







Family monetary incentives as a value-based care model for oral hygiene: rationale and design of the BEhavioral EConomics for Oral health iNnovation (BEECON) trial

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Keywords

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Abstract

Background: Effective prevention-focused, value-based strategies are needed to improve oral health. Despite evidence that monetary incentives can motivate healthy behavior, well-powered studies have yet to examine incentives for improving children's oral hygiene.

Aim: Describe the rationale and design of the BEhavioral EConomics for Oral health iNnovation (BEECON) trial, which tests lottery-based monetary incentives as a consumer-oriented, value-based care model for improving children's oral hygiene.

Design: Phase II, stratified, permuted block randomized, controlled, two-arm, parallel groups, prevention trial.

Setting: Study visits occur at three Los Angeles, CA health clinics.

Participants: Two hundred and forty-four parent-child dyads with a child aged 6-48 months.

Interventions: Eligible dyads were randomized in equal allocation to one of two groups: lottery incentive group or waitlist (delayed incentive) control group. Weekly lottery incentives were offered for 6 months based on Bluetooth-recorded toothbrushing frequency. Both groups received weekly text message feedback on toothbrushing performance.

Outcomes: The primary outcome was toothbrushing performance from baseline to 6 months, measured as the mean number of qualifying half-day Bluetooth-recorded episodes per week when the child's teeth were brushed. Secondary outcomes included toothbrushing performance sustainability through 12 months and dental caries status.

Conclusions: BEECON offers a consumer-oriented approach to promoting value-based oral health care. We hypothesize that lottery-based incentives can improve oral hygiene in young children. Study results will inform programming efforts to enhance oral disease prevention in young children.

Trial Registration: ClinicalTrials.gov identifier NCT03576326.

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Introduction

Early childhood caries (ECC) threatens child welfare, particularly among economically disadvantaged, underserved, and migrant children, remaining the most prevalent chronic childhood disease in the United States.^{1,2} National ECC prevalence (any decayed, extracted, or filled primary teeth) among 2-5 year olds was 21.4 percent in 2015-2016.³ Despite its prevalence, early intervention can prevent ECC.⁴

Brushing with fluoridated toothpaste 2 minutes twice-daily helps prevent ECC,^{5,6} although adherence to this recommendation remains low.^{7,8} Home-based monitoring and oral health education, while helpful for keeping teeth caries-free, are insufficient to motivate behavior change. Successful behavior change requires behavioral salience for family members and sustainability to enable habit formation.

Personal incentives are commonly part of health promotion programs, but rigorous evidence on effectively designing and targeting different populations is lacking. In fact, the National Institutes of Health (NIH) has made evaluating incentives for health-related behaviors a high-priority area for health economics research.⁹ Incentives may operate through at least three causal channels, delineated by theories of reasoned action and planned behavior (Figure 1).^{10,11} First, incentives can heighten one's intentions to perform the behavior by enhancing perceived toothbrushing benefits (behavioral beliefs), creating toothbrushing expectations (normative beliefs), and providing feedback to demonstrate one's own agency to undertake the behavior (control beliefs). Second, incentives heighten the salience of the behavior to the person, especially when performance feedback is delivered frequently. Third, incentives can help one develop a habit of regular behavioral performance, potentially continuing after incentive

removal. Contextual factors, such as parent's income and oral health knowledge, may appreciably modify incentive effects on toothbrushing.

One lesson from behavioral economics is that incentive design can critically affect the success of incentives in promoting sustained behavior change. Lottery incentives are an incentive type that have been effective in promoting various healthy behaviors.¹²⁻¹⁵ Lottery incentives can leverage several human psychology principles that magnify their perceived effects among participants, such as the tendency to over-react to low probability events and the participant engagement provided by variable reinforcement. Moreover, the lottery incentives' probabilistic nature makes them potentially more cost-effective than equal-sized fixed incentives. In our pilot trial of 36 parent-child dyads, a lottery incentive promoted 47 percent more toothbrushing episodes among young children compared with an equal-sized fixed incentive.¹⁶

Although studies show incentives can promote healthy behaviors,¹⁷ they have not been tested as a strategy for promoting oral hygiene, except our pilot. Oral health provides a promising domain, because early intervention can prevent expensive restorative treatment. Moreover, intervening early in a child's life can yield large returns over a lifetime.¹⁸ This creates an opportunity to apply value-based care (VBC) principles to oral health care and dentistry.

