ABSTRACT. A double-blind crossover trial involving a
c control diet and a diet eliminating artificial flavors, colors,
and natural salicylates as recommended by Feingold was
conducted on 15 hyperkinetic children. Teachers and
parents observed the children for one month prior to
treatment, using standardized rating scales. Both parents and
teachers reported fewer hyperkinetic symptoms on the K-P
diet as compared to the pretreatment baseline. The teachers
noted a highly significant reduction of symptoms on the K-P
diet as compared to the control diet but the parents did not.
The control diet ratings did not differ from the baseline
period ratings for either parents or teachers.

It is concluded that the K-P diet may reduce hyperkinetic
symptoms, though this result is put forth with caution in
view of several features inherent in the present study which
need further evaluation, including objective measures of
change, manipulation of the independent variable, and
reducing the independent variable to more specific compo-
nents. Pediatrics, 58:154-166. 1976, FOOD ADDITIVES, HYPER-
ACTIVITY.

In June 1973 a preliminary report was
presented by Feingold in which it was proposed
that hyperkinesis in childhood is associated with
the ingestion of salicylates, of compounds which
cross-react with salicylates, and with common
"food additives," i.e., artificial flavors and colors.
Other oral presentations, including a popular
book and testimony in the Congressional Record,
have served to popularize the hypothesis that this
common childhood behavior disorder may be
caused by artificial flavors and colors in food.

The medical literature shows that urticaria and
asthma can be induced by food additives and
dyes, and that strong allergic reactions occur to
some dyes in patients with aspirin hypersensitiv-
ity. Feingold noted that an adult patient with
aspirin hypersensitivity showed remission of
psychiatric disturbances when the patient was
placed on a diet free of natural salicylates, food
colors, and artificial flavors. Because of the
supposed cross-reactivity of salicylates and dyes
(e specially tartrazine, the yellow FD&C #5 dye),
Feingold treated hyperactive children with a diet
free of so-called natural salicylates (found in many
fruits) and all artificial colors and flavors.

A number of criticisms were immediately
raised against Feingold's claims (many of these
are summarized by the National Advisory
Committee on Hyperkinesis and Food Addi-
TABLE I

<table>
<thead>
<tr>
<th>Referral</th>
<th>Psychiatric Examination</th>
<th>Diagnosis</th>
<th>Diet Program Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 dropped out prior to exam</td>
<td>7 no significant pathology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>32 received exam</td>
<td>6 overanxious reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 mental retardation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>1 withdrawal pattern</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>17 hyperactive reaction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>37 children</td>
<td>2 unable to follow program</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>15 completed entire program</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

...tives). Included among the criticisms are that: (1) the patients reported upon were not described by any standard methods, nomenclature, or measurements; (2) no controls were utilized to compare changes against those in the children treated with the elimination diet (hereinafter referred to as the K-P diet); (3) no objective measures of change were employed; (4) the observer of change was not blind to the treatment being evaluated and had a vested interest in confirming the hypothesis; (5) alternative explanations based on commonly accepted placebo phenomena were not considered; (6) no measures of the actual dietary habits of the patients were presented to rule out the possibility of unintended harmful dietary effects or that changes in the diet other than artificial flavors and colors could cause the effect; and (7) claims of percentage improvement varied from one presentation to another, and no hard statistical numbers were ever employed. In short, the claims were strictly impressionistic, anecdotal, and lacking in objective evidence.

METHOD

Subjects

In order to be eligible for the study, children had to be between the ages of 6 years and 12 years 11 months, and have a low-normal or higher IQ. The children were examined by a child psychiatrist who utilized a standardized examination and rating scale, and had to agree that the child fit the criteria for hyperkinetic reaction of childhood (308.0 of the APA DSM II) based upon the medical and social history, parent and teacher symptom ratings, and the psychiatric rating scale. Demographic, history, physical and mental status examination, neurologic evaluation, and rating scales were all forms adopted by the National Institute of Mental Health Psychopharmacology Research Branch for conducting scientific trials in pediatric populations with drugs and related types of studies. The purpose of these instruments was to record in an objective and standardized manner the entire set of data available on each child.

