Randomized Clinical Trial of Behavioral Intervention and Nutrition Education to Improve Caloric Intake and Weight in Children With Cystic Fibrosis

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Objective: To evaluate the efficacy of a behavioral plus nutrition education intervention, Be In CHARGE!, compared with that of a nutrition education intervention alone on caloric intake and weight gain in children with cystic fibrosis and pancreatic insufficiency.

Design: Randomized controlled trial.

Setting: Cystic fibrosis centers in the eastern, midwestern, and southern United States.

Participants: Seventy-nine children aged 4 to 12 years below the 40th percentile for weight for age were recruited. Sixty-seven completed the intervention and 59 completed a 24-month follow-up assessment.

Intervention: Comparison of a behavioral plus nutrition education intervention with a nutrition education intervention alone.

Main Outcome Measures: Primary outcomes were changes from pretreatment to posttreatment in caloric intake and weight gain. Secondary outcomes were changes from pretreatment to posttreatment in percentage of the estimated energy requirement and body mass index z score. These outcomes were also examined 24 months posttreatment.

Results: After treatment, the behavioral plus nutrition education intervention as compared with the nutrition education intervention alone had a statistically greater average increase on the primary and secondary outcomes of caloric intake (mean, 872 vs 489 cal/d, respectively), percentage of the estimated energy requirement (mean, 148% vs 127%, respectively), weight gain (mean, 1.47 vs 0.92 kg, respectively), and body mass index z score (0.38 vs 0.18, respectively). At the 24-month follow-up, children in both conditions maintained an estimated energy requirement of around 120% and did not significantly differ on any outcomes.

Conclusions: A behavioral plus nutrition education intervention was more effective than a nutrition education intervention alone at increasing dietary intake and weight over a 9-week period. However, across the 24-month follow-up, both treatments achieved similar outcomes.

Trial Registration: clinicaltrials.gov Identifier: NCT00006169

Analyzed at 18 mo (1 dropped
participant randomized to a behavioral plus nutrition education intervention)

gery requirement (EER) and body mass index (BMI)

Secondary outcomes were percentage of the estimated en-
pretreatment to posttreatment in caloric intake and weight.

Figure 1

Figure 1. Consolidated Standards of Reporting Trials flowchart of participants randomized to a behavioral plus nutrition education intervention or a nutrition education intervention and assessed at each time point. FEV, indicates forced expiratory volume in the first second of expiration; CF, cystic fibrosis.

cation intervention with a nutrition education intervention alone (NE). Primary outcomes were differences from pretreatment to posttreatment in caloric intake and weight. Secondary outcomes were percentage of the estimated energy requirement (EER) and body mass index (BMI) z score (BMI is calculated as weight in kilograms divided by height in meters squared). We hypothesized that children receiving the behavioral plus nutrition education intervention would have a significantly greater increase in these outcomes than children receiving NE. To ex-
amine long-term effects of this intervention, participants were followed up for 2 years posttreatment. We hypothesized that children receiving the behavioral plus nutrition education intervention would have a significantly greater increase from pretreatment through the 24-month follow-up on these outcomes.

**METHODS**

**PARTICIPANTS**

Subjects were recruited from 5 CF centers located in the eastern, midwestern, and southern United States. The study was approved by the institutional review board at each medical center. Written informed consent and assent were obtained. Inclusion criteria were as follows: aged 4 to 12 years; diagnosis of CF by sweat test; pancreatic insufficiency; and weight for age or for height at or lower than the 40th percentile. Exclusion criteria included the following: having a medical condition that would affect growth or diet (eg, type 1 diabetes mellitus); being prescribed medication that would affect growth or appetite (eg, steroids); having significant developmental delay or a mental health diagnosis of depression or psychosis (parent or child); having a sputum culture positive for Burkholderia cepacia; having a forced expiratory volume in the first second of expiration (FEV) less than 40% of predicted; or receiving enteral or parenteral nutrition.

