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THE FUNCTIONAL RELATIONSHIP BETWEEN ARTIFICIAL FOOD COLORS AND HYPERACTIVITY

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The presence of a functional relationship between the ingestion of artificial food colors and an increase in the frequency and/or duration of selected behaviors that are representative of the hyperactive behavior syndrome was experimentally investigated. Two eight-year-old females, who had been on the Feingold K-P diet for a minimum of 11 months, were the subjects studied. The experimental design was a variation of the BAB design, with double-blind conditions. This design allowed an experimental analysis of the placebo phases as well as challenge phases. Data were obtained by trained observers on Out of Seat, On Task, and Physically Aggressive behaviors, as they occurred in the subjects' regular class setting. Results indicated (a) the existence of a functional relationship between the ingestion of artificial food colors and an increase in both the duration and frequency of hyperactive behaviors, (b) the absence of a placebo effect, and (c) differential sensitivity of the dependent variables to the challenge effects.

DESCRIPTORS: food additives, dietary management, hyperactive children

Certain relationships between diet and the physiological health of the body are fairly well understood. Questions, however, are often raised about the diet's effect on psychological or behavioral manifestations. Recently, Feingold presented a theory that attributes the behavioral syndrome of hyperactivity to the ingestion of "salicylate-like" natural compounds in foods and artificial flavors and colors. As a treatment for hyperactivity, Feingold (1975*b*, 1976) prescribed the K-P diet, which eliminates a wide variety of natural and processed foods, specifically those containing naturally occurring salicylates, *e.g.*, apples, berries, pork, and tomatoes, and all artificial flavors and colors, as well as various items containing artificial flavors and colors, *e.g.*, toothpastes, flavored medications, and mouthwashes. Feingold (1973, 1975*a*, 1975*b*, 1976) has made claims of dramatic improvements in patients who were treated with the K-P diet.

Studies that have attempted to investigate the efficacy of the K-P diet have fallen into two categories. Several uncontrolled clinical studies have been presented, often in the form of case studies (Feingold, 1973, 1975*a*, 1975*b*, 1976; Palmer, Rapoport, and Quinn, 1975; Stine, 1976). These clinical reports are characterized by their uniformly positive results, as well as their common faults, including a lack of experimental control, objective measures, "blind" observers, and an adequate explanation of the placebo phenomenon (Conners, 1975; Conners, Goyette, Southwick, and Andrulonis, 1976; Levine and Liden, 1976; Nutrition Foundation, 1976; Spring and Sandoval, 1976). Empirical studies have also been reported and are most notable for their varying degrees of experimental rigor. The empirical studies are ambiguous regarding positive findings when the K-P diet was used as a treatment approach (Cook and Woodhill, 1976; Conners *et al.*, 1976; Salzman, 1976). However, because of serious methodological flaws, including the lack of experimental controls, objective

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data, control for the placebo phenomena, the use of inappropriate statistical procedures, and the use of nonvalidated instruments, *i.e.,* parental questionnaires and hyperactivity indexes, the findings of these studies can be considered suspect. One of the most rigorous empirically based investigations was reported by Conners and his colleagues (1975, 1976)[2], in which they concluded that the data "strongly suggest" that the K-P diet reduced the perceived hyperactivity of some children. The National Institute of Education (1975), nevertheless, criticized this study for serious methodological errors, including several of those mentioned above and the fact that the study was not a test of the effects of food additives *per se,* but rather a test of two different diets (the K-P diet and a control diet that was similar to the K-P diet but excluded different foods).

Several reasonable conclusions can be reached following a review of the reported studies. First, while an adequate number of clinical studies have been reported, there is a paucity of studies that have employed even minimal experimental standards. Second, the previous empirical group research efforts seemed to focus on the attempt to quantify the treatment parameters on a subpopulation of hyperactive children who may be affected by artificial food additives. Important issues may be raised when group research designs are employed prematurely in a new area of research. Rather than drawing a sample of hyperactive children and experimentally controlling their dietary intake of artificial additives, the issue of whether the dietary restrictions work at all may best be answered by the use of a within-subjects design with a sample of children who are hypothesized to be responders to the diet. This study was designed to assess the potential influence of artificial food colors on the behavior of elementary-school-aged hyperactive children.

