

The Food Additive-Free Diet in the Treatment of Behavior Disorders: A Review

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ABSTRACT. A food additive-free diet has been recommended as a component of the treatment of developmental/behavioral disorders in children. This diet was initially developed by Dr. Benjamin Feingold for the treatment of aspirin sensitivity in adults, and then extended by him to the management, particularly, of hyperactivity and learning disability in children. The rationale for this diet and the methods employed in investigating its use are described. The claimed therapeutic effects of this diet have been investigated in a number of well-designed studies reviewed here. These studies generally refute a causal association between food additives and behavioral disturbance in children. Suggestions are made regarding the approach towards food additive-free diet therapy in the management of developmental/behavioral disorders.

INTRODUCTION

The effectiveness of special diets in the treatment of behavior disorders in children remains a controversial issue. A recent survey of medical practice in the State of Washington reported by Bennett et al¹ indicated that diets are regularly prescribed by primary care physicians in 45% of children diagnosed with attention deficit disorder (hyperactivity). Parent groups supporting dietary therapy continue to thrive. Books advocating special diets for children with behavior problems are commonplace on bookstore shelves. Television talk shows regularly highlight diet-behavior issues in children.

In contrast to this interest and acceptance of diet treatments, there exist a few well-controlled investigations of diet-behavior relationships in children that primarily refute any substantial relationship between diet and common behavioral syndromes. However, the medical literature is also replete with anecdotal reports and uncontrolled, and otherwise improperly designed, studies suggesting the existence of nutritional deficiencies and physiological abnormalities in children with behavior disorders.

Although dietary treatments have been proposed for a number of different kinds of behavior disorders, most frequently foods are claimed to produce or exacerbate hyperactivity, inattentiveness, and acting-out behaviors. Some of these behaviors are characteristic of children

with attention deficit disorder(s) which constitute the most common, serious behavioral syndrome(s) of childhood. Prevalence estimates range between 4 and 10% of school-age children affected by one or more of these attention deficit syndromes.^{2,3} Learning disabilities, which are also said to be favorably affected by dietary treatment, are common. The presence of clinically significant reading "backwardness," for example, in the Isle of Wight survey of 9- and 10-year-old children, was 47%.⁴ These figures document the magnitude of the clinical problem for which dietary therapy has been recommended. The search for effective treatment for these disorders is often accompanied by considerable emotional anguish, since they occur in children who are usually normal in appearance and, by definition, of average intelligence. Nonetheless, the behavioral and cognitive characteristics of these syndromes result in significant academic underachievement and serious disruptions within families and school classrooms. Families are often eager to embrace dietary treatment which they see as free from side effects. In addition, it is easy for parents and the general public to accept "bad" food as a major culprit in producing illness, general poor health, and behavioral disturbance.

The clinician often experiences these factors as pressure from families to employ dietary treatment. Since the health care provider is frequently asked to comment or advise regarding dietary treatments for behavior problems, this article will review the issues and research findings relevant to one of the most commonly employed dietary treatments for behavioral disorders, namely, the food additive-free, or Feingold, diet.

ORIGINS OF THE FEINGOLD DIET

The claim that the ingestion of food additives is causally related to hyperactivity and learning disability

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was first proposed by the late Dr. Benjamin Feingold, an allergy specialist. The claimed connection between food additives and hyperactive behavior evolved from his work with adult patients who were sensitive to aspirin. Such patients, who experience allergic-like symptoms in response to the ingestion of aspirin compounds, sometimes failed to improve with just the elimination of aspirin-containing medications. Therefore, a special diet was developed to eliminate salicylate-containing chemicals that occur naturally in some foods. The artificial food coloring, tartrazine (FD&C Yellow #5) was also eliminated because it had been shown to produce the same allergic-like symptoms in some aspirin-sensitive patients.^{5, 6} Because not all patients responded favorably to all of these exclusions, Dr. Feingold stated that: ". . . it was hypothesized that among the thousands of food colors and flavors incorporated into our food supply, there may be other additives, although unrelated chemically which may induce adverse clinical responses. On the basis of this premise, the so-called salicylate-free diet was expanded to include not only all foods containing natural salicylates, but also all sources of artificial flavors and colors, with and without a salicylate radical" (p. S19739).⁷ In summary, the salicylate-free diet used to treat these patients was devised to exclude all foods that contain artificial food colorings, artificial food flavorings, and foods that contain "the salicylate radical."