The BEhavioral EConomics for Oral health iNnovation (BEECON) trial aims to evaluate how lottery incentives promote ECC preventive health behaviors (toothbrushing performance) among young children, compared with a control group waitlisted to receive the incentive after the trial. Our sample predominantly includes children of Latino families who have been underrepresented in oral health studies and are at increased caries risk.¹⁹ Our

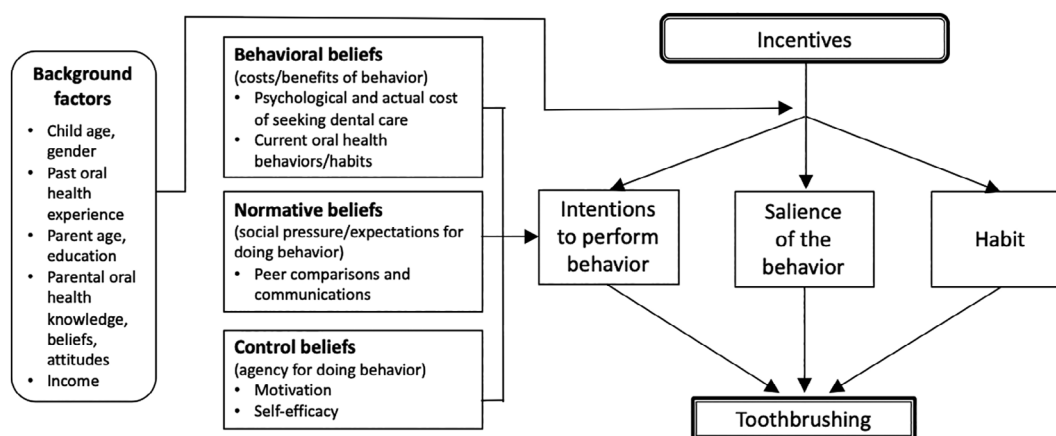


Figure 1 Conceptual model of how incentives can affect toothbrushing.^{10,11}

study's results will provide key evidence of whether incentives can improve oral hygiene and inform recommendations for pursuing a patient-oriented approach to value-based oral health care (VBOHC).

Methods

The BEECON trial is a collaboration between the University of California (San Francisco and Los Angeles campuses), the Venice Family Community (VFC) Health Center, and Early Head Start (EHS) and affiliated day care center programs serving vulnerable families in Los Angeles (LA) County. UCSF (responsible) and UCLA (relying) institutional review boards approved the trial.

Participant eligibility

Inclusion criteria

Parent/caregiver (hereafter, parent) to a child 6-48 months old with two fully erupted teeth enrolled in, or waitlisted for, a participating LA County EHS affiliated day care center or other area preschool; 18 years or older; speak/write/read either Spanish or English; own a smartphone with Google Play or iTunes and willing to download the free smartphone toothbrush app; not planning to move outside Los Angeles area for the next 18 months; willing to be contacted via text-messaging (SMS) for study-related notifications; willing to comply with all study procedures for study duration; and providing informed consent in English or Spanish.

Exclusion criteria

Participating child has known allergic reaction to study products; have >2 crowns on maxillary incisor teeth; participated in the BEECON pilot trial;¹⁶ sibling of a child

already in the study; current foster care enrollee; and have anything else putting him/her at increased risk or precluding full compliance with, or completion of the study. Participating parents cannot be unable or unwilling to install and use the smart powered toothbrushing app during the run-in period.

Recruitment

The study staff is recruiting participants from VFC, LA County EHS programs, affiliated day care centers, and other area preschools. Staff recruit participants through outreach to families during EHS monthly parent meetings, day care center meetings, health fairs, via telephone calls to interested parents, and from health clinic waiting rooms. Recruitment materials are also distributed to EHS home visitors (caseworkers) who are encouraged to share with the families they visited. EHS preschool enrollees are from families with income below the federal poverty level (FPL); 35 percent of enrollees can have family income below 130 percent FPL.²⁰⁻²² Potential participants are screened for eligibility using a structured questionnaire during an in-person or telephone interview with study personnel.

