

RESEARCH

VICISSITUDES OF FOLLOW-UP STUDIES: Differential Effects of Parent Training and Stimulant Medication with Hyperactives

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A two-year outcome study of 73 hyperactive children supports both previous short-term studies which suggested that stimulant medication is superior to parent training and long-term studies which found no differences between the two interventions. The discrepancy is discussed in light of complications that inevitably arise in outcome studies and that tend to preclude meaningful outcomes in long-term studies. The development of new research strategies is called for.

Despite the fact that hyperactivity is one of the most common behavior disorders of childhood, there are relatively few outcome studies reported in the literature.¹ Problems associated with subject selection, subject attrition, and the cost of intervention are primary factors in this deficit. Nevertheless, the last few years have seen reports of several meaningful intervention studies.^{10, 13, 16}

Perhaps it is because of difficulties and costs associated with the more behaviorally or psychologically oriented interventions that stimulant medication became the most widely used treatment for hyperactive children in the 1960s and 1970s. However, despite the fact that

stimulant medication has been demonstrated to have positive effects on the deficits of hyperactive children in the short-term,^{2, 7, 23} several problems are associated with its use. Approximately 25% of hyperactive children do not respond or respond adversely to stimulant medication¹⁴ and there is little or no indication that medication aids academic progress.³ Finally, long-term investigations have not been able to replicate the dramatic benefits of medication evidenced in short-term studies.²²

Behavioral interventions have also shown some success in ameliorating various aspects of the behavioral problems associated with hyperactivity.^{6, 18} As a result there have been a few reports

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of group studies comparing the effectiveness of stimulant medication and behavioral interventions with hyperactives.^{10, 13, 16, 24} In general, the results suggest that, on a short-term basis, the use of stimulant medication alone is more effective than behavioral interventions alone in improving classroom and social behavior and attentional deficits of hyperactive children. When the goal of treatment is improved academic performance, behavioral intervention is superior to stimulant medication, at least in special research classrooms. However, data concerning generalization and long-term benefits are lacking.¹

Firestone¹⁰ reported the results of a three-month intervention study comparing stimulant medication alone, stimulant medication plus parents trained in behavior modification, and placebo plus parent training. Like the previous research in this area, stimulant medication resulted in greater improvement in classroom behavior, attention, and impulse control when compared to parent training. Unlike the previous work, improvement in some aspect of academic achievement was also reported. In short, there was no evidence of significant benefit from the addition of parent training to stimulant medication. The present report extends the prior study¹⁰ by extending follow-up of the cohort to two years. Before a description of the method and presentation of the results is undertaken, consideration must be given to one of the most problematic areas in therapy outcome research, namely, attrition.^{11, 12}

The relative significance of lost subjects with respect to the overall results of an outcome study is often ignored and this has become increasingly more problematic in the interpretation of long-term results. Researchers often fail to report the number of subjects solic-

ited for an experiment and how many refused to participate. Many reports can also be faulted for not presenting data on the number of subjects who drop out once they agree to participate in a study and the reasons for this attrition. In the present study, for example, there are 73 subjects in the pre-post analysis, but only 30 subjects are considered for the two-year follow-up analysis. This is a loss of 43 subjects, more than half the initial sample. Only 19 of these children lacked second follow-up data because of staggered entry into the study (*i.e.*, they did not make it to the second-year mark by the time of this reporting). Only two children were lost because their families relocated during the course of the project. Thus, of the "lost" 43 subjects, only 21 (19+2) actually lacked two-year follow-up data. There were 22 children who remained in the study throughout, but whose data are not considered because of movement from their original experimental condition. These children were either placed on or removed from medication according to their treatment progress after the initial pre-post period. In essence, the reality of the child as a patient superceded the child's role as a subject. In many cases, children's treatment programs were modified a number of times in an attempt to provide optimal benefit. Clinicians recognize this as more typical of actual treatment conditions than the discrete treatment categories usually reported in the literature.

