

Influence of Financial Incentives on Oral Disease Management in Young Children (BEhavioral EConomics for Oral health iNnovation - BEECON)

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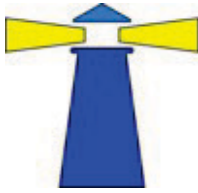
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CONSENT FOR PARENT AND PARENTAL PERMISSION FOR MINOR TO PARTICIPATE IN RESEARCH STUDY

University of California, Los Angeles (UCLA) and
University of California, San Francisco (UCSF)

BEECON TRIAL - Influence of Financial Incentives on Oral Disease Management in Young Children (BEhavioral EConomics for Oral health iNnovation)

Why is this study being done?

A team of dentists and scientists wish to study 1) parents' attitudes about their child's oral health and 2) helping parents stop cavities in young children, by brushing children's teeth and taking children to a dentist.

To be in this study,

Your child must be:

- At least 6 months old but less than 4 years old;
- with at least two fully erupted teeth;
- Enrolled in or waitlisted for one of the participating Los Angeles County Early Head Start or affiliated day care center program or site;
- Free of allergies to study products including plaque disclosing solution or fluoride varnish;
- Able to open his/her mouth without help, to allow the dentist to look at his/her teeth, clean them, and allow research assistants to photograph the teeth.
- Without more than 2 crowns on maxillary incisor teeth (#D, E, F, G, or equivalently #52, 51, 61, 62).

You, the parent or guardian, must:

- Be the child's primary caregiver who will be brushing the child's teeth every day (unfortunately, foster children are not eligible);
- Plan to live in the greater Los Angeles area for the next 18 months;
- Own a smart phone and be willing to download and keep a free app from the Google Play or Apple Store for the duration of the project; and,
- Be willing for study staff to contact you by SMS (text messaging) for study messages.

There will be 244 children with their parents in this study. Parents will be placed into one of two groups randomly by computer (like flipping a coin or rolling a die) that will have the same opportunities but at different times during the program.

This study is being paid for by the National Institutes of Health.

What will happen if we take part in this research study?

This study will last up to 18 months. If you and your child volunteer to join this study, we will ask you to do the following:

AT THE SCREENING (FIRST STUDY) VISIT (60-90 min):

- You will be asked questions about your child's oral health, past dental visits, and your family's dental attitudes, behaviors, and knowledge. We will keep your answers on a computer. The team will combine these answers with other families.
- You will be asked to watch a video about oral health.

- Your child will have a dental screening and red disclosing liquid painted on your child's teeth to check his or her plaque level. A photo of the teeth will be taken and kept in your child's dental study file. The photos may be used for presentations, publications, or research purposes but will not identify your child or publish your or your child's name.
- Additionally, fluoride varnish will be painted on your child's teeth to protect them from dental decay.
- You will learn how to brush your child's teeth with a special electric toothbrush that we will give your child. With our help, you will install a free app onto your smart phone, which will link to the study toothbrush and follow how well you're brushing your child's teeth.

AT HOME, you will be asked to:

- Practice brushing your child's teeth each morning and each evening for 1 minute each time using the special toothbrush and toothpaste that will be given to you at the first visit.
- Sync the electric toothbrush to your phone's app three times a week for 2 weeks. You will be paid \$1 for syncing on Wednesday, Friday, and Sunday for up to \$3 per week.

AT THE SECOND STUDY VISIT (About two weeks later, 60 min):

- We will see how you did at home with the smartphone app and toothbrushing with the special brush. If you would like to continue, you will be placed into one of two groups according to a random list from a computer. This means that neither you nor our staff can choose the group for you and your child.
 - Group 1: Entered into a weekly drawing for brushing children's teeth regularly for 6 months. Then you will continue brushing your child's teeth regularly for an additional 6 months without rewards for a total project time of 12 months.
 - Group 2: Not eligible for prizes or drawing during the first 12 months, but may earn drawing rewards later during months 13-18 for brushing children's teeth regularly.

AT HOME, you will be asked to:

- Brush your child's teeth each morning and each evening for 1 minute each time using the special toothbrush and toothpaste that will be given to you at the first visit.
- Sync the electric toothbrush to your phone's app three times a week for 3 months. You will be paid \$1 for syncing on each of these days: Wednesday, Friday, and Sunday for up to \$3 per week.

FUTURE VISITS

After the first two study visits, you and your child will be in this study for about 12-18 months (1-1.5 years) depending on the group you are randomly assigned to.

