Cover Page

A Pilot-Feasibility of a Home-based Intervention to Reduce Obesity Risk for Bottle-fed Infants

Protocol

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TITLE OF THE RESEARCH:

A Pilot-Feasibility of a Home-based Intervention to Reduce Obesity Risk for Bottle-fed Infants

BRIEF TITLE:

Opaque Bottle Feasibility Study (OBS-F)

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STATEMENT OF PURPOSE, BENEFITS, AND HYPOTHESES:

Rapid weight gain during the first year of life is a strong and consistent predictor of later development of obesity[1] leading researchers and government bodies to call for obesity prevention efforts starting during infancy.[2-4] Mounting evidence illustrates that bottle-fed infants (whether fed formula or expressed breast milk) are at significantly greater risk for rapid weight gain, gaining an excess of 70-90 grams/month across the first year when compared to their breastfed peers.[5-7] While the experience of breastfeeding may help mothers develop feeding practices that are responsive to infant satiety cues because they must learn to trust their infants' developing abilities to self-regulate intake,[8-12] bottle-feeding may facilitate controlling feeding practices due to mothers' abilities to feed in response to the amount of milk in the bottle,[13] leading to overfeeding and excess weight gain.[8-12]

Public health efforts to date have focused on breastfeeding promotion programs. Regardless, over 50% of US infants are exclusively formula-fed at 6 months of age.[14] Moreover, 40% of breastfed infants receive supplemental formula in a bottle,[15] and 70% receive expressed breast milk from a bottle on a regular basis.[16] Despite the ubiquity of bottle-usage, mothers receive little to no support for learning healthy bottle-feeding practices[17] and a paucity of research has focused on improving bottle-feeding mothers' responsiveness to infant cues. Previous efforts have focused on educating mothers about infant cues and offering less formula during each feeding, but have shown little success in modifying feeding behaviors or weight gain outcomes.[18] Thus, promotion of healthy bottle-feeding practices remains a realistic but under-utilized facet of obesity prevention efforts.

In the proposed research we take a novel, pragmatic approach to promote healthy bottle-feeding. Our previous research has explored whether a simple intervention - covering bottles with an opaque, weighted sleeve – can improve maternal responsiveness

to infant cues during bottle-feeding. Indeed, in an NIH-funded, laboratory-based trial (R03-HD080730), we illustrated mothers show significantly greater responsiveness and feed their infants 26% less when using opaque, weighted bottles compared to conventional, clear bottles.[13,19] While initially conceived as a promising adjunct to a larger obesity prevention approach, our laboratory findings suggest that opaque bottles may be a simple, yet potent, stand-alone tool for improving mothers' abilities to feed responsively and reducing infants' risk for overfeeding and rapid weight gain. In the proposed study, we aim to test this approach outside of the laboratory and enroll 100 new, formula-feeding mothers and infants (< 2 weeks old) into a randomized trial to examine the 12-week effects of using opaque, weighted bottles versus clear bottles for improving bottle-feeding interactions and reducing child obesity risk. We will use pre-established and state-of-the-art procedures to objectively measure infants' intake and mothers' responsiveness to infant cues (i.e., objective assessment of feeding patterns, coding of mother-infant bottle-feeding interactions) within their homes at the beginning and end of the 12-week study period. Intervention feasibility, fidelity, acceptability, and safety will be evaluated. Specific aims of the proposed research are:

AIM 1: To test the hypothesis that mothers who use opaque, weighted bottles for a 12-week intervention period will feed their infants less and be more responsive to their infants' cues compared to mothers who use clear bottles. Intake will be objectively assessed via change in bottle weight before and after feeding observations. Responsiveness to infant cues will be coded from video-records of feeding observations using the Nursing Child Assessment Parent-Child Interaction Feeding Scale.

AIM 2: To test the hypothesis that infants who are fed from opaque, weighted bottles will exhibit slower 12-week weight gain trajectories compared to infants who are fed from clear bottles. Infants' weight, length, skinfolds, and waist circumference will be measured at the beginning and end of the study; weight-for-length z-scores (WLZ) will be calculated using the WHO Growth Standards.