In the present report of results, only one such "switch" group was included. These were subjects who were put on medication as a result of very poor progress with parent-training plus placebo. The number of subjects in this group varies from seven at pre-post analysis to five at two-year follow-up. Thus, their inclusion is primarily for heuristic purposes.

Another problematic group of subjects in terms of design, analyses, and interpretation are the dropouts." These individuals dropped out before the post-testing (three months). Their reasons varied and included parents agreeing to participate in the study in order to obtain an assessment of their child and parents being opposed to the treatment of their children with medication.^{11, 12} In the present study, this category includes 61 subjects, all of whom participated in the pretest but who for one reason or another, did not participate in the actual program. As well, there were 20 subjects who had been referred to the program, but who, upon initial contact, declined even the pretest. It was not possible to ascertain the characteristics of these families in any systematic fashion, although anecdotal evidence revealed that a frequent comment from parents reflected the general theme of "It's not what I thought it would be."

In total, therefore, 154 families (73+61+20) had initially accepted the referral to the research program. Of these, 134 families (73+61) participated in the pretest. Only 73 families actually carried through to post-treatment assessments. Of the 73, only 52 families have two-year follow-up data; of those 52, only 30 are considered in the analysis at the two-year follow-up. In other words, 22% of the initial sample survived the two-year study in their assigned treatment conditions. The comparable figure for the pre-post analysis is 54% (73 of 134). It is proposed that subject attrition in the present study would not be dissimilar to that in other work with hyperactives, but for various reasons this information has often not been reported, resulting in misleading information or interpretations.

It should be noted that in the Province of Ontario, like the rest of Canada, the

cost of medical services and psychological services provided within medical settings is fully covered by the provincial health care plan. One might speculate that results with "patient-subjects" who receive payment for participation in research, or "patient-subjects" who are required to pay for services, might differ from those reported here.

METHOD

Subjects

Children between the ages of five and nine years, referred to the learning, psychiatry, or psychology outpatient services of the Children's Hospital of Eastern Ontario, were considered for participation in the study. Each child was referred by a physician who suggested a diagnosis of hyperactivity and each was judged by a clinical psychologist to fit the *DSM-III* criteria for Attention Deficit Disorder with Hyperactivity. All subjects demonstrated these symptoms of hyperactivity, both at home and at school and before three years of age. Additionally, only those children with a rating of 1.5 or higher on the Teachers Hyperactivity Index⁵ were included. Each child was required to have a Peabody Picture Vocabulary IQ of 85 or higher, and all children who showed definite signs of brain damage, epilepsy, or psychosis were excluded from the sample. There was a total of 73 subjects for the pre-post analysis, 52 for first follow-up analysis, and 30 for the second follow-up analysis.

Procedure

When a child met the criteria for inclusion in the study, the family was given a full description of the project in addition to information regarding methylphenidate. Further appointments for data collection and obtaining signed informed consent were scheduled once

the family agreed to participate. Following an initial pretesting, children were randomly assigned to one of three groups: parent training plus medication (PTMED), parent training plus placebo (PTPL), or medication only (MED). The placebo was identical in size, color, and shape to the methylphenidate used in the study. None of the pertinent research staff (therapists and those testing the children), parents, or teachers was aware of the medication conditions during the pre-post period.

All intervention was carried out by senior doctoral-level interns in clinical psychology, supervised by registered psychologists. Parents of children in the parent training groups (PTMED and PTPL) were provided with initial consultations averaging three sessions. During this time, they were asked to read a book on child management²⁰ and demonstrate a reasonable understanding of the behavioral principles contained therein. Having completed this, they were asked to join a parents' group in which more specific child-rearing behavior management programs were discussed for six sessions. Finally, the parents were taught how to cooperate efficiently with school personnel. In addition, two consultations were provided to the teachers involved.

