some of the above symptoms were reported. We cannot tell if something around 6% was a priori considered a "reasonable" prevalence figure for hyperkinesis, and the indetification process adjusted accordingly to include approximately that proportion of children. However this seems unlikely since there does not appear to be any available information on which an apriori judgement of 6% might be made.

Estimates of the prevalence of symptoms considered characteristic of hyperkinesis, and estimates of the prevalence of a condition severe enough to be labelled a hyperkinetic disorder are summarized in Table 8. The 5 studies in the latter group are, to my knowledge, the best available estimates of the prevalence of hyperkinesis in children. Among these 5 studies, the lowest estimate of the hyperkinetic disorder is 3%. That means for every million children, 30,000 have hyperkinesis. The one estimate of the number of children taking medication for hyperkinesis suggests that for every million children 17,300 are being treated with medication for hyperkinesis.

TABLE 8: ESTIMATES OF THE PREVALENCE OF HYPERKINETIC SYMPTOMS AND OF THE HYPERKINETIC DISORDER IN CHILDREN

Prevalence in Public School Children of Symptoms often Considered Characteristic of Hyperkinesis	Boys %	Girls %	Total %	Source
Hyperactivity; always on the go	30.3	13.8	22.5	Werry & Quay, 1971. Grades K,1 & 2, N=1753.
Restlessness, inability to sit still	49.7	27.8	39.4	"
Distractibility	48.2	28.3	38.8	"
Short attention span	43.5	25.8	35.1	"
Prevalence of Hyperkinesis				
Moderate and severe hyperkinetic behavioural disturbance			3.	"Report" 1971. Evidence ?
Diagnosed as hyperactive			4.	Stewart et al.1966. N=two first grade classes.
Treated for hyperactivity with medication			*1.73	Krager & Safer,1973. Public Elementary Schools, N=33,201.
Met an unspecified definition of hyperkinesis			10.	Huessy, 1967. Second grade, N=300
Extremely hyperactive, unable to sit still; marked inability to concentrate, distractible; extremely irritable.	8.7	3.2	5.9	Werner et al.1968. Birth cohort at age 10, N = 750.

* Study designed to estimate the number of children taking medications for hyperactivity, not designed to estimate the prevalence of the disorder.

2.5 CHARACTERISTICS OF CHILDREN CONSIDERED HYPERKINETIC

What are the characteristics of children who are considered hyperkinetic? One may presume from the appellation that such a child is highly active or more mobile than most other children. Some authors have attempted to quantify the motor activity of children with: pedometers (Bell, et al. cited in Wender, 1971, p.13); actometers attached to the wrist (Schulman, Kaspar & Throne, 1965; Millichap & Boldrey, 1967); stabilimetric seat cushions (Christensen & Sprague, 1973); a grid marked floor (Hutt, Hutt & Ounsted, 1963); and counting of specified behaviours (Patterson, Jones, Whittier & Wright, 1964). These studies show that activity levels do vary from child to child. However, the child who is reputed to be hyperkinetic has scored higher than other children on such measures in some studies (Hutt, Hutt & Ounsted, 1963; Sykes, Douglas, Weiss & Minde, 1971), but evidently not in others (Bell et al. cited in Wender, 1971, p.13).

In practice, hyperkinesis is seldom assessed by instruments designed to measure motor activity. Instead a clinician usually assesses the quantity and quality of a child's behaviour via his own observations, the reports of parents, and sometimes the reports of others such as teachers or psychologists. If a disturbing child's behavioural symptoms include overactivity, such a child may be diagnosed as hyperkinetic. Children given such diagnoses have been described in the literature, and their characteristics have

become known as part of the hyperkinetic syndrome.

Werry (1968a, p.585) reports that, when it became known that he was interested in "hyperactive" children, he occasionally saw children whose only symptom was "hyperactivity". However, Werry and other clinicians report that they more often face hyperkinetic children who have a bevy of concomitant problems including other behavioural, emotional, neurological or learning impairments. Of course those children with a very high activity level and other problems are no doubt more likely to be brought to the attention of clinicians. It is likely that the extent of overactivity, the extent of concomitant problems, the reactions of parents, teachers and others in the child's environment all influence whether or not a particular child is perceived as a problem and brought to clinical attention. The clinician and his setting in turn influence whether or not the child will be diagnosed as hyperkinetic and form the basis for a published description of the hyperkinetic syndrome. Perhaps the more accurate though less succinct appellation for this section would be "Characteristics of the hyperactive child - who arouses sufficient concern in someone (parent, teacher etc.) that he is brought to the attention of someone else (clinician, researcher etc.) who subsequently writes about him - syndrome."

One of three approaches has generally been used to formulate descriptions of the hyperkinetic syndrome:
1) descriptions and/or test results of children considered to

be hyperkinetic are presented (with only an implicit comparison to normal children); 2) descriptions and/or test results of a sample of hyperkinetic and a sample of normal children are presented and compared; 3) descriptions and/or test results of a sample of hyperkinetic children, a sample of other children referred for behavioural problems, and a sample of normal children, are presented and compared. In general the value of such studies increases from approach one to three. However, there are difficulties inherent in each approach, and these will be discussed as examples of each type of study are presented. This section is not an exhaustive review of papers discussing characteristics of hyperkinetic children, however, some of the better examples of each approach are presented here.

Using approach 1), Kenny, Clemmens, Hudson, Lentz, Cicci and Nair (1971) have provided information on characteristics of 100 children referred to a clinic because of "hyperactivity". The sample included 84 boys and 16 girls. The age at referral ranged from 2 to 16.

Most, 55%, of the children in this sample were referred by the school system; 39% were referred by medical sources, and 6% by other sources. The age of onset of hyperactivity given in the history was less than age 2 for 32% of the children. By age 6, when children are in school, an additional 49% reportedly had the onset of hyperactivity. In 64% of the children's families there was evidence of major

environmental pathology.

On psychological testing, IQ's ranged from 50 to 139. (Children with IQ's <50 were not accepted for the study.) In 31 of 68 children the WISC (Weschler Intelligence Scale for Children) verbal and performance IQ scores were within 5 points of each other. In 21 of 68 cases the verbal and performance scores showed at least a 10 point separation.

Neurological examinations were within normal limits for 52% of the children. In 48%, so called soft signs of neurological impairment were found. For example, 41 children had "poor fine motor coordination". No child showed gross neurological abnormalities in the examination. Of the 78 children who had EEG's: 38 were normal, 25 abnormal, and 15 had fourteen and/or six per second positive spike complexes.

Individual children were seen by an average of three members of the evaluation team, each of whom spent about 1 hour with the child and made a global judgement on the child's activity level. For 58 cases, no judge rated the child as hyperactive. For 29 cases, some judges rated the child as hyperactive and some did not. For 13 cases all judges considered the child to be hyperactive.

The data given in this report would be more informative if an explicit comparison had been made to a sample of normal children and to a sample of children referred for other behavioural problems. For example is the age of referral, age of onset, the source of referral, the IQ scores,

the proportion of families with pathology, and the amount of disagreement about diagnosis, typical of all children seen for behavioural problems or only of children seen for hyperkinesis ? The reports of neurological examinations may be particularly misleading without an explicit comparison to a sample of normal children. Werry, Minde, Guzman, Weiss, Dogan and Hoy (1972) report that a substantial proportion of otherwise normal children show EEG abnormalities. Therefore unless the EEG's of a group of hyperkinetic children, a group of children with other behavioural problems, and a group of normal children are compared with the same criteria by a "blind" observer (who is unaware of the child's diagnostic status), then one cannot tell if the quantity and quality of particular EEG abnormalities are more or less common in the hyperkinetic group.

In approach 2) to the formulation of a description of hyperkinesis, normal children are directly compared to children considered to be hyperkinetic. Seven such studies are summarized below, and the significant differences between normal and hyperkinetic children which have been noted in these studies are itemized in Table 9 (pp.63-65). Stewart, Pitts Craig, and Dieruf (1966) compared a sample of 37 hyperkinetic children to a sample of 36 non-hyperkinetic children selected from local schools. The primary criteria for selection of hyperkinetic cases from those children being seen at a clinic was that "overactivity and short attention

span were among the current symptoms described by the child's mother." The additional fact that the authors refer to the cases as "hyperactive children" suggests that they too considered them hyperactive, or hyperkinetic, i.e. that such a clinical diagnosis had been made, but this is not explicitly stated.

According to this study, there was no single characteristic which was present in every hyperkinetic child being seen at the clinic and absent in every normal child selected from the school. However, the number of symptoms in the two groups was quite different. The average number of symptoms reported per child among hyperkinetic children was 22, while the normal children averaged 3 out of a possible 55 symptoms. The range of symptoms scored positive among the hyperkinetic children was between 9 and 38, while the children considered normal had from 0 to 12 symptoms. In other words, children in the two groups could be distinguished fairly easily by their total number of symptoms, but not by the presence or absence of any one symptom.

Stewart et al. report a total of 43 symptoms which were significantly more common among the hyperkinetic children being seen at the clinic than among the normal children. According to the mothers' reports to the authors, greater than 50% of the clinic population and less than 10% of the controls had the following traits; can't sit still; wears out toys, furniture etc.; unpredictable; temper

tantrums; fights; unresponsive to discipline; doesn't complete project; doesn't stay with games; doesn't follow directions. These and other traits which were significantly more common among the hyperkinetic children than among the normal children in this study are listed in Table 9. (Stewart et al. do not show significance tests on the differences between the groups for each characteristic noted, however, I have done such tests and included in Table 9 only those characteristics which were significantly ($p < .05$) more common among the hyperkinetic children than among the normal children.)

Satterfield, Cantwell, Lesser and Podosin (1972) compared 31 hyperkinetic and 21 normal children, on parent and teacher completed symptom checklists. (Actually the final comparison of symptoms was between two subgroups of 14 each which were matched for age and IQ.) To be included in the study, hyperkinetics had to show "definite evidence of hyperactivity and distractibility" and at least 6 of 28 other symptoms reported to be more common among hyperkinetics than normals by Stewart et al. (1966). Bear in mind that this selection process ensured that each hyperkinetic child had at least 8 symptoms. In Satterfield et al.'s study the symptoms on the teacher and parent checklists which were significantly more common among hyperkinetic than among normal children were: fights with peers; unable to take correction; rocks, jiggles legs; dances, wiggles hands; unusually active; unable to sit through school period; unable

to follow directions; difficult to get to bed; poor relationships with peers; temper tantrums; does not complete projects; hard to get to sleep; wakes early; defiant; unable to sit through meals; and leaves doctor's office.

In a further publication, Satterfield (1973) reported the comparison of the 31 hyperkinetic children and the 21 normal children on EEG measurements when auditory stimuli were presented. They found that the hyperkinetic children as a group had significantly smaller evoked response amplitudes and significantly longer latency in response. "These differences may represent a delayed central nervous system maturation in the MBD child. Although the MBD and control groups were not matched on IQ, the evoked response latency differences cannot be accounted for on the basis of IQ differences, since a significant correlation between IQ and latency was not found (Satterfield, 1973, p.44).

Stevens, Stover and Backus (1970) tested 36 hyperkinetic and 36 normal children matched for age, sex and SES but not comparable with respect to IQ. Children were randomly assigned to one of three conditions during a rapid tapping task: a) free response; b) encouraged to tap rapidly; and c) pennies for increased rates of tapping. When subjects were allowed to tap at their own chosen rate, the hyperkinetics tapped significantly more rapidly than controls. Children in both groups tapped more rapidly with encouragement or pennies; the difference between these conditions and free

response was not statistically significant for the hyperkinetics but was for the normal children. In other words while the normal children tapped significantly slower than the hyperkinetics under free response, the normals tapped significantly faster than the hyperkinetics with encouragement or pennies for rapid tapping. It appears, unfortunately, that individual children were not tested under each of the three conditions which would have provided more confidence in the accuracy of the comparisons.

Freibergs and Douglas (1969) found that on a concept learning task hyperkinetic and normal children exhibited no significant differences in performance if 100% of correct responses were rewarded with marbles. However, if only 50% of correct responses were rewarded, the hyperkinetics did significantly more poorly than the normals in reaching a criterion of 10 consecutive correct responses. Both hyperkinetics and normals did more poorly under 50% reinforcement conditions, but this schedule particularly impaired the hyperkinetics' performance. This study suggests that the learning problems, which many hyperkinetic children have, may be mitigated by learning situations in which all or virtually all correct responses are reinforced.

A number of studies have been conducted at the Montreal Children's Hospital on hyperkinetic children, including comparisons to normal control groups. Statements of criteria for selection of cases in many of these studies

are similar to those provided by Campbell, Douglas and Morgenstern (1971, p.59): "hyperactivity was the chief complaint, had been a chronic problem from early childhood, was present throughout the day, and was reported to be a problem by both parents and teachers. Subjects were not accepted if they displayed gross signs of brain damage or if hyperactivity was a symptom which appeared to be secondary to some other problem such as psychosis, neurosis, or aggressive behaviour disorder. Only subjects of at least dull normal intelligence were included (WISC IQ of 80 or above)." There is no doubt some clinical judgement involved in translating a parent's tale into the conclusion that hyperactivity was the chief complaint, for as Werry (1968a, p.582) notes "parents and teachers seldom complain about a child's activity level; they complain about behaviour in a situational context, such as 'constantly getting into things,'; 'climbing so as to endanger himself,'; 'aggressiveness,'; 'inattentiveness, rowdiness and inability to remain seated in the classroom.'"

In the study of Campbell et al., cases were screened by a psychologist and a psychiatrist to determine whether they met the inclusion criteria. Controls were selected from Montreal schools and matched with cases for age, sex, SES and IQ. Testing revealed that the 19 hyperkinetics compared to 19 controls showed significantly more impulsivity, i.e. they responded more quickly on The Matching Familiar Figures Test. In addition the hyperkinetic children made

significantly more errors on The Matching Familiar Figures Test, The Children's Embedded Figures Test, and a Colour Distraction Test. The hyperkinetics' significantly longer time to complete the Colour Distraction Test indicated that they were more distractible than the normal children.

A study by Sykes, Douglas and Morgenstern (1972) was also connected with the Montreal Children's Hospital and used the entrance criteria previously noted from the study of Campbell et al. In the study by Sykes et al. 24 hyperkinetics, matched with 24 normal children on sex and age, showed significantly more non-observing behaviours during testing and significantly more errors on a Serial Reaction Task and a Continuous Performance Test. It appears to me from the description of the test administration that a tester was not in the same room with the child and equipment automatically presented the stimuli for the tests. Such tests would be less subject to the biases which can be created in test results from tester-testee interaction. It appears among the other studies discussed in this section, that Freibergs and Douglas (1969) also used automatic testing stimuli in the study of various reinforcement schedules, and that Satterfield et al. (1972) used automatic test stimuli in the study of EEG auditory evoked responses (though a tester was likely at least in the room for the latter).

Characteristics found in the 7 studies noted here, to significantly distinguish children who are diagnosed as hyperkinetic from normal children are listed in Table 9.

TABLE 9 : SOME CHARACTERISTICS WHICH DISTINGUISH CHILDREN DIAGNOSED AS HYPERKINETIC FROM NORMAL CHILDREN

A greater proportion ($p < .05$) of hyperkinetics are:	% Hyperkinetic with characteristic	% Normals with characteristic	SOURCE
1. Overactive	100%	33%	Stewart et al. 1966
2. Can't sit still	81	8	37 Hyperactives (Hyp.)
3. Restless in MD's waiting room	38	3	36 Normal (Nor.) Comparable for sex.
4. Talks too much	68	20	"
5. Wears out toys, furniture etc.	68	8	"
6. Fidgets	84	30	"
7. Gets into things	54	11	"
8. Unpredictable	59	3	"
9. Leaves class without permission	35	0	"
10. Unpredictable show of affection	38	3	"
11. Constant demand for candy etc.	41	6	"
12. Can't tolerate delay	46	8	"
13. Can't accept correction	35	0	"
14. Temper tantrums	51	0	"
15. Irritable	49	3	"
16. Fights	59	3	"
17. Teases	59	22	"
18. Destructive	41	0	"
19. Unresponsive to discipline	57	0	"
20. Defiant	49	0	"
21. Doesn't complete project	84	0	"
22. Doesn't stay with games	78	3	"
23. Doesn't listen to a whole story	49	0	"
24. Moves from one activity to another in class	46	6	"
25. Doesn't follow directions	62	3	"
26. Hard to get to bed	49	3	"
27. Lies	43	3	"
28. Accident prone	43	11	"
29. Reckless	49	3	"

TABLE 9 continued:

A greater proportion ($p < .05$) of hyperkinetics are:	% Hyperkinetics with characteristic	% Normals	SOURCE
30. Unpopular with peers	46	0	Stewart et al. 1966
31. Lying	43	3	37 Hyperactives (Hyp.)
32. Stealing	27	3	36 Normal (Nor.)
33. Vandalism	22	3	Comparable for sex.
34. Infant feeding problems	27	8	"
35. Infant sleep problems	22	3	"
36. Poor health in first year	24	3	"
37. Delayed speech development	35	6	"
38. Poor speech	54	25	"
39. Poor coordination	62	8	"
40. Strabismus	19	0	"
41. Repeat a school grade	41	5	"
42. Wetting by day	14	0	"
43. Public masturbation	19	0	"
44. Persistent poor appetite	24	6	"
45. Fights with peers	93	7	Satterfield et al. 1972
46. Unable to take correction	86	0	14 Hyperkinetics 14 Normals
47. Rocks, jiggles legs	86	14	Comparable for age, IQ.
48. Dances, wiggles hands	86	14	"
49. Unusually active	86	14	"
50. Unable to sit through school period	86	21	"
51. Unable to follow directions	79	7	"
52. Difficult to get to bed	79	7	"
53. Poor relationships with peers	71	0	"
54. Temper tantrums	71	7	"
55. Doesn't complete projects	71	7	"
56. Hard to get to sleep	71	7	"
57. Wakes early	71	7	"
58. Defiant	71	14	"
59. Unable to sit through meals	64	0	"
60. Leaves doctor's office	64	14	"

TABLE 9 continued :

Hyperkinetics have significantly ($p < .05$) : a) different mean scores (61-63), b) poorer mean scores (64-72) than normals on:	SOURCE
61. EEG auditory evoked response: amplitude smaller, latencies longer	Satterfield et al. 1973 31 Hyp., 21 Nor. Comparable for age
62. More rapid tapping than normals under free response	Stevens et al. 1970 36 Hyp., 36 Nor. Matched for age, sex, SES.
63. Less rapid tapping than normals when both encouraged or given pennies for rapid tapping	"
64. Trials to 10 consecutive correct responses when reinforced for 50% of correct responses	Freibergs & Douglas 1969 65 Hyp., 99 Nor. Comparable for age, sex, IQ.
65. Impulsivity = quick response on MFF.	Campbell et al. 1971 19 Hyp., 19 Nor. Matched for age, sex, IQ and SES.
66. Errors on MFF. (Matching Familiar Figures)	"
67. Errors on Children's Embedded Figures	"
68. Errors of Commission (Colour Distraction Test)	"
69. Distractibility = Longer time to complete each of 3 Colour Distraction Test Cards	
70. Errors on Serial Reaction Task	Sykes et al. 1972 24 Hyp., 24 Nor. Matched for age, sex, IQ
71. Errors on Continuous Performance Test (CPT)	"
72. Non-observing behaviour and multiple presses on CPT	

In studies, such as the seven previously discussed, in which hyperkinetics are compared to normal children, features are identified which are more common in the hyperkinetic group, or on which the hyperkinetic group has a lower mean performance. These features become known as part of the hyperkinetic syndrome. A major drawback to describing the syndrome with this approach is that what emerges may really be a description of the "problem-child-syndrome" not the hyperkinetic syndrome. The children in these studies are being seen by clinicians for behavioural problems, and the characteristics which distinguish them from normal children may be present in all children seen for behavioural problems including neuroses and psychoses. In order to mitigate the problems inherent in approach 2) one may compare a sample of hyperactive children, normal children, and children with other behaviour problems which is what is done in approach 3). Unfortunately it seems that fewer studies have been done using this approach. Two are discussed below.

Using approach 3), Conners (1970) compared 365 normal children, 166 children clinically assessed as hyperkinetic, and 137 children clinically assessed as neurotic. "A clinical differentiation was made into neurotic or hyperkinetic on the basis of social history, family dynamics, and school report. Neurotic children were those considered to suffer mainly from problems of anxiety, fearfulness, and

social inhibition. Hyperkinetics were defined as children who showed a restless, aggressive, impulsive, and distractible picture, usually dating from early childhood (p.669).

A 73 item symptom checklist was filled out by parents of the children in each group. After matching the groups for age, sex, and race, 53 of the 73 items significantly ($p<.05$) discriminated between patients and controls. In comparing hyperkinetics and neurotics, the 73 items were grouped into 24 sets of symptoms. On 10 of these sets there were significant ($p<.05$) differences between hyperkinetics and neurotics. The neurotic group had significantly more:

1) fears and worries (of new situations, people, being alone, illness, death)
2) speech problems (stuttering, hard to understand)
3) complaints (of headaches, stomach aches, vomiting, aches and pains, loose bowels).

The hyperkinetic group had significantly more:

1. wetting (bed-wetting; runs to bathroom constantly)
2. overasserts self (bullying; bragging and boasting; sassy to grown-ups)
3. problems with siblings (feels cheated; mean; fights constantly)
4. problems keeping friends (hits or kicks other children; wants to run things; picks on other children)
5. restless (can't keep still; always into things; fails to finish things he starts)
6. temper (stands there screaming; throws himself around; throws and breaks things; pouts and sulks)

7. lying (denies having done wrong; blames others for his mistakes; tells stories which did not happen).

Thus one can discriminate with a symptom checklist between children clinically assessed as neurotic and those clinically assessed as hyperkinetic. It should be stressed that the features which were more commonly associated with hyperkinetic children as a group, did not appear in every hyperkinetic child. In addition, it should be noted that a different set of clinicians might have assigned different diagnoses to many of these children -- thus affecting the list of traits which appear to be associated with neurosis or hyperkinesis. For example it is possible that some of the hyperkinetic children might instead be considered to have an "Unsocialized Aggressive Reaction" according to criteria established by other clinicians (Werry, 1973, p.136).

In another study using approach 3), a group at the Montreal Children's Hospital (Werry, Minde, Guzman, Weiss, Dogan & Hoy, 1972) compared the neurological status of hyperkinetic children, normal children, and neurotic children. Children with major neurological handicaps such as epilepsy or cerebral palsy, and children with IQ less than 80 were excluded from the study. The groups were matched for age, sex, and socio-economic class. Effort was made to keep neurologists blind to the child's psychiatric status, but this was reportedly unsuccessful because of the child's conversation during the examination. Results abstracted from this study are provided in Table10 (p.69)

TABLE 10: NEUROLOGICAL STATUS OF HYPERKINETIC, NEUROTIC, AND NORMAL CHILDREN

	Abnormal EEG	Major Signs 0	1	2+	Minor Signs 3+
Hyperkinetics N=20	35%	60%	15%	25%	80%
Neurotics N=20	50%	50%	35%	15%	10%
Normals N=20	35%	60%	25%	5%	15%
Significance :	N.S.	N.S.			p <.01

Adapted from Werry et al., 1972, p.448

There were no significant differences in the frequency of EEG abnormalities, or of major neurological abnormalities between the three groups. However, the proportion of hyperkinetics (16/20) who had three or more minor signs was significantly greater than in the neurotic group (2/10) or the normal group (3/10). The median number of minor signs among hyperkinetics was 10. The total number of signs examined neurologically was 140 and of these only 3 had an inter-observer reliability of less than 80%, and only 7 had an inter-observer reliability of less than 90%. Values for inter-observer reliability on the diagnostic categories are not provided.

