Prevention of Osteoporosis: A Randomized Clinical Trial to Increase Calcium Intake in Children with Juvenile Rheumatoid Arthritis

Lori J. Stark,[1,6] PhD, David M. Janicke,[2] PhD, Ann M. McGrath,[3] PhD, Laura M. Mackner,[4,7] PhD, Kevin A. Hommel,[1] PhD, and Daniel Lovell,[5,6] MD

[1]Division of Psychology, Cincinnati Children's Hospital Medical Center, [2]Department of Clinical and Health Psychology, University of Florida, [3]Department of Pediatrics, University of Kansas Medical Center, [4]Department of Pediatrics, Columbus Children's Hospital, [5]Division of Rheumatology, Cincinnati Children's Hospital Medical Center, [6]University of Cincinnati College of Medicine, and [7]Ohio State University

Objective To test the efficacy of a behavioral intervention (BI) compared to an enhanced standard of care (ESC) dietary counseling on increasing dietary calcium (Ca) intake in children with juvenile rheumatoid arthritis (JRA). **Methods** Three-day food diaries collected at baseline and posttreatment were analyzed for Ca intake in 49 children with JRA randomly assigned to either BI or an ESC treatment. **Results** Children in the BI ($N = 25$) demonstrated a significantly greater increase in average dietary Ca intake ($M = 839$) than children in the ESC ($N = 24$; $M = 420$) ($F = 14.39$; $p < .001$). Post hoc analysis revealed that children in both groups demonstrated significant gains in dietary Ca intake baseline to posttreatment. A significantly greater percentage of children in the BI (92%) attained the goal of 1500 mg/Ca at posttreatment compared to the ESC (17%), $X^2 = 28.09$; $p < .001$. **Conclusions** Behavioral intervention can have a positive impact on increasing dietary Ca intake. Future research will need to evaluate the maintenance of gains in dietary Ca intake following treatment cessation and the impact of increased Ca intake on bone mineral density.

Key words Behavioral Intervention; Calcium; Bone Health; JRA.

Osteoporosis is an enormous public health problem (Cassidy, Langman, Allen, & Hillman, 1995) for which there is no cure. It negatively impacts the quality of life of over 10 million adults in the United States, accounting for 1.5 million fractures and over $17 billion in health care costs annually (National Osteoporosis Foundation). Although osteoporosis is often thought of as a disease of the elderly, it is increasingly linked to bone development during childhood and adolescence (Saggese, Baroncelli, & Bertelloni, 2001), in that 40% of the adult skeletal mass is accumulated during this time (Bonjour, Theintz, Buchs, Slosman, & Rizzoli, 1991). Moreover, peak bone mass at physical maturity is one of the major determinants of risk for osteoporosis (NIH Consensus Statement on Osteoporosis Prevention Diagnosis and Therapy, 2000). Thus, suboptimal bone mineralization during childhood and adolescence is associated with greater risk of osteoporosis and subsequent fractures throughout the lifespan.

Bone mineralization is a multifactorial process (Leonard & Zemel, 2002). However, one modifiable risk factor that has received considerable attention is calcium (Ca) intake. Adequate dietary Ca intake is believed to be critical in developing strong bones and reducing the risk of osteoporosis (Tortolani, McCarthy, & Sponseller, 2002). Greater Ca intake during childhood has been found to be associated with greater bone mineral density (BMD) and decreased risk for fractures in adulthood (Kalkwarf,

All correspondence concerning this article should be addressed to Lori J. Stark, Cincinnati Children's Hospital Medical Center, 3333 Burnet Avenue, Division of Psychology, SEC-4, Cincinnati, Ohio 45229. E-mail: lori.stark@chmcc.org

Journal of Pediatric Psychology 30(5) pp. 377–386, 2005
doi:10.1093/jpepsy/jsi061
Advance Access publication February 23, 2005

Khoury, & Lanphear, 2003; Teegarden, Lyle, Proulx, Johnston, & Weaver, 1999). Unfortunately children are consuming an average of only 900 mg of Ca/day (Alaimo et al., 1994), far less than the NIH Consensus Conference on Optimal Calcium Intake (1994) recommendations of 1200–1500 mg/day. Well-controlled, longitudinal investigations have demonstrated the positive effects of Ca pill supplementation on BMD in healthy children (Lee et al., 1994; Johnston et al., 1992). However, the benefits of Ca supplementation on BMD have been found to diminish after supplementation is discontinued (Lee, Leung, Leung, & Cheng, 1996; Slemenda, Reister, Peacock, & Johnston, 1993).

Whereas many children are at risk for low BMD, children with chronic health conditions are at greater risk for low BMD and the onset of osteoporosis earlier in adulthood. Children with cystic fibrosis (CF) and Crohn's disease (CD) have been found to have lower BMD (Bhudhikanok et al., 1998; Henderson & Madsen, 1999) and a higher rate of fractures than healthy children (Baroncelli et al., 1997; Henderson & Specter, 1994). Failure to develop adequate bone mineralization has been described as "virtually universal in children with juvenile rheumatoid arthritis" (JRA; Cassidy & Hillman, 1997). Children diagnosed with JRA have been reported to have low BMD (Henderson et al., 1997) early in the disease and independent of steroid use (Hopp, Degan, Gallagher, & Cassidy, 1991). Compounding this issue is that children with JRA have been found to have poorer intestinal absorption of Ca (22%) than children without a chronic health condition (30.4%) (Abrams, Lipnick, Vieira, Stuff, & Yergey, 1993). Not surprisingly, as children with chronic conditions reach adulthood, they have higher fracture rates relative to adults without a history of a chronic health condition (Zak & Pederson, 2000). Prior to adulthood, 15–26% of children with JRA have been reported to have pathologic fractures (Elsasser et al., 1982). Despite the increased risk for low BMD, children with JRA are only consuming approximately 900 mg of Ca/day (Henderson et al. 1997).