Only those parents of children in the MED group were not told of the parent training groups and not provided with behavioral consultations. All parents were given the same instructions regarding medication. Medication regimens began just prior to the initiation of the group meetings. Parents were instructed to give their children medication in the morning and at noon every day including weekends. Dosages were raised or lowered in 5 mg steps based on parental and teacher reports of children's behavior by telephone over a three to four week period. Once having

established an optimal dosage for a particular child (decrease in problematic behavior and absence of negative side effects), children were given medication only on school days. The average dosage of methylphenidate was 22 mg/day with a minimum of 10 mg and a maximum of 30 mg.

Predictor Variables

The predictor variables were separated into treatment, familial, and subject categories. The treatment categories consisted of PTMED, PTPL, and MED. The familial categories included total family income plus, for each parent, age, IQ (WAIS), educational level, Locke-Wallace Marital Adjustment Score, and the MMPI Psychopathology Index. The child categories were age at referral, IQ, mean reaction time, total impulsive responses, school performance, Hyperactivity Index, and the Conduct Problem factor of the Quay-Peterson Questionnaire.²¹ In fact, a greater number of subjects was anticipated at the beginning of the study; this would have rendered the data more amenable to stepwise multiple regression and discriminant function analyses. While these statistics are available, they are not reported here due to the small sample size.

Criterion Variables

In order to decrease the number of dependent measures, given the modest number of subjects available, the criterion variables were chosen *a priori* based upon theoretical considerations. The variables selected were: mean reaction time, total impulsive responses, school performance, Hyperactivity Index, and Conduct Problem—all at follow-up. There are three follow-up periods in question: post-test (three months); first follow-up (10-12

months), and second follow-up (22–24 months).

Mean reaction time (\bar{XRT}) was measured using the delayed reaction time apparatus previously shown to discriminate between hyperactive and normal children.^{4, 8, 9} This provides two measures: mean reaction time and total impulsive responses. School performance was measured by the Gates-MacGinitie Reading Test Vocabulary Grade (GMVG). Hyperactivity was measured by the Hyperactivity Index, from the Conners Rating Scale for teachers. The conduct problem factor was taken from the Peterson-Quay Behavior Problem Checklist.

RESULTS

Statistical comparison of treatment groups was accomplished through analysis of variance with repeated measures. The level of significance for all statistical analyses was set at .05 or less and all significant analyses of variance (ANOVAs) were further analyzed using Tukey's procedure. Total impulsive responses was excluded from the present analysis, however, as it was the only criterion which failed to meet the as-

sumption of equal correlations (based on the Box's M statistic). As stated earlier, multiple regression and discriminant function analyses are not presented in this paper, although significant findings were not in evidence for predictions.

In TABLE 1, the group means and standard deviations for pre-post results are described with regard to the Hyperactivity Index. Analysis of variance with repeated measures revealed a significant effect only on the Condition \times Time interaction at post-test $F(2,70)=4.71$, $p<.05$. Tukey's procedure indicated that while there was no significant difference between the performance of the two medication groups, both these groups differed significantly (*i.e.*, more improved) from the placebo group. Similar results were found for Conduct Problem and Reaction Time at post-test, with significant Condition \times Time interactions $F(2,69)=3.21$, $p<.05$ and $F(2,70)=3.93$, $p<.05$, respectively. In both cases, Tukey's test indicated that children in the two medication groups performed significantly better than children in the placebo group.

With the Gates-MacGinitie verbal

Table 1
GROUP MEANS AND STANDARD DEVIATIONS FOR PRE-POST RESULTS ON ALL CRITERIA

CRITERION	PRE-TEST			POST-TEST		
	M	SD	(N)	M	SD	(N)
Hyperactivity Index						
MED	1.96	.37	(30)	0.91	.58	(30)*
PTPL	1.93	.35	(21)	1.37	.57	(21)
PTMED	1.85	.31	(22)	0.89	.49	(22)
Conduct Problem						
MED	9.50	2.89	(29)	5.75	3.53	(29)*
PTPL	9.57	2.78	(21)	8.33	4.14	(21)
PTMED	9.48	2.22	(22)	5.40	3.67	(22)
Reaction Time						
MED	.81	.27	(30)	.67	.24	(30)*
PTPL	.84	.28	(21)	.82	.23	(22)
PTMED	.84	.23	(22)	.68	.23	(22)
Verbal Grade						
MED	2.64	1.81	(29)	3.34	2.23	(29)
PTPL	2.81	2.27	(20)	3.23	2.47	(20)
PTMED	2.95	1.33	(21)	3.44	1.65	(21)