This study by Werry et al. demonstrates the importance of examining and describing characteristics of hyperkinetic children in comparison to control groups. If one knew simply that 35% of the hyperkinetic children showed abnormal EEG's, one might believe that this was an unusually high proportion. However in the study of Werry et al. 35% of normal children, and 50% of neurotic children also showed abnormal EEG's.

Each of the three approaches noted for describing the characteristics of hyperkinetic children is subject to the vagaries of interrater reliability in making diagnoses (hyperkinetic, neurotic, normal etc.) and in judging the presence or absence of the characteristics under question (restlessness, neurological signs etc.) In addition all

three approaches may be subject to the biases created by selecting samples which are not representative of the population which they are intended to represent. These problems notwithstanding, in these three approaches only the third approach can indicate whether a particular characteristic is more often present among a sample of hyperkinetic children than among normal children or among children having other behavioural (or medical) problems.

One should remember that the hyperkinetic samples described in this section are selected from clinic populations. Samples of children selected from the general population on the basis of high activity levels may not show the same associated characteristics. A summary of the findings discussed in this section from studies using approach 3) are presented in Table 11 (p.72).

In summary, the presence of a very high activity level does not ensure that any other deficits will be present. Authors have described a very large number of deficits which are more commonly found in hyperkinetic children brought to the attention of clinicians than in various control groups, and these deficits have become known as part of the hyperkinetic syndrome. By no means does every hyperkinetic child have every deficit associated with the syndrome.

TABLE 11: SOME CHARACTERISTICS WHICH DISTINGUISH CHILDREN DIAGNOSED AS HYPERKINETIC FROM NEUROTIC OR NORMAL CHILDREN

More Common ($p<.05$) in Hyperkinetics than in Neurotics or Normals are:	Source
1. wetting (bed-wetting; runs to bathroom constantly)	Conners, 1970 166 Hyperkinetics (Hyp.) 137 Neurotics (Neu.) 365 Normals (Nor.)
2. overasserts self (bullying; bragging & boasting; sassy to grown-ups)	"
3. problems with siblings (feels cheated; mean; fights constantly)	"
4. problems keeping friends (hits or kicks other children; wants to run things; picks on other children)	"
5. restless (can't keep still; always into things; fails to finish things he starts)	"
6. temper (stands there screaming; throws himself around; throws & breaks things, pouts & sulks)	"
7. lying (denies having done wrong; blames others for his mistakes; tells stories which did not happen)	"
8. three or more minor neurological signs	Werry et al., 1972 20 Hyp., 20 Neu., 20 Nor. Matched for age, sex, SES.

Given this state of knowledge, a clinician, to whom a child is referred for assessment of hyperkinesis might choose to get from parents, teachers, and standardized tests a fairly thorough picture of the child's strengths and weaknesses -- looking particularly for deficits which are reputed to be part of the syndrome, and for which effective treatment is available. The lack of certain deficits believed to be part of the syndrome does not necessarily mean that a hyperkinetic child does not need treatment. Similarly the absence of obvious hyperkinesis in the clinician's office does not mean that parent's and teacher's complaints should be ignored. Those children whom all observers rate as hyperkinetic may be the most serious cases, but less severe cases may also warrant treatment. Sleator and von Neumann (1974, p.21) report that "only 10 of our 46 subjects could have been diagnosed by office visit alone. These were the obvious hyperkinetic children whose restlessness, talkativeness, distractibility, and impulsivity were unmistakably deviant. All of the other 36 children behaved in a cooperative, controlled manner during the physician's examination, yet interview data from parents, teacher rating scales, and subsequent behaviour when visiting the Center left no doubt that they were hyperkinetic." Despite the fact that only 10 of the 46 would have been diagnosed as hyperkinetic by their behaviour in the first office visit alone, 36 of the 46 responded favourably to methylphenidate. In addition, the proportion of those benefited by methylphenidate

was in fact higher among the 36 who would not have been diagnosed as hyperkinetic from their behaviour in the first office visit alone. Further work is needed to refine methods of diagnosing hyperkinesis, and further work should be done to identify particular subgroups of hyperkinetic children who are likely to respond favourably to the various available treatments.

2.6 TREATMENTS FOR HYPERKINESIS

2.6.1 Introduction

Under the Index Medicus heading of Hyperkinesis, three subheadings directly related to treatment have appeared: "Drug Therapy"; "Therapy"; and "Surgery". Under "Drug Therapy" for hyperkinesis, one finds articles on: methylphenidate, dextroamphetamine, levoamphetamine, tetrabenazine, chlorpromazine, sulthiame, jatamansone, copper sulfate, imipramine, hydroxyzine, caffeine, lithium carbonate, pemoline, levodopa, nortriptyline and other drugs. The section on "Therapy" for hyperkinesis is rather lean and includes articles on: activity group therapy, video feedback, conditioning, and a few other non-drug therapies. Under "Surgery" for hyperkinesis one will find articles on stereotaxic dentatomy, stereotaxic hypothalamotomy, stereotaxic amygdalotomy, electrode implantation and other surgical procedures.

The group of articles on surgery for hyperkinesis generally appear to apply to children whose disorders are more severe than simple hyperkinesis. However, Balasubramaniam and Ramamurthi (1970) of India do report 100 cases of "hyperkinetic behaviour disorder" which presented with some combination of "uncontrollable restlessness, destructive tendencies and acts of aggression" who were given "stereotaxic amygdalotomy" to destroy part of the brain. Balasubramaniam

says that "the result has been gratifying in many cases", however the documented outcomes for these 100 cases are not impressive, as shown in Table 12.

TABLE 12: RESULTS OF STEREOTAXIC AMYGDALOTOMY FOR HYPERKINESIS

6	No need of any drug; patient is able to mingle easily with others
33	Very much docile and given only to occasional outbursts
36	Manageable when given drugs though not leading a useful life
12	Transient improvement but relapsed
4	No change
9	Died
100	Total

Given these unimpressive results from Balasubramaniam and Ramamurthi (1970, pp. 371-2), I am frankly appalled that the authors of the publication recommend destruction of part of the brain for such behaviour disorders. No North American author, to my knowledge, suggests brain surgery for the hyperkinetic behaviour disorder. The treatments commonly recommended for hyperkinesis by North American authors are stimulant drug therapy and supportive non-drug therapies such as counselling, behaviour modification or tutoring. The rest of this section on treatment will be devoted to discussion of the effectiveness of drug treatments and non-surgical non-drug treatments for hyperkinesis.

Evaluations of the effectiveness of certain of the treatments for hyperkinesis espoused by North American authors are plentiful, however such studies are highly variable in the quality of their research design. In order to best evaluate the relative effectiveness of two or more treatments (one of which may be a placebo or a non-treatment condition) for hyperkinesis or any other disorder, one needs a controlled clinical trial with attention to standards of good research design which include the following:

1) precise definition of the diagnostic criteria used for selection of patients, and specification of any socio-demographic selection criteria
2) adequate description of the characteristics of the selected study population
3) prognostic stratification
4) random allocation to alternative treatment conditions
5) attempts to ensure that the groups under study are comparable with respect to auxiliary treatment procedures
6) precise description of the treatment conditions
7) attention to compliance with therapy
8) utilization of relevant, reproducible outcome measures
9) double-blind assessment of outcomes
10) analysis of the results of alternative treatments to determine if the observed differences are statistically significant.

Few studies to be discussed in this section on treatment would meet all of the above standards. Despite this, these studies should be examined in order to assess the evidence that is available regarding the effectiveness of alternative treatments for hyperkinesis. The subsequent discussion of effectiveness of treatments for hyperkinesis is divided in to two sub-sections: Drug Treatments and Non-Drug Treatments.

2.6.2. Drug Treatments

Bradley (1937) is credited with the first studies of the effects of stimulant drugs on children with behaviour disorders, including some "hyperactive" children. Bradley and Brown in 1941 summarized the results of studying 100 children in a residential institution for treatment of behavioural disorders ranging from hyperactivity and destructiveness to extreme withdrawal. After treatment with benzedrine (amphetamine sulfate,) 72 of 100 children improved, 21 were unaffected and 7 got worse (Bradley 1941, p.97). Improvements were reported in behaviour and scholastic work. Unfortunately this group of children was not compared to a group treated with placebo, so we cannot tell how much of the improvement is attributable to the placebo effect and how much to the active drug.

Since Bradley's studies were published, scores of studies have been done to evaluate the effectiveness of drug therapy for children with behaviour problems. Lipman's (1971) bibliography lists many of the studies done prior to 1970. More recent drug studies are most easily located through Index Medicus.

Millichap and Fowler (1967) and Millichap (1973) reviewed many of the studies of drug treatment for children with behaviour disorders. By pooling the results of numerous studies Millichap and Fowler (1967, p.775) produced a table entitled "Drug Selection in Treatment of Hyperkinetic

Behaviour in Childhood" presented here as Table 13, p. 81.

In Table 13 drugs are listed in order of effectiveness, as determined by the percent of reported cases which improved with each of the given drugs. Note that methylphenidate is listed first and amphetamine second. In Millichap's (1973) review, studies on the following additional drugs were considered: thioridazine, hydroxyzine, promazine, fluphenazine, chlorprothizene, meprobamate, imipramine, diphenhydramine, diphenylhydantoin and primidone. Millichap (1973, p.321) then concluded that "methylphenidate is the treatment of choice, and amphetamine sulfate is the second most successful drug in the control of hyperactive behaviour. The properties of these two agents are similar, but methylphenidate has less tendency to produce anorexia.... The antianxiety and antipsychotic compounds are recommended as alternative therapies in patients who fail to respond to methylphenidate or dextroamphetamine. The antidepressant, imipramine, and the anticonvulsant, diphenylhydantoin, are also beneficial in some cases, whereas barbiturates, such as phenobarbital are contraindicated because they usually exacerbate hyperactivity."

TABLE 13: DRUG SELECTION IN TREATMENT OF HYPERKINETIC BEHAVIOUR IN CHILDHOOD*

NAME OF DRUG		Preparations	Average Dose range *	Total Patients tested	Patients improved per cent *	Patients with side effects per cent
Generic	Trade	(Mg)	Mg/Day ±			
Methylphenidate	Ritalin	Tabs. 5, 10, 20	5-60	337	83%	14%
Amphetamine	Dexedrine	Tabs. 5	5-30	610	69%	12%
Chlordiazepoxide	Librium	Caps. or Tabs. 5, 10, 25	5-30	237	60%	18%
Chlorpromazine	Thorazine	Tabs. 10, 25, 50, 100	10-50	153	55%	25%
Deanol	Deaner	Tabs. 25, 100	50-150	239	47%	7%
Reserpine	Serpasil, var.	Tabs. 0.1, 0.5, 1.0	0.25-0.5	165	34%	>1%
TOTALS				1741	62%	12%

* Drugs listed in order of choice according to efficacy and toxicity.
± Larger doses sometimes employed

Reproduced from Millichap & Fowler, 1967 p.775.

It would appear from other studies by Greenberg and Lipman (1971) and Krager and Safer (1974) that many physicians agree with Millichap that stimulant medication is the most appropriate drug treatment for hyperkinesis. Krager and Safer found that of 1139 children in Baltimore County Public Elementary Schools who were taking medication for hyperkinesis most were taking stimulants as shown in Table 14.

TABLE 14: MEDICATIONS TAKEN FOR HYPERKINESIS

Stimulants :	methylphenidate	59.0%
	dextroamphetamine	29.2%
Non-stimulants:	thioridazine	2.6%
	diphenhydramine	2.4%
	hydroxyzine	1.7%
	chlorpromazine	.5%
	other	4.6%
		100%

N= 755 children out of 65,897 in Public Schools = 1.73%

Adapted from Krager and Safer, 1974, p.1119.

Thus stimulants are at the top of the list of: 1) drugs prescribed for hyperkinesis and 2) drugs which appear to be effective in the treatment of hyperkinesis. With respect to the latter point, Millichap's previously noted reviews, include a valuable compilation of data and are recommended reading for anyone interested in treatment of hyperkinesis. However, it should be stressed that, as broad reviews, they necessarily include individual studies of highly variable quality, with diverse entrance, treatment and outcome criteria. Pooling the results of such variable

studies should lead only to tentative conclusions. For example, the data under "Patients improved, percent" in Table 13 on page 81 should be considered gross approximations since these figures were derived by averaging the percent of patients who improved in numerous studies with diverse methods of collecting patients, and diverse methods of assessing improvement. The characteristics of the population under study and the method of assessing improvement can drastically affect the percent of patients who are rated as improved. To be confident of one's conclusions about the relative effectiveness of numerous drugs one should ideally have a comparison of those drugs in a single well designed controlled clinical trial (including measures of the percent of patients improved and measures of the extent of their improvement in relevant areas). Unfortunately the drugs in Table 13 and additional drugs discussed in Millichap's later review have not all been compared in a single controlled clinical trial. To do so would require an enormous sample of children making such a study difficult if not impossible to implement. A more feasible approach to comparing the relative effectiveness of a large number of drugs is to include as many drugs as sample size will allow in each of a series of studies which uses identical entrance, treatment and outcome criteria. A few authors have done a series of studies with hyperkinetic children, but usually entrance, treatment, or outcome criteria have been modified in the process.

While the available studies of drug treatment for hyperkinesis are by no means identical with respect to entrance, treatment or outcome criteria it is important to examine the evidence they offer.

In Table 15 p.86, I have summarized all clinical trials of methylphenidate which I was aware of at the time this thesis was written. These studies were located through the heading of "Hyperkinesis" in Index Medicus, or Psychological Abstracts, or through the bibliographies of articles located via the previous two sources. Studies which were not available in journals were not sought (e.g. unpublished papers, papers delivered at conferences, or dissertations). Eighteen of the 20 studies in Table 15 were overlooked or unavailable at the time of Millichap's (1973) review. Studies were selected for inclusion in Table 15 if they met the following criteria : 1) all or some of the subjects in the study were described by the authors as hyperkinetic or hyperactive children; 2) the effectiveness of methylphenidate treatment was directly compared to that of placebo or other active drugs used in the same trial; and 3) quantitative data on treatment outcome were presented.

Criterion 1), that all or some of the subjects were described as hyperkinetic, permits inclusion of a fairly heterogeneous sample. This criterion was not made more stringent because there is no standard diagnostic criterion for hyperkinesis in widespread use. Criterion 1) excluded studies which might have included hyperkinetic children but did not

so specify, as in studies of "emotionally disturbed" children (Conners & Eisenberg, 1963; Conners, Eisenberg & Sharpe 1964) or delinquent children (Conners, Kramer, Rothschild & Schwartz, 1971). Exceptions to this criterion were made only for Conners (1971a, and 1972) studies of MBD children. Although Conners unfortunately did not specify how many, if any, subjects were hyperkinetic, these studies are included on the grounds that so many children currently given diagnoses of MBD are hyperkinetic.

Criterion 2), above excluded studies which compared methylphenidate treatment to pre-treatment data only as in: Lytton and Knobel (1959), Knobel (1959), Knobel (1962); Knobel, Wolman and Mason (1959), Nichamin and Comly (1964), and Hoffman, Engelhardt, Margolis, Polizos, Waizer and Rosenfeld (1974). A single report included in Table 15 partially violates criterion 2) that is the report by Weiss, Minde, Douglas, Werry and Sykes (1971) which compares the results of three trials each of which includes a single active drug and a placebo. Because the trials were done in the same setting, using the same study design, entrance criteria and <u>some</u> of the same outcome measures, one can with certain reservations compare the results.

Criterion 3) excluded articles which provided no data but made editorial remarks about the effectiveness of methylphenidate. No exceptions were made to criterion 3).

TABLE 15: A SUMMARY OF STUDIES OF METHYLPHENIDATE FOR HYPERKINESIS

SOURCE	DESIGN FEATURES 1.Number subjects Hyp.= hyper-kinetic 2.R=randomized C=crossover 3.DB=double-blind	TREATMENTS mg=mg maintenance dose/day M=methylphenidate P=placebo D=dextro-amphetamine $\bar{x}$=mean	OUTCOMES > means significantly better ($p<.05$)
1.Eisenberg Conners & Lawrence 1965	46 Hyp. ?R DB	6 weeks of: M 30mg P D 10mg	(M & D)>P on clinician rating, teacher rating, Porteus Maze, discrimination task & Clyde Mood Scale M vs. D no differences on clinician's rating.
2.Millichap, Aymat, Sturgis, Larsen & Egan 1968	30 Hyp. RC DB	3 weeks of: M .3-2.3mg/kg, $\bar{x}$=1.5mg/kg P	M>P or Pre-test on figure-ground perception (Frostig II) & IQ equivalent (Draw-A-Man) M>Pre-test on: finger tapping coordination; 4 tests of visual-motor perception (Frostig II, III, IV & Bender-Gestalt); auditory perception (Detroit); IQ equivalent (Draw-A-Man); motor activity (actometer); immaturity & conduct (Peterson-Quay).
3.Campbell, Douglas, & Morgenstern 1971	22 Hyp. RC DB	2 weeks of: M 10-100mg. $\bar{x}$=60mg P	M>P or Pre-test on slower reaction time, & fewer errors (MFF); & fewer errors (Colour Distraction test).

TABLE 15 continued:

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
4.Cohen, Douglas, Morgenstern 1971	20 Hyp. RC DB	14 days of: M max=100mg P	M>P in faster reaction time, less frequent redundant responses
5.Sykes Douglas Weiss, Minde, 1971	40 Hyp. R DB	5-7 weeks of: M=30-40mg P	M>P on 3 tasks of attention (CPT).
6.Weiss, Minde, Douglas, Werry & Sykes 1971	128(51 in M vs. P) (38 in D vs. P) (39 in Chl. vs. P) R DB	3-8 weeks of: M max= 200mg P Chlorpromazine max=800mg D max=80mg	Chl.>P on hyperactivity, & parents' global rating D>P on above plus distractibility M>P on above plus full scale IQ, verbal IQ (WISC); motor development (Lincoln-Oseretsky)[a]; visual-motor sequencing (ITPA)[ab]; oral reading, silent memory, spelling (Durrell)[ab]; symptoms (Peterson-Quay)[ab]; (a=not included in Chl. study; b=not included in D study).
7.Satterfield, Cantwell, Lesser, & Podosin 1972	31 Hyp. ? DB	3 weeks of: M to clinical response P	M>P on teacher rating of behaviour
8.Sykes Douglas & Morgenstern 1972	23 Hyp. RC DB	2 weeks of: M 10-100mg $\bar{X}$=57mg P	M>P or Pre-test on faster reaction time (CRT), & correct responses (SRT & CPT).

TABLE 15 continued:

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
9.Christensen & Sprague 1973	12 Hyp. - DB	5 sessions with: M .3mg/kg P	M>P on mean seat movement per minute (stabilimetric cushion).
10.Schnacken-berg 1973	11 Hyp. -C Independent observer	3 weeks of C, M dose, time ? Caffeine 200-300mg	C>No drug M>No drug M & C not significantly different on behaviour rating (David's)
11.Garfinkel 1974	8 Hyp. RC DB	7 weeks of: M 20mg P=Lactose 200mg Caffeine 160mg each added to decaf. coffee	M>Caf., P, & No drug (pre & post) on total behaviour score, aggressivity, hyperactivity (Conners), & decrease in errors (MFF) M>P on motor steadiness (Reitan holes and maze) & above M>No drug on inattentiveness, sociability (Conners) & above.
12.Sleator & von Neuman 1974	46 Hyp. (?R)C DB	4 weeks of: M .1, .3, .7 or 1mg/kg P	M .7mg > .3mg > .1mg or placebo on teachers' symptom ratings (Conners) & teachers' global rating.
B.13. Zimmerman & Burgemeister 1958	108, 26 Hyp. ? DB	6 months of: M 20-40mg $\bar{X}$= 30mg Reserpine $\bar{X}$=.75mg	No significant differences on reaction time, verbal IQ, performance quotient & clinical rating.
14.Creager & Van Riper 1967	30 some Hyp. RC DB	3 days of: M 40mg P	M>P for verbal productivity (incomplete utterances) M>P or Pre-test on total words and speech responses.

TABLE 15 continued:

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
15. Millichap & Boldrey 1967	14 some Hyp. - -	1 day of: M .25-.5mg/kg P Phenobarbital 2.5mg/kg	(Ph. & P)>M on motor activity (actometer) With M up 74% With P up 11% With Ph. down 10%
16. Knights & Hinton 1969	40, 17 Hyp. R DB	6 weeks of: M 40mg P	M>P on WISC performance IQ, fine motor coordination (duration maze, duration holes) & reduced activity (Werry-Weiss-Peters).
17. Sprague, Barnes, & Werry 1970	12, ~9 Hyp. RC DB	6 days of: M .25mg/kg or .35mg/kg P Thioridazine .75mg/kg or 1mg/kg	M>T or P on accuracy, faster reaction (Sternberg), reduced activity (stabilimetric cushion), on-task behaviour, & quality of day M>T on teacher initiated contact & above tests. M>P alone on isolation as punishment, & pupil initiated contact. No significant dose effects.
18. Conners 1971 a	69 MBD R DB	? 3 weeks ? of: M max=30mg P D max=15mg	(M & D)>P on IQ equivalent (Draw-A-Man) M vs. D no difference.
19. Conners 1972	75 MBD - same subjects as 1971? R DB	6 weeks of: M max=30mg P D max=15mg	M>P on: full scale IQ, verbal IQ, similarities, digit span, object assembly (WISC); perceptual quotient (Frostig); verbal fluency; teacher ratings (Conners); visual motor perception (Bender Gestalt), IQ equivalent (Draw-A-Man); Porteus Mazes; speech-noise test; & omissions and commissions on continuous vigilance test.

TABLE 15 continued:

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
19. Conners continued.			M>D on arithmetic & similarities (WISC).
20. Winsberg Press, Bialer, Kupietz 1974	18 some Hyp. RC DB	9-10days of: M max=30mg P D max=20mg	(M & D)> P in lowered hyper-activity & aggressiveness (Conners) M vs. D no differences.

Table 15 is displayed as follows. The first column gives the author(s) and date of publication for studies which include: A) only hyperactive children according to the author(s), B) some hyperactive children according to the author(s). The second column shows study design features including: 1) the number of subjects, and for studies in which not all subjects were hyperkinetic, the number which were hyperkinetic if noted in the article; 2) whether subjects were randomly (R) assigned to treatments, and whether the same subjects were crossed-over (C) to alternate treatments (which is advantageous in that it reduces the variance between treatment groups); and 3) whether the outcome measures were designed to be double-blind (DB) with neither the treated nor the treater(s) being told which of the alternative treatments is being administered.

The third column in Table 15 reproduces information on the drugs tested and the daily maintenance doses prescribed (after a variable number of days in gradually building to the maintenance dose). The fourth column shows all outcomes which were significantly different among the treatment conditions tested, and notes in addition where no significant differences were observed between conditions. Outcome measures are identified by the type of behaviour(s) being rated, e.g. activity level; and the name or abbreviation for the test instrument is given in parentheses (e.g. stabilimetric cushion) if it is available. Only

significant treatment effects are listed, that is additional significant age effects, or test order effects on outcome are not recorded in Table 15 because its primary purpose is to summarize the available information on the effectiveness of methylphenidate treatment relative to other treatments. Most of the studies in Table 15 included some outcome measures which did not show significant differences between treatments. These outcome measures are not individually listed in Table 15 because of space constraints, but information about them is provided later.

