Hyperkinesis and Food Additives: Testing the Feingold Hypothesis

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ABSTRACT. Teacher ratings, objective classroom and laboratory observational data, attention-concentration, and other psychological measures obtained on 36 school-age, hyperactive boys under experimental and control diet conditions yielded no support for the Feingold hypothesis. Parental ratings revealed positive behavioral changes for the experimental diet; however, they seemed primarily attributable to one diet sequence. Parents' behavioral ratings on ten hyperactive, preschool boys indicated a positive response to the experimental diet; again, laboratory observations showed no diet effect. *Pediatrics* 61:818-828, 1978, *hyperactivity, Feingold hypothesis, food additives, diet and behavior.*

Feingold has asserted that the ingestion of low-molecular-weight chemicals (including salicylates and artificial food colors and flavors) is an important factor in the development and maintenance of hyperactivity in children.[1] He has correlated the increasing consumption of food additives over the past decade with the reported increasing incidence of hyperkinetic-learning disabled children and has implied a causal relationship. These claims were widely reported by the press and were subsequently read into the *Congressional Record* in 1973.[2]

An investigation of the Feingold hypothesis conducted in Australia has reported a significant improvement in behavior of hyperactive children following four weeks on the Kaiser-Permanente (K-P) diet.[3] The parents were informed of the anticipated effects of the K-P diet and were told "if the diet was going to have an effect, they would see the results within four weeks, and if the child violated the diet his behavior would return to the pre-diet condition within two to four hours and could remain that way for up to ninety-six hours."

In this Australian study, 31 patients who had failed to respond to behavior modification therapy were tested for an allergic reaction to artificial colors, using methods described by Hawley and Buckley.[4] Fifteen of the 18 patients who had positive responses were placed on the K-P diet. The authors describe in considerable detail the procedure employed for determination of food color sensitivity. Unfortunately, the specific criteria used to identify the 15 children considered to be sensitive are not reported. No guidelines were provided for how artificial food flavors and salicylate sensitivity were determined, and it is unclear from the article whether such determinations were made. Behavior of the children was assessed by a 49-category questionnaire completed by the child's mother. Alternate possible explanations of the children's "favorable" response to the K-P diet include the absence of diet monitoring, unclear sample description, possible biasing of the parents' expectations, lack of control group or diet crossovers or the employment of a "blind" procedure, inadequate consideration of placebo effects, and the failure to use standardized validated rating scales.[5]

In another experiment by Conners et al., nine

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male hyperactive children followed the K-P diet for four weeks and were then given four weeks of a control diet.[6] Six other subjects received the opposite diet sequence. The participating families were given lists of food items permitted under each of the diet conditions. The control diet was arranged so that shopping, preparation, and monitoring demands were comparable to those of the K-P diet. Whether or not the procedures and safeguards of Conners and co-workers' study were sufficient to prevent diet identification and possible biasing of the subjective ratings was questioned by Levine and Liden.[7] A statistically significant reduction ($\overline{X} = 17.18$ versus $\overline{X} = 13.93$) in hyperactive behavior was reported only by the teachers when the K-P diet and the control diet ratings were compared. The Conners Parent-Teacher Questionnaire (P-TQ) rates hyperactive symptoms from 0 to 30 in order of increasing severity. A criterion score of 15 or greater was used in the selection of the hyperactive subjects. Thus, while the teacher scores on the P-TQ are different between the experimental and control diets, the improved mean rating still approaches the cutoff score of 15 used in that study as a significant indicator of hyperactivity. Reanalysis of these same data by Sprague demonstrated a pronounced interaction between diet and diet order. Sprague suggested that "the strongest statement that should be made is that the K-P diet did improve teacher ratings in only the group which received the control diet first and the K-P diet second."[8]

Feingold has advocated the removal of foods containing synthetic additives from school programs and has suggested the use of a logo to identify products that do not contain synthetic food colors and flavors.[9] Because of the major implications of his assertions and recommendations for the public and the food industry, the Nutrition Foundation, in 1975, assembled a committee of 14 medical, food, and behavioral scientists to conduct a systematic review of evidence on this subject.[10] The Committee's report to the Nutrition Foundation included the following conclusions:

1. Controlled studies have not shown that hyperkinesis is related to the ingestion of food colors.
2. A significant reduction of hyperactive behaviors when children are given the K-P diet has not been demonstrated experimentally.
3. The diet should be used only with competent medical supervision.