[2]An important unpublished study by Harley, Tomasi, Ray, Eichman, Matthews, Chun, Traisman, and Cleeland (Note 1) is well controlled and preliminary data analyses yielded largely negative results.

METHOD

Subjects

Two 8-yr-old females, who had been on the K-P diet for at least 11 months before the study began, served as subjects. There were five criteria that the subjects had to satisfy before they were considered eligible to participate. Briefly, these criteria were:

1. Previous diagnosis of hyperactivity by a physician, with a subsequent prescription of a psychostimulant medication.
2. If pharmacological intervention was implemented, it must have been discontinued for a minimum of four months immediately before participation.
3. Behavioral manifestations of hyperactivity present for a minimum of 2 yr.
4. Parents currently rely on the K-P diet as the apparently exclusive means of behavioral influence.
5. Children must have been on the K-P diet for a minimum of four months immediately before participation.

After a search of the community for subjects, two children were located who met the criteria and whose parents agreed to allow them to participate. Data were subsequently collected on only these two subjects.

Materials

The independent variable was a food item provided by the investigator to the subjects for daily consumption. The food item, an oatmeal-type cookie (Feingold, 1975*b,* p. 187) was present across all experimental conditions, except an initial baseline period. On two occasions, for each subject, the cookie contained a yellow artificial food color, tartrazine No. 5. The experimental solution was obtained by the following procedure (Hawley and Buckley, 1974): 2 cc basic food color (tartrazine No. 5, 4% solution) diluted with 8 cc of distilled water; 2 cc of this solution is further diluted with 8 cc of distilled

water, and then, 2 cc of this solution is diluted with 8 cc of distilled water. This last solution was the test solution and, when included in the recipe for the experimental food item, constituted the challenge condition. This concentration yielded 1.2 mg dye in each cookie. Given the similarity of the children's weights (24.7 and 25.6 kg), the children received 0.05 mg dye/kg.[3] Because concentrations of food colors in many products are considered proprietary, *e.g.,* "old family recipe" and "secret ingredients", it is difficult to compare this test solution to the concentrations found in commercially available foods. Nevertheless, it is thought to compare favorably with the artificial color concentration of commercial foodstuffs. At all other times, the recipe for the food item specifically excluded all artificial food additives and naturally occurring salicylates.

The parents of the children were responsible for providing information on two separate forms. One, a drug checklist was completed daily by parents, which included prescription and over-the-counter medications. Two, a log was provided for the parents to record their informal observations of their child's behavior. The log was open-ended so that parents were instructed to record only significant behavioral information, *e.g.,* increased motor behavior or disrupted sleep habits, rather than writing daily observations. Also included in the parents' log was a daily indication of whether the experimental food item was eaten on any given day.

[3]This research was approved by the University of Florida Human Subjects Committee. The ADI (Acceptable Daily Intake) level of FD&C Yellow #5 is 7.5 mg/kg (Noonan, 1972). The mg/kg of body weight dosage was computed from an original solution which contained approximately 29.7 grams of FD&C Yellow #5 (tartrazine) per liter. After consultation with Morley E. Russell, Associate Professor of Chemistry at Northern Illinois University, as well as representatives of the Food and Drug Administration and the food color industry, it is recommended that, due to variability of color content across manufactured solutions, the reported dosage levels may be considered accurate within a plus or minus 20% range.

Response Definition

Three dependent variables were selected. The dependent variables were specific, observable behaviors that are representative of behavioral categories that several authors (Dubey, 1976; Feingold, 1975*a,* 1976; Keogh, 1971; Knobel, 1962; Laufer and Denhoff, 1957; Marwit and Stenner, 1972) have described as being characteristic of the hyperactive behavior syndrome. These three dependent variables are operationally defined below.