The studies listed in Table 15 are above average in design. Most met a majority of the 10 previously itemized standards for good research design. In particular, most used random assignment to treatment and attempted to have double-blind assessment of outcomes by not overtly informing the treated or the treaters which medication a child was getting. It should be pointed out however that side-effects of active drugs may expose the type of treatment being administered. Weiss, Minde, Douglas, Werry and Sykes (1971) found that psychiatrists correctly guessed which patients were on active drugs (methylphenidate, chlorpromazine or dextroamphetamine) and which were on placebo for 100% and 80 to 90% of cases respectively, thus destroying the intended double-blind design.

It is conceivable that a drug with no true benefits but with fairly obvious side-effects would be rated as having

significant therapeutic benefit in a clinical trial. Imagine that such a drug, X, is being compared to a placebo. Clinicians believe that drug X works, and they can tell which patients are taking drug X by its side-effects. They may pass on their expectations of therapeutic benefit to patients taking drug X who in turn may alter their own expectations and in fact their own outcomes and/or an observer's notation of their outcomes. In short it may be necessary to have placebos which mimic active drugs in appearance, taste and side-effects if one really wants to make a double-blind comparison of therapeutic outcomes. With respect to the studies in Table 15, the double-blind designs were probably not "undone" by drug side-effects in most cases because most of the studies used a much lower dose than was being tested by Weiss et al. in 1971, and side-effects are thus less apparent.

The results of the studies in Table 15 are quite consistent. Looking at all of the studies, including those with exclusively hyperkinetic subjects (Section A) and those with some hyperkinetic subjects (Section B), we find that in virtually all instances where significant differences in therapeutic outcomes were found between treatment conditions, it was methylphenidate which was superior to: no drug (pre-test), placebo, or other active drugs including thioridazine, chlorpramazine (Tranquilizers), caffeine, and dextroamphetamine (stimulants). Therapeutic

outcomes included a wide variety of measures such as: global ratings by clinicians, parents and teachers; behavioural checklists; cognitive tests; motor tests; visual-motor tests; and verbal tests. (Some of the measures may be included in more than one of these broad categories.)

Information from the studies in Table 15 has been organized somewhat differently and presented in :

A) Table 16, on pages 95-8, to show the effectiveness of methylphenidate in comparison to placebo,
and

B) Table 17, on pages 102-4 , to show the effectiveness of methylphenidate in comparison to other active drugs used for hyperkinesis.

In both tables the information is organized to show:

1. the measures on which methylphenidate was significantly better (M>)
2. the measures on which methylphenidate and the alternative compound did not differ significantly (M=)
3. the measures on which methylphenidate was significantly poorer (M<).

Table 16 lists 51 different types of global, behavioural, motor, visual-motor, verbal and cognitive measures on which methylphenidate and placebo have differed significantly ($p < .05$) in therapeutic effectiveness in at least one of the drug studies of hyperkinesis reviewed for this thesis and previously summarized in Table 15. The evidence indicates that methylphenidate is significantly superior to placebo for hyperkinesis on virtually all of these measures.

TABLE 16: THE EFFECTIVENESS OF METHYLPHENIDATE VERSUS PLACEBO FOR HYPERKINESIS: MEASURES ON WHICH METHYLPHENIDATE (M) AND PLACEBO (P) HAVE DIFFERED SIGNIFICANTLY IN EFFECTIVENESS

	Number of studies in which measure included and :		
	M>P	M≈P	M<P*
GLOBAL MEASURES			
1. Clinician's ratings	1	0	0
2. Parent's ratings	1	0	0
3. Teachers ratings	3	0	0
BEHAVIOURAL MEASURES			
4. Aggressiveness (Conners Teacher-factor I)	2	0	0
5. (factor on Clyde Mood Scale)	1	0	0
6. Hyperactivity (Werry-Weiss-Peters)	1	0	0
7. (Conners Teacher - factor IV)	2	0	0
8. (Werry-Weiss-Peters)	1	0	0
9. Total symptoms (Peterson-Quay)	1	1	0
10. (unnamed teacher checklist)	1	0	0
11. (Conners Teacher & Werry-Weiss-Peters)	1	0	0
12. (Conners Parent-Teacher)	1	0	0
13. (Conners Teacher)	1	0	0
14. On-task behaviour (counting specified behaviours)	1	0	0
15. Pupil-initiated contacts with teacher (counted)	1	0	0
16. Punishment reduction (isolation)	1	0	0
MOTOR TESTS			
17. Fine-motor coordination (Reitan holes & maze)	2	0	0
18. Motor development (Lincoln Oseretsky)	1	0	0
19. Redundant motor responses	1	0	0
20. Faster reaction time (delayed reaction time task)	1	0	0

*M>P means methylphenidate was significantly ($p<.05$) better than placebo
M≈P means methylphenidate and placebo were not significantly different
M<P means methylphenidate was significantly ($p<.05$) poorer than placebo

The references for each measure are listed at the end of this table.

TABLE 16 continued :

	M>P	M=P	M<P
MOTOR TESTS cont.			
21. (Choice reaction time task)	1	0	0
22. (Sternberg)	1	0	0
23. Less impulsive reaction time (Matching Familiar Figures)	1	0	0
24. Reduced seat movement (stabilimetric cushion)	2	0	0
25. Reduced motor activity (wrist actometer)	0	1	1
VISUAL-MOTOR TESTS			
26. Visual-motor sequencing (I.T.P.A.)	1	0	0
27. Visual-motor perception (Bender Gestalt)	1	4	0
28. Perceptual quotient (Frostig)	1	1	0
29. Figure ground perception (Frostig II)	1	1	0
VERBAL TESTS			
30. Productivity (incomplete utterances)	1	0	0
31. Total words	1	0	0
32. Speech responses	1	0	0
33. Verbal fluency	1	0	0
34. Oral-reading (Durrell)	1	0	0
COGNITIVE MEASURES			
35. Full scale IQ (WISC)	2	1	0
36. Verbal IQ (WISC)	2	1	0
37. Performance IQ (WISC)	1	0	0
38. IQ equivalent (Draw-A-Man)	3	1	0
39. Digit span (WISC)	1	0	0
40. Object assembly (WISC)	1	0	0
41. Similarities (WISC)	1	0	0
42. Silent memory (Durrell)	1	0	0
43. Spelling (Durrell)	1	0	0
44. Porteus Mazes	2	0	0
45. Discrimination task	1	0	0
ATTENTION TESTS Scored by # correct or by type of error			
46. (Matching familiar figures)	2	0	0
47. (Serial Reaction Task)	1	0	0
48. (Continuous Performance Test)	4	0	0
49. (Sternberg)	1	0	0
50. (Colour distraction test)	1	0	0
51. (Speech discrimination in background noise)	1	0	0

TABLE 16[a]: ALL SOURCES: AND SAMPLE SIZES FOR CONFLICTING FINDINGS

MEASURE #	SOURCE M>P	N of Study	N of Study	SOURCE M=P and, where noted, M<P
1.	Eisenberg et al. 1965			
2.	Weiss et al. 1971			
3.	Eisenberg et al. 1965 Sleator & von Newman 1974 Sprague et al. 1970			
4.	Garfinkel, 1974			
5.	Winsberg et al. 1974 Eisenberg et al. 1965			
6.	Weiss et al. 1971			
7.	Garfinkel, 1974 Winsberg et al. 1974			
8.	Knights & Hinton 1969			
9.	Weiss et al. 1971	51	40	Knights & Hinton, 1969
10.	Satterfield et al. 1972			
11.	Garfinkel, 1974			
12.	Sleator & von Newman, 1974			
13.	Conners 1972			
14.	Sprague et al. 1970			
15.	" " "			
16.	" " "			
17.	Garfinkel, 1974 Knights & Hinton 1969			
18.	Weiss et al. 1971			
19.	Cohen et al. 1971			
20.	Cohen et al. 1971			
21.	Sykes et al. 1972			
22.	Sprague et al. 1970			
23.	Campbell et al. 1971			

TABLE 16a continued:

MEASURE #	SOURCE M>P	N of Study	N of Study	SOURCE M≈P and where noted, M<P
24.	Christensen & Sprague 1973 Sprague et al. 1970			
25.			30 14	Millichap et al. 1968 Millichap & Boldrey 1967 for M<P
26.	Weiss et al. 1971			
27.	Conners, 1972	75	30 51 8 40	Millichap et al. 1968 Weiss et al. 1971 Garfinkel 1974 Knights & Hinton 1969
28.	Conners, 1972	75	30	Millichap et al. 1968
29.	Millichap et al. 1968	30	8	Garfinkel 1974
30.	Creager & van Riper 1967			
31.	" " "			
32.	" " "			
33.	Conners 1972			
34.	Weiss et al. 1971			
35.	Weiss et al. 1971 Conners, 1972	51	40	Knights & Hinton 1969
36.	Weiss et al. 1971 Conners, 1972	51	40	Knights & Hinton 1969
37.	Knights & Hinton 1969			
38.	Millichap et al. 1968 Conners, 1971 a Conners, 1972	30 69 75	51	Weiss et al. 1971
39.	Conners, 1972			
40.	Conners, 1972			
41.	Conners, 1972			
42.	Weiss et al. 1971			
43.	Weiss et al. 1971			
44.	Eisenberg et al. 1965 Conners, 1972			
45.	Eisenberg et al. 1965			
46.	Campbell et al. 1971 Garfinkel, 1974			
47.	Sykes et al. 1972			
48.	Sykes et al. 1971 Weiss et al. 1971 Sykes et al. 1972 Conners, 1972			
49.	Sprague et al. 1970			
50.	Campbell et al 1971			
51.	Conners, 1972			

In those instances where methylphenidate was significantly superior to placebo on a particular measure in one study but not in another, the latter study had a smaller sample size. This is shown in Table 16a, and indicates that the failure to detect a significant difference between methylphenidate and placebo on the measures in question might be explained simply by the smaller sample size.

There is one measure (# 25) on which methylphenidate did significantly more poorly than placebo in one study. However, there is a later study by the same lead author, done over a longer period, with a larger sample, in which methylphenidate and placebo did not differ significantly -- though the trend favoured methylphenidate.

There is one additional set of measures (#21-24) which offer seemingly conflicting evidence. Measures 21-23 indicate that methylphenidate groups had significantly faster responses in test situations than placebo groups. Only one of the three studies involved reported accuracy on the test given; and in this study accuracy was significantly better with methylphenidate (Sprague et al., 1970). However all three studies interpreted the faster responses as an improvement in performance. In contrast, measure 24 indicates that the methylphenidate group had significantly slower responses than the placebo group. The slower less impulsive responses and the significantly better accuracy ratings on the Matching Familiar Figures test are interpreted as improved performance in this study (Campbell et al., 1971).

The apparent conflict over the effects of methylphenidate on reaction time could be resolved by assuming that methylphenidate is better than placebo in allowing a hyperkinetic child to regulate reaction time in whichever way (faster or slower) is appropriate for the task at hand.

For every measure in Table 16, the total available evidence favours the superiority of methylphenidate over placebo. The findings of methylphenidate's superiority to placebo (M>P column in Table 16) come from 17 separate studies with a total of 573 subjects. (It may be that some of the same subjects were used by some authors in repeated studies but this is not so stated in their publications.) All of these 17 studies employed double-blind techniques for administering treatment and assessing outcome. Eight used a randomized-crossover study design, most of the others state that a randomized design was used. As a group these studies are relatively strong in research design; and they provide extensive, consistent evidence for the superiority of methylphenidate over placebo in the treatment of hyperkinesis. This conclusion pertains to the therapeutic outcomes at the end of a period ranging from several days to several weeks of methylphenidate or placebo treatment. We do not know how the longer term outcomes compare. However with the evidence currently available, I personally would consider it unethical to treat any hyperkinetic child with placebo <u>on a long term basis</u> in order to make such a comparison.

We turn now to those studies in which methylphenidate has been compared to other active drugs used in the treatment of hyperkinesis. Table 17 pp.102-4 summarizes the results of these studies.

The studies in Table 17 suggest the following conclusions regarding the effectiveness of methylphenidate versus other active drugs tested for hyperkinetic children in the specified doses:

1. Methylphenidate is significantly better than thioridazine (a tranquilizer) for some important dimensions of behaviour but no different for others.
2. Methylphenidate appears to be better than chlorpromazine (a tranquilizer) but the direct evidence is scanty.
3. Methylphenidate does not appear to be any different from reserpine (a tranquilizer) according to a 1958 study on 108 subjects ranging in age from 4 to 33 years and ranging in diagnosis from hyperactive (N=26) to withdrawn (N=19). The mix of age and diagnoses in this study might have masked the fact that in relatively homogeneous diagnostic and age groups one might observe differential effects of the two drugs tested.
4. Methylphenidate significantly increases motor activity (up 74%), while phenobarbital (down 10%) does not, according to Millichap and Boldrey's (1967) study. Contrary evidence regarding the effects of methylphenidate on motor activity was collected in a later study by

TABLE 17: THE EFFECTIVENESS OF METHYLPHENIDATE VERSUS OTHER ACTIVE DRUGS FOR HYPERKINESIS

	SOURCE		
	**M>	M≃	M<
1. THIORIDAZINE .75-1.0mg/kg/day vs. M .25-.35mg/kg/day on:			
Quality of day (teacher's rating)	Sprague et.al. 1970		
On-task behaviour	"		
Accuracy (Sternberg)	"		
Reaction time (Sternberg)	"		
Reduced activity (stabilimetric cushion)	"		
Teacher initiated contact			
8 Behavioural measures		Sprague et al. 1970	
2. CHLORPROMAZINE 800mg/day-max. vs. M. 200mg/day-max. on:			
Full scale IQ (WISC)	Weiss* et al 1971		
Verbal IQ (WISC)			
3. RESERPINE $\bar{x}$ = .75mg/day vs. M 20-40mg/day on:			
Verbal IQ		Zimmerman & Bergeme. 1958	
Performance quotient			
Clinical rating			
4. PHENOBARBITAL 2.5mg/kg/day vs. M .25-.5mg/kg/day on :			
Motor activity (wrist actometer) -- up with M, down with Ph.			Millichap & Boldrey 1967

* M and Chl. not compared directly, however M>P and Chl. ≃ P on these two measures

**M> Methylphenidate significantly better ($p<.05$)
M≃ Methylphenidate not significantly different ($p<.05$)
M< Methylphenidate significantly poorer ($p<.05$)

TABLE 17: continued

	SOURCE		
	**M >	M ≃	M <
5. CAFFEINE 160mg/day vs. M 20mg/day on:			
Total behaviour symptoms (Conners & Werry - Weiss)	Garfinkel 1974		
Aggressivity (Conners Teacher-factor I)	"		
Hyperactivity (Conners Teacher-factor IV)	"		
Decrease in Errors (Kagan M.F.F.)	"		
Inattentiveness (Conners Teacher-factor II)		Garfinkel 1974	
Anxiety (Conners Teacher-factor III)		"	
Sociability (Conners Teacher-factor V)		"	
Visual-motor Perception (Bender Gestalt)		"	
Visual perception (Frostig II & IV)		"	
Motor coordination and steadiness (Reitan maze & holes)		"	
CAFFEINE 200-300mg/day vs. M unknown dose on:		Schnack-enberg	
Behaviour rating by teacher		1973	
6. DEXTROAMPHETAMINE 15mg/day vs. M 30mg/day on:			
Arithmetic (WISC)	Conners		
Similarities (WISC)	1972		
Full scale IQ (WISC)		Conners	
Verbal IQ (WISC)		1972	
Digit span (WISC)		"	
Object assembly (WISC)		"	
Perceptual quotient (Frostig)		"	
Verbal fluency		"	
Teacher symptom ratings (Conners)		"	
Visual-motor perception (Bender Gestalt)		"	
Embedded Figures test		"	
Maze solving & motor control (Porteus Mazes)		"	
Auditory attending (Speech-Noise test)		"	
Visual attending (Continuous Vigilance test)		"	
Scholastic achievement (WRAT)		"	

TABLE 17: continued

	SOURCE	
**M >	M ≃	M <
6. DEXTROAMPHETAMINE continued		
Rote learning	Conners 1972	
IQ equivalent (Draw-A-Man)	1971 a	
Social Maturity (Draw-A-Man)	Conners 1971 a	
DEXTROAMPHETAMINE 10mg/day vs. M 30mg/day on:		
Clinician's rating of improvement	Eisenberg et al. 1965	
DEXTROAMPHETAMINE 20mg/day vs. M 30mg/day on:		
Hyperactivity (Conners Teacher-factor IV)	Winsberg et al 1974	
Aggressiveness (Conners Teacher-factor I)		
Inattentiveness (Conners Teacher-factor II)		

Millichap et al. (1968) using an actometer, and in other studies using stabilimetric cushions (Sprague et al. 1970; Christensen & Sprague 1973).

5. Methylphenidate is significantly better than caffeine (both stimulants) for some important dimensions of behaviour but no different for others. It would be useful to find out if higher doses of caffeine would produce therapeutic outcomes which were equivalent to methylphenidate and side-effects which were less problematic.
6. Methylphenidate treatment does not appear to be any different than dextroamphetamine treatment (both stimulants) according to 20 different measures of therapeutic outcome. For two measures, the WISC arithmetic and similarities subtests (WISC = Weschler Intelligence Scale for Children), methylphenidate seems to be significantly better than dextroamphetamine.

Thus the evidence to date is that in the dosages tested methylphenidate is equal or superior to every compound to which it has been directly compared in the treatment of hyperkinetic children. There are numerous drugs to which methylphenidate has not been directly compared. One could proceed to make indirect comparisons between methylphenidate and further active drugs by assuming that methylphenidate (M) and dextroamphetamine (D) are equivalent in therapeutic effectiveness, and therefore those drugs (X) which are

inferior to dextroamphetamine would also be inferior to methylphenidate. In other words, if M is equivalent to D, and D is better than X, then M is better than X. A review of studies in which dextroamphetamine has been directly compared to other active drugs has not been undertaken for this thesis. The review which has been presented here provides evidence which indicates that methylphenidate is equal or superior in therapeutic effectiveness to every compound to which it has been directly compared in the treatment of hyperkinesis. These compounds include: placebo, thioridazine, chlorpromazine, reserpine, phenobarbital, caffeine, and dextroamphetamine.

The reason for methylphenidate's therapeutic effectiveness is not fully understood. Information and speculation about its mode of action in the body will not be elaborated here. However it is worth noting one simple yet plausible explanation for its apparent effect on many measures of therapeutic outcome. Methylphenidate as a central nervous system stimulant seems to increase hyperkinetic children's attention span as coffee seems to do for many of us. With improved attention, a hyperkinetic child may perform better on numerous cognitive tests, and may in addition exhibit fewer frenetic transitions from one activity to another (hyperactivity), thus accomplishing more on the few activities at hand. This in turn prompts parents and teachers to rate the hyperkinetic child's behaviour as improved.

This raises the question of whether or not children considered normal would show similar improvements in cognitive function and behaviour if they took methylphenidate. Perhaps on standardized tests such as the WISC, normal children would show greater improvement in performance with methylphenidate than with placebo, as hyperkinetic children do (and as I suspect adults may do given methylphenidate or caffeine rather than placebo). The behavioural ratings of normal children might not improve significantly with methylphenidate since they are already in the broad band of acceptable behaviour. While hyperkinetic and normal children might show similar improvements (particularly in test performance) with methylphenidate, this would not affect my own personal judgement that hyperkinetic children show sufficient deficits to warrant the treatment while normal children do not.

If in fact the evidence is so good that methylphenidate works as well or better than placebo or other active drugs to which it has been compared in the treatment of hyperkinesis, why should we perform any research on alternative treatments for hyperkinesis? There are several reasons.

First, some hyperkinetic children treated with methylphenidate may improve to a "statistically significant" degree and yet still exhibit major deficits (Conrad, Dworkin, Shai, Tobiessen 1971, p.517) which call for more complete

or effective modes of treatment.

In addition, a substantial proportion of hyperkinetic children do not seem to respond to stimulants. That proportion varies in different studies from about 10% (Knobel, 1962) to 22% (Sleator and von Neuman, 1974). The proportion of non-responders may be affected by the type of child included in the study, the method of judging non-response, or it may simply be an estimate of the proportion of subjects who have not actually taken enough medication for therapeutic effects -- whether by failure of physicians to prescribe adequate dosage, or by failure of parents to administer the medication. (One survey of the literature indicates that this rate of non-response is consistent with the rates of non-compliance with prescribed medications among children and adults (Haynes, in press)).

At any rate this points up the need to measure compliance with methylphenidate medication so that we can find out if non-responders are non-compliers or compliers for whom the prescribed methylphenidate treatment is not effective.

There is a further group of hyperkinetic children who are rated as worse after administration of methylphenidate (Satterfield, 1973). It is conceivable that this is a result of random variations in ratings among those who have not taken the prescribed medication. Measures of compliance in trials of methylphenidate would tell us if this is the case or if in fact some medication compliers do get significantly

worse.

For those hyperkinetic children who respond to methylphenidate, but still have major problems, for the medication taking non-responders, and for the medication taking adverse responders, we need to develop and evaluate further methods of treatment.

Another issue, which is relevant to the consideration of alternative treatments for hyperkinesis, is the fact that methylphenidate may produce significant side-effects.

The Compendium of Pharmaceutical and Specialties (1974, p.431) lists the following possible side-effects: nervousness, insomnia, hypersensitivity reactions, anorexia, nausea, dizziness, palpitations, headache, dyskinesia, drowsiness, skin rash, blood pressure changes, pulse changes, tachycardia, angina, cardia arrhythmia, abdominal pain, weight loss, overt psychotic behaviour and psychic dependence. Of course these side-effects do not occur in all patients, and in the few cases where side-effects are an obvious problem, medication can be terminated. Within those studies in Table 15 which reported on side-effects, side-effects usually occurred in a minority of patients and were mitigated somewhat by altering dosage or time of administration. In a few instances medication was terminated because of severe side-effects.

There are three specific reports of side-effects worth discussing further.

Knights and Hinton (1969, p.649) in their randomized trial found side-effects on weight, blood pressure and heart rate after 6 weeks of methylphenidate treatment (see Table 18, p.111). The effect of methylphenidate in increasing heart rate was significantly greater than placebo, while the effects on increasing diastolic blood pressure and on decreasing weight approached statistical significance for methylphenidate compared to placebo.

Safer and Allen (1973) surveyed the changes in height and weight over several years for hyperkinetic children taking either methylphenidate, or dextroamphetamine, or no medication because of parental resistance (non-random assignment). Information has been abstracted from that study and presented in Table 18. "The difference between the group means showed the following statistically significant results. For percentile weight loss, dextroamphetamine produced greater loss than any other group, and both the high doses and the entire methylphenidate group showed greater losses than controls. For percentile height, the high dose of methylphenidate and dextroamphetamine did not significantly differ, and both showed greater losses than controls. The low dose of methylphenidate showed no significant differences from controls [underline mine]."