AIM 3: To examine the feasibility, fidelity, adherence, acceptability (e.g., perceived barriers to use), and safety (e.g., feeding adequacy) of the opaque, weighted bottle intervention. We will collect both objective and subjective data related to bottle use. We will also assess mothers' perceptions of the opaque bottles, any perceived barriers to their use, and whether baseline characteristics of mothers (e.g., weight status, race/ethnicity, socioeconomic status, parity, other non-maternal caregiver feeding practices and styles) and infants (e.g., sex, weight status, temperament) moderate intervention effects.

The proposed study is a critical step toward understanding the potential for opaque, weighted bottles as a practical solution for reducing obesity risk during infancy. Additionally, given the demographics of our community (35% Hispanic; 34% minority races), we have the opportunity to test this intervention in a diverse sample that includes a large proportion of families of lower socioeconomic status, two major risk factors for unhealthy bottle-feeding practices and childhood obesity.[20,21]

METHODS:

Design and Sample

Design. We have designed a 12-week randomized clinical trial to explore the efficacy

and feasibility of a 12-week opaque, weighted bottle intervention. Previous research suggests that, during early infancy, 12 weeks is a sufficient duration of follow-up to capture divergences in growth trajectories related to feeding mode, and that the window between 12-24 weeks is when associations between feeding mode and excess weight gain emerge.[44] Mother-infant dyads will be randomized to use conventional, clear bottles (*clear* group) or opaque, weighted bottles (*opaque* group). Dyads will participate in home-based assessments of bottle-feeding interactions at study entry and 12 weeks, with brief assessments at 2 and 6 weeks.

Subjects and Recruitment. A total of 100 mother-infant dyads will participate. We will use recruitment methods similar to those effectively used in our previous research.[13,45-47] Mothers will be recruited through ads in local newspapers; targeted social media ads; Women, Infant & Children (WIC) offices; OB/GYN and pediatrician offices; mass mailings; online sites; and a list of past participants who have asked to be notified of future studies. See **Appendix 1** for example recruitment materials.

Given San Luis Obispo and Santa Barbara Counties are predominately White and Hispanic (66% White, 35% Hispanic, 2% Black, and 4% Asian),[48] we will over-sample Black mothers to increase sample diversity (targets: 55% White, 35% Hispanic, 13% Black, 4% Asian).[49] Both English and Spanish-speaking mothers and their healthy, term infants of either sex will be eligible.

Inclusion criteria for the dyads include:

1) mothers 18-40-years of age
2) infants <8-weeks of age
3) mother is planning to bottle-feed, or is currently bottle-feeding, her infant
4) mother predominantly or solely responsible for infant feeding
5) dyad has a pediatrician and plans to attend infant well-visits
6) mother is willing to use stainless-steel bottles and to provide the study will her current bottles, which would be returned after study completion
7) prior to the introduction of solid foods

To protect infants who might be at risk for underfeeding or inadequate growth, exclusion criteria for infants include known risk factors:[50]

1) preterm birth (i.e., gestational age <37 weeks)
2) low birth weight (<2500 g)
3) maternal smoking during pregnancy
4) current or past medical conditions that interfere with oral feeding
5) history of slow growth or failure to thrive
6) weight for length percentile <5th
7) diagnosed developmental delay (e.g., Down's syndrome)

While we anticipate this will be rare, any mother reporting that they typically use opaque bottles prior to entry will also be excluded.

Research assistants will provide study information to mothers who respond to our recruitment efforts. Mothers who express interest in participating in our study will be screened by trained research assistants to assess study eligibility (see **Appendix 2** for screening and telephone scripts).

Procedures to Retain Sample. To promote retention, we will conduct home-based assessments to minimize participant burden. We will compensate participants a total of $100 (2 pre-test assessments @ $20 each, 2 brief intermediate assessments @ $10 each, and 2 post-test assessments @ $20 each; see **Table**).

Randomization. Mothers will be randomized using a computer-generated randomization scheme. Mothers will be informed of the group to which they are randomized by unblinded research assistants at the end of the Home-Based Pre-Test 2 (see **Table**).