1. *On task*—subject looking at the relevant assigned task stimulus, including all periods not interrupted by a minimum of 5 sec of not looking at the task stimulus. The unit of measurement for this variable is duration, *i.e.,* the number of minutes spent emitting this response.

2. *Out-of-seat*—not having posterior on the seat portion of the desk, chair, or bench. The units of measurement for this variable are frequency per minute of occurrence and duration in minutes. Frequency and duration measures were collected to determine whether changes in these behaviors were concurrent.

3. *Physical aggression*—defined as hits, slaps, swipes, kicks, bites, or scratches directed toward other people. The unit of measurement for this variable was frequency per minute of occurrence.

Procedures

Experimental design. The experimental design was a variation of the BAB design (Huck, Cormier, and Bounds, 1974) and was a BNCN with one replication for each subject (BNCNCN). These experimental conditions are summarized below:

B = K-P diet, no experimental food item
N = K-P diet, experimental food item present
C = K-P diet, experimental food item with artificial color

Double-blind. The introduction of the artificial colors occurred under double-blind conditions in which the observers, the child, and her parents were unaware of the timing of the

introduction. The double-blind condition was obtained by providing the food items in consecutively numbered containers, with only the experimenter being aware of the specific food item that contained the artificial colors. The subjects ate one cookie per day with breakfast, at approximately 7:00 to 7:30 a.m.

Following the experiment, the food items were subjected to two different types of tests to determine if the challenge item was identical in color to the neutral item. One, two groups of five adults were given cookies that they were to identify as being colored or neutral. None of the 10 raters selected the colored cookies at a rate higher than could be expected by chance. Two, sample challenge cookies were broken and placed on paper napkins for a period of 24 hr. The artificial colors did not "bleed" onto the napkins.

The observers were also kept in a "blind" condition with regard to the intent of the study. They were told that the purpose of the research was to determine whether hyperactive behaviors were consistent across settings. To this end, the school-based data they collected would be compared with data that was being collected in the home by other observers.

While the parents were not "blind" as to the intent of the study, they were unaware of its design. The experimenter informed the parents that their child would be participating in a group study, of unspecified size, in which some children would receive additives while others would not. They were not provided information about their child's "group membership". Nevertheless, both sets of parents gave their informed consent, being fully aware that their child may have been selected to be in the experimental group.

Placebo. The placebo effects of the experimental food item were monitored through the collection of data across all phases, including before the neutral food item was introduced. These data provide direct information regarding any placebo effects.

Data collection. The data were collected during daily continuous observations of the children in their normal school environment over a period of six weeks. These observations occurred either at 10:30 a.m. or 11:00 a.m. each day and lasted 30 min. Duration measures were recorded on a stopwatch. Frequency data were recorded by tally-marks on a recording sheet, which were later divided by number of minutes observed.

Data were collected by graduate students in the Department of Special Education, University of Florida. The observers received at least 12 hr preservice and inservice training in the following specific skills: (a) the operational definitions of the dependent variables, (b) accurate observations of the dependent variables, (c) the use of the stopwatch, and (d) observational techniques (Koorland and Rose, *in press*), including classroom entry behaviors, observer behavior during the observation period, and classroom exit behaviors. The observer training consisted of direct instruction, videotape viewing, and role playing. Simulated data were collected during the videotape and role-playing portions of their training.

Observer reliability. Observer reliability was impossible to obtain in the subjects' classrooms, due to a variety of externally imposed conditions that were out of the investigator's control. In lieu of *in situ* reliability checks, observer reliability was determined by comparing the observer's data against prerecorded absolute standard data on several videotapes of children in classroom settings. Reliability checks were taken in this manner on several separate occasions during the study, as well as pre- and postchecks. These data were compared using the "exact agreement method" (Repp, Deitz, Boles, Deitz, and Repp, 1976), in which artificially established 2-min intervals were scored as intervals of agreement if the observer and the standard data sheets showed the recording of the same number of responses. These 2-min intervals were established for the sole purpose of determining observer agreement because the data were actually collected continuously. The exact agreement method produces a conservative agreement percentage, especially when large time intervals are used (Repp *et al.*, 1976). Observer reliability

was determined by forming a ratio between the standard data and the observer data, regarding each dependent variable (Johnson and Bolstad, 1973). The results of the observer reliability checks were: for Observer A (a) on task: 82.4%, (b) out of seat: 94.1%, and (c) physical aggression: 100%; for Observer B (a) on task: 82.4%, (b) out of set: 88.2%, and (c) physical aggression: 100%.