**RECRUITMENT AND RANDOMIZATION**

Medical records of children aged 4 to 12 years were reviewed for inclusion and exclusion criteria. Families of children meeting inclusion criteria were sent a letter introducing the study. As enrollment was rolling, letters were sent to 20 potential participants at a time in the order they appeared on the center’s roster of patients. A follow-up telephone call was made by the study staff 10 days after the mailing to describe the study in detail, verify inclusion and exclusion criteria, and invite participation. If a family agreed, a home visit was scheduled to get informed consent and collect questionnaire data (not reported here) and families were asked about time conflicts with treatment sessions (morning or afternoon). If a family had a schedule conflict, they were assigned to the time of day without a conflict. Families with no schedule conflicts were assigned to morning or afternoon sessions by a coin flip. Once all families who agreed to participate had been assigned to time of day, the time of day (morning or afternoon) was then randomized to the treatment arm by a coin flip by the research assistant and postdoctoral fellow together. This yielded a group size of 2 to 5 families per treatment condition. Families were told that the study was comparing 2 approaches to improving nutrition, one that focused on diet and one that focused on diet and child behavior. Families were never explicitly told which treatment they had been assigned.

In 3 prior studies of this behavioral intervention, an effect size of 1.58 SDs for weight gain was achieved. Because a potentially efficacious alternative treatment was used, the effect size was estimated more conservatively to be 0.90 SD. A sample size of 25 subjects per group with a significance level of .05 yielded 87% power; therefore, 79 children were recruited between 1996 and 1999 to allow for an estimated 60% retention rate across the 27 months of the study. A total of 426 medical records were reviewed (Figure 1). Of these, 249 were excluded; 231 did not meet inclusion criteria or met an exclusion criterion, and an additional 18 were excluded for other reasons including participation in another research study where weight was an outcome (n = 13), having a sibling who had been
randomized to the trial (n=4), and being excluded by the physician because the child had not been told that he or she had CF (n=1). Of the 177 who met eligibility, 164 could be contacted by telephone. Of these 164, 83 declined participation and 79 agreed and were randomized to treatment.

STUDY DESIGN

Subjects in each condition attended a 90-minute baseline session (session 1, pretreatment), followed 2 weeks later by 5 weekly group sessions (sessions 2-6), and finally followed 2 weeks later by a posttreatment assessment and review session (session 7). Thus, there was a span of 9 weeks between pretreatment and posttreatment data collection. Participants were followed up at 3, 6, 12, 18, and 24 months after treatment. Parents and children were seen in simultaneous but separate groups. The group sessions followed a written manual. Parent group sessions were conducted by a PhD-level psychologist and a registered dietitian. Child groups were conducted by a postdoctoral fellow or graduate student in psychology.

INTERVENTIONS

Caloric Goals

Breakfast, lunch, dinner, and snack were each expected to increase by 250 cal/d, yielding a total increase of 1000 cal/d by the end of treatment. One type of meal (eg, breakfast, lunch) was targeted per session. Once a meal was addressed in treatment, caloric intake for that meal was expected to remain at the new goal level.

Pulmonary Function

Anthropometrics

Pulmonary function was assessed by FEV1, using equations set forth by Wang et al.23 We chose to use FEV1 because it is considered the most reliable and valid indicator of lung functioning in children with CF.22,23

Caloric Intake

Caloric intake was assessed via daily food monitoring by parents. The average of 14 days between sessions 1 and 2 served as pretreatment and the 14 days between sessions 6 and 7 served as posttreatment. Parents kept a 7-day food record before the 3-, 6-, 12-, 18-, and 24-month follow-up. Caloric intake was examined as absolute calories per day and as a percentage of the EER. Percentage of the EER was calculated by subtracting the EER for an active child of the same age and sex18 from the individual subject’s caloric intake × 100.