Central to this study was the use of two symptom rating scales filled out by parents and teachers. The teacher scale is a 39-item list of common behavioral problems found in school-age children. The parent scale is a 93-item symptom list covering a wide variety of behavioral reactions in children. Both scales have been demonstrated to have satisfactory reliability and validity. Most of the present report will deal with data from a ten-item subscale ("hyperkinesis index") which measures the cardinal symptoms of the hyperkinetic syndrome. The ten items are identical for parents and teachers. Since each item is scored 0, 1, 2, or 3, scores may range from zero through 30. It should be emphasized that these scales do not diagnose hyperkinesis; diagnosis is a complex judgment based upon all of the data available to the clinician; but studies have shown that a cut-off score of 15 on the ten-item scale is an efficient discriminator between diagnosed patients and classroom controls, and that the...
scale is sensitive to change brought about by other therapies.

Table I shows that, of 37 children referred for the study, 15 completed the entire program, with the other children largely having dropped out prior to the actual start of the experiment itself.

In addition to symptoms of moderate to severe degree, the children had to have a history of at least two years' duration of the major symptoms of the hyperkinetic syndrome. Most had in fact been seen as problems by parents from a relatively early age.

The mean age of the obtained sample was 105.4 months (± 18.35 months).

**Design**

Prior to treatment parents and teachers independently completed semiweekly questionnaires regarding the child's current behavior, utilizing the abbreviated ten-item symptom scale ("pretreatment period"). These measures were collected for two weeks, and, if the child was on medication, the medication was then discontinued and the ratings continued for another two weeks ("baseline period"). If the child was not on medication, the ratings were similarly collected for the two-week baseline period.

At this point the children were randomly assigned to either the experimental (K-P) diet or a control diet. Parents and teachers continued to observe the children with weekly symptom ratings for four weeks. At this point the parents were interviewed by the principal investigator, the school reports were examined, and a judgment was made without knowledge of the diet condition as to overall global improvement, using the Clinical Global Impressions (CGI) scale. The same procedure was then followed for the next one month while the child was on the alternative diet.

**Experimental and Control Diets**

Prior to the start of the diets the parents met with the nutritionist who explained the particular diet the child was assigned to, giving the parent a list of items to be excluded, as well as a list of acceptable items. Procedures regarding compliance were discussed and general matters regarding food selection, preparation, and recording were outlined.

The control diet was devised with the following criteria in mind: (1) The diet should involve the same degree of time in preparation, shopping, and monitoring as the K-P diet; (2) the items in the control diet should be drawn from the same food groupings and categories where possible as the K-P diet; (3) the two diets should be nonoverlapping, i.e., items on the control diet should allow for eating of items excluded on the K-P diet, and **vice versa**; (4) the control diet should be as palatable and easy to follow as the K-P diet; and (5) the control diet should appear plausible and reasonable as a possibly effective treatment.

With regard to this last point, care was taken in the instructions to parents to make each diet seem worthwhile and as likely to provide benefit as the experimental diet. At no times were the words K-P, Feingold diet, experimental diet, or control diet used. Instead, parents were told that their child would try both diets, that either might produce improvement, and that it was necessary to have both diets to compare them with each other. They were told we were studying dietary factors in behavior problems, and that there might be a number of separate food items that could cause behavioral difficulties, and that only by systematically comparing different approaches could we be sure which diet(s) might be effective.
for their child. The two exclusion diets are provided in the Appendix.

### Assessment of Prior Dietary Status

A nutritionist collected dietary information on each child using a dietary questionnaire, 24-hour recall, and food frequency measure.

**Dietary Questionnaire**—Parents supplied information pertaining to the food habits of their child: number of meals and snacks per day, foods eaten for meals and snacks, meal times, food likes and dislikes, problems at the meal table, food allergies, and other medical complications.

