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Soy Intervention in Adolescent Girls: Design and Implementation

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Abstract

The purpose of this study was to explore the feasibility of implementing a soy intervention in female adolescents. Twenty girls, ages 8 to 14, were recruited to consume 1 daily serving of soymilk or soy nuts. They also provided 9 weekly urine samples over a 2-month period. Information about the study foods and procedures was collected through post-study questionnaires. Adherence to the intervention was successful using strategies that addressed both girls' and mothers' needs. The use of conveniently packaged soy foods, activities to maintain motivation, and frequent contact maintained participation. Future studies should also consider the maturity and sense of responsibility of participants to achieve compliance.

Keywords

soy foods; adolescence; girls; nutritional intervention; compliance

INTRODUCTION

It has been hypothesized that exposure to soy foods early in life may play an important role in decreasing the risk for breast cancer in adulthood. Two recent epidemiologic studies among pre- and postmenopausal women assessed soy intake retrospectively and reported half the risk of breast cancer among women reporting a high soy intake during adolescence.^{1,2} Experimental studies among animals strongly support the protective effect of prepubertal soy consumption.^{3,4} Isoflavones, phytoestrogens contained in soy, may affect circulating estrogen levels during adolescence, or they may accelerate maturation of the developing breast. To date, neither of these hypothetical mechanisms nor the feasibility of a soy intervention among adolescents has been investigated. The majority of published nutritional intervention studies in this age group modified the existing diet rather than adding novel foods.^{5–7} Developing methods that appeal to and accommodate this age group is important for the success of such an intervention. The purpose of our study was to explore the feasibility of implementing a soy intervention in female adolescents. This article describes soy foods, the intervention strategy, and the study procedures of a soy-based dietary intervention and presents a qualitative evaluation of the major study components.

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DESCRIPTION OF THE INTERVENTION

Study Population and Recruitment

For this pilot study, we recruited 20 girls, ages 8 to 14 years, from 2 sources. We distributed flyers explaining the purpose of the study within the Cancer Research Center of Hawaii and mailed similar letters to premenopausal women who had previously participated in a soy intervention.⁸ Interested mothers who had seen the flyer would contact the study staff. Eligibility requirements were determined at a pre-screening telephone call with the parent of a prospective participant. At a screening visit, a nutritionist provided a detailed explanation of the study, and the girls and parents gave written informed consent. Self-determined ethnicity and medication use were recorded at that time. The majority of girls were in the 8-11-year age range ($n = 12$), with a mean age of 10.7 ± 2.0 years. Three girls reported Caucasian ancestry only; 6 girls were exclusively of Asian (primarily Japanese) descent, and the remaining 8 girls were of mixed ethnicity. At baseline, usual soy intake ranged from 0 to 3 servings per week, and no food allergies related to soy were reported. We received 22 inquiries about the study, 20 girls started the study, and 17 girls completed the 8-week protocol. Two girls were unable to consume the soy foods after 1 week; one of them developed flu-like symptoms while eating her soy foods and thought that this might have been related to the soy. A third dropout no longer wanted to collect urine samples after 3 weeks. However, she was included in this final report of 18 participants. The University of Hawaii Committee on Human Studies approved the recruitment and study protocol.

Soy Intervention

The girls were asked to consume 1 daily serving of either soymilk (8.45 oz) or soy nuts (1 oz) for an 8-week period (Table 1). In a previous study, women consumed 2 servings a day based on isoflavone amounts (30-50 mg/day) equivalent to diets consumed in Asian countries.⁸ Based on these data, smaller servings (providing at least 30 mg) were considered for this age group. The plain, sweetened soymilk and honey-roasted soy nuts were both individually packaged (drink box and snack bag). The soymilk is fortified with 200 mg calcium and 40 IU vitamin D per serving. Girls already accustomed to tofu or to a certain brand of soymilk were encouraged to continue these alternatives instead of the foods provided. The isoflavone content of the 2 foods is similar to that of tofu (see Table 1). To help determine soy food choices for the duration of the study, the girls participated in a baseline soy food taste test. They were asked to rank the soymilk and soy nuts on a scale of 1 ("no way!") to 5 ("hurray!"). At the end of the study, a final taste test determined any changes in ratings. After an initial dietary assessment, individualized nutrition counseling provided ideas on how to incorporate the soy foods into the diet daily while minimizing excessive weight gain (eg, replace sodas or drinks with soymilk). In addition, basic nutrition education, such as the US Department of Agriculture's Food Guide Pyramid, healthful eating habits, and facts about fruits and vegetables, was offered to the girls. During the 8 weeks, the girls used laminated, calendar-style "sticker sheets" featuring the colorful "Soy Girls" logo (Figure) to track daily soy intake and weekly urine collections. If applicable, yellow star stickers were placed on the sticker sheet to mark the start of a menstrual cycle. Colorful magnets were provided for hanging the sticker sheet in a visible area, such as on the refrigerator.