TABLE 18: SOME SIDE-EFFECTS OF STIMULANT MEDICATION

A. Side-effects of medication taken for 6 weeks on:

	Weight (lbs)	Diastolic BP (mm)	Heart Rate (beats/min)
Methylphenidate 40mg/day	-1.5	+1.9	+15.6
Placebo	+ .4	-2.7	+ 2.9
	p <.10	p <.10	p <.01

Adapted from Knights and Hinton 1969, p.649

B. Side-effects of medication taken during about 3 years on:

	Percentile Weight			Percentile Height			
	Initial	Final	Change	Initial	Final	Change	N
Dextroamphetamine	68.8	48.4	-20.4	65.4	51.9	-13.5	29
Methylphenidate	49.0	42.6	- 6.4	47.1	41.9	- 5.2	20
- high dose >20mg/day			-10.0			- 9.4	10
- low dose <20mg/day			- 2.7			- 1.0	10
Drug-refused controls	46.1	52.9	+ 6.8	43.1	44.4	+ 1.3	14

Adapted from Safer and Allen 1973, pp.661-662

Reinforcing these findings on side-effects, is Conners (1972, pp.703-704) randomized trial in which methylphenidate and dextroamphetamine reportedly produced significantly more insomnia and anorexia than placebo, and in which dextroamphetamine (max. 15 mg/day) produced significantly more of these side-effects than methylphenidate (max. 30 mg/day).

Because of such side-effects some clinicians are reluctant to use any stimulant medications for children. Others choose to use methylphenidate because of its demonstrated effectiveness and because of its apparently lower rate of side-effects. These clinicians may argue that the repurcussions of hyperkinesis on social interactions and on school performance are more damaging than the side-effects of methylphenidate. Other clinicians advise conjoint use of stimulants and non-drug therapies to give the hyperkinetic child the opportunity for maximal therapeutic benefits.

In the next section are reviewed all available studies of non-drug treatments for hyperkinesis which met criteria equivalent to those used in selecting studies of methylphenidate for review.

2.6.3. Non-Drug Treatments

Studies of non-drug therapy for hyperkinesis seem to be less common than drug studies. The same technique was used to locate both types of studies. That is, appropriate articles were identified through the heading of "Hyperkinesis" in Index Medicus and Psychological Abstracts, or through the bibliographies of articles so located. Unpublished studies were not sought. Twenty studies meeting the criteria specified earlier were located for the review of the literature on methylphenidate. Many studies of other drugs for hyperkinesis would have met comparable criteria. In contrast, only 19 studies which met specified criteria were located for this review of the entire non-drug treatment literature. I suspect that the proportion of (located studies/existing studies) is higher for the drug review than for the non-drug review. However I believe that the number of existing studies which would meet the study-selection-criteria is higher in the drug literature than in the non-drug literature. Studies from the non-drug review appear in Table 19.

The criteria for selection of non-drug studies for hyperkinesis were equivalent to those used in selecting studies of methylphenidate:

1) all or some of the subjects in the study were described by the authors as hyperkinetic or hyperactive children,

2) the effectiveness of a non-drug treatment was directly compared to that of placebo or other active treatment(s) used

in the same trial,
3) quantitative data on treatment outcomes were presented,
4) the study sample was not drawn exclusively from a group of mentally retarded children. (This criterionwas not specifically used to select studies for the drug review, and the rationale for its use here will be explained.)

According to criterionone for selecting studies for review, subjects had to be described as hyperkinetic or hyperactive. In both the drug (Table 15) and non-drug review (Table 19), studies of MBD children were included even if the author did not specify the number of children with and without hyperactivity. In addition, a few studies were included in the non-drug review in which children were described as overactive, distractible, seldom stays in seat etc. I felt such children could be considered hyperkinetic though they were not identified by that term in the publications in question. (Similar studies would have been eligible for the drug review had they come to my attention.)

Studies are listed in section B of Table 19 if:
a) children were described as being overactive, distractible etc., but were not termed hyperkinetic or hyperactive; b) children were stated to have MBD, and it was not stated whether they were or were not hyperkinetic or c) some children in the study were stated to be hyperkinetic or hyperactive while others were not. Column two in the table differentiates these three types of studies with one of the following notations after the number of subjects: a) Over; b) MBD; c) Some Hyp.

TABLE 19: A SUMMARY OF STUDIES OF NON-DRUG TREATMENT FOR HYPERKINESIS

SOURCE	DESIGN FEATURES 1. # of subjects Hyp.=hyperactive Over.=overactive 2.R=randomized PP=pre-post PPR=pre-post-reversal 3.DB=double-blind Ind.=independent See text for further explanations	TREATMENTS	OUTCOMES >means significantly better ($p < .05$)
A.1 Eisenberg Gilbert Cytryn & Molling 1961	23 Hyp. R DB for drugs	7 weeks of: A) Psychotherapy, 5 sessions B) Psychotherapy plus placebo C) Psychotherapy plus perphenazine 8-16mg	No significant differences between A, B, & C, after drugs stopped, in global improvement rating.
2. Patterson Jones Whittier & Wright 1964	2 Hyp. - -	17 sessions of: A)candy for attending B)normal class procedure	A>B on lower non-attending during treatment and ~1 month post treatment.

TABLE 19: continued

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
3. Hawkins Peterson Schweid & Bijou 1966	1 Hyp. PPR -	Total of several months for A) attention, praise, contact for desired behaviour. Told to stop undesirable behaviour. If repeated, put in room for ≃ 5 min. 6 sessions B) reversal 14 sessions C) same as A 6 sessions D) follow-up 3 sessions	Frequency of undesirable behaviour down in A (from 18-35/hr to 1-8/hr); up in B, down in C; remained low in D.
4. Patterson & Brodsky 1966	1 Hyp. PP -	9 days of: A) multiple intervention: for temper tantrums held to floor; social and candy reinforcers for appropriate play & other behaviour.	Tantrums down from ~30min/day to zero; negative and isolated behaviours down to near zero; positive interactions with peers up.
5. Pihl 1967	2 Hyp. PP Ind.	5 sessions of: A) points, exchangeable for money, stamps etc., earned for remaining seated.	A better than pre-test on time seated (~ 85% vs. ~ 30% of session).
6. Quay Sprague Werry & McQueen 1967	5 Hyp. PPR -	Total of 120 sessions (days) for: A) candy and head pats for attending. 65 days B) head pats for attending 30 days C) extinction=reinforcers withdrawn. 25 days	Frequency orienting toward teacher: up signif. during A; down signif. in A to B transition; up signif. during B; down signif. during C.

TABLE 19: continued

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
7. Palkes Stewart & Kahana 1968	20 Hyp. R ?-	1 session of: A) no training B) self-directed verbal reminders to stop, listen, look and think before answering test question	B>A on Porteus Maze qualitative, & quantitative scores B> pre-test on Porteus Maze.
8. Freibergs & Douglas 1969	65 Hyp. (& 99 normals) R Ind.	2 sessions of: concept learning task with A) marbles for 100% of correct responses B) marbles for 50% of correct responses C) like A with longer inter-trial interval	A & C >B on concept learning for Hyp. & for controls B-controls > B-Hyp. on concept learning A & C no significant differences for Hyp. & controls.
9. Scott 1970	4 Hyp. - -	4 trials of: A) normal classroom-open desks B) open desks plus music C) work at 3-sided booth D) booths plus music	A, B, C, D, significantly different on # correct arithmetic problems. A was poorest. For 3 of 4 children B was best.
10. Stevens Stover & Backus 1970	36 Hyp. (& 36 normals) R Ind.	3 x 15 second trials of: A) free response on rapid tapping B) encouraged to tap rapidly C) pennies for increased tapping	A, B & C not significantly different for Hyp. B & C > A on rapid tapping for controls A-Hyp.> A-control on rapid tap. B & C-control > B&C-Hyp. on rapid tapping.

TABLE 19: continued

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
11. Conrad Dworkin Shai & Tobiessen 1971	68 Hyp. R DB for drugs ? Ind.? non-drugs	4-6 months of: A) placebo, no tutoring B) placebo, & perceptual-cognitive-motor tutoring C) dextroamphetamine, no tutoring D) dextroamphetamine, tutoring Drug ~ 10-15mg/day Tutoring ~ 40 sessions	Tutoring > No tutoring: B > A on WISC information D > C on Teacher Behaviour Rating (B.R.) Dex. > Placebo: C > A on Parent B.R., Frostig IV, V, & P.Q. D > B on Teacher B.R. & Parent B.R. Also C > B on Parent B.R. D > A on Motor Pattern, Teacher B.R., Parent B.R., & WISC information.
12. Christen-sen & Sprague 1973	12 Hyp. not R DB for drugs Ind. for non-drugs	3 sessions of 1), 5 sessions of 2): A) methylphenidate 1. without conditioning 2. with conditioning B) placebo 1. without conditioning 2. with conditioning	A.2 > A.1; B.2 > B.1; A.1 > B.1; A.2 > B.2 in 1/5 of sessions on: lower mean seat movement per minute (stabilimetric cushion).
13. Kauffman & Hallahan 1973	1 Hyp. PPR -	Total of 19 days for: A) reinforcement-1 = praise and candy or toy privileges for desirable play behaviour B) reversal-1 C) DISTAR teaching with praise and/or food for appropriate behaviour & correct responses D) reversal-2 E) reinforcement-2	Rough physical behaviour rapidly reduced in A, up in reversals, low in C and E.

TABLE 19: continued

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
B.14 Walker & Buckley 1968	1 Over. PPR -	Total of 42 sessions for: A) points earned toward a model for attending in individual setting. 15 sessions B) extinction. 14 sessions C) similar to A but in class setting. 13 sessions	% attending went from ~25% in baseline to ~93% in A, to ~44% in B, and to ~90% in C.
15. Wadsworth 1971	10, ~7 Over. PP -	Total of 14 months for: A) consultation with teacher 3 months B) tutoring with child 3 months C) rules and reinforcers for desired behaviour; in hall for disruptive behaviour; some time in regular class; 3 months D) most of time in regular class. 5 months	C & D> pre-test on rate of gain in Slosson Oral Reading. A, B, C, D,> pre-test on behaviour score. C> A on behaviour score.
16. McKenzie Clark Wolf, Kothera & Benson 1968	8 Over. PP Ind.	Several months of: A) weekly allowance based on average weekly grades	A > pre-test on percentage of attending to reading and arithmetic.

TABLE 19: continued

SOURCE	DESIGN FEATURES	TREATMENTS	OUTCOMES
17. Madsen Becker & Thomas 1968	3 Over. PP Ind.	Total of ~7 months for: A) rules for conduct B) rules plus ignore deviance C) B plus praise desired behaviour D) reversal to baseline procedures E) as in C	C & E >pre-test on reduced inappropriate behaviours.
18. Friedman Dale & Wagner 1973	50 MBD R -	8 months of: A) stimulant drug (dextroamphetamine or methylphenidate) B) stimulant drug, plus 10 sessions of perceptual-motor training, plus 8 sessions of group counselling for parents.	No significant differences in A & B on Bender, or Parents', Teachers' or Pediatricians' ratings of improvement.
19. Johnson & Brown 1969	1 Over. PP -	16 sessions including: instruction, discussion, modelling & reinforcement for mother in use of attention to reinforce child's on-task behaviour	On-task behaviour of child up from 5min/30min. to 5min/13 min. in arithmetic sessions with mother.

The use of study-selection criterion two regarding the comparison of a non-drug treatment to placebo or other active treatment(s) merits some discussion. In the drug review, the identification of a placebo treatment and an active treatment was straightforward. It was simple to exclude studies from review which had neither placebo nor a second active treatment but merely a pre-post comparison of methylphenidate treated children. This is more problematic in non-drug studies. If for example, a study compared a "conventional" method of disciplining children to the same teacher's newly introduced method, this could be considered merely a pre-post comparison, or it could be considered a within subject comparison of two active treatments. Some studies include a reversal to the pre-treatment condition for a pre-post-reversal comparison which gives one more confidence in the results. Both types of studies are included in Table 19 and noted as PP. (pre-post) or PPR. (pre-post-reversal).

The third study-selection-criterion regarding quantitative measures of treatment outcome had no exceptions in the drug or non-drug review. That is, review articles or editorials extolling the virtues of a particular therapy were not included (though they were used to locate relevant studies).

The fourth study-selection criterion excluded studies which had only mentally retarded subjects. While this

criterion was not used to exclude studies from the drug review, it appears that none of the drug studies in Table 15 had a sample drawn exclusively from a group of mentally retarded children. Most (12 out of 20) studies in Table 15 reported that none of their samples were mentally retarded or had an IQ less than 80. Five studies do not specify the IQ range present (Christensen & Sprague, 1973; Millichap & Boldrey, 1967; Schackenberg, 1973; Sleator & von Neuman, 1974; Sprague et al., 1970). However of these five, two give the mean IQ, which was 94.25 in one study (Christensen & Sprague, 1973) and 98.6 in another (Sprague et al., 1970) indicating that some part of the sample had IQ's above 80. Three other studies note the inclusion of some subjects who were mentally retarded or had IQ's less than 80 at pre-test (Zimmerman & Burgemeister, 1958; Millichap et al., 1968; Winsberg et al., 1974).

In an effort to make the subjects in the non-drug treatment review similar to those in the drug treatment review, I did not seek non-drug studies whose titles indicated that they were conducted among retarded children, nor did I include studies when I found from the text that they were conducted among exclusively retarded subjects. Studies which had some subjects with IQ's above 80 and some subjects with IQ's below 80 were eligible for both the drug and non-drug review. These criteria made decisions about inclusion or exclusion of a study in the review quite obvious in most cases.

One somewhat ambiguous case was a study by Hawkins, Peterson, Schweid and Bijou (1966) of a single subject with Stanford Binet IQ Scores of 72 and 80. It was included in the non-drug review. Incidentally there may be numerous studies of treatment for hyperkinetic retarded children since hyperactivity is reputedly a big problem among retarded children. Furthermore the same treatments may be appropriate for retarded children and non-retarded hyperkinetic children. However studies of exclusively mentally retarded children are not included in the non-drug review in an effort to try to make the subjects in question similar to those included in the drug review.

Only a few further comments about Table 19 are required. In evaluations of non-drug treatments it is impossible to have a double-blind assessment. That is, both the treated and the treater can observe what treatment is being administered. However it is possible and desirable to have an independent assessment by someone or something (mechanical) who is uninformed about the exact nature of the study, its subjects, treatments, or expected outcomes. The use or lack of use of independent assessment of outcome is indicated in column two in Table 19 with the notation "independent" or "-" respectively.

In column four are listed treatment outcomes. If the original authors analyzed treatment outcomes with statistical tests this is indicated with notations such as "A>B" meaning

treatment A was significantly better than B ($p<.05$), or with phrases such as "no significant differences between A and B". If statistical test(s) were not reported, the outcomes are listed without such notation (e.g. attending up 50% in A).

The non-drug studies listed in Table 19 are in general not as good in their research design as the previous group of drug studies reviewed. Three design features found in almost every drug study reviewed are absent in many of the non-drug studies. First, many of the non-drug studies did not employ random assignment of subjects to alternative treatment. Some used only a pre-post comparison from an old and a new treatment procedure. Some did use a relatively strong pre-post-reversal design in which a group of subjects goes through a series of applications and withdrawals of a particular treatment, in order to assess its effects. Of course one can argue that the outcomes observed in this fashion with a non-drug treatment are a placebo effect generated by the expectations of those involved. It may therefore be preferable to compare two non-drug treatments or a non-drug and drug-treatment for which one can generate equally good expectations or placebo effects. Thus any observed differences can more readily be attributed to actual differences in the treatment procedures.

The second design feature which differed in the drug and non-drug studies reviewed was the assessment of outcomes.

Virtually all of the drug studies attempted to achieve double-blind assessment of outcomes. While this is impossible in a non-drug study, since treater and treated can observe the nature of the treatment administered, it is possible to have an independent assessment of non-drug treatment outcomes in which the assessor does not know which child has received which treatment prior to assessment. Unfortunately the majority (13/19) of the non-drug studies reviewed failed to have independent assessment of treatment outcomes. One can argue then that the results may be biased by the assessor's expectations and hopes for demonstrating treatment effectiveness.

The third feature of the non-drug studies which distinguishes them from the drug studies is the lack in six of 19 non-drug studies of data analyses to determine if observed differences in treatment outcomes are statistically significant. Such analyses would enhance the studies; however, as they stand there is at least enough data for a reader to make his/her own judgement of whether the observed differences in treatment outcome are modest, moderate or dramatic. Thus the non-drug studies as a group have some weaknesses which future researchers in this area should try to avoid. Nevertheless we should take a look at the results of the non-drug studies.

Among the 19 studies in Table 19, 14 used some type of behaviour modification treatment which may be called

conditioning. Six studies (including one of the 14) tested other non-drug treatments which would not be called conditioning. The aspects of these six studies which would not be termed conditioning will be discussed first. All of the outcomes assessed in these six studies are listed in Table 20. The studies and their conclusions may be summarized as follows:

1) Palkes et al. (1968) found that hyperkinetic children randomly assigned to one session of training in verbally reminding themselves to stop, look, listen and think before answering, did significantly better on the Porteus Maze qualitative and quantitative scores than children randomly assigned to no training.
2) Wadsworth (1971) in a pre-post comparison found that overactive children improved significantly in behaviour but not in their rate of improvement in reading after a special teacher consulted with the children's regular teacher.
3) Scott (1970) with a very small sample (N=4) did not make pair-wise comparisons of treatments, but he did find a significant difference in the number of correct responses to arithmetic problems among four situations: open desk, open desk with music, 3-sided booth, 3-sided booth with music. The open desk situation gave the poorest results, and for 3 of 4 children the open desk with music gave the best results.

TABLE 20: EVALUATION OF MISCELLANEOUS NON-DRUG TREATMENTS FOR HYPERKINESIS

TREATMENTS AND OUTCOME MEASURES	SOURCE * T>	SOURCE * T≈	SOURCE * T<
1. T= Self directed verbal reminders to stop, look listen and think before answering vs. No reminders on :			
a) Porteus Maze qualitative scores	Palkes et al. 1968		
b) test quotients			
2. T= Consultation with teacher vs. No consultation on:			
a) Behaviour rating by teacher	Wadsworth		
b) Rate of learning reading		1971	
3. T= Open desks plus music during arithmetic vs. Open desks vs. 3-sided booth vs. 3-sided booth plus music on:			
a) # correct in arithmetic		Scott 1970	
4. T= Psychotherapy for parents and child vs. Psychotherapy & placebo vs. Psychotherapy & perphenazine on:			
a) Global rating of improvement by clinician		Eisenberg et al. 1961	

* T> means treatment T was significantly better ($p<.05$) than the alternative.
T≈ means treatment T and the alternative were not significantly different.
T< means treatment T was significantly poorer ($p<.05$) than the alternative.

TABLE 20 continued:

TREATMENT & OUTCOME MEASURES	SOURCE T >	SOURCE T ≈	SOURCE T <
5. T= Counselling for parents plus perceptual-motor training & stimulant drugs for child vs. stimulant drugs for child on:			
a) Bender-Gestalt		Friedman et al. 1973	
b) Parent rating of child's improvement			
c) Teacher rating of child's improvement			
d) Pediatrician's rating of child's improvement			
6. T= Perceptual-cognitive-motor tutoring plus placebo vs. No tutoring plus placebo on:			
a) WISC information	Conrad		
b) 33 measures of behavioural, cognitive, perceptual & motor function		Conrad 1971 on 33 measures	
T= Perceptual-cognitive-motor tutoring plus dextroamphetamine vs. No tutoring plus dextroamphetamine on:			
a) Behaviour rating by teacher	Conrad		
b) 33 measures of behavioural, cognitive, perceptual & motor function		Conrad 1971 on 33 measures	

4) Eisenberg et al., (1961) found no significant differences in global ratings of improvement among hyperkinetic children randomly assigned to psychotherapy for parents and child, psychotherapy plus placebo, or psychotherapy plus perphenazine.

Several very prominent authors in this field (Lipman, 1973, p.1; Weiss, Werry, Minde, Douglas & Sykes, 1968, p.145; Wender, 1971, p.120; Werry, 1968a, p.592) have made statements, based on the studies of Eisenberg et al. (1961, 1965), which suggest that psychotherapy is relatively unfruitful for hyperkinetic children. This may be so; it is possible that these authors have drawn their conclusions from published materials and from oral presentations they have heard by Eisenberg. However it seems to me that such a conclusion cannot be drawn from the studies of Eisenberg et al. (1961, 1965) because these studies do not show psychotherapy to be any more or less effective than other treatments for hyperkinetic children, and there was no untreated group of hyperkinetic children for comparison. In fact, Eisenberg et al. did one study in which 26% (12/46) of hyperkinetic children treated with stimulant drugs showed "marked" improvement (1965, p.128) while, in an earlier series of studies, 28% (37.133) of hyperkinetic children treated with brief psychotherapy with or without placebo showed "marked" improvement (1965, p.126).

One cannot be at all confident that outcomes were

judged in the same fashion in the various studies, however this series of studies suggests that psychotherapy is no more or less effective than stimulant medications for hyperkinetic children. I suspect that the various authors, who concluded that psychotherapy is not particularly useful for hyperkinetics, reached this conclusion partially by noting in the study of Eisenberg et al. (1961) that the proportion of neurotic children who markedly improved with psychotherapy was greater than the proportion of hyperkinetic children who markedly improved with the same treatment. However, it may be that neurosis is more likely to improve than hyperkinesis with any of a number of treatments, or even with no treatment, because of the nature of the two disorders not the nature of the treatments applied.

5) Friedman et al. (1973) found that treatment outcomes at 8 months were not significantly different for children randomly assigned to programs of:

   A) stimulant drugs; and perceptual-motor training with an educational therapist; and group counselling for the parents, with a psychiatric social worker, focused on common problems in dealing with the children

   B) stimulant drugs alone.

   Their outcome measures at 8 months were global ratings of improvement by parents, teachers, and clinicians, and a pass-fail classification on the Bender Gestalt test of visual-motor skills. It is possible that with these

outcome measures they missed subtle but important differences in therapeutic outcomes which might have been picked up by other measures (e.g. Conners' Questionnaires re. behaviour, WISC subtests etc.).

6) Conrad et al. (1971) did a study in which 68 hyperkinetic children were randomly assigned to: a) placebo; b) placebo plus perceptual-cognitive-motor tutoring; c) dextroamphetamine; d) dextroamphetamine plus tutoring.

The groups which received tutoring did significantly better on only 2 of 34 measures of behavioural, cognitive, perceptual and motor function. These two measures were the WISC information and the teacher behaviour rating. The complete battery of 34 tests included 13 scores from the WISC, 7 from the Frostig Developmental Test of Visual Perception, 4 measures of hyperactivity or behaviour, and 10 other measures of motor, perceptual and cognitive function. Looking at the pre-post gains on the 34 measures, including those which were not statistically significant, it appears to me that the greatest gains were made by: a) the placebo group on one measure, b) the placebo plus tutoring group on three measures, c) the dextroamphetamine group on 14 measures and d) the dextroamphetamine plus tutoring group on 16 measures. In comparing the latter two groups, the only significant difference in their pre-post gains was

on the teacher behaviour rating. The dextroamphetamine group had a mean change of 2.59, and the dextroamphetamine plus tutoring group had a mean change of 2.19 ($p < .05$) on a scale where 1. was dramatic improvement, 2. was definite improvement, 3. was no change and 4. was worse. It is not clear whether teachers were aware of which children were in the special tutoring sessions and which were not. If their assessments were independent and valid, then tutoring seems to make a difference of .4 on a 4 point scale or a 10% gain over no tutoring. Conrad et al. (1971, p.517) say "it should be mentioned that of the 68 children involved in the study, only three had made sufficient progress during the year to no longer meet the initial criteria for inclusion in the study [which included high scores on a hyperkinetic scale plus specified deficits on one or more of the Bender-Gestalt, Frostig, or WISC]. Thus despite the impressive gains made by the children in the experimental groups, most of them still needed remedial help at the conclusion of the study."