Experimental Conditions

1. ***Control Group: Conventional, Clear Bottles:*** These mothers will receive usual care from their pediatric providers and each mother will be given 12 conventional, clear bottles of various sizes (4-12 ounces) that are compatible with a variety of different nipples manufactured by leading bottle companies. Mothers will also be given a handout about paced bottle-feeding (see **Appendix 3**), which includes messages about feeding in response to infant cues.
2. ***Intervention Group: Opaque Bottles:*** These mothers will receive everything provided to the *clear* group, but will instead receive 12 opaque, weighted bottles of various sizes (4-12 ounces). These bottles will be stainless steel (Pura Kiki, California, USA) and compatible with a variety of different nipples manufactured by leading bottle companies. These bottles weigh ~70g more than comparable plastic bottles, which is similar to the amount of added weight used in our pilot work. Mothers in the intervention group will also receive a handout about how opaque bottles can help them attend to infant cues.

For both groups, we will replace *all* of the mother's current bottles with study bottles and will ensure that the study bottles match the size of the bottles the mother currently uses; we will also supply any additional bottles needed for infant care in other settings (e.g., child care). Mothers will be asked to use the study bottles for all bottle feedings, regardless of whether the mother or another caregiver is feeding the infant. Monthly phone calls from the study interventionist will query about any need to replace bottles or any feeding difficulties; we will also instruct the mother to contact us if she needs more bottles. We anticipate that the features of allowing mothers to continue using their preferred nipple and replacing <u>all</u> of the mothers' bottles with study bottles will encourage compliance.

Assessments and Measures

As illustrated in the **Table**, we will conduct two assessments (separated by one day) at both study entry and completion to objectively measure infant intake and maternal responsiveness. Two brief visits will occur at weeks 2 and 6 to assess infant growth and maternal adherence to the intervention. All assessments will be administered by blinded research assistants.

Table. Example Assessment Timeline and Type of Bottles Used during Feeding Observations

Study Week:	**1**	**1**	**2**	**6**	**12**	**12**
Assessment Type:	Pre-Test 1*	Pre-Test 2*	Brief visit for growth check	Brief visit for growth check	Post-Test 1*	Post-Test 2*
Bottle used during observation: Clear Bottle Group	Clear	Opaque			Opaque	Clear
Opaque Bottle Group	Opaque	Clear			Clear	Opaque

*Home-based assessments within the same week will be separated by one day; conditions will be counterbalanced.

Home-Based Assessments. Two research assistants will visit the mother's home in the morning (to control for infants' circadian rhythms and variations in intake[51]) and will arrive approximately one hour prior to a time when an infant typically takes a bottle-feeding. Mothers will be asked to hide all bottles prior to each visit to ensure research assistants remain blinded. We will call the mother the evening before each visit to assess whether any disruptive events that may negatively influence the infant's behavior (e.g., colds, teething) occurred; if a disruptive event is reported during this phone call, the visit will be rescheduled. After a short acclimation period, we will interview the mother about when the infant last fed and slept and will conduct additional assessments. When the mother and infant are ready to feed, we will set-up two video cameras (GoPro Hero 4, California, USA) at two different angles (to obtain clear views of both the mother and the infant) ~10 feet in front of a location where the mother typically bottle-feeds her infant and will record the mother feeding her infant using clear or opaque bottles. The mother will be instructed to feed her infant as she normally would at home and the research assistants will wait in another room to minimize any possible influence on the mother's or infant's feeding behaviors. Additional questionnaires will be completed after feeding.

Measures. We will evaluate our intervention along multiple dimensions to fully understand the impact of opaque bottles on feeding outcomes and the feasibility of scaling this intervention for larger trials.

- **Infant intake** will be assessed by weighing the infant's bottle before and after each feeding observation using a top-loading balance (SP601 Scout Pro Portable Balance, Ohaus, New Jersey, USA). We will also note the type of nipple used and will control for nipple flow rate in all analyses.
- **Maternal responsiveness to infant cues** will be objectively assessed by video-coding of all feeding observations. After each visit, three trained coders who are unaware of the experimental conditions and hypotheses of the study will code videos using the NCAFS,[38] a reliable and valid means of observing and rating mother-child interactions during a feeding session. The NCAFS is validated for use with mothers and their 0-1-year-old infants, can be applied to a breast or bottle-feeding episodes, and has been used during both lab- and home-based feeding observations. It contains 76 observable behaviors that are organized into six subscales; for the proposed research, we will

focus the Maternal Sensitivity to Infant Cues subscale. Reliability will be established prior to full coding of all videos. To this end, coders will code 10 common videos, and will double-code 10 additional videos. Inter-coder comparison of the 10 common videos will be used to establish inter-coder reliability. Intra-coder comparison of the 10 double-coded videos will be used to establish intra-coder reliability. Full coding will not commence until a Kappa > 0.80 is reached for all coders. The PI is certified in this coding system and has it previously.[13,19,53]