Only one published study on Ca supplementation in children with chronic health conditions exists. Warady, Lindsley, Robinson, and Lukert (1994) reported an 11% increase in lumbar spine BMD in 10 children with rheumatic disease during a 6-month trial of 1000 mg/day of Ca carbonate. However, given that gains in BMD do not maintain for children after supplementation is withdrawn (Lee et al., 1996; Slemenda et al., 1993), children need increased Ca intake on a consistent basis to optimize peak bone mass at physical maturity. Unfortunately rates of adherence to long-term pill regimens are poor (Rapoff & Barnard, 1991). Adherence to a Ca pill supplementation may be especially troublesome for children with chronic health conditions who may already be burdened with a complex and intrusive treatment regimen. Thus, Ca by pill supplementation may not be the best method to ensure optimal Ca intake. Furthermore, some evidence suggests that increasing Ca intake through food sources, especially dairy, may lead to greater gains in BMD than Ca delivered via pill supplementation (Chan, Hoffman & McMurry, 1995).

One possible approach to increasing dietary Ca intake is behavioral intervention. Behavioral treatments have shown efficacy in increasing energy intake in children with CF, with maintenance of treatment gains 24 months after treatment (Stark et al., 2003). Stark, Mackner, Kessler, Opipari, and Quittner (2002) recently reported on the potential of a behavioral intervention to increase Ca intake in children with CF. Although not directly targeting Ca intake, secondary analysis found that daily dietary Ca intake increased from 1006 to 1467 mg following an 8-week behavioral intervention for energy intake, with maintenance at 12 months after treatment.

The purpose of this study was to conduct a randomized controlled trial of a behavioral intervention to increase dietary Ca intake in children with JRA. In the current study, a 6-session BI was compared to a 3-session Enhanced Standard of Care (ESC) nutrition counseling program on dietary Ca intake over an 8-week period. The ESC was designed to be equivalent to nutrition consultation that could be provided in a standard medical setting to children with JRA and was, therefore, not equivalent to the BI on the number of treatment sessions. It was hypothesized that the BI would lead to greater increases in dietary Ca intake baseline to posttreatment compared to the ESC program. There has been some speculation that, in general, Ca intake is below recommended levels because of a misperception by children and adolescents that dairy foods are fattening (Graetzer, 2002). Therefore, we conducted exploratory analysis to determine whether energy intake or percent fat in the diet increased following intervention to increase Ca.

Method

Participants

Participants were 49 children with JRA recruited from the outpatient rheumatology centers at three large, pediatric medical centers in the Midwest. All children had a diagnosis of JRA based on the American College of Rheumatology classification standards, lived within 90 min of one of the three medical centers, and were between

4- and 10-years of age at enrollment. Children were excluded if they had a diagnosis of any other pediatric health condition affecting growth (e.g., steroid dependent asthma and inflammatory bowel disease), non–English-speaking parents, or a developmental delay. Children were also excluded if they had used systemic corticosteroids within 3 months prior to recruitment or if they were taking a Ca supplement (more than 100 mg/day).

Measures

Dietary Intake. Weighed food diaries were obtained on 7 consecutive days at baseline and posttreatment for all subjects. Parents of all subjects were taught how to keep a food diary during a 90-min baseline assessment session and supplied with a food scale, graduated measuring cup, and standard measuring cups and spoons to ensure accuracy of food and beverage measurement. Three days from each 7-day food record, the first two weekdays and the first weekend day, were analyzed by a registered dietician in the General Clinical Research Center (GCRC), who was unaware of the subject's treatment condition, using the Food Processor nutrient analysis program (Food Processor software, ESHA research, Salem, Oregon). Three-day food diaries have been found to be highly correlated with 7 (Stuff, Garza, Smith, Nichols, & Montandon, 1983) and 28 day food records (Daniels, 1984; St. Jeor, Guthrie, & Jones, 1983) on calories, protein, fat, carbohydrates, and Ca intake and, therefore, are considered representative of typical intake over a longer period of time. Information was obtained on total daily Ca, calorie, and percent protein, carbohydrate, and fat intake.

Demographic Questionnaire. Information about the child and family including ethnic background, parent's age and employment status, marital status, family size, and total family income was gathered via a self-report questionnaire.

Procedures

Subject Recruitment. Eligible families were identified via chart review and sent a letter and brochure from the principal investigator and their rheumatologist describing the "Building Stronger Bones Project". A stamped return address postcard was included for families to send back if they did not wish to be contacted further about the study. A trained research assistant then called the families to invite participation. Intervention groups were conducted approximately once every 4 months, with a rolling recruitment and minimum of six families per intervention cycle. Participants were stratified on an estimate of their typical Ca intake at the time of enrollment to ensure similarity of Ca intake at baseline across the two conditions. Ca intake was estimated via three screening questions about the child's typical daily consumption of milk, cheese and yogurt and the children were classified as having a low (<500 mg/day), medium (between 500 and 1000 mg/day), or high (>1000 mg/day) Ca intake. After stratification by estimated Ca intake classification, a block randomization protocol was utilized with a block size of two within each strata of Ca intake. The randomization sequence was generated and kept by personnel separate from personnel conducting recruitment calls and the intervention. The study was approved by the institutional review board at each institution and informed consent was obtained from a parent of each participant. See Fig. 1 for participant flow through the study.