We now turn to the 14 studies of some type of conditioning for hyperkinetic children, the results of which are displayed in Table 21, page 133. Conditioning is used here to mean the systematic application of "positive consequences" to increase desired behaviours, and the systematic application of "negative consequences" to decrease undesired behaviours.

TABLE 21: THE EFFECTIVENESS OF CONDITIONING IN THE TREATMENT OF HYPERKINESIS

OUTCOME MEASURES	SOURCE* C >	C ≈	C <
BEHAVIOURAL MEASURES:			
Decreasing undesirable behaviours; or Increasing desirable behaviours:			
1) biting, kicking, pushing, shouting "No", etc. .. down	(Hawkins et al.1966) (Kaufman & H.1973)		
2) tantrums & isolation .. down positive interactions .. up	(Patterson & B.1966)		
3) staying seated .. up	(Pihl 1967)		
4) wiggling in seat .. down	Christensen & S.1973		
5) in seat, pays attention, participates, doesn't hit or scream etc. .. up	Wadsworth 1971		
6) out of seat, pushing, slapping ignores teacher etc. .. down	Madsen et al. 1968		
7) shuffling chair, looking out window, wiggling, fiddling, walking around etc. .. down	Patterson et al. 1964		
8) attending to task .. up	(Walker & B.1968)		
9) " to arithmetic .. up	McKenzie et al.1968 (Johnson & B.1969)		
10) " to reading .. up	McKenzie et al.1968		
11) " to teacher .. up	Quay et al.1967		

* If the source is listed in parentheses, this means a statistical test of significance was not reported but the difference appears to me to be appreciable.

C > means conditioning significantly better ($p<.05$).
C ≈ means conditioning not significantly different ($p<.05$).
C < means conditioning significantly poorer ($p<.05$).

TABLE 21 continued :

OUTCOME MEASURES	SOURCE C >	C ≈	C <
COGNITIVE TESTS:			
12) Concept learning to criteria of 10 consecutive correct responses (C=100% of correct responses (c.r.) reinforced vs. 50% of c.r. reinforced)	Freibergs & D. 1969		
13) Slosson Oral Reading - rate of improvement	Wadsworth 1971		
MOTOR TESTS:			
14) Tapping-task (C=encouraged or given pennies for rapid tapping vs. free choice rate of tapping)		Stevens et al. 1970	

In the studies reviewed here, the following positive consequences were employed: attention, praise, encouragement, candy, marbles, money, privileges, or points toward some reward. In the same group of studies, the following negative consequences were employed: ignoring, absence of other positive consequences, instructions to stop, time-out, or restraint. In five of the studies, teachers dispensed the reinforcers (Kauffman & Hallahan, 1973; Madsen et al. 1968; Quay et al. 1967; Walker & Buckley, 1968). In five studies, parents dispensed reinforcers (Hawkins et al. 1966; Johnson & Brown, 1969; McKenzie et al. 1968; Patterson & Brodsky, 1966; Pihl, 1967). In seven studies reinforcers were dispensed instead (or in addition) by experimenters or machines in an experimental setting (Christensen & Sprague, 1973; Freibergs & Douglas 1969; Patterson et al. 1964; Patterson & Brodsky, 1966; Pihl, 1967; Walker & Buckley, 1968). In these 14 studies the procedure to which conditioning was compared was some type of "non-conditioning" procedure in which the responses to childrens' behaviours were less consistently contingent on the "desirability" or "undesirability" of the behaviours. That is, positive and negative reinforcements or consequences were less systematically applied in the "non-conditioning" phase.

As shown in Table 21, conditioning procedures were superior to other procedures on virtually every dimension assessed in 14 studies. (This may indicate a judicious choice of outcome measures or the non-reporting of dimensions

which failed to show improvement.) In the reports available, hyperkinetic children treated with conditioning procedures had superior results on numerous measures of behaviour and on a few measures of cognitive performance. The one study which did not show significantly different results between conditioning and non-conditioning procedures may have been too short (three 15 second trials) or tested the hyperkinetic children on a task where they were already performing close to their limit.

Note that six of the 14 studies on conditioning did not report statistical tests of significance of their findings. I have examined such findings without doing statistical tests, and the reported differences appear to me to be appreciable. These studies are noted in parentheses in Table 21. The reader of course may refer to the original publication to see if he/she agrees with my judgement. Of the 13 studies which found conditioning to be superior to non-conditioning, two used an independent person for assessments (Madsen et al., 1968; McKenzie et al., 1968) and three used a mechanical device for assessments of outcome (Christensen & Sprague, 1973; Freibergs & Douglas, 1968; Pihl, 1967) both of which lend greater credibility to the findings. However if independent observers have somehow been led to expect improvement, they may be no more nor less biased in their observations than experimenters or therapists.

The total number of hyperkinetic children treated in the 13 studies with positive findings was 109. The studies with the larger samples

did not report the percent of individual children who improved with conditioning procedures (Christensen & Sprague, 1973; Freibergs & Douglas, 1969; Quay et al. 1967). However among the ten studies which did report individual improvement there was a total of 27 hyperkinetic, or overactive, distractible children. Of these, 26 were treated with conditioning procedures, and all of these 26 improved. In comparison, of 337 children treated with methylphenidate, 83% improved according to Millichap's (1967, p.775) review. Of course it is possible that the studies which failed to demonstrate improvement of hyperkinetic children with conditioning have not been written up and published. In addition the method of judging improvement was different in the drug studies referred to in the review. The possibility exists too that the subjects were somehow different.

While the conditioning studies are less extensive and less rigorous methodologically than the drug studies reviewed, 12 of them do provide consistent evidence that conditioning procedures are more effective than non-drug, "non-conditioning" procedures in improving the behaviour of hyperkinetic children. In addition, two of the studies provide evidence that cognitive performance or learning may be significantly enhanced with the application of conditioning.

From one of the 14 studies, which is by Christensen and Sprague (1973), a comparison can be made of conditioning and methylphenidate treatment. Hyperkinetic subjects in this

study were given either methylphenidate or placebo prior to sessions of film, discussion and quiz for which they received: A) in three such sessions, a fixed amount of money for their participating, and B) in five subsequent sessions, an amount of money contingent on reduced seat movement. The latter procedure is conditioning of reduced seat movement. (This study qualified for the review of drug studies in Table 15 and for the review of non-drug studies in Table 20. It is included in both.) Both the administration of methylphenidate and the conditioning procedure were associated with significant reduction of seat movement (measured by a stabilimetric cushion). Subjects on methylphenidate plus conditioning had the lowest rate of seat movement per minute. Those on methylphenidate and no conditioning, or on placebo and conditioning, had higher rates of seat movement than the first group but differed little from each other. Those on no conditioning and placebo had the highest rates of seat movement.

Now one may argue that the amount of buttocks movement exhibited by a seated child is not a very important dimension of behaviour. However reduction of buttocks movement was associated with increases in accuracy in a test situation in one study (Sprague et al. 1970). The exciting possibilities, which the study by Christensen and Sprague (1973) suggests, are that:

1) in some areas of behaviour, conditioning and methylphenidate

may be equally effective for the hyperkinetic child, and 2) methylphenidate and conditioning combined may be more beneficial for the hyperkinetic child than either treatment alone.

Sprague and Sleator (1973, p.729) have called for further research to find out more about the effects of combined drug and non-drug therapies. Rapoport (1973) reports that she is planning a study comparing the effects of methylphenidate, imipramine, and behaviour modification for hyperkinetic children. It is possible that a number of other people are currently hopeful about, or developing, or even using a combination of stimulant medication and conditioning (behaviour modification) for hyperkinetic children.

2.7 SUMMARY OF THE LITERATURE AND RATIONALE FOR RESEARCH PROTOCOL

This chapter will provide a summary of the literature reviewed and of some of the conclusions and recommendations which are based on that review.

Terminology regarding hyperkinetic children varies considerably from place to place and includes such labels as hyperactivity, the hyperkinetic behaviour disorder, and the hyperkinetic reaction of childhood. Hyperkinesis is considered one subset of disorders labelled minimal brain dysfunction. Since minimal brain dysfunction also includes hypokinesis, learning disabilities, and a variety of other disorders, authors should specify what subsets of the disorder they are dealing with when they speak of minimal brain dysfunction.

The definition of hyperkinesis which is probably in most widespread usage at the moment is that provided by the American Psychiatric Association's Diagnostic and Statistical Manual. "This disorder is characterized by overactivity, restlessness, distractibility, and short attention span". (1968, p.49).

A National Institute of Mental Health Sub-Committee developed similar criteria for the diagnosis of the "hyperactive reaction" : "hyperactivity - with a high and conspicuous level of gross motor activity .... and disorder of attention with higher distractibility and shorter attention span than appropriate for chronological age". (Werry, 1973, p.139).

In addition to listing necessary and sufficient criteria for the diagnosis of hyperkinesis, this sub-committee formulated a system of mutually exclusive and exhaustive diagnostic categories for child psychiatry. It would be useful for those responsible for the child psychiatry section of the next revision of the International Classification of Diseases (see Rutter, 1969) to consider the work of the NIMH sub-committee (Werry, 1973).

When a definition for hyperkinesis is introduced in the next revision of the International Classification of Diseases, this may prompt an increase in the number of children identified (some correctly and some incorrectly) as having the disorder. It is not yet known how frequently clinicians using the proposed ICD-9 definition (Rutter, 1969, p.58) or the NIMH sub-committee criteria (Werry, 1973, pp.139-140) will agree or disagree over whether or not an individual child is hyperkinetic.

In order to reach high interrater agreement on the presence or absence of hyperkinesis, it may be necessary to develop and utilize quantitative measures of overactivity, restlessness, distractibility, and attention span in diagnosis. A few workers have attempted to measure activity levels with actometers (Millichap & Boldrey, 1967), stabilimetric seat cushions (Christensen & Sprague, 1973) or other mechanical devices, but norms are not currently available for such measures. Similarly, a few tests of attention span have been

developed, but there are no well developed norms (Kassinove & Simmers, 1968; Sykes, et al., 1972).

The type of instrument which currently seems most appropriate for use in attempting to standardize the diagnosis of hyperkinesis is a behaviour checklist which covers all of the symptoms considered characteristic of hyperkinesis. The best known behaviour checklist which does this is Conners Parent-Teacher Questionnaire (Table 3, p. 30). Interrater reliability for this instrument is not known, nor is normative data currently available. Determination of both would be useful. It has been reported that a score of 15 is 2 standard deviations above the mean on Conners Parent-Teacher Questionnaire and it has been suggested that this score be used as a criterion for identifying children for whom treatment for hyperkinesis is appropriate. (Sleater & von Neuman, 1974). Clinicians who are looking for instruments to assist them in the diagnosis of hyperkinesis may find Conners Parent-Teacher Questionnaire a convenient and useful tool. It would be appropriate for a clinician to ask both a parent and a teacher to rate a child on this questionnaire when doing an assessment for hyperkinesis.

Future study may demonstrate that differing interventions are appropriate for children who score high on this questionnaire in only one setting rather than in both

home and school. For example, it is conceivalbe that children who score consistently high on such a questionnaire in a variety of settings are the ones for whom drug treatment will be most beneficial, whereas children who get high hyperkinesis ratings in some settings but not in others are the ones for whom behavioural interventions in the setting in question are most appropriate. Further study may also indicate whether or not it is beneficial to intervene when children score somewhat less than 15 on Conners Parent-Teacher Questionnaire. It would be useful to explore how varying cut-off scores on the Conners Parent-Teacher Questionnaire affect the sensitivity, specificity and predictive value of this diagnostic instrument in relation to response to treatment.

If one used two standard deviations above the mean on Conners Parent-Teacher Questionnaire as a criterion for diagnosis of hyperkinesis and <u>if</u> scores on this questionnaire are normally distributed, then by virtue of the characteristics of the normal distribution the prevalence of hyperkinetic children would be 2.28 per cent. This figure is reasonably close to the 1.73 per cent of children being given medications for hyperkinesis according to a 1973 study (Krager & Safer, 1974).

Other estimates of the prevalence of the hyperkinetic disorder are somewhat higher than this -- ranging from 3 to 10 per cent with a mean of about 6 per cent (Report 1971; Stewart, et al., 1966; Werner, et al., 1968; Huessy, 1967).

Part of the variation in these estimates probably results from variation in the definitions of hyperkinesis from study to study. However, even the lowest estimate suggests that about 30,000 out of every million children are hyperkinetic. It is not clear how many of these children are receiving some sort of treatment or intervention. While we know that only about 17,300 out of every million children receive medication for hyperkinesis (Krager & Safer, 1974), it is not clear if other children with the disorder remain untreated or receive some non-drug therapy.

The etiology and the natural history of hyperkinesis are poorly researched. A review of the work in these areas was not included with this thesis. However, a summary of the state of knowledge in these areas was provided through excerpts from a 1971 report: "We know little about definitive causes. The disorder has been ascribed to biological, psychological, social, or environmental factors, or a combination of these. There is speculation that the core set of symptoms - those affecting control of attention and motor activity - may have their origin in events taking place before the child is born or during the birth process, or they may be related to some infection or injury in early life .... usually the excessive activity and attentional disturbances are less apparent after puberty. Specialists citing experience, and some fragmentary research data, believe that treatment enables many to lead productive lives as adults, while severly afflicted children who remain untreated may be

significantly at risk for adult disorders. Extensive research is still required on these points" (Report 1971; pp.24-25).

Most of the studies done on etiology or natural history of hyperkinesis have been retrospective. One of the few long-term prospective studies which concerned itself with hyperkinesis was the Kauai Pregnancy Study in which a birth cohort of 866 children was followed for 10 years. (Werner, et al. 1968). Their findings indicate that lack of educational stimulation and lack of emotional support in the home are more strongly associated with hyperkinesis than is severity of perinatal stress (Werner, et al. 1968). It is quite conceivable that both perinantal stress and environmental situations can potentiate hyperkinetic behaviour in children.

Treatments for hyperkinetic children have been both drug and non-drug in nature. In North America the most commonly used drug treatment for hyperkinesis is the stimulant medication - methylphenidate (Krager & Safer, 1974). The evidence from short-term studies consistently indicates that methylphenidate is significantly more effective than placebo in improving behaviour, cognitive performance, and attention of hyperkinetic children (Campbell, et al., 1971; Christensen & Sprague, 1973; Cohen, et al., 1971; Conners, 1971a; Conners, 1972; Eisenberg, et al., 1965; Garfinkel, 1974; Knights & Hinton, 1969; Millichap, et al., 1968; Sleater & von Neuman, 1974; Sprague, et al., 1970; Satterfield, et al., 1972;

Sykes, et al., 1971; Sykes, et al., 1972; Weiss, et al., 1971; Winsberg, et al., 1974).

The comparisons of methylphenidate to active drugs indicate that it is equal or superior to every compound to which it has been compared. It is significantly superior in effectiveness to thioridazone (Sprague, et al., 1970) and chlorpromazine (Weiss, et al., 1971). In the dosage tested methylphenidate is significantly superior in effectiveness to caffeine (Garfinkel, 1974), or at least equal in effectiveness to caffeine (Schnachenberg, 1973). In the dosages tested methylphenidate is approximately equal in effectiveness to dextroamphetamine (Conners, 1971a, 1972; Eisenberg, et al., 1965; Winsberg, et al., 1974) but causes fewer side-effects than dextroamphetamine (Conners, 1972; Safer & Allen, 1973; Safer, et al., 1972).

Among the studies of non-drug therapy for hyperkinesis, behaviour modification (or conditioning) has the most extensive evidence for effectiveness. In general the non-drug studies have not been as rigorous in research methodology (e.g. lack of random assignment, "blind" observers) as the drug studies of hyperkinetic children. Nevertheless, they do provide consistent evidence that conditioning or systematic application of reinforcing and non-reinforcing contingencies can significantly improve the behaviour of hyperkinetic children.

Only one study has directly compared methylphenidate to conditioning among hyperkinetic children (Christensen & Sprague 1773). Each of these treatments alone was associated with significant and approximately equal reduction in buttocks movement among hyperkinetic children in a classroom-like situation. The two treatments in combination were associated with the lowest rates of buttocks movement. This study suggests the possibility that for hyperkinetic children in general, methylphendiate plus behaviour modification may be more effective than either treatment alone in improving behaviour attention span, and cognitive performance.

Currently, the use of stimulant medications for hyperkinesis is often quite separate from the use of behaviour modification strategies to reduce hyperkinesis. Those who have studied the two treatments and often those who apply the two treatments operate in different realms. The separation of these two treatments by disciplinary boundaries may mean that each discipline offers to hyperkinetic children only part of a potentially potent therapeutic package.

The assumption by some has been that when the cause of the hyperkinesis is organic, drug treatment will be effective; whereas if the cause of the hyperkinetic behaviour is environmental, behavioural interventions are appropriate. However, Christensen and Sprague's study (1973) suggests that for at least some hyperkinetic children either methylphenidate

or conditioning will alter behaviour and that the two in combination will be the most effective. It is conceivable that hyperkinetic children in general, irrespective of the etiology of their disorder, may benefit more from a combined stimulant drug and behaviour modification program than from either treatment alone. That is the hypothesis that the research protocol in the next section of this thesis is designed to test. If the evidence is good that methylphenidate and behaviour modification in combination is significantly more effective than either treatment alone, then such a program could be offered to at least some of the estimated 2 to 10 per cent of children who are hyperkinetic. Further work could then be done to develop and test an economical fashion of delivering such a treatment package to all who may benefit, perhaps through interdisciplinary primary care teams.

3. PROTOCOL FOR A TRIAL OF METHYLPHENIDATE AND BEHAVIOUR MODIFICATION, ALONE AND IN COMBINATION, FOR THE TREATMENT OF HYPERKINETIC CHILDREN

3.1. INTRODUCTION

This research protocol is offered as a set of guidelines which could be adapted for use in a variety of settings. It is not proposed with the intention of implementation in a specific setting, so details about specific personnel and arrangements for implementation of specific procedures are not covered in the protocol. Detailed arrangements would be required before actual implementation of this protocol, and such arrangements should be compatible with good research design and with the characteristics of the setting in question.

The objective of the research which is proposed here is to test the following hypotheses regarding the treatment of hyperkinetic children.

Primary hypotheses to be tested:

1) A regimen of methylphenidate and behaviour modification combined is more effective than methylphenidate alone.
2) A regimen of methylphenidate and behaviour modification combined is more effective than behaviour modification alone.

Secondary hypothesis to be tested:

3) Methylphenidate alone is more effective than behaviour modification alone.

It is proposed that the effectiveness of the three treatments be compared at the end of 8 weeks. With a serial intake of children, the study could be conducted over the course of one year. Further specifications regarding the selection criteria for hyperkinetic children, the treatment regimens, and the measures of effectiveness are provided in later sections of this protocol.

Methylphenidate and behaviour modification were selected for comparison, alone and in combination, because they are currently the most promising drug and non-drug treatments known for hyperkinesis. There is extensive evidence that methylphenidate is more effective than placebo and several other drugs to which it has been directly compared in the treatment of hyperkinetic children. However, some hyperkinetic children do not improve when methylphenidate is prescribed, and others improve but still exhibit major deficits relative to their peers (see 2.6.2. Drug Treatments). There is, in addition, fairly extensive evidence that behaviour modification procedures (in which reinforcers are applied or withdrawn in a systematic fashion designed to increase desired behaviours and decrease undesired behaviours) are more effective than other procedures in which reinforcers are less systematically applied when treating hyperkinetic children (see 2.6.3. Non-Drug Treatments). The relative effectiveness of these two treatments alone or in combination on the cognitive function, interpersonal behaviour, and self-concept

of hyperkinetic children is not known. It seems reasonable to speculate that the two treatments in combination will be significantly more effective than either of the treatments used in isolation for hyperkinetic children.

A no-treatment or placebo treatment is not included for comparison to the other three treatments because there is already extensive evidence that such groups fare more poorly than the treated groups. Thus in my judgement it would be unethical to leave hyperkinetic children untreated or to treat them with placebo.

An outline of the proposed study is provided in Table 22. Further details are provided in subsequent sections of the protocol.

TABLE 22: OUTLINE OF THE PROPOSED STUDY

TO COMPARE METHYLPHENIDATE AND BEHAVIOUR MODIFICATION, ALONE AND IN COMBINATION, IN THE TREATMENT OF HYPERKINETIC CHILDREN.

Primary hypothases to be tested: methylphenidate and behaviour modification combined are more effective than either regimen alone.

Secondary hypothesis to be tested: methylphenidate alone is more effective than behaviour modification alone in the treatment of hyperkinetic children.

A). 105 children selected for the study according to the following criteria:

1) Score on Conners Parent-Teacher Questionnaire $\geq$ 15 according to parents
2) " " " " " " " according to teacher
3) No psychosis, cerebral palsy, epilepsy, or brain tumor
4) IQ $\geq$ 80
5) Age 6-10 years
6) In school
7) Teachers consent given
8) Not currently on stimulant medication or in a behaviour modification program
9) Parental consent given

B). Pre-Treatment Assessments

1) Family function : acc. husband and wife
2) Conners Parent Questionnaire : 8 factors
3) Conners Teacher Questionnaire : 5 factors
4) WISC-R : full scale, verbal, performance IQ
5) WRAT : reading, spelling, arithmetic grade level
6) Continuous Performance Test of attention
7) Piers-Harris Children's self concept
8) Percentile height
9) Percentile Weight
10) Blood pressure : systolic, diastolic
11) Pulse rate

C). Assignment to Treatments by "Minimization"

- designed to make treatment groups comparable with respect to numerous variables.

TABLE 22 continued:

D). 8 weeks of one of the Following Treatments

1) Methylphenidate .7mg/kg/day maintenance dose
2) Behaviour Modification Program
3) Methylphenidate plus Behaviour Modification Program.

E). Post-Treatment Assessments

as per pre-treatment assessments plus measures of compliance with treatment.

F). Data Analysis

1) Analysis of variance to determine if the three treatment groups were comparable prior to treatment, and in their pre-post changes.
2) Assessment of the relationship between compliance with treatment and pre-post changes.
3) Testing of the hypotheses through appropriate univariate and multivariate analyses to determine which pairs of treatments differed significantly on individual measures of effectiveness and side-effects and on overall assessment of effectiveness and side-effects.

G). Dissemination of Study Results

3.2. THE SAMPLE OF HYPERKINETIC CHILDREN

3.2.1. Selection Criteria

The following are proposed as criteria for identifying children who are eligible for the study:

1. The child's score on the Conners Parent-Teacher Questionnaire (Table 3, p. 30) is equal to or greater than 15 when completed by the child's parent(s).
2. The child's score on the Conners Parent-Teacher Questionnaire is equal to or greater than 15 when completed by the child's major teacher.

Criteria 1 and 2 are the diagnostic selection criteria. (The other selection criteria pertain to sample homogeneity, ethics etc.) As discussed in section 2.5 on Diagnosis, 15 is reportedly two standard deviations above the normal mean on the Conners Parent-Teacher Questionnaire. High scores indicate a greater degree of hyperkinetic symptoms, and these symptoms are reportedly particularly responsive to stimulant medication. If age-specific norms become available for Conners Parent-Teacher Questionnaire then they should be used to identify age-specific scores for use in selection criteria 1 and 2.

3. The child is not judged to have psychosis, cerebral palsy, epilepsy, brain tumor, or disorders severe enough to contraindicate current administration of the proposed treatments (such as a comorbid condition which requires

hospitalization or introduction of another major drug regimen).

The presence of hyperkinesis and any of the above conditions would call for treatments other than those proposed here.