The assumed relationship between aspirin sensitivity in adults and hyperactivity and learning disability in children was based upon Dr. Feingold's assertion that the symptoms of aspirin sensitivity were sometimes behavioral, thus producing the behavioral problems associated with learning disability and hyperactivity. Others have assumed that aspirin sensitivity is an example of an allergic phenomenon, thus associating this dietary treatment with the ongoing controversy as to whether foods and other allergens can sometimes produce purely behavioral symptoms. However, Dr. Feingold has correctly pointed out that aspirin sensitivity is not an allergic phenomenon but stems from an idiosyncratic reaction to a specific chemical in the susceptible person.⁸ Nonetheless, the anecdotal literature indicates continuing confusion as to whether the food additive-free diet is treating an allergy problem.

Reports by Dr. Feingold began appearing in 1973. In 1975, he published a book entitled "Why Your Child Is Hyperactive"⁹ that spelled out his claims linking the salicylate-free diet and hyperactivity and learning disability. In it he stated that there has been a sharp increase in the incidence of hyperactivity-learning disability and that a "graph projecting the dollar-value increase in artificial flavors looked very much like a graph indicating the rising trend of hyperactivity-learning disability for the same period" (p. 21).⁹ This statement, repeated in several of his articles, suggests a causal relationship between an increase in the industrial use of artificial flavorings and colorings and an increase in hyperactivity or learning disability. Although there has been a significant increase in the awareness of these disorders as reflected by the number of magazine articles, books, and scientific arti-

cles devoted to the topic, there is no evidence that hyperactivity or learning disability have increased in prevalence.

THE FEINGOLD CLAIMS

Dr. Feingold claimed that when treated with the salicylate and additive-free diet, 50% of hyperactive and learning disabled children would achieve a "full response, while 75% can be removed from drug management, even if full response to other symptoms is not achieved" (p. 71).⁹ He summarized his findings as follows:

The cardinal features observed following management with the salicylate-free diet include: 1) the rapid, dramatic change in behavior. Although the history of hyperkinesis with associated disturbances is usually of many years duration (three to four years), and at times dates back to infancy, a favorable response is observed within days after instituting the dietary control. The child loses his hyperkinesis, his motor incoordination, and becomes well adjusted to his environment. The sleep pattern improves. 2) Drugs that have been administered for several years can usually be discontinued after about two or three weeks of management and rarely beyond one month. 3) Improved scholastic achievement is also dramatic. Within a single quarter at school, the child will show much improvement in his reading and writing ability as well as with numbers. This is consistent with the observation that these children have either a normal or a high IQ (p. S19740).⁷

Dr. Feingold stated that further evidence of the association between specific foods and behavior comes from "the ability to 'turn on and turn off' the pattern of hyperkinesis. . ."¹⁰ by which he means that children who ingest the excluded foods show a return of their symptoms, followed by an improvement when they resume strict adherence to the diet. These phenomena are repeatedly described in the clinical cases reported in his articles and book. He stated that the greatest improvement is seen in young children below the age of 6, and he urged the entire family to participate in the diet in order to encourage strict adherence on the part of the child (p. 75).⁹ On the basis of these claims, Dr. Feingold recommended that legislation be adopted that would require a complete ingredient statement on all food labels and "a symbol or symbols, which would signify that no synthetic colors or flavors are present in the product" (pp. 77-78).⁹ He also recommended that Federally subsidized school lunch programs exclude additive-containing foods (a step that was taken in a number of local school districts).