Baseline Assessment and Diet Diary Training. At the first session, informed consent and baseline measures were obtained. For both the BI and ESC conditions, separate but simultaneous groups were conducted for parents and children. Parents were taught how to record and keep a food diary, and children were engaged in a fun activity and were given a high-Ca snack or meal.

Intervention

Behavioral Intervention. Families in the BI had six visits over an 8 week period: a baseline assessment, four weekly treatment sessions beginning 2 weeks after baseline (sessions 2–5), and a posttreatment assessment session occurring 8 weeks after baseline. Parents and children were seen in separate groups of three to six people that were conducted simultaneously, lasting 60–90 min depending on group size. Parent groups were led by a Ph.D. psychologist or postdoctoral fellow with the assistance of a trained research assistant. Child groups were led by a postdoctoral fellow or two trained research assistants.

Parent Group. Parents were provided with nutritional information and child behavior management strategies focused on motivating their children to eat foods presented to them and reach their Ca goals. As evidence suggests that maximal accretion of bone has been found at Ca intake of 1480 mg/day (Jackman et al., 1997), the overall goal of the intervention was to increase Ca intake to 1500 mg/day. In providing nutritional information, a stepwise approach was utilized so that each session focused on increasing Ca to 400 mg at a particular meal beginning with breakfast and proceeding across lunch, dinner and to 300 mg at snack. At each session parents were provided feedback via graphs of their child's average Ca intake at each meal and total Ca intake per day during the previous weeks. Parents were also given

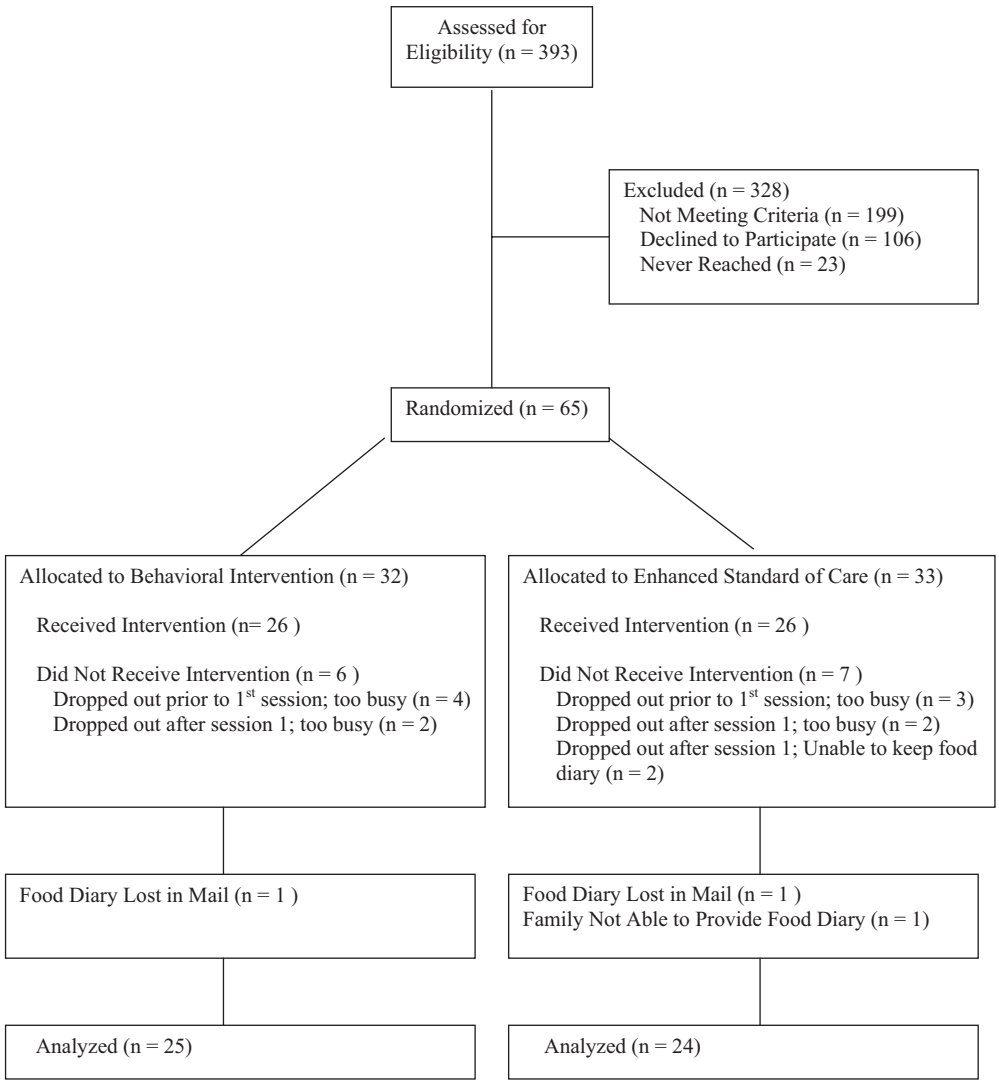

Figure 1. Participant Flow Chart through Randomization.

detailed information about strategies to boost their child's Ca intake including serving alternative high-Ca foods, adding Ca "boosters" (e.g., cheese) to increase the Ca content of dishes, and provided high-Ca recipes for the targeted meal. Parents were also provided with individualized suggestions on how high-Ca foods could be incorporated into their child's diet. Parents in the BI kept daily diet diaries on their child's food or beverage intake throughout treatment.

