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

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STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the International Conference on Harmonisation guidelines for Good Clinical Practice (ICH E6), the Code of Federal Regulations on the Protection of Human Subjects (45 CFR Part 46), and the NIDCR Clinical Terms of Award. All personnel involved in the conduct of this study have completed human subjects protection training.

SIGNATURE PAGE

The signature below constitutes the approval of this protocol and the attachments, and provides the necessary assurances that this trial will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality, and according to local legal and regulatory requirements and applicable US federal regulations and ICH guidelines.

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LIST OF ABBREVIATIONS

AAP	American Academy of Pediatrics
ADA	American Dental Association
AE	Adverse Event/Adverse Experience
ASTDD BSS	Association of State and Territorial Dental Directors' Basic Screening Survey
CAPI	Computer Assisted Personal Interview
CC	Coordinating Center
CDMP	Clinical Data Management Plan
CFR	Code of Federal Regulations
CHR	Committee on Human Research
CI	Confidence Interval
CMP	Clinical Monitoring Plan
CRF	Case Report Form
CRO	Contract Research Organization
CROMS	Clinical Research Operations and Management Support
CTMS	Clinical Trials Management System
dmfs	Number of decayed, missing, and filled tooth surfaces
DSMB	Data and Safety Monitoring Board
ECC	Early Childhood Caries
ECOHIS	Early Childhood Oral Health Impact Scale
eCRF	Electronic Case Report Form
EDC	Electronic Data Collection
EHS	Early Head Start
FDA	Food and Drug Administration
FFR	Federal Financial Report
GIFVT	Glass Ionomer and Fluoride Varnish Trial
GLMM	Generalized Linear Mixed Model
ICER	Incremental Cost Effectiveness Ratio
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
ID	Identification
IRB	Institutional Review Board

ITT	Intention-To-Treat
MICE	Multiple Imputation using Chained Equations
N	Number (typically refers to subjects)
NIDCR	National Institute of Dental and Craniofacial Research, NIH
NIH	National Institutes of Health
OCTOM	Office of Clinical Trials Operations and Management, NIDCR, NIH
OHDC	Oral Health Disparities in Children
OHI-S	Debris Index of the Simplified Oral Hygiene Index
OHI-MIS	Debris Index of the Simplified Oral Hygiene Index for Maxillary Incisors
OHRP	Office for Human Research Protections
PHI	Protected Health Information
PI	Principal Investigator
PII	Personal Identifying Information
QALYs	Quality Adjusted Life Years
RCT	Randomized Controlled Trial
ROI	Return on Investment
SAE	Serious Adverse Event/Serious Adverse Experience
TB	Toothbrush
TP	Toothpaste
UP	Unanticipated Problem
US	United States

PROTOCOL SUMMARY

Title:

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

Précis:

Rewards have facilitated positive changes in health-promoting behaviors (e.g. smoking cessation, weight loss, and blood glucose and hypertension management). Behavioral economic interventions, especially with small incentives, can lead to healthy behaviors even after incentives end. The project's overall goal is to assess the efficacy of rewards towards promoting early childhood caries (ECC) preventive health behaviors (toothbrushing performance) for young children of predominantly Latino parents/caregivers in Early Head Start (EHS) and day care center programs. In this trial, eligible consenting parent-child participant dyads, within strata and permuted blocks, will be randomized in equal allocation to one of two groups: 1) Monetary Reward or 2) Delayed Monetary Reward Control. Strata will be based on site and smartphone operating system (iOS or Android). Participants in the Monetary Reward group will be eligible to enter into a weekly drawing to receive incentives (rewards) during the first 6 months of the trial. Children will be followed for 12 months to determine reward effects on toothbrushing, fluoride toothpaste (TP) use, plaque score, and caries screening status. Results will inform researchers and public health practitioners on the longer-term maintenance of behavioral changes and oral health screening status following removal of the rewards.

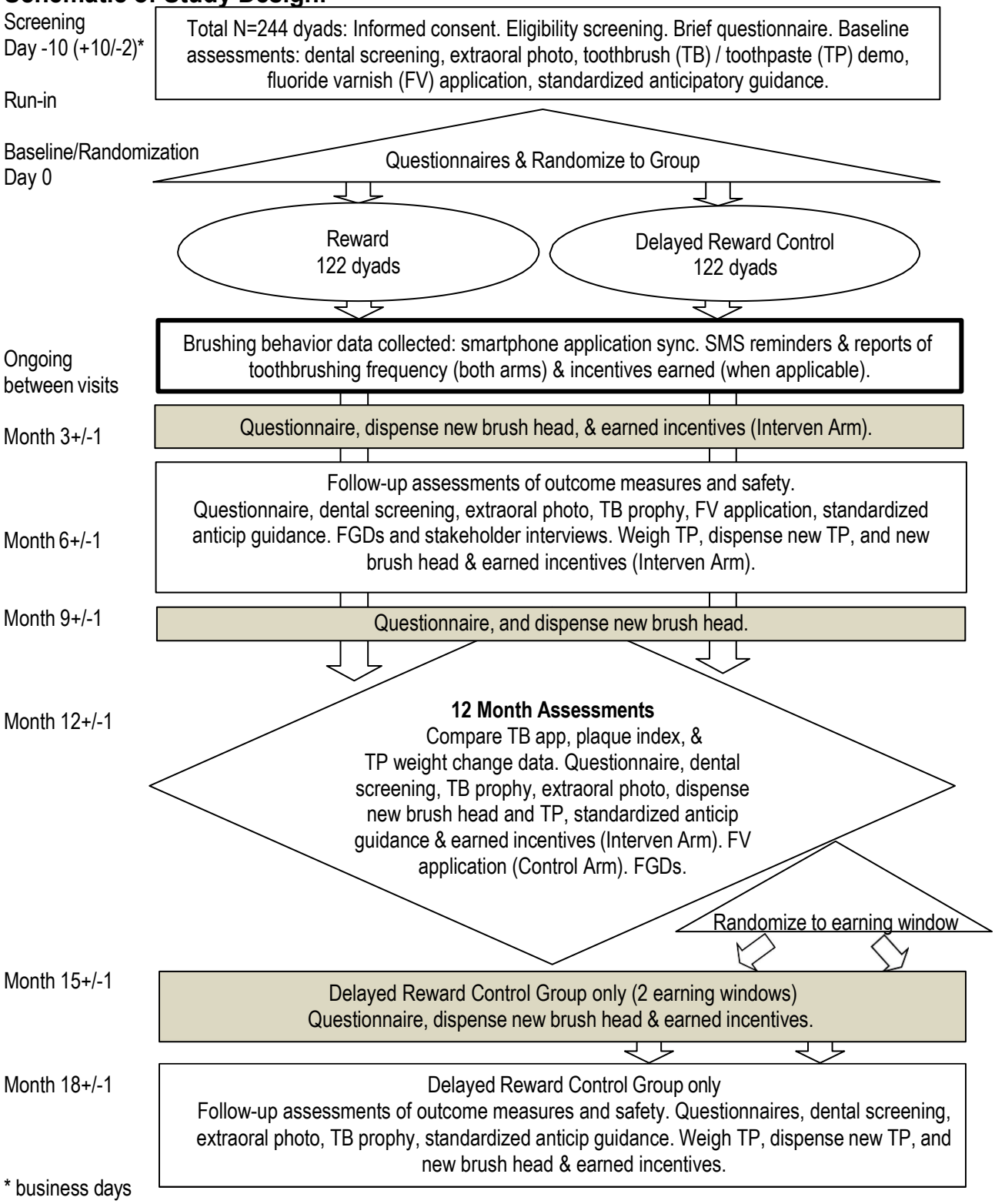
Objectives:

1. The primary objective of this randomized controlled trial (RCT) is to compare the impact of Monetary Rewards (weekly drawings for those with qualifying toothbrushing sessions) versus Delayed Reward Control through 6 months on ECC preventive behaviors. The primary outcome measure is toothbrushing performance, measured as follows: mean of the number of qualifying half-day toothbrushing episodes per week, through the Month 6 visit. (A Bluetooth-recorded toothbrushing episode qualifies if it lasts at least one minute within one of 14 half-day windows in the week.) . 2. Secondary objectives are: to assess the impact of the Monetary Rewards Intervention versus Delayed Reward Control on toothbrushing performance through 12 months to assess sustainability of the

	behavior after the drawing incentives cease, through 1 month to assess short-term (immediate) impact on the behavior after the drawing incentives and powered toothbrush use begin (i.e. may include novelty effect of power toothbrushes in all participants), and through 3 months to assess mid-term impact on the behavior after the drawing incentives and powered toothbrush use begin (i.e. after potential novelty effect of power toothbrushes ends in all participants); to estimate the short- and long-term cost effectiveness and return on investment of rewards in improving parent/caregiver behaviors and children's oral health; and to assess potential mediation effects of beliefs (behavioral, normative, and control) on intermediate outcomes (intentions, salience, and habit) and primary outcome (toothbrushing performance). The secondary outcome measures are toothbrushing performance, measured as follows: mean number of qualifying half-day toothbrushing episodes per week, through the Month 12, Month 1, and Month 3 visits and net costs to calculate incremental cost effectiveness ratio.
Population:	The study population will be primarily Hispanic/Latino parent-child (ages 6 months to <48 months) dyads and other high-risk racial/ethnic groups from underserved communities in Los Angeles County (N=488 participants, 244 dyads).
Phase:	II
Number of Sites:	Up to 6 Los Angeles County Early Head Start (EHS) and affiliated day care / preschool centers; the study visits will occur at Los Angeles Venice Family Clinic locations at Simms/Mann, Lou Colen, and Robert Levine centers.
Description of Intervention:	The Monetary Reward intervention is a drawing reward, in which participants are eligible for weekly rewards based on toothbrushing performance.
Study Duration:	(a) 25 months from opening enrollment to completing data collection and (b) 32 months from opening enrollment to final data analyses.
Subject Participation Duration:	Each parent/caregiver-child dyad will complete the trial visits in approximately 12 months. The Delayed Reward Control group participants will have the option to continue for another 6

	months (i.e., 18 total months) to earn the same monetary rewards as the intervention group.
Estimated Time to Complete Enrollment:	Approximately 14 months.

Schematic of Study Design:



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2 INTRODUCTION: BACKGROUND INFORMATION AND SCIENTIFIC RATIONALE

2.1 Background Information

Early childhood caries (ECC) remains the most prevalent chronic childhood disease in the United States (Vargas et al., 1998; Poland & Hale, 2003; CDC, 2001) and poses a serious threat to child welfare, particularly among economically disadvantaged, underserved, and migrant children (Ramos-Gomez et al., 2007; DHF, 2006). National ECC prevalence (any decayed, extracted, or filled primary teeth (deft)) among 2–5 year olds was 23% in 2011-2012 (Dye et al., 2015). Mexican-Americans had double the ECC severity of non-Hispanic Whites (Wiener et al., 2015).

Since dental disease risk increases as a child's teeth erupt (ADA, 2014), brushing with fluoridated toothpaste (TP) (smear for children under 3 years old, pea-sized for those 3-6 years old) for 2 minutes twice daily (Creeth et al., 2009) can help prevent ECC. For 1- to 2-year old children, professional application of fluoride varnish (FV) over 2 years is efficacious (Weintraub et al., 2006; Gansky et al., 2007) and the standard of care for prevention. Powered toothbrushes can provide better plaque removal than manual toothbrushes (Yacoob et al. 2014), but may also have a short-term novelty effect. Research participants using powered toothbrushes may also experience a Hawthorne effect from knowing they are in a research study. Both the novelty and Hawthorne effects have been reported to abate after 12 weeks among college students in a randomized controlled trial (RCT) evaluating plaque levels (McCracken et al. 2000).

