Soy- and Rice-Based Processed Complementary Food Increases Nutrient Intakes in Infants and Is Equally Acceptable with or without Added Milk Powder\(^1,2\)

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Abstract

Processed complementary foods (PCF) might mitigate several complementary feeding barriers in developing countries. Efficacy trials, however, have not shown substantial improvements in child growth, possibly due to inadequate formative research to assess acceptability and identify pitfalls. Milk powder might improve palatability of PCF but incurs a higher cost.

We compared the acceptability of an instant soy-rice PCF without (SR) and with (SRM) milk powder. Best practices for formative evaluation of PCF are not established. We therefore compared findings from randomized trials of SR vs. SRM in 1-d sensory tests (\(n = 71\) mother-infant dyads) vs. Trials of Improved Practices (TIPs), a 2-wk in-home mixed methods evaluation (\(n = 54\) dyads). TIPs included interviews, disappearance rates, observations, and 24-h dietary recalls to assess acceptance, consumption of the 50 g/d ration, and impact on diet. Although mothers preferred SRM to SR in the sensory tests, children in the TIPs consumed \(>50\) g/d of SR (87 \(\pm\) 9 g/d) and SRM (89 \(\pm\) 8 g/d) with no difference between the foods (\(P = 0.55\)). Despite some replacement of family food, energy (574 kJ/d; \(P < 0.001\)) and protein (19 g protein/d; \(P < 0.001\)) increased in both groups. Mothers’ preferences for milk, more sugar in SR, and preparation with hot water were concerns raised in the sensory tests that proved insignificant in TIPs. However, TIPs uncovered new concerns of overconsumption and food safety. We found milk did not improve the acceptability of the soy-rice PCF and recommend TIPs as a useful tool for formative research of PCF interventions. J. Nutr. 138: 1963–1968, 2008.

Introduction

Processed complementary foods (PCF)\(^5\) have long been proposed as a component of infant and young child feeding interventions because of their potential to mitigate several common barriers to optimal complementary feeding in resource-poor areas. PCF can supply appropriate levels of nutrients via a fortified cereal/legume mixture and provide a precooked, instant product that may be easily prepared 1 serving at a time, thus avoiding storage of leftovers (1). Use of PCF has been widespread and successful in improving growth and micronutrient status in many Latin American countries (1–3).

In contrast to evidence from Latin America, efficacy trials with PCF in sub-Saharan Africa and South Asia have had inconclusive effects on growth and micronutrient status (4–6). In addition to problems with trial design and fortificant bioavailability, researchers cite problems with contextual and behavioral issues. In Ghana, study children may have been less zinc deficient than anticipated, limiting their potential to benefit from the provision of the fortified PCF (4). In India, replacement of breast milk was an unanticipated obstacle to improving diets and therefore growth (6). In Tanzania and India, mothers did not feed adequate amounts of the PCF (5,6).

The use of milk powder in PCF might improve palatability and therefore increase intakes and positive health effects. Milk powder is a high-quality source of protein and calcium and there is evidence that other milk constituents have specific benefits for child growth (1). However, milk powder is an expensive and usually imported commodity, with implications for economic feasibility.

To predict compliance with PCF interventions, previous research included very short-term acceptability studies that did not identify the problems eventually encountered (4,5). Acceptability studies have typically been 1-d sensory panels of mothers, with or without their children, or assessment of infant consumption of the PCF during very structured feeding observations (7–10).

Trials of Improved Practices (TIPs) are a formative research approach for identifying practices to promote in health behavior change interventions. Originally designed to identify acceptable...
and feasible practices to improve child feeding (11), TIPs have also been used in programs on family planning, malaria prevention, and indoor air pollution (12). TIPs involve assessment of household conditions by program or research staff, followed by negotiation with families to try 1-3 improved practices for a short period. Follow-up interviews assess responses to the new behaviors, elucidating which practices are most acceptable and feasible in a population, and the factors that influence household responses (11). The use of TIPs has been recommended prior to implementation of infant feeding interventions (13) but requires more resources and time than simple sensory tests.

