UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

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Randomized clinical trial: evaluation of the effectiveness of an application for mobile phones as an aid in the control of early childhood caries

Estudo clínico randomizado: avaliação da efetividade de um aplicativo para celulares como um auxiliar no controle da cárie da primeira infância

BAURU
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Orientador: Prof. Dr. Thiago Cruvinel da Silva

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“Quando a gente acha que tem todas as respostas,

vem a vida e muda todas as perguntas.”

Luis Fernando Verissimo

RESUMO

Considerando os impactos causados pela cárie da primeira infância (CPI) na vida das crianças e de seus familiares, bem como a grande difusão e influência dos meios digitais sobre a saúde das pessoas, este estudo dividiu-se em duas etapas, objetivando (1) a investigação das perspectivas dos pais sobre esta doença e (2) a avaliação da efetividade do envio de mensagens de texto via celular aos pais ou responsáveis como método auxiliar para o controle da CPI. Na primeira fase, três grupos focais (n=17) foram realizados com pais ou cuidadores de crianças atendidas nas Clínicas de Odontopediatria da Faculdade de Odontologia de Bauru. As reuniões foram gravadas em áudio e vídeo, e seu conteúdo foi transcrito na íntegra. Então, as passagens textuais foram codificadas e qualitativamente analisadas usando o software NVivo 12 Plus. Os participantes associaram a presença de lesões de cárie dentária com consequências negativas para as crianças, como problemas na dentição permanente, discriminação e danos psicológicos. Embora a higiene bucal regular e a alimentação saudável tenham sido reconhecidas como fatores importantes para o controle da CPI, dúvidas específicas sobre a dieta, uso de dentifrício, higiene bucal e erupção dentária foram detectados entre os pais. Além disso, os pais declararam que seus filhos escovam os dentes sozinhos, ingerem carboidratos fermentáveis com frequência e dormem durante a amamentação sem remoção de biofilme dentário, devido à falta de cooperação, permissividade e conveniência. Embora os pais ou cuidadores entendam os efeitos desfavoráveis da CPI na qualidade de vida das crianças, suas atitudes no manejo da doença são imprecisas e influenciadas por suas rotinas diárias, dúvidas e crenças. Na segunda fase, um estudo clínico randomizado, simples-cego e paralelo foi conduzido com 80 pares de pais e filhos com idades entre 36 e 60 meses, recrutados em pré-escolas na periferia da cidade de Bauru-SP. Os participantes foram alocados aleatoriamente em dois grupos, controle e intervenção (n=40 em cada), estratificados pelos níveis de alfabetismo em eSaúde dos pais (eHEALS) e idade, sexo e estado de saúde bucal das crianças. A cada duas semanas, mensagens de texto com conteúdos relativos ao controle da CPI, produzidas a partir dos achados da primeira fase, foram enviadas aos pais do grupo intervenção via WhatsApp. O índice de placa visível (IPV), o índice periodontal comunitário (IPC) e o Sistema Internacional de Detecção e Avaliação de Cárie (ICDAS) foram avaliados no baseline, e após 3 e 6 meses de

acompanhamento após profilaxia profissional com escova elétrica. Além disso, os escores de eHEALS e os hábitos alimentarem foram determinados no baseline e no acompanhamento de 6 meses. Valores de *P*<0,05 foram considerados significativos. Apesar da semelhança entre os escores médios de IPV, IPC e ICDAS entre os grupos, um aumento significativo nos níveis de eHEALS e no consumo de doces sem açúcar foi detectado no grupo intervenção após 6 meses, especialmente entre os apres com pais engajados. Portanto, as mensagens de texto não foram efetivas para impedir a progressão da CPI em crianças pré-escolares de baixa renda, embora elas pareçam ser benéficas para aumentar os níveis de alfabetismo em eSaúde dos pais e de consumo de doces livres de açúcar.

Palavras-chave: e-Saúde, Cárie Dentária, Ensaio Clínico Controlado Randomizado

ABSTRACT

Randomized clinical trial: evaluation of the effectiveness of an application for mobile phones as an aid in early childhood caries control

Considering the impacts caused by early childhood caries (ECC) on the quality of life of children and their families, as well as the great diffusion and influence of digital media on people's health, this study was divided into two stages, aiming (1) to investigate the parental perspectives on this disease, and (2) to evaluate the effectiveness of text messages sent via cellphones to the parents or caregivers as an adjuvant method for ECC control. In first phase, three focus groups were conducted with attendees of the Clinics of Paediatric Dentistry from the Bauru School of Dentistry. The meetings were audio- and video-recorded, and the contents were transcribed verbatim. Then, textual passages were coded and qualitatively analyzes using the software NVivo 12 Plus. The participants associated the presence of dental caries lesions with negative consequences for children, such as problems for permanent dentition, discrimination, and psychological damages. Although regular oral hygiene and healthy diet were recognized as important factors for the prevention of ECC, specific doubts about feeding, toothpaste usage, oral hygiene, and dental eruption were detected among parents. Additionally, they declared that their children brush teeth alone, intake fermentable carbohydrates frequently, and sleep during breastfeeding without dental plaque removal, because uncooperativeness, permissiveness, and convenience. Despite the parents and caregivers understand the unfavorable effects of ECC on children's quality of life, their attitudes in disease management are inaccurate and influenced by their daily routines, doubts, and beliefs. In second phase, a single-blinded, randomized, and parallel-group study was conducted with 104 dyads of parents and children aged between 36-60 months, recruited in preschools from periphery of city of Bauru-SP. The participants were randomly allocated into two groups, control and intervention (n=52), stratified by eHealth literacy levels of parents (eHEALS), and age, gender, and oral health status of children. Every 2 weeks, text messages, with ECC control-related contents and that were produced from the first phase findings, were sent to parents of intervention

group via WhatsApp. Visible plaque index, community periodontal index, and the International Caries Detection and Assessment System (ICDAS) were assessed at baseline, 3- and 6-month follow-up after professional electric toothbrushing. Also, eHEALS and dietary habits were determined at baseline and 6-month follow-up. P values <0.05 were considered significant. Despite similar scores of VPI, CPI, and ICDAS between groups, a significant increase of eHEALS scores and free-sugar sweets consumption were detected in the intervention group after 6 months, especially among those dyads with engaged parents. Therefore, mobile text messages were not effective to arrest the progression of ECC in low socioeconomic preschoolers, although they seemed beneficial to improve parental eHealth literacy levels and free-sugar sweet intake by children.

Keywords: eHealth, Dental Caries, Randomized Controlled Trial

SUMÁRIO

1 INTRODUÇÃO

1 INTRODUÇÃO

Apesar do declínio da cárie dentária entre crianças, o seu aparecimento precoce ainda é um desafio de saúde pública para os países desenvolvidos e em desenvolvimento do Ocidente.[1,2] Ela acomete cerca de 621 milhões de crianças na fase da dentição decídua, sendo a décima doença crônica mais prevalente,[3] e estando associada a grupos de baixo poder socioeconômico.[4] A cárie da primeira infância (CPI) é definida como a presença de um ou mais dentes decíduos cariados (cavitados ou não), ausentes (devido à cárie) ou restaurados em crianças com menos de seis anos de idade.[5]

A importância da prevenção da CPI foi amplamente discutida na literatura.[6-8] A identificação de fatores de risco individuais, o aconselhamento parental e a promoção de saúde têm desempenhado papel importante na prevenção da doença,[1] evitando possíveis danos à qualidade de vida das crianças e seus familiares, tais como alterações na mastigação e fala, dor, problemas psicológicos, e efeitos negativos sobre o peso e crescimento da criança.[9-11] Além disso, aproximadamente 94% das crianças diagnosticadas com CPI também apresentam lesões de cárie na dentição permanente.[12]

O desenvolvimento de aparelhos smartphones criou um vasto campo para o acesso às informações em saúde devido a sua portabilidade, praticidade e velocidade.[13] Setenta e um por cento dos brasileiros utilizam a Internet diariamente, sendo que 101 milhões (44%) deles a utilizam em seus smartphones.[14] A propagação sem precedentes de tecnologias móveis, bem como sua aplicação inovadora em saúde, desenvolveu um novo campo de pesquisa: a mHealth, ou saúde móvel.[15] Estima-se que 660 milhões de downloads de aplicativos de saúde são realizados anulamente.[16] Intervenções de saúde utilizando-se aparelhos móveis podem beneficiar um grande número de pessoas, permitindo o acesso e fornecendo informações de cuidados em saúde inclusive em locais com baixa disponibilidade de recursos materiais e humanos.[17] O desenvolvimento de produtos e serviços relacionados à mHealth deve ser pautado sobre as necessidades da população-alvo, oferecendo suporte, por exemplo, aos programas de cuidado de saúde pré-existentes.[18]

Atualmente, um dos aplicativos móveis com maior número de downloads do mundo é o WhatsApp Messenger™, possuindo cerca de 2 bilhões de usuários.[19] Sua principal característica é conectar pessoas por meio de mensagens eletrônicas gratuitas, necessitando apenas de uma conexão à internet do tipo WI-FI.[20,21] O WhatsApp Messenger™ tem se mostrado promissor como ferramenta de comunicação profissional com as pessoas, sendo um meio propagador de informações relacionadas à saúde.[22]

Para o nosso conhecimento, a utilização de dispositivos móveis para a educação das pessoas e prevenção de doenças odontológicas ainda é escassa. Além disso, novas abordagens preventivas para a cárie da primeira infância são necessárias, com o objetivo de aumentar a adesão e o engajamento dos pais ou responsáveis com comportamentos relacionados à saúde.

2 ARTIGOS

2 ARTIGOS

Esta disseração é apresentada no formato de dois manuscritos, escritos de acordo com as instruções e diretrizes dos periódicos *International Journal of Paediatric Dentistry* e *Journal of Dentistry*, respectivamente.

- ARTIGO 1 – Parental perspectives on early childhood caries: A qualitative study

- ARTIGO 2 – Can parental-oriented educational mobile text messages be effective to aid in the control of early childhood caries in low socioeconomic children? A randomized controlled trial

Parental perspectives on early childhood caries: A qualitative study

Abstract

Background: Early childhood caries (ECC) affects about 621 million children worldwide, causing chronic pain, infections, sleeping disorders, and tooth extraction. **Aim**: To determine perspectives of parents and caregivers of preschoolers regarding ECC. **Design**: Three focus groups were conducted with attendees of the Clinics of Paediatric Dentistry from the Bauru School of Dentistry. The meetings were video- and audio-recorded, and the contents were transcribed verbatim. Then, textual passages were examined and coded using the software NVivo 12 Plus. **Results**: The participants associated the presence of dental caries lesions with negative consequences for children, such as problems for permanent dentition, discrimination, and psychological damages. Although regular oral hygiene and healthy diet were recognized as important factors for the prevention of ECC, specific doubts about feeding, toothpaste usage, oral hygiene, and dental eruption were detected among parents. Additionally, they declared that their children brush teeth alone, intake fermentable carbohydrates frequently, and sleep during breastfeeding without dental plaque removal, because uncooperativeness, permissiveness, and convenience. **Conclusions**: Based on these results, parents and caregivers understand the unfavorable effects of ECC on children's quality of life; however, their attitudes against the disease seemed to be inaccurate, influenced by their daily routines, doubts, and beliefs.