Types of Rewards. Incentives are a common component of health promotion programs. Recognizing the important role that incentives can play, NIH has placed the evaluation of incentives on health-related behaviors among its highest priority areas for health economics research (NIH, NOT-OD-16-025, 2015).

Lottery prizes (a type of monetary incentive) have been more successful than non-monetary incentives for encouraging more physical activity (Wing et al., 1996), smoking

cessation, and blood donation (Dey et al., 1999; Goette & Stutzer, 2008), but not for encouraging prenatal visit attendance (Laken & Ager, 1995). Non-monetary incentives (e.g., social recognition, gifts) have effectively boosted immunization (Banerjee et al., 2010; Birkhead et al., 1995; Nexoe et al., 1997; Satterthwaite, 1997) and follow-up cancer screening visits (Marcus et al., 1992; Mayer & Kellogg, 1989), and non-monetary incentives may work as well as material gifts especially if aimed at reducing barriers (e.g., transportation) (Melnikow et al., 1997; Smith et al., 1990).

Large incentives may displace intrinsic motivation for behavior change with the expectation of extrinsic rewards to achieve the same health goals, and consequently remove motivation to adhere to new behaviors once rewards are withdrawn (Gneezy & Rustichini, 2000). Similarly, incentives may alter expectations of interpersonal trust (e.g., between patients and doctors) if exchanges with incentives are viewed as monetary transactions (Heyman & Ariely, 2003).

Incentive form and size to motivate sustained behavior change must reflect contextual factors, including interpersonal relations and reciprocity. Populations place different value on the reward associated with different incentive types (i.e., if the reward is viewed simply as a commercial transaction versus as an added symbolic value of interpersonal trust (vis-à-vis social exchange theory) (Gneezy & Rustichini, 2000; Homans, 1974; Burns, 1973).

Lastly, incentive payout form and size affect program sustainability. While cash transfer programs conditional on children's school and health visit attendance (conditional cash transfers) successfully alleviate poverty and promote social goals, health and nutrition, they have high administrative costs (Handa & Davis, 2006). Moreover, policy makers may prefer in-kind to cash transfers (Das et al., 2005). For the same cost, differently structured incentives may have substantially different effects (Volpp et al., 2009; Haisley et al., 2012). Although some studies have included a cost-effectiveness calculation to evaluate an incentive's added value to preventive health behaviors (Kane et al., 2004), none have done so for oral health.

The project's overall goal is to assess the efficacy of rewards towards promoting ECC preventive health behaviors (toothbrushing adherence) for young children of predominantly Latino parents/caregivers in Early Head Start (EHS) and day care center programs.

2.2 Rationale

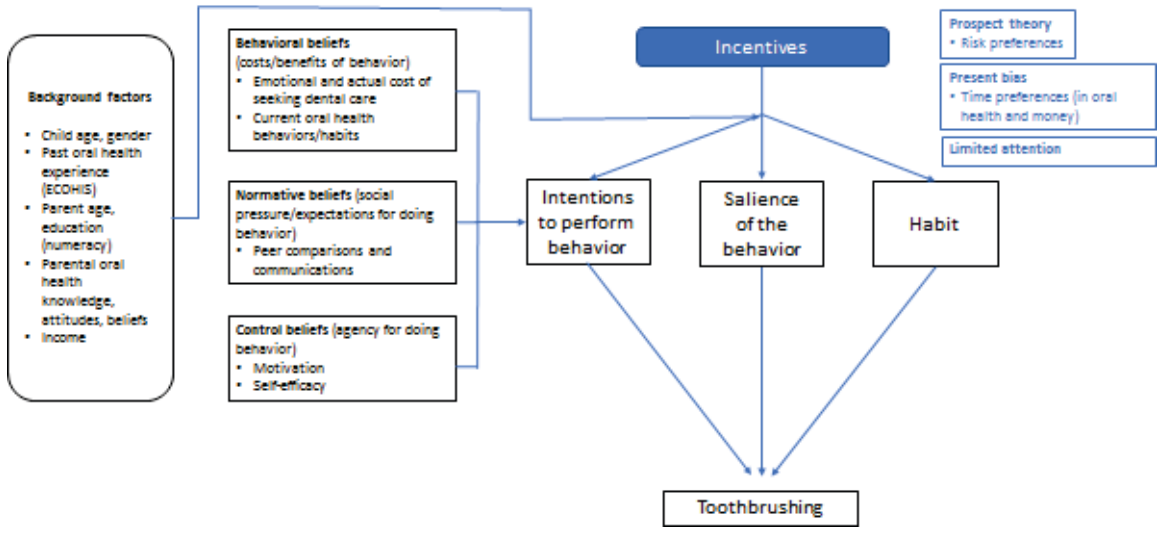
Numerous factors may contribute to parents/caregivers' inability to provide ADA- or AAP-recommended oral health prevention for their children (i.e., consume fluoridated water, brush with a smear/pea-sized amount of fluoridated TP for 2 minutes twice daily, and attend regular oral health appointments by age one or within six months of first tooth eruption). Minimal oral health knowledge and/or literacy, financial obstacles, and

competing influences, such as daily stress, work, housing priorities, childcare needs, transportation, or geographic location, are a few considerations that may result in failure to follow these oral health recommendations. Further, cultural influences may lead to distrust of fluoride, or believing preventive oral care is unnecessary (Butani et al., 2008).

Prospect Theory and Present Bias

The intervention – weekly drawings based on qualifying toothbrushing sessions – draws on insights from several theories from the field of behavioral economics. The design of the drawing is based on aspects of *prospect theory* (Kahneman & Tversky, 1979). Participants who fail to meet the weekly threshold for earning rewards are informed if they would have won the drawing in order to leverage loss aversion and regret aversion, a sense that a person does not want to give up something that is hers. The drawing also leverages nonlinear probability weighting from prospect theory, in which people have a tendency to overweight small probabilities. The reward design also incorporates the theoretical construct, *present-biased preferences* (also known as present bias or hyperbolic discounting) (Ainslie, 1992; Laibson, 1997). This is the tendency to overweight immediate costs and benefits relative to those in the future. The weekly rewards are a way to provide relatively immediate and frequent feedback, both of which can help counter present bias. Rewards may have additional theoretical benefits: increasing salience of the targeted behavior, offsetting a person's limited attention, and promoting habit formation. The following figure shows where in the decision pathway the intervention is hypothesized to affect the preventive behavior, as well as some of the covariates affecting behavior.

Conceptual model: How incentives can affect toothbrushing



Rewards have facilitated positive changes in health-promoting behaviors, such as quitting smoking (Marteau et al., 2009; Rogers et al., 2014), weight loss (John et al., 2011), and managing blood glucose and blood pressure (Sen et al., 2014). Conditional rewards are particularly effective in encouraging behavioral changes; in some cases small incentives can be equally effective or more effective than larger ones (Marteau et al., 2009; Sen et al., 2014). These “behavioral economic” interventions can lead to healthy behaviors even after incentives end, particularly with smaller incentives (Sen et al., 2014). To date, no study has evaluated such a program for oral health.

2.3 Potential Risks and Benefits

2.3.1 Potential Risks

This study poses minimal risk to participants. Study participation is completely voluntary, and participants may discontinue participation at any time without prejudice. Regarding study questionnaires, parent participants may experience psychological discomfort in discussing personal health information or negative experiences at a dental or other relevant office (such as enrolling a child in Medicaid). As with any study, there is the potential for loss of confidentiality. Appropriate precautions will be taken to mitigate this risk. Parents/guardians will be reminded not to change the app profile study ID number to any personal identifying information; if they do it will be transmitted to Philips Sonicare. These include the use of unique study codes for participants and password-protected computers for data storage. Compliance with all Institutional Review Board (IRB) regulations concerning data collection, data storage, and data destruction will be strictly observed. Data will be accessible to research personnel only and will be stored and coded according to guidelines set forth by the UCSF IRB.

The child participant could have potential mechanical trauma to the teeth or gingiva from the powered toothbrush. Parents will be carefully instructed on proper brushing techniques to reduce possible oral discomfort.

Additionally, there is a rare chance of tooth brush head disintegration (bristles falling out), which is a potential choking hazard. The powered toothbrush should always be used with adult supervision, and children should be discouraged from chewing on the brush head.

Even though it is extremely unlikely that a child will get access to and eat the TP, using TP pumps will further reduce the chance of toxicity since the pumps require dexterity that children in the study age range likely lack, and the pumps limit the amount of TP dispensed at any one time. Parents will be advised to keep the TP on a counter and out of the reach of all children in the household.

There is a possibility that a participant may experience an allergic reaction to the TP, FV, and/or plaque disclosing solution; however, the likelihood from TP and FV is extremely rare, while the likelihood from disclosing solution is also rare according to the package insert. Parents/caregivers will be instructed to contact the study's Project Manager in the unlikely event that an allergic reaction to a study product is suspected.

Any adverse reactions will be reported as outlined in Section 9.

All parent/caregiver participants will be asked if they are willing to be contacted again for research purposes. For those who agree, personal identifying information (PII), including contact information, will be requested for subsequent contact and interviewing, creating the risk of a loss of confidentiality of contact information. All participants will be informed of this risk and of steps taken to reduce this possibility.

2.3.2 Potential Benefits

Each child participating in this trial, regardless of study group, will have a dental screening and FV applied to his/her teeth as the current standard of care, unless the parent reports that it has been applied within the past month. Each child participant will also receive oral hygiene aids, such as a powered smart toothbrush (TB), brush heads, and fluoride TP pumps. As needed, children with early care or urgent care needs (treatment class 2 or 3 as documented in the ASTDD BSS form) will be provided with referrals for dental visits to providers who agree to take their insurance. In addition, parents/caregivers will be provided Anticipatory Guidance in a standardized video format in English or Spanish; families participating in this study may benefit from the Anticipatory Guidance information.

Overall, participants in the study may benefit from an increased awareness of oral health prevention behaviors.

3 OBJECTIVES

3.1 Study Objectives

3.1.1 Primary

The primary objective of this RCT is to compare the impact of Monetary Rewards (weekly drawings for those with qualifying toothbrushing sessions) versus Delayed Reward Control through 6 months in predominantly Latino parents/caregivers to increase ECC preventive behaviors of their children enrolled in or waitlisted for a participating Los Angeles County EHS or affiliated day care center program.

3.1.2 Secondary

The secondary objectives are as follows:

- To assess the impact of the Monetary Rewards Intervention versus Delayed Reward Control on toothbrushing performance:
    - Through 12 months to assess sustainability of the behavior after the drawing incentives cease.
    - Through 1 month to assess short-term (immediate) impact on the behavior after the drawing incentives and powered toothbrush use begin (i.e. may include novelty effect of power toothbrushes in all participants).
    - Through 3 months to assess mid-term impact on the behavior after the drawing incentives and powered toothbrush use begin (i.e. after potential novelty effect of power toothbrushes ends in all participants).
- To estimate the short- and long-term cost effectiveness and return on investment of rewards in improving parent/caregiver behaviors and children's oral health.
- To assess potential mediation effects of beliefs (behavioral, normative, and control) on intermediate outcomes (intentions, salience, and habit) and primary outcome (toothbrushing performance).