We present results from an acceptability study of 2 PCF studied in preparation for a planned efficacy trial in Zanzibar. Because efficacy trials are expensive and time-consuming, we conducted an in-depth acceptability trial to gain insight into the potential impact and pitfalls of introducing a PCF in this low-income African setting. We had 2 objectives: 1) to compare the acceptability of a soy-rice PCF with or without milk powder; and 2) to compare the knowledge gained using 1-d sensory tests compared with 2-wk at-home TIPs.

Methods

Study setting
We conducted the study in Pemba Island, Zanzibar, Tanzania from January, 2006 to March, 2006. Three study sites were selected purposively to maximize sample diversity: 1 semiurban (urban), 1 inland rural (inland), and 1 coastal rural (coastal) site.

Trial foods
Two soy and rice-based extruded products were used in this study (InstaLIFE International and InstaPRO International). The soy and rice only (SR) product contained a mixture of 50% full-fat soybean, a common PCF legume (14,15), and 50% rice extruded together, dried and milled. The extrusion process made SR fully digestible and instant, requiring only reconstitution with water. The soy and rice with milk (SRM) product was 50% SR mixed with 50% nonfat dry milk powder after milling. Because the lactose in SRM made it sweeter than SR, 7.5% wt:wt powdered sugar was added to SR to provide similar sweetness. This formative study was not designed to assess impact on micronutrient status and the fortificant premix was not yet optimized for infants, with final decisions pending findings on infant consumption. The products used in the studies were fortified with B vitamins, vitamins C and D, and iodine, but not with iron, zinc, or vitamin A, all key nutrients for infants (formulations and macronutrient composition in Table 1). Among these, iron is of greatest concern for organoleptic changes. Following this fieldwork, we conducted sensory trials in U.S. adults with iron-fortified SR and SRM and found no negative taste differences compared with 2-wk at-home TIPs.

Table 1: Trial product formulation and macronutrient content

<table>
<thead>
<tr>
<th></th>
<th>SR</th>
<th>SRM</th>
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<tbody>
<tr>
<td>50:50 Soy rice</td>
<td>92.5</td>
<td>50.0</td>
</tr>
<tr>
<td>Sugar</td>
<td>7.5</td>
<td>0</td>
</tr>
<tr>
<td>Dry skim milk</td>
<td>0</td>
<td>50.0</td>
</tr>
<tr>
<td>Energy, kJ/100 g</td>
<td>1716.6</td>
<td>1607.7</td>
</tr>
<tr>
<td>Protein</td>
<td>21.3</td>
<td>29.0</td>
</tr>
<tr>
<td>Fat</td>
<td>8.1</td>
<td>3.2</td>
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</table>

1 A fortificant premix was added to the final formulation at 0.32% wt:wt. The premix contained recommended target levels (11) of B vitamins, vitamins C and D, and iodine, given that there were only trace amounts of these micronutrients in the unfortified product. Vitamin A, iron, and zinc were not added pending results on daily consumption during TIPs.

Thus, the lack of iron fortificant in the trial products is unlikely to have affected our findings.

Enrollment
Mothers with infants aged 10-15 mo (n = 125 dyads) participated in the trial. This is the age range at which the prevalence of stunting and wasting is greatest in this population (16) and a previous trial in Ghana found the greatest benefit from a complementary food intervention after 9 mo of age (4); From a representative list of women who attended antenatal care (17), we randomly selected infants evenly distributed across the age range at each site.

Trial protocol
We conducted the study in 2 parts: 1-d sensory tests (n = 71 dyads) and 2-wk home trials (n = 54 dyads). Four 1-d sensory tests were conducted at each site to compare the acceptability of SR and SRM. Mothers prepared 25-g samples of the 2 porridges, preparing one at a time so that an observer could ask the mother about each porridge individually. The order of the porridges was randomly assigned to dyads.