Keywords: child, dental caries, health behaviour, oral health, qualitative research

1. INTRODUCTION

Early childhood caries (ECC) is defined as 'the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled surfaces, in any primary tooth of a child under age six'.[1] It affects about 621 million children worldwide, representing a great challenge for public health systems because its negative consequences, such as chronic pain, infections, sleeping disorders, and tooth extraction.[2,3] In Brazil, 53.4% of 5-year-old children were diagnosed with ECC in 2010, even after a significant reduction of incidence of dental caries in the general population.[4]

Dental caries is a sugar- and biofilm-dependent disease,[5] resulted from consecutive demineralization processes linked to the metabolism of fermentable carbohydrates by acidogenic and aciduric microorganisms.[6] The adoption of measures as toothbrushing and flossing are essential for controlling the disease, especially within a context of a high personal consumption of free sugars observed in developing countries,[6-8] influenced by behavioural, cultural, and psychological aspects.[9]

Uncooperative behaviours of preschoolers during oral hygiene, however, hamper the quality of mechanical removal of dental plaque performed by parents,[10] which makes the reduction of children's consumption of fermentable carbohydrates a priority strategy for achieving better prevention of ECC in early stages of life.[11] As this dietary commitment depends on the adherence and engagement of informed and educated families,[12] the lack of awareness of dental teams on parents' demands could negatively impact on the communication and relationship between people and professionals, interfering on the understanding of information, decision-making process, and health outcomes.[13,14]

Therefore, the aim of this study was to determine qualitatively the parental perspectives on ECC, to guide instructional strategies and clinical interventions.

2. METHODS

The authors followed the recommendations of the consolidated criteria for reporting qualitative research (COREQ).[15]

2.1. Ethics

This study was approved by the Human Research Ethics Committee of the Bauru School of Dentistry, in accordance with the ethical standards of the Declaration of Helsinki.

2.2. Participants

A convenience sample of parents and caregivers of children attended in the Clinics of Paediatric Dentistry of the Bauru School of Dentistry was invited face to face to participate in this study. There was no consideration about the exclusion criteria of sample.

2.3. Focus groups

Focus groups are defined as a research method of data collection through moderated discussion, based on people's perceptions and experiences about a specific topic of interest of researchers.[16] The participants were invited to engage into a meeting session performed during the clinical attendance of children. Three distinct groups were composed by 5 or 6 participants and two trained researchers, being one moderator (ML; DDS, Master's student, male) and one assistant (APS; DDS, MSc, PhD student, female).[17] The participants did not have previous relationship with researchers. The meetings were pilot-tested and conducted as described by Krueger and Casey.[18] Participants were asked to take a seat in a comfortable and silent room and write their own names on a badge for identification purposes. Also, they were invited to sign a free consent form for agreeing with their participation. Snacks and drinks were freely available for all participants, to make them more relaxed and stimulated to cooperate. Initially, the moderator started welcoming and offering basic explanation about the thematic interest, presenting the background, ground rules, and an opening question about ECC. The interaction between participants was promoted by script-based activities, to detect concepts and topics emerged from a 90-minutes session. For instance, parents were advised to classify specific oral health preventive measures as easy or difficult, being also asked to mention their feelings about a picture of a child with severe dental caries lesions. The moderator noted the answers on a flipchart, identifying ideas to be discussed subsequently. At the end of each session, the assistant read aloud field notes to confirm the main perspectives emerged from discussions with all participants, to guarantee that they were linked to a collective opinion produced by that group. After sessions, the

moderator and the assistant achieved consensus about data saturation. The meetings were video- and audio-recorded for further qualitative analysis. The transcripts were not returned to participants for comments or corrections.

2.4. Data analysis

The content analysis was performed using the software NVivo® 12 Plus (QSR International, Melbourne, Australia). The recorded contents were transcribed verbatim and examined comprehensively. Following, a researcher developed a list of codes based on specific topics (for more details, see results). Thematic nodes and subnodes emerged from the aggregation of significant textual passages coded similarly, which were represented by conceptual map, hierarchy charts, cluster analysis, and decision trees.

3. RESULTS

3.1. Sample caractheristics

The final sample consisted of 17 participants with mean age of 34.9 years and income of US$ 591.17. It was noted a predominance of women (82.3%), white people (70.5%), and individuals with ≥12 years of education (70.5%). Five invited individuals refused to participate because disinterest or lack of time.

3.2. Conceptual map

The ideas and concepts emerged from the focus groups were organized in eight different nodes, named as their attributes as ‘prevention’, ‘beliefs’, ‘disease’, ‘consequences’, ‘diet’, ‘breastfeeding’, ‘doubts’, and ‘dentist-patient relationship’. Fourteen primary subnodes were originated from the first six nodes. Eight secondary subnodes were derived from the subnodes ‘dentist relevance’ (n= 2) and ‘hygiene’ (n= 6) (Figure 1), both emerged from the node ‘prevention’.

3.3. Hierarchy charts

Most issues discussed in focus groups were linked to the node ‘prevention’, followed by ‘beliefs’, ‘disease’, ‘consequences’, ‘diet’, ‘breastfeeding’, ‘doubts’, and ‘dentist-patient relationship’ (Figure 2).

3.4. Cluster analysis

Two main clusters were detected by the aggregation of similar nodes. The cluster 1 consisted of the nodes ‘dentist-patient relationship’, ‘doubts’, ‘beliefs’, and ‘breastfeeding’, while the cluster 2 was comprised of ‘consequences’, ‘diet’, ‘disease’, and ‘prevention’ (Figure 3).

3.5. Decision trees

These analyses were performed to identify which themes were more discussed for the participants of focus groups, regarding the word with 5+ syllables most frequently found in the transcriptions of each node (see Figure 4). The results are presented below.

3.5.1. Prevention

The most common word found in this node was ‘brush’. The participants confirmed that they received orientation about the prevention of dental caries, considering it extremely important to oral health maintenance; however, they reported practical difficulties to follow professional counselling due to the negative behaviours of children. Additionally, parents and caregivers permit their children brushing teeth alone, independently of their age and psychomotor development. A synthesis of these aspects can be found in the following speech (participant #11): ‘In a rush day, it's hard. Besides working, people have their families and a lot of things to do. It is too hard! Either we give up or we forget it. My son manipulates me! I ask him to brush his teeth and he says that he is going. When I ask him again, he says he's already brushed (his teeth). But when I see his brush, it is completely dry. So, it's my word against his’.

3.5.2. Beliefs

The word ‘antibiotics’ guided this analysis. The opinion of participants varied between those who believe or not in the contribution of these remedies in the progression of dental caries. The opinions were linked to beliefs in the increase of dental fragility (participant #15), as follows: ‘I believe that antibiotics cause dental caries, because they weaken teeth. So, the antibiotics make teeth more susceptible to dental caries’.

3.5.3. Disease

The word adopted for guiding this analysis was ‘teeth’. The participants considered that dental caries is caused by the absence of oral hygiene and unhealthy eating habits, mainly associated with the consumption of sugar-rich foods. Regarding the onset of the disease, they believe that it occurs in any moment after dental eruption. The following speech (participant #2) is representative of this node: ‘feeding is basic, isn't it? Bad brushing for sure! I think candies are important to, but they are not the prime factor’.

3.5.4. Consequences

In this node, the main findings were related to the word ‘child’. The participants believe that children with extensive dental caries lesions are psychologically affected by the discrimination of their schoolmates. These findings are depicted in the following sentence (participant #3): ‘I have a pity because those children are discriminated. The kids create nicknames for all. This child (pointing to the picture)… I imagine which others are going to say’. Additionally, parents also think that dental caries cause negative consequences to permanent dentition.

3.5.5. Diet

This analysis was guided from the word ‘sugar.’ The participants agreed that children usually intake a great amount of sugar, being very difficult to reduce this daily habit; however, they had a controversial opinion on the role of sugar in the progression of dental caries. The absence of dental hygiene is the main factor for the onset of the disease for those do not believe in that association. These results can be illustrated as follows: ‘I think sweets don't cause caries. I have diabetes, but I’ve never eaten sweets. So, I cannot affirm that diabetes was caused by sweets. Then, I think the problem of caries is not related to sweets. I’m in favor of giving sweets to children, but I’m in favor of oral hygiene at first place…it has to start early’. (participant #16).

3.5.6. Breastfeeding

These main findings were related to the term ‘baby bottle’. The babies were frequently bottle-fed with sweetened liquids at night. Also, parents admitted they do not provide adequate oral hygiene for asleep babies, because compassion or convenience. The following speech (participant #12) illustrates these results: ‘In my case, I think it's more difficult because when I see, she's already dozing. So, I am

honest. I have pity on waking her up. If she wakes up, she won't sleep anymore. I'm always afraid of she wakes up and I'm going bed after 2 am'.

3.5.7. Doubts

This analysis was directed by the word 'doubts'. The doubts of participants were associated to feeding, toothpaste, oral hygiene, and dental eruption. An example of these findings is demonstrated as follows: 'We bought a toothbrush for our kids, but we were not sure about it was the correct one. This also happened with the toothpaste'. (participant #4).

3.5.8. Dentist-patient relationship

The word used for guiding this analysis was 'dentist'. Most participants affirmed that they never experienced relationship problems with their dentists, as follows: 'I take my daughters to dentist since they're little, and I never had anything to complain about'. (participant #16); however, conflicting reports as 'the dentist made my kid cry', 'the dentist was rude with my child' (participant #14), or 'the dentist said it was a milk tooth, but I think it was a permanent one' (participant #7) also emerged from these discussions

4. DISCUSSION

To our knowledge, this is the first focus group-based study that investigated the perspectives of parents and caregivers of children on ECC. This research design is desirable to amplify the professional view of a specific condition or disease, oriented directly by its own target audience. It permits a better interaction between participants, selected from homogeneous samples with similar needs and interests. Also, it empowers people to give their opinions about a specific issue, making possible more spontaneous thoughts and reflections, facilitating openness and disclosure. The discussion based on arguments and counterarguments favours the construction of collective concepts emerged from social debate, differently of ideas derived from individual judgements of investigators.[19] Hence, the outcomes obtained from focus groups enable a better elucidation of how opinions are constructed in comparison to questionnaires.[20]

The interests that emerged during the meetings were associated with knowledge, doubts, beliefs, and attitudes of parents in respect of ECC. The role of preventive

measures, such as adequate dental hygiene and low consumption of sugary-rich foods, was commonly recognized to the achievement of better oral health outcomes, although the indulgence with children's behaviours and the adoption of convenient daily routines hampered the parental engagement into healthy practices. These attitudes can be resulted from specific doubts and beliefs about feeding, toothpaste, oral hygiene, and dental eruption, including antibiotics and genetics as aetiological factors for cavities. Additionally, extensive dental caries lesions were linked to problems for permanent dentition, discrimination of children, and psychological damages.