3.2 Study Outcome Measures

3.2.1 Primary

The primary outcome is toothbrushing performance through the Month 6 visit, measured with a Bluetooth-enabled toothbrush, and expressed as a mean of the number of qualifying half-day toothbrushing episodes per week. A toothbrushing session recorded with the app qualifies to contribute to the weekly count if it lasts at least one minute and occurs within one of the 14 possible half-day windows during a week; only one session per half-day window contributes to the weekly count, which can range from 0 to 14.

A participant qualifies for weekly drawing eligibility as follows:

- Low threshold - if the child's teeth were brushed at least once per day for at least one minute each day of the week;
- High threshold - if the child's teeth were brushed at least once per half-day for at least one minute each day of the week.

3.2.2 Secondary

Intermediate toothbrushing performance measures are as follows:

- Mean of the number of qualifying half-day toothbrushing episodes per week, through 1 month for short-term effects
- Mean of the number of qualifying half-day toothbrushing episodes per week, through the Month 3 visit for mid-term effects after any novelty effect would be expected to end,
- Mean of the number of qualifying half-day toothbrushing episodes per week, from Month 6 visit to Month 12 visit for longer-term effects

For the outcomes listed above, the minimum qualifying length of time is 1 minute.

Additional secondary oral health measures will be ascertained:

- Debris Index of the Simplified Oral Hygiene Index for Maxillary Incisors (OHI-MIS) to measure plaque on primary maxillary incisor facial (labial) tooth surfaces at Month 6 and Month 12 visits (mean of 4 ordinal scores)
- TP pump weight change (grams) at Month 6 and Month 12 visits
- Binary measure of Association of State and Territorial Dental Directors Basic Screening Survey (ASTDD BSS) untreated caries status (dt>0) at Month 6 and Month 12 visits
- Binary measure of ASTDD BSS caries experience status (dmft>0) at Month 6 and Month 12 visits; m is missing due to caries only
- Binary measure of ASTDD BSS severe caries (dmft 4+) status at Month 6 and Month 12 visits; m is missing due to caries only
- Binary measure of a dental visit in the past 12 months, obtained through EHS ChildPlus database which records annual dental visit and other required health screenings

To assess potential mediation effects of beliefs (behavioral, normative, and control) on intermediate outcomes (intentions, salience, and habit) and primary outcome (toothbrushing performance), the aforementioned primary and secondary outcome measures will be assessed. Behavioral, normative, and control beliefs will be collected via the BRFQ at each study visit (see Section 8.3). Intentions, salience, and habit will be collected with components of the BRFQ (e.g. intentions to brush child's teeth in the next 6 months, preventive habits for one's self and for one's child, age started brushing study child's teeth.).

To estimate the short- and long-term cost effectiveness and return on investment of rewards in improving parent/caregiver behaviors and children's oral health, net costs will be ascertained (as detailed in Section 12.4).

During the qualitative process evaluations at the Month 6 and Month 12 visits, the following will be ascertained: oral health behaviors and health habits, dental care

motivation behavior, toothbrushing and reactions to the powered toothbrush, toothpaste pump use, toothbrush syncing, Sonicare app use, text message reminders, opportunity costs, incentives, overall satisfaction, and perspectives on behavior data tracking for personal use and outside monitoring purposes.

4 STUDY DESIGN

We will conduct a stratified RCT testing the impact of monetary rewards on ECC preventive behaviors and oral health. Eligible child-parent/caregiver participant dyads will be consented, enrolled, and, following a 2 week run-in, randomized within strata and permuted blocks in equal allocation to one of two groups: 1) Monetary Rewards or 2) Delayed Reward Control. Strata will be based on site and smartphone operating system. The intervention will be offered for 6 months, and children (ages 6 months through <48 months) will be followed for 12 months to determine reward effects on dental visit attendance, toothbrushing, fluoride TP use, OHI-MIS plaque score , and caries screening status. Results will inform researchers and public health practitioners on the longer-term maintenance of behavioral changes and oral health screening status following removal of the rewards.

The study population will be predominantly low income Hispanics/Latinos who are parents/caregivers with children enrolled in, or waitlisted for, one of the participating Los Angeles County EHS or affiliated day care center programs. After enrollment parents/caregivers will use powered toothbrushes for a 2 week run-in to ensure their technology works and they are willing to follow study procedures; after the enrollment visit and run-in, randomization will occur at a separate visit. Participants who are unable to provide data during the run-in period will not be randomized or continue in the study.

Participants in the Monetary Reward group will be eligible to earn one of two incentive amounts every week for the first 6 months of the trial. A participant who meets a low or high threshold will earn entry in that week’s drawing for financial incentives (See Section 6.1 for additional details).

In the Delayed Monetary Reward Control group, participants will receive feedback on their toothbrushing performance during the first 12 months of the trial. After the Month 12 follow-up visit, the Control group participants will have the option to participate in a delayed 6-month extension by being randomized to one of two groups to earn the same expected monetary rewards the intervention group was eligible to earn through Month 6; both Control groups will have weekly drawings (as in the intervention group though 6 months), but one Control group will be randomized into drawing results shared weekly (as in the intervention group through 6 months), while the other randomized Control group will have the 13 weekly drawing results only shared quarterly, with equal reward amounts and the same probabilities for high and low thresholds.

Toothbrushing performance will be ascertained via Philips Sonicare for Kids (S4K) powered toothbrushes and brush heads, which will be synced with a custom BEECON study version of their existing S4K smartphone application. Data to be transmitted includes toothbrushing start time, toothbrushing duration, application start time, and whether toothbrushing was conducted with the application open or without the application (offline).

SMS text message notifications will be sent via Twilio and REDCap to remind participants to sync the powered toothbrush to the smartphone app. Further, all study participants will be sent weekly SMS text messages with feedback on toothbrushing progress, and, if in the intervention group, the incentives earned.

Additionally, participants will undergo study visits every 3 months. At screening and Month 6, 12, and 18visits the participating child will receive an ASTDD BSS dental screening after parents/caregivers provide a brief child medical history, and a OHI-MIS plaque score will be determined. Participants in each group will be provided a new TP pump at the Month 6 and Month 12 visits and 1 new brush head at each study visit (every 3 months). Questionnaires will be configured in REDCap.

Four focus group discussions (FGDs) of trial participants will be conducted after the Month 6 visit, and two FGDs of intervention arm participants will be conducted after the Month 12 visit. Participants will be chosen based on study performance (e.g., above and below high and low thresholds of toothbrushing adherence).

Stakeholder interviews (6-12) with EHS and affiliated day care center staff will be conducted after the Month 6 visit.

5 STUDY ENROLLMENT AND WITHDRAWAL

5.1 Subject Inclusion Criteria

Child
To be eligible to participate in this study, a child must meet all of the following criteria, to be verified during a screening visit:

- at least 6 months old but less than 4 years (48 months).
- at least 2 fully erupted teeth.
- enrolled in, or waitlisted for, one of the participating Los Angeles County EHS or affiliated day care center or area clinic programs.

Parent/caregiver

To be eligible to participate in this study, a parent/caregiver must meet all of the following criteria, to be verified during a screening visit:

- Provide signed and dated informed consent form in English or Spanish.
- Agree to comply with all study procedures and be available for the duration of the study.
- Aged 18 and older.
- Speak either English or Spanish and self-reported ability to read and write either English or Spanish.
- Be a parent or caregiver of a child at least 6 months old but less than 4 years (48 months), with at least 2 fully erupted teeth and enrolled in, or waitlisted for, one of the participating Los Angeles County EHS or affiliated day care center or area clinic programs.
- Not be planning to move residence for the next 18 months outside the greater Los Angeles area.
- Own a smartphone with the Google Play or iTunes store and be willing to download and install the smart powered TB app at the Screening visit and keep it installed for the duration of the project. [If the app cannot be properly installed by the baseline visit, the participant will not be randomized.]
- Be willing to be contacted via text-messaging (SMS) for study related notifications, such as incentives earned or reminders to sync the TB.

Stakeholder
To be eligible to participate in the stakeholder interviews, a staff member must meet all of the following criteria:

- Be a staff member at a participating study site (e.g. EHS or affiliated day care center).
- Verbally agree to participate after being provided a study information sheet.

5.2 Subject Exclusion Criteria

Child
A child who meets any of the following criteria will be excluded from participation in this study:

- Known allergic reaction to components of the study product(s).

- Uncooperative or behaviorally unsuited (assessed during a TB prophylaxis, ASTDD BSS caries screening, and photograph of maxillary incisors at the screening visit).
- More than 2 crowns on maxillary incisor teeth (#D, E, F, G, or equivalently #52, 51, 61, 62).
- Participated in the pilot trial.
- A sibling of a child enrolled in the study (the family's oldest child in the eligible age range will be the study child).
- Enrolled in foster care.
- Anything else that would place him/her at increased health risk or preclude the individual's full compliance with or completion of the study.

Parent/caregiver
A parent/caregiver who meets any of the following will be excluded from participation in the study:

- Participated in the pilot trial.
- Unable or unwilling to install and use the smart powered TB app during the run-in period.

5.3 Strategies for Recruitment and Retention

Recruitment Plans: Participants will be recruited from Los Angeles County EHS or affiliated day care centers; the study visits will occur at Los Angeles Venice Family Clinic locations at Simms/Mann, Lou Colen, and Robert Levine centers. The EHS and affiliated day care centers had a 2016-2017 enrollment of 661 center-based and 616 home-based children for 1277 total children; thus, fewer than one in five child-parent dyads would need to be enrolled for the RCT. Venice Family Clinic has more than 10 Early Head Start sites and Volunteers of America – Los Angeles has more than 35 sites. Should the study team determine that recruitment/enrollment is lagging, pediatrician (non-dental) clinics affiliated with or adjacent to EHS and day care centers in Los Angeles may be recruited as additional recruitment sites for this trial (with this group comprising one stratum).

Using a standardized recruitment script similar to those used in the recently completed glass ionomer sealant and fluoride varnish trial (GIFVT) and BEECON pilot trial, research study personnel will contact EHS and day care center families to determine interest in study participation. Outreach may occur at the EHS center, during EHS

monthly parent meetings, at day care center meetings, health fairs, or via telephone calls to interested parents/caregivers who contact study staff. Recruitment is estimated to continue for 14 months with a goal of enrolling approximately 17 children per month (approximately 21 business days per month) to achieve the target sample size. Pilot trial enrollment was completed in less time than originally planned: 36 participants in 29 business days.

Mailings and flyers with study recruitment information may also be sent out or posted in the EHS and day care facilities. The monthly EHS newsletter may also include an invitation to participate in this trial.

Retention Plan: This trial will utilize a 2-week run-in phase to decrease initial post-randomization drop-out and increase retention. Because study participant retention is essential, research staff may attempt to contact participating parents/caregivers via postcard mailings, SMS text messages, and phone calls between the visits throughout the study to update contact information and remind them about follow-up appointments. Additionally, parents/ caregivers will receive text message reminders to sync the powered TB to their smartphone app. Finally, all study participants will be sent weekly SMS text messages with toothbrushing performance status per smart TB data, and the incentive earned if assigned to the incentive group. Remuneration for syncing and/or rewards will be provided at follow-up visits, and participants will be remunerated for attending each follow-up visit, encouraging regular attendance. This trial expects to have 85% retention over 1 year, based on the team's recently completed GIFVT, which had 85% retention over 2 years.