Primary outcomes of the study were change in caloric intake and weight from pretreatment to posttreatment. Secondary outcomes were percentage of the EER and BMI z score from pretreatment to posttreatment. These 4 outcomes were also examined 24 months following treatment along with the following outcomes that could only be examined over a period longer than 9 weeks: height, height-for-age BMI score, and FEV1.

Parent Satisfaction Questionnaire

The Parent Satisfaction Questionnaire assessed parents’ satisfaction with their child’s progress, the effect of the program on the child’s caloric intake and mealtime behavior, the overall approach used to manage caloric intake and child behavior, the group leader’s teaching skills, and whether they would recommend the program to a friend. This questionnaire used a 7-point scale (higher numbers indicated greater satisfaction).

Behavioral Plus Nutrition Education Intervention

The behavioral plus nutrition education intervention followed the protocol Behavioral Intervention for Change Around Nutrition and Energy! (Be In CHARGE!) developed by Stark and colleagues.12-15 This is available online at http://www.oup.com/us/pediatricpsych.

Parent Group. In addition to nutrition education, parents received training in child behavioral management strategies.17 Parents were taught to use differential attention for appropriate and inappropriate eating behaviors and to use sticker charts and home-based privileges to reward the children for meeting caloric goals.

Child Group. Children participated in nutrition education and a practice meal. During the practice meal, goal setting and differential attention were used to encourage children to try new foods and meet their caloric goals. Trophies were awarded contingent on meeting the previous week’s caloric goals.

Data Collection

Primary outcomes of the study were change in caloric intake and weight from pretreatment to posttreatment. Secondary outcomes were percentage of the EER and BMI z score from pretreatment to posttreatment. These 4 outcomes were also examined 24 months following treatment along with the following outcomes that could only be examined over a period longer than 9 weeks: height, height-for-age BMI score, and FEV1.
The demographic variables in Table 1 were compared between the 2 groups using t tests for continuous variables and \( \chi^2 \) tests for categorical variables. Prior to determining whether the primary end points differed between the 2 conditions, we assessed for differences in our primary outcomes by site and by therapist. Using linear models on difference scores from pretreatment to posttreatment for change in caloric intake and weight, no significant differences were found due to psychologist (caloric intake: \( P = .80 \); weight: \( P = .90 \)) or site (caloric intake: \( P = .99 \); weight: \( P = .91 \)). Sample size precluded analysis of the effects of more complex site and therapist interactions.

The primary analyses were performed using linear modeling in SAS version 9.1 statistical software (SAS Institute, Cary, North Carolina). The dependent variables were difference scores from pretreatment to posttreatment for caloric intake, percentage of the EER, weight, BMI \( z \) score. The independent variable was a fixed effect for group (behavioral plus nutrition education intervention vs NE intervention). Percentage of the coefficient of fat absorption was used as a covariate in the weight gain and BMI \( z \) score models because the 2 groups were found to differ on percentage of the coefficient of fat absorption at pretreatment (79% in the behavioral plus nutrition education intervention vs 85% in the NE intervention; \( P = .02 \)). Parent Satisfaction Questionnaire variables were compared with \( t \) tests.

No dropouts received active treatment. Only 1 dropout from the NE intervention and 2 dropouts from the behavioral plus nutrition education intervention had a pretreatment weight measurement but no further participation, thus the percentage of change could not be calculated. Aside from these early dropouts, there were no missing pretreatment or posttreatment data for any of the subjects (n=67) in the study.