In our opinion, these results can be explained by the social inequality observed in Brazil.[21] The lack of specific policies for controlling ECC combined with limited public facilities hinder the access of most population to basic information and care for preventing the disease.[22,23] In this sense, a considerable percentage of preschoolers have never used oral health services, despite the recommendation of the first dental visit between 6 and 12 months old.[24,25] Also, low education levels corroborate to the underutilization of health care,[26] leading people to have difficulties to access, understand, appraise, and use health information and services.[27] Moreover, low health literacy is associated with negative beliefs of parents that interfere in the prompt management of oral conditions and challenge dentist-person relationship.[14,28,29]

Indeed, the natural history of chronic oral diseases is directly influenced by biopsychosocial aspects, such as sense of coherence (SOS) and locus of control (LOC).[30] The model of SOS supported by the Antonovsky's salutogenic theory consists in the ability of individuals to deal with the presence of stressors in their daily routines.[31] To face uncooperative children, parents adopted indulgent behaviours and convenient habits in response to exhaustive work journeys, which is associated with low levels of SOS. A previous study demonstrated a positive correlation between low levels of parental SOS and the presence of dental caries in children.[32] Additionally, parents seemed to believe that children's oral health conditions are resulted from luck, fate or chance,[30] associated with external LOC as dental interventions and antibiotics usage.[33] This aspect indicates an increased risk of dental caries in children, since people with the predominance of internal sense of control present higher adherence and engagement levels to preventive measures, because their beliefs on the role of positive attitudes towards healthy outcomes.[34]

These results have practical implications for paediatric dentists. The lack of adherence and engagement of parents with the prevention of ECC emphasizes the importance of the development of participatory models as children- and family-centred care for better oral health outcomes.[35,36] The doubts presented by the participants can guide the construction of clinical protocols and effective health education strategies to cover gaps emerged directly from interested groups. For instance, these findings can be employed to promote beneficial health behavioural changes on electronic basis, contributing to decrease healthcare disparities and costs.[37,38] In this scenario, the elucidation of doubts and beliefs also can contribute to the development of strategies to minimize the electronic consumption, propagation, and deleterious effects of mis- or disinformation on specific communities, since individuals are more predisposed to accept ideas related to their own convictions.[39,40]

This study presents some limitations. First, these perspectives were obtained from a convenience sample composed by attendees of a paediatric dental clinic, which do not represent the general perceptions of parents and caregivers about ECC. This common limitation of qualitative studies was minimized by the conduction of different focus groups to increase the volume and diversity of data collection. Second, since inclusion criteria of sample disregarded the oral health status of children, the perceptions synthesized in this paper reflect the opinions of both parents with or without experiences with ECC. We believe that this characterization permitted more balanced arguments towards the construction of a collective idea about the disease. Third, as participants were previously informed that the moderator was a dentist, the groups might be concerned about their answers, choosing ‘the best’ argument or position about specific issues. To avoid this behaviour, the participants were oriented to speak freely, without limitations or judgements. Nevertheless, it is not possible to guarantee that all individuals were completely comfortable to express their own opinions.

In conclusion, parents and caregivers can understand the unfavourable effects of ECC on children's quality of life; however, their attitudes against the disease seemed to be inaccurate, influenced by daily routines, doubts and beliefs. These findings indicate the importance of the development of participatory models of health care, regarding children's and parents’ needs to construct effective health education strategies.

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FIGURES

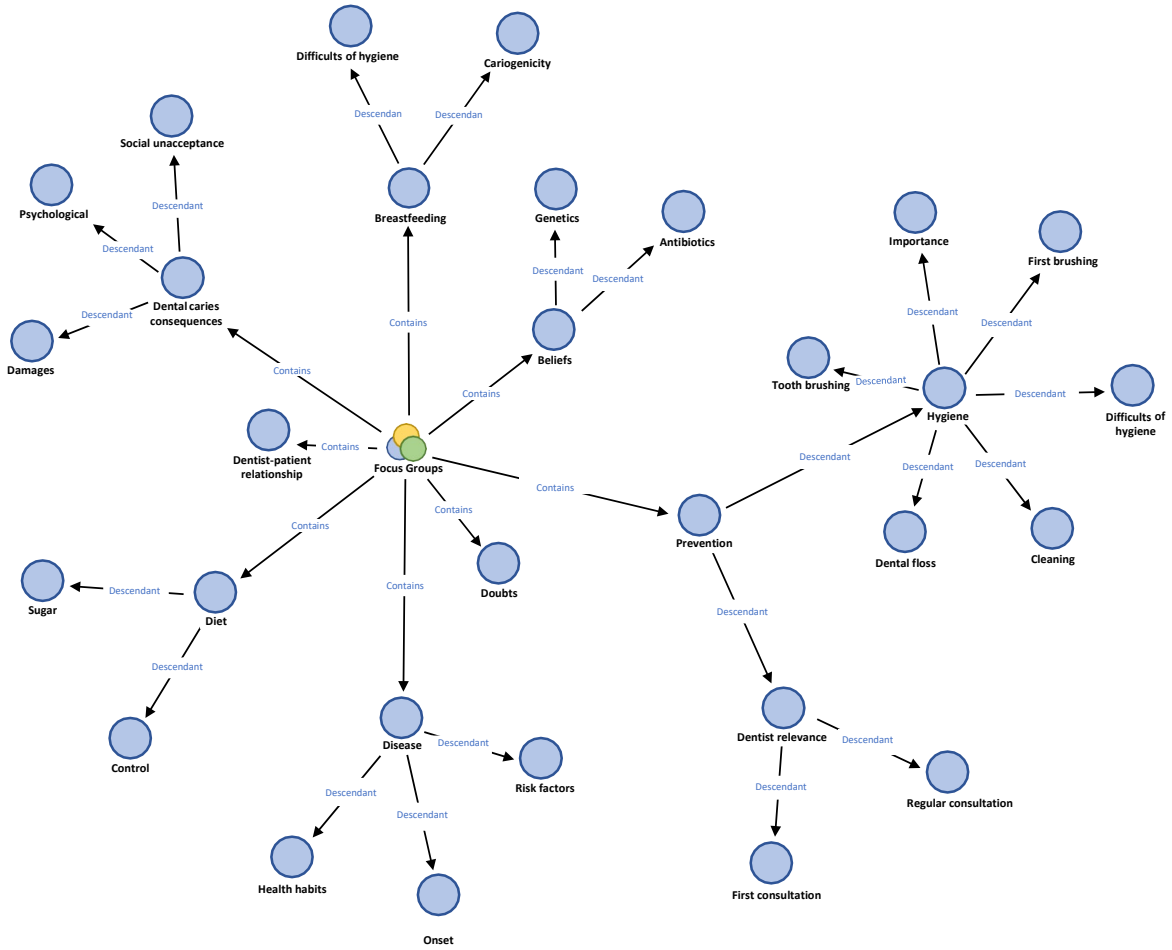

Fig. 1. Conceptual map demonstrating the relationship of topics emerged from the discussions of focus groups

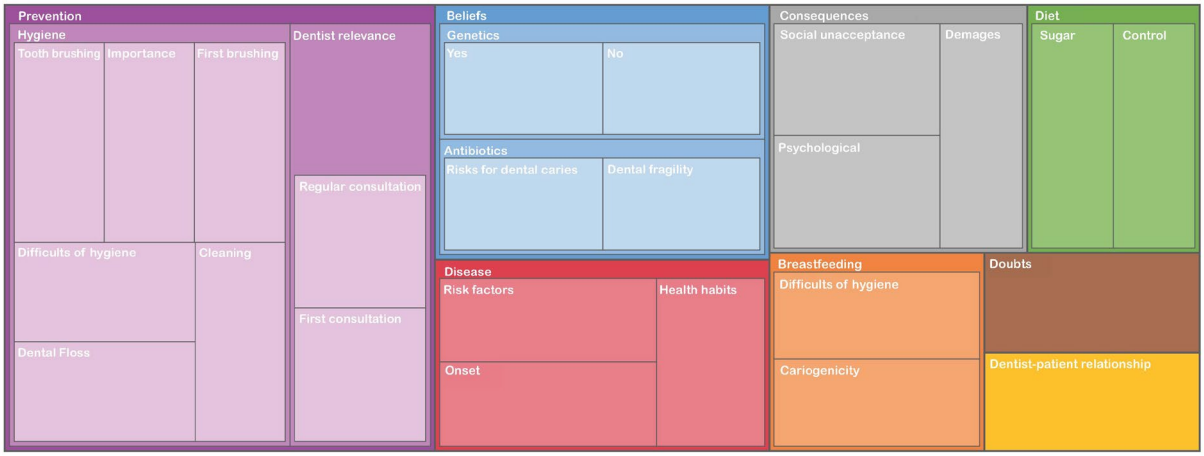

Fig. 2. Hierarchy charts showing the relative volumes of information of specific topics emerged from the discussions of focus groups