- **Maternal feeding style**, including responsive and pressuring feeding, will also be subjectively assessed at study entry and completion using the Infant Feeding Style Questionnaire (IFSQ; see **Appendix 4**), which assesses maternal behaviors (e.g., control) and beliefs (e.g., concern about feeding) related to infant feeding.[52] This scale has been validated in diverse samples of mothers with young infants[52] and the PI has used this measure in previous research.[13,53]
- **Infant growth** will be assessed during all home-based assessments by trained research assistants measuring infant weight and height in triplicate using a portable infant scale/infantometer (models 334 and 233; Seca, Hamburg, Germany). To minimize bias, infants will always be weighed and measured while only wearing a clean diaper and prior to the observed feeding. We will use the World Health Organization (WHO) Anthro software version 3.0.1 (http://www.who.int/childgrowth/en/) to calculate age- and sex-specific weight-for-length z-scores (WLZ) based on the WHO growth standards. We will also assess infant adiposity by infant skin-fold thickness and waist circumference using standard protocols.[54]
- **Feasibility, Fidelity, Adherence, and Acceptability** will be assessed through a number of objective and subjective measures (see **Appendix 5**). Feasibility of recruitment and retention will be evaluated by: (a) tracking the number of women who respond to advertisements, are eligible, but decline participation; (b) examining whether recruitment targets are met across different ethnic/racial strata; (c) assessing the number of participants who agree to participate but drop out or are lost to follow-up, and determining reasons for drop out. To assess feasibility and fidelity of treatment conditions, interventionists will track distribution of the informational brochure (in each group) and brief phone calls completed. We will ask participants about any cross-bottle usage (e.g., the *clear* group using opaque bottles or *vice versa*). Adherence will be assessed by mothers' self-reports of the extent to which they used their assigned bottles (i.e., estimated percentage of feedings) at the 2-, 6-, and 12-week assessments. During these assessments, we will also assess whether infants experienced any illnesses that might have interfered with their typical feeding behaviors or weight gain, or whether mothers changed bottles, nipples, or formulas. We will also objectively measure bottle-usage and feeding patterns by affixing a light-weight, proprietary intake-tracking device to the bottoms of the bottles of all mothers within both the control and intervention groups. We developed this device to allow for objective and unobtrusive tracking of infants' intake in free-living settings; the device tracks infant feeding patterns by assessing the weight of the bottle before and after each feeding and time stamping each feed start and end. The device is dishwasher safe and has the capacity to store 6-months of feeding data, thus can be used for the entire duration of the proposed study. Although this device is still under development, preliminary tests have shown it is highly valid, with measurement error <0.05 oz. Acceptability will be

assessed by querying mothers about their perceptions of their bottles and any barriers to use of the bottles.

- **Additional potential moderators of intervention effects**: We will also assess: infant sex; infant temperament, assessed by the Infant Behavior Questionnaire-Revised Very Short Form (IBQ-RVS; see **Appendix 6**);[54] infant feeding history, including if and when solid foods are introduced, assessed by maternal retrospective report (see **Appendix 7**); maternal weight status, assessed using an adult scale/stadiometer (models 876 and 213; Seca, Hamburg, Germany) during the home-based assessments and through self-reported pre-pregnancy weight and gestational weight gain (see **Appendix 8**); family demographics, including parity, marital status, maternal education, race/ethnicity, assessed by a demographic questionnaire (see **Appendix 9**); maternal perceptions of the infant's eating behaviors (e.g., satiety responsiveness, food responsiveness) via the Baby Eating Behaviors Questionnaire (BEBQ; see **Appendix 10**); mothers' parenting confidence (see **Appendix 11**); mothers' level of distracted parenting (see **Appendix 12**); and non-maternal caregivers' involvement in child feeding assessed using the Non-Maternal Caregivers questionnaire from the Infant Care, Feeding and Risk of Obesity Study,[57] a measure that queries mothers about the frequency to which anyone, other than themselves, was responsible for feeding their infants on a typical day (see **Appendix 13**).