Trial design

The BEECON parallel-group, two-arm, stratified permuted block randomized controlled trial with parents of children under 4 years old is ongoing. BEECON assesses efficacy of monetary rewards to promote toothbrushing adherence to prevent ECC in young children of predominantly Latino parents enrolled in EHS and day care center programs. Eligible child-parent dyads are consented, enrolled, and after a 2-week run-in (trial) period, randomized in equal allocation to either: a) lottery incentive or b) waitlist (delayed incentive) control. Participants' toothbrushing

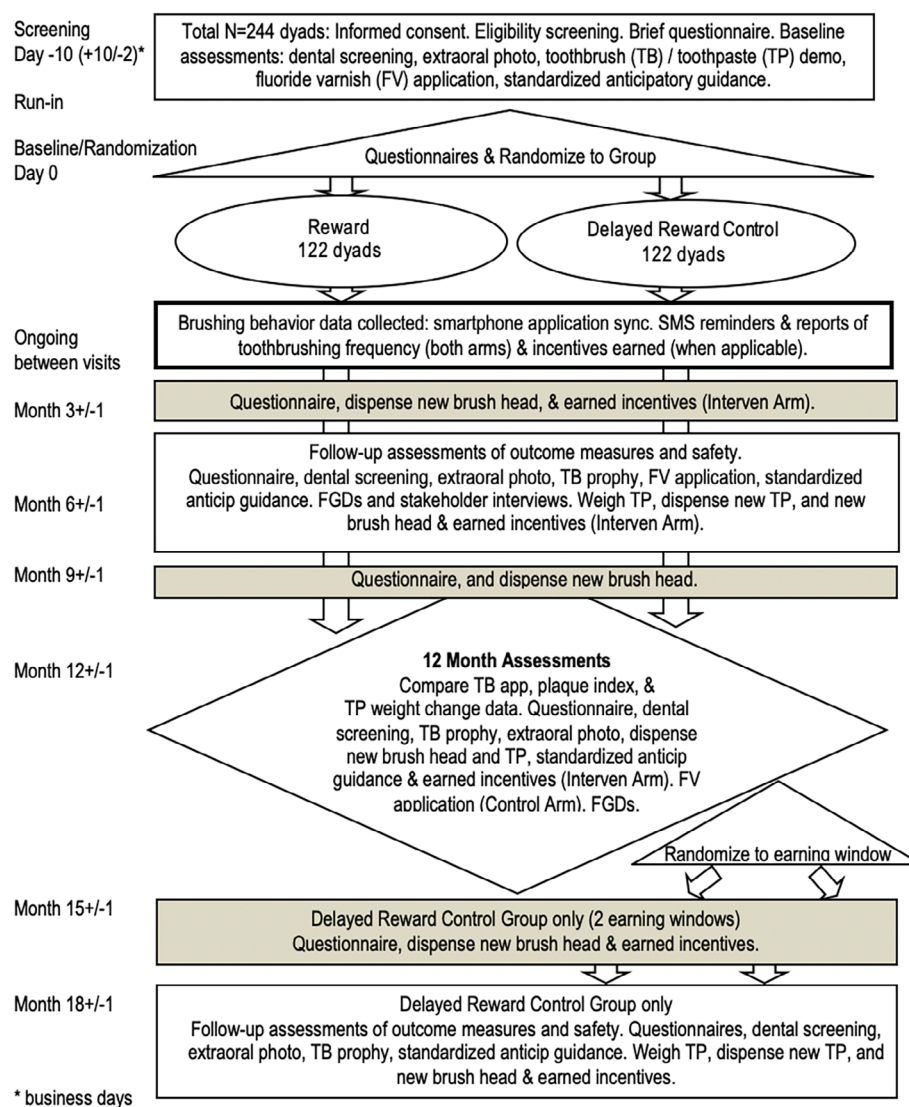


Figure 2 Schematic of study design. [Color figure can be viewed at wileyonlinelibrary.com]

performance is monitored for 12 months (18 months for the waitlist group) with a primary endpoint of 6 months, and plaque score is assessed at 6 and 12 months.