The 2-wk home trials were based on TIPs but modified to allow detailed dietary assessment and to evaluate longer-term acceptability and ability of children to consume the minimum targeted ration of 50 g/d (1) of SR and SRM. In each site, we enrolled 18 mother/infant dyads who had not participated in the sensory tests. Within each site, age-matched pairs of infants were randomly assigned SR or SRM by the flip of a coin.

During the enrollment visit, fieldworkers conducted a 24-h recall. During the 2nd visit, we delivered the assigned trial food, demonstrated how to measure and prepare a 50-g serving, and asked the mother to: 1) feed at least 50 g/d dry SR or SRM; 2) continue breast-feeding and feeding nutritious family foods as usual; 3) not share the infant's food; and 4) feed as much SR or SRM as the child wanted. Teams of 2 fieldworkers visited the mother and child 3 more times, for a total of 5 visits, to monitor changes in dietary intake, acceptance, and consumption of trial food. To discourage sharing of the infant's food, fieldworkers provided family rations ad libitum for the duration of the 2-wk trial. On d 14, mothers responded to questions about food sharing. All protocols and consent forms were approved by Institutional Review Boards of Cornell University and the Zanzibar Ministry of Health. Informed consent was obtained from all participating families.

Data collection methods

Reactions to SR and SRM. During the sensory tests, mothers rated product characteristics on a 5-point hedonic scale. Characteristics included appearance, ease of preparation, mother's and child's reactions to tasting, and mother's willingness to feed the porridges. Observers recorded verbatim any comments the mothers made in regard to each question. Finally, mothers were asked which porridge they preferred.

During the TIPs, semistructured interviews were conducted using a prepared set of open-ended questions. Follow-up interviews focused on how often the mother tried feeding the porridge, reactions of the mother, baby, and other family members to the new porridge, and the mother's willingness to continue feeding it. Feeding observations were conducted during the 3rd visit on d 5.

Energy density and daily consumption. We calculated energy densities of the porridge as prepared by the mothers during sensory tests, food demonstrations, and feeding observations. The primary measurement of daily consumption was the household disappearance rate of SR or SRM. Consumption based on the disappearance rate was positively correlated with intakes based on the 24-h recalls (r = 0.64; P < 0.001).

Dietary intake. Fieldworkers conducted 4 24-h dietary recalls for each child: on visits 1 and 2 to determine baseline dietary intakes and on visits 4 and 5 (d 10 and 14) to determine dietary intakes after the introduction of SR or SRM. Sample amounts of food that the child consumed were weighed by staff. If weighed samples were not feasible, staff recorded qualitative descriptions of amounts that were then reproduced and weighed in the laboratory. If no amount was reported (8% of food items), median portion sizes of that food from the same child were used.
or, if not available, from other children. Interviewers asked mothers for all the ingredients in a mixed dish and probed as to whether the child ate some of all the ingredients.

Reported food intakes were converted to daily intakes of energy, fat, and protein. Nutrient composition of raw foods and nonmixed foods were taken from an East African foods database if available, or, if not, from a general African food database or the USDA database (18–20). To estimate nutrient composition of local mixed dishes, research staff prepared the recipes, weighing the raw ingredients and the final cooked product. Standard algorithms for estimating nutrient composition of recipes were used (21,22). Frequencies of all foods mentioned for all children at each 24-h dietary recall were also compared pre- and postintervention.

Data analysis

Quantitative data. Data on dietary intake, energy density, and consumption of SR and SRM were analyzed using a multi-level model with age, gender, site, time (pre- or postintervention), and type of food as fixed effects and child as a random factor. Significant effects were followed with multiple comparisons with Bonferroni correction. Non-breast-feeding children (n = 5) and children who were ill on both days (pre- or postintervention, n = 4) were excluded from the dietary intake analysis. We used chi-square tests to compare proportions. P-values < 0.05 were considered statistically significant. Analyses were conducted using JMP 6.0 or STATA 8.0.

Qualitative data. Fieldworkers’ detailed notes on interview responses and observations were translated from Swahili into English. Using software for qualitative data analysis, ATLAS.ti, text segments were labeled with codes identifying content related to specific aspects of acceptability of the new foods and related themes. The coded data were then tabulated and summarized according to themes that emerged from the data (23).