5.4 Treatment Assignment Procedures

A randomization schedule will be generated by the Coordinating Center (CC) and stored in REDCap to randomize consenting parent/caregiver-child dyads into one of two groups. Once eligibility is confirmed, informed consent is documented, the run-in period is completed, and a staff member confirms the app has been properly installed and maintained, the project manager will click the "randomize" button in REDCap to reveal group assignment for the parent/caregiver-child dyad.

5.4.1 Randomization Procedures

A custom SAS program using PROC PLAN stratifying on site (facility type) and phone type (iPhone or Android) as well as permuted blocks of varying sizes will be utilized with a random seed based on the date the program is first modified from the program used in the pilot trial. The randomization schedule will be stored on the secure UCSF CC server in a restricted permissions folder, as well as, in REDCap. Only staff needing to administer the intervention, or the DSMB if needed for safety reasons, will be unblinded before completion of the trial. Randomized arm assignment will not be unblinded to

other team members until the trial is completed or has been stopped early by NIDCR or the DSMB.

5.4.2 Masking Procedures

An independent dental examiner and PIs will be blinded to participants' group assignment, and participants will be told that the examiner and PIs cannot answer any incentive questions and they should not mention the incentive program to them. Due to the nature of the intervention, the staff explaining the study arms after randomization and providing the incentive gift cards at Month 3, 6, 9, 12, 15, and 18 visits cannot be blinded. At the Month 6 and 12 visits, dental screenings will precede monetary incentive payment.

5.5 Subject Withdrawal

Participants may withdraw voluntarily from the study at any time.

5.5.1 Reasons for Withdrawal

Participants may decide not to answer any Computer Assisted Personal Interview (CAPI) item or not to participate in the study at any time without penalty.

Participants are free to withdraw from participation in the study at any time upon request, for any reason, without penalty or loss of benefits as a member of their EHS or affiliated day care program or health clinic. This may occur due to discomfort with questions or practical concerns that limit the time available (e.g., pressing employment schedule or child care needs).

An investigator may terminate a study participant's participation in the study if:

- Any clinical adverse event (AE) or other medical condition or situation occurs such that continued participation in the study would not be in his/her best interest.

- The participant meets an exclusion criterion (either newly developed or not previously recognized) that precludes further study participation.

- Participants who are unable to provide app data during the run-in period will be withdrawn prior to randomization.

5.5.2 Handling of Subject Withdrawals or Subject Discontinuation of Study Intervention

If parent/caregiver informs the study staff that he/she does not wish to continue with the study any further, the staff member will document the reason(s) and remove the parent and child from the study. The participant will be encouraged to continue with regular oral health preventive behaviors and dental examinations at the child's dental home, which could detect early signs of disease. A participant's withdrawal from this study will not influence his/her future relations with any of the study's collaborating institutions, including but not limited to LA County EHS and affiliate day care center sites, UCSF, UCLA, or the child's medical or dental care provider. Randomized participants who withdraw will not be replaced. All study data provided before withdrawing will be used for analysis, unless the participant asks that her/his data and her/his child's data not be used.

5.6 Premature Termination or Suspension of Study

This study may be suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to Drs. Stuart Gansky and Francisco Ramos-Gomez (PIs). If the study is prematurely terminated or suspended, the PIs will promptly inform the IRB and will provide the reason(s) for the termination or suspension.

Circumstances that may warrant termination include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to subjects.
- Insufficient adherence to protocol requirements.
- Data that are not sufficiently complete and/or evaluable.
- Determination of futility.

6 STUDY INTERVENTION

6.1 Study Behavioral or Social Intervention(s) Description

In the Drawing Monetary Reward group, participants will be eligible to earn one of two types of entries with different winning probabilities each week during the 6-month incentive intervention period. Caregivers in the drawing payment group will be informed that the drawing will occur every week through the first 6 months of the trial. Participants will be sent a text message about entering into a drawing every week; the participant can click the REDCap survey link in the text to select a 2-digit number or let his or her number be chosen at random. The amount of winnings possible depends on the

participant's level of toothbrushing performance. A participant who meets the low adherence threshold (brushing his/her child's teeth once per day for 7 days in a week) will be eligible for an 18% chance (matching one digit with the winning number) of winning $25 and a 1% chance (matching both digits in order) of winning $50 (an expected payout of $5; 81%x$0 + 18%x$25 + 1%x$50=$5). A participant who meets the high adherence threshold (brushing his/her child's teeth twice per day for 14 days in a week) will be eligible for a 34% chance (matching either digit without regard to order) of winning $25 and a 3% chance (matching both digits without regard to order) of winning $50 (an expected payout of $10; 63%x$0 + 34%x$25 + 3%x$50). Participants who fail to reach either adherence threshold will receive a text message that states what they would have won had they brushed more regularly, thereby taking advantage of a psychological tendency toward anticipated regret to motivate future brushing.

In the Delayed Monetary Reward Control group, participants will not be eligible to receive any performance-based rewards during the first 12 months, but will receive information on their toothbrushing performance. After the 12-month follow-up visit, the Control group participants will have the option to participate in a delayed 6-month open label extension to earn the same monetary rewards the intervention group was eligible to earn until Month 6. This is not a formal part of this trial, but rather a necessary condition of the trial design to assure that all participating parents/caregivers have the chance to earn the same monetary incentives. Control participants who choose the 6-month extension will follow the same procedures (i.e., texting notifications) as the Monetary Reward intervention group from the 12-month follow-up to an 18-month follow-up; they will be randomized into one of two groups which will convey weekly drawing information to participants either weekly or quarterly. At the 18-month follow-up visit, they will be able to collect the earned incentives when the child attends the visit and the returned TP pump is weighed.

After the Month 6 visit through the end of the trial (Month 12), participants will continue to sync their powered toothbrushes and will receive incentives for syncing, but will not be eligible to receive rewards for toothbrushing performance, to assess behavior maintenance after the rewards have ended.

6.2 Administration of Intervention

All participants will be instructed to sync their smart powered toothbrushing data to the app three times per week. Failure to sync three times per week will disqualify the participant from receiving any incentives that week for those in an incentive group. All participants, regardless of group assignment, will receive a fixed payment of $1 per sync for syncing their data up to three times per week (Wednesdays, Fridays, and Sundays, specifically). A text message reminder to sync the app will be sent to participants before each of these three times every week.

First, all participants will enter two initial “practice” (run-in) weeks at the start of the intervention, during which participants will sync their toothbrushing data (and be eligible for up to $3 of incentives for syncing), but will not be eligible for the performance-based toothbrushing reward. Following the two practice weeks, intervention group participants are eligible to earn rewards over the first 24 weeks (6 months), while Delayed Monetary Reward Control group participants may earn rewards between the 12-month visit and 18-month visit.

All participants will be sent text messages of their toothbrushing performance status each week, per the powered toothbrushing data. For participants assigned to the intervention group, the text message will include the amount earned and the total gift card balance accrued to date for the previous 3-month period. Additionally, participants will have the option to have text messages sent to other family members who regularly brush the child’s teeth and who consent by text message to receiving messages. Contact information for all family members will be obtained at the baseline visit.

Thus, the total expected payout value of attaining the high toothbrushing adherence threshold throughout the 6-month intervention period is $240.

To claim any incentives, including for syncing data, a parent/caregiver and child must attend the follow-up visits. Based on developmental stage telephone survey preferences, all earned reward payments will be awarded as gift cards at the Month 3 and Month 6 visits for the Monetary Reward group, and Month 15 and Month 18 visits for the Delayed Monetary Reward Control group. Syncing payments will be awarded as gift cards at all follow-up appointments.

6.3 Procedures for Training Interventionists and Monitoring Intervention Fidelity

The Project Manager will train all research staff members on how to explain intervention procedures and incentive program details to participants in English or Spanish utilizing a communication script. The Project Manager or another supervisor will assess fidelity from 100% of audio recordings during the training period and then from a randomly selected 10% of recordings every week thereafter during participant accrual. A study-specific checklist of intervention procedures and incentive program details will be used to evaluate fidelity from the recordings. Checklists with less than 90% fidelity during the training period or during baseline visits will be declared inadequate and require staff re-training by the Project Manager. A study co-investigator will train the Project Manager to code fidelity data from the recordings.

6.4 Assessment of Subject Compliance with Study Intervention

Study team staff will document that the information was presented and that the parent/caregiver explained the procedures back in his/her own words. Throughout the

study intervention, a random selection of 5% of SMS text messages to parents/caregivers will ask for a reply to verify receipt.

7 STUDY SCHEDULE

7.1 Screening

Each child will be scheduled for a screening visit with his/her parent/caregiver.

7.1.1 Screening Visit (Visit 1, T = business day -10)

- Explain purpose and procedures of study to prospective parent/caregiver participant. Verify inclusion/exclusion criteria.
- Obtain and document consent from subject on study consent form electronically with DocuSign.
- Study staff download app on parent's/caregiver's smartphone and sync the TB to his/her smartphone. Walk parent through the app. Explain how to sync.
- Administer CAPI questionnaire to parent/caregiver.
- Record medical history and perform ASTDD BSS dental screening on child participant's teeth (by blinded dental provider); record decay and assess treatment urgency. Children with urgent treatment needs will be referred with a warm handoff to staff at the corresponding dental clinic.
- Apply plaque disclosing agent to child's teeth (by blinded dental provider).
- Take extraoral photograph(s) of the facial surfaces of child's anterior teeth.
- Give the family the Oral Hygiene Kit, which includes the smart powered toothbrush and fluoride TP pump. Attach label with child's name.
- Instruct the parent/caregiver on how to use the TP pump to show the proper amount of TP, and how to brush the child's teeth. Have the parent brush off the child's plaque disclosing solution.
- Apply FV to the child's teeth (by dental provider).
- Have the parent/caregiver watch the standardized Anticipatory Guidance presentation on a tablet.

7.1.2 Baseline (Post-Run-In/Randomization) Visit (Visit 2, T = 0 [+10/-2])

- Administer CAPI questionnaire to parent/caregiver.
- Click the REDCap "randomize" button to reveal participant's randomized assignment to arm. Explain the intervention procedures and rewards program (if assigned to the Intervention Arm) to the parent/caregiver and have her/him explain it back in her/his own words. Explain control procedures (if assigned to the Control Arm) to the parent/caregiver and have her/him explain it back in her/his own words.
- Schedule the family's next visit (in approximately 3 months) and give the parent/caregiver $30 compensation for attending the baseline visit.

7.2 Intermediate Visits

7.2.1 Month 3 Follow-Up Study Visit (Visit 2, T = business day 65 ± 28)

During this Month 3 follow-up visit, the following procedures will be completed by trained staff members.

- Administer CAPI questionnaire to parent/caregiver.
- Dispense new brush head.
- Dispense earned rewards to the parent/caregiver *(Intervention Arm).*
- Dispense syncing payments to the parent/caregiver (*both groups*).
- Schedule the family's next visit (in approximately 3 months) and give the parent/caregiver $30 compensation for attending the 3-month visit.

7.2.2 Month 6 Follow-Up Study Visit (Visit 3, T = business day 130 ± 28)

During the Month 6 follow-up visit, the following procedures will be completed by trained staff members.

- Perform follow-up assessments of outcome measures and safety.
- Administer CAPI questionnaire to parent/caregiver.
- Record medical history and perform ASTDD BSS dental screening on child participant's teeth (by blinded dental provider); record decay and assess treatment urgency. Children with urgent treatment needs will be referred with a warm handoff to staff at the corresponding dental clinic.