**Twenty-four-Hour Recall**—Parents were asked to recall everything consumed by the child during the previous day. The time, place, a description of preparation, and judged amount for each food item were also recorded. Food models were used to assist in assessing the amount.

**Food Frequency Measure**—Given a list of foods, parents were asked to indicate the number of times or frequency each food is usually consumed by their child during a “typical” week.

The 24-hour recall, frequency, and questionnaire were used together to determine the adequacy of prior dietary habits of the children.\(^8\)-\(^12\) Data from recall and frequency were grouped according to the basic four food groups and, with the data from the questionnaire, judged for adequacy and appropriate dietary patterns which would be conducive to sound nutritional practices. Problems or poor eating habits were discussed with the parents.

### Dietary Compliance and Nutrient Monitoring

During the 12-week program, parents kept diet records, recording everything their child consumed, for six days each month. The time, place, food, a detailed description and the method of preparation, and the weighed or measured amount consumed were to be recorded. Three- to seven-day diet records have been shown to give reliable dietary information for nutrient analysis.\(^8\)-\(^12\) In addition, parents maintained a list of infractions that occurred during each of the diet periods, and completed a dietary degree of difficulty questionnaire at the conclusion of each diet period to assess the comparability of the difficulty in following the control and experimental diets.

### Determination of Nutrient Intake

Diet records were coded using the USDA Home and Garden Handbook,\(^13\) and analyzed with the Diet Research Program for calories, protein, carbohydrate, fat, calcium, iron, vitamin A, thiamin, riboflavin, niacin, and vitamin C. Averages for the nutrients were calculated for each individual based on the six-day diet records (representing one month) for the three-month periods, i.e., three sets of averages for each individual. Group averages were tabulated for each one-month period.

The computed nutrient intake data reported the contribution in gram units and percentage by meals (breakfast, lunch, dinner, and snack) for individuals and group. Percentages of the Recommended Dietary Allowances (RDA) were calculated for breakfast, lunch, dinner, and snack,\(^14\) total for each individual average intake, and for the group intake during baseline, K-P diet, and control diet.

### Recommended Dietary Allowances

The RDAs are the levels of intake of essential nutrients considered, in the judgment of the Food and Nutrition Board on the basis of available scientific knowledge, to be adequate to meet the known nutritional needs of practically all healthy persons.

In order to meet these needs, the levels of nutrients listed in the RDA have an added margin of safety to cover individual variation. The RDA was established as a standard for populations. When dealing with individuals or small groups, two thirds of the RDA is, by convention, taken as a cut-off point in assessing adequate or poor diets.

Levels of nutrients listed by the RDA have been categorized by sex and age groupings. Thus, the percentages of the RDA tabulated from the dietary records in the present study have incorporated both sex and age of the subjects studied.

### RESULTS

#### Clinical Global Impressions

Table II shows the principal investigator’s judgment of improvement based upon interview with the parents, the parent symptom ratings, and the teachers’ symptom ratings. The project coordinator met with parents prior to each of the two final interviews following each diet, and reminded parents not to mention any specific foods involved in the diet. The principal investigator also reminded the parents at the start of the interview not to reveal which diet their child had been on. Then a semistructured interview was conducted in which the parents’ view of overall changes, somatic changes, peer and family changes, the child’s reaction to the diets, and any
knowledge of changes in school were elicited. At this point, if the interview was following the first diet, regardless of what changes the parent noted or failed to find, the parent was strongly exhorted to give the other diet a fair try, to be scrupulous in following and monitoring it, and to encourage the child to follow the new diet. If the child had improved, parents were told he conceivably could improve even more on the second diet, and, if unimproved, the second diet might offer hope of more change. In this way an effort was made to have the second diet uninfluenced by results from the first diet.

Table II shows that significantly more of the K-P diet trials were rated as improved than the control diet, using a Wilcoxon signed ranks test ($P < .01$).