In addition to dietary information, parents were taught behavioral child management skills to assist them in motivating their children to make changes in their diet. Specifically, parents were taught to use a sticker chart to provide their child feedback on their progress in meeting their Ca goals. In session 2, parents were taught to use differential attention to praise their child when they placed a sticker on the child's sticker chart at each meal the child met their Ca goal and to ignore or refrain from commenting or coaxing their child at meals they did not meet their Ca goal, but to simply not put a sticker the child's sticker chart for that meal. Throughout treatment trophies were awarded in session each week if the child achieved their daily Ca goals at home on 5 out of 7 days between sessions. In session 3, parents were taught to identify rules and consequences for mealtimes. These rules primarily targeted problem behaviors of skipping meals such as breakfast on school days and lunch on weekends. In session 4, parents were taught contingency management where home based rewards such as computer privileges or special time with parents were given by the parent when a child met their Ca goal for the meal or day. Parents were also taught to use shaping to introduce new foods to their child. At session 6, problem solving was conducted to assist parents in

implementing the behavioral strategies to solve any barriers to the consumption of high-Ca foods and meeting daily Ca goals.

Child Group. Children were taught the importance of a high-Ca diet and how to identify high-Ca foods using age-appropriate language, and fun, educational activities. At each treatment session, children were given a practice meal and required to consume their Ca goal for that meal in order to earn a prize during the session. Behavioral techniques such as differential attention and shaping were employed in the group session to help motivate children to reach their Ca goal during the practice meal. Children were taught about the use of sticker charts to help them track their progress in meeting their Ca goals as described above.

Participant Adherence to the Behavior Protocol. Adherence to the behavioral protocol was examined by assessing the accuracy of the parents awarding or withholding stickers on the child's sticker chart. Accuracy in the use of the sticker chart was assessed by comparing stickers awarded/withheld on the sticker chart by meal or snack and overall daily Ca goal to the Ca intake in mg as recorded on the diet diary for each meal or snack and the total Ca for the day. Accurate usage was scored by meal or snack and total daily Ca if the diet diary showed the Ca intake in mg met the child's Ca goal and a sticker was placed on the child's sticker chart for that meal or snack, accurate usage was also scored if the child did not meet the Ca goal by meal or snack or total daily Ca and there was no sticker awarded on the chart. Reliability was assessed by having a second person independently score agreement on accurate use of the sticker chart using the formula number of agreements on accuracy/number of agreements + number of disagreements on accuracy and was 83% agreement for accuracy by meal or snack and 81% agreement on accuracy for Total Daily Ca.

Enhanced Standard of Care. ESC was designed to approximate the typical delivery of dietary counseling that would be available in a medical center setting in terms of number and length of sessions, but contain the identical nutritional information as the BI. The participants in the ESC had three visits over an 8 week period: baseline assessment, one treatment session (2 weeks after baseline), and posttreatment assessment (8 weeks after baseline). After a group baseline assessment session, which was identical in training content to the BI, the families in the ESC condition were seen individually for one 60-min intervention session (session 2) and one 60-min posttreatment assessment and feedback session (Session 3). Specifically, at Session 2 parents and children received nutritional information about optimal Ca intake and JRA. Similar to families in the BI, parents and children received feedback via graphs of their child's average Ca intake at each meal and total Ca intake per day during the baseline period, a notebook with handouts on foods high in Ca organized by meal (breakfast, lunch, dinner, and snack), and verbal suggestions for high-Ca food recommendations designed specifically for their child. The same dietary goal of increasing Ca intake to 1500 mg/day was set, and parents and children were encouraged to think of achieving 400 mg of Ca at each meal and 300 mg at snacks across each day.

At the interval corresponding to the posttreatment assessment visit (Week 8) for the BI group, the ESC families returned for posttreatment assessment visit. During this visit, the most recent food diary was reviewed, and families received feedback on their child's dietary Ca intake relative to the baseline period and the goal of 1500 mg of Ca/day. Families and children were always acknowledged for the gains made in Ca intake even if they did not meet the goal of 1500 mg/day and encouraged to continue trying to meet or to maintain the Ca goal of 1500 mg/day following Session 3.

Treatment Integrity. Treatment leaders were provided written treatment manuals, one for each intervention (BI and ESC) and separate manuals for the parent and child groups of the BI. They also received extensive training on the implementation of the two interventions. This training included page by page review of the treatment manual followed sequentially by role play with other treatment personnel and then role play with adults and children who were not participants in the study. Treatment leaders participated in weekly supervision throughout the project that included viewing of videotaped treatment sessions to ensure the interventions were accurately being implemented.

Data Analysis. Repeated measures analyses of variance using the statistical package SPSS (Version 11.0; SPSS, Inc. Chicago Illinois) were conducted to examine changes in dietary Ca and other measures of nutrient intake (i.e., calories, protein, and fat). The main hypothesis was that the BI would produce significantly greater changes in Ca intake than the ESC condition. Effect size was calculated using data from a study that examined changes in Ca secondary to caloric intake in CF (Stark et al., 2002) because no previous study has specifically targeted dietary Ca intake. Using the formulas described by Cohen (1977), the effect size for that study was 1.74 standard deviation units. Because the current study is the first to target dietary Ca intake and employ a control group, a more conservative effect size of .56 was used to estimate power. For an

effect size of .56, a sample of 24 subjects per group provides power of .80 to detect differences at the .05 level of significance.