### Long-term Outcome Across 24-month Follow-up

Intent to treat was followed in the analysis. The 2 treatments were compared over time using linear mixed modeling with a repeated-measures design and an autoregressive variance-covariance structure in SAS version 9.1 statistical software. The factors in the model were group (random effect), time (3, 6, 12, 18, and 24 months), and the interaction of group with time. The difference scores from pretreatment for caloric intake, percentage of the EER, weight, BMI \( z \) score, height, height-for-age \( z \) score, and FEV\textsubscript{1} across each of the 5 time points were the dependent variables. Missing data from the long-term follow-up assessments were minimal (<10% for weight, BMI \( z \) score, height, and height-for-age \( z \) score. Approximately 20% of the caloric intake and percentage of the EER data were missing from follow-up and 22% of the FEV\textsubscript{1} data were missing. There were no statistically significant differences in age, sex, or primary or secondary outcome variables at pretreatment between subjects with and without missing follow-up data. For the variables with more than 10% missing data, the analyses were run for all observed data, data for only those who never missed a visit, and data with 3 sets of imputed values for missing visits using SOLAS for Missing Data Analysis version 3.0 statistical software (Statistical Solutions, Saugus, Massachusetts). All 3 analyses were nonsignificant with 1 exception. One set of imputed values for the FEV\textsubscript{1} variable resulted in a significant interaction. However, the observed data and the other 2 sets of imputed values for this variable were not significant, so only nonimputed data are reported.

### Results

#### Study Population

Of 79 enrolled children, 39 were assigned to the behavioral plus nutrition education intervention and 40 to the NE intervention. This represents a recruitment rate of 44% of the eligible children and 48% of families who could be contacted (Figure 1). There were 6 dropouts in both arms prior to treatment, leaving 67 children for analysis. There were no statistically significant differences between the conditions on demographic variables (\( P > .05 \)) or FEV\textsubscript{1} (\( P = .57 \)). However, children in the behavioral plus nutrition education intervention had lower fat absorption at enrollment than children in the NE intervention (\( P = .02 \)) (Table 1).

#### Pretreatment to Posttreatment Efficacy

**Caloric Intake**

Children receiving the behavioral plus nutrition education intervention achieved a significantly greater increase in daily caloric intake than children receiving the NE in-

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**Table 1. Characteristics for Families in the Behavioral Plus Nutrition Education Intervention and the Nutrition Education Intervention**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Behavioral Plus Nutrition Education (n=33)</th>
<th>Nutrition Education (n=34)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child age, mean (SD), y</td>
<td>7.5 (2.7)</td>
<td>7.4 (2.9)</td>
</tr>
<tr>
<td>Female, No. (%)</td>
<td>17 (62)</td>
<td>14 (41)</td>
</tr>
<tr>
<td>White, No. (%)</td>
<td>33 (100)</td>
<td>32 (94)</td>
</tr>
<tr>
<td>Weight-for-age percentile, mean (SD)</td>
<td>23 (19.6)</td>
<td>25 (14.0)</td>
</tr>
<tr>
<td>FEV\textsubscript{1}, mean (SD), % predicted</td>
<td>88 (18)</td>
<td>92 (18)</td>
</tr>
<tr>
<td></td>
<td>(n=17)</td>
<td>(n=19)</td>
</tr>
<tr>
<td>Fat absorption, mean (SD), %</td>
<td>79 (12.5)</td>
<td>85 (15.4)*</td>
</tr>
<tr>
<td>Mother’s age, mean (SD), y</td>
<td>34.5 (6.0)</td>
<td>32.8 (6.0)</td>
</tr>
<tr>
<td>Father’s age, mean (SD), y</td>
<td>37.5 (6.5)</td>
<td>36.4 (6.1)</td>
</tr>
<tr>
<td>Father’s education, mean (SD), y</td>
<td>14.3 (2.4)</td>
<td>14.5 (2.4)</td>
</tr>
<tr>
<td></td>
<td>(n=30)</td>
<td>(n=31)</td>
</tr>
<tr>
<td>Income before taxes, No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>$0-$9999</td>
<td>1 (3)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>$10 000-$19 999</td>
<td>3 (9)</td>
<td>4 (12)</td>
</tr>
<tr>
<td>$20 000-$29 999</td>
<td>2 (6)</td>
<td>6 (18)</td>
</tr>
<tr>
<td>$30 000-$39 999</td>
<td>4 (12)</td>
<td>3 (9)</td>
</tr>
<tr>
<td>$40 000-$49 999</td>
<td>6 (18)</td>
<td>2 (6)</td>
</tr>
<tr>
<td>&gt;$50 000</td>
<td>17 (52)</td>
<td>17 (50)</td>
</tr>
</tbody>
</table>

Abbreviation: FEV\textsubscript{1}, forced expiratory volume in the first second of expiration.