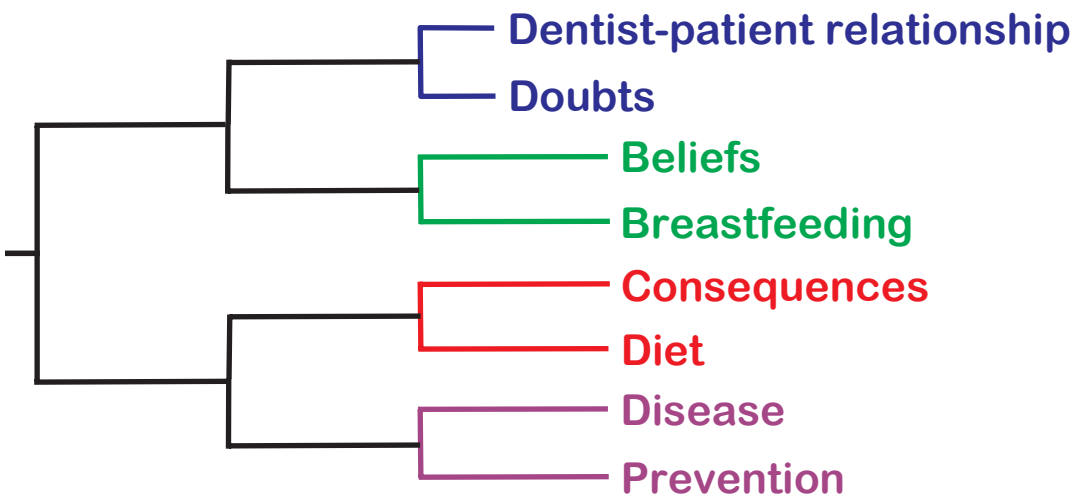

Fig. 3. Cluster analysis depicting the aggregation of nodes by their similarity

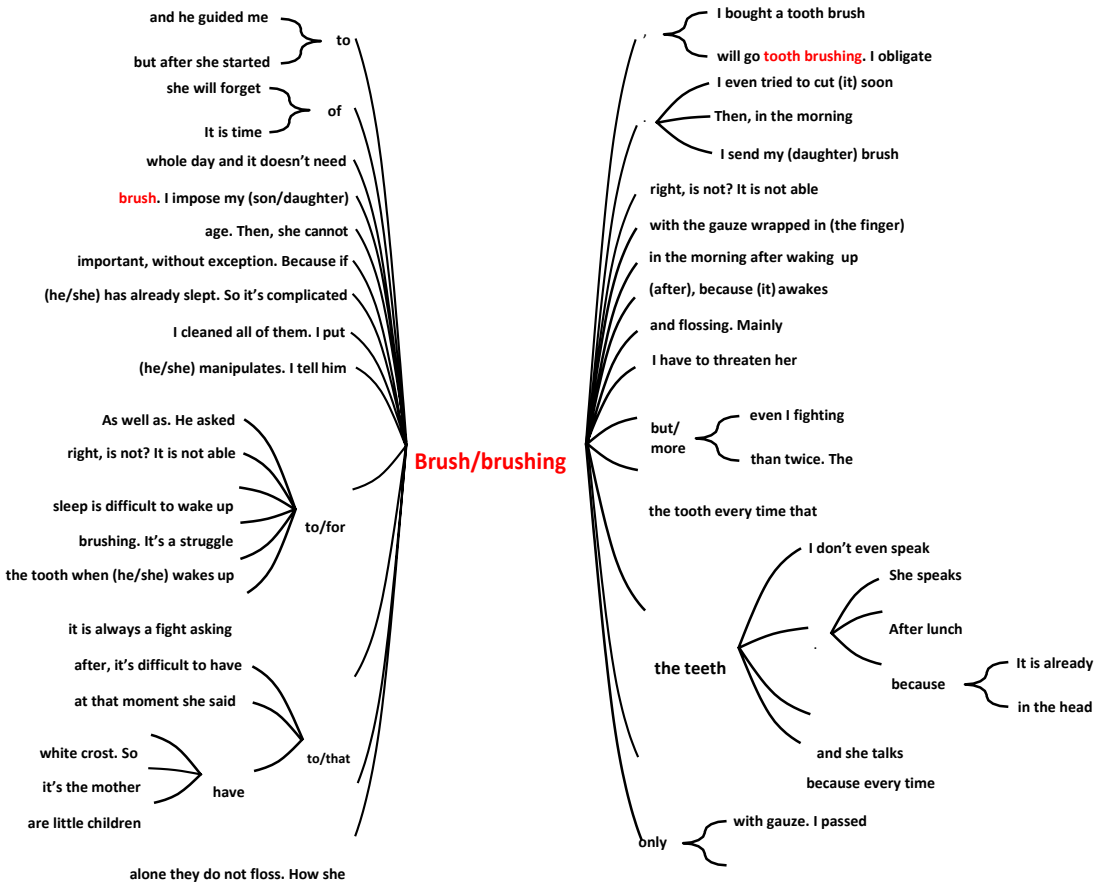

Fig. 4. Decision tree showing the relationship of most frequently terms with the words brush/brushing

Can parental-oriented educational mobile text messages be effective to aid in the control of early childhood caries in low socioeconomic children? A randomized controlled trial

ABSTRACT

Objectives: To evaluate the effectiveness of educational messages in the control of early childhood caries (ECC) in low socioeconomic children.

Methods: A single-blinded, randomized, and parallel-group study was conducted with 104 dyads of parents and children aged between 36-60 months, recruited in preschools from Bauru-SP. The participants were randomly allocated into control and intervention groups (n=52 each), stratified by eHealth literacy levels (eHEALS) of parents, and age, gender, and oral health status of children. Every 2 weeks, text messages were sent to parents of intervention group via WhatsApp. Visible plaque index (VPI), community periodontal index (CPI), and the International Caries Detection and Assessment System (ICDAS) were assessed at baseline, 3- and 6-month follow-up after professional electric toothbrushing. Also, eHEALS and dietary habits were determined at baseline and 6-month follow-up.

Results: Despite similar scores of VPI, CPI, and ICDAS between groups, a significant increase of eHEALS scores and free-sugar sweets consumption were detected in the intervention group after 6 months, especially among those dyads with engaged parents.

Conclusion: Therefore, mobile text messages were not effective to arrest the progression of ECC in low socioeconomic preschoolers, although they seemed beneficial to improve parental eHealth literacy levels and free-sugar sweet intake by children.

Clinical significance: These findings demonstrate that parental-oriented WhatsApp messages have a potential to contribute in the oral health education in low socioeconomic populations; however, the effectiveness of this strategy was limited to control ECC, depending on the engagement of parents in consuming information towards risk behavior changes.

Keywords: eHealth, Early Childhood Caries, Dental Caries, Randomized Controlled Trial, mHealth

1. INTRODUCTION

Early childhood caries (ECC) is defined as the presence of one or more decayed (non-cavitated or cavitated lesions), missing (due to caries), or filled surfaces, in any primary tooth of a child under age six [1]. It has a complex etiology, being a biofilm- and sugar-dependent disease, influenced by environmental, socioeconomic, biological, and behavioral factors [2]. ECC is the tenth most prevalent non-communicable disease worldwide [3], impacting the quality of life of preschoolers and their families [4], because its physical, social, and psychological damages [5].

The higher prevalence of ECC among low socioeconomic populations can be explained by several aspects, such as negative health beliefs, external locus of control, and limited levels of self-efficacy, oral health knowledge, and health literacy [5-7], which hamper the adherence and engagement of parents with strategies to deleterious behavior changes. The influence of these drawbacks on oral health outcomes may be overcame by parental education [8], in a context of family- and child-centered care [9]. Thus, personal approaches as motivational interviews, home visits, and telephone contacts have proven effective in the management of ECC [10, 11].

Despite that, the increase of parental knowledge in low-income populations does not necessarily reduce ECC-related behaviors or caries incidence [12]. In developing countries, barriers as low income, limited health infrastructure and high costs of services, prevent the access of families and children to health education [13, 14]. In Brazil, 29% of adults are functional illiterates, and 71% have inadequate oral health literacy [15, 16], whose tend to underuse preventive services and misinterpret health information [17].

Indeed, the dissemination of information and communication technologies (ICTs) empowered individuals to obtain knowledge and to make decisions about their own health conditions [18, 19]. For instance, 101 million of Brazilian people access the Internet using their smartphones [20]. It is well-known that mobile health (mHealth) interventions based on text messages (reminder, alert, motivation, and prevention) have a significant potential to improve the self-management of several non-communicable diseases [21-23], such as diabetes, hypertension, and obesity [24, 25]. Regarding dental care, these strategies are also being considered promising to improve oral hygiene, plaque removal, gingivitis, and oral health literacy [26, 27].

There is a consensus about the lack of clinical trials testing specific interventions against ECC and its risk factors [5]. Therefore, the aim of this study was to evaluate the effectiveness of oral health educational text messages to aid in the control of early childhood caries in low socioeconomic children, regarding caries experience, dental biofilm, and dietary habits. The null hypotheses were that educational mobile text messages would have no effect on the progression of dental caries (H_0), presence of visible dental plaque ($H_0´$), periodontal health ($H_0´´$), and frequency of sugar consumption ($H_0´´´$) in children, as well as on the eHealth literacy levels ($H_0´´´´$) of parents or caregivers after 6-month follow-up.

2. METHODS

2.1. Trial Design

This study was designed as a single-blind, 2-parallel arm, and randomized controlled trial (RCT) with 6-month follow-up [28]. This research protocol was reviewed and approved by the Council on Ethics in Human Research from the Bauru School of Dentistry, in accordance with the ethical standards of the Declaration of Helsinki, registered in Brazilian Registry of Clinical Trials Universal, and assigned with the universal trial number U1111-1216-1393. This article was written in accordance with the checklist and guidelines of the Consolidated Standards of Reporting Trials of Electronic and Mobile Health (CONSORT EHEALTH; beta version 1.5) [29].

2.2. Participants

Dyads of parents and children were recruited during visits to preschools from Bauru, if satisfying the following inclusion criteria: (i) children aged between 36 and 60 months; (ii) children with low socioeconomic levels; (iii) children with an ICDAS score < 4 [30]; (iv) parents or caregivers with a mobile phone with Internet access; (v) parents or caregivers who accepted to participate in all stages of research by signing a written informed consent form; and (vi) parents or caregivers who already had WhatsApp Messenger app installed on their smartphones, or those who agreed to install it for the participation in the study.

The risk of dental caries was based on the information collected during the anamnesis and clinical examination, which was performed by two trained and calibrated dentists (ML and APS). Children were examined in preschools, using

artificial lighting, following the visible plaque index (VPI) [31], the community periodontal index (CPI) [32], and the International Caries Detection and Assessment System (ICDAS) criteria for caries detection [30]. VPI was determined by the observation of dental plaque on the buccal dental surfaces of 6 deciduous teeth (#55, #53, #51, #71, #73 and #75) [31]. The periodontal health status of children was assessed considering 2 parameters of analysis: presence of bleeding and detection of dental calculus [32].

The levels of eHealth literacy of parents or caregivers were determined by the application of a previously validated Brazilian version of the eHealth Literacy Scale (eHEALS) [33]. It was applied by a trained professional, who provided the participants with a sheet containing 8 items related to skills needed for the adequate consumption of eHealth information. The answers of each item were arranged into a 5-point Likert scale, with options ranging from *completely agree* to *strongly disagree* [33]. The participants were instructed to classify each item according to their own perception, achieving a total score varying from 8 to 40, with higher scores representing higher self-perceived eHealth literacy. Finally, parents or caregivers were invited to answer a questionnaire containing sociodemographic and child-related health information, such as age, gender, race, and education level.

2.3. Intervention

Initially, dentists brushed children´s teeth with electric toothbrushes (Vitality Precision Clean, Oral B, P&G, Cincinnati, United States), and then, performed clinical exams for the measurement of oral health parameters. Every 2 weeks, the parents or caregivers of the intervention group received educational mobile text messages related to the control of ECC via WhatsApp Messenger. The messages were developed in accordance with the results found by Lotto et al [34], employing an easily understandable language. To improve the access of participants to the educational contents, simultaneously, the audios of readings of text messages were also sent to parents and caregivers. The participants were instructed to activate the function *read receipts* to confirm their adherence and engagement with the intervention. Along the intervention, some parents or caregivers refused in receiving additional educational mobile text messages consistently. This condition divided the intervention group between two subgroups of participants, engaged and non-

engaged ones. This reluctance was interpreted as a self-perception of parents in dealing adequately with their children´s oral health care.

2.4. Follow-up examinations and outcomes

Two trained and calibrated dentists (ML and APS) (kappa intraexaminer = 0.726 and 0.832; kappa interxaminer = 0.754) evaluated all children for the measurement of VPI [31], the community periodontal index (CPI) [32], and ICDAS [30], to assess the presence of risk factors for dental caries and the progression of ECC in preschoolers of both groups at baseline, 3- and 6-month follow-ups. The CPI of deciduous teeth was scored as healthy (0), gingival bleeding (1), and presence of dental calculus (2), in accordance to Almeida et al. [35].

The ICDAS training and calibration were performed by an official calibrator (DR), according to the following recommendations: (i) 4 h of didactic sessions including presentation of images, and discussions about ICDAS codes and examination protocol, (ii) two days of training with the number of teeth coded with ICDAS between 0 and 6, including examination of patients with decayed teeth and teeth extracted in the laboratory, and (iii) the review of examination findings to identify differences in the interpretation of exams until reaching the consensus among examiners [30].

Additionally, the influence of dietary habits on the progression of ECC was evaluated by the application of the questionnaire of Llena and Forner [36] at baseline and 6-month follow-up. This instrument determines the frequency of consumption of 9 categories of foods: (1) foods containing sticky sugars: dried fruit, candies containing sugar, jellies, jams, and sauces; (2) food containing starch and sugar: cookies, cereals, and industrialized cakes; (3) candy without sugars; (4) milk and dairy products containing sugar: chocolate, yogurt, creams, ice creams and flans; (5) milk and dairy products without sugar: pure milk, sugar-free yogurt, and cheese; (6) sugary beverages: juices and soft drinks; (7) fruits: fruits and juices; (8) semi hydrolyzed starch-rich foods: potato chips, French fries, industrialized bread, and rolls; and (9) sugar-free foods: nuts, bread, pasta, and noodles. The frequencies of consumption were classified as high (every day or every week) or low (once a month or never) levels.