Study visits are scheduled every 3 months for all participants (Figure 2). During the initial, 6-, 12-, and 18-month visits, the participating child a) receives an Association of State and Territorial Dental Directors Basic Screening Survey (ASTDD BSS) dental screening after the parents complete a brief child medical history questionnaire, and b) have a plaque photo taken and scored using the Debris Index of the Simplified Oral Hygiene Index (OHI-S) modified for only the primary maxillary incisors (denoted OHI-MIS).²³ During follow-up visits, participants receive a new toothpaste pump (6- and 12-month visits) and toothbrush head (every 3 months). All participant responses to

questionnaires are entered into the REDCap clinical trials management system.

Interventions

Lottery group participants are eligible for weekly monetary incentives for the first 6 months.

Lottery incentive group

Lottery group participants are entered into a weekly combined (two-tiered) drawing that offers a higher probability of a smaller reward (\$25) and a lower probability of a larger reward (\$50). Probabilities of winning depend on whether a lower performance threshold (seven qualifying

episodes per week) or a higher performance threshold (14 qualifying episodes per week) has been met.

Lottery group participants are sent a SMS text message about drawing entries every week; participants can reply with a two-digit number 00-99 or have a randomly chosen number. Participants meeting the *lower* performance threshold win \$25 if one digit matches the winning number in order (18 percent probability) and \$50 if both digits match in order (1 percent probability). Participants meeting the *higher* performance threshold win \$25 if one digit matches the winning number irrespective of order (34 percent probability) and \$50 if both digits match irrespective of order (4 percent probability). Thus, the chance of winning roughly doubles for meeting the higher versus lower performance threshold. The total expected value is \$5 per week for the lower performance drawing and \$10 per week for the higher performance drawing. The incentive amounts were selected to be comparable to prior studies that have used daily lottery incentives for health behavior maintenance, and based on our development stage findings described below. Participants failing to reach either performance threshold are entered into the lower performance drawing, and if chosen as a winner receive a message stating what they would have won had they brushed more regularly, thereby taking advantage of a psychological tendency toward anticipated regret to motivate future brushing.

Waitlist (delayed incentive) control group

Control group participants receive feedback on their toothbrushing performance during the trial's first 12 months. After the 12-month follow-up visit, these participants can exit the trial or to participate in a delayed 6-month extension. Remaining participants can earn the same lottery incentives as the intervention group over 6 months. Remaining participants are randomly assigned with equal allocation to weekly drawing (identical to the intervention group, with the same performance thresholds) or to quarterly drawing. Quarterly lottery group participants have weekly toothbrushing performance determine entry into 13 independent drawings performed simultaneously after Months 15 and 18, with each drawing having equal incentive amounts and the same probabilities as the weekly drawing. The EHS and Community Advisory Board (CAB) members expressed concern about providing equal incentive opportunity to participants. Since the design required there to be a "no incentive" control group for scientific comparison, a control group with a delayed incentive program provided after the main trial ended addressed both needs.

Figure 3 shows toothbrushing performance data flows via the Philips Sonicare for Kids (S4K) powered

toothbrush and brush heads. The S4K toothbrush is synchronized to the S4K smartphone application, which includes a custom BEECON feature to link data to our database. Data transmitted to the Amazon Cloud and then UCSF Coordinating Center from the toothbrush include: application start time, toothbrushing start time, toothbrushing duration, and whether the toothbrushing occurred with the application open or offline. Information flow occurs rapidly allowing for study feedback to each participant. This approach could be applied to precision dentistry whereby patients can assess their own and their children's oral health outcomes.

After data transfer to the REDCap database, participants receive study SMS notifications via Twilio in REDCap. Notifications include reminders Wednesdays, Fridays, and Saturdays for participants to synchronize the powered toothbrush to the S4K smartphone application. Participants in both groups receive \$3 per week to synchronize their toothbrush three times. Additionally, participants are sent weekly SMS messages including feedback weekly toothbrushing performance and earnings summary and cumulative earnings since enrollment. Syncing and toothbrushing performance payments are distributed at follow-up visits.

Retention

The study team regularly contacts participants via SMS messages and phone calls to update contact information and provide appointment reminders. Additionally, the study team provides participants tech support if they have any S4K app problems.

Randomization, concealment, and masking

Stratifying on site (facility type) and phone type (iPhone or Android) as well as permuted blocks of varying sizes, the randomization schedule remained concealed in REDCap until each participant was ready to be randomized.