* $p<.05$.

grade score, however, there were no significant changes or between-group differences at post-testing. It is evident, as with each of the other criteria, that within-groups changes remain significant throughout the follow-up period. This is not a remarkable finding considering that grade level can be expected to improve to some degree with the child's attendance at school.

The data for subjects remaining in the study through the first follow-up are presented in TABLE 2 and those remaining for the second follow-up in TABLE 3. The treatment groups did not differ in their two-year rate of attrition (40%, 38%, and 45%, respectively, for MED,

PTPL, and PTMED). Although demographic and dependent variables might have been analyzed to examine whether certain characteristics might distinguish the group with respect to those who did not terminate their participation, the small *N*s prohibit any meaningful comparisons. Clinical experience would suggest, for example, that both symptom amelioration (*e.g.*, success on medication) and symptom deterioration (*e.g.*, failure to respond to parent training) might account for patients electing to discontinue treatment.

There was no statistical evidence of long-term difference among the three groups. Nevertheless, the progress of

Table 2
GROUP MEANS AND STANDARD DEVIATIONS AT FIRST FOLLOW-UP ON ALL CRITERIA

CRITERION	PRE-TEST			POST-TEST		
	<i>M</i>	<i>SD</i>	(<i>N</i>)	<i>M</i>	<i>SD</i>	(<i>N</i>)
Hyperactivity Index						
MED	1.97	.37	(22)	.88	.61	(22)
PTPL	1.86	.33	(13)	1.21	.52	(13)
PTMED	1.87	.34	(16)	.98	.51	(16)
Conduct Problem						
MED	9.64	3.18	(21)	6.14	3.87	(21)
PTPL	9.46	4.32	(13)	7.46	3.91	(13)
PTMED	9.15	2.09	(16)	6.25	3.89	(16)
Reaction Time						
MED	.79	.27	(23)	.66	.23	(23)
PTPL	.78	.23	(13)	.77	.30	(13)
PTMED	.84	.22	(16)	.66	.22	(16)
Verbal Grade						
MED	2.64	1.72	(22)	3.26	1.82	(22)
PTPL	3.16	2.32	(12)	3.56	2.50	(12)
PTMED	2.94	.95	(15)	3.47	1.14	(15)
	FIRST FOLLOW-UP					
CRITERION	<i>M</i>	<i>SD</i>	(<i>N</i>)			
Hyperactivity Index						
MED	.96	.54	(22)			
PTPL	1.27	.62	(13)			
PTMED	.96	.43	(16)			
Conduct Problem						
MED	6.29	3.88	(21)			
PTPL	7.61	4.22	(13)			
PTMED	6.28	4.25	(16)			
Reaction Time						
MED	.59	.16	(33)			
PTPL	.66	.21	(13)			
PTMED	.59	.20	(16)			
Verbal Grade						
MED	3.46	1.98	(22)			
PTPL	3.97	2.39	(12)			
PTMED	3.96	1.22	(15)			