*Significantly different, \( P = .02 \).
Parents in both groups reported high ratings of satisfaction with treatment (P = .001). At posttreatment, children receiving the behavioral plus nutrition education intervention averaged 383 cal/d more than children receiving the NE intervention. In addition, children receiving the behavioral plus nutrition education intervention achieved a significantly greater increase in percentage of the EER (48%) from pretreatment to posttreatment than children receiving the NE intervention (27%) (P = .001), with children receiving the behavioral plus nutrition education intervention achieving an EER of 148% compared with those receiving the NE intervention achieving 127% (Table 2).

### Weight

Children receiving the behavioral plus nutrition education intervention gained significantly more weight, an average of 1.47 kg across the 9 weeks from pretreatment to posttreatment, compared with children receiving the NE intervention, who gained an average of 0.92 kg (P = .01). The change in weight resulted in a significantly greater improvement in the BMI z score at posttreatment for children receiving the behavioral plus nutrition education intervention (0.38) compared with those receiving the NE intervention (0.18) (P = .03) (Table 2).

### Parent Satisfaction

Parents in both groups reported high ratings of satisfaction with treatment (≥6 on a 7-point scale) with no statistically significant difference on 8 of 9 dimensions (P > .05). For approach used to increase child’s caloric intake, the behavioral plus nutrition education intervention was rated superior (P = .005). However, ratings of both groups were higher than 6.

### 2-YEAR FOLLOW-UP

There were no statistically significant group × time interactions across the 5 follow-up assessment points for caloric intake, percentage of the EER, weight, BMI z score, height, height-for-age z score, or FEV1 (Table 3). By the 6-month follow-up, children receiving the behavioral plus nutrition education intervention increased from 148% EER at posttreatment to 129% EER and remained near 120% EER for the duration of the study (Figure 2). Children receiving the NE intervention remained near 120% EER from posttreatment across all follow-up.

### COMMENT

To our knowledge, this study is the first test of a behavioral plus nutrition education intervention to improve caloric intake and weight gain in children with CF compared with an alternative treatment condition of NE, with a large enough sample to detect differences on these variables. As hypothesized, the behavioral plus nutrition education intervention resulted in significantly greater increases in caloric intake and weight gain from pretreatment to posttreatment than the NE intervention. In addition to being more efficacious, the behavioral plus nutrition education intervention showed consistency on the primary outcomes with previous behavioral studies. The average increase in caloric intake of 872 cal/d in this study was similar to the caloric increase of 785 to 1000 cal/d from our previous studies.13,15 Similarly, the average weight gain of 1.47 kg seen from pretreatment to posttreatment replicates our previous reports of average weight gain of 1.42 kg13 to 1.70 kg.14

In contrast to our previous work using a wait-list control,13 children receiving NE increased both their caloric intake and weight over the 9 weeks of treatment. Clearly, the structure and delivery of nutrition education provided in this study are different from the standard of care, and this likely has implications for how to improve the efficacy of standard nutritional care. This is especially worth noting because in this study both interventions led to a virtually identical EER of approximately 120% across the

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**Table 2. Pretreatment to Posttreatment Caloric Intake, Percentage of the Estimated Energy Requirement, Weight, and Body Mass Index z Score for Children Receiving the Behavioral Plus Nutrition Education Intervention and the Nutrition Education Intervention**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Behavioral Plus Nutrition Education</th>
<th>Nutrition Education</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pretreatment, Mean (SD) (n=33)</td>
<td>Pretreatment, Mean (SD) (n=34)</td>
</tr>
<tr>
<td>Caloric intake, cal/d</td>
<td>1793 (350)</td>
<td>1826 (476)</td>
</tr>
<tr>
<td>% of EER</td>
<td>100 (16)</td>
<td>100 (16)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>21.79 (6.44)</td>
<td>22.62 (7.45)</td>
</tr>
<tr>
<td>BMI z score</td>
<td>−0.77 (1.12)</td>
<td>−0.49 (0.71)</td>
</tr>
</tbody>
</table>