The eHEALS was also applied for both groups at 6-month follow-up, in order to measure the influence of the intervention on the eHealth literacy levels of parents or caregivers.

2.5. Sample size

The calculation of sample size was performed using the Open Source Epidemiologic Statistics for Public Health, following the criteria and outcomes described by Zotti et al. [37]. It resulted in a total of 104 dyads of parents or children, considering a power of 80%, a significant level of 5% and attrition of 30%.

2.6. Randomization

The dyads were randomly allocated to control or intervention groups (n=52 each), stratified by eHEALS levels of parents or caregivers, and the ICDAS, age, and gender of children. The randomization was performed using the platform Jerrydallal.com [38], through mixed block sizes for the allocation of participants.

2.7. Blinding

This is a single-blind study. Although neither participants nor investigators were informed about the allocation groups of dyads, the parents or caregivers of intervention group were obviously conscious about the educational messages that they received over time.

The blinding of allocations was guaranteed by using closed and opaque envelopes, which were maintained confidentially by an independent researcher.

2.8. Data analysis

Statistical analysis was performed using SPSS Statistics software 21.0 (IBM SPSS Statistics). The data was presented with descriptive statistics, being examined for lost values, outliers, normality, and homogeneity. To investigate the quality of randomization, potential differences between the characteristics of participants of the control and intervention groups were determined systematically, applying Student *t* tests for continuous variables and Chi-square test for categorical variables. The multiple data imputation was applied to missing values, since they did not meet the criteria of the completely random missing data (MCAR).

The groups and intervention subgroups (engaged and non-engaged participants) were compared using the principle of intention-to-treat [39].

All quantitative variables were submitted to Kolmogorov-Smirnov and Levene tests to check normality and homogeneity of variances, respectively. As these assumptions were not reached, statistical comparisons were conducted using nonparametric tests. The results of VPI, CPI, ICDAS and eHEALS were compared intergroup and intragroup by Mann-Whitney U and Friedman tests, respectively. Fischer´s exact and McNemar tests were employed to detect differences in the distribution of the frequency of food consumption inter- and intragroup over time, respectively. P values <0.05 was considered significant.

3. RESULTS

3.1. Participants

A total of 415 children were screened during the recruitment, being excluded 89 (21.45%) for not meeting the inclusion criteria and 222 (53.49%) for declining to participate. A hundred and four dyads of parents and children were enrolled into the study. They were randomly allocated in control and intervention groups (n=52 each). Throughout the study, 3 children (5.76%) of the control group and 5 children (9.61%) of the intervention group failed to attend in dental appointments (attrition of 7.69%). During the follow-up period, 16 (34.0%) parents of the intervention group refused to receive educational mobile text messages, being 12 (24.0%) along the first 3 months. The recruitment, randomization, allocation, and follow-up of participants are outlined in the CONSORT EHEALTH flow diagram (Figure 1).

3.2. Characterization of groups

The sociodemographic and clinical characteristics of groups are depicted in Tables 1, 2, and 3. At baseline, both groups were statistically similar in mean age, gender distribution, parental eHEALS levels, VPI, ICDAS, and frequency of sugar consumption. Differently, CPI was significantly higher in the intervention group. All children were recruited in preschools located in low socioeconomic suburbs of the city.

3.3. Primary outcomes

VPI, CPI, ICDAS, and most frequency of sugar consumption were not statistically different between groups at 3- and 6-month follow-ups (Tables 2 and 3); however, the percentage of progression of ICDAS was lower in the intervention group (42.5% *vs.* 54.3%) after 6 months, especially when considering only children with engaged parents (32.5%). Besides, it was possible to detect the maintenance of the number of free-caries children in the intervention group (ICDAS=0, n=5), instead a considerable reduction observed in the control group (n=10 to 4).

Also, VPI tended to decrease indistinctly while the difference of CPI found between groups at baseline was not sustained over time. Interestingly, the participants of the intervention group significantly increased their consumption of sugar-free sweets, as opposed to control group.

3.4. Secondary outcomes

At 6-month follow-up, eHEALS scores significantly increased in engaged parents (+8,78%), while a non-significant decrease was observed in the control group (-2,08%); nevertheless, the electronic health literacy levels of parents were statistically similar between groups (Table 2).

4. DISCUSSION

These findings indicate a limited effectiveness of mobile text messages to control ECC in low socioeconomic children, without significant statistical differences for clinical and educational outcomes between groups; however, the intervention was effective to improve parental eHealth literacy levels and free-sugar sweets intake in children. Overall, preschoolers of both groups tended to present a better control of dental biofilm. Additionally, from qualitative analysis, it is possible to realize a lower progression of dental demineralization and the maintenance of caries-free children in the intervention group after 6 months.

Distinct aspects could explain these findings. The significant increment of ICDAS observed in both groups indicates a rapid progression of dental demineralization among these preschoolers [40]; however, once there was the maintenance of caries-free children in the intervention group over time, future studies should clarify the beneficial effect of text messages on the management of ECC at longer follow-ups. Also, the indistinctly stability of VPI and CPI scores might be caused by the periodic

professional electric toothbrush [41], and by the Hawthorne effect [42]. It is based on the theory that people enrolled in clinical trials change or improve their behaviors because their awareness about the research [26, 43]. Moreover, the mean of eHEALS at baseline was < 26, corresponding to individuals with inadequate levels of electronic health literacy, and consequently, associated negatively with mHealth usage [44, 45]. Despite that, higher levels of eHEALS scores were detected in engaged parents at 6-month follow-up, which might indicate an increasingly effectiveness of longer educational interventions. Finally, to guarantee the visualization of messages by all participants, independently of their Internet data package, only text messages were sent via WhatsApp, without including more attractive communication resources, such as figures, videos or illustrations [46].

The early childhood is a critical period to define healthy eating behaviors towards the control of dental caries [47]. Although sugar consumption is discouraged during the first years of life, it exceeds that recommended for the management of ECC in most developing countries, due to cultural, social, and economic issues [48]. For instance, parents report difficulties in decreasing sugar-rich dietary habits, even though they understand their harmful behaviors [34]. On the other hand, the intervention seemed effective to concern parents about the role of sugar on caries development, since detected a significant increase of free-sugar sweets intake by children. This finding must be interpreted with caution, especially because the consumption of cariogenic foods remained high in both groups. In this sense, this result could be influenced by the inaccuracy of information provided by participants during data collection, which would be justified by social desirability biases, i.e., when individuals deny some undesirable traits [49].

Previous parental-oriented educational interventions for controlling ECC in low socioeconomic children achieved limited outcomes [12, 50, 51]. Notwithstanding, only a study demonstrated a positive influence of educational messages on the engagement and attitudes against ECC, although those results were not related to clinical measures [52]. In addition, the effect of mHealth approaches seemed modest on the management of unhealthy behaviors [53, 54], which corroborate with the difficulty of this intervention in changing oral hygiene and dietary habits. Differently, some mobile strategies were able to improve oral health aspects, although they were usually conducted with samples from developed countries, of different age groups,

during shorter follow-ups [27, 37, 55, 56], i.e., in conditions with greater access to preventive dental services, autonomy for performing oral hygiene, and possible slower progression of dental demineralization [57, 58].

Despite having a limited effectiveness on ECC, this model seemed feasible to aid in parental behavior changes, to develop personalized messages for child and family-centered care, aiming to obtain gains in the clinical practice for low-income populations, besides training and empowering parents or caregivers for adequate decision-making related to their children's health. Also, text messages can be important to gather oral health-related information, to the elucidation of doubts and beliefs that may arise from inadvertent consumption of mis- or disinformation [59]; however, as this strategy can not be sufficient to achieve the satisfactory management of the disease, dentists must offer support to all personal demands, making constant improvements in the process of professional-person communication.

This study presents some limitations. First, the sample was recruited only at schools previously authorized by the local education authority, limiting the data collection to predetermined poor communities. Even though, this sample adequately represented low socioeconomic people, who are more commonly affected by ECC. Second, not all parents or caregivers returned completing questionnaires at 6-month follow-up, which could influence the interpretation of eHEALS and dietary habits outcomes; however, this was compensated by missing data imputation during statistical analysis. Third, parents of the intervention group may get exhausted from consuming periodic educational text messages about a health issue that they were not used to discuss out of dental office. To minimize this discomfort, the messages were sent only every two weeks. Fourth, the educational messages were formulated from doubts and beliefs of other parental groups [33], limiting the availability of contents for these participants. In contrast, the educational messages addressed the management of ECC-related risk behaviors. Finally, this study needed to be discontinued due to COVID-19, preventing the participants' feedback on their general impressions and satisfaction about this novel approach for health promotion.

In conclusion, parental-oriented mobile text messages were not effective to arrest the progression of ECC in low socioeconomic preschoolers, although they were beneficial to increase parental eHealth literacy levels and free-sugar sweet intake in

children, especially when parents were engaged with the intervention. Therefore, the hypotheses H_0, H_0' and H_0'' were accepted, and H_0''' *and* H_0'''' were rejected. Further studies should be performed with other populations and longer follow-ups, to elucidate the role of this promising educational strategy for controlling ECC.

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TABLES

Table 1. Sociodemographic characteristics of participants at baseline

	Control	**Intervention**	**Total**
	n= 52	n= 52	n= 104
Age (children)			
Mean±SD	3.58±0.57	3.44±0.57	3.51±0.57
Median (*P*)	4.00	3.00 (*P*=0.195)	3.00
Gender (children)			
Female	29 (55.7%)	28 (53.8%)	57 (100%)
Male (*P*)	23 (44.3%)	24 (46.2%) (*P*=0.845)	47 (100%)
eHEALS (parents)			
Mean±SD	24.53±8.50	24.02±8.14	24.28±8.28
Median (*P*)	25.50	25.00 (*P*=0.943)	25.00

Table 2. Mean (±SD) and median (IQR) of VPI, IPC, ICDAS and eHEALS according to groups over time. *P* values represent the significance level of differences between intervention group and its subgroups with control group. *P'* values represent the significance level of differences between groups with their values at baseline