Dr. Feingold repeatedly stated that the behavior problems produced by food additives are not due to an allergic mechanism, although he suggested that some children who do not respond to the salicylate-free diet may have a behavior problem produced by allergy: "Although adverse behavioral responses attributed to allergy without apparent involvement of additives have been reported, allergy does not seem to be a frequent, primary cause of hyperkinesis. When allergic disease does accompany hy-

peractivity-learning disability, in some cases it may be necessary to institute management for the allergy in order for the salicylate-free diet to be effective" (p. S19740).⁷

As has been indicated by the above review of Dr. Feingold's claims, many of his assertions are vague. The vague quality of his claims is illustrated best by the closing paragraph of his address to Congress reprinted in the Congressional Record:

The control of hyperkinesis with subsequent improvement in scholastic achievement has been demonstrated following management with the salicylate-free diet. The precise identification of the specific factors among the thousands of food additives has not been determined. The nature of the pharmacological behavior of these chemicals is also undetermined. The incidence of hyperactivity-learning disability among school children is not known but is generally recognized as being high and consistently rising. Nevertheless, with the recognition that this basic data is lacking (sic), in view of the critical state of the problem and its extremely wide distribution among the school children, it would seem advisable that a broad-based program for the management of hyperactivity-learning disability with the salicylate-free diet be developed. The gains are many, and the risks are nil. The program involves no danger to the health and behavior of the child, nor are any drugs involved.⁷

The evidence marshalled by Dr. Feingold in support of these claims consisted entirely of clinical case descriptions. He encouraged parents to keep diaries of their child's behavior, and his book and articles contain case reports extracted from these diaries. These clinical reports include vivid descriptions of the return of hyperactive symptoms following the ingestion of specific foods prohibited on the diet. For example:

On July 2nd, Johnny C. began the K-P (Kaiser-Permanente, the name he gave to the diet) diet, and on July 8th, a startling six days later, his mother reported: 'he's become very quiet, less irritable; easy to control.'

On July 13, I noted: 'Changed child. More self-control than on Ritalin. Able to reason with parents and peers, less distractable. Decreased Ritalin to once a day, at 7 a.m.: Stelazine only at night.'

On the 15th, Johnny C. ate a bakery doughnut at 7 a.m. and by 10 a.m. was 'hyperactive, unable to use self-control.' Twenty-four hours later, after the food had cleared his system, he was back to the new normal. (p. 39).⁹

Such dramatic reports of improved behavior, followed by deterioration with the consumption of a forbidden food, are very convincing to most readers. However, such statements should be viewed with great caution since the treatment (the diet) is applied with the full knowledge of both patient and physician and since change in behavior, the expected outcome of treatment, can be strikingly affected by nonspecific factors such as enthusiasm and expectation. It is important in behavioral research to ensure that the change in behavior is due only to the specific

treatment given. Other, nontreatment effects, known as placebo or Hawthorne effects, can powerfully influence behavior, as indicated by studies that repeatedly demonstrate a measurable improvement in 35% of patients with a sham or fake procedure.¹¹ In recognition of this important principle of behavioral research, the National Advisory Committee on Hyperkinesis and Food Additives recommended that studies be conducted under double-blind conditions and with the use of experimental and control (placebo) diets.¹² The U.S. Department of Health, Education and Welfare's Interagency Collaborative Group on Hyperkinesis also recommended that any studies of the Feingold claims be conducted under double-blind conditions and with placebo controls.¹³

The kinds of behavioral problems said to be helped by the Feingold diet were subsequently expanded by Dr. Feingold and others to include the behavior of juvenile delinquents and mentally retarded children. The diet was also said to result in improvement in some cases of epilepsy, enuresis, and headache.¹⁴ It should be emphasized that neither he nor others submitted data to support these claims.

PROBLEMS IN RESEARCH DESIGN

The vagueness of Dr. Feingold's claims made it difficult to design appropriate studies either to confirm or refute his assertions. Since the following considerations are common to all investigations of this issue, they will be discussed before research study outcomes are reported.