A second panel of experts was brought together by the U.S. Food and Drug Administration to form the Interagency Collaborative Group on Hyperkinesis. A preliminary report[11] from that group released in January 1976 stated that studies to date "have neither proven nor disproven the hypothesis that a diet free of artificial food colors and flavors reduces the symptoms in a significant number of children with the hyperkinetic behavior syndrome." However, the report further noted that "the evidence taken as a whole is sufficient to merit further investigation into the relationship of diet and the hyperkinetic syndrome."

Prompted by the controversy just described and following the research design suggestions of these two interdisciplinary groups, we initiated the first double-blind crossover study of the Feingold hypothesis to obtain objective laboratory and classroom observational data in addition to subjective parent-teacher ratings on hyperactive children under control and experimental diet conditions.

METHODS

Subject Selection

Our subjects were selected from boys residing within the general Madison, Wisconsin, vicinity who were referred to our hospital for evaluation of "hyperactivity." Local pediatricians and physicians were contacted to request referral of additional prospective subjects.

Children selected for inclusion in the study had to meet at least two of the following three criteria: (1) a score of 15 or greater on the Conners P-TQ, indicative of moderate-severe behavioral disruption primarily associated with hyperactivity[12] as rated by at least one parent; (2) a score of 15 or greater rated by the child's teacher; and (3) if the child was given a rating of less than 15 by either source, a primary diagnosis of hyperkinetic reaction[13] by the child's physician was required to meet the selection criteria. The mean parent and teacher P-TQ selection ratings were 23.60 (SD = 2.99) and 17.26 (SD = 4.07), respectively, for the school-age sample. The ten preschool subjects had a mean parent P-TQ rating of 22.80 (SD = 3.58). Children with a history of psychopathology, convulsive disorder, or an IQ below 85 were not accepted as project participants.

Procedure

The project was divided into three phases: spring (N = 10), summer (N = 10), and fall (N = 26) of 1975. Subjects between the ages of 6 years 0 months and 12 years 11 months ($\overline{X} = 114.9$ months, SD = 21.8) were included in the spring and fall samples. Preschool boys

TABLE I

EXAMPLES OF FOODS NOT PERMITTED ON STUDY DIETS

Restricted from K-P diet	
	Breakfast cereals with artificial colors/flavors
	Salicylate-containing foods,* e.g., almonds, apples, apricots, oranges, tomatoes, cucumbers, strawberries
	Bologna, ham, frozen fish
	Flavored yogurt, ice cream,† instant breakfast drinks
	Cake mixes, raisin bread, flavored gelatins, cake
	Any food item containing artificial food colors or flavors and/or salicylates
Restricted from both diets	
	All soft drinks (except 7-UP)
	Aspirin compounds
	Cough drops
	Toothpaste (baking soda substituted)
	Medications (clearance required from project pediatrician)

*Analysis for salicylic acid and methyl salicylate by thin-layer chromatography with a 0.2-μg sensitivity was negative for oranges, tangelos, grapefruit, strawberries, almonds, and lemons. The tests were performed by Samy Ashoor and F. S. Chu at the Food Research Institute, University of Wisconsin—Madison.

†Our K-P diet permitted two flavors of ice cream specially prepared at the University of Wisconsin Dairy that were free of artificial flavors and colors. Two flavors of ice cream from the same source but containing usual amounts of artificial flavors and colors were provided for the control diet.

between the ages of 3 years 0 months and 5 years 11 months ($\bar{X}$ = 56 months, SD = 13.6) were studied in the summer sample.

Following the initial standardized interview[14] and a two-week baseline period, subjects were randomly assigned either to the experimental (Feingold-K-P) diet or the control diet. Assignments to the diet conditions were made by the project dietitian (Mary-Lynne Mason, R.D.); the medical and psychological team members, classroom and grid room observers, parents, and teachers did not know which diet a particular child was receiving, i.e., a double-blind procedure. Use of medications for controlling hyperactivity was terminated two weeks prior to baseline. In the spring and summer, subjects were on each diet for three weeks. For the fall group, the two diets were in effect for four weeks each. Diet order was counterbalanced for each of the three samples.

Three major evaluations were made on each child in addition to a neurological and physical examination. At the end of the two-week baseline and at the conclusion of each diet interval, neuropsychological data and laboratory observations were obtained. An average of three classroom observations per week was obtained throughout the study. Behavioral ratings using the Conners P-TQ were made weekly by the child's parents and teacher during the entire study.

Representative samples of classroom activity settings and times of day were obtained for each subject by including group and individual work assignments, structured and unstructured activity settings, and both morning and afternoon classes. In each setting, a hyperactive subject and his control were monitored for alternating five-minute intervals by the observer to help eliminate the possible confounding effect of changing classroom activities. Total observation time devoted to the hyperactive subject and his matched control was approximately ten hours over the course of the study.