**Table 3**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Behavioral Plus Nutrition Education</th>
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<tr>
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<td>−0.49 (0.71)</td>
</tr>
</tbody>
</table>

**Abbreviations:** BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CI, confidence interval; EER, estimated energy requirement.

*Based on the difference of the change from pretreatment (behavioral plus nutrition education − nutrition education).

*Based on a linear model on the difference score, with a fixed effect for group and percentage of the coefficient of fat absorption used as a covariate for weight and BMI z score analyses.*
behavioral plus nutrition education intervention and very different from typical nutritional care provided in a fast-paced clinical setting. Typical dietary counseling does not occur weekly, specify caloric targets that gradually increase, provide weekly caloric graphs with feedback on how close a child came to his or her targets, or provide individualized, written suggestions for increasing caloric intake based on usual food and beverage preferences. The structure of the dietary information in the NE intervention was very behavioral and used strategies known to positively affect dietary outcome. Self-monitoring, for example, is highly correlated with weight outcome in studies of obesity, and providing tailored feedback is very potent in supporting behavioral change. This study indicates that we can make significant improvements in the energy and weight outcomes of children with CF by making the important dietary education already available in CF centers more behavioral in its delivery. Making modifications to standard nutritional care such as providing families with individualized energy goals, tailoring based on the child’s existing diet, targeting 1 meal a time, having families self-monitor their child’s dietary intake, and presenting these data graphically may reduce the anxiety and uncertainty that parents express about their child’s eating patterns.11,23 And improve skills and outcomes.

While this study did not have a standard-of-care treatment condition against which the gain in caloric intake of the NE can be compared, there have been numerous studies reporting that the typical caloric intake of children with CF is about 100% of the recommended energy for children and not the 120% to 150% recommended for CF and achieved in this study. Thus, the data from this trial suggest that a more intensive intervention that is behavior-based, even if focused exclusively on nutrition education, could have a greater effect.

Table 3. Two-Year Outcomes on Caloric Intake, Percentage of the Estimated Energy Requirement, Weight, Body Mass Index z Score, Height, Height-for-Age z Score, and Forced Expiratory Volume in the First Second of Expiration for Children Receiving the Behavioral Plus Nutrition Education Intervention and the Nutrition Education Intervention