Results

Study Population

Figure 1 depicts the flow of subjects through the randomized trial. Sixty-five families, or 38% of eligible families who could be contacted, agreed to participate and were randomized to treatment, 32 to the BI program and 33 to the ESC program. The primary reasons for declining participation were 40.6% too busy, 16% too far to travel weekly, 10.4% too many Dr's visits/X-rays/blood draws, 9.4% not interested, 5.7% JRA in remission or parent felt child got enough Ca, 13.2% miscellaneous (e.g., birth of new baby, death/illness of relative, and moving), and 4.7% sent "Decline to be contacted" cards. Thirteen families dropped out of treatment, six in the BI and seven in the ESC. Eight families dropped out prior to the baseline session and the signing of informed consent, while five families dropped out after the baseline session. An additional three families were unable to be included in the analysis because they did not provide diet diaries at either baseline or posttreatment. Because no Ca data were available at baseline for 10 of the 13 dropouts, an intent to treat analysis could not be employed, and 49 subjects are thus included in the analyses.

Demographic Characteristics of Sample

Characteristics of children whose families agreed to participate were compared to children whose families declined participation and those who dropped out of treatment. Multivariate analysis of variance examining difference in age, gender, illness duration, JRA subtype, and number of medications as a function of participant status (i.e., participant, decline, and dropout) was significant, $F(6,278) = 5.17$, $p < .01$. Post hoc analysis utilizing Tukey's HSD test for multiple comparisons revealed a significant difference between participants, declines, and drop outs on age, $F(2,141) = 4.62$, $p < .05$. Participants were younger ($M = 6.29 \pm 1.95$ years) than those who declined ($M = 7.38 \pm 2.06$ years) and those who dropped out ($M = 7.22 \pm 1.97$ years). Significant differences were also found on number of medications, $F(2,141) = 10.15$, $p < .01$. Participants were on more medications ($M = 2.04 \pm 1.73$) than those who declined ($M = 1.31 \pm .22$), but fewer medications than those who dropped out ($M = 3.38 \pm 1.41$). Participants did not differ from declines or dropouts on gender, illness duration or JRA subtype. Demographic data on participants by treatment group are presented in Table I. There were no significant differences between the children and their families assigned to BI or ESC with respect to child age, parental age, family size, and socioeconomic status.

Changes in Ca Intake

There was no difference in Ca intake at baseline between the two conditions ($F = .01$; $p > .05$). Children in the BI increased their Ca intake from 972 mg/day (±372) at baseline to 1811 mg/day (±324) at posttreatment, representing an average increase of 829 mg of Ca/day. Children in the ESC increased from 961 mg of Ca/day (±438) at baseline to 1281 mg of Ca/day (±358) at posttreatment, representing an average increase of 320 mg of

Table I. Demographic Characteristics of Families in the Behavioral Intervention and Enhanced Standard of Care Intervention Groups

	Behavioral Intervention ($n = 25$)	Enhanced Standard of Care ($n = 24$)
Child age	6.1 years (±2.0)	6.8 years (±2.0)
Female	76%	87%
% Caucasian	96%	92%
Number of children in the home	2.5 (±1.5)	2.5 (±1.0)
Mother's age	34.2 years (±4.9)	36.7 years (±5.7)
Father's age	35.4 years (±5.3) ($n = 24$)	38.0 years (±5.6) ($n = 23$)
Income before taxes		
$10,000–19,999	4%	8%
$20,000–29,999	0%	4%
$30,000–39,999	4%	8%
$40,000–49,999	12%	8%
>$50,000	80%	67%
Missing	0%	4%
Average Hollingshead score	44.5 (±10.7)	48.2 (±10.5)
Average Hollingshead level	Category IV	Category IV

Ca/day. Repeated measures analysis demonstrated a significant group by time interaction for Ca intake with children in the BI achieving a greater increase in dietary Ca intake from baseline to posttreatment compared to the ESC condition ($F = 14.39$; $p < .001$).

The clinical significance of this change in Ca intake was examined by comparing the percent of children in each group who were consuming an average of 1500 mg of Ca/day at baseline and posttreatment. Few children in either group were consuming 1500 mg of Ca/day and there were no differences between groups at baseline, $X^2 = 1.09$, $p < .05$. At posttreatment, however, 92% of children in the BI achieved the treatment goal of 1500 mg of Ca/day and this was significantly greater than the 17% of children in the ESC condition meeting this goal ($X^2 = 28.09$; $p < .001$). No adverse or side effects were found to occur during the trial.

Changes in Intake of Other Nutrients

The average number of calories and the percentage of calories from protein, carbohydrates, and fat consumed per day are displayed in Table II. There was no difference between intervention groups at baseline on total calories or percent calories from protein, carbohydrates, or fat. Repeated measures analysis of variance demonstrated no main effect for time ($F = 2.71$; $p > .05$) nor a group by time interaction effect ($F = 1.76$; $p > .05$) for total calories consumed per day or percent of calories from carbohydrates ($F = .44$; $p > .05$) or fat ($F = .02$; $p > .05$). Repeated measures analysis of variance also showed no group by time interaction effect for the percent of total calories from protein ($F = 3.45$; $p > .05$), carbohydrates ($F = .44$; $p > .05$), and fat ($F = .26$; $p > .05$). However, there was a significant main effect for time for the percent of calories from protein ($F = 5.76$; $p < .05$), indicating an increase from baseline to posttreatment across both groups.