4. The child's Full Scale IQ is equal to or greater than 80 on the Weschler Intelligence Scale for Children - Revised (WISC-R).

It may in fact be appropriate to provide the same treatments to hyperkinetic children with IQ's less than 80. However, this criteria is included to enhance the sample homogeneity and to enhance the comparability of this sample to the numerous samples of hyperkinetic children currently being studied. (This is a popular selection criterion for studies of hyperkinetic children and children with minimal brain dysfunction.)

5. The child's age is between 6 years, 0 months and 10 years, 11 months.

While it may be useful to treat hyperkinesis before age 5, this criterion is designed to exclude many young children who are not in school, and for whom certain portions of the pre and post-treatment assessment battery are not appropriate. (The WISC-R is designed for children 6-16.) The upper age limit for children in the study is rather arbitrary and could be lowered or raised somewhat to suit the available sample.

6. The child is in school currently and is expected to remain with the same teacher over the remainder of the study.

This allows pre and post-treatment assessments to be made by the same teacher. The resultant pre-post difference will be a more accurate measure than one calculated from the reports of two different teachers.

7. The child's teacher agrees to complete a behaviour checklist describing the child's behaviour prior to and at the completion of treatment.

8. The child is not currently receiving any stimulant medication or a behaviour modification treatment judged to be similar to the one to be used in the study.

Obviously the change a child makes from pre to post-treatment cannot be assessed if the child is already receiving the treatment under study.

9. Informed consent is given by the parents for their own and their child's entry into the study.

The nature of the treatment and test procedures should be explained to the parents. Inclusion of a family which is unwilling to comply with the study procedures should be considered unethical. In addition, such a family would be unlikely to remain compliant with treatment and test procedures throughout the study.

3.2.2. Sample Collection

The actual procedure for collecting the sample of children who meet selection criteria 1 through 9 could take place in several ways. Let us indulge in the quixotism that all of the personnel required for such a study do exist, are guaranteed of funding, are eager to embark on this adventure, and have the bounteous good fortune of a blessing from the school system. They want only of a sample to be studied. Now, the potential sample could be identified in one of two major fashions -- through clinicians or through schools.

Note that 35 children are to be included in each treatment group for a total of 105 hyperkinetic children in the three treatment groups to be compared. (The rationale for this sample size is provided in the subsequent section.) Let us assume that about 2% of children would qualify for the study by virtue of their scores on Conners Parent-Teacher Questionnaire. (In a normal distribution 2.28% of the population is above two standard deviations from the mean.) Let us assume that only half of this group (a guess), or 1% of all children, would make their way into the study population. (Some would already be in treatment, the families of others would refuse to cooperate etc.) Thus one would need a population base of 10,500 children to generate the sample size of 105 hyperkinetic children eligible for the study.

With the first sampling technique of identifying eligible children through clinical practices, one would need

the cooperation of clinical practices serving a population of about 10,500 children. Thus one would need to conduct the study at a regional referral centre and obtain the agreement of numerous primary care clinicians to refer potentially eligible children to the study group, rather than treating such children themselves as they might normally do.

One would want cooperating clinicians to be familiar with Conners Parent-Teacher Questionnaire, and to refer to the study group all children who: they suspected would score 15 or higher on this questionnaire; were between 6 and 10 years old; and had no apparent psychosis, cerebral palsy, epilepsy, brain tumor, or IQ below 80. If clinicians failed to refer a substantial proportion of potentially eligible children because they wanted to ensure that certain children got a particular form of treatment (e.g. methylphenidate), then the resultant study sample might not be representative of all hyperkinetic children who would meet the study selection criteria. This would be a serious threat to the validity and generalizability of the study results.

The second technique of sampling in the schools would be somewhat less susceptible to the bias created by clinicians referring an atypical subset of hyperkinetic children to the study. In addition it would be somewhat easier to collect an adequate number of children by using this sampling technique. However this sampling technique involves more work since a fairly major screening procedure is required. Assuming again

that a population of 10,500 children would generate 105 children who would meet all of the study selection criteria, one would need to screen approximately 10,500 children. To identify an equal number of children at each age for inclusion in the study, one would need to screen approximately 2,100 children at each year of age between 6 and 10 years. One could screen the appropriate grades in sequence rather than en masse so that eligible children could be entered into the study soon after the time of their identification. The screening could be conducted in public and private schools, assuming the boards, principals, and teachers of both agreed to cooperate. It would be particularly important to include special education classes (for children with learning disabilities and/or behaviour problems) in the screening process because such classes may include a substantial proportion of children who are appropriate for the study.

The screening test would be Conners Parent-Teacher Questionnaire which asks for ratings of 10 behavioural items. Teachers would be asked to complete this questionnaire for every child in their class (taking one or two minutes per child). From the completed questionnaires, study personnel could determine the mean score and standard deviation by year of age. Children who scored higher than two standard deviations from the mean (2.28% of children if it is a normal distribution) could be considered potential subjects for the

study. (This is more appropriate than using 15 as the cut off score for all ages.) Study personnel would contact the parents of such children in order to make arrangements to find out if these children would meet the other criteria for eligibility to the study. For the child to be eligible for the study, one might want to require that the parent's rating of the child on Conners Parent-Teacher Questionnaire also be as high as the previously identified score of two standard deviations from the mean for the child's age. However this criterion could be relaxed by a few points to guard against the possibility of excluding appropriate children if parental ratings in general are slightly lower than teacher ratings. After contacting parents of potentially eligible children, study personnel should also contact identified family physicians of the appropriate children to find out if these clinicians are agreeable to their patients being treated according to the proposed regimens under the supervision of study personnel. It is possible that clinicians' refusals will make the resultant study sample an atypical sample of hyperkinetic children. However, it seems to me that this sampling technique, in which the clinician's consent is actively requested for individual children, is more likely to generate a representative sample than is the first technique in which study personnel simply wait for clinicians to refer children and the withholding of certain children need not be overt.

Thus the second technique of sampling in the schools seems more likely to generate a representative sample of children who would meet the study selection criteria, which would make the study results more valid. However, sampling in the schools also requires more effort and the cooperation of more people. The feasibility of the two major sampling techniques discussed here must be considered in the setting in which the study is to be implemented before deciding which technique to utilize. Both sampling techniques require the cooperation of an extensive array of clinicians, school personnel and parents. Achievement of this cooperation will require concerted effort by study personnel. Such cooperation can be greatly facilitated by principal investigators who are already well respected and influential in the setting in question.

3.2.3. Sample Size

The recommended sample size for the proposed study is 35 children in each group or 105 hyperkinetic children in total. The method of arriving at these figures is explained in this section.

Eleven separate tests have been selected for use in the pre-treatment and post-treatment assessments. From these assessments the pre-post change will be calculated for each child and an analysis of variance will be performed to see if the mean pre-post changes differ significantly among the three treatment groups. Whether or not one concludes that a statistically significant difference exists between two or more treatments on a particular test depends upon :

1) how large the differences are in the mean pre-post changes between treatment groups;
2) the amount of variability of all of the pre-post changes around the mean pre-post change as expressed by the pooled standard deviation;
3) the level one chooses for α , the probability that such a large difference between treatment groups might occur by chance alone;
4) the number of treatment groups;
5) the sample size in each treatment group.

If one wishes to make an estimate of the sample size required to conclude that a statistically significant difference exists between treatments, then one needs each of

the values described in 1) through 4) above. In addition one needs to decide what is an acceptable level for $(1-\beta)$ which is the power of the test, or the probability that the experiment will in fact be able to detect a significant difference between treatments when a true difference exists. One would like the power of the test to be as high as possible, that is as close to 1 as possible. However, increasing the power means increasing the sample size, so the power which one is willing to accept depends upon financial and practical constraints. The power of .80 was used for making the sample size estimates in this section. Naturally if one wishes to have a higher power to one's tests then sample size must be increased, while acceptance of a lower power means a decrease in sample size.

A conventional level was selected for $\alpha = .05$. The number of treatment groups is three, and the degrees of freedom for groups is $3-1 = 2$. An equal sample size is to be used in each group. Estimates of σ, the standard deviation of pre-post change scores for each testing instrument, were gathered from the literature. Estimates of $\bar{X}_1-\bar{X}_2$, the difference on each test in pre-post change which may be considered clinically important (and which one would therefore like to detect if it exists), were made from information I had about the testing instruments and discussions with a number of clinicians.

The subsequent estimates of sample size are based on: $\alpha = .05$; $1-\beta = .80$; (groups - 1) =2; and $f = \frac{(\bar{X}_1 - \bar{X}_2)}{\sigma}$ .408 (see Cohen 1969, pp. 269-271 for an explanation of .408 as a multiplier). With these values it is a simple matter to look up the required sample size in Cohen (1969, p.377). The values for: σ, and the source of these values, $\bar{X}_1 - \bar{X}_2$, f, and the estimates of sample size are summarized in Table 23 .

Note in Table 23 , that a sample size of 50 in each group is adequate for each of the items shown except factors I, III and VIII of Conners Parent Questionnaire which call for much larger sample sizes. One may decide not to worry about these three factors.

Note also that one could drop the sample size to 35 for each group and still retain a power of .8 or more for most of the items. The test most jeopardized by dropping sample size to 35 for each group would be the WRAT. With a sample size of 35, the power of the experiment to pick up the difference of .3 grade levels between treatment groups on the WRAT Reading, Spelling, and Arithmetic would be between .64 and .73. One may consider sacrificing some of the power of the experiment to pick up treatment differences on the WRAT, since it would likely be substantially less costly to gather and treat 35 in each treatment group rather than 50. The total sample size would thus be 105 instead of 150 which is a reduction of about 43% in sample size.

In summary, a sample size of 35 per treatment group is recommended for this study. However, if it happens that in the setting in question, the collection and treatment of 50 per group is just as feasible and only a little more costly than the collection and treatment of 35 per group, then a sample size of 50 per group would be advisable.

TABLE 23: ESTIMATES OF SAMPLE SIZE REQUIRED TO TEST METHYLPHENIDATE VERSUS BEHAVIOUR MODIFICATION VERSUS METHYLPHENIDATE PLUS BEHAVIOUR MODIFICATION FOR HYPERKINETIC CHILDREN.

TEST		σ	$\bar{X}_1 - \bar{X}_2$	$f = \frac{(\bar{X}_1 - \bar{X}_2).408}{\sigma}$	Sample Size per group
A. Family function		?			
B. Conners Parent Questionnaire total		?			
I	Conduct Problem	8.98	4	.18	106
II	Anxiety	4.30	4	.38	23
III	Impulsive-Hyperactive	9.35	4	.17	119
IV	Learning Problem	2.94	2	.28	42
V	Psychosomatic	2.04	3	.60	10
VI	Perfectionism	2.27	2	.36	26
VII	Antisocial	1.69	2	.48	15
VIII	Muscular Tension	5.91	2	.14	180
C. Conners Teacher Questionnaire total		?			
I	Conduct Problem	9.43	9	.39	22
II	Inattentive-Passive	2.88	3	.43	19
III	Tension-Anxiety	3.96	4	.41	20
IV	Hyperactivity	3.86	4	.42	20
V	Sociability	2.54	2	.32	32
D. WISC	Full Scale IQ	6.50	10	.63	9
	Verbal IQ	7.83	10	.52	13
	Performance IQ	9.33	10	.44	18
E. WRAT	Reading grade level	.47	.3	.26	49
	Spelling grade level	.45	.3	.27	46
	Arithmetic grade level	.42	.3	.29	39
F. Continuous Performance Test		?			
G. Piers-Harris Childrens Self-Concept		?			
H. Percentile Height		18.20	15	.34	29
I. Percentile Weight		11.25	15	.54	12
J. Blood Pressure - systolic		?			
diastolic		8.46	10	.48	15
K. Pulse Rate		13.63	10	.30	36

TABLE 23 continued.

Sample size per group is based on Cohen (1969, p.377).

Estimates of σ are calculated* from data provided in:

A. not available
B. Conners, Taylor, Kurtz and Fournier (1972, p.331)
C. Conners (1969, p.887)
D. Conners, Taylor, Kurtz, and Fournier (1972, p.333)
E. " " " " " " "
F. not available
G. " "
H. Safer and Allen (1973, p.661)
I. " " " " "
J. Knights and Hinton (1969, p.649)
K. " " " " "

* $\sigma \approx \dfrac{\bar{X}_1 - \bar{X}_2}{t\sqrt{\frac{1}{n_1} + \frac{1}{n_2}}}$ where data from t-tests were provided (See Dixon & Massey, 1969, p.116)

$\sigma \approx \dfrac{s_m^2}{f}$ where data from analyses of variance were provided (See Dixon & Massey, 1969 pp.156-161)

3.3 PRE-TREATMENT ASSESSMENTS

When children meet all of the previously outlined selection criteria, they may be accepted for the study. At this point, pre-treatment assessment of each child should be made. The measures in Table 24 are recommended for use in the pre-treatment assessment and for later use in the post-treatment assessment of each child.

The tests in Table 24 were selected because each measures an important dimension on which the three treatments under study may have significantly different impact. Most of the measures have been used previously in studies of hyperkinetic children (B-F, H-K); the others (A, G,) are considered useful additions to such a battery. Each of the tests is an assessment of some dimension of the child's function except test A which is a measure of general family function. Note that tests A-G are measures on which the treatments are expected to have beneficial impact (measures of treatment effectiveness), and that in general the combined treatment of methylphenidate and behaviour modification is expected to be more effective than either of the individual treatments. Tests H-K are measures of treatment side-effects, and the two treatments which include methylphenidate may show greater physical side-effects than the behaviour modification treatment.

To complete their respective sections of the assessment battery will require a few minutes by parents and teachers and two sessions by the child and psychometrist. The first session between child and psychometrist could include tests

TABLE 24 : PRE-POST TREATMENT ASSESSMENT BATTERY IN THE STUDY OF HYPERKINESIS

TEST	Estimated Time to Complete	Completed by
A.1) Family function - average	3 min	parents
2) acc. wife		
3) acc. husband		
B.4) Conners Parent Questionnaire Total	30 min	parents
5) I Conduct Problem		
6) II Anxiety		
7) III Impulsive-Hyperactive		
8) IV Learning Problem		
9) V Psychosomatic		
10) VI Perfectionism		
11) VII Antisocial		
12) VIII Muscular Tension		
13) Severity of Problem		
14) Mean score for items of most concern		
C.15) Conners Teacher Questionnaire Total	15 min	teacher
16) I Conduct Problem		
17) II Inattentive-Passive		
18) III Tension-Anxiety		
19) IV Hyperactivity		
20) V Sociability		
21) Severity of Problem		
22) Academic Achievement Change (post-test only)		
23) Overall Behaviour Change (post-test only)		
24) Group Participation Change (post-test only)		
25) Attitude Toward Authority Change (post-test only)		
D. Weschler Intelligence Scale for Children - Revised	60-90 min	child & psychometrist
26) Full Scale IQ		
27) Verbal IQ		
28) Performance IQ		
E. Wide Range Achievement Test	20-30 min	"
29) Reading grade level		
30) Spelling grade level		
31) Arithmetic grade level		
F. Continuous Performance Test	30 min	"
32) Visual attention-absolute score		
33) Auditory attention-absolute score		

TABLE 24 continued

TEST	Estimated Time to Complete	Completed by
G.34) Piers-Harris Children's Self-Concept	15-20 min	Child & Psycho-metrist
H.35) Percentile Height	3 min	"
I.36) Percentile Weight	3 min	"
J.37) Blood Pressure - systolic	3 min	"
38) Diastolic		
K.39) Pulse Rate	3 min	"

D and H-K, and the second session could include tests E-G. Thus each session would last about 1½ hours. It is suggested that items H-K on height, weight, blood pressure and pulse be administered by a single psychometrist trained in these procedures rather than by a variety of participating clinicians who would likely exhibit more variability in their measurement techniques than a single assessor.

Tests B and C appear as appendices to this thesis. Tests D-I are available through the sources listed with the respective test in the references section. Test A is presented below along with a few words about each of the test instruments.

A) Family Function

This item was designed to get a single, simple measure of family function. Parents can be asked to independently answer the following question;

> "In general how would you say your family members get along with each other -- very well: or very poorly? Make a mark which crosses through the line below indicating how close to very well or very poorly you would rate the way your family members (you, spouse, and children) get along with each other.
>
> Very poorly ———————————————— Very well"

The line is 100 millimeters long. By measuring the distance of the mark from the 0 point, one can get a measure of family function ranging from 0 to 100. This rating scale has not been pretested.

Alternatively one could use a better tested measure of family function such as the Rundquist and Sletto Family Scale or others described by Straus (1969).

B) Conners Parent Questionnaire

This is a checklist to be completed by parents as a description of their child's behaviour. It includes 93 behavioural items, such as "restless" on which a child is rated: not at all, just a little, pretty much, or very much. In addition to rating their child on each item, parents are asked to circle the items they are most concerned about in their child. There are eight factor scores which can be derived from this questionnaire. The factors are termed: Conduct Problem, Anxiety, Compulsive-Hyperactive, Learning Problem, Psychosomatic, Perfectionism, Antisocial, and Muscular Tension.

Hyperkinetic children have significantly higher (poorer) scores on parts of this behaviour rating questionnaire when compared to neurotic or normal children (Conners 1970). It is expected that each of the three treatments described in this protocol will have some impact on the measures derived from this questionnaire.

An individual parent can fill out this questionnaire, or spouses can fill it out together. It is important that the raters (individual or joint) be the same at pre and post-treatment testing.

C) Conners Teacher Questionnaire

This is a 39 item checklist to be completed by a teacher as a description of a child's behaviour. In addition to the 39 items it includes one item on the overall severity of the child's problem, and four items to be rated at the end of treatment in the change in academic achievement, overall behaviour, group participation and attitude toward authority. Five factor scores are based on the 39 items. The factors are Conduct Problem, Inattentive-Passive, Tension-Anxiety, Hyperactivity and Sociability.

Hyperkinetic children have significantly different scores than normal children on each of the five factors derived from this questionnaire according to Conners'(1973) report of Sprague et al. (in press). Hyperkinetic children show significantly more improvement on total scores and certain factor scores on this questionnaire when randomly assigned to methylphenidate as opposed to placebo (Conners, 1972; Garfinkel, 1974). This questionnaire has not been used in studies of behaviour modification treatment of hyperkinetic children; however, other behavioural measures among hyperkinetic children have shown significant improvement with behaviour modification treatments (Madsen et al. 1968; McKenzie et al. 1968; Patterson et al. 1964; Wadsworth 1971; Quay et al. 1967).

Conners Teacher Questionnaire will be an important test in the proposed study because it will be a rating of a major portion of the child's behaviour by an observer who will

not be informed of which type of treatment the child receives.

D) Weschler Intelligence Scale for Children - Revised (WISC-R)

The WISC is probably the most widely used measure of intelligence. It has recently been revised and restandardized for children 6 - 16 years. It includes 12 possible sub-tests -- 5 of which need to be given to compute the Verbal IQ, another 5 of which need to be given to compute the Performance IQ. The Full Scale IQ is computed from these 10 sub-tests. Raw scores have been standardized to a mean of 100 and a standard deviation of 15 at each age level.

Hyperkinetic children have shown significantly more improvement on the WISC Full Scale IQ, Verbal IQ, Performance IQ, and several of the sub-tests when randomly assigned to methylphenidate as opposed to placebo (Conners, 1972; Knights & Hinton, 1969, Weiss et al. 1971). This suggests that a child's functional intelligence, or at least his test performance is improved by methylphenidate, It is not known if behaviour modification treatment can improve measures of intelligence among hyperkinetic children.

Children should be given the WISC-R in their first formal pre-treatment assessment session so that those with Full Scale, Verbal or Performance IQ's below 80 can be excluded from the study though still offered treatment.

E) Wide Range Achievement Test

This test provides measures of the reading, arithmetic, and spelling grade levels of a child.

The WRAT evidently did not reveal significant differences between 6 weeks of methylphenidate or placebo treatment in one study (Conners, 1972). However in another study of 8 weeks of dextroamphetamine, cylert and placebo treatment, dextroamphetamine compared to placebo treatment groups showed differences in their amounts of improvement on the WRAT which were statistically significant for the spelling test and approached statistical significance for the reading test (Conners et al. 1972). Thus it seems reasonable to speculate that over a sufficient period of time and with a sufficient sample size, methylphenidate would likewise show a significantly greater impact than placebo on WRAT grade levels.

The WRAT has not been used in studies of behaviour modification treatment for hyperkinetic children, however, rates of improvement in the Slosson Oral Reading Test have significantly improved with behaviour modification treatment (Wadsworth, 1971). Thus behaviour modification treatment may also show an impact on the WRAT.

F) Continuous Performance Test

This test is presumed to be a measure of attention. It can be given in visual and/or auditory form. In either form, letters are presented rapidly, and the child is

instructed to note the presentation of a particular letter or sequence of letters.

Hyperkinetic children show deficits on this test when compared to normal children (Sykes et al. 1972) and show significantly more improvement on this test with methylphenidate treatment than with placebo treatment (Conners, 1972; Sykes et al. 1971; Sykes et al. 1972; Weiss et al. 1971).

There is some speculation that improvements of attention with methylphenidate underlie many of the other cognitive and behavioural improvements observed. While this test has not been used in studies of behaviour modification treatments for hyperkinetic children, other measures of attention have improved significantly with behavioural modification treatments (McKenzie et al. 1968; Quay et al. 1967).

G) Piers-Harris Children's Self Concept

This test contains 80 statements such as "I am a happy person" to which a child responds yes or no. Test items may be read by a child who is at or above the grade 3 level; the test items may be read to a child below that level. This test has not previously been used in studies of hyperkinetic children and, as of this writing, I have not seen a copy of this test. However, judging from its description in the Seventh Mental Measurements Yearbook (Buros, 1972, p.306) it would appear that it may be a useful

addition to the battery of tests used in the study of hyperkinetic children. Some people are concerned that either methylphenidate or behaviour modification treatments may adversely affect a child's sense of self-control and thus his self-concept. It seems to me that the treatments in this protocol are more likely to be accompanied by improvements in self-concept as behaviour and intellectual function improve.

H) Percentile Height

This value indicates what percentage of children of the same age and sex are shorter (or taller) than the child in question. Measurements should be taken with the child standing in stocking feet.

In one study, 10 hyperkinetic children on 20mg or more of methylphenidate per day over the course of about three years showed a mean reduction of 10 percentile points in height, while 14 hyperkinetic children whose parents refused the drug showed a mean gain of 6.8 percentile points in height -- a statistically significant difference between groups (Safer and Allen, 1973). It is expected that behaviour modification treatment will have no effect on percentile height; and that .7mg/kg/day of methylphenidate will have very little effect on percentile height.

I) Percentile Weight

This value indicates what percentage of children of the same age and sex weigh less (or more) than the child

in question. Measurements should be made with the child in light undergarments.

In one study, 10 hyperkinetic children on 20mg or more of methylphenidate per day over the course of about three years showed a mean reduction of 9.4 percentile points in weight, while 14 hyperkinetic children whose parents refused the drug showed a mean gain of 1.29 percentile points in weight. The difference between groups is statistically significant (Safer and Allen, 1973). It is expected that behaviour modification treatment will have no effect on percentile weight, and that 7mg/kg/day of methylphenidate will have very little effect on percentile weight.

J) Blood Pressure

The measure of systolic (first phase) and diastolic (fifth phase) blood pressure in the arterial system should be made with a pediatric-sized cuff while the child is seated. The same arm should be used at pre and post-testing for an individual child.