- Apply plaque disclosing agent to child's teeth (by blinded dental provider).
- Take extraoral photograph(s) of the facial surfaces of child's anterior teeth.
- Brush off plaque disclosing solution.
- Apply FV to the child's teeth (by dental provider).
- Have the parent/caregiver watch the Anticipatory Guidance presentation on a tablet.
- Record weight of TP pump.
- Dispense new toothbrush head and TP pump.
- Dispense earned rewards to the parent/caregiver *(Intervention Arm).*
- Dispense syncing payments to the parent/caregiver (*both groups*).
- Schedule the family's next visit (in approximately 3 months) and give the parent/caregiver $30 compensation for attending the 6-month visit.
- After this visit, perform FGDs and stakeholder interviews

7.2.3 Month 9 Follow-Up Study Visit (Visit 4, T = business day 195 ± 28)

During the Month 9 follow-up visit, the following procedures will be completed by trained staff members.

- Administer CAPI questionnaire to parent/caregiver.
- Dispense new toothbrush head.
- Dispense earned rewards to the parent/caregiver *(Intervention Arm.)*
- Dispense syncing payments to the parent/caregiver (*both groups*).
- Schedule the family's next visit (in approximately 3 months) and give the parent/caregiver $30 compensation for attending the 9-month visit.

7.2.4 Month 12 Follow-Up Study Visit (Visit 5, T = business day 260 ± 28)

The Month 12 visit is the final study visit for participants randomized to the incentive group. During this visit, a trained staff member will complete the final questionnaire and post-test with the parent/caregiver.

- Administer CAPI questionnaire to parent/caregiver.
- Collect the TP pump. Record weight of TP pump.
- Record medical history and perform ASTDD BSS dental screening on child participant's teeth (by blinded dental provider); record decay and assess treatment urgency. Children with urgent treatment needs will be referred with a warm handoff to staff at the corresponding dental clinic.
- Apply plaque disclosing agent to child's teeth (by blinded dental provider).
- Take extraoral photograph(s) of the facial surfaces of child's anterior teeth.
- Brush off plaque disclosing solution.
- Apply FV to the child's teeth (by dental provider) (Continuing delayed control arm only).
- Give the parent/caregiver an electronic tablet to watch the Anticipatory Guidance presentation.
- Give the parent/caregiver the accumulated rewards (*Intervention Group)*.
- Distribute 1 new toothbrush head and new TP pump.
- Dispense syncing payments to the parent/caregiver (*both groups*).
- Give the parent/caregiver $30 compensation for attending this 12-month visit.
- After this visit, perform FGDs.
- *Optional for Control Group only:* Randomize Control Group participants who want to continue into 1 of 2 groups: weekly or quarterly drawing result communication. Explain the intervention procedures and Monetary Rewards program to the parent/caregiver and have her/him explain it back in her/his own words (teachback). Schedule the family's next visit (in approximately 3 months).

7.2.5 Month 15 Follow-Up Study Visit (Optional for Control Group Only, Visit 6, T = business day 325 ± 28)

During this Month 15 follow-up visit, the following procedures will be completed by trained staff members.

- Administer CAPI questionnaire to parent/caregiver.

- Dispense new toothbrush head.
- Dispense earned rewards to the parent/caregiver.
- Dispense syncing payments to the parent/caregiver.
- Schedule the family's next visit (in approximately 3 months) and give the parent/caregiver $30 compensation for attending the 15-month visit.

7.2.6 Month 18 Follow-up Study Visit (Optional for Control Group Only, Visit 7, T = business day 390 ± 28)

The Month 18 study visit is the final visit for participants randomized to the Delayed Reward Control Group. During this visit, a trained staff member will complete the final questionnaire and post-test with the parent/caregiver following the established protocol.
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- Administer CAPI questionnaire to parent/caregiver.
- Collect the TP pump. Record weight of TP pump.
- Record medical history and perform ASTDD BSS dental screening on child participant's teeth (by blinded dental provider); record decay and assess treatment urgency. Children with urgent treatment needs will be referred with a warm handoff to staff at the corresponding dental clinic.
- Apply plaque disclosing agent to child's teeth (by blinded dental provider).
- Take extraoral photograph(s) of the facial surfaces of child's anterior teeth.
- Brush off plaque disclosing solution.
- Give the parent/caregiver an electronic tablet to watch the Anticipatory Guidance presentation.
- Give the parent/caregiver the accumulated rewards. Distribute 1 new toothbrush head and new TP pump.
- Dispense syncing payments to the parent/caregiver.
- Give the parent/caregiver $30 compensation for attending this final visit.

7.3 Withdrawal Visit

No early termination or withdrawal visits are anticipated, but in the event that this occurs, such a visit would follow the same guidelines established for a final study visit as long as the parent/caregiver is willing.

7.4 Unscheduled Visit

Although no unscheduled visits are anticipated, it is possible a participant may have a problem with the smartphone app, or Bluetooth toothbrushes and ask for study staff to help. Any such additional visits will be logged into REDCap. All adverse events will be reported as outlined in Section 9.

8 STUDY PROCEDURES /EVALUATIONS

8.1 Oral Examination Procedures

The clinical procedures and evaluations for this study will consist of the following: child's medical history will be evaluated via a self-reported standardized questionnaire administered to the parent/caregiver at the enrollment/baseline visit. A trained dental provider will perform the ASTDD BSS dental screening examination. Then, after applying disclosing solution, a study staff member will take photographs of anterior teeth with the study iPhone camera to record plaque levels. A central rater will determine a plaque score from an image of the facial (labial) surfaces of anterior teeth, following the Debris Index of the Simplified Oral Hygiene Index (OHI-S) modified for only the primary maxillary incisors (labeled the Debris Index of the Simplified Oral Hygiene Index for Maxillary Incisors and denoted as OHI-MIS). The OHI-MIS evaluator will be trained and calibrated as per CC protocol. Annually, the OHI-MIS evaluator will rerate 30 randomly selected photos during an intra-rater reliability plaque score calibration. After study staff demonstrate and observe parent/caregiver performance of study procedures, the dental provider will apply FV.

8.2 Focus Groups and Interviews

Four focus group discussions (FGDs) of approximately 10 people per arm will be conducted in English and Spanish after the Month 6 visit. Two FGDs of intervention arm participants (one in English and one in Spanish) will be conducted after the Month 12 visit. Participants will be chosen based on study performance (e.g., above and below high and low thresholds of toothbrushing performance). Each FGD session will be about 45-60 minutes in duration. The FGDs will focus on topics related to participants' involvement in the intervention: oral health behaviors and health habits, dental care motivation behavior, toothbrushing and reactions to the powered toothbrush, toothpaste pump use, toothbrush syncing, Sonicare app use, text message reminders, opportunity

costs, incentives, overall satisfaction, and perspectives on behavior data tracking for personal use and outside monitoring purposes. Semi-structured discussion guides will be developed and refined for comprehension, relevancy, and appropriateness prior to conducting all interviews. Participants will receive a $30 grocery store gift card for their time and participation.

In addition, 6 to 12 stakeholder interviews will be conducted with EHS and affiliated day care center staff after the Month 6 visit. Semi-structured interview guides will be refined for comprehension, relevancy, and appropriateness prior to conducting all interviews. Topics include how stakeholders were involved in executing the intervention, perceptions of the value the intervention added for the population served, the most challenging aspect for their organization, and recommendations for improvements. Based on prior feedback, stakeholders (staff) will receive a retailer gift card.

8.3 Questionnaires

Research staff will administer CAPI questionnaires to parents/caregivers during each study visit, with data entered directly into the EDC; questionnaire data will be analyzed for changes in self-reported behaviors and perceptions, including relevant common data elements (CDEs) identified by the Oral Health Disparities Consortium Collaborative Working Groups. Questionnaire items include demographics, behavioral beliefs (e.g. current brushing behaviors, dental visit attendance), normative beliefs (e.g. peer comparisons), control beliefs (e.g. motivation, and self-efficacy) from BRFQ (Albino et al., 2017), economic module (time preferences, risk preferences, ambiguity aversion, numeracy, overconfidence, and limited attention/memory), and Early Childhood Oral Health Impact Scale (ECOHIS) (Pahel et al. 2007). Follow-up questionnaires will assess satisfaction/acceptance of the incentives and study procedures, as well as adherence with study procedures, such as whether others in the household used the child's powered toothbrush or TP pump.

8.4 Anticipatory Guidance

A short health education video in English or Spanish will provide parents/caregivers with key preventive oral health messages appropriate for the child's age, such as the importance of fluoride supplements, healthy snacking and how to prevent the spread of bacteria that causes caries.

8.5 Toothbrushing Performance and Frequency

8.5.1 Smart Toothbrushes

During the baseline visit, all participants will receive a "smart" powered toothbrush (e.g., Philips Oral Healthcare). The toothbrush uses Bluetooth technology to transmit data on brushing timing, frequency, and duration from the toothbrush to an app installed on the

participant's smartphone. The vendor (i.e., Philips Oral Healthcare) has provided a script which the Coordinating Center has scheduled to run weekly to securely transmit coded (indirectly identifiable) participants' brushing data to REDCap.

8.6 Dental Visit Attendance

For children enrolled at an EHS, preventive dental visit attendance of participating children will be ascertained through dental exam data from Head Start's ChildPlus Management Software health module at baseline and the Month 12 follow-up. In addition, for all children, parents will be asked about the date of the last dental visit within the baseline and Month 12 follow-up questionnaire.

8.7 Study Products

The Project Manager will maintain a log of disclosing solution, FV, and TP shipments, including batch numbers and expiration dates. The study products will be stored in the Project Manager's office at UCLA.

8.7.1 Plaque Disclosing Solution

At the baseline, Month 6, and Month 12 follow-up visits, the dental provider will apply Henry Schein Reveal Liquid plaque disclosing agent to the child's teeth with a microbrush for OHI-MIS plaque assessment.

8.7.2 Fluoride Varnish

Vanish Fluoride Varnish (3M) is a varnish that is applied to the teeth and enhances enamel acid and boosts salivary fluoride levels. The product contains fluoride, calcium and phosphate (but not CPP-ACP), which helps the product remain on the teeth longer and provides extra protection. Vanish Fluoride Varnish can be applied quickly without color change to the teeth. A dental provider will apply the fluoride varnish with a microbrush.

8.7.3 Fluoride Toothpaste Pump

Study participants will be instructed to use fluoridated TP based on the recent ADA consensus guideline (2014) that recommends all children use fluoride TP to help prevent dental disease. The study will use Colgate Maximum Cavity Protection Pump Fluoride Toothpaste (Colgate-Palmolive Company) (mild bubble fruit flavored).

The parents/caregivers will be instructed on how to dispense a smear or pea-sized amount (depending on child's age) of fluoride TP onto the toothbrush for the child, as per study guidelines.

If a child experiences an adverse reaction to the fluoride TP, he/she will be provided clinical guidance (e.g., discontinue use of the product); based on clinical judgment and appropriate input from oversight groups, use may be re-started. However, no modification of study product dosage will be made.

8.8 COVID-19 Modifications

The COVID-19 pandemic resulted in “stay at home” orders in Los Angeles county, causing the BEECON study move to remote/telephonic visits starting on 16 March 2020. Starting 01 October 2020, in accordance with state, county, UCLA, and community health center guidance, the Venice Family Clinic allowed BEECON to resume in-person visits. BEECON will continue to utilize a hybrid of remote/telephonic visits and conducting in-person dental screens as the clinic and public health guidelines allow.