Only staff administering the intervention are unblinded before trial completion. Other study team members, including an independent dental examiner, are blinded to group assignments until trial completion. Due to the intervention's nature, staff explaining study arms after randomization and providing incentive gift cards every 3 months cannot be blinded. During Month 6 and 12 visits, dental screenings precede compensation.

Statistical analysis

Intention-to-treat (as-randomized) analysis will use linear mixed-effects models (LMMs) for the number of toothbrushing episodes (identity link) with a random effect for parent-child dyad, using restricted maximum likelihood

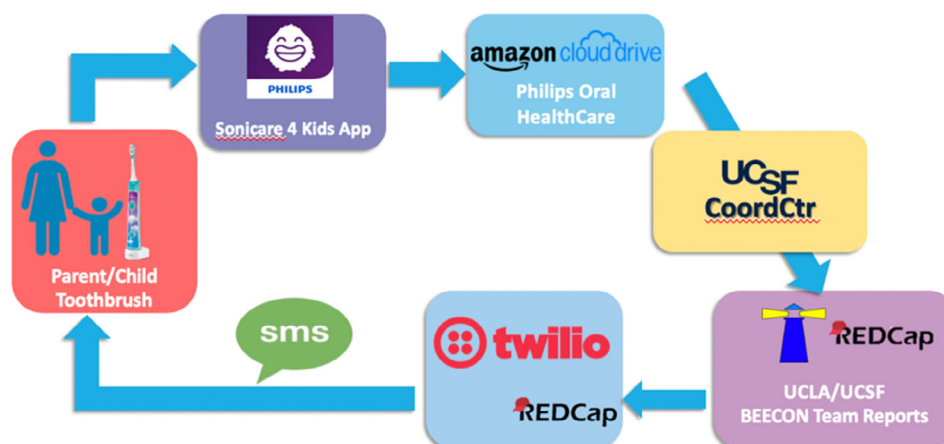


Figure 3 Flow of toothbrushing data. [Color figure can be viewed at wileyonlinelibrary.com]

with variance components covariance structure and Kenward-Roger denominator degrees of freedom. LMMs will adjust for stratification factors (site and smartphone operating system), time, and group \times time effects. 95 percent confidence intervals (CIs) will be reported. LMMs make fewer missing data assumptions than other methods, which assume missingness completely at random. Multiple imputation for arbitrary missing patterns with standard software will also be used for sensitivity analyses.

Data collection and intervention protocols

Initial screening visit

Initial screening visits are scheduled after participants confirm interest in study participation. During initial screening, parents provide written consent; the toothbrushing app is downloaded onto the parent's smartphone; and research staff demonstrate using the toothpaste pump, the toothbrush, and how to synchronize it to the smartphone app. Parents are instructed to use the powered toothbrush for a 2-week run-in period to ensure the equipment works and they can follow study procedures. Participants completing the run-in are randomized at the baseline visit.

Questionnaires

Trained bilingual research staff administer computer-assisted personal interview questionnaires to parents during each study visit, entering data directly into REDCap. Questionnaire data are analyzed for changes in self-reported behaviors and perceptions. 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,

self-efficacy), economic attitudes (e.g., time and risk preferences), Early Childhood Oral Health Impact Scale (ECOHS), and technology readiness.²⁴⁻²⁶ Follow-up questionnaires assess satisfaction/acceptance of incentives and study procedures, as well as adherence with study procedures, for example, others in the household using the child's powered toothbrush or toothpaste pump.

Oral examination procedures and examiner reliability

Study clinical procedures and evaluations consist of: child's medical history evaluation via parent-reported standardized questionnaire at enrollment/baseline visits. Trained dental providers perform ASTDD BSS dental screening examinations. Then, after applying disclosing solution, study staff take anterior teeth photographs with the study iPhone camera to document plaque levels. A calibrated dentist rates OHI-MIS plaque scores from facial (labial) anterior tooth surface photographs. After study staff demonstrate and observe parents perform study procedures, the dental provider applies fluoride varnish.

Anticipatory guidance

A short health education video in English or Spanish at visits provides parents with key preventive oral health messages appropriate for the child's age, for example, importance of fluoride usage, healthy snacking, and preventing bacterial spread that causes caries.²⁷

Results

Developmental and pilot results

A pretrial developmental survey with mostly Hispanic Early Head Start parents ($N = 75$) found several interesting findings regarding mobile device use, preferred incentives,

and current oral health behaviors that helped shape the trial design.