Statistical Considerations

Data Analysis. All quantitative analyses will be conducted using SAS v.9.4 (SAS Institute Inc., North Carolina, USA). Qualitative interview data will be transcribed and sorted into thematic categories using constant comparison within the framework of grounded theory.[58] We will use linear regression to model the change in infant intake and maternal responsiveness (**Aim 1**) and change in WLZ, skinfolds, waist circumference (**Aim 2**) by the primary study variable of *clear* versus *opaque* group. For **Aim 3,** we will examine the feasibility, fidelity, adherence, acceptability, and safety of the intervention by summarizing quantitative and qualitative data related to recruitment and retention, mothers' use of their assigned bottles, perceptions of and barriers to using the bottles, and any issues related to infant inadequate weight gain or weight loss. We will then explore whether variations in intervention feasibility, fidelity, adherence, acceptability or safety are correlated with baseline characteristics of mothers (e.g., weight status, race/ethnicity, socioeconomic status, parity, feeding practices and styles, non-maternal caregiver involvement in feeding) and infants (e.g., sex, birth weight, weight status, temperament). Finally, we will assess whether the effects of the intervention on infant intake, maternal responsiveness, and infant WLZ change are moderated by the following factors: nipple type; mothers' adherence to the intervention, race/ethnicity, parity, or feeding practices and styles; infants' sex, temperament, and timing of solid food introduction; and the extent to which non-maternal caregivers are feeding the infant. Moderation will be explored by including a group by moderator interaction term in the linear regression models used to explore **Aims 1** and **2**. All inferential analyses will be preceded by appropriate descriptive statistics and graphs to determine that assumptions for linear regression are satisfied.

Power calculations. The proposed sample size (n=100) was selected so that there will be adequate power to test for statistical significance for study aims. Because our previous research has shown <10% attrition after 12 weeks, we conservatively estimate 20% of participants will drop out and 120 mother-infant dyads will be recruited to account for this predicted attrition rate. For Aim 1, which examines the impact of bottle type on infant intake and maternal responsiveness, there is 80% power to detect a 19.1 mL difference in intake and 1.32 point difference in change of NCAFS score from baseline to 12-week follow-up between the *clear* and *opaque* groups, using $\alpha = .05$. For Aim 2, which examines the impact of bottle type on weight for length z-scores (WLZ), there is 80% power ($\alpha = .05$) to detect a difference of 0.59 in change of WLZ from baseline to 12-week follow-up between the *clear* and *opaque* groups. Given rapid weight gain has been defined as z-score change ≥0.67 SD,[1,24,25] a between-group difference in WLZ change of this magnitude (0.59 SD) would be clinically significant. Power calculations are based on a pilot study for which the between-subject standard deviation for infant intake was 33.7 mL and for the NCAFS scales is 1.91; this calculation also assumes that the mothers assigned to the *clear* group will have a higher correlation in scores between baseline and 12-week follow-up ($r = .55$), whereas mothers assigned to the *opaque* group will have a lower correlation in scores between baseline and 12-week follow-up ($r = .40$).[59,60] The latter calculation assumes the standard deviation for WLZ is 1.0, and that the correlation between WLZs over 12-weeks for infants is $r = .45$.[60]

Potential Risks and Plan for Data Safety and Monitoring

Potential Risks. The risk involved in this study is considered minimal. Some infants or mothers may dislike using the bottles we offer during the infant-feeding study, thus may perceive the experience of using these bottles as unpleasant. It is also possible that an unintended consequence of the opaque bottles will be that mothers and caregivers under-feed their infants, resulting in inadequate growth for their infants. Some mothers may feel uncomfortable answering questions about their attitudes about and concern for their infants' feeding and weight gain patterns. Additionally, some dyads may experience discomfort related to having their feedings video-recorded or having our research staff present in their homes. There is also risk of breach of confidentiality given that video records are being collected.

Plan for Data Safety and Monitoring. We have developed effective procedures for protecting participants' safety and confidentiality. All participants will be assured that they have the right to opt out of any part of the study with which they feel uncomfortable. Additionally, we will check-in with mothers and infants frequently to monitor infants for insufficient growth (<20-30g/day) or weight loss. The research assistants will monitor the participants for adverse events, including inadequate infant growth.