Results

Participants

Mothers’ median level of education was primary school (Table 2). Most fathers were fishermen in the coastal site, farmers in the inland site, and civil servants or teachers in the urban site. Most mothers identified themselves as housewives or farmers and were 20–30 y old. Most were experienced mothers, with only 16 of the 125 dyads including first children.

Milk vs. no milk

The majority of mothers in the sensory tests rated both SR and SRM highly for taste, infant’s reaction, ease of preparation, and their willingness to feed the porridge. According to fieldworkers’ ratings, the majority of infants reacted well to both of the porridges, with 76.3% of infants “liking” SRM and 64.9% “liking” SR; the reactions of the 2 groups did not differ (P = 0.30). When asked directly which product they preferred, 74% of mothers preferred SRM. Their reasons were: 1) mothers liked the milk (51%); 2) mothers liked the sweetness of SRM (34%); and 3) mothers perceived that the baby ate more of the SRM (17%). However, in the 2-wk TIPs, infants’ consumption of SR (87 ± 9.4 g/d dry product) and SRM (89 ± 8.7 g/d dry product) did not differ (P = 0.55).

Comparison of 1-d test and 2-wk TIPs

Interviews with mothers. Mothers’ views on preparation, taste, and motivation to feed the porridges did not differ between sensory tests and TIPs. Most felt that preparation was convenient, noting that it was “quick to prepare,” and “you don’t have to boil water.” The mothers generally liked the milk and sweetness of SRM and often commented in sensory tests and TIPs that SR had too little sugar. Mothers assumed that the porridges were made of common foods such as groundnuts, maize, biscuits, and other cereals and they regarded mixtures of these types of ingredients as healthy. Approximately 10–20% of mothers in both sensory tests and TIPs commented that the porridges tasted “cold” and needed to be made with hot water. The motivation most frequently mentioned by mothers (in sensory trials and TIPs) for feeding either product was that these were healthy and nutritious foods that would be good for their children. The 2nd most common motivation was that the child liked the foods.

There were, however, some differences between sensory test and TIPs results. First, ease of preparation and familiarity of ingredients were mentioned frequently during the TIPs, but

<table>
<thead>
<tr>
<th>TABLE 2 Demographic characteristics of study participants</th>
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<tbody>
<tr>
<td><strong>Sensory tests</strong></td>
</tr>
<tr>
<td>Coastal</td>
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<tr>
<td>----------</td>
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<tr>
<td>n</td>
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<tr>
<td>Age of child, mo</td>
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<tr>
<td>10–11</td>
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<td>12–13</td>
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<td>14–15</td>
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<tr>
<td>Males, %</td>
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<tr>
<td>Age of mother, y</td>
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<td>20–29</td>
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<td>30–39</td>
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<td>40–49</td>
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<tr>
<td>50+</td>
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<tr>
<td>Educational level</td>
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<td>No primary school</td>
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<td>Some primary school</td>
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<td>Completed primary school</td>
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<td>Secondary school</td>
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<td>1st child</td>
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rarely during sensory tests. Second, during TIPs, mothers became less concerned that the prepared food was cold, a concern they had raised in the sensory tests. Although 16.7% of mothers in the sensory tests and 14.8% of mothers in TIPs initially said the porridges needed to be made with warm or hot water, only 5.6% of mothers in TIPs actually did so. Finally, only TIPs allowed in-home assessment of consumption and potential impact on diet, as reported below.

**Energy density and daily consumption.** Overdilution of the porridges was not a problem. On average, mothers mixed SR with water in a 2:1 proportion compared with 1:5:1 for SRM, likely due to the higher starch content in SR making it more viscous. As a result, the energy density of prepared SRM (8.00 ± 0.13 kJ/g) was higher during sensory tests and TIPs than SR (5.74 ± 0.13 kJ/g) (P < 0.001). During feeding observations, almost one-half of all mothers added extra ingredients to the porridges. Most commonly, they added sugar to SR, although 6 mothers added sugar to SRM. Three mothers added milk to SR. Children in all age groups ate on average >50 g/d dry product for both SR and SRM (Fig. 1). Children aged 10–11 mo consumed less food per day than children aged 12–15 mo (P < 0.001). Unexpectedly, TIPs data revealed a potential problem of consumption. Children in the inland site consumed more food per day than children in the coastal and urban sites (P < 0.001). In the inland site, children 10–11 mo old ate on average double our target daily intake and those 12–15 mo old ate 3 times our target intake. There were no significant interactions.