Study Protocol

After the screening visit, the girls completed a 1-week trial with the chosen soy food(s). A pick-up date for the remainder of the soy foods was scheduled after assessment of compliance and willingness to continue the study. The girls were allowed to change the chosen soy food or modify the combination of soymilk and nuts at this point. At week 4, a midpoint telephone call assessed compliance with study protocol with respect to soy consumption and urine collection. The nutritionist also recorded new medications, health problems, and menstrual

information and addressed problems at that time. If we were unable to reach a girl for a follow-up telephone call, the mother was interviewed instead. Twice during the study, mailings containing a “5 A Day” nutrition puzzle,⁹ memos of encouragement, and reminders were sent to the subjects. A post-study questionnaire was mailed to both the girl and the parent prior to the final visit, when frozen urine samples, any leftover food and stickers, sticker sheets, and post-study questionnaires were collected. On return of the sticker sheet, the girls received bookstore gift certificates. At the screening and at the final visit, height and weight were measured by a stadiometer and a balance scale. Also at the screening and final visit, girls completed a Tanner staging questionnaire,¹⁰ which assessed stage of maturation using pictorial scales for breast and pubic hair development. To allow privacy, the girls were offered the choice to complete the questions without the presence of their parents. If appropriate, menstruation history and, if appropriate, the age at menarche were recorded as part of the questionnaire. Each girl collected 9 urine samples. The procedure was described, and the use of the collection containers was demonstrated to girls and mothers at the first visit. In addition, the families took a detailed instruction sheet home. The girls collected their first morning urine sample, chose the most convenient weekend day, and tried again on the next day if they had missed their designated day. The urine was collected in 15 mL cryovials and was placed in a cardboard box with compartments labeled 1 to 9, which was stored in an airtight plastic container in the home freezer until the time of the final visit.

Dietary Assessment

The girls completed 3-day food records (adapted from R. Novotny, USDA FAM study 1999-2003, unpublished) at baseline and at the end of the study. Each girl wrote down her food intake over 3 consecutive days, including 1 weekend day. We used plastic food models to describe portion sizes, and girls were given measuring cups, spoons, and a laminated placemat with concentric circles and a ruler¹¹ to measure portion sizes. After the food records were completed, they were reviewed with the girls to clarify and account for any missing information. To evaluate usual soy intake, a validated soy food frequency questionnaire was also administered¹² at the screening visit.

DESCRIPTION OF THE EVALUATION: POST-STUDY QUESTIONNAIRE

The final questionnaire addressed the girls’ thoughts about soy foods and study procedures. The girls described their preferences for different soy foods and the optimal preparation (eg, soymilk on cereal or in a smoothie). The girls were asked to rate the study procedures (eg, collecting urine samples); to express their ideas about telephone calls, mailings, communication through electronic mail, and rewards; and to provide additional comments. A separate questionnaire for the parents elicited opinions about study procedures and asked for relevant observation. For example, we asked, “Was your daughter motivated to eat her soy food, collect her urine, and use her sticker sheet? Or was this study more work for you than for her?” The parent was also asked to comment on the suitability of language, helpfulness of the sticker sheet, telephone calls, and rewards and to suggest ways to make the study more manageable.