**Teacher and Parent Ratings**—Table III presents the summary of hyperkinesis index scores for the two raters, together with a summary of statistical analyses. Table IV presents hyperkinesis index scores broken down by the order in which each treatment was received. The data indicate that the K-P diet is significantly more effective than the control diet for the teachers ($P < .005$), but not for the parents, while for both teachers and parents the K-P diet is significantly better than the baseline period ($P < .05$), whereas the control diet does not differ from the baseline.

Figure 1 shows that both parents and teachers note approximately a 15% reduction in symptoms on the K-P diet, relative to a 3% or smaller reduction on the control diet. Figure 2 shows the same data broken down by order of treatment, where it may be seen that the bulk of the improvement on the K-P diet was noted when it followed the control diet (however, the order by treatment interaction was nonsignificant).

Figures 3 and 4 show the average hyperkinesis index scores for all patients across the 12 weeks of the study, for parents and teachers, respectively. Figures 5 and 6 present data from two individual subjects which illustrate the remarkably close agreement between changes in behavior noted by parents and teachers at different points in the experiment. The congruence of these ratings provides assurance that the fluctuations are probably reflecting real behavioral changes and not idiosyncratic rating errors or unreliability of the scales.

Table V presents the analyses of variance summary table for the parent and teacher index scores and baseline-corrected (difference) scores. In the latter procedure, the mean of the baseline scores was subtracted from the mean of the scores for each diet period to correct for initial starting level of symptoms prior to treatment.
Fig. 3. Parent symptom report for 15 patients at pretreatment, baseline (off medication), control, and K-P diet conditions. (Note: each child had both diets assigned in random order.) Lower score indicates improvement on hyperkinisis index.

Fig. 4. Teacher symptom report for 15 patients at pretreatment, baseline (off medication), control, and K-P diet conditions. (Note: each child had both diets assigned in random order.) Lower score indicates improvement on hyperkinisis index.
Prior Dietary Habits

Inspection of the 24-hour recall, dietary questionnaire, and food frequency measure indicated profound individual differences in the 15 children participating in the study. Two children had dietary habits which could be considered poor in most respects and which would be likely to worsen on restrictive diets without close supervision: one child had a good appetite, but did not like and rarely ate fruits and vegetables—this child’s diet consisted mainly of cereal with milk, crackers and cheese, and bread; the second child was reported to have a poor appetite and be a picky eater who would not eat anything he did not like, particularly vegetables—he would not eat anything if one of his food dislikes was among the foods served.

Six children had some dietary habits which, though presently not a problem, could develop in the future into various forms of malnutrition. Two of these six children were reported by the mother to be overweight, and four were “picky” eaters and usually avoided foods they did not like—notably fruits and vegetables.

The remaining seven children were reported to be good eaters with no apparent nutritional problems.

Nutrient Analyses of Diet Records

Pretreatment-Baseline—Nutrient analysis from diet records kept during pretreatment-baseline seemed to indicate that the nutrient intake for the group was good to adequate. Table VI reveals the percentage of the RDA of calories and eight nutrients for the group’s average period intake. During this period, all nutrients exceeded 66% of the RDA with protein, calcium, vitamin A, riboflavin, and vitamin C exceeding 100% of the RDA. However, large individual variations existed, as can be seen from the magnitude of the standard deviations also presented in Table VI. Thus, although there were no apparent nutrient deficiencies in the nutrients analyzed, the possibility that certain individuals may have undesirable intakes does exist. (Note: the nature of the RDA is such that evaluation of individuals should not be made on analysis of intake alone [e.g., individual needs vary and may not compare similarly to a standard]; for this reason individual comparisons will not be discussed further).
TABLE V
ANALYSIS OF VARIANCE OF PARENT AND TEACHER INDEX SCORES AND BASELINE-CORRECTED SCORES