The PI will hold primary responsibility for ensuring that the proposed trial is conducted according to protocol and carrying out the above data safety and monitoring plan. However, the PI will also identify a local pediatrician to serve as the Data and Safety Monitor (DSM) for the proposed study. Given that feeding interactions and infant growth are of primary interest, we will identify a local pediatrician with particular expertise in this area and have several pediatricians affiliated with our research center who have this expertise. Once appointed, the DSM will help ensure that our protocol and intervention and assessment of adverse events are in line with local pediatric providers' usual care plans. The DSM will meet with the PI and Co-I's quarterly to review and evaluate the accumulated study data for participant safety, study conduct and progress, and alignment with pediatric providers' usual care plans. The DSM will also serve as a consultant to assist with safety monitoring and we will also ensure that all enrolled families have a pediatrician with whom they regularly consult to add an additional layer of monitoring and protection.

Infants who exhibit slower than expected growth will be referred to their pediatrician or emergency services for further consultation and will be removed from the study if the PI and/or DSM deem study participation harmful to the infant or family.

We will also employ strategies we have used in previous studies to minimize discomfort, including having familiar research staff present in the homes during assessments, and moving to another room or outside the home (if another room is not available) during video-recorded feeding interactions. The PI has significant expertise in coding video-recorded feeding interactions and ensuring mother and infant comfort and confidentiality during this process. Furthermore, all research assistants will be trained to ensure that assessments are conducted in a professional and nonjudgmental manner.

Adverse events determined by the PI to be unanticipated problems involving risks to subjects or to others will be reported by the PI to the IRB within 10 days. Adverse events that are reviewed by the PI and not determined to be unanticipated problems involving

risks to subjects or to others will be reported per IRB policy at the time of continuing review.

All study personnel will be informed by the PI about any unanticipated problems involving risks to subjects or to others. If any protocol changes are needed, the PI will submit a modification request to the IRB. Protocol changes will not be implemented prior to the IRB approval unless necessary to eliminate apparent immediate hazards to the research participants. In such a case, the IRB will be promptly notified of the change following implementation (within 10 working days). Protocol adherence will be monitored by the PI during bi-monthly meetings with the research assistants. If the PI is made aware of an unanticipated protocol deviation, the PI will report this deviation to the IRB within 10 days.

To protect participant confidentiality, all participant data will be treated as confidential. Our research team has significant expertise in maintaining data integrity and confidentiality in studies involved video records and clinical trials and will employ that expertise in the present study. Specifically, participants will be informed of this potential for breach of confidentiality, video files will be immediately downloaded to secure servers at respective sites and deleted from video cameras immediately. Records will be safeguarded according to the policies of HIPAA, our IRB, and the applicable state laws governing the conduct of the studies, which promote the protection of confidential health information.

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Informed Consent Form

INFORMED CONSENT TO PARTICIPATE IN THE RESEARCH PROJECT

Why are we doing this research?

A research project for observing infant feeding interactions is being conducted by Drs. Alison Ventura and Suzanne Phelan in the Department of Kinesiology and Public Health at California Polytechnic State University, San Luis Obispo. The purpose of the study is to help us to better understand infant feeding during typical bottle-feeding situations. We are interested in looking at whether the type of bottle used influences infant feeding. What we learn from this study will help us to figure out how to promote healthy feeding during early infancy.

What you should know about this research study:

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- Feel free to ask all the questions you want before and after you decide.

What will your family be asked to do?

You and your infant are being asked to take part in this 12-week study. If you agree to participate, we will provide you with new bottles with which to feed your infant and we will ask you to use these bottles for the entire 12-week study. If you need more bottles or different sized bottles or nipple, we will be happy to provide those. Some mothers in this study will be given stainless steel bottles and some mothers in this study will be given plastic bottles; the type of bottle that you are given will be determined by chance.

All study assessments will occur in your home. We will visit two times at the beginning of the study and end of the study (after 12 weeks). We will also briefly check-in with you after 2 and 6 weeks to see how everything is going. All visits will occur at the same time on all days. At the start of each visit, we will change your infant into a fresh diaper, then will measure his or her weight and length. We will also measure your weight and height.

For the 3 days leading up to, and on the days of, the visits that occur at the beginning and end of the study, you will be asked to complete daily food logs of when and what you feed your infant. We will also call you during this 3-day period to remind you to fill out the logs and ask you about other feeding behaviors.