RESULTS

The frequencies and durations of the dependent variables were analyzed in two ways. Visual inspection of graphic presentations of the data was used to determine the stability of data within phases, as well as the magnitude and consistency of change across phases. A randomization test was performed to determine the probability of obtaining by chance a difference between means across phases that was as large as, or larger than, those obtained by comparing the challenge data to the nonchallenge data.

Visual Inspection

Graphic displays of the data as they appeared before any mathematical summary procedures were performed are shown in Figures 1 and 2. Figure 1 displays the graphic presentation of Subject 1's data. Subject 1 received artificial colors twice during the study. An additional introduction was a dietary infraction, *i.e.,* a chocolate bar. The data from this infraction are presented in Figure 1, but were not considered when performing further data analyses. The effects of the ingestion of the artificial colors are apparent after visual inspection.

As can be seen in Figure 2, Subject 2 received artificial colors twice during the study. Dietary infractions constituted the first two nonbaseline phases, with the first infraction being the ingestion of tomatoes. The second infraction consisted of the ingestion of a commercially available poultry preparation. The latter two introductions (Phase C) were experimentally controlled. As with Subject 1, the data from the dietary infractions were included in the graphic presentation but were not considered during further data analyses. Subject 2's dietary infraction data, while appearing to represent three consecutive days' data, are actually separated by a weekend (between Days 3 and 6), during which data were not collected. The effects of the artificial colors and natural salicylates were consistent and a visual inspection of both subjects' data indicated changes of sufficient magnitude to warrant further analysis.

The dietary infractions were reported by the parents on the parent log, wherein the parents noted behavioral changes that correlated perfectly with the behavioral data obtained by the investigator. Due to the open-ended nature of the parents' log, only "significant" changes in their child's behavior were noted. In every instance of dietary infraction, the parents acquired information regarding the infraction after the observers had collected data for that day. The investigator became aware of the parent-reported infractions only when the logs were collected at the end of each week.

Randomization Test

A randomization test was performed to determine the probabilities of obtaining by chance a set of data that would equal or exceed the data values obtained during the challenge phases. An empirical probability distribution was developed by pooling all the data points for each subject and repeatedly drawing systematically the number of challenge data points, *e.g.,* four for Subject 1. Means were calculated for those data remaining in the pool, with the difference being tabulated. This procedure continued until all the possible combinations for each subject were tabulated. The probabilities of obtaining by chance differences in means equal to or greater than the difference between the challenge data and nonchallenge data are presented in Table 1.

DISCUSSION

Given the data presented above, there appeared to be a functional relationship between