<table>
<thead>
<tr>
<th>Source of Variance</th>
<th>df</th>
<th>Parents</th>
<th></th>
<th>Teachers</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Between-subject</td>
<td>14</td>
<td>3.016</td>
<td>1.021</td>
<td>0.183</td>
<td>3.456</td>
</tr>
<tr>
<td>Order</td>
<td>1</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Within-subject</td>
<td>15</td>
<td>4.748*</td>
<td>2.633</td>
<td>6.834*</td>
<td>13.464†</td>
</tr>
<tr>
<td>Treatments</td>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order X treatment</td>
<td>1</td>
<td>2.729</td>
<td>2.279</td>
<td>4.048</td>
<td>0.565</td>
</tr>
<tr>
<td>Error</td>
<td>13</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*P < .05.
†P < .005.

Adequacy of Intake on Trial Diets—Nutrient intake during K-P and control diet periods are also presented in Table VI. As was the case with the pretreatment-baseline period, the nutritional intake during both trial diets was good to adequate, with all nutrients exceeding 66% of the RDA.

Treatment Differences—Statistical analyses comparing nutritional intake while following the K-P diet versus pretreatment-baseline indicated lower calcium, riboflavin, and vitamin C on the K-P diet (similar trends were observed with all other nutrients with the exception of niacin). Comparisons between K-P and control diets revealed only two statistically significant differences: carbohydrate intake was less on the K-P diet, but niacin intake was greater. No differences were observed between the control diet and pretreatment-baseline.

Contribution of Breakfast—Reports have been made that the consumption of breakfast has a direct bearing on a person’s activities during the morning. It is generally suggested that breakfast supply one third of the days calories and nutrients. Table VII shows the percentage contribution made by selected nutrients to breakfast during the three periods. For this group, most nutrients are considerably less than 33%. Apparently breakfast was a small meal consisting of dairy food, grain food, and a source of vitamin C. The K-P diet severely reduced the vitamin C sources taken at breakfast.

DIETARY DEGREE OF DIFFICULTY AND DIETARY COMPLIANCE MEASURES

The dietary degree of difficulty questionnaires were converted to numerical scores and averaged for each diet (possible score of 0 to 25, 25 being very difficult to follow). The mean dietary degree of difficulty score, as reported by parents, was 8.27 for the control diet and 9.53 for the K-P diet, indicating that the K-P diet was perceived to be slightly more difficult to follow than the control diet.

The mean number of infractions reported per week for each of the diet periods was 1.50 for the control diet and 1.33 for the K-P diet, indicating close adherence to both diets. Viewed in conjunction with the dietary degree of difficulty questionnaire results, these data indicate a high degree of correspondence between diets on measures of overall dietary difficulty.

DISCUSSION

The results of this study strongly suggest that a diet free of most natural salicylates, artificial flavors, and artificial colors reduces the perceived hyperactivity of some children suffering from hyperkinetic impulse disorder. Teachers who observed the children over a 12-week period without knowledge of when the child started his diet and without knowledge of the fact that there were two diets which were employed, rated the children as less hyperactive while the children were on the diet recommended by Feingold. The difference obtained between the ratings when the children were on the K-P diet and when they were on the control diet would have occurred by chance only 5 in 1,000 times. Similarly, the teachers rated the children as significantly improved over the baseline period on the K-P diet but not while on the control diet.

The results from ratings by parents are slightly different in that parents did not detect a differ-
TABLE VI
Nutrient Intake

