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

participants randomized to a behavioral plus nutrition education 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 examine 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<sub>1</sub>) 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 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

### CONSOLIDATED STANDARDS OF REPORTING TRIALS

<table>
<thead>
<tr>
<th>Recruitment and Randomization</th>
<th>Allocation and Treatment</th>
<th>Participants</th>
<th>Baseline Characteristics</th>
<th>Outcomes</th>
<th>Discontinuations</th>
<th>Follow-up</th>
<th>Analysis</th>
<th>Conclusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received intervention</td>
<td>Allocated to treatment</td>
<td>Randomized</td>
<td>Baseline characteristics</td>
<td>Outcomes</td>
<td>Discontinuations</td>
<td>Follow-up</td>
<td>Analysis</td>
<td>Conclusions</td>
</tr>
<tr>
<td>33</td>
<td>39</td>
<td>79</td>
<td>4 to 12 years</td>
<td>CF</td>
<td>4 to 12 years</td>
<td>24 months</td>
<td>4 to 12 years</td>
<td>24 months</td>
</tr>
</tbody>
</table>

*CF, cystic fibrosis.*

**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<sub>1</sub>, indicates forced expiratory volume in the first second of expiration; CF, cystic fibrosis.
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.

NE Intervention
Parent Group. The nutrition education was identical in both the behavioral plus nutrition education intervention and NE intervention groups. Parents were provided with information on the caloric content of their child’s meals, caloric goals for each meal, and recommendations on how to achieve these goals including cooking methods, caloric boosters, and high-calorie foods. At each session, parents were given graphs of their child’s actual caloric intake compared with their weekly goal. In the NE group, no behavioral child management training was provided.

Child Group. The child group used fun activities to teach about “high-energy” foods. A practice meal was provided, but consumption was not required. For the children receiving the NE intervention, the same energy goals as children receiving the behavioral plus nutrition education intervention were provided but without rewards for meeting goals. Children were given trophies for session attendance.

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 z score, and FEV1.

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.

Anthropometrics
Weight and height were measured in triplicate by a single trained measurer at each site following the guidelines established by Cameron.19 To provide a context for growth outcomes, weight and height were standardized by converting them to BMI z scores for age and sex and height-for-age z scores using the Centers for Disease Control and Prevention growth curves.20

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).

Pulmonary Function
Pulmonary function was assessed by FEV1, using equations set forth by Wang et al.21 We chose to use FEV1 because it is considered the most reliable and valid indicator of lung functioning in children with CF.22,23

Treatment Fidelity
Treatment fidelity was assessed by raters coding 4 videotapes from each of the 7 sessions for each intervention. The NE sessions contained 95% of the key nutrition components and 0% of the behavioral components. The behavioral plus nutrition education sessions contained 97% of the key nutrition components and 93% of the key behavioral components. Interrater reliability, calculated as the percentage of agreement on 25% of the tapes, was 97% for the behavioral components and 95% for the nutrition components.
The demographic variables in Table 1 were compared between the 2 groups using t tests for continuous variables and x2 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: \(P = .84\)). 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, Inc, Cary, North Carolina). The dependent variables were difference scores from pretreatment to posttreatment for caloric intake, percentage of the EER, weight, BMI z score, height, height-for-age z score, and FEV1, 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 FEV1 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 FEV1 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 FEV1 \((P = .57)\). 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-
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 $\times$ 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 decreased 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.

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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 Pretreatment, Mean (SD) (n=33)</th>
<th>Posttreatment, Mean (SD) (n=33)</th>
<th>Change From Pretreatment, Mean (SD) [95% CI]</th>
<th>Nutrition Education Pretreatment, Mean (SD) (n=34)</th>
<th>Posttreatment, Mean (SD) (n=34)</th>
<th>Change From Pretreatment, Mean (SD) [95% CI]</th>
<th>Difference Between Groups, Mean (SD) [95% CI]</th>
<th>$P$ Value $^{b}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caloric intake, cal/d</td>
<td>1793 (350)</td>
<td>2665 (553)</td>
<td>872 (478) [703 to 1042]</td>
<td>1826 (476)</td>
<td>2315 (549)</td>
<td>489 (314) [379 to 599]</td>
<td>383 (403) [186 to 580]</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>% of EER</td>
<td>100 (16)</td>
<td>148 (30)</td>
<td>48 (29) [38 to 58]</td>
<td>100 (16)</td>
<td>127 (25)</td>
<td>27 (19) [20 to 33]</td>
<td>21 (24) [9 to 33]</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>21.79 (6.44)</td>
<td>23.26 (7.10)</td>
<td>1.47 (1.27) [1.02 to 1.92]</td>
<td>22.62 (7.45)</td>
<td>23.54 (7.78)</td>
<td>0.92 (1.03) [0.56 to 1.28]</td>
<td>0.55 (1.16) [−0.02 to 1.11]</td>
<td>.01</td>
</tr>
<tr>
<td>BMI $z$ score</td>
<td>−0.77 (1.12)</td>
<td>−0.39 (1.08)</td>
<td>0.38 (0.46) [0.21 to 0.54]</td>
<td>−0.49 (0.71)</td>
<td>−0.31 (0.81)</td>
<td>0.18 (0.47) [0.02 to 0.35]</td>
<td>0.20 (0.47) [−0.03 to 0.42]</td>
<td>.03</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.

$^{a}$Based on the difference of the change from pretreatment (behavioral plus nutrition education – nutrition education).

$^{b}$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.*
2-year follow-up. Thus, while the behavioral plus nutrition education intervention achieved a greater improvement in caloric intake and weight gain in the short-term, over the longer-term both were very successful maintaining the 2002 consensus guidelines for energy intake and intakes 20% higher than those at pretreatment. The similar caloric intake between the 2 treatment groups likely was the mechanism that accounted for the lack of difference in BMI z scores across the 2-year follow-up.

We believe that the unexpected outcome on caloric intake and growth during the follow-up period in the NE group was probably because this condition contained key components that made it similar to certain aspects of the 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 calorie 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 at a time, having families self-monitor their child's dietary intake, 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 at a time, having families self-monitor their child’s dietary intake, and providing tailored feedback is very potent in supporting behavioral change.
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.33 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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