	Baseline		**3-month follow-up**			**6-month follow-up**		
	Control	**Intervention**	**Control**	**Intervention**		**Control**	**Intervention**	
VPI	0.39±0.34 0.33(0.67) n= 52	0.43±0.32 0.33(0.50) n= 52 *P*=0.538	0.39±0.32 0.33(0.67) n= 51 *P'*=0.739	0.47±0.34 0.50(0.53) n= 50 *P*= 0.240 *P'*=0.034	***engaged*** 0.47±0.33 0.50(0.53) n= 38 *P*= 0.253 *P'*=0.072 ***non-engaged*** 0.49±0.37 0.42(0.71) n= 12 *P*= 0.409 *P'*=0.480	0.31±0.33 0.17(0.67) n= 49 *P'*=0.086	0.37±0.31 0.33(0.50) n= 47 *P*= 0.295 *P'*=0.465	***engaged*** 0.36±0.30 0.33(0.33) n= 31 *P*= 0.344 *P'*=0.819 ***non-engaged*** 0.40±0.34 0.33(0.62) n= 16 *P*= 0.287 *P'*=0.366
CPI	0.06±0.99 0.00(0.10) n=52	0.13±0.16 0.05(0.20) n=52 *P*=0.025	0.12±0.17 0.05(0.20) n=51 *P'*=0.048	0.20±0.30 0.00(0.30) n=50 *P*=0.871 *P'*=0.862	***engaged*** 0.22±0.33 0.02(0.35) n=38 *P*=0.699 *P'*=0.433 ***non-engaged*** 0.12±0.19 0.00(0.20) n=12 *P*=0.690 *P'*=0.257	0.13±0.20 0.00(0.20) n=49 *P'*=0.144	0.14±0.23 0.05(0.20) n=47 *P*=0.704 *P'*=0.590	***engaged*** 0.14±0.25 0.05(0.15) n=31 *P*=0.941 *P'*=0.670 ***non-engaged*** 0.15±0.18 0.10(0.20) n=16 *P*=0.467 *P'*=0.739
	0.35±0.32 0.28(0.54) n=52	0.40±0.41 0.25(0.49) n=52 *P*=0.500	0.43±0.37 0.30(0.65) n=51 *P'*<0.001	0.54±0.50 0.48(0.61) n=50 *P*=0.434 *P'*<0.001	***engaged*** 0.54±0.45 0.50(0.56) n=38 *P*=0.327	0.54±0.42 0.40(0.60) n=49 *P'*<0.001	0.57±0.50 0.55(0.70) n=47 *P*=0.873 *P'*<0.001	***engaged*** 0.53±0.44 0.55(0.65) n=31 *P*=0.801

ICDAS			*P'*=0.739 ***non-engaged*** 0.55±0.65 0.35(0.88) n=12 *P*=0.937 *P'*=0.035			*P'*<0.001 ***non-engaged*** 0.63±0.61 0.60(0.98) n=16 *P*=0.861 *P'*=0.002
	24.53±8.50 25.50(12.0) n=52	24.02±8.14 25.00(11.0) n=52 *P*=0.943		24.02±8.62 24.00(12.0) n=48 *P'*=0.274	25.50±8.52 27.50(13.0) n=46 *P*=0.422 *P'*=0.058	***engaged*** 26.13±6.72 28.00(12.0) n=30 *P*=0.308 *P'*=0.041
eHEALS						***non-engaged*** 24.31±11.32 26.00(22.0) n=16 *P*=0.913 *P'*=0.763

Table 3. Percentage of children with high frequency of consumption of different foods in control and intervention groups over time. Distinct superscript lowercase letters indicate significant statistical differences between groups, while distinct superscript uppercase letters indicate significant statistical differences between times (P<0.05).

Foods	Baseline		6-month follow-up	
	Control	Intervention	Control	Intervention
Sticky sugar-rich foods	67.3^{a,A}	67.3^{a,A}	76.6^{a,A}	77.8^{a,A}
Foods containing starch and sugar	55.8^{a,A}	55.8^{a,A}	61.7^{a,A}	68.9^{a,A}
Sugar-free sweets	21.2^{a,A}	9.6^{a,A}	12.8^{a,A}	24.4^{a,B}
Sugared milk and dairy products	73.1^{a,A}	65.4^{a,A}	80.9^{a,A}	73.3^{a,A}
Non-sugary milk and dairy products	44.2^{a,A}	30.8^{a,A}	40.4^{a,A}	42.2^{a,A}
Sugary liquids	69.2^{a,A}	76.9^{a,A}	63.8^{a,A}	64.4^{a,A}
Fruit	69.2^{a,A}	65.4^{a,A}	76.6^{a,A}	73.3^{a,A}
Foods rich in semi-hydrolyzed starch	59.6^{a,A}	67.3^{a,A}	57.4^{a,A}	55.5^{a,A}
Sugar-free foods	75.0^{a,A}	69.2^{a,A}	63.9^{a,A}	57.8^{a,A}

FIGURES

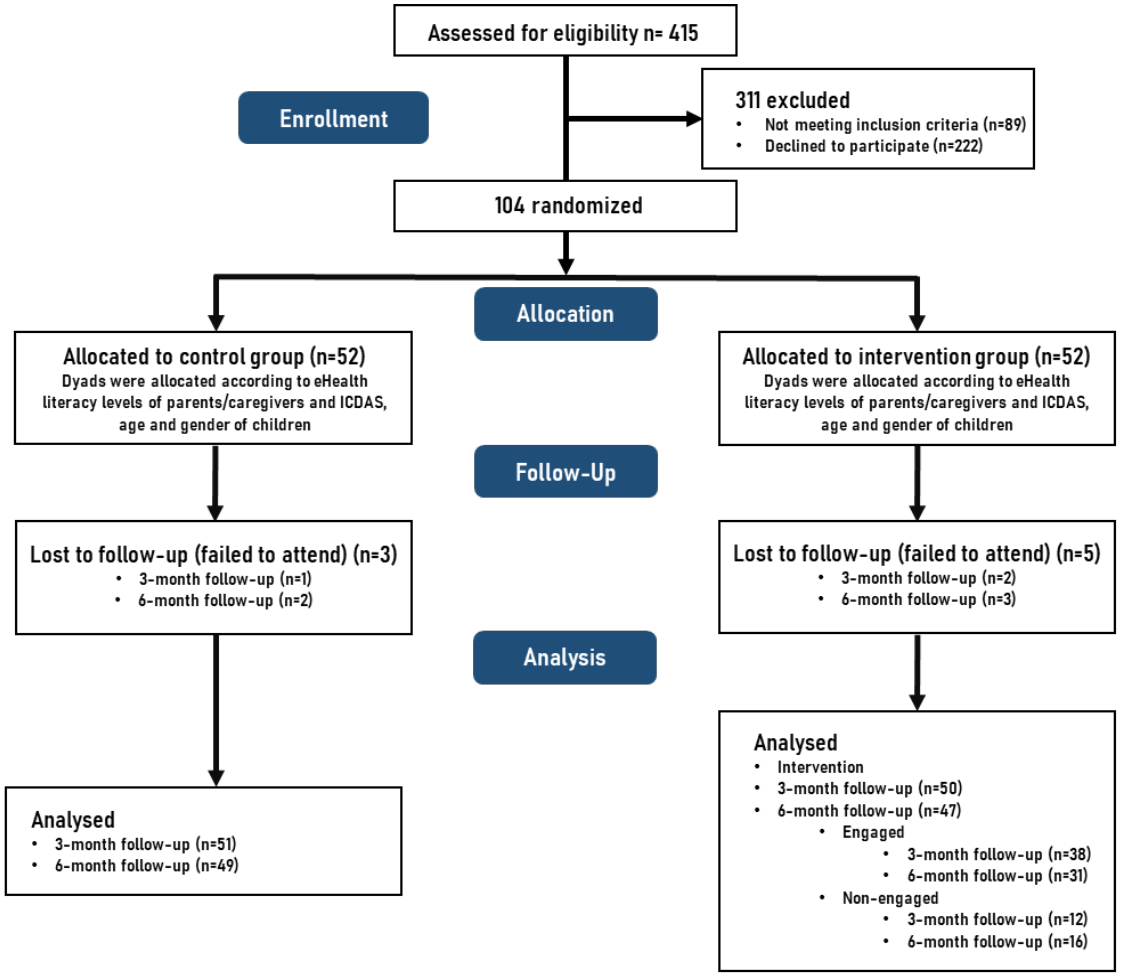

Figure 1. Flow diagram

3 DISCUSSÃO

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Esse capítulo é apresentado em formato de considerações finais, como segue:

1. Os interesses dos pais ou responsáveis que emergiram durante os grupos focais foram associados a seus conhecimentos, dúvidas, crenças e atitudes relacionadas à CPI.

2. As principais dúvidas e crenças relacionavam-se a alimentação, uso de dentifrício, higiene bucal, erupção dentária e desenvolvimento da doença, incluindo o uso de antibióticos e genética como fatores etiológicos para a CPI.

3. O papel de medidas para o manejo da doença, como higiene bucal adequada e baixo consumo de alimentos ricos em açúcar, foi comumente reconhecido pelos familiares como importante para se alcançar melhores resultados em saúde. Entretanto, devido às dúvidas, crenças e dificuldades encontradas durante suas rotinas diárias, as atitudes contra a doença mostraram-se imprecisas.

4. A falta de engajamento dos pais com o controle da CPI enfatiza a importância de modelos participativos, como cuidado centrado na criança e na família, para obtenção de melhores resultados em saúde.

5. As dúvidas apresentadas pelos participantes podem nortear a construção de protocolos clínicos e estratégias eficazes em saúde, para preencher lacunas emergidas diretamente dos grupos interessados.

6. O envio de mensagens de texto educacionais com conteúdos relacionados a CPI para os pais não se mostrou clinicamente eficaz para o controle da doença em crianças em vulnerabilidade social.

7. O consumo das mensagens eletrônicas aumentou siginificativamente os níveis de alfabetismo em saúde eletrônica dos pais engajados. Embora os resultados sejam derivados da auto-percepção dos participantes, podem ser considerados um parâmetro de melhoria da experiência do consumo de informação em saúde na Internet.

8. O consumo das mensagens eletrônicas parece ter influenciado o nível de preocupação dos pais em relatar o aumento do consumo de doces sem açúcar por seus filhos, o que pode indicar um entendimento diferente do intuito das mensagens relacionadas à dieta. Tal divergência pode ser explicada pelo baixo nível de alfabetismo em saúde eletrônica dos participantes do estudo.

9. Apesar de apresentar uma eficácia limitada, este estudo mostrou a viabilidade do uso de estratégias de saúde móvel para desfechos em Odontopediatria. Além disso, pode servir como base para o desenvolvimento de futuros estudos clínicos randomizados, com foco em diferentes populações e tempos de acompanhamento.

10. A abordagem apresentada neste estudo abre possibilidades para o desenvolvimento de mensagens personalizadas, centradas nas necessidades individuais da criança e de sua família; proporcionando treinamento e capacitação aos pais ou responsáveis para tomadas de decisão adequadas relacionadas à saúde bucal de seus filhos.

11. O envio de mensagens educacionais é importante para que os pais tenham uma fonte confiável de informações relacionadas à saúde bucal da criança, elucidando dúvidas e crenças que possam surgir do consumo inadvertido de desinformações.

12. Em teoria, o envio de mensagens eletrônicas pelo cirurgião-dentista pode contribuir para estimular os pais a serem mais ativos na busca por informações em saúde bucal relacionada à criança, mantendo contato direto com o profissional. Entretanto, novos estudos devem ser realizados para a confirmação desta hipótese.

4 CONCLUSÃO

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Baseado nestes resultados, podemos concluir que:

- Pais e cuidadores entendem os efeitos desfavoráveis da CPI na qualidade de vida das crianças. No entanto, as atitudes contra a doença são imprecisas, influenciadas por rotinas diárias, dúvidas e crenças. Tais achados indicam a importância do desenvolvimento de modelos participativos de atenção à saúde.

- Mensagens de texto educativas orientadas aos pais não foram eficazes para impedir a progressão da CPI em pré-escolares em vulnerabilidade socioeconômica, embora pareçam benéficas para aumentar os níveis de alfabetismo em saúde eletrônica dos pais e a preocupação em ingestão de doces sem açúcar pelas crianças, principalmente entre os pais ou cuidadores envolvidos com a intervenção.