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Pretreatment-Baseline</th>
<th>Control</th>
<th>K-P</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% of RDA</td>
<td>SD</td>
<td>% of RDA</td>
</tr>
<tr>
<td>Calories</td>
<td>80.4</td>
<td>24.8</td>
<td>82.1</td>
</tr>
<tr>
<td>Protein</td>
<td>204.7</td>
<td>62.3</td>
<td>206.3</td>
</tr>
<tr>
<td>Fat (gm)</td>
<td>79.5</td>
<td>27.4</td>
<td>75.5</td>
</tr>
<tr>
<td>CHO (gm)</td>
<td>228.5</td>
<td>68.9</td>
<td>242.6</td>
</tr>
<tr>
<td>Calcium</td>
<td>127.9</td>
<td>59.1</td>
<td>120.9</td>
</tr>
<tr>
<td>Iron</td>
<td>99.3</td>
<td>35.5</td>
<td>99.6</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>128.5</td>
<td>137.7</td>
<td>123.7</td>
</tr>
<tr>
<td>Thiamin</td>
<td>95.8</td>
<td>43.5</td>
<td>91.9</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>157.5</td>
<td>65.0</td>
<td>151.1</td>
</tr>
<tr>
<td>Niacin</td>
<td>84.2</td>
<td>38.6</td>
<td>78.3</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>221.2</td>
<td>182.4</td>
<td>239.5</td>
</tr>
</tbody>
</table>

ence in behavior between the K-P and control diets, although they noted the effect as compared with the baseline period. The fact that the parents did not detect a difference between the two special diets could mean that subjective factors associated with a change in diet of any kind mask whatever therapeutic effect might be present in the K-P diet. This interpretation is supported by the fact that whereas the baseline means for parents and teachers are very similar (16.3 and 16.5, respectively), the control diet means are somewhat different (15.7 vs. 17.2).

Another possibility is that the children are in fact not noticeably different at home, but are observed to respond better in a more structured situation where task expectations are clearly established, and where the teacher has a long baseline of comparison of the same children over many months. Similar findings of weak or marginal effects on behavior as rated by parents in contrast to clear effects noted by teachers has been found in drug studies with hyperkinetic children. It has been generally assumed that the demands on the child's attention and goal-oriented behavior are greater in the classroom, and therefore that any improvements in these areas will be more evident.

It was found in this study that the bulk of the positive changes noted by both parents and

Fig. 6. Graph showing individual case over 12-week treatment period. Lower score indicates improvement on hyperkinesis index.
mental diet. Such an effect could be due either to the fact that the more responsive children happened, by chance, to fall into the sequence involving the control diet first; or the results could be due to the fact that the observers have a clearer basis on which to judge improvement after the control diet has failed to produce any noticeable changes. Although this finding weakens the argument that the obtained differences are reflecting the K-P diet rather than some nonspecific factors, it should be noted that such findings are quite common in psychopharmacologic research involving crossover designs. For example, in a double-blind crossover study involving dextroamphetamine and hyperkinetics, the results shown in Table VIII were obtained on the teacher questionnaire (using a somewhat different set of items). It is clear that the drug effect is much more pronounced in the group which received placebo first. Thus, even when objective measures substantiate improvement in behavioral functioning in the first period of evaluation, the teachers may be less aware of the improvement until they see the lack of improvement on another treatment.

Inspection of the individual ratings of children in the study shows that only four or five of the children were seen as improved by both parents and teachers. This fact is apparent from inspection of the clinical global impressions which took into account both parent and teacher effects. The findings suggest that there may be a small subgroup of hyperkinetic children who are showing the changes induced by the K-P diet. Further research will be required to determine if such children are physiologically different from non-improvers.

It would be hazardous at this point to draw too many conclusions from this experiment, given the small size of the sample and the lack of complete consistency in the results. Any thoughtful observer will understand that a major intervention into dietary habits of a family will produce behavioral effects, regardless of the specific diets, a phenomenon well understood in the management of such conditions as juvenile diabetes. The results would have been substantially clarified if it had been possible to have objective measures of function uncontaminated by the psychological factors which are bound to operate in the family-school-child system. At this point the results point to the need for considerable further investigation.

A matter of some concern is the extent to which the K-P diet reduced the nutrient intake of the children. As a group the children still had intakes above the RDA, but dietary problems could arise for certain individuals over a prolonged period of time. Dietary counseling and/or careful monitoring by a physician should be considered until the long-term effects of the diet can be evaluated more thoroughly. It was particularly notable that the children as a whole were poor in terms of the contribution of breakfast to the total RDA of nutrient intake, and the fact that vitamin C is substantially reduced on the K-P diet makes the role of breakfast potentially more of a problem in this group of children.