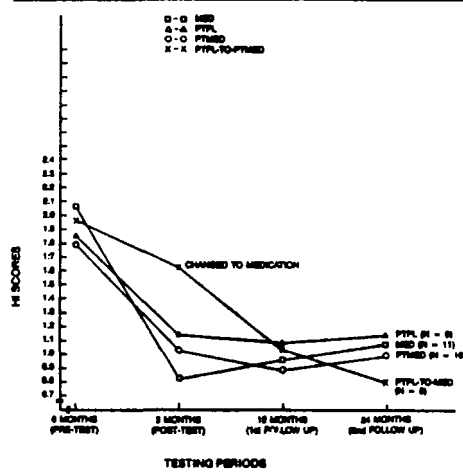
Table 3
GROUP MEANS AND STANDARD DEVIATION AT SECOND FOLLOW-UP ON ALL CRITERIA

CRITERION	PRE-TEST			POST-TEST		
	M	SD	(N)	M	SD	(N)
Hyperactivity Index						
MED	2.03	.39	(11)	.81	.44	(11)
PTPL	1.83	.28	(9)	1.12	.56	(9)
PTMED	1.81	.38	(10)	1.03	.46	(10)
Conduct Problem						
MED	9.59	3.61	(11)	6.45	4.42	(11)
PTPL	9.56	4.37	(9)	6.89	4.23	(9)
PTMED	8.90	2.23	(10)	5.80	2.81	(10)
Reaction Time						
MED	.77	.16	(12)	.64	.19	(12)
PTPL	.82	.16	(8)	.75	.22	(8)
PTMED	.86	.24	(10)	.66	.27	(10)
Verbal Grade						
MED	2.51	1.35	(10)	3.42	1.54	(10)
PTPL	2.42	1.96	(8)	2.51	1.82	(8)
PTMED	.95	3.47	(9)	3.46	1.22	(9)
CRITERION	FIRST FOLLOW-UP			SECOND FOLLOW-UP		
	M	SD	(N)	M	SD	(N)
Hyperactivity Index						
MED	.96	.59	(11)	1.09	.60	(11)
PTPL	1.07	.55	(9)	1.09	.63	(9)
PTMED	.92	.36	(10)	1.06	.59	(10)
Conduct Problem						
MED	5.91	3.61	(11)	6.97	4.41	(11)
PTPL	6.44	4.02	(9)	4.51	3.57	(9)
PTMED	6.43	3.36	(10)	5.98	3.63	(10)
Reaction Time						
MED	.59	.13	(12)	.60	.11	(12)
PTPL	.70	.15	(8)	.64	.14	(8)
PTMED	.63	.25	(10)	.52	.12	(10)
Verbal Grade						
MED	3.56	1.82	(10)	4.56	1.70	(10)
PTPL	3.23	2.16	(8)	4.29	2.74	(8)
PTMED	3.97	1.34	(9)	5.14	1.92	(9)

each of the groups throughout the study is illustrated in FIGURES 1-4. The progress of a fourth group is also plotted. This is the placebo-changed-to-medication group (PTPL-to-PTMED), which represents all subjects who were changed from their original PTPL condition after the post-tests were administered ($N=7$ at post-test; $N=5$ at second follow-up). What appears in each of these figures, therefore, are the separate plots for the "pure" groups (*i.e.*, those groups comprising subjects who remained in their original condition throughout the study). It should be mentioned that when the data from these pure groups are subjected to

analyses of variance with repeated measures at the three-month post-testing, all previous significant comparisons vanish. Based on the pure groups alone, there is no evidence even for a short-term advantage for children treated with medication. It is possible, however, that the loss in degrees of freedom on the pure group pre-post ANOVA may account, at least in part, for the failure to find significant differences among treatment groups. The η^2 coefficients for the total group ($N=73$) on the interaction term in the analyses for TCHI, TPQCP, and $\bar{X}RT$ are .13, .11, and .10, respectively. The coefficients for the same analysis on pure groups alone,