9 ASSESSMENT OF SAFETY

9.1 Specification of Safety Parameters

The Principal Investigator (PI) will report safety events for the study (unanticipated problems [UPs], adverse events [AEs], serious adverse events [SAEs]) to the Institutional Review Board (IRB) in accordance with the IRB’s requirements.

The PI will also report UPs involving risks to subjects to NIDCR. This will include UPs that meet the definition of a SAE. AEs that are temporally associated with the administration by study personnel of FV will be recorded in an adverse event log, and this log will be monitored to identify events that meet the definition of a UP. If a UP is identified, it must be reported.

9.1.1 Unanticipated Problems (UPs)

The Office for Human Research Protections (OHRP) considers unanticipated problems (UPs) involving risks to subjects or others to include, in general, any incident, experience, or outcome that meets **all** of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

- Related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

9.1.2 Adverse Events

OHRP defines an adverse event as any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research (modified from the definition of adverse events in the 1996 International Conference on Harmonization E-6 Guidelines for Good Clinical Practice).

AEs will be recorded in REDCap, and the PI will monitor these events to grade severity, relationship to the study product, and assess whether the nature, severity, frequency is unexpected, and thus warrants reporting as a UP.

9.1.3 Serious Adverse Events (SAEs)

A serious adverse event (SAE) is one that meets one or more of the following criteria:

- Results in death.
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred).
- Results in inpatient hospitalization or prolongation of existing hospitalization.
- Results in a persistent or significant disability or incapacity.
- Results in a congenital anomaly or birth defect.
- An important medical event that may not result in death, be life threatening, or require hospitalization may be considered an SAE when, based upon appropriate medical judgment, the event may jeopardize the subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

9.2 Time Period and Frequency for Event Assessment and Follow-Up

AEs, UPs, and SAEs will be recorded in the data collection system throughout the study. Events will be followed for outcome information until resolution or stabilization.

The Study PI will record all reportable events with start dates occurring any time after informed consent is obtained until seven (for non-serious AEs) or 30 days (for SAEs) after the last day of study participation. Parents/caregivers will be instructed to report

any doctor office or emergency room visits in the three days after the fluoride varnish application. At the 6- and 12-month follow-up study visits, the staff will inquire about the occurrence of AE/SAEs including FV-related AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

9.3 Characteristics of an Adverse Event

9.3.1 Relationship to Study Intervention

To assess relationship of an event to study intervention, the following guidelines are used:

1. Related (Possible, Probable, Definite)
    a. The event is known to occur with the study intervention.
    b. There is a temporal relationship between the intervention and event onset.
    c. The event abates when the intervention is discontinued.
    d. The event reappears upon a re-challenge with the intervention.
2. Not Related (Unlikely, Not Related)
    a. There is no temporal relationship between the intervention and event onset.
    b. An alternate etiology has been established.

9.3.2 Expectedness of AEs

The study PI will be responsible for determining whether an AE is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the intervention.

9.3.3 Severity of Event

Severity of Event: All reportable AEs will be assessed by a clinician study PI or co-investigator using the following guidelines to quantify intensity:

1. Mild: events require minimal or no treatment and do not interfere with the participant's daily activities.

2. Moderate: events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.

3. Severe: events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually incapacitating

9.4 Reporting Procedures

9.4.1 Unanticipated Problem (UP) Reporting to IRB and NIDCR

Incidents or events that meet the OHRP criteria for UPs require the creation and completion of an UP report form. OHRP recommends that PIs include the following information when reporting an AE, or any other incident, experience, or outcome as an UP to the IRB:

- Appropriate identifying information for the research protocol, such as the title, investigator's name, and the IRB project number;
- A detailed description of the AE, incident, experience, or outcome;
- An explanation of the basis for determining that the AE, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs that are (a) SAEs or (b) definitely, probably, or possibly related to study procedures will be reported to the UCSF IRB (CHR) and to NIDCR within 5 working days of a PI becoming aware of the event, unless life-threatening or resulting in death in which case they will be reported within 24 hours (according to SAE reporting procedures outlined in 9.4.2).
- All UPs should be reported to appropriate institutional officials (as required by an institution's written reporting procedures), the supporting agency head (or designee), and OHRP within one (1) month of the IRB's receipt of the report of the problem from a PI.

All UPs will be reported to NIDCR's centralized reporting system via Rho Product Safety:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 1-919-287-3998
- Product Safety Email: *rho_productsafety@rhoworld.com*
- CC Safety Email: *OHDCSAE@ucsf.edu*
- CC Safety Fax Line: 1-415-502-8447

General questions about UP reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231
- International: 1-919-595-6486

9.4.2 Serious Adverse Event Reporting to IRB and NIDCR

In the unlikely event that an AE or SAE incident occurs during this study, any AE meeting the specified SAE criteria will be submitted within 5 work days of a PI's awareness in the UCSF electronic IRB system to the UCSF CHR and on an SAE form to NIDCR's centralized safety system via Rho Product Safety. This report may be sent by fax or email. Once submitted, Rho Product Safety will send a confirmation email to the PIs within one (1) business day. The investigator should contact Rho Product Safety if this confirmation is not received. This process applies to both initial and follow-up SAE reports.

SAE Reporting Contact Information:

- Product Safety Fax Line (US): 1-888-746-3293
- Product Safety Fax Line (International): 919-287-3998
- Product Safety Email: *rho_productsafety@rhoworld.com*
- CC Safety Email: *OHDCSAE@ucsf.edu*
- CC Safety Fax Line: 1-415-502-8447

General questions about SAE reporting can be directed to the Rho Product Safety Help Line (available 8:00AM – 5:00PM Eastern Time):

- US: 1-888-746-7231

- International: 919-595-6486

The study clinician will complete a SAE form and submit via fax or email within the following timelines:

- All deaths and immediately life-threatening events, whether related or unrelated, will be recorded on the SAE form and submitted to Product Safety within 24 hours of site awareness.

- SAEs other than death and immediately life-threatening events, regardless of relationship, will be reported by fax within 5 work days of site awareness.

All SAEs will be followed until resolution or stabilization.

9.4.3 Reporting of SAEs and AEs to FDA

Any AE meeting the specified SAE criteria and being rated as related (possible, probable, definite) to FV administration will be submitted to the FDA using the MedWatch voluntary reporting system (*https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home*).

9.4.4 Events of Special Interest

Suspected child abuse reporting is mandatory because the study participants include minors; any incidents will be reported to an EHS or day care center supervisor. California law stipulates that a provider seeing a child as a patient is not required to report domestic violence or abuse of the parent/caregiver. But the parent/caregiver may choose to make his/her own report by contacting police. We do not anticipate any other events of special interest during the short duration of this study.

10 STUDY OVERSIGHT

The principal investigators will be responsible for study oversight, including monitoring safety, ensuring that the study is conducted according to the protocol and ensuring data integrity. The PIs will review the data for safety concerns and data trends at regular intervals, and will report Unanticipated Problems (UPs), protocol deviations, or any other significant events that arise during the conduct of the study to the IRB, NIDCR, and Data and Safety Monitoring Board (DSMB) in accordance with their prescribed timelines.

In addition to the PIs' responsibility for oversight, study oversight will be under the direction of a DSMB composed of members with appropriate clinical, statistical, scientific, and ethical expertise. The NIDCR will appoint the Board. The DSMB will meet annually to assess safety and efficacy data, study progress, and data integrity for the

study. If concerns arise, more frequent meetings may be held. The DSMB will operate under the rules of an NIDCR-approved charter that will be approved at the organizational meeting of the DSMB. The DSMB will provide recommendations to the NIDCR.

11 CLINICAL SITE MONITORING

Clinical site monitoring is conducted to ensure that the rights of human subjects are protected, that the study is implemented in accordance with the protocol and/or other operating procedures, and that the quality and integrity of study data and data collection methods are maintained. Monitoring for this study will be performed by NIDCR's Clinical Research Operations and Management Support (CROMS) contractor. The monitor will evaluate study processes and documentation based on NIDCR standards and the International Conference on Harmonisation (ICH), E6: Good Clinical Practice guidelines (GCP).

Details of clinical site monitoring will be documented in a Clinical Monitoring Plan (CMP) developed by the CROMS contractor, in collaboration with the NIDCR Office of Clinical Trials and Operations Management (OCTOM) and the NIDCR Program Official/Project Scientist. The CMP will specify the frequency of monitoring, monitoring procedures, the level of clinical site monitoring activities (e.g., the percentage of subject data to be reviewed), and the distribution of monitoring reports. Some monitoring activities may be performed remotely, while others will take place at the study site(s). Staff from the CROMS contractor will conduct monitoring activities and provide reports of the findings and associated action items in accordance with the details described in the CMP. Documentation of monitoring activities and findings will be provided to the site study team, the study PIs, OCTOM, and the NIDCR. The NIDCR reserves the right to conduct independent audits as necessary.

12 STATISTICAL CONSIDERATIONS

Statistical Design, Power, and Statistical Analysis Plan:

12.1 Study Hypotheses

Primary Null Hypothesis H0: No difference between intervention and control group participants in mean number of qualifying half-day toothbrushing episodes per week, through Month 6 visit.

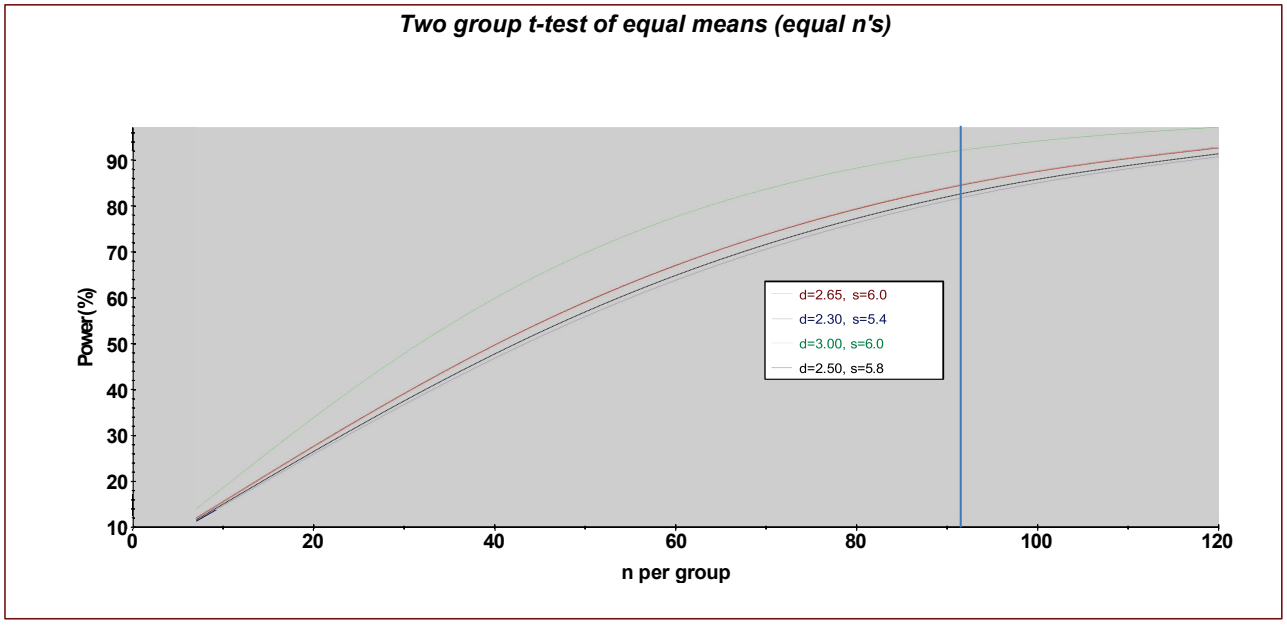
Primary Alternate Hypothesis HA: Intervention and control group participants differ in mean number of qualifying half-day toothbrushing episodes in per week, through the Month 6 visit.