Specifying the Diet

Foods are complex substances. In addition to carbohydrates, proteins, fats, vitamins, and minerals, they contain many other chemicals which give them their characteristic taste and flavor. Dr. Feingold did not specify which chemicals and at what concentration should be allowed or excluded from the additive-free diet. He stated, for example, that one must remove all food that contains "a salicylate radical." He referred to "old German literature" to determine which foods contained this chemical. However, salicylate is a general chemical term that includes many different compounds containing the basic salicylate radical.¹⁵ These variations include sodium salicylate, salicylic acid, methyl salicylate, and aspirin (acetyl salicylic acid). Dr. Feingold did not specify which, or whether all, of these chemical entities should be excluded and at what dose level they may produce behavioral changes. In addition, accurate studies specifying the quantitative level of salicylates in specific foods are limited. In his book, Dr. Feingold published a list of fruits and vegetables that must be excluded because they contain "natural salicylates." This list of common foods includes almonds, apples, apricots, berries, cherries, currants, grapes and raisins, nectarines, oranges, peaches, plums, and prunes. Limes, lemons and grapefruits are permitted. In the vegetable category, the diet excludes tomatoes and cucumbers and all products containing these two vegetables. Since the publication of Dr.

Feingold's book, scientists at the Del Monte Research Laboratories have determined the salicylic acid content in parts per million in most of the fruits and vegetables processed by their company. They found levels that varied from less than 0.1 to 0.8 ppm. In their analysis, cherries, which are excluded in the published Feingold diet, contain less than 0.1 ppm while carrots and corn, which are allowed in the Feingold diet, contain greater than 0.3 ppm. Some tomato products, such as whole peeled tomatoes and tomato wedges, contain less than 0.1 ppm, while tomato juice contains 0.16 ppm and tomato sauce contains 0.30 ppm.¹⁶ The above cited examples illustrate the problem in subjecting the Feingold claims to scientific investigation. In the absence of information that would determine the exclusion or inclusion of specific foods, most studies have administered the diet according to the criteria published by Dr. Feingold. This has been done with the realization that the published diet may not exclude some sources of salicylate and may exclude foods that contain no appreciable amount of these chemical substances.

Although his diet was originally based upon the exclusion of salicylates, Dr. Feingold said in later years that salicylate-containing foods could usually be reintroduced into the diet of responsive patients without producing any deterioration in behavior (p. 120).⁹ Because of this decreased emphasis on salicylates as the offending foods and because the elimination of salicylate-containing foods, according to Dr. Feingold's criteria, resulted in a drastic reduction of available fruits and vegetables, some studies utilized a "modified Feingold diet" which is a diet that excludes artificial colorings and flavorings but not all foods that are claimed to contain salicylates.

It is also difficult to specify what is meant by "artificial food flavorings." Approximately 80% of the compounds listed as intentional food additives fall into the category of flavorings. The chemical components of synthetic food flavorings are often identical to the chemicals contained in natural foods. These synthetic flavors are usually formulated from compounds first identified in foods. The reason for excluding food flavorings is vague. Dr. Feingold stated:

Following the exclusion of tartrazine, some of the failures, but not all, responded. Accordingly, on the basis of the clinical relationship between aspirin and tartrazine (FD&C Yellow #5), it was hypothesized that among the thousands of food colors and flavors incorporated into our food supply, there may be other additives, although unrelated chemically, which may induce adverse clinical responses. On the basis of this premise, the so-called salicylate-free diet was expanded to include not only foods containing natural salicylates, but also all sources of artificial flavors and colors, with and without a salicylate radical. . . . In view of the complexity of the formulae for flavors, the necessity for the empirical exclusion of all artificial flavors can be readily appreciated. (p. S19739).⁷

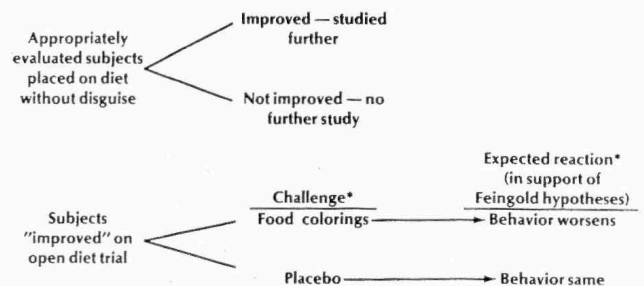
Again, as in the case of salicylates, studies have employed the diet published by Dr. Feingold which excludes

all foods, the labels of which state that they contain artificial flavorings. This is done with the realization that many of the chemicals presumably excluded by this diet are actually contained in natural foods.