Knights and Hinton (1969) in comparing methylphenidate and placebo treatment groups found a difference in pre-post diastolic blood pressures of 4.6mm which approached statistical significance. It is expected that behaviour modification treatment will have no effect on blood pressure, and that .7mg/kg/day of methylphenidate will have very little effect on blood pressure.

K) Pulse

This measure of heart rate is conventionally taken at the wrist prior to the measurement of blood pressure.

Knights and Hinton (1969) found that children treated with 40mg/day of methylphenidate showed an increase in mean heart rate from 78 to 94 beats per minute which was significantly different than the mean pre-post measure observed with placebo treatment. It is expected that behaviour modification treatment will have no effect on pulse, while .7mg/kg/day of methylphenidate may result in some increase in pulse rate.

3.4 ASSIGNMENT TO TREATMENTS

Randomization to treatment is commonly used in well designed clinical trials in order to try to make the various treatment groups comparable with respect to patient characteristics. If it is known that certain patient characteristics have a particularly important influence on treatment outcome, then one may choose to enhance the comparability of the treatment groups with respect to these characteristics by stratified randomization. For example, if it is anticipated that intelligence will have an important influence on treatment outcome, then one may create intelligence-strata (such as IQ below 100, and IQ above 100) and within these strata randomize pairs of patients to alternative treatments. With stratified randomization one is then assured that equal numbers of patients with IQ above 100 and with IQ below 100 will be in each treatment group. However, if there are several characteristics which may have an important influence on outcome, and if one attempts to stratify for each of these, then an unwieldly number of substrata are generated. Given four characteristics, each with two strata, one would generate 16 substrata within which patients should be randomized to treatments. There may be insufficient numbers of patients falling into each stratum to allow each of the treatment groups to receive equal

numbers of patients from each stratum. The procedure becomes increasingly awkward with increasing numbers of strata so many investigators rely on straight randomization to make treatment groups comparable.

A new procedure called minimization has been proposed as an alternative method of assigning patients to various treatment groups (Taves, 1974). Using minimization, an experimenter may readily take into consideration as many variables as he/she wishes to make comparable in the various treatment groups. In addition, the variables can be given different weights based on their presumed importance in influencing treatment outcome. In a variety of computer simulations, minimization was shown to be superior to simple randomization in creating comparable treatment groups. Its effectiveness in generating comparable treatment groups was not compared by computer simulations to stratified randomization, however intuitively it seems at least as good as stratified randomization, and it is more feasible than stratified randomization when there are many variables for which treatment groups should be made comparable.

Basically minimization works by taking each patient who becomes eligible for treatment and assigning that patient <u>on paper</u> to each of the treatment groups in turn. Whichever assignment creates the least amount of dissimilarity between the various groups of patients is the assignment to be made. Take an example, where one is

concerned only about making the groups comparable with respect to sex. Group A currently has 2 boys and 1 girl, while group B has 4 boys. The next patient to be assigned happens to be a girl. She will be assigned to group B because that creates the least amount of dissimilarity between the two groups with respect to sex. When there are several variables being considered in the minimization process, it would be unlikely for anyone to guess with greater than chance accuracy what the assignment would be unless one knew exactly what the variables and their substrata were and did the appropriate calculations. (i.e. Clinicians could not readily engineer the assignment of a particular patient to a particular treatment.) The calculations are conceptually quite simple (see Taves, 1974) but in fact quite cumbersome to do by hand if there are several variables and several treatment groups under consideration. One could write a computer program for the calculations required and thus make the assignment to treatment a quite convenient procedure. If one lacks computer facilities, one could consider using the minimization procedure with a small number of variables and doing the calculations by hand. In this study, the few variables to be included in a hand calculation could be the child's age (1 year strata), IQ (15 point strata), and sum of scores on Conners Parent-Teacher Questionnaire as filled out by parents and teachers (10 point strata). If one has computer facilities then the variables

and strata in Table 25 could be employed in the minimization procedure.

The variables are the pre-treatment test scores plus age and sex. These variables have each been divided into four strata, except where there were indications for doing otherwise (e.g. sex has two strata -- male and female, age has five strata -- one for each year of age between 6 and 10). Each of these variables may have some influence on the potential for change with treatment, and therefore it is reasonable to attempt to make the groups of children assigned to the three treatments comparable with respect to these variables. A weighting of one is suggested for each variable since we do not know whether any are more important than others in influencing the potential for change with treatment.

If two or more children are available for assignment to treatment at the same time, the best combination of assignments can be chosen. Taves (1974, p.452) reports that a computer program for the minimization procedure, with the ability to identify the best combination of assignments, is available from the American Documentation Institute, Auxiliary Publication Service, Library of Congress.

TABLE 25: VARIABLES AND STRATA FOR USE IN THE MINIMIZATION PROCEDURE OF ASSIGNING CHILDREN TO TREATMENTS

VARIABLE	STRATA			
1. Family Function - average	0-25	26-50	51-75	76-100
2. " " acc. wife	"	"	"	"
3. " " acc. husband	"	"	"	"
4. Conners Parent Questionnaire total	0-99	100-149	150-199	200-279
5. Conduct Problem factor	0-5	6-10	11-15	16-21
6. Anxiety factor	"	"	"	"
7. Impulsive Hyperactive factor	0-6	7-12	13-18	19-24
8. Learning Problem factor	0-3	4-6	7-9	10-12
9. Psychosomatic factor	0-3	4-7	8-11	12-15
10. Perfectionism factor	0-2	3-4	5-6	7-9
11. Antisocial factor	0-3	4-6	7-9	10-12
12. Muscular Tension factor	"	"	"	"
13. Severity of Problem	0	1	2	3
14. Mean Score for items of most concern	0-1.5	1.5^{+}-2	2^{+}-2.5	2.5^{+}-3
15. Conners Teacher Questionnaire total	0-30	31-60	61-90	91-117
16. Conduct Problem factor	0-9	10-19	20-29	30-39
17. Inattentive-Passive factor	0-4	5-8	9-13	14-18
18. Tension Anxiety "	"	"	"	"
19. Hyperactivity "	"	"	"	"
20. Sociability "	"	"	"	"
21. Severity of Problem	0	1	2	3
22. Full Scale IQ	80-95	96-105	136-120	121 & up
23. Verbal IQ	"	"	"	"
24. Performance IQ	"	"	"	"
25. WRAT Reading	1-1.9;	2-2.9;	3-3.9;	4-4.9; 5-5.9 6- up
26. " Spelling	"	"	"	" "
27. " Arithmetic	"	"	"	" "
28. CPT Visual Attention	0-25	26-50	51-75	76-100
29. CPT Auditory Attention	"	"	"	"
30. Piers-Harris Children's Self concept	?	?	?	?
31. Percentile Height	1-25	26-50	51-75	76-100
32. Percentile Weight	"	"	"	"
33. Systolic BP	below 110	110-114	115-120	121 & up
34. Diastolic BP	below 62	62-68	69-75	76 & up
35. Pulse	below 80	80-84	85-90	91 & up
36. Age	6; 7;	8;	9; 10	
37. Sex	Female		Male	

3.5 TREATMENTS FOR HYPERKINESIS

There are three treatment groups in the proposed study. One receives methylphenidate, another receives a behaviour modification program, and the third receives the two treatments in combination. Eight weeks is the suggested length of treatment for the study. This time period is suggested for three major reasons. First, it is close to the minimum time one would need to pick up significant treatment effects on some of the outcome measures (WRAT, percentile weight, percentile height). Second, it is close to the maximum time that some clinicians would be willing to withhold stimulant drug treatment -- the best tested treatment for hyperkinesis. Third, treatment packages of eight weeks allow serial intake of sufficient numbers of children to complete the trial in one year as shown in Table 29 (p.214).

Administration of the two treatments in combination should be identical to their administration in the individual treatment programs. Therefore only the administration of the individual treatment programs need be described.

3.5.1. Methylphenidate Treatment

Methylphenidate, or Ritalin as it is known by its trade name, should be prescribed and monitored by participating clinicians. The starting dose suggested here for all children is 5.0mg/day. The daily dose can be increased by 5.0mg each day to a suggested maintenance dose of approximately .7mg/kg/day for each child. The drug administration schedule shown in Table 26 would achieve the closest available approximation to .7mg/kg/day using 2.5mg B.I.D. increments. (CIBA manufactures Ritalin in 10 and 20mg tablets which are scored in the middle for division into two parts. These tablets can also be fairly readily cut into quarters of 2.5mg each.)

The initial dose and incremental dose of 5mg/day are suggested here because with this schedule any child under 53kg can be brought to the presumably therapeutic dose of .7mg/kg/day within less than a week. I am guessing (since there is no information on this point) that gradually increasing the dose to .7mg/kg/day during the first week will cause somewhat fewer problems with side-effects than starting directly at .7mg/kg/day.

TABLE 26: METHYLPHENIDATE DOSAGE BASED ON BODY WEIGHT

DAY	MORNING DOSE	MID-DAY DOSE	TOTAL DAILY DOSE	MAINTENANCE DOSE ≈ .7mg/kg/day
1	2.5mg	2.5mg	5.0mg	
2	5.0	5.0	10.0	←10.72-17.85 kg
3	7.5	7.5	15.0	←17.86-25.00
4	10.0	10.0	20.0	←25.01-32.14
5	12.5	12.5	25.0	←32.15-39.28
6	15.0	15.0	30.0	←39.29-46.42
7	17.5	17.5	35.0	←46.43-53.57

* After gradually increasing daily dosage as indicated for day 1, 2, and so on, the maintenance dose can be used to achieve the closest approximation to .7mg/kg/day available when using 2.5mg B.I.D. increments.

The dose of approximately .7mg/kg/day is suggested as the maintenance dose in this study for two major reasons -- effectiveness and lack of side-effects. Sleator and von Neuman (1974) report significantly greater therapeutic benefits as measured by "blind" teacher ratings with the doses of .7mg/kg/day than with .3mg/kg/day or .1mg/kg/day or placebo. Unfortunately it is not clear in their publication if the order of the doses was randomized or if they were increased gradually from low to high. If the latter is true, the increase in improvement seen on the high doses might be attributable to gradual development of improved school behaviour set off by the first low doses of methylphenidate. At any rate with the minimal information available on the dose-effectiveness relationship it appears that .7mg/kg/day is a reasonable dose for achieving therapeutic effectiveness.

Additional information suggests that .7mg/kg/day may also be a fairly safe dose in avoiding side-effects on percentile weight, percentile height, heart rate, and pulse. In Safer and Allen's (1973) study, doses of methylphenidate up to 20mg/day were not associated with any significant reduction in percentile weight or percentile height while higher doses were associated with such reductions. The children started on methylphenidate at a mean age of 7.4 years and a mean percentile weight of 49 which is equivalent to about 23kg. It seems reasonable to posit that if up to 20mg/day of methylphenidate had no significant effect on percentile weight and height for children who started at a mean weight of 23kg, that a somewhat higher total daily dose would also be safe for children with greater body mass. Using the schedule in Table 26, only children above 32.14kg would receive more than 20mg/day. Given the information currently available, I would guess that this dosage schedule would have very little effect on percentile weight and height.

Knights and Hinton's (1969) study monitored the effect of 40mg/day of methylphenidate versus placebo on heart rate and diastolic blood pressure (among other variables). The difference in pre-post scores for the two treatment groups was significant ($p \leq .01$) for heart rate with the methylphenidate group showing a mean increase in heart rate of 15.6 beats/minute, and approached statistical significance

for diastolic blood pressure ($p \leq .10$) with the methylphenidate group showing a mean increase of 1.9mm. Using the dosage schedule in Table 26, it would be unlikely for children to receive a dose as high as 40mg/day. It is not known if lower doses will eliminate possible side-effects on heart rate and pulse but it is likely that lower doses will reduce side-effects.

For the drug treatment program, study personnel should prepare dated envelopes containing the appropriate medication for the child according to the schedule in Table 26. Two envelopes should be prepared for each day -- one for a morning dose, and one for a mid-day dose. (A divided dosage is quite commonly used for stimulant medication.)

For the purposes of the study, school personnel should not be involved in administering medication (as is commonly done for hyperkinetic children) so that teachers may remain blind to the children's treatment regimen and thus independent observers of the children's behaviour.

Parents can be given a one months supply of medication for their child with instructions on its administration. Medication should be used only on the date and time (morning, mid-day) marked on the package. When a dose is missed it should be left in the package. The morning package of medication should be given at breakfast time. The mid-day dose should be given as close as possible to the mid-point in the child's day (e.g. at lunch if the child comes

home for lunch, or after school). Parents should be informed that children on methylphenidate may show some temporary insomnia and decrease in appetite (Conners, 1972; Conners 1971b; Winsberg et al. 1974). Parents should be instructed to phone the study clinician if these or other side-effects become a problem. In such cases reduction in medication can be considered by parents and clinician, and when it seems warranted medication can be adjusted until side-effects are no longer problematic. If for example medication packets containing a maintenance dose of 15mg B.I.D. have been given to the parents and side-effects are problematic, then parents could be instructed to give 15mg in the morning and 10mg at mid-day, leaving the other 5mg tablet in the medication package. Study personnel should carefully record date , reasons, and amount of each medication reduction.

It is possible that for some children, less than .7mg/kg/day would be as effective as .7mg/kg/day. One could attempt to find out by keeping medication at .7mg/kg/day for a few weeks while getting blind teacher ratings on the child, and then reducing medication and getting additional blind teacher ratings for a few weeks. This sort of experimentation and adjustment is not proposed for inclusion in the present study though it could be attempted with some children upon termination of the study.

Parents should be asked to return all medication envelopes and remaining medication when they come for a

visit plus additional medication at 4 week intervals. From the remaining medication tablets and knowledge of any prescribed reductions resulting from side-effects, study personnel can make an estimate of compliance with drug treatment (e.g. 70% of prescribed milligrams were taken).

3.5.2. Behaviour Modification Program

The behaviour modification program is more difficult to define precisely and will be more complex to administer than the methylphenidate treatment. Because there are so many possible variations to a behaviour modification program, it is difficult to establish what the ideal mode of administration is. Recall that 13 of 14 studies in section 2.6.3. report that behaviour modification procedures are more effective than other procedures in improving hyperkinetic children's behaviours; however, the behaviour modification programs were applied in numerous ways including: working directly with the child, teaching parents how to improve their child's behaviour, and aiding teachers to improve a child's behaviour. It is not really clear which of these techniques and which of the many possible variations within these techniques is the most effective. Therefore, the program suggested in this section is a pot-pourri of techniques which have been used in a variety of other behaviour modification programs and which in combination seem to make sense for this study. Many of the programs from which I have borrowed are described by Berkowitz and Graziano (1972).

The primary objective of the behaviour modification program would be to assist parents to interact with their children in a fashion which optimizes desired behaviours and minimizes undesired behaviours.

Work with children alone is not suggested here because improvements in behaviour in the experimental setting may not generalize to the home setting if parents are not applying similar methods for increasing desired behaviours and decreasing undesired behaviours. Work with teachers may be very helpful in improving children's behaviour, however it is not suggested for this study because teachers are the only persons who can observe and rate a substantial portion of the children's behaviour while remaining blind (unbiased) to the nature of the treatment conditions under evaluation. The individual who offers the behaviour modification sessions should be experienced and successful in the use of conditioning to modify children's behaviours, and should also be experienced and successful in teaching parents how to use conditioning. The formal qualifications of such a person might be psychologist, nurse, child care worker, teacher etc.

The eight weekly sessions in the behaviour modification program could be conducted as follows:

1) Instructor meets with each set of parents for ~1 hour (which is ~14 hours of sessions per week for the instructor if cohorts of 21 children enter the study at the same time.)
2) As per 1).
3) Instructor meets with each set of parents and child for ~1½ hours (≈ 21 hours weekly/instructor)

4) As per 3.

5-8) Instructor meets with 4 groups of 3-4 couples each for ≈1½ hours per group (≈6 hours weekly/instructor).

Note that the last four sessions are designed in part to require fewer hours per week from the instructor. If screening in schools is used, then a new cohort will enter treatment when the previous cohort is half way through treatment. Thus one cohort will be receiving a total of 14 to 21 hours of individual sessions per week from the instructor while another cohort receives 6 hours of group sessions per week from the instructor for a total of 20-27 hours per week of sessions. There should not need to be much preparation for these sessions on the part of the instructor. That is the instructor should already be well versed in the principles and the art of assisting parents to modify their own parental behaviours and in turn the behaviours of their children. The sessions should be at a time which is convenient for parents, which will mean that the instructor should be willing to work a reasonable mix of mornings, afternoons and evenings. If possible both parents should attend each session but this is not a prerequisite to acceptance or continuation of the parents in the program.

The content of the behaviour modification sessions could be as follows:

Session 1). The instructor and parents should jointly set specific goals of behavioural change for the child, and

jointly plan procedures to be used in reaching these goals. Goals may be defined in terms of behaviours to be decreased and behaviours to be increased in the child during the program. The Conners Parent Questionnaire can be used to facilitate selection of a short list of behaviours to be decreased because it asks parents to rate their child on 93 items of behaviour and to circle those behaviours which are the most troublesome. The circled items with any modifications, additions or deletions which parents and instructor agree to could be the behaviours to be decreased.

Parents and instructor can decide upon a behaviour to displace each of the behaviours to be decreased. For example if running around during meals is to be decreased, then the behaviour to displace it is sitting calmly at the table. If avoidance of chores is the behaviour to be decreased, then completion of chores is the behaviour to be increased.

A single set of behaviours including one behaviour to be decreased and another to be increased in its place can be chosen for the first attentions of instructor and parents. Using this set of behaviours as an example, the instructor can discuss with the parents the behaviour modification procedures which could be used by the parents to increase the desired behaviour and to decrease the undesired behaviour.

These procedures are based on the following principles. A) Reinforcers which follow a behaviour tend to strengthen or encourage the recurrence of that behaviour. Reinforcers

may be social such as smiling, attention, interest, praise and affectionate contact, or non-social such as a special dessert, money, particular toys, television privileges or a late bedtime. Most of these act as reinforcers to most children. However, some things may be reinforcers to some children and not to others or to a particular child at one time and not at another time. Observation and trial and error will help disclose those things which act as reinforcers for an individual child (or adult) and therefore, increase or strengthen particular behaviours in that individual.

Initially reinforcers should be applied immediately following each behaviour which is an approximation of the desired behaviour. Subsequently reinforcers should be applied only following behaviours which are a small step closer to the actual desired behaviour. This is called shaping a behaviour. Once the desired behaviour has been established, occasional reinforcement will maintain it. However, there is some evidence that hyperkinetic children require more reinforcement than normal children to maintain comparable levels of performance (Freibergs & Douglas, 1969).

B) When certain consequences follow a given behaviour, that behaviour tends to decrease in strenth or frequency. Such consequences include: lack of attention interest, praise, or other reinforcers; five or ten minute time-out periods when the child is to be without playmates or toys; and temporary loss of some portion of allowance or privileges.

If severe punishment is used to decrease undesired behaviours, the long term consequence is likely to be efforts by the person punished to totally avoid the source of the punishment.

At the end of the first session parents can be given a self-instruction manual on behaviour modification principles and methods. I have seen two such manuals -- one by Becker (1971) and one by Patterson and Guillion (1971). For the proposed study, I would recommend the latter entitled Living with Children: New Methods for Parents and Teachers. It is clearly and pleasantly written in a programmed learning fashion (as is the former), and it can be completed more rapidly than the former. It contains about 50 pages on behaviour modification in general, and another 40 pages with six sub-sections pertaining to specific types of children -- one of which is the overly active, noisy child. Many parents could complete this manual within the week before the next session. Other parents may take longer to complete it.

Session 2) Instructor and parents can meet for the parents to describe their progress and problems in efforts to modify their child's behaviour, and for the instructor to offer encouragement and suggestions.

The efforts of the parents after this session can be directed to:

A. charting the frequency of a particular behaviour they would like to see changed in their child (Patterson and Guillion include graph paper laid out for this purpose);

B) applying appropriate reinforcing and/or non-reinforcing consequences and

C) charting the change in the selected behaviour over time.

Session 3) The instructor, parents, and child can meet to discuss the behaviour modification efforts taking place in the home. In a fashion which is suited to the child's age and intelligence, the instructor can explain that not only do parents influence the behaviour of children but children influence the behaviour of parents. A child, like a parent, can offer reinforcers for the behaviour of others in a fashion which increases the probability of desired behaviours from others and decreases the probability of undesired behaviours from others.

The child can then be asked what behaviour of his or her parents is most bothersome to the child. Let us say that it is nagging about room clean up. The behaviour which is desired by the child from the parent in this case is friendly reminders or no reminders about room clean up. When the desired behaviour occurs (e.g.a morning with no reminder) the child can offer what would probably be the most potent reinforcer to the parent for the desired no-nagging behaviour and that is a room clean up by the child. The parent in turn can strengthen the desired room clean up behaviour in the child with a compliment. Other examples can be discussed with parents and child. There will likely be instances where the instructor will regard the expectations of either parents or child regarding the other's behaviour as inappropriate. In

such instances, the goal of the instructor will be to modify expectations not behaviours.

Session 4) Instructor, parents and child can meet again. Components of this session might be:

A) The instructor and the child interact in a game or a task while the parents observe. The instructor can thus model adult reinforcing and non-reinforcing behaviours following certain behaviours of the child.

B) The parents and child interact in a game or task while the instructor observes. Parents can thus practice use of reinforcing and non-reinforcing behaviours. In ensuing discussion, the instructor can highlight particular features of the interactions.

Certain facilities and equipment can augment these procedures. For example this session may be conducted in two rooms with a one-way glass between. A videotape of the session may be made for replay in the ensuing discussion. A sound or light signal system can be used to indicate to parents when to offer reinforcers for the child's behaviour.

Sessions 5-8) Instructor and groups of three to five couples can meet. These groupings should contain parents who are within the same treatment regimen (e.g. behaviour modification only, or behaviour modification and methylphenidate).

In these sessions the instructor can encourage the

couples to share the information which they individually have which might prove useful to the rest of the group in their current efforts at behaviour modification in their children. and in themselves.

Supplementary films and or readings might be utilized within and between these sessions. A good source of information for the instructor about possible supplementary readings of value to parents and/or the instructor is Behaviour Modification in Child and School Mental Health : an annotated bibliography on applications with parents and teachers by Brown (1972)

Measures of compliance with treatment in the behaviour modification program are difficult to make since there will be no observers in the home to see how often the parents actually implement the behaviour modification procedures. A readily available, though by no means ideal measure of compliance with this treatment regimen, is the proportion of the available behaviour modification sessions which are actually attended by the parents. If it is a two parent family then the total of possible attendances is 2 parents x 8 sessions = 16 attendances. In a one parent family the total possible attendances is 8. Compliance can be expressed as the ratio of actual to possible attendances.

3.6. POST-TREATMENT ASSESSMENTS AND DATA ANALYSIS

The post-treatment assessment battery should be identical in content and administration to the pre-treatment battery. That is the same parent or parents, the same teacher and the same psychometrist should be involved in the evaluation of each child. Identical testing instruments should be used. Every effort should be made to withhold from the psychometrist information regarding which treatment a child is receiving.

For the subsequent data analysis computer facilities are virtually essential. Hand calculations would take an inordinate amount of time to complete.

For each child in the study the following information will be available: identification number, age, sex, pre-treatment values for each of the variables listed in Table 24 (pp. 169), post-treatment values for each of the variables listed in Table 24 (pp. 169), and compliance with treatment. From these values a pre-post change can be computed for each subject on each variable. Four of the variables (21-25) will not have individual pre-test and post-test values, but will have a value for pre-post change. These values should be treated like the pre-post values for other variables.