Classroom data were collected by a team of student observers trained in a series of laboratory, videotape, and field (classroom) training exercises. The observers were initially trained to a predetermined level of criterion accuracy (r = .80); inter-observer agreement checks and criterion retraining sessions were held throughout the study and it was found that this level of inter-observer reliability was maintained.

In the experimental diet, naturally occurring and added salicylates, synthetic food dyes, and artificial flavors were eliminated following the diet as outlined by Feingold.[15] Ingredient labeling was used to determine which foods contained artificial flavors and/or colors. In those cases where labeling was not indicated, industry practice was considered. For example, cheddar cheese is generally colored with annatto, an extract from a tropical seed. Process cheese may be colored with one or more certified food colors. Hence, the experimental diet contained only natural cheese, whereas the control diet contained both process and natural cheese. Table I presents some of the foods claimed by Feingold to contain salicylates and also lists other substances proscribed by his diet and therefore not used in the present study. Ordinary levels of synthetic food dyes, food colorings, and salicylates were present in the control diet. The two diets were designed to be comparable in appearance, variety, nutritional value, and palatability. Because of concern expressed by earlier investigators[6] that the K-P diet may be deficient in vitamin C, all the children were given 50 mg of vitamin C daily during the experimental and control diets.

Dietary Compliance

Several steps were taken to maximize dietary compliance, obviously a critical factor. First, all the investigators met with the participating families in a general meeting, and while the importance of compliance was stressed, the families were informed that certain infractions of the diet would undoubtedly occur, and such infractions should be carefully documented and reported. Second, the dietitians made initial individual home visits to ascertain family eating habits, reinforce the importance of compliance, and instruct the parents in maintaining dietary records. Finally, arrangements were made to have all previously purchased foods removed from the house and to have each family's entire food supplies delivered to their homes weekly.

All family members were placed on the diet to minimize the possible treatment effects related to the experimental subject and his special diet, and also to reduce his temptation to eat other foods that would ordinarily be available to "non-involved" family members. The weekly food deliveries also contributed to the blind aspect of the project, since families were informed that they would be on various diets over a six- to eight-week period, and were not told they would be on one of two diets. In addition to providing the family's ordinary food needs, supplementary food was delivered for special occasions such as holidays, guests, family dinners, etc. At school, children customarily provided treats or snacks for their classmates on their birthdays. To avoid diet disruption in these situations we made arrangements to deliver approved treats to the entire class when any child in the room had a birthday.

Several other procedures were included to obscure the diet manipulations. Special production runs were made to prepare identically packaged chocolate bars and specialty cakes, with one containing standard ingredients and the other free of artificial flavors or colors. The production and coding of these specially prepared food items were directly supervised by one of the authors (E.T.). Also, a number of pseudo-dietary manipulations and distractions were incorporated into the diets. For example, the family might be provided with hot dogs, potato chips, and cookies one week, and these items would be absent from the next week's menu. This might be interpreted by the child and/or his parents as evidence of being on two distinct diets, but these items (depending on brand selection) were permitted on both the control and experimental diets. Finally, sweet potatoes were systematically introduced and removed throughout the dietary phase as another pseudo-manipulation distracting technique.

Dietary Infractions

At the conclusion of each diet week the dietitian visited the subject's home to review the dietary records, give menu suggestions, inspect the kitchen for removal of particular food items not permitted for the coming week, and help maintain motivation for observing the dietary conditions. Reports from parents and teachers indicate that subjects were conscientious in maintaining strict adherence to the diet program. The average number of reported dietary deviations was only 0.65 per week for the school-age children (median = 0.25), and only 1.33 per week for the preschool sample (median = 0.75). Within one week of the completion of the study, parents of the experimental subjects were interviewed and requested to describe the diet schedule and sequence they thought their child had been assigned. In not a single instance did the parents correctly identify the actual sequence and timing of the diet crossovers that were employed.

RESULTS

Neurological Findings

Figure 1 summarizes the examination findings of the 36 school-age boys. Fourteen subjects had positive neurological findings: five had perinatal or developmental histories sometimes associated with neurological impairment, eight had positive neurological signs, and five had abnormal EEGs. Four of the 14 subjects had two of these three atypical neurological signs. The remaining 22 subjects were considered neurologically normal. In the preschool group, two of the ten children had abnormal neurological histories, but focal neurological signs and the EEG results were normal for this group. Results of standard hematology tests, erythrocyte lead levels, and urinalysis were within the normal range for all 46 subjects. "Soft" neurological signs were found in three of the preschool sample and in a majority of the school-age children. In general, the neurological findings on the subjects were similar to those reported in other studies[16] of hyperactive children, including difficulties in gross motor skills, motor persistence, graphesthesia/stereognosis, and finger-tapping speed.