Adherence to Behavioral Treatment. Agreement on accurate usage of stickers on the sticker charts by meal or snack was 83% (range 36% to 100%) and on Total Daily Ca was 81% (range 44% to 100%).

Discussion

This study is the first randomized, clinical trial to demonstrate the efficacy of a behavioral intervention designed to increase dietary Ca intake in children with a chronic health condition, JRA. The gains in Ca intake achieved in the current study were not only statistically significant, but also clinically significant. Ninety-two percent of the children in the BI achieved the targeted intake of 1500 mg of Ca/day, the upper level of intake recommended by the NIH Consensus Conference (1994) on Ca intake. In contrast, only 17% of the children in the ESC condition achieved 1500 mg of Ca/day by posttreatment.

The improvement in Ca intake was achieved without compromising dietary intake in other areas. It has been hypothesized that children and adolescents may avoid Ca rich (i.e., dairy) products, in part, because they fear the consumption of such products will increase fat intake (Graetzer, 2002). In this study, neither an increase in total calories or percent calories from fat was found to coincide with the increase in Ca intake. Recently studies of Ca intake and body fat in young children, ages 24–60 months, have found that higher Ca intake and greater number of servings of dairy foods to be longitudinally associated with lower body fat at age 70 months (Carruth & Skinner, 2001). Thus, improving Ca intake may also have important health benefits beyond BMD.

The positive results with Ca intake are similar to the positive changes in calorie intake found with CF using a similar model of BI (Stark et al., 2003) thus supporting the applicability of this model of BI across dietary components and disease conditions. The BI has multiple components which makes it difficult to identify the "active ingredient" in treatment. In this study, the BI treatment differed from the ESC dietary intervention on the number of health care contacts as well as behavioral

Table II. Average Daily Intake of the Other Nutrients at Baseline and Posttreatment for the Behavioral Intervention and Enhanced Standard of Care (ESC) Intervention

		% Total Calories		
	Total Calories	Protein	Carbohydrates	Fat
Behavioral intervention				
Baseline	1560 (±374)	13.2	56.2	31.8
Posttreatment	1741 (±353)	15.1	54.6	32.5
ESC intervention				
Baseline	1628 (±420)	14.2	54.9	33.2
Posttreatment	1647 (±418)	14.4	54.4	32.8

child management strategies taught. The differential contact was purposely incorporated in the design of the study but does leave open the possibility that the difference in Ca intake between groups may be due to the amount of contact time with a health care professional or time spent in treatment. However, in our study comparing BI for caloric intake in children with CF to a nutrition education condition, we found the caloric intake improved in the BI almost twice as much as it did in the nutrition education condition even though participants in the two conditions had the same number and length of health care contacts (Stark et al., 2003). Thus, we would argue that the differences in Ca intake in the current study are not likely to be due to time and contact alone. We believe several elements of the BI are more likely to account for the difference between the groups, including specific behavior management strategies, use of weekly goals and a stepwise approach to increase Ca intake gradually, and active involvement of children in the intervention process through educational activities and incentives (sticker charts and trophies) for reaching Ca goals.

Whereas the BI was more effective than the ESC, the ESC intervention was more effective than expected. Typically nutrition education programs have demonstrated increases in knowledge about nutrition, but not changes in eating behavior (Bell, Durie, & Forstner, 1984). There are a number of possible reasons for the improvement noted by children in the ESC condition. Although the number and length of contact with health care professionals was designed to be similar to a typical dietary counseling visit, the specific content was enhanced. For example, families in the ESC received feedback via graphs on their child's baseline Ca intake, the daily Ca goal of 1500 mg/day was broken down by meal and parents were instructed to target 400 mg Ca per meal, and parents were verbally provided feedback regarding substitute Ca foods tailored for their child. Few, if any, of these enhanced components of the intervention are regularly provided during typical dietary counseling.

The absence of a no treatment control group is a limitation in this study. As both interventions in the current study resulted in increases in dietary Ca intake, dietary Ca changes may be a function of time or reactivity due to monitoring that would have occurred without intervention. Although this interpretation is possible, cross sectional data on children's Ca intake indicate that no appreciable change occurs in Ca intake across time, and that it is more likely to decrease as children increase in age (Alaimo et al., 1994). Moreover, parental report of children's Ca intake may be vulnerable to reporting bias. All families were encouraged to increase Ca intake. As a result, parents may have over-reported their child's Ca or food intake. The lack of a reliability measure for dietary intake limits our ability to estimate over-reporting bias. As there are no gold standards for objectively quantifying Ca intake, it becomes important to examine the impact of Ca intake on physiological outcome measures of BMD. Increased Ca intake via pill supplementation has resulted in improved BMD in children (Lloyd et al., 1992; Lee et al., 1994); therefore, it will be important to follow this cohort of children to examine outcomes of BMD.

Finally, the recruitment rate is also a limitation of the current study as only 38% of families of eligible children participated, and participants may have differed from non-participants in ways that may have impacted their behavior and thus may limit the generalizability of the present findings. In general, participants were approximately 1 year younger than children whose families declined and dropped out, and participants were on a greater number of medications than children who declined, but fewer medications than children who dropped out. It may be that participants were more highly motivated than the general population of children with JRA to change their dietary intake, and that the intervention is more successful with younger children. These possibilities remain to be explored. It is important to note that there are no available data on typical recruitment for randomized clinical trials (RCTs) and few studies even report recruitment rates (Stinson, McGrath, & Yamada, 2003). Thus, it is difficult to compare the recruitment of the current study to other RCTs.