**Ethical Considerations**

Whenever an unproven treatment for children is undertaken for the first time, difficult issues arise in the ethics of experimentation which affect the manner in which the trial is conducted. In the present study two issues were addressed which partially determined the nature of the experiment: the use of a “challenge” diet to contrast with the experimental diet; and the use of essentially a placebo comparison. The very nature of the question addressed was whether the results of

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>Pretreatment Baseline (%)</th>
<th>Control Diet (%)</th>
<th>K-P Diet (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calories</td>
<td>17</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>Protein</td>
<td>15</td>
<td>14</td>
<td>14</td>
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<tr>
<td>Calcium</td>
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<td>20</td>
<td>23</td>
</tr>
<tr>
<td>Iron</td>
<td>17</td>
<td>18</td>
<td>15</td>
</tr>
<tr>
<td>Vitamin A</td>
<td>14</td>
<td>15</td>
<td>11</td>
</tr>
<tr>
<td>Thiamin</td>
<td>22</td>
<td>26</td>
<td>20</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>20</td>
<td>21</td>
<td>21</td>
</tr>
<tr>
<td>Niacin</td>
<td>11</td>
<td>15</td>
<td>10</td>
</tr>
<tr>
<td>Vitamin C</td>
<td>30</td>
<td>31</td>
<td>18</td>
</tr>
</tbody>
</table>

**Table VIII**

**Crossover-Design Teacher Questionnaire Results** (Conners et al.15)

<table>
<thead>
<tr>
<th>Order of Treatment</th>
<th>No.</th>
<th>Pretreatment</th>
<th>Dexedrine</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug first</td>
<td>28</td>
<td>29.1</td>
<td>20.6</td>
<td>26.0</td>
</tr>
<tr>
<td>Placebo first</td>
<td>24</td>
<td>22.6</td>
<td>12.8</td>
<td>21.2</td>
</tr>
<tr>
<td>Combined</td>
<td>52</td>
<td>25.6</td>
<td>16.7</td>
<td>23.6</td>
</tr>
</tbody>
</table>
Feingold might be simply attributable to nonspecific factors, including the placebo effect of engaging in a new dietary procedure. The first issue, that of using a diet containing putatively harmful substances (actually the child's regular diet with the exception of changes introduced in order to control for nonspecific effects such as extra time in food preparation, reading labels, admonishing the child, engaging the child in a joint effort, etc.), has been addressed by the Nutrition Foundation, whose task force report on the matter stated:

The subject and the family will benefit from participation in such experiments whether:

(a) a challenge material can be incriminated, and thereby the opportunity of avoidance of a specific offending material results; or
(b) there is confirmed in a well controlled setting the value of the restricted diet as opposed to other factors; or
(c) no benefit occurs and thereby a troublesome exclusion diet of indefinite duration is avoided.

Interdiction of challenge feeding may occur at any point it is considered to be indicated. Feingold reports that there is rapid recovery (upon reestablishing his regimen) from the exacerbations that children on his regimen experience upon breaking of compliance.4

We would fully concur with the logic of this argument. However, the second issue of not telling the parents that the control diet is probably worthless raises an important issue of deception in such experiments. The fact that Feingold's claims had been widely publicized at the time of the experiment obviously precluded the possibility of informing the parents that a "placebo" would be involved in one of the trials. (That is, a usual procedure would be to tell the parent that a placebo would be used at some time, but not to inform them at which particular time, thus maintaining the blind of the experiment.) In this case the parents would clearly recognize which was the "real" diet and which was not, thus vitiating the purpose of the control diet.