There will be at least 6 visits total including your first visit. We will see you every 3 months and we will see your child twice a year for dental screenings (about every 6 months). After 12 weeks (3 months), we will see you for your first follow up appointment.

- The 3 month, 9 month, and 15 month (if applicable) visits will last about 30 min.
- The 6 month, 12 month, and 18 month (if applicable) visits will last about 60 min including a dental screening and fluoride varnish painted on your child's teeth.
- You will be asked similar questions about your child's oral health, dental visits and your family's dental attitudes, behaviors, and knowledge.
- You will be asked to watch a video about oral health.
- At dental screening visits a red liquid will be painted onto your child's teeth to check his or her plaque level. A photo of the teeth will be taken and kept in your child's dental study file.

- At follow-up visits you will receive additional brush heads, toothpaste (every 6 mo), syncing and visit payments, and rewards earned (if applicable).

IMPORTANT INFORMATION ABOUT ALL STUDY VISITS:

- We will not take X-rays. If the study dentist thinks your child needs dental treatment, your child will be referred to a dental clinic or his or her regular dentist for evaluation and treatment.
- Your child might not see the same dentist or dental assistant at each visit.

If you are enrolled in Early Head Start, your child's recent dental attendance date will be obtained from the Early Head Start record keeping software.

How much time will it take to be in this research study?

The study will involve 6-8 in-person study visits. At home, it will take you only a few minutes to sync the electric toothbrush with your smart phone app and it will only take a few minutes per week to read study SMS text messages.

If enrolled in Group 2, you will have the opportunity to earn rewards following the initial 12 months and you will receive your rewards at the 15 month and 18 month follow-up visits. If you are in Group 2 and choose to continue you will again be placed into one of two groups randomly by computer (like flipping a coin or rolling a die) that will have the same number of opportunities to receive the same rewards; one group will be eligible for 13 weekly drawings every 3 months and told about them weekly; the other group will be eligible for 13 drawings every 3 months and told about them every 3 months.

You may be invited to a focus group discussion, which will occur in either Spanish or English, and you may choose which language you prefer. During the group discussion, the facilitator will introduce some topics and allow parents to openly discuss their opinions and suggestions. The group discussion will be audio recorded so the research team can later review carefully what has been said. The focus group discussion will last about 2 hours.

Since this is a group discussion, others in the group will know what you say. We will keep the information you tell us confidential, and we will not share it in a way, which will identify you.

Being in the study is voluntary. It will not affect your future or current relationship with Venice Family Clinic, Westside Children's Center, Early Head Start, your child's day care center, the University of California San Francisco, the University of California Los Angeles, or your child's medical or dental care. You can stop participating at any time without penalty; you will not lose any daycare or health benefits to you or your child if you choose to withdraw.

Are there any potential risks or discomforts that we can expect from this study?

The red plaque disclosing solution (GUM Red-Cote Liquid brand), fluoride varnish (3M ESPE Vanish), and fluoride toothpaste (Colgate brand) have not shown any risks or discomforts other than those from regular dental care. In the rare case of an allergic reaction, your child may encounter brief swelling of the gums, trouble breathing in children with asthma, or nausea or vomiting in some children who take in too much fluoride. In the rare case that this occurs, your child will be treated by the attending clinician. If your child has had this type of reaction to fluoride varnish in the past, he/she cannot participate in this study. The plaque disclosing liquid and fluoride varnish would then be brushed off your child's teeth. If not used according to instructions, the electric toothbrush could make your child's teeth or gums sore. In rare cases

the tooth brush head bristles may fall out and could be a choking hazard; discourage your child from chewing the brush head.

Please keep the fluoride toothpaste out of the reach of young children so that only the correct dosage (smear for under 3 years old or pea size for 3 years and older) is used at all times.

Unknown risks: The researchers will let you know if they learn anything about these products that might make you change your mind about being in the study.

Some questions asked in the survey may make you feel uncomfortable. You may choose not to answer any question you do not want to answer.

Are there any potential benefits if we participate?

The benefits for your child include a dental screening, fluoride varnish, oral health education, and toothbrushing tools such as toothbrush and toothpaste. The information that you provide will help us to understand ways to improve oral health care for young children and help your child have better dental health and fewer cavities.

Your child will receive the toothbrush, toothpaste, brush heads, screenings and fluoride varnish from the dental provider at no cost to you.

Will we be paid for participating?