Finally, in recent years, many written versions of the Feingold diet also exclude the preservatives BHA (butylated hydroxyanisole) and BHT (butylated hydroxytoluene). These preservatives were not mentioned in any of the earlier publications or published statements by Dr. Feingold and are not related to the initial basis for his diet, namely, a diet aimed at treating aspirin sensitivity. This restriction appears to have been incorporated from suggestions made by others.

Providing a Placebo Control

In the 1975 report to The Nutrition Foundation, the National Advisory Committee on Hyperkinesia and Food Additives recommended that studies designed to test the Feingold hypothesis employ a "challenge design," which would necessitate the production of an appropriate challenge material. A typical challenge design study is illustrated in Figure 1. Subjects are placed on the restrictive diet (in this case the Feingold diet) and then, while continuing to observe the dietary restrictions, specific substances that have been removed from the diet are fed to the subjects in the form of a challenge. If the subject has improved on the restrictive diet and, if this improvement is due to the elimination of specific chemicals, the subject should then deteriorate when those chemicals are again consumed under experimental conditions. Since deterioration in behavior might occur because the experimenter, the subject, and his family are expecting that to happen (placebo effect), the challenge must be made by offering, in a double-blind fashion, a placebo as well as food containing the suspected substance. The active challenge is a food that contains the chemicals previously excluded in the diet, and the placebo looks and tastes just like the active challenge but does not contain the presumably offending chemicals.¹² This type of challenge study seemed particularly appropriate since Dr. Feingold repeatedly stated "that any infraction of the diet, either deliberate or fortuitous, induced a recurrence of the clinical pattern within two or four hours with persistence for 24 hours to 96 hours (4 days). In other words, we could turn the pattern on and off at will."¹⁷



* All subjects remain on restricted diet through this part of study.

FIGURE 1. Research design of challenge studies.

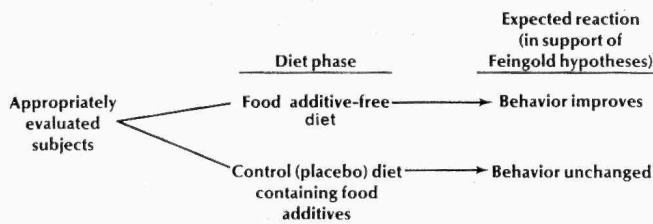


FIGURE 2. Research design of control diet studies.

A different research design compares the effects of treatment over a 2- to 4-week period, with a food additive-free diet and a "control" or placebo diet that does not exclude these additives, as illustrated in Figure 2. Construction of a placebo diet that is indistinguishable from the food additive-free diet is so difficult and expensive that only two studies employed this type of design. The adequacy of the placebo blind has been questioned in both studies.

In order to carry out challenge studies, it was necessary to produce carefully designed, appropriate challenge materials. Initially, consideration was given to which chemicals and to what concentration should be incorporated into the challenge substance. Because treatment was in the form of a diet, the challenge chemicals were incorporated into a food rather than a tablet or capsule. A challenge food was prepared that contained only artificial food colorings as constituents not permitted on the published Feingold diet. This decision was based primarily upon Dr. Feingold's continuing emphasis on food colors as the primary offending chemicals. As previously stated, he said that salicylates could gradually be added back to the diet, suggesting his belief that these chemicals seldom produce the behavioral problems of hyperactivity and learning disability. There were also practical reasons why artificial flavorings were not contained in

the challenge material. Such a challenge substance would have to be prepared from a list of over 1000 chemicals, and a mixture of flavorings could not be disguised in the placebo food. Also, the theoretical justification for excluding artificial flavorings was weak, since many of the chemicals contained in artificial food flavorings are identical to those that occur naturally in foods.