LESSONS LEARNED

Soy Foods

After trying the soy foods, the majority of girls requested a combination of soymilk and soy nuts, with a higher frequency of soy nuts. A few girls preferred a single type of soy food: soymilk (n = 3), soy nuts (n = 2), or tofu (n = 1). Eating soy foods every day was considered “manageable” for half of the girls. Only one girl, who had no history of consuming soy foods, considered it to be a “hard” task; the remaining girls found it “easy.” Difficulties included

remembering to eat or drink the food and having a busy schedule. The mothers indicated that the most important attributes of the study soy foods were their convenience and that they needed no preparation. One mother commented, “I preferred the individual containers. These can easily be put into school lunch boxes. Also, my daughters could take the soymilk out of the refrigerator without my help.” The ease of not having to measure out the soymilk was also mentioned. However, families who already consumed soy-milk preferred the larger container.

Several girls favored a brand of soymilk other than the one provided, which the mothers agreed to supply. The flavor of the soymilk appeared to be crucial in determining the girls’ ability to complete the study. In the initial taste test, 8 girls rated the soymilk above 3 (of 5), 4 rated it a 3, and 6 rated it below 3. The “taste of the soymilk” was the most common reason for not consuming it daily. Two of the girls did not like the texture, and one of them “got tired of it.” Because the study provided only one flavor, some girls found it monotonous and boring. In a post-study taste test of 3 soymilk flavors, chocolate was preferred over strawberry and plain. A brand of plain, sweetened soymilk other than the one used in the study also ranked close to the chocolate soymilk. The girls attributed the overall success of consuming soymilk to previous exposure and to initial approval of the taste. Among 11 girls using soymilk regularly, the average intake ranged from 2 to 7 servings per week. Although the soymilk was primarily consumed straight from the box, other forms of consumption, such as mixed in a smoothie or in combination with cereal or cookies, were also mentioned. The majority of girls preferred to have the soymilk as a breakfast drink or afternoon snack. The serving size of the soy nuts was often considered too large despite the recommendation to distribute it throughout the day. Although the initial feedback on the taste of the honey-roasted soy nuts was positive, the girls frequently became bored with the taste. They suggested that other flavors and a smaller volume might be more acceptable. For the 10 girls who consumed soy nuts, the average intake ranged from 1 to 7 servings per week. The soy nuts were primarily consumed straight from the package, although sprinkling them on a salad or creating “chocolate” soy nuts was also mentioned. The most common eating occasion for the soy nuts was as an afternoon snack. Two girls did not like the soy nuts because they “tasted horrible” or “turned mushy after a while, like peanut butter.” Other soy foods consumed by some girls were Boca brand vegetarian burgers, miso soup, and soy bars. The idea of having the ability to “pick and choose” a food appeared to make a daily serving more interesting. Although tofu was suggested as an option, concern was expressed that because it does not come packaged in single servings, it would need to be measured out. Green soybeans, soy bars, soy granola, soy meat substitutes, miso soup, and soy butters were also suggested as alternatives for future studies. However, the amount needed to provide equivalent doses of isoflavones may preclude the use of some of these products.

Study Protocol

We observed differences in the ability to adhere to study procedures according to the age of the girls. For example, detailed explanations were needed for the younger girls (ages 8-11), whereas the older girls were able to grasp the information much faster. Although we used the same educational materials and study procedures (eg, stickers/sticker sheet) for all girls, the use of age-appropriate educational material and methods may be warranted.¹³ For example, the younger girls liked the “5 A Day” nutrition maze/word find puzzles more than did the older girls. The general consensus of the mothers was that the nutrition education material was valuable because it made their daughters more aware of what they were eating. Learning about portion sizes using the measuring utensils and the reinforcement of good nutritional habits by a professional were also noted as beneficial.

Sensitivity to the level of knowledge about pubertal development appeared to be an important issue. When the girls were completing the Tanner staging questionnaire, we noticed that several girls were not familiar with the term “menstruation.” In future studies, we will assess the stage

of pubertal development prior to asking about menstruation and restrict that question to girls who are stage 3 or higher, when menarche normally occurs.¹⁰ The girls appreciated the option to be alone when completing the Tanner staging questionnaire. Follow-up by telephone about menstruation was not reliable because the girls did not appear to be comfortable discussing it. The developmental questions were well accepted by the mothers; for some girls, they reinforced what they were learning in school.