Secondary hypotheses relate to differences between intervention and control group participants in the secondary outcomes. (See Sections 3.1.2 and 3.2.2.)

Secondary hypotheses also relate to behavioral economic measures mediating the relationship between the intervention and toothbrushing. (See Sections 2.2 & 12.4.)

12.2 Sample Size Considerations

With 2 parallel groups, the sample size calculation was conservatively conducted for one continuous outcome using short-term pilot data; the mean number of qualifying brushing episodes in a half-day window per week through 6 weeks was 5.5 with a standard deviation (SD) of 4.8 for a coefficient of variation (CV) of 0.87. To be more conservative, a SD 25% larger (i.e. 6.0) was used. The mean percent of qualifying brushing episodes (out of 14 half-days per week) was 63% with a SD=32% for a CV=0.514. A sample size of 91 in each group is estimated to have 84% power to detect a difference in means of 2.65 with a common SD of 6.0 using a two group t-test with 2-sided alpha=0.05.



In addition, a sample size of 91 in each group was estimated to have 85% power to detect a 1.25-fold change in means (expected ratio) between intervention and control with the larger (more conservative) CV=0.525 using a two group 2-sided t-test with alpha=0.05. With a CV=0.567 and a 1.25-fold change or a CV=0.695 and a 1.30-fold change, n=91 per group is still estimated to have 80% power.

Assuming 75% retention over 12 months, a total of 244 parent-child dyads (N=488) will need to be enrolled. (Retention was 85% over 24 months in the team's recently completed glass ionomer sealant and fluoride varnish trial (GIFVT) in a similar

population. Retention was 75% over 2 months in the BEECON pilot trial, but retention procedures have been added including a 2 week run-in to eliminate people enrolling only for the powered toothbrush.)

Sample sizes for semi-structured interviews and focus group discussions are based on prior experience. Focus group discussions with a total of 40 parent/caregiver participants are expected to reach saturation, but it is possible an additional focus group discussion will be needed to reach saturation.

12.3 Planned Interim Analyses (if applicable)

No interim analyses are planned unless the DSMB recommends interim analyses.

12.4 Final Analysis Plan

Intent-to-treat (ITT) analyses standard in incentive based behavioral economics studies will be utilized (e.g. Halpern *et al.* 2015, Patel *et al.* 2016). Generalized linear mixed models (GLMMs) will be used to compare primary and secondary outcomes over time between groups. GLMMs make fewer missing data assumptions than other methods, which assume missing data are missing completely at random. Identity link will be used for numeric (interval) outcomes (e.g., mean number of qualifying half-day toothbrushing episodes per week, through Month 6 visit; mean OHI-MIS plaque score; and TP pump weight change). The group x time interaction will also be assessed; short-term effects will be assessed for 1 month of the intervention, mid-term effects after the novelty effect of powered toothbrushing usually ends for the Month 3 Visit, and long-term effects for the Month 6 Visit (primary outcome), as well as, maintenance of behavior after removing the incentives for the Month 12 Visit. Recent, powerful Precision Medicine methods which do not inflate Type I error will be used to detect heterogeneity of treatment effects by groups of participants based on baseline characteristics (e.g., Lazar *et al.* 2013). Multiple imputation using chained equations (MICE) for arbitrary missingness patterns (Raghunathan *et al.* 2001; van Buuren 2007) will be used for sensitivity analyses. Supplemental analyses will also explore: a) trajectories of mean number of qualifying half-day brushing episodes per week over time; as well as b1) variability in morning brushing times, b2) variability in evening brushing times, and c) variability in weekday versus weekend brushing times associated with mean number of qualifying half-day brushing episodes, OHI-MIS plaque scores, and ASTDD BSS caries screening measures.

To examine potential impact of timing of drawing reward communication time, GLMM analyses as above will be performed comparing the weekly and quarterly drawing result communication arms for primary and secondary outcome data from Month 12 to Month 18.

To investigate the behavioral economics mechanisms through which behavior change outcomes may have operated, **mediation analyses** will be conducted with the measures of risk preferences (i.e., for the presence of prospect theory tendencies), time preferences (i.e., for the presence of present bias), and forgetfulness (i.e., for attention). Each of these factors will be investigated in separate models to assess the extent the particular underlying construct lies within the pathway toward toothbrushing behavior change (i.e., by reducing the estimate of the ITT main effect).

In addition, because parents and children with different backgrounds (e.g., child's age, parent's/caregiver's education) and behavioral, normative, and control beliefs may respond differently to the incentives given, heterogeneity of treatment effect analyses will be conducted to identify groups influenced by the intervention. For example, the UH2 pilot (White *et al.* 2020) suggested the intervention on toothbrushing frequency may vary by child age (<24mo vs ≥24mo). The results of these analyses will also inform the sampling frame for the parent FGDs so that important dimensions of diversity can be represented.

We will assess **cost-effectiveness** and **return on investment** in three steps. First, we will assess the net cost of the intervention and its consequences, using micro-costing and modeling techniques. Costs for the intervention itself will include mainly personnel to implement the intervention (in particular, training on toothbrush software use), the cost of the toothbrush, the value of the financial incentives, and incentive administration. This will be assessed through a combination of financial record review (e.g., expenditures and human resources) and observation of project activities via staff activity logs. We will also cost the change in health care utilization precipitated by the intervention: both increased preventive care and decreased restorative care. This will be assessed combining utilization with standard values for unit cost, based on payment rates by Medi-Cal and other payers. Together, these generate net costs. We will also estimate toothbrushing time (including preparation) by caregivers. Second, we will quantify the health benefits of the intervention, including dental health events (e.g., number of carious lesions) and quality-adjusted life years (QALYs) which translate morbidity in the short term (measured in Aim 4) and long term (projected based on published longitudinal clinical studies) into a standard metric of health status. Health state utility data (for QALYs) will derive from studies in the literature. The analysis of expected costs and QALYs in the intermediate and long-term will be structured using a spreadsheet-based decision-analysis created for this purpose in consultation with clinical experts. Third, we will calculate the economic outcome measures including **incremental cost-effectiveness ratio (ICER)** and **return on investment (ROI)**. The ICER is the ratio of net cost to health gain, comparing the intervention and control arms. It is indicated if the intervention has a net cost (i.e., does not save money) while improving health outcomes (QALYs gained). The ROI calculates annual rate of return over a specified time period (e.g., 30 years), by comparing expenditures and savings in each year. It is indicated if the intervention generates net savings, i.e., reductions in dental care costs exceed implementation costs. We will also calculate ROI using

willingness-to-pay for a QALY gained. All analyses will be repeated for 1, 2, 5, 10, & 20 years, and subjected to extensive sensitivity analyses to test the impact of uncertainty on results.

The FGD and stakeholder interview audio recordings will be transcribed. One research assistant will transcribe the English interviews and third party translating services, Language Service Solutions (LSS), will translate and transcribe Spanish interviews into English. One fluent Spanish and English reading, writing, and speaking research assistant will review all LSS English translated transcriptions for cultural language accuracy. Two independent coders will use general thematic analysis to code excerpts (i.e., parent codes and child sub-codes will be derived from data rather than *a priori*) from interview transcripts using web-based Dedoose qualitative software. To develop the final codebook, each coder will iteratively review several transcripts to develop an initial list of codes, which will then be merged and reconciled to refine code definitions and hierarchies, a process that will be repeated until only minor adjustments to the codebook result. Using the agreed-upon codebook, each coder will then individually code each transcript and results will be compared and discussed to calibrate intercoder reliability. Preliminary themes relating to factors explaining the intervention impact and perspectives on behavior change motivation, as well as overall program acceptability will be analyzed and discussed to reach theme consensus.

13 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

Study staff will maintain appropriate medical and research records for this study, in compliance with ICH E6, Section 4.9 and regulatory and institutional requirements for the protection of confidentiality of subjects. Study staff will permit authorized representatives of NIDCR and regulatory agencies to examine (and when required by applicable law, to copy) research records for the purposes of quality assurance reviews, audits, and evaluation of the study safety, progress and data validity.

Data collected in this study will take the form of toothbrushing data collected electronically via a Bluetooth-enabled toothbrush and a smartphone app, parent/caregiver drawing incentive data, parent/caregiver questionnaires administered in structured CAPIs, dental examination data, iPhone photographs of anterior teeth for OHI-MIS plaque score assessments, audio recordings from focus groups and interviews that will be transcribed, and cost data obtained from staff activity logs. FGDs and interviews will be digitally audiorecorded. Source documents for this study are: parent/caregiver questionnaires collected with electronic case report forms (eCRFs) during structured interviews, electronic smart toothbrushing performance data, digital photos of teeth saved as electronic image files, and dental examination data which will be collected electronically in REDCap. All data and source documents will be stored on password-protected computers with full hard drive encryption and secure servers behind a firewall.

Any paper informed consent forms administered if the electronic system is offline will be stored in locked cabinets.

14 QUALITY CONTROL AND QUALITY ASSURANCE

All staff will be appropriately trained in his/her position's duties with appropriate Human Subjects Research training; they will be provided with full information about the study such as background and significance, specific aims, milestones, study designs, procedures and analytic plans. All team members will be encouraged to view themselves as crucial team members encouraged to comment, ask questions, and make suggestions to ensure the highest study quality; robust and rigorous data will be gathered and handled according to protocol. Fidelity monitoring using audio recordings as described in Section 6.3 will help to ensure consistency when study staff explain intervention procedures and incentive program details to participants.

Working with the CC, we will use the REDCap web-based clinical trials management system (CTMS) to manage the trial visit schedule, group assignment, eCRFs, and AE and UP reporting. After training from the CC, staff will directly enter participant data into the CTMS.

Conventional EDC data-checking routines will assess data completeness and will ensure data are input successfully and within reasonable ranges. Checks will be done shortly after data collection. CC quality assessment reports will be provided to the team on a routine basis and will be reviewed regularly. After data-cleaning procedures, files for specific data collection will be validated and locked. Additionally, reports of electronic data collected will be provided to and reviewed with the study team for quality management purposes.

The study PIs will rigorously and periodically monitor study activities and engage in study team meetings to ensure that procedures are being performed correctly in the field in the proper sequence. If any breach is discovered, the particular activity will be undertaken a second time and monitored closely for full compliance with the approved procedures.

15 ETHICS/PROTECTION OF HUMAN SUBJECTS

15.1 Ethical Standard

The investigator will ensure that this study is conducted in full conformity with the principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, as drafted by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (April 18, 1979) and codified in 45 CFR Part 46 and/or the ICH E6.

15.2 Institutional Review Board (IRB)

The protocol, informed consent form(s), recruitment materials, and all subject materials will be submitted to the IRB for review and approval. Approval of both the protocol and the consent form must be obtained before any subject is enrolled. Any amendment to the protocol, study procedures or instruments will require review and approval by the IRB before the changes are implemented in the study. UCSF's Committee on Human Research (CHR) will be the reviewing IRB while UCLA's CHR will be the relying IRB, formalized with an official Notice of Intent to Rely through the University of California system.