**Impact on diet.** During the final TIPs interview, mothers were asked about any changes in feeding. The majority (67%) reported no changes in breast-feeding frequency and most who did report a change reported decreased breast-feeding. Thirty-three of 54 mothers reported that the baby had begun to refuse some other foods during the intervention, but 35 mothers also reported that the baby was eating more frequently after the intervention. The 24-h recalls showed an average increase of 1 feeding per day over the 2-wk period, from 3.35 to 4.34 feedings (P < 0.001). The reported frequency of some family foods changed during the intervention (Fig. 2). The most commonly reported family foods in the 24-h dietary recalls before the intervention were rice, tea, bread rolls, fish stew, boiled cassava, and mango. After the introduction of SR and SRM, frequency of reporting these foods decreased, suggesting some replacement by the PCF.

Dietary recall data indicated that energy and protein intakes from complementary foods increased significantly in all sites with the introduction of SR and SRM (Table 3). Assuming an average intake of breast milk in all age groups, 35% of children were below the estimated energy requirements at baseline (13) compared with 11% by the end of the intervention (P = 0.015). Protein intakes were generally adequate preintervention as well as postintervention. Children consuming SRM experienced a significant decrease in fat intake, whereas children consuming SR did not. This was expected given that the nonfat milk powder displaced 25% of the full-fat soy in SRM. It is worth noting that the percentages of energy from fat in these products (18% for SR and 7.5% for SRM) are lower than the recommended 24–28% for PCF (1). These were levels set for the manufacturers’ base formulation and could not be altered for the study. Other significant determinants of energy and protein intakes included site, age, and sex (for energy only).

The only reported leakage of the infant food to other family members occurred when siblings or the mother occasionally ate the leftovers of porridge prepared for the infant. Mothers stated that provision of the family food was crucial to deter sharing of the infant food among family members.

**Discussion**

**Milk vs. no milk.** Milk powder was not necessary for the acceptability of the soy-rice PCF, nor did it improve the acceptability. Despite mothers’ preference for SRM during the sensory tests, children ate the same amount of SRM and SR during the TIPs. This was in contrast to our expectation that children would find the milk product more palatable and eat more of it. Milk is high in lactose and children have a preference for sweet foods even as early as birth (24). However, a study in Burkina Faso found that although children did like sweetened porridges, more sugar did not lead to higher intakes (25). The lack of a milk effect in our study might be explained by our addition of 7.5% sugar to SR, making both products mildly sweet. In this context at least, there is little need to include a high-cost ingredient (milk) to ensure palatability.

**Comparison of findings from 1-d vs. 2-wk acceptability methods.** Several concerns raised by sensory tests proved
insubstantial during TIPs. One was the preference for the milk product expressed by the mothers in the sensory tests, as noted above. Similarly in Peru, an acceptability study of porridges containing lyophilized liver or thigh meat found that, despite a negative reaction by mothers, infants readily consumed the meat porridges (7).

Based on the sensory tests, we were unsure whether or not children would consume the recommended 50 g/d of SR, given that some mothers preferred SRM, felt sugar needed to be added to SR, and expressed a desire to use hot water to prepare the porridges, all of which might limit feeding frequency and, ultimately, intake. However, TIPs showed that neither milk nor preparation with hot water was necessary for acceptability and mothers easily added sugar if desired.