Respondents reported that in the week prior to taking the survey, 91 percent sent a text message, 89 percent made a voice telephone call, and 72 percent used social media (e.g., Facebook, Instagram) with their cell phones. Overall, more respondents sent texts than made phone calls. In the prior year, only 13 percent of respondents changed their cell phone number or ran out of minutes or data in a month.

Also, 79 percent of survey participants reported an adult in the household brushed their children's teeth ≥ 2 times per day and 84 percent were willing to participate in a program giving a reward for brushing children's teeth twice-daily. About 75 percent of respondents preferred store gift cards or cash over diapers or phone credits. Rewards are being provided as store gift cards. Respondents overwhelmingly preferred to be paid after the full 3 months (69 percent) or monthly (25 percent) rather than weekly (3 percent) or daily (3 percent). Regarding willingness to accept (WTA) incentives for brushing teeth twice-daily for 3 months, 91 percent (59/65) of respondents reported a WTA of \$0-10 for brushing their own children's teeth; the minimum amount for an EHS parent "like themselves" to brush a child's teeth was a mean of \$40 (95 percent CI = \$28-\$52) and median of \$20. Fixed incentive amounts in the pilot (\$5 per week for a lower threshold and \$10 per week for a higher threshold of toothbrushing performance) were designed to just exceed the average WTA to motivate most participants. Lottery incentive amounts were designed with equal expected values (amount multiplied by probability of being selected) for the same performance thresholds as fixed reward amounts. Based on parent interviews and CAB advice, the control group was a delayed (post-trial), open-label reward (same modality used for the intervention arm), so each randomized participant has the opportunity to earn the same rewards.

Respondents were less likely to be "very much" sure their children always had their teeth brushed twice per day (61 percent) than they wanted to (83 percent; McNemar Chi-square test $P < 0.001$) or thought was important (80 percent; McNemar Chi-square test $P < 0.001$). Discrepancies of self-efficacy (sureness) with want or importance were much smaller for dental check-ups and always using fluoride toothpaste (with only fluoride toothpaste sure (71 percent) and importance (80 percent) being a fairly large discrepancy; McNemar Chi-square test $P = 0.008$).

Qualitative research for main trial

During the main trial, five focus group discussions (FGDs) – 3 for the lottery group (2 in English, 1 in Spanish), 2 for the control group (1 English, 1 Spanish) – were held with participants after Month 6 July-September 2019. Hour-

long discussions focused on topics related to participants' study involvement: toothbrushing and experience with study tools including the powered toothbrush, toothpaste pump, S4K smartphone app and experience synchronizing their toothbrush to app, SMS reminders, oral health behaviors, dental care, overall satisfaction, and perspectives on behavior tracking via technology. Participants received a \$30 grocery store gift card for participation. FGD data are being coded, combined, and analyzed along with feedback to be collected in another FGD round after the trial ends. The future FGDs will also inquire about COVID-19 impact. Post-baseline FGD data cannot be presented for the ongoing trial until Month 6 is complete for all participants.

Additionally, seven key informant interviews were conducted in September-October 2019 after the first FGD round was complete: five with EHS home visitors and two with EHS management staff. A process evaluation framework guided these half-hour semi-structured interviews in English.²⁸ Interviews were audio recorded, transcribed, coded, and thematically analyzed in Dedoose. Interviews covered topics including how stakeholders were involved in study execution, perceptions of study benefits to the population served, any challenges faced during study involvement, and general study feedback. Key informants received a \$30 gift card for their participation.

Key informants were all female. The two managers each had over 20 years of experience, and home visitors' experience ranged 7-29 years. Overall, staff were knowledgeable about BEECON and their roles related to recruitment; they shared observations about study impact on families, which was generally positive. Many staff recognized and mentioned the importance of promoting oral hygiene; some staff mentioned building a routine and educating families about first dental visits in particular. One home visitor commented that "dental, oral, is really very new for the families," and other staff echoed that oral health was not a priority for many families. One manager noted that "everybody who participated learned something from the program." Managers expressed that families were interested in BEECON, and that the program was "really successful." Home visitors working closely with families noticed their increased awareness, motivation, and attention to children's oral health.