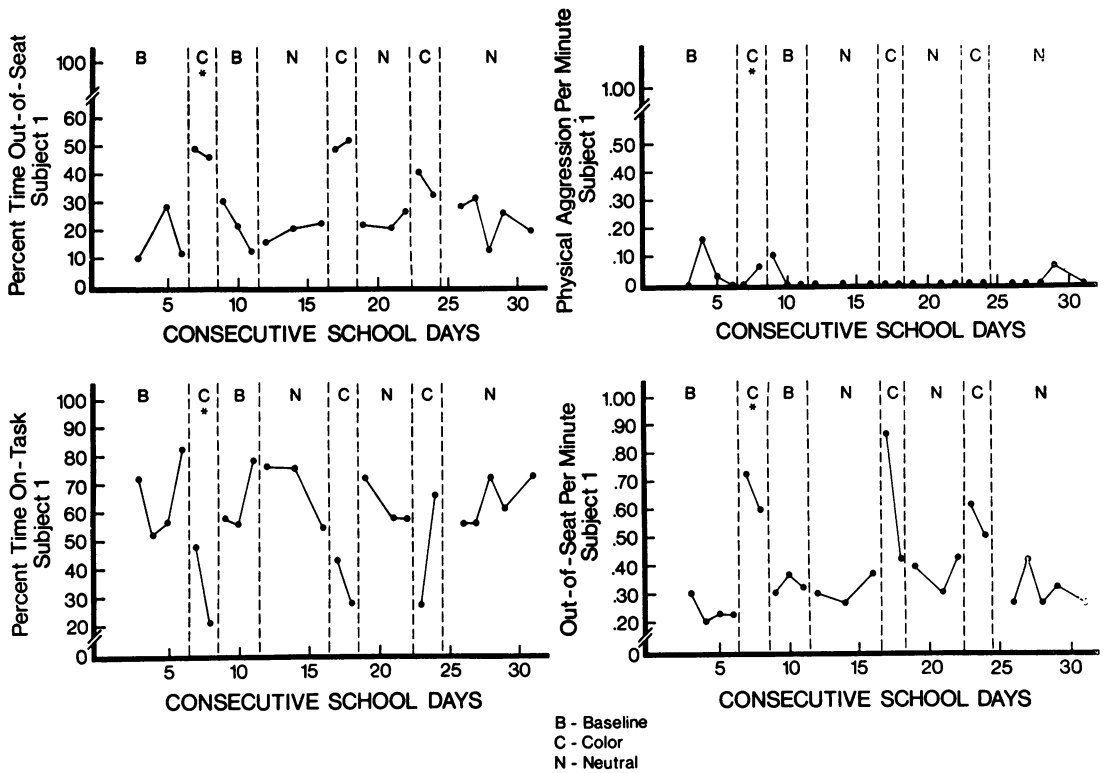

Fig. 1. A comparison of typical hyperactive responses during periods when artificial food colors were ingested and not ingested by Subject 1. *Denotes dietary infraction wherein artificial colors were not experimentally introduced, but were reportedly consumed.

the ingestion of artificial food colors and (a) an increase in the frequencies and duration of out-of-seat behavior and (b) a decrease in the duration of on-task behavior by subjects. The frequencies of physically aggressive behaviors were far less conclusive, but this inconclusiveness may be due to the extremely low rates of this behavior. While most other studies have focused on comparisons of behavioral effects in the presence of two different diets, this study focused on the manipulation of a single, critical variable, *i.e.*, artificial food colors, and the subsequent investigation of the frequency and/or duration of selected behavior. Further, there was a selection of subjects who had been on the K-P diet for at least four months who might be expected to be more likely to respond to a challenge diet than a randomly selected group of hyperactive children.

There were at least two problems that appeared during the study. While it was not felt that either presented a serious threat to the findings of the study, the reader should be aware of them. The first problem was unique to Subject 2 and was caused by her school's environment. Subject 2 attended a private school that adhered to an "open" school philosophy. Many times

Table 1

Probabilities of chance occurrence of differences equalling or exceeding challenge and nonchallenge phases difference.

	Probability		
Subjects	*Out of Seat per Minute*	*Per cent Time* Out of Seat*	*Per cent Time on Task*
Subject 1	0.0004	0.0001	0.0015
Subject 2	0 0090	0.0045	0.0045

*The correlation between out of seat per minute and per cent time out of seat was 0.72 for Subject 1 and 0.37 for Subject 2.