Artificial coloring of commercially prepared foods is accomplished by the use of nine FD&C approved colors that are used either alone or in combinations to achieve the desired results. It was possible to specially manufacture a challenge cookie or candy that contained a blend of these nine colors. The proportion of each individual color in the blend was based upon the amount of each color actually used on a per capita basis in food production, as illustrated in Table 1. For example, 1.7% of all of the FD&C colors used by the food industry are accounted for by Blue #2. Therefore, the blend of colors used to produce the challenge material contains Blue #2 in a proportion of 1.7% of the total color used. Since some of the challenge studies were conducted in Canada, and since Canada has banned the use of Red #40 but allows the use of Red #2, and since the United States has banned the use of Red #2 but allows the use of Red #40, two different color blends, reflecting these differences, were prepared for use in Canada and the U.S.

Difference in appearance of the placebo and the challenge food substance was effectively masked by the brown color of chocolate, permitted in Dr. Feingold's diet. The same amount of chocolate was present in both the placebo and the color-containing foodstuffs. The placebo and active challenge material were tested by food taste panels who could not distinguish between them.

The dose of colors contained in these foods was based upon a calculation of the average daily per capita disappearance of food colors in this country. The amount of FD&C color actually used in food production must be certified by the United States Food and Drug Administration each year. The amount of each color certified in the years 1973 and 1974 was used in this calculation. The total amount of color certified was then divided by the United States population yielding the total figure of 27.29 mg of FD&C color certified per person per day, as indicated in Table 2. Since this was an estimate of the amount of food coloring consumed by each person in a whole day, half that amount was incorporated into each portion of the challenge food since food intake is spread over several hours and the total daily amount of coloring is not usually ingested at one time.

Following the first few challenge studies, concern was expressed that the dose of food coloring employed may be much less than the amount of coloring typically consumed by children. It was argued by some that children, on the average, consume a much higher proportion of artificially colored foods than do adults. Therefore, in preparation for the study by Weiss et al, a project that was funded by the Food and Drug Administration, new calculations were made of the average daily consumption of artificial colorings by children. These calculations were based on estimates of the amount and kind of foods con-

TABLE 1. Percentage of Food Colors Contained in Challenge Material—in the United States and Canada

Food Color	Percentage Contained in Blend	
	U.S. ^a	Canada ^b
FD&C Blue #1	3.12	3.12
FD&C Blue #2	1.70	1.70
FD&C Green #3	0.13	0.13
FD&C Red #2		38.28
FD&C Red #3	6.08	6.08
FD&C Red #4	0.50	0.50
FD&C Red #40	38.28	
FD&C Yellow #5	26.91	26.91
FD&C Yellow #6	22.74	22.74
Certified Orange B	0.54	0.54
	100.00	100.00

^aFrom notarized letter to Mr. A.J. Karas, McCormick & Co., Inc., from Samuel Zuckerman, Ph.D., Vice President, H. Kohnstamm & Co., Inc., dated February 20, 1976.

^bFrom notarized letter to Mr. A.J. Karas, McCormick & Co., Inc., from Samuel Zuckerman, Ph.D., Vice President, H. Kohnstamm & Co., Inc., dated February 27, 1976.

TABLE 2. Data Used in Calculation of Dose of Food Colors in Challenge Material

FD&C Color	Average Amount of Color Certified Per Yr (lb/yr)	Average Intake (mg/person/day)
Blue #1	143,576	0.85
Blue #2	78,143	0.46
Green #3	5,964	0.04
Red #2	1,025,886	6.08
Red #3	280,090	1.66
Red #4	23,206	0.14
Red #40	737,475	4.37
Yellow #5	1,239,024	7.34
Yellow #6	1,047,487	6.20
Orange B	24,718	0.15
		27.29 mg

sumed by children and calculated according to estimates of the artificial food coloring content of those specific foods. This re-estimate led to the conclusion that children consume, on the average, 36 mg of artificial food coloring daily.¹⁸ Therefore, a new challenge material was prepared specifically for this study. This challenge material was a soda pop drink, and the presence or absence of color was disguised using cranberry juice to mask the color difference.