15.3 Informed Consent Process

Informed consent is a process that is initiated prior to the individual agreeing to participate in the study and continues throughout study participation. Discussion of risks and possible benefits of study participation will be provided to potential participants and their families. A consent form describing in detail the study procedures and risks will be given to the participant. Consent forms will be IRB-approved, and the participant is required to read and review the document on a digital tablet in English or Spanish or have the document read to him or her. The investigator or designee will explain the research study to the participant and answer any questions that may arise. The participant will electronically sign (with UCSF IRB-approved DocuSign) the informed consent document prior to any study-related assessments or procedures. Participants will be given the opportunity to discuss the study with their surrogates or think about it prior to agreeing to participate. They may withdraw consent at any time throughout the course of the study. A copy of the electronic signed informed consent document will be emailed to participants along with the Bill of Experimental Subject's Rights in English or Spanish (as per California law) for their records; participants who do not have email will be provided a paper copy of each. The rights and welfare of the subjects will be protected by emphasizing to them that the quality of their clinical care will not be adversely affected if they decline to participate in this study.

The consent process will be electronically documented in the clinical research record.

15.4 Exclusion of Women, Minorities, and Children (Special Populations)

Inclusion and exclusion criteria have been developed, which do not include any exclusions based on gender or race/ethnicity.

15.5 Subject Confidentiality

Subject confidentiality is strictly held in trust by the investigators, study staff, and the sponsor(s) and their agents.

The study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Authorized representatives of the sponsor may inspect all study documents and records required to be maintained by the investigator for the study subjects. The clinical study site will permit access to such records.
No individual identities will be used in any reports or publications resulting from this study. No identifying information will be transmitted from the clinical site or UCSF to NIDCR.

eCRFs, which contain the participants' personal identifying information will be kept separately from other data.

16 DATA HANDLING AND RECORD KEEPING

The investigators are responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. The investigators will maintain adequate case histories of study subjects, including accurate eCRFs, and source documentation.

16.1 Data Management Responsibilities

Data collection and accurate documentation are the responsibility of the study staff under the supervision of the PIs. All source documents must be reviewed by the study team and data entry staff, who will ensure that they are accurate and complete. UPs and AEs must be reviewed by the PIs or their designees.

16.2 Data Capture Methods

Data stored electronically will include informed consent documents. Data will be collected electronically through REDCap eCRFs and will include oral health screening data, TP pump weights, and questionnaire data. ChildPlus dental attendance visit data will be obtained from the EHS computer database and entered into a REDCap eCRF. Smart toothbrush toothbrushing data and SMS text message data will be obtained as separate databases from the toothbrush vendor and the SMS text messaging provider. Photographic images of maxillary incisors will be collected with iPhone camera in regular mode or burst mode if needed. FGDs and interviews will be audiorecorded and transcribed.

16.3 Types of Data

Types of data will include eCRFs in the REDCap EDC, electronic image files, smart toothbrushing data, SMS text message data, FGD and stakeholder interview audiorecordings, and safety data.

16.4 Schedule and Content of Reports

The study team will utilize monthly reports and figures to monitor enrollment and retention and will provide monthly enrollment/retention reports to NIDCR for review. Accrual and data completion will be tabulated at least fortnightly. The analytic database will be cleaned and locked as described in the OHDC CC Clinical Data Management Plan (CDMP).

16.5 Study Records Retention

Study records will be maintained for at least three years after the date that the grant federal financial report (FFR) is submitted to the NIH.

The study will maintain participant records, including data from dental records; electronic informed consent records for minors will be retained based on the UC Counsel General's recommendation, which is that records be kept for seven years after a child reaches 18 years old (the age of majority), or until the child is 25. This could mean that participant records would be retained for up to 25 years after the end of the study, depending upon enrollment date in the study.

Each individual will be assigned a unique study identification (ID) code number to be used on all study instruments, documents or files. A coding key containing the basic information about participants (e.g., names) and their assigned study ID numbers will be securely kept (password protected and encrypted) in the REDCap CTMS. All coded (indirectly identifiable) data will be kept indefinitely.

Master files will be stored on a UCSF secure server (e.g., via password protection and encryption) for possible later use in specific analyses, and all other copies erased from any portable disk, flash drive, or other media.

16.6 Protocol Deviations

A protocol deviation is any noncompliance with the clinical study protocol or good clinical practice requirements. The noncompliance may be on the part of the participant, the investigator, or study staff. As a result of deviations, study staff may develop corrective actions, which will be implemented promptly.

These practices are consistent with investigator and sponsor obligations in ICH E6:

- Compliance with Protocol, Sections 4.5.1, 4.5.2, 4.5.3, and 4.5.4.
- Quality Assurance and Quality Control, Section 5.1.1
- Noncompliance, Sections 5.20.1 and 5.20.2.

16.6.1 Robust Action Plan

One type of deviation that has occurred repeatedly throughout the study has been names appearing in the brushing data that is sent to Philips. This has been a result of an adult in a participating household changing the assigned SID# to a name within the profile. As a result, the BEECON staff developed a **Robust Action Plan** to try to prevent any future deviations from occurring:
Robust Action Plan to prevent recurrence of this type of event:

Currently, members of the BEECON research team are taking multiple measures to prevent protocol violation / incidents from occurring:

1. **Verbal explanation during Screening Visits with participants**
    - ***Modified Informed Consent PowerPoint* - first explanation**
        - Research Assistant #1 first addresses the issue of confidentiality during the modified informed consent explanation PowerPoint (version 1.1, approved 28Aug2018) which is shown in English/Spanish to participants early in the initial screening visit. Slide with language below:
            - "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 no names, addresses, telephone numbers, or specific date information will 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."
        - In addition to showing participants this slide, Research Assistant #1 also states “One of the ways we protect your child’s identity is by assigning them a Study ID #. It is up to you as their parent/guardian to maintain this confidentiality by not changing the ID # in the app to your child’s name or initials.”
    - ***App download* - second explanation**
        - When Research Assistant #2 is downloading the Sonicare For Kids (S4K) app onto the participant’s phone, they refer back to the confidentiality portion of the modified informed consent explanation PowerPoint (version 1.1, approved 28Aug2018) that the participant just reviewed and emphasize that the Study ID # that they are entering into the S4K app should be the only thing entered into the profile.
        - Participants are asked to give verbal confirmation that they understand the Study ID # needs to be the only thing added to the profile in the S4K app.

- ***Summary of visit* - third explanation**
  - Before the participant leaves the Screening Visit, the Research Assistants provide a verbal summary of the visit- reiterating again that the profile in the S4K app is set up and that they should not change it from the Study ID # to the child's name or initials.

2. **Informed Consent Forms modified** (version 1.3, 15Aug2018)
   - In August 2018 the informed consent forms were modified so that parents/guardians would be aware of the potential risk of lack of privacy if personal identifying information was added into the study app profile. The specific language that was added was:
     - "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."
3. **Handout**
   - In April 2019, the study team created a 1/4 page handout on brightly colored paper that outlines the importance of participants not to change the Study ID # to a first or last name or initial. Participants receive this at their initial screening visit.
4. **Vendor changes to app**
   - The study team worked with the vendor to develop a system to lock the study ID # in the app once it has been entered by the Research Assistant. This modification to the app occurred on 7/12/19.
   - Since this release of the lock on the app, the study team determined that participants were still able to add an additional profile into the app so after working with the vendor - they have developed a system to prevent participants from being able to add additional profiles. This update was released on 5/15/20 but it does not prevent parents from being prompted to enter in the child's name if the app is deleted from the phone and then re-downloaded.
5. **Teach-back language**
   - They study team has developed teach-back language to add at the end of every visit which will hopefully improve participant understanding of the consequences of adding their child's name to the app and help participants to remember that the best thing to do if they have to re-install and set up the app is to contact BEECON staff. Language is as follows:
     - **BEECON RA:** *"As a reminder- if you get a new phone or the S4K app gets deleted and has to be re-downloaded, please reach out to us for assistance. It is important that if this happens,* ***a name*** *is not added to the app during the re-downloaded process, otherwise Philips Sonicare will see* ***the name****."*
     - *"So, what will happen if you enter* ***a name*** *in the profile on the app?"*
     - **PARTICIPANT** will hopefully respond: *"Philips Sonicare may see* ***the name****"*
     - **BEECON RA:** "*So, what will you do if you get a new phone or have to delete the app and need to re-download it?"*
     - **PARTICIPANT** will hopefully respond: *"I will contact the BEECON staff"*

All deviations from the protocol must be addressed in study subject source documents and promptly reported to NIDCR and the local IRB, according to their requirements.

17 PUBLICATION/DATA SHARING POLICY

This study will comply with the *NIH Public Access Policy*, which ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive *PubMed Central* upon acceptance for publication.

Data from this study will be shared in accordance with the NIH Data Sharing Policy. *https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm*

Investigators are strongly encouraged to decide on authorship of scientific documents prior to writing them. The principles set forth in the International Committee of Medical Journal Editors' (ICMJE) Uniform Requirements for Manuscripts Submitted to Biomedical Journals (the "Vancouver Rules") are to be followed. These standards can be reviewed online at *http://www.icmje.org*.

In the event of disagreement, an ad hoc Publication Committee appointed by the three MPIs will provide resolution.

The ICMJE member journals have adopted a clinical trials registration policy as a condition for publication. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like. Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. The ICMJE policy requires that all clinical trials be registered in a public trials registry such as *ClinicalTrials.gov*, which is sponsored by the National Library of Medicine. Other biomedical journals are considering adopting similar policies. For interventional clinical trials performed under NIDCR grants and cooperative agreements, it is the grantee's responsibility to register the trial in an acceptable registry, so the research results may be considered for publication in ICMJE member journals. The ICMJE does not review specific studies to determine whether registration is necessary; instead, the committee recommends that researchers who have questions about the need to register err on the side of registration or consult the editorial office of the journal in which they wish to publish.

U.S. Public Law 110-85 (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the sponsor or

designated principal investigator) register and report results of certain "applicable clinical trials:"

Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation;

Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.

NIH grantees must take specific *steps to ensure compliance* with NIH implementation of FDAAA.

The National Institutes of Health (NIH) has issued a policy to promote broad and responsible dissemination of information from NIH-funded clinical trials through ClinicalTrials.gov. The policy establishes the expectation that all investigators conducting clinical trials funded in whole or in part by the NIH will ensure that these trials are registered at ClinicalTrials.gov, and that results information of these trials is submitted to ClinicalTrials.gov. Please see *https://www.federalregister.gov/documents/2016/09/21/2016-22379/nih-policy-on-the-dissemination-of-nih-funded-clinical-trial-information*

18 LITERATURE REFERENCES

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SUPPLEMENTAL MATERIALS

These separate documents are relevant to the protocol, but they are not considered part of the protocol. They are stored and modified separately. As such, modifications to these documents do not require protocol amendments.

- Parent/Caregiver Informed Consent Form
- Questionnaire (Baseline (first) visit)
- Questionnaire (3-month follow-up visit)
- Questionnaire (6-month follow-up visit)
- Questionnaire (9-month follow-up visit)
- Questionnaire (12-month follow-up (final for intervention arm) visit)
- Questionnaire (15-month follow-up visit)
- Questionnaire (18-month follow-up (final for control arm) visit)
- Oral Health Screening Form (with ADA Treatment Urgency Classification)
- Plaque Assessment Form (OHI-MIS)
- Manual of Procedures

APPENDICES