Discussion

BEECON through the lens of VBC

A shift in care structure is beginning in medicine from a fee-for-service model to a fee-for-value model known as VBC.²⁹ VBC offers incentives for health care providers to provide the best care at the lowest cost for the patient.²⁹

This model improves care quality for the patient and reduces patient spending.²⁹ Provider reimbursement under a VBC model is designed to reduce disease burden, improve quality of care and patient satisfaction, and ultimately lower costs of care.²⁹

VBOHC is a critical element of oral health's future, focusing on prevention rather than treatment.³⁰ It emphasizes early intervention and disease prevention while promoting minimally invasive procedures. Similar to VBC, VBOHC shifts from today's fee-for-service model to valuing high-quality care and oral health outcomes.³⁰ Unlike in medicine, limited VBOHC research exists.³¹ The need for VBOHC evidence-based research provides a unique opportunity to examine the BEECON trial's study design and how it can be applied to a VBC framework to create a new model for consumer-focused incentives.

The BEECON trial targets resources toward prevention in young children, which can help keep them healthy throughout their lives. This in turn makes the traditional VBC payments to providers more meaningful by incentivizing high-quality care for those who need dentist care. Patient incentives are a complementary intervention that provide a more holistic approach – incentivizing both the patient and provider for things under their own control. This contrasts with a traditional approach of incentivizing providers through the payment system, which neglects patients and burdens providers with performance targets only partly under their control.

From a patient perspective, three issues need to be considered for a VBC approach to be efficient³²: a) outcomes matter most to patients; b) give patients ways to track and monitor their oral health outcomes and those of their children, and c) account for the cost of achieving patients' health goals.³² BEECON was designed with these three components in mind: empowering participants to achieve their family's oral health goals at low cost and with feedback on their own performance.³²

Notably, monetary incentives could improve VBC by increasing parent motivation to provide preventive care. Preventive oral health care is relatively low cost and averts dental disease, avoiding high cost treatments. However, recognizing the need for and engagement in preventive care requires parents to understand the reward of good health is not necessarily seen and often ignored until the status deteriorates, at which point it can become very costly to restore. As such, incentivizing individuals to engage in preventive oral care may lead to significant savings in health care cost. BEECON's monetary incentives contribute to VBOHC by extrinsically motivating both parents and children to increase their intention to achieve healthy behavior, increase salience of the behavior, and reducing unnecessary ECC disease burden by establishing healthy habits. The intervention is targeted at a critical life

stage where children are learning to become independent, and if toothbrushing behaviors are built at this age, they set the child up for successful prevention over his/her lifetime.¹⁸ BEECON hypothesizes that the time-limited incentives will motivate parents to develop healthy habits for good preventive care and oral hygiene for their children while also helping them form this positive habit that will continue beyond the trial and for the rest of their lives, thereby improving child dental outcomes during the short and long term.

Strengths and limitations

The proposed study has several strengths. We propose a novel intervention strategy for promoting oral hygiene in young children, building on success using lottery incentives in our pilot and other health behaviors. Moreover, we use a novel digital tool set that integrates objective toothbrushing and SMS text data into a clinical trials management system to measure toothbrushing behavior. Our pilot demonstrated this approach is feasible and reliable to collect objective toothbrushing data. We also follow participants for 12 months, allowing us to assess whether incentives have sustainability 6 months after the incentives end. Another strength is including a large number of Latino/Hispanic families whose children are at high risk of dental caries and relatively underrepresented in clinical trials in dentistry.

The proposed study also has some limitations. The study includes only 244 patients from three sites. Although our sample size is well powered to detect clinically important effects, it is not clear that our results will extrapolate to other settings.

Summary and significance

BEECON responds to gaps in evidence of using monetary incentives to promote oral hygiene. Results are expected to inform designing scalable monetary incentive programs to address oral health, especially among disadvantaged and underserved individuals. Additionally, in a disease prevention management model, with early interventions, promoting families' oral health and well-being has policy implications from third party payers' perspectives resulting in reduced rates based on active family participation.

Trial status

The BEECON trial enrollment began in May 2018 and ended in November 2019; 6-month outcome assessment is expected to end in December 2020; however, COVID-19 may delay completion.

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Conflict of interest

Dr. Gansky's brother is a 3M employee, in a different division than the one that provided in-kind product.

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