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Pretreatment, Mean (SD)</th>
<th>24-mo Follow-up, Mean (SD)</th>
<th>Change From Pretreatment, Mean (SD) [95% CI]a</th>
<th>Pretreatment, Mean (SD)</th>
<th>24-mo Follow-up, Mean (SD)</th>
<th>Change From Pretreatment, Mean (SD) [95% CI]a</th>
<th>Difference Between Groups, Mean (SD) [95% CI]b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caloric intake, cal/d</td>
<td>1793 (350)</td>
<td>2523 (620)</td>
<td>721 (522)</td>
<td>1826 (476)</td>
<td>2411 (577)</td>
<td>585 (436)</td>
<td>188 (482)</td>
</tr>
<tr>
<td>% of EER</td>
<td>100 (16)</td>
<td>102 (19)</td>
<td>2 (25)</td>
<td>100 (16)</td>
<td>117 (22)</td>
<td>17 (25)</td>
<td>9 (25)</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>21.79 (6.44)</td>
<td>28.51 (9.77)</td>
<td>6.79 (3.60)</td>
<td>22.62 (7.45)</td>
<td>29.51 (10.84)</td>
<td>6.97 (3.67)</td>
<td>0.52 (3.64)</td>
</tr>
<tr>
<td>BMI z score</td>
<td>-0.77 (1.12)</td>
<td>-0.56 (0.90)</td>
<td>0.13 (0.81)</td>
<td>-0.74 (0.71)</td>
<td>-0.71 (0.66)</td>
<td>-0.22 (0.50)</td>
<td>0.35 (0.67)</td>
</tr>
<tr>
<td>Height, cm</td>
<td>118.93 (14.87)</td>
<td>131.07 (14.66)</td>
<td>13.34 (1.93)</td>
<td>119.35 (16.44)</td>
<td>133.87 (17.01)</td>
<td>14.54 (2.93)</td>
<td>-0.20 (2.50)</td>
</tr>
<tr>
<td>Height-for-age z score</td>
<td>-0.95 (0.78)</td>
<td>-0.87 (0.77)</td>
<td>0.03 (0.30)</td>
<td>-0.74 (0.69)</td>
<td>-0.72 (0.74)</td>
<td>0.04 (0.32)</td>
<td>-0.01 (0.31)</td>
</tr>
<tr>
<td>FEV1, % predicted</td>
<td>88 (18)</td>
<td>87 (18)</td>
<td>0.16 (22)</td>
<td>92 (18)</td>
<td>87 (17)</td>
<td>5 (13)</td>
<td>5 (18)</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CI, confidence interval; EER, estimated energy requirement; FEV1, forced expiratory volume in the first second of expiration.

a Value of change from pretreatment does not equal value of 24-month follow-up minus pretreatment owing to subject attrition at follow-up.

b Based on the difference of the change from pretreatment (behavioral plus nutrition education – nutrition education).

Figure 2. The percentage of the estimated energy requirement (EER) for the children in the behavioral plus nutrition education intervention and the nutrition education intervention at pretreatment, posttreatment, and the 6-, 12-, 18-, and 24-month follow-up.
than nutrition intervention as it has been reported to be delivered in usual care models.

The exact amount of energy necessary for weight gain in children with CF is not known. In a recent review of the empirical literature, the energy intake associated with weight gain in similarly aged children with CF ranged from 110% to 200% of the energy needs of the children without CF.31 Our pretreatment to posttreatment data show that achieving an EER of 148% led to greater weight gain than achieving an EER of 127%. After the intensive treatment phase, children in both treatment arms returned to standard care. For the children receiving the behavioral plus nutrition education intervention to have maintained an EER of 148%, they would have had to continually increase their absolute caloric intake over time as they grew bigger and older. Therefore, in addition to making standard nutritional care more behavioral, future research should investigate ways to maintain the treatment gain of 148% EER achieved by the behavioral intervention after intensive treatment concludes.

While our results are encouraging, this study has several limitations. Our recruitment rate was only 44% of eligible children, thereby limiting generalization of the treatment effects to those families willing and able to attend weekly treatment. As with any behavioral intervention, it is not possible to keep subjects unaware of the treatment they are receiving or to keep therapists unaware of the treatment they are providing. Finally, because the study was conducted prior to widespread adoption of the Consolidated Standards of Reporting Trials guidelines, aspects such as randomization allocation, sequence, and concealment were not met and may have introduced the type of bias that these procedures are designed to eliminate.

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Author Contributions: Study concept and design: Stark, Quittner, Powers, Opipari-Arrigan, and Stallings. Acquisition of data: Stark, Quittner, Opipari-Arrigan, and Duggan. Analysis and interpretation of data: Stark, Quittner, Powers, Opipari-Arrigan, Bean, Duggan, and Stallings. Drafting of the manuscript: Stark, Quittner, Powers, and Opipari-Arrigan. Critical revision of the manuscript for important intellectual content: Bean, Duggan, and Stallings. Statistical analysis: Powers, Opipari-Arrigan, and Bean. Obtained funding: Stark and Quittner. Administrative, technical, and material support: Stark, Quittner, Powers, Duggan, and Stallings. Study supervision: Stark, Quittner, and Powers.

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