During each home visit that occurs at the beginning and end of the study, a trained research assistant will ask you to bottle-feed your infant as you normally would at home using the bottles we provide. The entire feeding session will be video-recorded. The video-recorder will be placed at the far corner of the room, about 10 to 12 feet from you and your infant. The research assistant will step into another room during the feeding. After you feed your infant, the research assistant will ask some questions about the feeding and questions related to parenting experiences and your infant's personality. We will also ask about infant feeding attitudes and practices, health history, and eating behaviors.

How long will the study last?

Participation for your family will occur over a 12-week period. We estimate each home visit will last 1-2 hours, thus, participation in study assessments will take between 6-12 hours of your time.

Is there any way being in this study could be bad for your family?

The risk involved in this study is minimal. You or your infant may dislike using the bottles we offer during the infant-feeding study. It possible that your formula could sour or spoil if not handled correctly. Additionally, it is possible that your infant may be allergic to the materials used to make the bottles and nipples we will use in the study. You may feel uncomfortable answering questions we ask about your infant's feeding and health history. You may omit any questionnaire items you prefer not to answer and you have the right to opt out of any part of the study at any time.

We do not expect any other risks to participating in this study. If you or your infant should experience any discomfort related to this study, please be aware that you may contact Dr. Alison Ventura at (805) 756-5693 or akventur@calpoly.edu for assistance.

You and your infant are not required to participate in this research and you may discontinue your participation at any time without penalty. If you agree to take part in the research now and stop at any time it will not be held against you. But, if you do not want to be part of the study, we may still keep and use your study information.

What happens to the information we collect?

To ensure your and your infant's privacy and confidentiality, all videotapes, data sheets, and questionnaires with your information will be coded. When we want access to this information for later study, we will refer to the coded information so that your identity cannot be traced. All records and videotapes are kept in a locked file that only personnel have access to.

In any written or oral presentation of research results, your identity will be kept private. Records that identify you may be inspected by authorized individuals such as the Cal Poly institutional review board (IRB), or employees conducting peer review activities. You consent to such inspections and to the copying of excerpts of your records, if required by any of these representatives. All study personnel have been trained at Cal Poly on the rights of human subjects. They are familiar with the rules for handling personal information.

Will being in this study help you in any way?

We cannot promise any benefits to you or your infant from your taking part in this research. However, you may enjoy becoming more aware of your infant's behaviors. You may also appreciate learning about new research in nutrition, food preferences, and caregiver-infant interactions. We also cannot promise any benefits to others from your taking part in this research. However, the findings from this study may help us to understand how best to promote healthy development during infancy.

Will you be compensated for your time?

If you agree to take part in this research study, we will pay you a total of $100 to compensate you for your time. This includes $20 for each of 4 home visits and $10 for each of 2 check-ins. Your family will be compensated at the end of each home visit. Your family will not be compensated for visit days that you do not attend because you do not show up, withdraw, or are removed from the study.

Can you be removed from the research without your OK?

The person in charge of the research study or the sponsor can remove you and your infant from the research study without your approval. Possible reasons for removal include:

- If all or part of the study is stopped for any reason by the investigator or Cal Poly.
- If participation in the study is adversely affecting your family.
- If you fail to adhere to requirements for participation established by the researcher.

Who should you contact for more information?

If you have questions regarding this study or would like to be informed of the results when the study is completed, please feel free to contact Dr. Alison Ventura at (805) 756-5693 or akventur@calpoly.edu.

If you have concerns regarding the manner in which the study is conducted, you may contact Dr. Michael Black, Chair of the Cal Poly Institutional Review Board, at (805) 756-2894, mblack@calpoly.edu, or Ms. Debbie Hart, Compliance Officer, at (805) 756-1508, dahart@calpoly.edu.

If you agree to voluntarily participate in this research project as described, please indicate your agreement by signing below.

Signature of Participant	Date
Signature of Researcher	Date

If you agree to allow your infant to voluntarily participate in this research project as described, please indicate your agreement by signing below.

Name of Child Involved in this Research: _____

Signature of Parent/Guardian	Date
Signature of Researcher	Date

Please keep one copy of this form for your reference.
Thank you for your participation in this research!