For your time, effort and travel expenses, you will receive a \$30 grocery voucher for each completed study visit plus \$1 for syncing once a day on Wednesdays, Fridays, and Sundays for up to \$3 per week, and any drawing rewards.

Will information about our participation be kept confidential?

All efforts will be made to keep your personal information private and confidential. The research team will have access to information about you and your child, but names, addresses, telephone numbers, and specific date information will not be used in any reports. However, if you or a member of your household change the app profile from the study identification number to the child's name this data will be sent to Philips/Sonicare.

Authorized organizations may look at the brushing habits tracked by the smart toothbrush for research, accuracy, and data analysis; these include Philips Oral Healthcare, and UCSF and UCLA's Institutional Review Boards. Other government agencies involved in keeping research safe for people including The National Institute of Dental and Craniofacial Research (NIDCR) – a component of the National Institutes of Health (NIH) – and the Food and Drug Administration (FDA) may look at the data. Other University of California personnel also may need to review the records of, or receive information about, individual participants and may see your or your child's name. Everyone with access to your files will keep the information as confidential as the law allows.

Access to study records: Your child's individual dental screening information will only be made available to the treating physician or dentist in the event of a health problem to provide the best health care. When the study is over, you will be able to obtain a copy of the study's results but not your child's individual data or records.

Keeping study records: Dr. Ramos-Gomez, Dr. Gansky, and their research team will keep your records in their office. Records for minors will be retained based on recommendations from the NIH, or if no guideline is established, based on the UC Counsel General's recommendation, which is that records be kept for 7 years after a child reaches 18 years old (the age of majority), or until the child is 25. This could mean that your child's records would be kept digitally for up to

25 years after the end of the study. Your child's personal health information cannot be used for additional research without additional approval from either you or a review committee.

What are the costs of taking part in this study?

To send notifications and reminders, unless your phone plan has unlimited texts, standard SMS text messaging rates may apply.

Who can I contact if I have questions about this study?

The research team:

The person who signed below has explained the study to you and can answer any further questions. The project phone line is (424) 371-6725 and the research assistant can answer any questions in Spanish or English. You may also call study Project Manager, Helen Lindau, at (310) 825-3477. You may also contact Dr. Francisco Ramos-Gomez, who is bilingual in Spanish and English, at (310) 825-9460 in Los Angeles, or Dr. Stuart Gansky at (415) 502-8094 in San Francisco.

If you have questions about your rights as a human subject and participant in this study, you may call the office of the Institutional Review Board at the University of California, San Francisco at (415) 476-1814.

CONSENT

The UCSF and UCLA Institutional Review Boards have approved this consent form, signified by the Boards' stamp. You may ask to view the Boards' approval stamps at any time from any study team member. The consent form must be reviewed annually and expires on the date indicated on the stamp.

If your child is injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415-476-1814.

Your signature below indicates that you:

- Have read the information in this document;
- Have had a chance to ask any questions you may have about the study;
- Agree to be in the study and for your child to be in the study;
- Have been told that you can change your mind and withdraw your consent to participate at anytime;
- Have been given a copy of the Experimental Subject's Bill of Rights to keep and either emailed a copy of this consent form or a printed copy;
- Have been told that by signing the consent form you are not giving up any of your legal rights;
- Allow research staff to obtain dental attendance information from Early Head Start's record keeping software; and,
- Allow research staff to obtain brushing data collected by the Sonicare app and toothbrush from Philips Oral Healthcare. This data includes: time when brushing started, duration of brushing, was brushing connected to the app, was brushing not connected to the app, and duration of app session.

Please also indicate if you wish your child's intraoral (inside the child's mouth) pictures to be used for other scientific purposes after the end of this study.

- ☐ I agree to allow the intraoral pictures of my child to be used anonymously (unlinked) for other future research studies.
- ☐ I do not wish for the intraoral pictures of my child to be used for other future research studies.

We also ask that you inform us if you do not wish to be contacted in the future for possible participation in other research programs.

- ☐ I agree to be contacted for other future research studies.
- ☐ I do not wish to be contacted for other future research studies.

SIGNATURE OF PARENT OR LEGAL GUARDIAN

Name of Child

Name of Parent or Legal Guardian

Signature of Parent or Legal Guardian

Date

SIGNATURE OF PERSON OBTAINING CONSENT AND PARENTAL PERMISSION

Name of Person Obtaining Consent and
Parental Permission

Contact Number

Signature of Person Obtaining Consent and
Parental Permission

Date