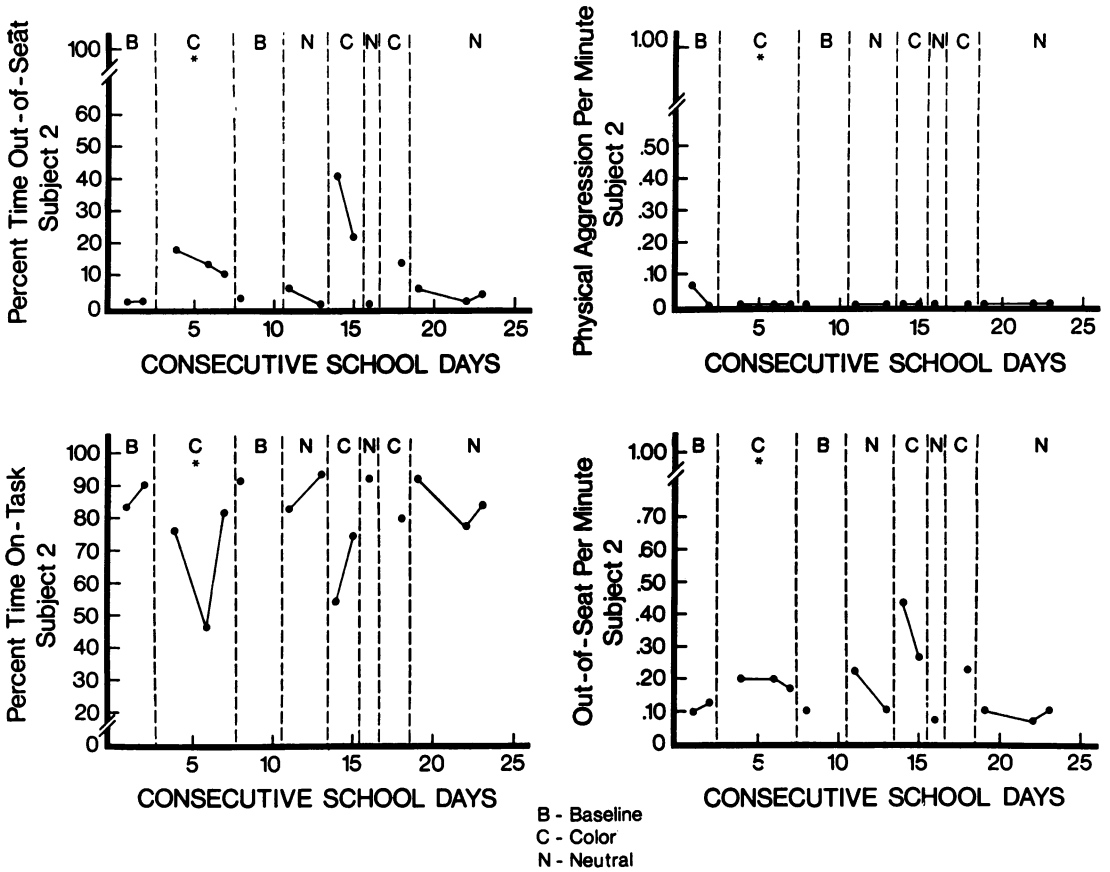

Fig. 2. A comparison of typical hyperactive responses during periods when artificial food colors were ingested and not ingested by Subject 2. *Denotes dietary infraction wherein artificial colors were not experimentally introduced, but were reportedly consumed.

classes were cancelled so that the children would be free to participate in enrichment activities, such as serving lunch to members of the community. This school policy led to a reduced number of observation periods available for data collection which, in turn, led to fewer data points being available for analysis. As a result, preplanned experimental interventions occasionally occurred before sufficient data were obtained regarding the steady-state condition of the nontreatment phase. In spite of this problem and the resultant loss of data, the accumulated data allowed conclusions to be drawn about the treatment effects. In future studies, this problem could best be avoided by either selecting subjects that were in a more traditional school environment or by selecting dependent measures that are more amenable to a less structured setting.

The second problem concerned the instances when the children did not adhere to the dietary restrictions of the K-P diet. Fortunately, these dietary infractions were few and the dependent measures were sensitive enough to demonstrate a change in the subjects' behavior when the infractions occurred. These changes would have remained unexplained, however, had the parents not been responsible for keeping a daily log in which they noted the infractions after the day's data were collected. This problem can best be overcome in future studies by having more control over the subjects' dietary intake or by requiring that parents furnish supplementary di-

etary and behavioral information, as was done in this study.

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