It should be noted that there is a technical limitation to the amount of food coloring that can be incorporated into a food without coloring the mouth and fingers, permitting recognition of the color containing material and thus preventing the disguise of the placebo challenge. It was possible to incorporate 13.0 mg of a color blend into a cookie and 36.0 mg into a soft drink without jeopardizing the placebo disguise, but food technologists stated that larger amounts would begin to be noticeable.

Defining and Assessing the Study Population

The National Advisory Committee on Hyperkinesia and Food Additives made several specific recommendations regarding measures that should be used to define and then follow a population of hyperactive children in studies of the Feingold hypothesis. The studies reviewed here were all conducted by groups already involved and familiar with research involving hyperactive and learning disabled children. All of the reported studies used some type of standardized measure to define the study population. The one investigation that did not (the Weiss study) looked at children who behaved in ways that disturbed their parents but did not necessarily meet criteria for the diagnosis of the hyperactive syndrome. In that study, target symptoms were identified prior to the study and then followed during the course of the experiment. Such a research design is appropriate as long as the challenge is administered using double-blind techniques.

RESEARCH RESULTS

Summarized here are the results of only those studies that met minimal standards of appropriate research de-

sign. This means that: (1) some type of standardized measure was used to define the study population and to follow the subject's progress; (2) experimental variables were applied under double-blind conditions using appropriate placebo controls; and (3) a sufficient number of children were studied to allow for appropriate statistical analyses.

The studies that met these minimal criteria are summarized in Table 3. The two control diet studies revealed improvement on the Feingold diet but only as indicated by behavioral questionnaires. A number of objective laboratory and observational measures were included in the studies by Harley,^{19, 20} and these measures showed no differences between the two diets. The Conners control diet study²¹ employed only behavioral questionnaires as the dependent variable. In both studies order effects were pronounced, that is, improvement was noted on behavioral questionnaires primarily when the Feingold diet came after the control diet. The combination of findings seen only (1) on questionnaires, and (2) when treatments were administered in a certain order, suggests that families may not have been blind to the nature of the two treatments. The informed family who cared to scrutinize the diets could easily have distinguished the Feingold from the control diet.

The initial work by Conners and Goyette seemed to reveal a short-term, immediate effect of food colorings on certain kinds of laboratory-based cognitive tasks.²² However, these investigators were not able to replicate these studies and, therefore, dismissed their significance. The reader who wishes to delve further into the difficulties of diet-behavior studies will be enlightened by the monograph by Conners²³ that reviews 4 years of research in this area. Conners urges investigators to attempt replication of any study with questionable findings. The studies by Levy and Hobbes^{28, 29} from Australia support this recommendation.

The study of Swanson and Kinsbourne²⁴ remains as the only investigation that has shown deterioration on a laboratory learning task in the period immediately following ingestion of a large dose of food coloring. Even in this study, which should be replicated, no changes in behavior were seen. The one remaining study to show some effect of food coloring is that of Weiss et al.²⁵ Only 1 of 22 pre-school-age children showed a consistent pattern of worsening of behavior following the food coloring challenge. Unfortunately, this child was not in nursery school and, therefore, results are based only upon the report of the mother.

Several of the challenge studies employed an initial stage when the Feingold diet was instituted as an open, "non-blinded," treatment. In these instances, from 40 to 60% of children did improve in behavior by parent report only. In none of these studies was an objective measure of improvement employed during such an open diet trial. However, this parent-reported improvement in behavior is similar to what was stated by Feingold and others. The lack of difference between the diet treatment and a placebo comparison suggests that the placebo effects of expectation and altered perception play an important role in the improvement reported following dietary treatment.