Owing to busy schedules, it was often difficult to reach the girls during the day. The majority of the girls accepted the telephone calls as a reminder or motivator to continue with their soy foods, but, according to the mothers, there was also some negative feedback about the calls, because of, for example, guilty feelings about not eating the foods. The mothers said that these follow-up telephone calls were important to make the girls feel more responsible, connected, and committed to the study, and, as one mother commented, “very grown up.” Because of the timing of this study during the summer, we cannot predict whether the overall positive compliance would be different during the school year. The more regimented schedule during the year may make it easier to include study procedures.

Most of the girls found the urine collections “easy” and “manageable” and wanted to complete the procedure alone. However, some of the younger girls needed some assistance. Busy schedules often made it difficult to remember the urine collection on the designated day. Activities on the weekend, such as sleepovers at a friend’s house, determined the day of urine collection for the girls. Flexibility with the collection day (eg, collecting 1 day before or later or postponing collection until after a trip) and the sticker sheet were found to be very important for obtaining all samples. The majority of mothers and daughters accepted at-home freezer storage of the urine samples. The idea of collecting their urine into a cup was considered unusual and did not appeal to several girls at the beginning, but only one girl discontinued the study for this reason. It was also important that other family members (such as younger siblings) should not notice the urine collection.

The motivation to complete the study was frequently maintained through encouragement by the mothers. For some of the girls, the mother took on the responsibility to remind her to complete the study procedures. There was a suggestion that the sticker sheets were more helpful to the mothers than to the girls. As proposed by one mother, regular incentives may be a better way to motivate the girls along the way. Targeting groups of girls who already know each other might assist with study compliance and motivation because they may support each other. Although the gift certificates for books at the end of the study were appreciated, other ideas for incentives were offered, such as movie passes and gift certificates for clothing, sport stores, shopping malls, or a local smoothie shop.

Dietary Assessment

According to most girls, completing the food records was manageable, in particular for girls who had previously completed one in school. The mothers were very involved with this part of the study and sometimes wrote down the foods for their daughters. Difficulty remembering everything and the time it takes to write everything down were mentioned as problems. The girls enjoyed touching and playing with the food models and described them, as well as the assistance from the parents and the measuring cups, as helpful.

IMPLICATIONS FOR RESEARCH AND PRACTICE

This 8-week pilot project demonstrated that girls between 8 and 14 years are able to incorporate 1 serving of soy per day and collect a weekly urine sample. The sticker sheets demonstrated 89% adherence with the daily soy servings and 100% compliance with the urine collections. However, a variety of soy foods and activities were required to maintain participation for this

relatively short time period. This suggests that future long-term studies need to include many different types of soy foods and suggestions for preparation, offer age-appropriate activities, and maintain frequent contact with the participating girls. To investigate the effects of soy on hormonal and breast development, a longer nutritional intervention and observation period will be necessary because we must assume that the possible protection from soy consumption during adolescence observed in 2 case-control studies^{1,2} was a result of long-term exposure. We learned from the mothers that it would be important to assess the maturity and sense of responsibility of potential participants to achieve compliance in such a study. The girls need to understand the importance of research to take an active role. In addition, their motivation would have to be maintained with the help of frequent contact and activities and possibly group support. The overall design and strategies used for this pilot study can be considered a starting point for designing future studies, but a number of improvements need to be developed. Dividing the girls into smaller age groups may allow the selection of materials that are more appropriate for their intellectual development (eg, easy nutrition games vs the Internet). Further testing of the educational materials is advisable because generating true interest in the information¹³ is the key to teaching new, applicable concepts to girls participating in such a study.

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Figure.
"Soy Girls" study logo.

Table 1

Nutritional Content of Soy Foods*

Variable	Soy Milk, Plain	Soy Nuts	Tofu
Serving Size	8.45 oz	1/3 cup	3/4 cup
Weight, g	250	28	189
Energy, kcal	250	132	115
Protein, g	7	10	12
Fat, g	5	7	7
Isoflavones, mg†	38	31	38

* Nutrient profiles from the Cancer Research Center of Hawaii nutrient database.

† Dr. Adrian Franke's laboratory.