Our method of handling this problem was to inform the parents that both diets were experimental, that neither had been proven to be effective, and that either might cause improvement. In any case, we assured them that having the two diets would better enable us to tell for that child whether one diet was worth continuing and more effective. All of these statements were true and, we believe, not misleading. In actual fact it was precisely the difference between the two diets that determined the course of action with regard to continuing the child on the diet or returning him to another diet. One mother whose child showed a strong placebo improvement on the control diet (or possibly a spontaneous improvement unrelated to diet) was convinced the control diet was better and wished to continue. We informed her that the diet had not proven effective with other children and was probably related to improvement only insofar as nonspecific factors of food preparation, shopping, etc., affected her relationship with the child. In short, we believe that the use of a placebo control is justified if it directly relates to clinical decisions affecting the benefit of the patient. In order for this to be true it is almost mandatory that the child be exposed both to the placebo and the active treatment, that is, to use some sort of crossover or within-subject design. Our own skepticism initially about the food-additive-free diet led us to be fully comfortable with the assertion that both diets were unproven and there was as yet no evidence that one was actually better than another, this being, of course the reason for the trial. Such considerations may lead many more future placebo-controlled studies to use a single-case, within-subject design so that knowledge of the placebo effect is directly relevant to the care of the individual patient, not just "children in general" or hypothetical unborn generations of children. No matter how relevant such populations are for medicine and science in general, it is our opinion that the experiment should resort to these necessary forms of experimental controls in such a manner as to bear on the particular patient at hand.

RECOMMENDATIONS

The K-P diet produced consistently poorer nutrient intake than the control diet or baseline period, especially for vitamin C. However, the effects were not nutritionally serious inasmuch as the children were still having nutrient intake above the RDA. Long-term consequences of the diet would have to be followed with caution.

The following recommendations are made:

1. Further studies employing objective measures, challenge testing of the putative harmful agents, and other controls are required before definitive recommendations are made on any large-scale basis.

2. Careful monitoring of nutritional status and dietary habits are recommended before children are placed on the K-P diet.

3. Food intake at breakfast needs special care in hyperkinetic children.

4. Biochemical and clinical testing to determine the possible mechanisms involved should be undertaken, especially on clearly defined subjects who improve on the K-P diet, but further validation of the basic clinical effects is still required.

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APPENDIX

K-P Diet
These foods are to be eliminated from diet.

Cereals and Grain Products
All breakfast cereals with artificial colors or flavors, etc., with artificial flavors or colors (i.e., from bakery)
Manufactured pie crusts
Frozen baked mixes
Prepared poultry stuffing

Fruits
Almonds
Apples
Apricots
Berries—blackberries, blueberries, boysenberries, gooseberries, raspberries, strawberries
Cherries
Currents—grapes and raisins or any products made of grapes, (e.g., wine, wine vinegar, jellies)
Nectarines
Oranges
Peaches

Vegetables
Tomatoes and all tomato products
Cucumbers (pickles)

Protein Sources
Meats
Bologna, luncheon meats*
Salami
Frankfurters
Sausage*
Meat loaf*
Ham, bacon, pork*
All barbecued types of chicken
All turkey prepared with basting, called “self-basting”
Frozen fish fillets that are dyed or flavored—fish sticks or patties, dyed or flavored

Dairy Products
Manufactured ice cream or ice milk unless label specifies no synthetic coloring or flavoring
Colored cheeses (i.e., processed or yellow or orange)
All instant breakfast drinks and preparations
Flavored yogurt
Prepared chocolate milk
Colored butter

Beverages
Cider
Wine
Beer
Diet drinks
Tea, hot or cold
All carbonated beverages except 7-UP

Miscellaneous
Sherberts, ices, gelatin, junkets, puddings with artificial flavor or coloring
Powdered pudding, jello, and drink mixes
All desert mixes
All manufactured candy—hard or soft
Oleomargarine
Prepared mustard
All mint-flavored and wintergreen-flavored items
Gum
Oil of wintergreen
Cloves
Jam or jellies made with artificial colors or flavors and