The TIPs raised 2 major concerns that could not be detected in the sensory tests. Although consuming the targeted amount of at least 50 g/d was not a problem for the majority of children in the TIPs, overconsumption of the porridges emerged as a concern. There are very limited data on PCF intakes by children and the fact that some children in our study ate much more than the recommended amount of 50 g/d highlights the need to conduct formative research in intervention settings prior to finalizing fortification levels. If this PCF had been fortified to recommended levels (1), 12- to 15-mo old children in the inland site would have consumed 38.2 ± 6.5 mg/d (mean ± SEM) iron and 20.5 ± 3.3 mg/d zinc compared with the RDA of 7 mg/d for iron and 3 mg/d for zinc (upper limits: 40 mg/d for iron, 7 mg/d for zinc). On the other hand, children in the urban site would have consumed the appropriate levels of iron and zinc, because their daily intakes of PCF were within ~10 g of the target ration. Other acceptability studies have looked at ad libitum consumption but usually on a single serving, one-time basis (7,10), whereas the intakes we measured were 2-wk averages in the home setting. We chose not to limit the amount of food and to encourage the mothers to feed as much as the infant wanted but counseled not to reduce breast-feeding or other nutritious family foods. Our study illustrates the difficulties of setting fortification levels over various age ranges as discussed by Lutter and Dewey (1), and site-level differences in intake emerged as an additional context-specific influence (Fig. 1). The high levels of consumption were certainly influenced by the unlimited availability of free food during this trial, an unlikely circumstance under most program contexts. Nonetheless, potential overconsumption of PCF should be considered when developing interventions to ensure that consumption of fortified foods is kept within safe limits. We concur with WHO recommendations that fortification levels of PCF should be determined from formative research on current dietary intakes and consumption ranges of the PCF in the target population (26). In-depth TIPs proved to be an appropriate formative methodology to gather such information.

Another concern that emerged in the TIPs was food safety. The field staff discovered that most mothers did not comply with instructions to use cool, boiled water to prepare the porridges but instead used untreated water from local taps. Preparing PCF using untreated water in unsanitary household conditions contributed to high levels of microbial contamination. We subsequently carried out a microbiological study of complementary foods in this population, including the soy-rice PCF studied here.
When the instant PCF was mixed with unboiled water, 75% of households had coliform contamination levels above international guidelines (27). Mothers customarily give this water to infants to drink and said that boiling water was not feasible. However, we found that mothers complied with the instruction to avoid storage of the prepared product, thereby preventing further microbial growth, and our limited monitoring of morbidity did not indicate any increase in diarrhea. Ideally, educational or material interventions to improve hygiene and sanitation would be offered alongside the promotion of instant products and, in efficacy trials, data on diarrhea would be collected to identify functional consequences associated with preparing such foods using untreated water.

The TIPs (including 24-h recalls) also helped gauge the potential impact of this intervention in an efficacy trial by assessing actual intake of PCF over time, risk of replacement of other foods in infants’ diets, and leakage of the food supplement to other family members. From the dietary intake data over 2 wk, we conclude that there would be potential to benefit from this intervention. Although there was some replacement, feeding frequency and overall energy and protein intakes from complementary foods increased significantly. More specific and persuasive educational messages would likely help prevent the replacement of nutritious foods such as fish stew and breast milk. Sharing of the infants’ food was deterred by providing food for the family. These findings have important implications for the design of efficacy trials, but do not mean that food sharing would not occur if the new foods were purchased by families or provided in smaller amounts by a social program.

Implementation and analysis of TIPs with repeated 24-h dietary recalls required considerably more time and expertise than did the sensory tests and training required 10 d verses 3 d OR as opposed to 3 d for the sensory tests. The sensory tests for all 3 sites were conducted simultaneously in 1 wk, but the 2-wk TIPs, with the same staff, could be conducted in only 2 sites simultaneously and required 4 wk total to complete. However, considering the depth of information gained and the documented pitfalls in previous efficacy trials not guided by in-depth formative work, the extra investment in a TIPs-based acceptability trial seems justified. In conclusion, we found milk did not improve the acceptability of the soy-rice PCF, and we recommend TIPs as a useful tool for formative research on PCF interventions.

**Literature Cited**