TABLE 3. Feingold Diet Studies

Principal Author	Subjects		Study Design		Results	Issues Regarding Interpretation
	No.	Age (yr)	Control Challenge	Diet		
Harley et al ¹⁹	36 10	6-12 3-5		x	No change on objective laboratory and observational measures. Some improvement on parent and/or teacher questionnaires.	Pronounced "order" effects. Degree of "blind" on control diet.
Harley et al ²⁰	9*	6-12	x		No effects except? improvement in one child.	
Conners et al ²¹	15	6-12		x	Improvement on teacher questionnaires only.	Pronounced "order" effects. Degree of "blind" on control diet.
Goyette et al ²²	16	6-12	x		No difference except decreased performance on sustained attention task, 1 hour after color challenge.	
Goyette et al ²²	13*	6-12	x		Worse on parent questionnaires only, during 3 hours after challenge.	
Conners ²³	30	6-12	x		Replication of two Goyette studies. No changes noted.	
Conners ²³	9*	6-12	x		No differences on several laboratory studies.	
Swanson and Kinsbourne ²⁴	40	6-12	x		No difference on behavior questionnaires. Worse on one laboratory task 2 hours after color challenge.	Much higher dose of color challenge (150 mg vs. 26 mg).
Weiss et al ²⁵	22	2-7	x		No change except in one child observed by parent only.	Higher dose of color challenge (36 mg vs. 26 mg). Repeated challenges.
Mattes and Gittleman ²⁶	14	6-12	x		No differences.	Higher dose of color challenge (36 mg vs. 26 mg). Repeated challenges.
Williams et al ²⁷	26	6-12	x		Definite improvement on stimulant medication. Slightly increased, improved on Feingold diet plus medication.	Compared diet to stimulant medication.
Levy and Dumbrell ²⁸	22	4-8	x		Equivocal improvement on parent questionnaire only.	Challenged with tartrazine only.
Levy and Hobbes ²⁹	8	4-8	x		Replication of above study. No difference.	Larger dose of tartrazine than in above study.

*These subjects had participated in this investigator's previous studies and do not represent *new* subjects.

In summary, approximately 240 children were evaluated in these studies. At most, only 2 or 3 (1%) demonstrated any consistent behavioral change in the expected direction. The 20 most hyperactive children in the Swanson study performed less well on a laboratory learning task during a short period after the ingestion of a large dose of food coloring. However, no behavioral change was noted. Over 90% of the children studied showed no significant change of any kind when challenged with food colorings.

CONCLUSIONS AND RECOMMENDATIONS

Despite the research findings that show little, if any, effect of food colorings and other additives on the behavior of hyperactive children, many parents and other adults are convinced of those effects. The perception of causal connection between changed behavior (or other bodily symptoms) and recently ingested food, is compelling.

This is due, in part, to the unique, sustained effect of food as the conditioned stimulus in studies of reinforcement.³⁰ For example, in animal studies, when food (the conditioned stimulus) is paired with an emetic agent (with vomiting as the conditioned response), the animal learns to avoid that food after only one learning trial, and extinction occurs much more slowly than it does in experiments using other types of conditioned stimuli. This same phenomenon is seen in humans. Thus, changes in bodily sensation are likely to be convincingly connected with food, even when the two events are unrelated.

The physician may be required to respond to parents who are convinced of the food-behavior relationships that they have perceived. Management of these issues can be difficult because explanations providing scientifically correct information may not be accepted. Confronting this issue with further argument is often counterproductive, especially when the health care provider becomes

angry out of frustration. Since the treatment in question (the special diet) is not inherently harmful to the child, a more cautious, and usually more successful, approach is to acknowledge that dietary treatment is the parents' choice, while stating in clear and simple terms the information based upon scientific investigation. The clinician should continue to follow the child, pursuing other aspects of treatment and periodically inquiring about the nature of the diet being used, the strictness of adherence, and any signs of emotional friction surrounding the diet. Over time, families begin to relax the strictness of the diet and begin to acknowledge that there is no dramatic behavioral deterioration as a result. In this way, the belief in food additive-free diet-behavior relationships are altered without losing the treatment alliance with the family.

The clinician's skillful handling of dietary aspects of the management of behavioral-developmental disorders in children requires knowledge of the scientific issues, which are reviewed here, as well as an understanding of the relevant psychological factors. With respect to the putative role of food colorings, flavorings, and salicylates in the etiology of behavioral and cognitive disturbance, the scientific evidence suggests little, if any, relationship. Belief, however, in the efficacy of dietary treatment is widespread and firmly held. The psychological factors underlying this belief are based, in part, upon the power of food to function as a conditioned stimulus. An approach combining the understanding of these factors with knowledge of the scientific issues is suggested.

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