The first step in the data analysis should be to determine how comparable the three treatment groups were prior to treatment on numerous characteristics which might affect treatment outcome. The characteristics which should be looked at in this analysis are age, sex, and each of the pre-treatment assessment variables. The minimization procedure of assigning children to treatments should do a good job of making the treatment groups comparable on all of these variables, however it is worth checking to see if the minimization procedure was successful in this task. In order to determine if the three treatment groups are comparable with respect to all of these variables considered together, one may perform a multivariate analysis of variance. A computer program for this analysis is available in BMD: Biomedical Computer Programs, X - series Supplement edited by Dixon (1971, pp. 64-73). The output from the program includes : A) the F - statistic for the multivariate analysis of variance which will indicate if the three treatment groups were comparable prior to treatment on all of the variables considered together, and B) the F - statistic for the univariate analyses of variance which will indicate if the three treatment groups were comparable prior to treatment on each of the variables considered individually. One would expect that by chance alone some of the individual F - statistics from the univariate analyses of variance might be significant, but that the F - statistic from the multivariate

analysis of variance would not be significant. If it turns out that the treatment groups were significantly different ($\alpha = .05$) prior to treatment (which is unlikely) then one should consider doing subsequent analyses using analysis of covariance or using comparable subgroups of the three main groups.

The second part of the data analysis will be to measure the correlation of treatment compliance with each of the outcome measures (where outcome is the pre-post change). For each subject there will be a single measure of compliance with treatment and a measure of outcome on 39 variables. The correlation coefficients can be computed with a BMD program (Dixon, 1971, 49-59). This analysis will suggest: A) those variables which are affected by methylphenidate treatment (the ones which have a significant correlation with compliance with methylphenidate treatment offered alone), and B) those variables which are significantly affected by behaviour modification treatment (the ones which have a significant correlation with compliance with behaviour modification treatment offered alone).

For outcome measures which have a significant correlation with compliance, one could look at the cross tabulation plots of compliance versus outcome to see how many cases there are which show no improvement or get worse though their measure of compliance with treatment is good. If there are cases who consistently exhibit lack of improvement on these outcome measures while having a high measure of compliance, this suggests that one of two possible

situations exists. Firstly, these cases may truly be individuals who do not respond favourably to the treatment in question. The alternative explanation, which cannot be ruled out, is that in fact these cases were not compliant with treatment and that is why their treatment response was not favourable. Compliance would be overestimated for individuals in the medication group whose parents did not return all of their unconsumed medication. Compliance would be overestimated in the behaviour modification group for individuals whose parents came to the sessions more frequently than they applied behaviour modification at home.

If it happens that there are no cases who fail to respond when compliance with treatment is good, then this suggests that in the future clinicians, who see hyperkinetic children who are treatment non-responders, should attend first to compliance with treatment before considering dropping the treatment.

The third and most important phase in the data analysis will be to determine if the three treatment groups differ significantly in their pre-post change on the 39 variables listed in Table 24. To do this one should consider the variables individually, perform an analysis of variance to see if the mean values for the three treatment groups are significantly different, and if so go on to do pair-wise comparisons of treatment groups using a multiple range test. This analysis is available in BMD (Dixon, 1971, pp.572-585).

When a comparison of the three treatment groups has been made in this fashion for the 39 variables, one should summarize the results in a comprehensible fashion, for example as shown in Table 27, p.208.

Using Table 27, one can readily see how each of the treatments were ranked on each variable - where a ranking of 1 means the best and 3 the poorest. The lowest sum of rankings suggests which is the best of the three treatments. One can also see from Table 27 when the observed differences between pairs of treatment groups are significantly different. One treatment may have a better ranking than another on a particular variable, but the two treatments may not be significantly different.

Bear in mind that the 39 outcome measures are intercorrelated. One may want to go on to do an analysis which indicates whether pairs of treatments are significantly different when one takes into consideration all of the outcome measures or subsets of the outcome measures such as the measures of effectiveness or the measures of side-effects. One can do this analysis with a BMD program for discriminant analysis for two groups (Dixon, 1971, 185-195). If one finds that two groups are significantly different when a number of variables are considered simultaneously, then one must look again at the univariate test results (as in Table 27) to see which of the two treatments is the preferable one.

This may be difficult to determine unless the univariate tests are consistent in pointing to one of the two in the pair under consideration as the better treatment.

TABLE 27 COMPARISON OF
A) METHYLPHENIDATE B) BEHAVIOUR MODIFICATION
C) METHYLPHENIDATE PLUS BEHAVIOUR MODIFICATION

Test Variable	Rank of Superiority** A	B	C	Significant Differences* Avs.B	Bvs.C	Avs.C
A.1) Family function average	3	2	1			
2) acc. wife	3	2	1			
3) acc. husband	1	3	2			
≷				*		
C.15) Conners Teacher Q. Total	2	3	1		*	*
16) Conduct Problem	2	3	1			*
17) Inattentive-Passive	2	3	1		*	
18) Tension-Anxiety	1	3	2		*	
19) Hyperactivity	3	2	1			*
20) Sociability	3	2	1			*
21) Severity of Problem	2	3	1			*
≷				*		
					*	*
					*	*
K.39) Pulse Rate	3	1	2			
Sum of Rankings	80	102	52			

* The asterisk has been placed under the letter representing the treatment which is significantly better. For measures of effectiveness (1-34) better means more improvement. For measures of side-effects (35-39) better means less side-effects. The absence of an asterisk means no significant difference was observed.

** Superiority for measures of effectiveness (1-34) means greater improvement. Superiority for measures of side-effects (35-39) means lesser side-effects.

3.7 ESTIMATED RESOURCES REQUIRED FOR THE PROPOSED RESEARCH

An estimate of the budget required from a granting agency to conduct the proposed research is given in Table 28. The estimate of funds required from a granting agency totals $58,350. The figures are based on the following assumptions.

a) the principal investigator has independent support and negotiates the necessary co-operation of clinicians, school boards, principals, and teachers prior to the beginning of the study;

b) screening is conducted in the schools to identify children who are eligible for the study;

c) the study schedule shown in Table 29, is followed and the study is completed within one year.

If screening is not conducted in the schools then: a) the flow of children into the study would be less predictable; b) personnel may be very busy with a heavy case load at some time and have no cases at other times; c) more personnel may be required to cover times of peak influx of cases; and d) personnel may need to be employed for a longer period of time to allow for the collection of 105 children in total for the study.

It appears that screening would allow for the least costly implementation of the study within one year. It might be possible in some settings for the study to be implemented for the same total cost, but be extended over

more than a year if: the case influx was appropriate for part time study personnel, and appropriate part time study personnel were available.

The responsibilities of the personnel listed on the budget could be as follows :

1. Principal investigator
   a. to negotiate co-operation of clinicians, school boards, principals and teachers prior to the study.
   b. to make arrangements required for implementation of the study (including adaptation of study design to characteristics of the local setting).
   c. to supervise: the implementation of the study, the analysis of results, and the write-up and dissemination of results.
2. Project Co-ordinator
   a. act as liaison between study and schools
   b. responsible for the administration of the screening, and the collection of screening results
   c. analyze the screening results for identification of eligible children
   d. contact parents of eligible children
   e. contact family physicians of eligible children
   f. assign children to treatments with the minimization procedure

g. responsible for collection of pre-post ratings from teachers

h. supervise and assist in the coding of pre-post assessments for computerization

i. conduct the data analyses

j. draft summaries of the study and its results for publication.

3. Physician

a. conduct the assessment of children for selection to the study

b. responsible for the methylphenidate treatment

4. Instructor in Behaviour Modification

a. plan implementation of the behaviour modification program

b. provide the behaviour modification program

c. assist in the write-up of study results for dissemination.

5. Psychometrist

a. perform and score all pre-treatment tests on children

b. perform and score all post-treatment tests on children

c. assist in the coding of pre-post assessments for computerization.

6. Secretary

a. type all correspondence with schools, parents, clinicians

b. prepare dated daily medication envelopes for each child

c. file all materials pertaining to the study

d. answer calls for study personnel

e. make appointments for assessments and treatment

f. handle xeroxing and printing

g. type write-ups of study results

TABLE 28 : ESTIMATED BUDGET FOR THE PROPOSED RESEARCH

	Funding from Granting Agency	
Personnel		
Principal investigator	Nil	
Project Co-ordinator (1 year Sept.-Aug.)	$14,000	
Physician for selection assessment and methylphenidate treatment	Nil (OHIP)	
Instructor in Behaviour Modification (1 year)	16,000	
Psychometrist (1 year)	10,000	
Secretary (1 year)	7,000	
15% fringe benefits	7,050	
Services		
Clinical and Statistical Consultant Services @ $150/day plus expenses	600	
Computer Personnel Services @ $10/hour	400	
Keypunching of data onto computer cards @ $5/hour	50	
Computer time	500	
Supplies		
Testing materials commercially available	350	
Printing of some testing forms	300	
Behaviour modification self-instruction manuals	450	
Stationery, stamps, xerox	500	
Methylphenidate	Nil	(CIBA)
Miscellaneous expenditures not predicted in advance	500	
Travel		
For school liaison	150	
Two scientific meetings for reporting of results	500	
TOTAL	$58,350	

TABLE 29 : STUDY SCHEDULE

I) Schedule for screening by teachers in the last school week in the month:

Cohort	Month							
A)	September	screen	2,100	10	year	olds	→ ~42	eligible
B)	October	"	"	9	"	"	"	"
C)	November	"	"	8	"	"	"	"
D)	December	"	"	7	"	"	"	"
E)	January	"	"	6	"	"	"	"

II) Schedule for:

One selection appointment with study clinician (S)
Two pre-treatment assessment sessions with psychometrist (Pre)
Eight weeks of treatment with clinician and/or behaviour modifier (T)
Two post-treatment assessment sessions with psychometrist (Post)

Candidates → ~21 children selected per cohort

A) S: Oct; Pre: 3 wks Oct-mid Nov; T: mid Nov-mid Jan; Post: 3 wks mid Jan-Feb.
B) S: Nov; Pre: 3 wks Nov-mid Dec; T: mid Dec-mid Feb; Post: 3 wks mid Feb-Mar.
C) S: Dec; Pre: 3 wks Dec-mid Jan; T: mid Jan-mid Mar; Post: 3 wks mid Mar-Apr.
D) S: Jan; Pre: 3 wks Jan-mid Feb; T: mid Feb-mid Apr; Post: 3 wks mid Apr-May.
E) S: Feb; Pre: 3 wks Feb-mid Mar; T: mid Mar-mid May; Post: 3 wks mid May-June.

III) Schedule for 8 weeks of treatment

A) Methylphenidate Group (~7/cohort)
Weeks 1, 4, & 8 meet with clinician to get medication and instructions.

B) Behaviour Modification Group (~7/cohort)
Weeks 1-8 meet once per week with instructor

C) Methylphenidate & Behaviour Modification Group (~7/cohort)
Weeks 1, 4, & 8 meet with clinician to get medication and instructions.
Weeks 1-8 meet once per week with instructor.

4. SUMMARY

This thesis is composed of two major sections - a literature review and a research proposal pertaining to hyperkinetic children. The literature review includes an overview of the state of knowledge pertaining to hyperkinesis and a detailed examination of definitions and diagnosis, prevalence, characteristics of hyperkinetic children, and drug and non-drug treatments for hyperkinesis.

Based on the information gained from the literature review, a protocol was developed for a study to test the hypothesis that .7mg/kg/day of methylphenidate plus 8 sessions of behaviour modification will be more effective in the treatment of hyperkinetic children than either treatment regimen alone. The proposed study calls for :

A) screening of school children for hyperkinesis via teachers' completion of Conners Parent-Teacher Questionnaire;

B) selection of 105 children who are eligible for the study;

C) pre-treatment assessments including Family Function, Conners Parent Questionnaire, Conners Teacher Questionnaire, WISC-R, WRAT, Piers-Harris Children's Self-Concept, Continuous Performance Test, Percentile Height, Percentile Weight, Blood Pressure and Pulse;

D) assignment to treatments via a procedure designed to

minimize dissimilarities between treatment groups;

E) eight weeks of either methylphenidate plus behaviour modification, or methylphenidate alone, or behaviour modification alone;

F) post-treatment assessments as per the pre-treatment assessments plus measures of compliance with treatment;

G) data analysis to determine which of the three treatments is the most effective and which has the fewest side-effects in the treatment of hyperkinetic children.

The proposed study would take a year to complete and would cost about $58,000. In my view that is a small investment for information which would be of potential benefit to probably at least 20,000 of every 1,000,000 children. The proposed study is by no means the only research pertaining to hyperkinesis which needs to be done. However, in my view it is an evaluation of treatments which is strongly called for given our current state of knowledge regarding the treatment of hyperkinetic children.

APPENDIX 1

MH 9-35
1 73

DEPARTMENT OF HEALTH EDUCATION AND WELFARE PUBLIC HEALTH SERVICE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO 68 R965

CONNERS TEACHER QUESTIONNAIRE

PATIENT INITIALS — FIRST INITIAL — SECOND INITIAL

NUMBER MALES 001 TO 499, FEMALES 500 TO 998

PATIENT 5 6 7 8 9

RATER 5 6 7 8 9

PERIOD 5 6 7 8 9
Hours 1 Days 2 Weeks 3 Months 4

PLEASE USE A NO. 2 LEAD PENCIL. BE SURE TO MAKE MARKS HEAVY AND DARK. ERASE COMPLETELY ANY MARKS YOU WISH TO CHANGE

Listed below are descriptive terms of behavior. Mark in the column which best describes this child. ANSWER ALL ITEMS.

CLASSROOM BEHAVIOR	Not at All	Just a Little	Pretty Much	Very Much
1. Fidgeting	0	1	2	3
2. Hums and makes other odd noises	0	1	2	3
3. Demands must be met immediately; gets frustrated	0	1	2	3
4. Coordination poor	0	1	2	3
5. Restless (overactive)	0	1	2	3
6. Excitable, impulsive	0	1	2	3
7. Inattentive, distractable	0	1	2	3
8. Fails to finish things he starts (short attention span)	0	1	2	3
9. Sensitive to criticism	0	1	2	3
10. Serious or sad	0	1	2	3
11. Daydreams	0	1	2	3
12. Sullen or sulky	0	1	2	3
13. Cries	0	1	2	3
14. Disturbs other children	0	1	2	3
15. Quarrelsome	0	1	2	3
16. Mood changes quickly	0	1	2	3
17. Acts "smart"	0	1	2	3
18. Destructive	0	1	2	3
19. Steals	0	1	2	3
20. Lies	0	1	2	3
21. Temper outbursts (explosive and unpredictable behavior)	0	1	2	3

GROUP PARTICIPATION	Not at All	Just a Little	Pretty Much	Very Much
22. Isolates himself from other children	0	1	2	3
23. Appears to be unaccepted by group	0	1	2	3
24. Appears to be easily led	0	1	2	3
25. No sense of fair play	0	1	2	3
26. Appears to lack leadership	0	1	2	3
27. Does not get along with opposite sex	0	1	2	3
28. Does not get along with same sex	0	1	2	3
29. Teases other children or interferes with their activities	0	1	2	3

ATTITUDE TOWARD AUTHORITY	Not at All	Just a Little	Pretty Much	Very Much
30. Submissive	0	1	2	3
31. Defiant	0	1	2	3
32. Impudent	0	1	2	3
33. Shy	0	1	2	3
34. Fearful	0	1	2	3
35. Excessive demands for teachers attention	0	1	2	3
36. Stubborn	0	1	2	3
37. Anxious to please	0	1	2	3
38. Uncooperative	0	1	2	3
39 Attendance problem	0	1	2	3

	None	Mild	Moderate	Severe
40. Considering your total teaching experience with children of this age, how much of a problem is the child at this time?	0	1	2	3

41. What changes have you observed in this child since the start of the study? *(Omit this item at the initial rating)*

	Much Improved	Slightly Improved	No Change	Slightly Worse	Much Worse
Academic Achievement	1	2	3	4	5
Overall Behavior	1	2	3	4	5
Group Participation	1	2	3	4	5
Attitude Toward Authority	1	2	3	4	5

From Psychopharmacology Bulletin -- Special Issue, 1973, p.219

APPENDIX 2

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION
NATIONAL INSTITUTE OF MENTAL HEALTH

FORM APPROVED
OMB NO 68-R043

CONNERS PARENT QUESTIONNAIRE

Listed below are items concerning children's behavior or the problems they sometimes have. Read each item carefully and decide how much you think your child has been bothered by this problem during the last month. NOT AT ALL, JUST A LITTLE, PRETTY MUCH, or VERY MUCH.

Indicate your choice by filling in the space (▬) in the appropriate column to the right of each item.

ANSWER ALL ITEMS.

OBSERVATION			Not at all	Just a little	Pretty much	Very much
PROBLEMS OF EATING:	1. Picky and finicky	1.	0	1	2	3
	2. Will not eat enough	2.	0	1	2	3
	3 Overweight	3.	0	1	2	3
PROBLEMS OF SLEEP:	4. Restless	4.	0	1	2	3
	5. Nightmares	5.	0	1	2	3
	6. Awakens at night	6.	0	1	2	3
	7 Cannot fall asleep	7.	0	1	2	3
FEAR AND WORRIES:	8. Afraid of new situations	8.	0	1	2	3
	9 Afraid of people	9.	0	1	2	3
	10 Afraid of being alone	10.	0	1	2	3
	11. Worries about illness and death	11.	0	1	2	3
MUSCULAR TENSION:	12. Gets stiff and rigid	12.	0	1	2	3
	13. Twitches, jerks, etc.	13.	0	1	2	3
	14. Shakes	14	0	1	2	3
SPEECH PROBLEMS	15 Stuttering	15.	0	1	2	3
	16. Hard to understand	16.	0	1	2	3
WETTING:	17. Bed wetting	17.	0	1	2	3
	18. Runs to bathroom	18.	0	1	2	3
BOWEL PROBLEMS:	19. Soiling self	19.	0	1	2	3
	20. Holds back bowel movements	20.	0	1	2	3
COMPLAINS OF FOLLOWING SYMPTOMS EVEN THOUGH DOCTOR CAN FIND NOTHING WRONG:	21. Headaches	21.	0	1	2	3
	22. Stomachaches	22.	0	1	2	3
	23 Vomiting	23.	0	1	2	3
	24. Aches and pains	24.	0	1	2	3
	25. Loose bowels	25	0	1	2	3
PROBLEMS OF SUCKING, CHEWING or PICKING	26. Sucks thumb	26.	0	1	2	3
	27. Bites or picks nails	27.	0	1	2	3
	28. Chews on clothes, blankets, or others	28.	0	1	2	3
	29. Picks at things such as hair, clothing, etc	29	0	1	2	3
CHILDISH OR IMMATURE:	30. Does not act his age	30.	0	1	2	3
	31. Cries	31.	0	1	2	3
	32. Wants help doing things he should do alone	32.	0	1	2	3
	33. Clings to parents or other adults	33.	0	1	2	3
	34 Baby talk	34	0	1	2	3
TROUBLE WITH FEELINGS:	35. Keeps anger to himself	35.	0	1	2	3
	36. Lets himself get pushed around by other children.	36.	0	1	2	3
	37. Unhappy	37.	0	1	2	3
	38 Carries a chip on his shoulder	38	0	1	2	3

From Psychopharmacology Bulletin -- Special Issue, 1973 pp.231-233

APPENDIX 2: cont. CONNERS PARENT QUESTIONNAIRE

	OBSERVATION		Not at all	Just a little	Pretty much	Very much
OVER-ASSERTS HIMSELF:	39. Bullying	39.	0	1	2	3
	40. Bragging and boasting	40.	0	1	2	3
	41. Sassy to grown-ups	41.	0	1	2	3
PROBLEMS MAKING FRIENDS:	42. Shy	42.	0	1	2	3
	43. Afraid they do not like him	43.	0	1	2	3
	44. Feelings easily hurt	44.	0	1	2	3
	45. Has no friends	45.	0	1	2	3
PROBLEMS WITH BROTHERS AND SISTERS:	46. Feels cheated	46.	0	1	2	3
	47. Mean	47.	0	1	2	3
	48. Fights	48.	0	1	2	3
PROBLEMS KEEPING FRIENDS:	49. Disturbs other children	49.	0	1	2	3
	50. Wants to run things	50.	0	1	2	3
	51. Picks on other children	51.	0	1	2	3
RESTLESS:	52. Restless (overactive)	52.	0	1	2	3
	53. Excitable, impulsive	53.	0	1	2	3
	54. Fails to finish things he starts (short attention span)	54.	0	1	2	3
TEMPER:	55. Temper outbursts, explosive and unpredictable behavior	55.	0	1	2	3
	56. Throws himself around	56.	0	1	2	3
	57. Throws and breaks things	57.	0	1	2	3
	58. Pouts and sulks	58.	0	1	2	3
SEX:	59. Plays with own sex organs	59.	0	1	2	3
	60. Involved in sex play with others	60.	0	1	2	3
	61. Modest about his body	61.	0	1	2	3
PROBLEMS IN SCHOOL:	62. Learning is a problem	62.	0	1	2	3
	63. Does not like to go to school	63.	0	1	2	3
	64. Is afraid to go to school	64.	0	1	2	3
	65. Daydreams	65.	0	1	2	3
	66. Truancy	66.	0	1	2	3
	67. Will not obey school rules	67.	0	1	2	3
LYING:	68. Denies having done wrong	68.	0	1	2	3
	69. Blames others for his mistakes	69.	0	1	2	3
	70. Tells stories which did not happen	70	0	1	2	3
STEALING:	71. From parents	71.	0	1	2	3
	72. At school	72.	0	1	2	3
	73. From stores and other places	73.	0	1	2	3
FIRE-SETTING:	74. Sets fires	74.	0	1	2	3
TROUBLE WITH POLICE:	75. Gets into trouble with police	75.	0	1	2	3

APPENDIX 2: cont. CONNERS PARENT QUESTIONNAIRE

OBSERVATION		Not at all	Just a little	Pretty much	Very much
PERFECTIONISM	76 Everything must be just so ..... 76.	0	1	2	3
	77 Things must be done some way every time .. .. 77.	0	1	2	3
	78. Sets goals too high. 78.	0	1	2	3
ADDITIONAL PROBLEMS	79. Inattentive, easily distracted ... . 79.	0	1	2	3
	80. Fidgeting ..... 80.	0	1	2	3
	81. Cannot be left alone 81.	0	1	2	3
	82. Climbing, gets into things ..... 82.	0	1	2	3
	83. A very early riser .. 83.	0	1	2	3
	84. Will run around between mouthfuls at meals ..... 84.	0	1	2	3
	85. Demands must be met immediately —easily frustrated . 85.	0	1	2	3
	86 Cannot stand too much excitement . . 86	0	1	2	3
	87. Laces and zippers are open ..... 87.	0	1	2	3
	88. Cries ..... 88.	0	1	2	3
	89 Unable to stop a repetitive activity .. 89.	0	1	2	3
	90. Acts as if driven by a motor ..... 90.	0	1	2	3
	91. Mood changes quickly ..... 91.	0	1	2	3
	92. Poorly aware of surroundings or time of day ..... 92.	0	1	2	3
	93. Clumsy ..... 93.	0	1	2	3

	None	Mild	Mod-erate	Severe
94. How serious a problem do you think your child has at this time? ... . 94.	0	1	2	3

Please add any other problems you have with your child.

Indicate the items you are most concerned about or those you think are the most important problems your child has by placing a circle around the number (1-93) of those items.

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