One barrier to recruitment appeared to be the time commitment to treatment as this was the most frequently cited reason for declining. Thus, the time commitment of BI may limit its utility. It may be possible to increase participation by decreasing the number of treatment visits. However, to accomplish decreasing the number of treatment sessions, future research must focus on identifying the salient components of the BI treatment. A potential method of abbreviating the current treatment is to tailor the behavioral strategies taught to address the individual family's barriers to achieving a high-Ca diet instead of teaching all strategies to all families. The current study utilized a group intervention; however, it is unclear whether this is the most efficacious or cost efficient method of treatment delivery. Alternative methods of treatment delivery also need to be explored such as individual sessions and delivery during a regularly scheduled clinic visit.

Poor bone health is a significant concern for a large number of children not just children with JRA or chronic

illness. Brief, efficacious interventions that can help establish healthy, high-Ca consumption patterns in diverse groups of children may provide a lifetime of benefit. The current randomized, clinical trial is a critical step in the prevention of osteoporosis in children with JRA and potentially other chronic health conditions by demonstrating the ability to improve dietary Ca consumption through BI.

Acknowledgments

This research was supported by a Clinical Science Grant from the Arthritis Foundation, NIH/NIDDK Grant #DK59492 to Lori J. Stark, Ph.D., and by USPHS Grant # MO1 RR 08084 from the General Clinical Research Centers Program, National Center for Research Resources, NIH. The authors thank Drs David Glass, Murray Passo, Brent Graham, Thomas Griffin, Robert Colbert, Alexei Grom, Gloria Higgins, and Suzanne Bowyer for their assistance in enrolling families and conducting treatment groups for this investigation.

Received October 1, 2003; revisions received March 15, 2004 accepted April 7, 2004

References

Abrams, S. A., Lipnick, R. N., Vieira, N. E., Stuff, J. E., & Yergey, A. L. (1993). Calcium absorption and metabolism in children with juvenile rheumatoid arthritis assessed using stable isotopes. *Journal of Rheumatology*, *20*, 1196–1200.

Alaimo, K., McDowell, M. A., Breifel, R. R., Bischof, A. M., Caughman, C. R., Loria, C. M., et al. (1994). *Dietary intake of vitamins, minerals, and fiber of persons ages 2 months and over in the United States: Third National Health and Nutrition Examination Survey, Phase 1. Advance Data from Vital and Health Statistics, no. 258. U.S. Department of Health and Human Services*. Hyattsville, MD: National Center for Health Statistics.

Baroncelli, G. I., DeLuca, F., Magazzu, G., Arrigo, T., Sferlazzas, C., Catena, C., et al. (1997). Bone demineralization in Cystic Fibrosis: Evidence of imbalance between bone formation and degradation. *Pediatric Research*, *41*, 391–401.

Bell, L., Durie, P., & Forstner, G. G. (1984). What do children with cystic fibrosis eat? *Journal of Pediatric Gastroenterology and Nutrition*, *3*, S137–S146.

Bhudhikanok, G. S., Wang, M. C., Marcus, R., Harkins, A., Moss, R. B., & Bachrach, L. K. (1998). Bone acquisition and loss in children and adults with cystic fibrosis: A longitudinal study. *Journal of Pediatrics*, *133*, 18–27.

Bonjour, J. P., Theintz, G., Buchs, B., Slosman, D., & Rizzoli, R. (1991). Critical years and stages of puberty for spinal and femoral bone mass accumulation during adolescence. *Journal of Clinical Endocrinology and Metabolism*, *73*, 555–563.

Carruth, B. R., & Skinner, J. D. (2001). The role of dietary calcium and other nutrients in moderating body fat in preschool children. *International Journal of Obesity and Related Metabolic Disorders*, *25*, 559–566.

Cassidy, J. T., & Hillman, L. S. (1997). Abnormalities in skeletal growth in children with juvenile rhaumatoid arthritis. *Rheumatic Disease Clinics of North America*, *23*, 499–522.

Cassidy, J. T., Langman, C. B., Allen, S. H., & Hillman, L. S. (1995). Bone mineral metabolism in children with juvenile rheumatoid arthritis. *Pediatric Clinics of North America*, *42*, 1017–1033.

Chan, G. M., Hoffman, K., & McMurry, M. (1995). Effects of dairy products on bone and body composition in pubertal girls. *Journal of Pediatrics*, *126*, 551–556.

Cohen, J. (1977). Statistical Power Analysis for the Behavioral Sciences. New York: Academic Press.

Daniels, L. A. (1984). Collection of dietary data from children with cystic fibrosis: Some problems and practicalities. *Human Nutrition*, *38*, 110–118.

Elsasser, U., Wilkins, B., Hesp, R., Thurnham, D. I., Reeve, J., & Ansell, B. M. (1982). Bone rarefaction and crush fractures in juvenile chronic arthritis. *Archives of Disease in Childhood*, *57*, 377–380.

Graetzer, K. (2002). *Lessons learned from the milk mustache campaign*. Paper presented at the National Calcium Summitt II, Washington, DC

Henderson, C. J., Cawkwell, G. D., Specker, B. L., Sierra, R. I., Wilmott, R. W., Campaigne, B. N., et al. (1997). Predictors of total body bone mineral density in non-corticosteroid-treated prepubertal children with juvenile rheumatoid arthritis. *Arthritis and Rheumatism*, *40*, 1967–1975.