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REFERÊNCIAS

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APÊNDICE

APÊNDICE A – Tabela de apresentação das mensagens de texto enviadas aos pais ou responsáveis durante o estudo clínico randomizado

Data	Mensagem	Visualizada	Não visualizada
13/09/2019	Você sabia que crianças podem ter cárie? Desde o nascimento dos primeiros dentes devemos realizar a escovação e evitar o consumo excessivo de açúcares para evitarmos esta doença. Mesmo em dentes de leite, a cárie pode causar dor, problemas na alimentação, perda do dente e consequência para a dentição permanente. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie e sempre que tiver dúvidas procure seu cirurgião-dentista.	**44**	**8**
27/09/2019	Qual escova e pasta de dentes devo utilizar para escovar os dentes do meu filho ou da minha filha? Crianças em idade pré-escolar devem escovar os dentes com uma escova com a cabeça pequena, já que as escovas para adultos são muito grandes e podem machucar a criança durante a escovação. No caso da pasta de dente, evite usar aquelas que tem sabor de frutas, porque a criança vai querer engolir. Utilize a mesma pasta de dentes que você usa para escovar os seus dentes. Apenas tome o cuidado de usar uma quantidade pequena de pasta, igual ao do tamanho de um grão de arroz cru, como você pode ver na imagem abaixo. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas as vezes que você tiver dúvidas sobre a saúde	**41**	**11**

	bucal de sua família, procure um dentista.		
11/10/2019	Quantas vezes durante o dia eu devo escovar os dentes e passar o fio dental? O ideal é escovarmos os dentes das crianças pelo menos duas vezes ao dia: quando a criança acordar e antes de dormir. A escovação antes de dormir é muito importante, pois durante a noite, a nossa boca produz menos saliva, que é responsável por ajudar na autolimpeza dos dentes. Por causa disso, o risco para desenvolver cárie dentária é maior durante à noite. Passar o fio dental pelo menos uma vez ao dia é também muito importante para prevenir a cárie, porque a escova não consegue limpar entre os dentes. Lembre-se: a prevenção é o melhor caminho para a saúde dos dentes. Todas as vezes que você tiver alguma dúvida, procure um dentista.	**41**	**11**
25/10/2019	O fato do meu filho ou minha filha tomar antibiótico fará com que ele, ou ela tenha cárie? A resposta é não. A cárie está relacionada a falta de higiene bucal e ao consumo excessivo de açúcares. A utilização de antibióticos do tipo Tetraciclina no momento da formação dentária pode ocasionar uma coloração acastanhada nos dentes. Entretanto, apesar da mudança de cor, esses dentes não sofrem alteração em sua estrutura, ou seja, o uso desses antibióticos não irá estragar, enfraquecer ou causar cárie nos dentes. Além disso, sabendo desse problema estético, atualmente os pediatras evitam o uso de Tetraciclina em pacientes infantis. Lembre-se: a prevenção é o melhor caminho para a saúde dos dentes. Todas às vezes que você tiver	**40**	**12**

	alguma dúvida, procure um dentista.		
08/11/2019	A cárie dentária tem algum envolvimento genético? Não. O fato dos pais da criança apresentarem histórico de cárie, não fará com que ela desenvolva cárie. A prevenção da cárie está relacionada a hábitos bucais e alimentares saudáveis. Se em algum momento os pais forem diagnosticados com cárie, será por causa da ausência de higiene bucal, aliada ao consumo excessivo de açúcares. Dessa forma, se a criança possuir esses mesmos hábitos, possivelmente também desenvolverá esta doença. Lembre-se: a prevenção é o melhor caminho para a saúde dos dentes. Todas às vezes que você tiver alguma dúvida, procure um dentista.	**38**	**14**
22/11/2019	Qual é a quantidade adequada de açúcar que meu filho ou filha pode comer durante o dia? A recomendação da Organização Mundial da Saúde é reduzir o consumo de açúcares para menos de 10% de todas a calorias consumidas durante um dia. Além disso, devemos evitar o consumo de doces em vários períodos do dia, priorizando os períodos após as principais refeições, como o almoço e o jantar. A diminuição do consumo de açúcares é importante para evitar a cárie dentária e outras doenças, como obesidade e diabetes. Lembre-se: a prevenção é o melhor caminho para a saúde dos dentes. Todas às vezes que você tiver alguma dúvida, procure um dentista.	**38**	**14**

06/12/2019	A pasta de dente que eu uso para escovar os dentes do meu filho ou minha filha deve conter flúor? Sim. O flúor incorporado nas pastas age na superfície do dente quando escovamos, ajudando a prevenir a cárie dentária. Por isso, seu uso é muito importante. Entretanto, devemos observar a quantidade de pasta de dente que colocamos para escovar os dentes das crianças, evitando que elas consumam uma quantidade de flúor maior do que a recomendada. A quantidade ideal de pasta com flúor que devemos utilizar para escovar os dentes das crianças deve ser equivalente a um grão de arroz cru. O flúor na quantidade correta acarretará somente benefícios ao seu filho. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas as vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**36**	**14**
20/12/2019	Meu filho ou minha filha escova os dentes e passa o fio dental sozinho (a), isso é um problema? Sim. Crianças menores de 10 anos ainda não tem sua parte motora desenvolvida completamente e assim apresentam dificuldade para realizar a higiene bucal de maneira adequada. Dessa forma, a higienização dessas crianças sempre deve ser supervisionada por um adulto, que complementará a escovação dentária e a passagem do fio dental nas áreas em que a criança não conseguir limpar satisfatoriamente. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas às vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**34**	**16**

03/01/2020	A cárie dentária se desenvolve igualmente em adultos e crianças? Sim. A cárie é causada pela ação de bactérias que decompõe alimentos açucarados da nossa dieta, o que produz ácidos capazes de dissolver o esmalte dos dentes. Essas bactérias que se organizam em forma de placa bacteriana e se aderem aos dentes, podem ser removidas com a escovação dentária e o uso do fio dental. Por isso, devemos limitar o consumo de açúcares e higienizar os dentes das crianças regularmente. Outros fatores como genética e a utilização de antibióticos não causam e nem ajudam a causar a cárie. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas às vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**34**	**16**
17/01/2020	A cárie dentária em dentes de leite prejudica a saúde dos dentes permanentes? Sim. A evolução da cárie dentária em dentes de leite causa dor, dificuldades para a criança se alimentar, e até a perda do dente antes do período correto. Esses fatores podem ocasionar problemas no desenvolvimento e nascimento dos dentes permanentes, afetando a saúde bucal e qualidade de vida da criança. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas às vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**34**	**16**

31/01/2020	De quanto em quanto tempo devo levar meu filho ou minha filha no dentista? A frequência de atendimentos será baseada nas necessidades individuas da criança e essas serão estabelecidas pelo cirurgião-dentista na primeira consulta. De modo geral, recomenda-se levar as crianças para um atendimento odontológico a cada 6 meses. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas às vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**34**	**16**
14/02/2020	Meu filho ou minha filha deve usar enxaguante bucal para prevenir a cárie? Não. Por mais que os enxaguantes sejam mais uma opção para a higienização bucal, o seu uso deve ser restrito a crianças com alto risco de desenvolver cárie dentária e somente com indicação de um dentista. Vale lembrar que a utilização de enxaguantes bucais nunca substitui a escovação dentária e o uso de fio dental. Além disso, crianças menores de 7 anos podem acabar engolindo o produto enquanto usam, podendo gerar prejuízos nos dentes permanentes, como a Fluorose. A melhor maneira de prevenir a cárie é reduzir o consumo de açúcares, além de passar o fio dental e escovar os dentes com frequência. Lembre-se que a prevenção é o meio mais fácil para evitar a cárie. E todas às vezes que você tiver dúvidas sobre a saúde bucal de sua família, procure um dentista.	**33**	**17**
28/02/2020	Como a cárie está relacionada a alimentos com açúcar, devemos	**32**	**18**

controlar a frequência e quantidade de doces que as crianças consomem; principalmente aqueles que se mantem muito tempo em contato com os dentes, como balas, pirulitos ou chupeta adoçada com mel ou açúcar. Da mesma forma, o consumo prolongado de mamadeira ou copos com bico contendo bebidas adoçadas, tais como, Leite com açúcar ou Nescau, Mucilon, Neston, Farinha Lactea ou Sucos e refrigerantes não são recomendados durante o dia ou a noite. Todas essas bebidas devem ser consumidas no copo (sem bico) e no horário das refeições. E lembre-se os dentes devem ser escovados duas vezes ao dia com pasta contendo flúor.

ANEXOS

ANEXO A – Parecer consubstanciado do Comite de Ética em Pesquisa (CEP) da Faculdade de Odontologia de Bauru autorizando a execução da pesquisa – Parte 1

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Estudo clínico randomizado: avaliação da efetividade de um aplicativo para celulares como um auxiliar na prevenção da cárie precoce da infância

Pesquisador: MATHEUS LOTTO DE ALMEIDA SOUZA

Área Temática:

Versão: 3

CAAE: 90563618.6.0000.5417

Instituição Proponente: Universidade de São Paulo - Faculdade de Odontologia de Bauru

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.909.483

Apresentação do Projeto:

Idem parecer 2.820.893

Objetivo da Pesquisa:

Idem parecer 2.820.893

Avaliação dos Riscos e Benefícios:

Idem parecer 2.820.893

Comentários e Considerações sobre a Pesquisa:

Idem parecer 2.820.893

Considerações sobre os Termos de apresentação obrigatória:

Idem parecer 2.820.893

Recomendações:

Sem recomendações. As alterações sugeridas foram acatadas pelo pesquisador.

Conclusões ou Pendências e Lista de Inadequações:

Sugiro aprovação.

Considerações Finais a critério do CEP:

Esse projeto foi considerado APROVADO na reunião ordinária do CEP de 19/09/2018, com base nas normas éticas da Resolução CNS 466/12. Ao término da pesquisa o CEP-FOB/USP exige a

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Telefone: (14)3235-8356 **Fax:** (14)3235-8356 **E-mail:** cep@fob.usp.br

ANEXO B – Parecer consubstanciado do Comite de Ética em Pesquisa (CEP) da Faculdade de Odontologia de Bauru autorizando a execução da pesquisa – Parte 2

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.909.483

apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1102046.pdf	30/08/2018 20:40:51		Aceito
Outros	Resposta_ao_parecer_CEP.pdf	30/08/2018 20:40:18	MATHEUS LOTTO DE ALMEIDA	Aceito
Outros	aquiescencia.pdf	30/08/2018 20:31:02	MATHEUS LOTTO DE ALMEIDA	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_Matheus_Mestrado_CEP.pdf	13/07/2018 12:05:12	MATHEUS LOTTO DE ALMEIDA SOUZA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Estudo_Clinico.pdf	13/07/2018 12:02:25	MATHEUS LOTTO DE ALMEIDA SOUZA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Grupos_Focais.pdf	13/07/2018 12:02:15	MATHEUS LOTTO DE ALMEIDA SOUZA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termo_de_Assentimento_Matheus.pdf	23/05/2018 20:51:09	MATHEUS LOTTO DE ALMEIDA SOUZA	Aceito
Outros	Declaracao_de_compromisso.pdf	23/05/2018 20:46:32	MATHEUS LOTTO DE ALMEIDA	Aceito
Outros	Carta_de_encaminhamento.pdf	23/05/2018 20:39:48	MATHEUS LOTTO DE ALMEIDA	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Assentimento.pdf	23/05/2018 20:33:48	MATHEUS LOTTO DE ALMEIDA SOUZA	Aceito
Declaração de Pesquisadores	Questionario_Pesquisador_CEP.pdf	23/05/2018 20:20:42	MATHEUS LOTTO DE ALMEIDA	Aceito
Folha de Rosto	Folha_de_rosto.pdf	23/05/2018 20:19:49	MATHEUS LOTTO DE ALMEIDA	Aceito

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ANEXO C – Parecer consubstanciado do Comite de Ética em Pesquisa (CEP) da Faculdade de Odontologia de Bauru autorizando a execução da pesquisa – Parte 3

USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP

Continuação do Parecer: 2.909.483

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

BAURU, 21 de Setembro de 2018

Assinado por:
Ana Lúcia Pompéia Fraga de Almeida
(Coordenador(a))

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ANEXO D – Termo de Concentimento Livre e Esclarecido (TCLE) da fase 1 do estudo – Parte 1

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva
Área Departamental de Odontopediatria

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Convidamos o(a) senhor(a) a participar como voluntário(a) da pesquisa "Estudo clínico randomizado: avaliação da efetividade de um aplicativo para celulares como um auxiliar na prevenção da cárie precoce da infância", de responsabilidade de Matheus Lotto de Almeida Souza. Após ser esclarecido(a) sobre as informações a seguir, no caso de aceitar o convite, assine no final do documento, que está escrito em duas vias, sendo uma via sua e a outra via do pesquisador responsável. O(A) senhor(a) poderá recusar-se a participar da pesquisa ou retirar seu consentimento livre e esclarecido em qualquer fase da pesquisa, sem nenhum prejuízo para o(a) senhor(a) ou para seu filho(a).