Figure 1
CONNERS' HYPERACTIVITY INDEX SCORES FOR ALL TESTING PERIODS

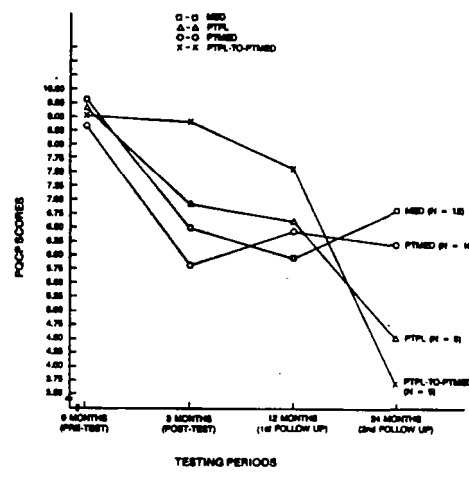


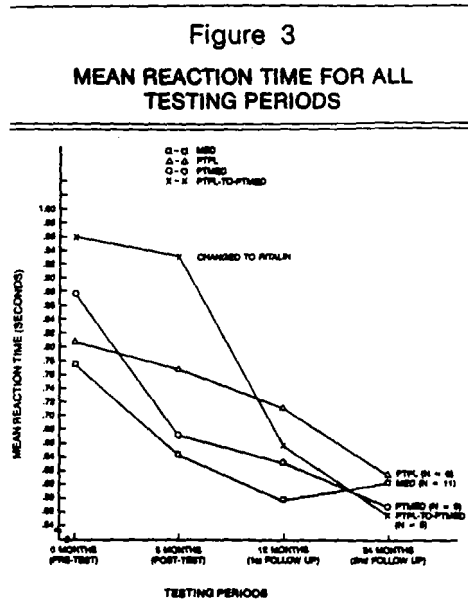
however, are considerably smaller at .03, .03, and .005, respectively. It is evident, therefore, that the magnitude of treatment effect has been reduced considerably in the pure group comparisons. In any event, changes in a child's experimental group were made because of very poor clinical progress by children which necessitated a change in treatment. It is of interest to note with regard to the Hyperactivity Index (FIGURE 1) that this poor progress resulted in a mean rating at three-month post-test of 1.60 in the "change" group compared with means in MED, PTPL, and PTMED of 0.98, 1.20, and 0.88, respectively. It was at this point that the change from placebo to medication was made and from this point the change group showed dramatic improvement, with a mean rating of 1.05 at first follow-up compared with a mean rating of 1.27 for the PTPL group. One might speculate that, had the three original groups been held steadfast in their assigned conditions, the differences found at post-test may have endured through first follow-up. On the other hand, it is

evident that the switch to medication was of some benefit to the change-group children, judging by the slope of their progress not only on the Hyperactivity Index but on each of the other criteria as well. Moreover, the benefit appears to be quite stable insofar as the improvement in the change group seems to surpass the performance of the three original groups on each of the criteria. The specific analyses of the Conduct Problem and Reaction Time data are similar to those already presented for the Hyperactivity Index. The progress of the groups on these measures is presented in FIGURES 2-4.

The issues raised by consideration of these data relate more to the decision as to which data most accurately reflect the clinical phenomena. For example, analyses of variance on pure groups only at post-test reveal no differences. On the other hand, it is evident that had subjects been confined to their original treatment, differences would be found not only at three-month post-test but likely at later follow-ups as well. Furthermore, there is the curious but evi-

Figure 2
PETERSON-QUAY: CONDUCT PROBLEMS SCORES FOR ALL TESTING PERIODS





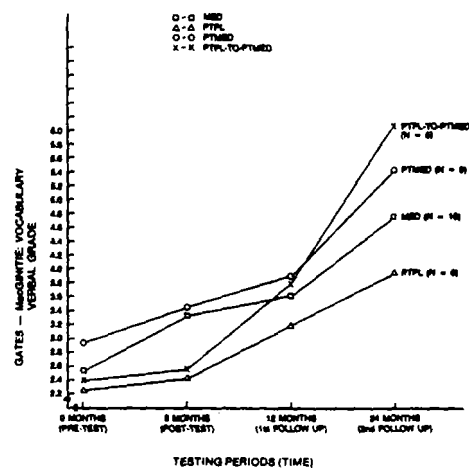
dently consistent performance of at least one of the groups of children (PTPL-to-PTMED) that were switched out of the planned experimental design. On the basis of simple ANOVAs they showed no pretest differences compared to the PTPL group except for greater difficulties of inattention. (This analysis is not presented due to the small *N* and limited space.)

DISCUSSION

There are a number of important considerations arising from the present study. In the first place, the pre-post results of the 73 subjects who participated in the study essentially replicate the findings reported by Firestone,¹⁰ and those reported by Gittelman-Klein.¹³ The only exception is that the present study did not find improved academic performance in the medication group, which suggests that this finding in the original study was probably spurious. There is little doubt, on the basis of these reports, that stimulant medication offers effective short-term amelioration for problems of attention, behavioral

disturbance, and hyperactivity for certain children. Having said that, however, there are some mitigating elements in this present report. For example, when the pre-post comparisons are made with only those subjects remaining in their assigned treatment conditions throughout the study, eliminating dropouts and subjects who changed conditions, the pre-post differences vanish. This is, of course, also true for the pure groups at two-year follow-up. This raises perhaps the most important consideration for further study. It is evident from the present research that analyses of dropouts and subjects who change experimental conditions are crucial to an overall understanding of the interaction between treatment and outcome^{11, 12} For example, had the Gittelman-Klein study¹³ extended its data collection several months, it might well have found a similar phenomenon insofar as retroactive comparisons of pure groups may have failed to support the findings of the short-term investigation. The fact that, in the present

Figure 4
GATES-MACGINITIE GRADE ACHIEVEMENT:
VOCABULARY VERBAL SCORES FOR ALL
TESTING PERIODS



study, only 22% of the initial sample is considered at two-year follow-up does not answer the question as to the meaningfulness of the other 78%, the majority of whom were dropouts before the post-test. It is additionally important to note that, whatever the possible outcomes with full participation and full adherence, there is a characteristic of the 22% that is not easily integrated with the outcome data, except for its acknowledgment, and that is their "decision" to remain in the program and whatever motivation or perseverance that might reflect.

A final consideration from the present study is the analysis of the "change" group. Subjects in this group showed consistent improvement throughout the study once they were placed on medication, having been removed from the parent-training-plus-placebo group. Their only pre-test difference from the other subjects in the placebo group was on the measure of attention. One might speculate as to the possibility of retrieving evidence from unwieldy outcome data which could support post-facto hypotheses. In this case, it might be argued that the change group represents more homogeneous "true" or "constitutional" hyperactives that might be more accurately diagnosed if better diagnostic criteria were available. These data may also lead to the interpretation that to maximize medication responsiveness in a group of hyperactive children, medication should only be prescribed after behavioral intervention is shown ineffective.

In conclusion, it is clear that the results reported by others with respect to short-term outcome studies comparing stimulant medication and behavioral parent training are supported by the present results. Stimulant medication alone leads to improved attention and behavior, with parent training adding little in

terms of the dependent measures. In addition, the long-term outcome results of the present study also support the bulk of previous reports suggesting no long-term benefit of stimulant medication on the major deficits of the hyperactive child^{3, 22}. However, a finer analysis of the events transpiring during the long term, in the present study, provides meaningful data concerning all long-term outcome research. It appears evident that dropout data and information concerning children who change from the experimentally assigned conditions are essential to understanding clinical phenomena. Presentation of this information is a necessary component of outcome studies. Furthermore, the strict analysis of criteria evidence *vis-a-vis a priori* hypotheses in intervention studies may inappropriately confine outcome results. The development by scientific journals of new conventions concerning research design, statistical analyses, and publication criteria is necessary if intervention research is to continue developing. For example, perhaps more details should be required concerning subject selection, refusal to participate, and dropouts throughout the duration of a study. In addition, descriptive data on small groups of subjects who may have violated experimental procedures, under supervision of investigators, may provide useful insights and might be included for heuristic purposes. As well, the prediction of dropouts and of those who are likely to require a change in treatment regimen (via discriminant function analysis, for example) may be quite informative, particularly if research protocols are sufficiently similar to allow for the pooling of data.

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