Henderson, R. C., & Madsen, C. D. (1999). Bone mineral content and body composition in children and young adults with Cystic Fibrosis. *Pediatric Pulmonology*, *27*, 80–84.

Henderson, R. C., & Specter, B. B. (1994). Kyphosis and fractures in children and young adults with cystic fibrosis. *Journal of Pediatrics*, *125*, 208–212.

Hopp, R., Degan, J., Gallagher, J. C., & Cassidy, J. T. (1991). Estimation of bone mineral density in children with juvenile rheumatoid arthritis. *Journal of Rheumatology*, *18*, 1235–1239.

Jackman, L. A., Millane, S. S., Martin, B. R., Wood, O. B., McCabe, G. P., Peacock, M., et al. (1997). Calcium retention in relation to calcium intake and postmenarcheal age in adolescent females. *American Journal of Clinical Nutrition*, *66*, 327–333.

Johnston, C. C., Miller, J. Z., Slemenda, C. W., Reister, T. K., Hui, S., Christian, J. C., & Peacock, M. (1992). Calcium supplementation and increases in bone mineral density in children. *New England Journal of Medicine*, *327*, 82–87.

Kalkwarf, H. J., Khoury, J. C., & Lanphear, B. P. (2003). Milk intake during childhood and adolescence, adult bone density, and osteoporotic fractures in US women. *American Journal of Clinical Nutrition*, *77*, 257–265.

Lee, W. T., Leung, S. S., Leung, D. M., & Cheng, J. C. (1996). A follow-up study on the effects of calcium-supplement withdrawal and puberty on bone acquisition of children. *American Journal of Clinical Nutrition*, *64*, 71–77.

Lee, W. T., Leung, S. S., Wang, S. H., Xu, Y. C., Zeng, W. P., Lau, J., et al. (1994). Double-blind, controlled calcium supplementation and bone mineral accretion in children accustomed to a low-calcium diet. *American Journal of Clinical Nutrition*, *60*, 744–750.

Leonard, M. B., & Zemel, B. S. (2002). Current concepts in pediatric bone disease. *Pediatric Clinics of North America*, *49*, 143–173.

National, Osteoporosis Foundation. (n.d.). *Osteoporosis Fast Facts*. from http://www.nof.org/osteoporosis/stats.html/. Accessed March 12, 2004.

NIH, Consensus Conference. (1994). Optimal Calcium Intake. *Journal of the American Medical Association*, *272*, 1942–1948.

NIH:Osteoporosis prevention diagnosis and therapy. (2000). *NIH Consensus Statement*, *17*, 1–36.

Rapoff, M. A., & Barnard, M. U. (1991). Compliance with pediatric medical regimens. In J. A. Cramer, & B. Spilker (Ed.), *Patient Compliance in Medical Practice and Clinical Trials* (pp. 73–98). New York: Raven Press.

Saggese, G., Baroncelli, G. I., & Bertelloni, S. (2001). Osteoporosis in children and adolescents: Diagnosis, risk factors, and prevention. *Journal of Pediatric Endocrinology & Metabolism*, *14*, 833–839.

Slemenda, C. W., Reister, T. K., Peacock, M., & Johnston, C. C., Jr. (1993). Bone growth in children following the cessation of calcium supplementation. *Journal of Bone and Mineral Research*, *8*, S154.

St., Jeor, S. T., Guthrie, H. A., & Jones, M. B. (1983). Variability in nutrient intake in a 28-day period. *Journal of the American Dietary Association*, *83*, 155–162.

Stark, L. J., Mackner, L. M., Kessler, J. H., Opipari, L. C., & Quittner, A. L. (2002). Preliminary findings for calcium intake in children with Cystic Fibrosis following behavioral intervention for caloric intake. *Children's Health Care*, *32*, 107–118.

Stark, L. J., Opipari, L. C., Spieth, L., Jelalian, E., Quittner, A. L., Higgins, L., et al. (2003). Contribution of behavior therapy to dietary treatment in cystic fibrosis: A randomized controlled study with two-year follow-up. *Behavior Therapy*, *34*, 237–258.

Stinson, J. N., McGrath, P. J., & Yamada, J. T. (2003). Clinical trials in the Journal of Pediatric Psychology: Applying the CONSORT statement. *Journal of Pediatric Psychology*, *28*, 159–167.

Stuff, J. E., Garza, C., Smith, E. O., Nichols, B. L., & Montandon, C. M. (1983). A comparison of dietary methods in nutritional studies. *American Journal of Clinical Nutrition*, *37*, 300–306.

Teegarden, D., Lyle, R. M., Proulx, W. R., Johnston, C. C., & Weaver, C. M. (1999). Previous milk consumption is associated with greater bone density in young women. *American Journal of Clinical Nutrition, 69*, 1014–1017.

Tortolani, P. J., McCarthy, E. F., & Sponseller, P. D. (2002). Bone mineral density deficiency in children. *Journal of the American Academy of Orthopedic Surgery*, *10*, 57–66.

Warady, B. D., Lindsley, C. B., Robinson, F. G., & Lukert, B. P. (1994). Effects of nutritional supplementation on bone mineral status of children with rheumatic diseases receiving corticosteroid therapy. *Journal of Rheumatology, 21*, 530–535.

Zak, M., & Pederson, F. K. (2000). Juvenile chronic arthritis into adulthood: A long-term follow-up study. *Rheumatology*, *39*, 198–204.