Observational data were obtained in the classroom for 34 of the 36 school-age hyperactive subjects and for 34 corresponding controls matched on the basis of classroom, age, academic grade, and teachers' judgment of academic abili-

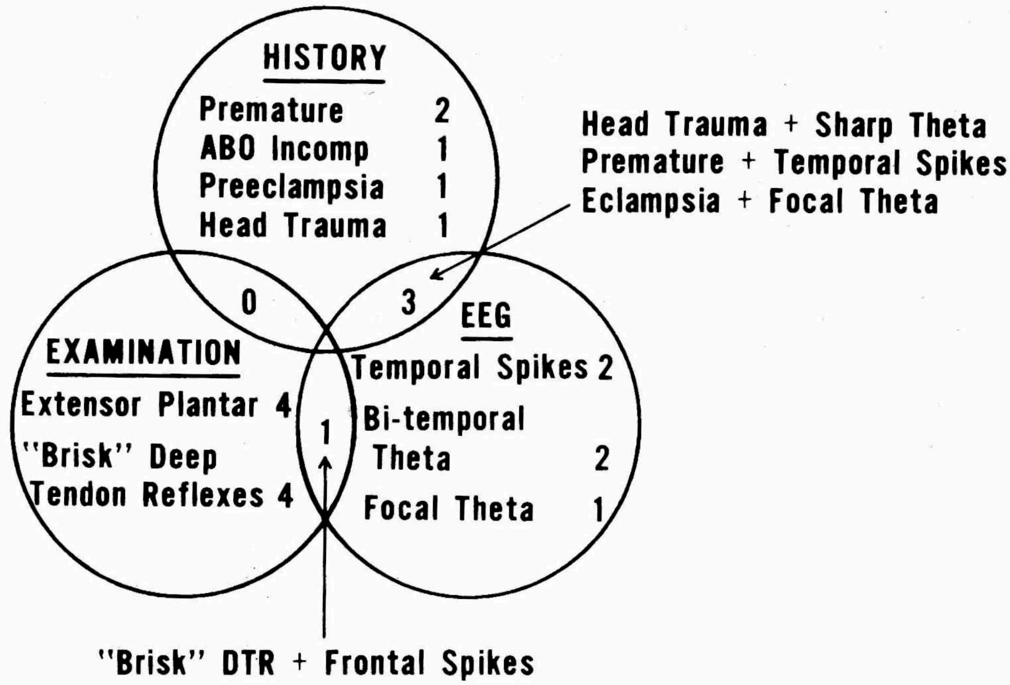

FIG. 1. Neurological examination information. ABO Incomp = ABO blood type incompatibility.

ty. Subjects were observed throughout the baseline and experimental periods. The trained observers were not aware of the dietary manipulations, nor were they aware of the identity or diagnosis of the hyperactive subjects. A fixed category coding system was used for the sequential and coincidental recording of frequency and duration of specified classroom behaviors.[17]

Attending-to-task was defined as the proportion of time attending to any classroom activity that was defined as appropriate by the teacher. Periods of time spent in activities specifically defined as inappropriate and periods of distraction from any assigned classroom activity were excluded from attending-to-task. Control subjects were found to exhibit a significantly higher proportion of attending-to-task than hyperactive subjects. There was no significant effect of diet on the level of attending-to-task for hyperactive subjects, nor were there effects attributable to diet order or interaction of diet and order. Two-way analysis of variance was performed on all of the classroom dependent variables, allowing for analysis of diet, diet order, and their possible interactions.

Restless motor activity, defined as the proportion of time spent in such activities as repetitive finger-tapping, movement of the arms or legs, and looking around while seated at a desk, differentiated the subject groups, with the hyperactive boys exhibiting a significantly higher rate. No significant effects of diet, diet order, or interaction of diet and diet order were found in the analysis of the level of restless motor activity in the hyperactive subjects.

Classroom disruption, defined as the rate per minute of behaviors such as interpersonal aggression, excessive loudness, inappropriate movement about the room, and interruption of teacher or classmates, was also observed to occur at a significantly higher rate in the hyperactive subject sample than in the control sample. The experimental diet manipulation, however, produced no significant effect on the rate of classroom disruption displayed by the hyperactive subjects.

In summary, classroom observation data indicated that although there were significant differences between the hyperactive and normal control subjects, with the hyperactive subjects showing higher frequencies of inattentive, restless, and disruptive behaviors, there were no significant changes in these observed indicators of hyperactivity attributable to the experimental diet, order of diet manipulations, or interaction of diet and order.

As a control for the natural variability of behavior across different classroom settings, 22 of the 36 hyperactive subjects and 16 nonhyperactive control subjects were observed during a standardized laboratory activity task. The 16 control subjects consisted of 11 of the 34 children used as controls in the classroom observation phase plus 5 controls selected by the teachers of the experimental subjects, employing the selec-

TABLE II

Classroom and Laboratory Observational Data

		Diets		Subjects	
		Experimental	Control	Hyperactive	Control
Classroom observations					
Attending-to-task (proportion of total time)	X̄	0.795	0.790	0.784*	0.836
	SD	0.086	0.109	0.092	0.085
Restless motor activity (proportion of total time)	X̄	0.409	0.420	0.413*	0.363
	SD	0.107	0.109	0.141	0.138
Classroom disruption (rate per minute)	X̄	0.483	0.377	0.308*	0.186
	SD	0.670	0.323	0.192	0.142
Laboratory observations					
Attending-to-task (proportion of total time)	X̄	0.651	0.651	0.682*	0.883
	SD	0.228	0.249	0.271	0.092
Locomotion (grid crossings per minute)	X̄	0.939	1.548	1.102*	0.356
	SD	1.337	2.302	1.250	0.422
	Median	0.600	0.731	0.630	0.070

*Hyperactive subjects versus control subjects, $P < .05$.

tion criteria used for the 34 classroom controls. A separate team of observers, uninformed regarding the experimental hypothesis, collected data on locomotor activity and attending-to-task under free-play and restricted-activity instructional conditions. This procedure was similar to the procedure described by Routh et al.[18] Hyperactive subjects were observed in the laboratory setting during the baseline period and at the end of each diet period. Control subjects were observed during the baseline period. Interjudge reliability exceeded $r = .80$ for all behavioral dimensions.

Data from the laboratory setting provided support for the validity of the classroom observations (Table II). The rate of locomotor activity and the proportion of time spent in attending-to-task differed significantly for the hyperactive and control subjects. Hyperactive subjects moved about the laboratory room at a significantly higher rate during the free-play period and also were less able to attend to task when given instructions to remain at one desk and work only with a specific object. No significant effects of diet or diet order were observed. These results paralleled the classroom findings of significant differences in the observed behavior of hyperactive subjects and control subjects and no effect of the diet manipulation of the observed behavior of the hyperactive subjects.

Neuropsychological Tests

Neuropsychological evaluations made at the end of baseline and each diet period included tests of general intelligence, memory, motor speed and coordination, reaction time, vigilance, concentration/attention, and basic academic skills.[19] The tests employed in this study were selected for their documented potential in discriminating hyperactive and control children and/or showing improvement following treatment with psychotropic medication,[20] or because of the intrinsic pertinence of the test to the subject under investigation (e.g., academic achievement measures). A series of 2 × 2 analyses of variance (diet × diet order) were used to analyze the neuropsychological variables for the hyperactive subjects (the first data columns in Table III).[21] Although two significant diet × diet order interactions were identified (Table III) and static steadiness was improved in the experimental diet condition, no other significant improvement on the neuropsychological tests was found on the K-P diet when the two diet conditions were contrasted. Significantly better performance was found on the control diet for coding, dominant hand finger-tapping speed, reading, and Porteus maze tests in comparison to the experimental diet.

Group test score means over the three examinations are shown in the last three columns of Table III, as are the significant intergroup comparisons. The 17 hyperactive subjects in the diet order group experimental diet first (EXP-CNT) were compared with the 10 control, nonhyperactive subjects across the three separate neuropsychological testings. Complete neuropsychological data were collected on only ten of the 34 classroom control subjects. Separate 2 × 2 analyses of variance (group × testing) with

TABLE III

COMPARISON OF NEUROPSYCHOLOGICAL TEST SCORES ON EXPERIMENTAL VERSUS CONTROL DIETS AND IN HYPERACTIVE VERSUS CONTROL SUBJECTS

		Diets (N = 36)		Subjects		
		Experimental	Control	Hyperactive		Control (N = 10)
				EXP/CNT* (N = 17)	CNT/EXP (N = 19)	
Wechsler Intelligence Scale for Children†						
Digit span	X̄	9.19	9.75	9.98	8.95	10.10
	SD	3.07	3.05	2.67	2.89	2.76
Coding	X̄	11.28	12.08‡	11.31§	10.74§‖	13.23
	SD	2.20	2.80	2.85	2.83	2.94
Wide Range Achievement Test						
Reading	X̄	4.94	5.12‡	4.97§#	4.74§#	5.21
	SD	2.60	2.70	2.06	2.98	2.36
Spelling	X̄	3.69	3.77	3.62§	3.61§	3.93
	SD	2.01	2.03	1.50	2.38	1.80
Arithmetic	X̄	3.29	3.18	3.35	3.05	3.42
	SD	1.29	1.09	0.87	1.41	1.30
Finger-tapping speed**						
Dominant hand	X̄	34.25	35.25††	34.98§	33.68	35.40
	SD	4.95	6.13	4.66	6.21	5.85
Nondominant	X̄	31.11	32.56‡	32.00	30.79	33.40
	SD	4.67	4.87	4.48	5.05	5.95
Kinetic steadiness‡‡						
Dominant hand	X̄	1.46	1.28	1.40§	1.58	0.93
	SD	1.82	1.66	1.62	1.89	1.39
Nondominant	X̄	2.51	2.70	2.57	3.06	2.21
	SD	2.39	2.77	3.05	2.94	3.05
Grooved pegboard§§						
Dominant hand	X̄	73.81	70.89	72.24§	77.63§	73.40
	SD	17.14	15.88	17.12	21.93	16.66
Nondominant	X̄	81.56	80.69	76.84§	88.32§	77.10
	SD	23.29	21.32	20.40	23.65	17.30

repeated measures were used to compare the two groups. The same analyses were performed for the 19 hyperactive subjects receiving the other diet sequence (CNT-EXP).

As with the classroom-laboratory observational data, significantly better performances were found in the control versus the hyperactive subjects on a number of the neuropsychological measures employed, including visual-motor learning, motor steadiness, reaction time, and attention. The hyperactive subjects had poorer performances than the control group on the coding subtest, dominant hand static steadiness, Knox cubes, and reaction time measures. Evidence of a practice effect of the three examinations is indicated by the significant main effect for testing for nine of the dependent variables.

Tabulation of parent and teacher ratings on the Conners P-TQ showed that 13 of the 36 mothers of the children in the school-age group rated their sons' behavior as improved on the experimental compared to the control diet and 6 rated their children's behavior as worsened. Seventeen mothers indicated no change (operationally defined as less than 10% change in either direction). Of the 30 fathers of this group, 14 rated their sons' behavior as improved, 13 as unchanged, and 3 as worsened. Only 6 of the 36 teachers rated the children as less hyperactive, 10 as worsened, and 20 as unchanged. Agreement between the parent and teacher P-TQ ratings was infrequent, with the behavior of only four of the 36 children consistently rated by both the parents and teachers as improved on the experimental diet. Analysis of variance of the mean P-TQ scores indicated a significant diet effect, with improved behavior found on the experimental diet for the father and mother ratings, but not for the teacher ratings. The diet × diet order interaction was significant for the mothers' and fathers' ratings; indicating

TABLE III (CONTINUED)

		Diets (N = 36)		Subjects		
		Experimental	*Control*	*Hyperactive*		*Control (N = 10)*
				EXP/CNT° (N = 17)	*CNT/EXP* (N = 19)	
Static steadiness‡‡						
Dominant hand	X̄	4.91‖‖	6.91	6.02§‖	6.09	2.83
	SD	3.87	6.29	4.60	6.17	3.64
Nondominant	X̄	11.09‖‖	13.97	10.70	12.99	7.57
	SD	8.75	9.56	6.75	10.78	6.98
Knox cubes¶¶	X̄	10.54	10.54	10.81‖	9.89‖	12.30
	SD	2.78	3.18	2.63	3.21	2.23
Porteus maze##	X̄	121.30	126.30‡	121.20§	124.00§	127.30
	SD	12.67	9.97	13.93	10.83	9.90
Continuous performance test°°°	X̄	87.03	87.11††	86.42	86.48	89.29
	SD	11.29	12.54	10.73	12.92	12.18
Reaction time†††	X̄	1.19	1.29‡‡‡	1.23‖‡‡‡	1.20‖‡‡‡§§§	0.93
	SD	0.64	0.66	0.63	0.62	0.46

°EXP/CNT = experimental diet first followed by control diet. CNT/EXP = control diet first followed by experimental diet. The test scores are averaged over the three neuropsychological evaluations.
†Age-corrected standard scores on digit recall and visual-motor learning tasks.
‡Better performance on the control diet, $P < .05$.
§Effect of the three separate testings, $P < .05$.
‖Hyperactive subjects' performance worse than controls,' $P < .05$.
¶ Grade placement equivalency score.
#Group × testing interaction, $P < .05$.
°°Number of taps in ten seconds.
††Diet × diet sequence interaction, $P < .05$.
‡‡Contact time (seconds) on stylus-maze tracing and hand tremor tasks.
§§Time to complete (seconds) fine finger dexterity task.
‖‖Better performance on the experimental diet, $P < .05$.
¶¶ Raw score mean of two trials: immediate visual memory span task.
##Age-corrected score (test quotient): planning, foresight, motor control task.
°°°Relative scores on the x-series = (number of correct responses ÷ total number of responses) × 100 – visual vigilance attention task.
†††Response latency (seconds) on one-, two-, and four-choice visual response task.
‡‡‡RT choice, $P < .01$.
§§§Choice × trial, $P < .01$; group × choice × testing, $P < .05$.

the diet order of control diet first and experimental diet second resulted in a decrease in severity of hyperactive symptoms on the experimental diet. Twelve of the 13 children showing a positive response to the experimental diet as indicated by mother P-TQ ratings were in this diet sequence, as were 11 of the 14 children whose behavior was rated as improved by their fathers. The mean mother, father, and teacher ratings on the P-TQ for the hyperactive subjects are shown in Figure 2. Since the mean P-TQ mother, father, and teacher ratings across the ten-week observation period were highly similar for the control group, these scores were averaged (Fig. 2).

All ten mothers and four of the seven fathers of the preschool sample rated their children's behavior as improved on the experimental diet, and no diet × diet order interactions were found. The locomotor activity of the same ten subjects was observed in a standard laboratory setting at the end of the baseline and of each dietary interval. The frequency of movement varied considerably within the sample and across diet periods, but in contrast to the parental ratings, no significant decrease in activity level attributable to the experimental diet was observed. The parental rating data are certainly of considerable interest and potential significance. However, the small sample size, the absence of teacher ratings, and the failure to find corresponding diet-related improvement in the laboratory observation situation or on neuropsychological measures[19] necessarily impose interpretative constraints on the significance of the subjective parental ratings.

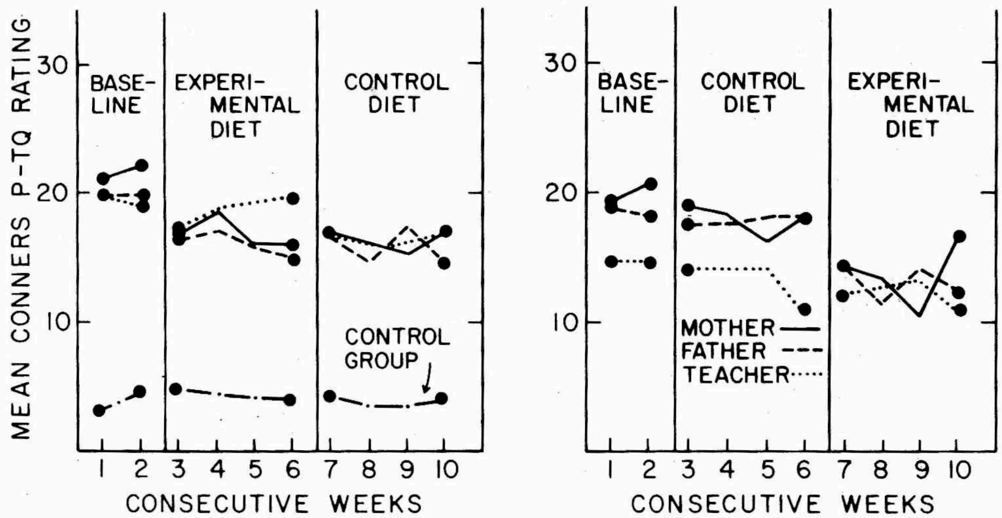

FIG. 2. Mean Conners P-TQ weekly ratings for two diet sequences for hyperactive school-age subjects. Composite mother, father, and teacher P-TQ ratings are given for ten control subjects across ten-week period.

DISCUSSION

With the possible exception of a small preschool sample on whom only limited data could be obtained, the overall results do not provide convincing support for the efficacy of the experimental (Feingold) diet. The frequency with which positive diet effects were judged to be present was highest in the subjective parent ratings, declined sharply in the teacher ratings, and essentially disappeared in the objective neuropsychological, classroom, and laboratory observational data. It might be noted that judgments of hyperactive behaviors in children made by parents have been found to be in general less reliable and sensitive than teacher observations.[22]

The few significant findings related to diet that did emerge must be conservatively interpreted for several reasons. Given the very large number of statistical tests conducted, some differences obtained may be due to chance alone. Positive effects of the diet were primarily restricted to the sequence of control diet first and experimental diet second, a diet order effect which has been observed in another investigation of the Feingold hypothesis.[6,8] Although no satisfactory explanation is readily apparent, this finding may in part be referrable to a recent study[22] reporting that rating scale data of this kind are unstable over time, with subsequent parental ratings showing a decline in degree of judged hyperactivity vis-à-vis their pretest or pretreatment ratings of the children. Whatever the reason, the fact that the experimental diet seems to "work" only when a control diet is given first would appear to attenuate the claimed efficacy of the experimental diet.

While there may well exist a subset of hyperactive children whose behavior is adversely affected by artificial food colors, the results of the present study of boys aged 6 to 12 suggest either that such a subset is very small or that the relationship of diet manipulation to behavioral change is much less dramatic and predictable than has been described in anecdotal clinical reports.[15]

Preschool Sample

The attentive reader of this report has undoubtedly sensed, if not specifically identified, our discomfort and uncertainty in the manner of presenting the results on the preschool sample. We have chosen to emphasize the findings on the school-age sample because we believe our experimental design for this group meets our intended criteria with respect to sufficient number of subjects, employment of selection methods clearly appropriate for this age sample, and the availability of multiple sources of objective data regarding changes in hyperactive behaviors.

We have been unwilling to grant equal credence or weighting to the parental rating scale data generated by the preschool parents for several reasons: first, the sample of only ten preschoolers versus the larger group of 36 school-age subjects and the unavailability of teacher rating data on the same subjects; second, the failure to find parallel changes in neuropsychological test scores[19] or in grid room observational measurements; third, the fact that the Conners P-TQ was employed as one criterion for subject selection despite the fact that the scale was developed for and validated on school-age children; and finally, the well-recognized difficulty of establishing firm and unequivocal criteria for the diagnosis and/or measurement of hyperactivity in preschool as opposed to school-age subjects.[23,24] Nevertheless, objectivity and completeness in reporting our data require us to repeat our finding that ten of ten mothers and four of seven fathers of the preschool sample rated their children's behavior as improved on the experimental (K-P) diet and that, unlike the school-age boys, no diet × diet order interaction was evident in statistical analysis.

While we feel confident that the cause-effect relationship asserted by Feingold is seriously overstated with respect to school-age children, we are not in a position to refute his claims regarding the possible causative effect played by artificial food colors in preschool children. For this reason, if further studies were to be conducted, larger numbers of preschool-age subjects should be employed, using objective outcome measures.

Conclusion

The Interagency Collaborative Group on Hyperkinesis Committee[11] has recommended a two-stage research strategy to investigate the Feingold hypothesis; the first stage was to establish the efficacy, if any, of the K-P diet by comparing the behavior of hyperactive children under K-P and control diet conditions. The present report represents our findings from the stage 1 phase of the recommended protocol. The second strategy suggested by the committee was to use those children who had shown the best response to the diet manipulation in the initial study in a subsequent challenge study in which the child serves as his own control and is repeatedly challenged by food substances containing specified amounts and kinds of artificial food colors and/or flavors. We are now nearing completion of stage 2 of this project, having placed a small group of children selected from the present study on the K-P diet and using challenge (artificial food colors mixture) versus placebo materials in a double-blind multiple crossover sequence.

The results of this pending study and those of other investigators in the United States, Canada, and Australia who are conducting similar challenge studies may provide a sufficiently diversified data base to permit unequivocal conclusions to be offered regarding the role played by artificial food colors in the development and/or maintenance of hyperactive behavior in children. In view of the greater suggested response of younger than of older children to dietary manipulation in our study, prospective investigations of either a "first" or "second" stage nature should emphasize the collection of a greater number and range of observational, laboratory, and rating scale data on preschool children than was available to the Wisconsin investigative team. Recent preliminary findings by Goyette et al.[25] also suggest that younger children may display a greater adverse response to synthetic food colors. These caveats and expressions of dissatisfaction with the technical shortcomings of our preschool study, however, must not obscure or detract from our primarily negative and nonsupportive findings with regard to Feingold's assertions regarding the efficacy of his diet for the reduction of hyperactive behaviors in school-age boys.

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