Os pesquisadores irão avaliar se a utilização do WhattsApp auxilia na prevenção da cárie de mamadeira. Isso é importante para nos ajudar a entender as principais dúvidas das pessoas para prevenir a cárie nos dentes de bebês e crianças pequenas. Isso vai nos ajudar a diminuir o número de casos dessa doença. O(A) senhor(a) vai ser convidado(a) a participar de reuniões sobre a cárie de mamadeira. Nesse grupo, você e outros pais receberão informações sobre a doença, podendo tirar suas dúvidas e falar suas possíveis preocupações. As reuniões serão gravadas para que os pesquisadores desenvolvam um material que será enviado pelo WhattsApp, para ajudar os pais de outras crianças a prevenirem a cárie na boca dos filhos deles. As reuniões acontecerão até que todas as dúvidas sejam resolvidas.

O(A) senhor(a) poderá ficar estressado e cansado pela demora da discussão em grupo, além de poder ficar envergonhado por não conseguir responder alguma das questões propostas. Para diminuir e/ou evitar esses sentimentos, as reuniões serão orientadas por um dentista, sendo realizadas em uma sala fechada e com ar condicionado e cadeiras confortáveis para você sentar. Qualquer informação dita na reunião não será informada a ninguém. O(A) senhor(a) poderá sair da pesquisa a qualquer momento e por qualquer motivo. Todos os seus dados pessoais e respostas serão confidenciais, sendo garantido o sigilo de sua participação na pesquisa.

Após as reuniões, o(a) senhor(a) será informado(a) sobre as informações que desenvolvemos para serem utilizadas no WhattsApp. Isso poderá auxiliá-lo(a) a observar a importância de sua participação no grupo e como isso poderá ajudar outros pais.

O(A) senhor(a) não receberá nenhum tipo de benefício financeiro para participar da pesquisa. As entrevistas serão realizadas durante o atendimento de seu filho(a) na Clínica de Odontopediatria, portanto, em dias que o(a) senhor(a) necessitar comparecer à clínica como acompanhante. Nesse caso, as despesas com transporte e alimentação serão de sua própria responsabilidade. Excepcionalmente, quando for necessário que o(a) senhor(a) compareça na Clínica de Odontopediatria apenas para participar da pesquisa, seus gastos com transporte e alimentação serão ressarcidos. Caso lhe aconteça algum dano decorrente de sua participação nesta pesquisa, é lhe assegurado o direito à indenização.

Caso o(a) senhor(a) aceite participar da pesquisa, os pesquisadores não poderão garantir o seu atendimento clínico odontológico. Seu filho(a) continuará sendo atendido(a) normalmente na Clínica de Odontopediatria, até a conclusão do tratamento curativo e preventivo.

O(A) senhor(a) receberá uma cópia do presente termo onde contém o nome, telefone e endereço eletrônico do pesquisador responsável, para que o(a) senhor(a) possa localizá-lo a qualquer tempo. Seu nome é Matheus Lotto de Almeida Souza, mestrando da disciplina de Odontopediatria. Em caso de dúvidas sobre a execução da pesquisa, o telefone para o contato com o pesquisador responsável é (14) 99796-4853. Para contatá-lo via e-mail, o endereço eletrônico é matheus.lotto.souza@gmail.com. Em caso de dúvidas em relação ao envolvimento ético da pesquisa, entre em contato com o Comitê de Ética em Pesquisa em Seres Humanos da FOB-USP pelo telefone (14) 3235-8356, ou via e-mail: cep@fob.usp.br.

Pelo presente instrumento que atende às exigências legais, o Sr. (a) _____, portador da cédula de identidade _____, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente dos serviços e procedimentos aos quais será submetido, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Art. 9º do Código de Ética Odontológica).

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável:

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: dep-oosc@usp.br – Fone (0xx14) 3235-8224 / 3235-8318 - Fax (0xx14) 3223-4679
http://www.fob.usp.br

ANEXO E – Termo de Concentimento Livre e Esclarecido (TCLE) da fase 1 do estudo – Parte 2

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva
Área Departamental de Odontopediatria

Por fim, como pesquisador(a) responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e item IV.5.a e na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o sujeito da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, SP, _____ de _____ de _____.

_____ _____
Assinatura do Sujeito da Pesquisa Matheus Lotto de Almeida Souza
Pesquisador Responsável

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:
Comitê de Ética em Pesquisa
Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **13h30 às 17 horas**, em dias úteis.
Alameda Dr. Octávio Pinheiro Brisolla, 9-75
Vila Universitária – Bauru – SP – CEP 17012-901
Telefone/FAX(14)3235-8356
e-mail: cep@fob.usp.br

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável:

ANEXO F – Termo de Concentimento Livre e Esclarecido (TCLE) da fase 2 do estudo – Parte 1

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva
Área Departamental de Odontopediatria

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Convidamos o(a) senhor(a) a participar como voluntário(a) da pesquisa "Estudo clínico randomizado: avaliação da efetividade de um aplicativo para celulares como um auxiliar na prevenção da cárie precoce da infância", de responsabilidade de Matheus Lotto de Almeida Souza. Após ser esclarecido(a) sobre as informações a seguir, no caso de aceitar o convite, assine no final do documento, que está escrito em duas vias, sendo uma via sua e a outra via do pesquisador responsável. O(A) senhor(a) poderá recusar-se a participar da pesquisa ou retirar seu consentimento livre e esclarecido em qualquer fase da pesquisa, sem nenhum prejuízo para o(a) senhor(a) ou para o(a) seu(ua) filho(a).

Os pesquisadores irão avaliar se a utilização do WhattsApp auxilia na prevenção da cárie de mamadeira. Isso é importante para nos ajudar a entender as principais dúvidas das pessoas para prevenir a cárie nos dentes de bebês e crianças pequenas. Isso vai poder nos ajudar a diminuir o número de casos dessa doença. O(A) senhor(a) vai ser convidado(a) a aceitar que os pesquisadores enviem mensagens sobre saúde bucal para o seu celular a cada quinze dias, através do WhattsApp. Além disso, seu filho(a) passará por uma avaliação de saúde bucal na escola, a cada 3 meses, pelo período de um ano.

O(A) senhor(a) poderá ficar irritado ou estressado devido ao recebimento das mensagens. Para diminuir e/ou evitar estes sentimentos, garantimos que as mensagens só serão recebidas a cada 15 dias. O(A) senhor(a) poderá solicitar a paralisação do recebimento das mensagens a qualquer momento e por qualquer motivo. Todos os seus dados pessoais e respostas serão confidenciais, sendo garantido o sigilo de sua participação na pesquisa.

Após os procedimentos de avaliação do seu filho, o(a) senhor(a) será informado(a) se a saúde bucal dele melhorou. Isso poderá auxiliá-lo(a) a observar a importância da sua participação na pesquisa e como o envio de mensagens também poderá auxiliar outros pais a prevenir a doença.

O(A) senhor(a) não receberá nenhum tipo de benefício financeiro para participar da pesquisa. Excepcionalmente, quando for necessário que o(a) senhor(a) compareça na escola apenas para participar da pesquisa, seus gastos com transporte e alimentação serão ressarcidos. Caso lhe aconteça algum dano decorrente de sua participação nesta pesquisa, é lhe assegurado o direito à indenização.

Caso o(a) senhor(a) aceite participar da pesquisa, os pesquisadores não poderão garantir o seu atendimento clínico odontológico. Seu filho(a) continuará sendo atendido(a) normalmente na escola, até a conclusão do tratamento curativo e preventivo.

(A) senhor(a) receberá uma cópia do presente termo onde contém o nome, telefone e endereço eletrônico do pesquisador responsável, para que o(a) senhor(a) possa localizá-lo a qualquer tempo. Seu nome é Matheus Lotto de Almeida Souza, mestrando da disciplina de Odontopediatria. Em caso de dúvidas sobre a execução da pesquisa, o telefone para o contato com o pesquisador responsável é (14) 99796-4853. Para contatá-lo via e-mail, o endereço eletrônico é matheus.lotto.souza@gmail.com. Em caso de dúvidas em relação ao envolvimento ético da pesquisa, entre em contato com o Comitê de Ética em Pesquisa em Seres Humanos da FOB-USP pelo telefone (14) 3235-8356, ou via e-mail: cep@fob.usp.br.

Pelo presente instrumento que atende às exigências legais, o Sr. (a) _____, portador da cédula de identidade _____, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, ciente dos serviços e procedimentos aos quais será submetido, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Art. 9º do Código de Ética Odontológica).

Por fim, como pesquisador(a) responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e item IV.5.a e na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o sujeito da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável:

Al. Dr. Octávio Pinheiro Brisolla, 9-75 – Bauru-SP – CEP 17012-901 – C.P. 73
e-mail: dep-oosc@usp.br – Fone (0xx14) 3235-8224 / 3235-8318 - Fax (0xx14) 3223-4679
http://www.fob.usp.br

ANEXO G – Termo de Concentimento Livre e Esclarecido (TCLE) da fase 2 do estudo – Parte 2

Universidade de São Paulo
Faculdade de Odontologia de Bauru

Departamento de Odontopediatria, Ortodontia e Saúde Coletiva
Área Departamental de Odontopediatria

Bauru, SP, _____ de _____ de _____.

_____ _____
Assinatura do Sujeito da Pesquisa Matheus Lotto de Almeida Souza
Pesquisador Responsável

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

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Comitê de Ética em Pesquisa
Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **13h30 às 17 horas**, em dias úteis.
Alameda Dr. Octávio Pinheiro Brisolla, 9-75
Vila Universitária – Bauru – SP – CEP 17012-901
Telefone/FAX(14)3235-8356
e-mail: cep@fob.usp.br

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável: