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Kamilla França

Condição de Saúde Bucal em Crianças com Complexidade Médica Domiciliadas

*Oral Health Condition in Children with Medical Complexity in
Home Care Services*

Dissertação apresentada à Faculdade de Odontologia da Universidade Federal de Uberlândia, como requisito parcial para obtenção do Título de Mestre em Odontologia na Área de Clínica Odontológica Integrada.

Uberlândia, 2021

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Orientadora: Prof^a. Dr^a. Ana Paula Turrioni

Banca Examinadora:

Prof^a. Dr^a. Ana Paula Turrioni

Prof. Dr. Alessandra Maia de Castro Prado

Prof^a. Dr^a. Daniela Prócida Raggio

Uberlândia, 2021



UNIVERSIDADE FEDERAL DE UBERLÂNDIA
 Coordenação do Programa de Pós-Graduação em Odontologia
 Av. Pará, 1720, Bloco 4L, Anexo B, Sala 35 - Bairro Umarama, Uberlândia-MG, CEP 38400-902
 Telefone: (34) 3225-8115/8108 - www.ppgoufu.com - copod@umarama.ufu.br



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DEDICATÓRIA

Dedico este trabalho aos amores da minha vida:

Minha mãe, minhas irmãs e meus amigos.

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*Viva como se fosse morrer amanhã.
Aprenda como se fosse viver para sempre.
Mahatma Ghandi*

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Resumo

RESUMO

As Crianças com Complexidade Médica Domiciliadas (CCMD) apresentam multipatologias e o uso de polifármacos. O comprometimento sistêmico desses pacientes pediátricos requer suporte de uma equipe multiprofissional, sendo relevante a abordagem em saúde bucal visto a inter-relação com a saúde sistêmica. A atenção domiciliar em saúde bucal melhora o acesso aos serviços de odontologia, e deve enfatizar a prevenção, promoção e cuidados em saúde bucal que tenham impacto na melhora da saúde como um todo. O objetivo do estudo foi avaliar a saúde bucal das CCMD, bem como os hábitos de dieta e higiene bucal realizados pelos cuidadores. Além de verificar a composição de saliva e placa dentária e suas possíveis correlações com a saúde bucal ou sistêmica. Um estudo transversal foi realizado com 56 CCMD. Os cuidadores responderam a um questionário sobre diagnóstico da doença, história clínica, história dentária e rotina de higiene bucal. Além do exame clínico, amostras de saliva e placa dentária foram coletados e analisados por espectroscopia de infravermelho com transformada de Fourier. foram utilizadas as análises descritivas e bivariadas, e os testes de correlação t de Student e Kendall. Após análise dos dados, pôde-se concluir que: 1- parte significativa das CCMD apresentou higiene oral deficiente, cálculo dentário, gengivite, e hiperplasia gengival; 2- existe correlação entre cálculo dentário, gengivite, e hiperplasia gengival, tanto com o uso de anticonvulsivante quanto com a alimentação por gastrostomia; 3- as CCMD apresentaram alterações orais, as quais carecem de acompanhamento odontológico regular; 4 - existem diferenças na composição salivar e na placa bacteriana entre CCMD e crianças saudáveis; 5- os níveis de CO₂ da placa e saliva estiveram correlacionados com a presença de cálculo e hiperplasia gengival.

Palavras-Chave: Serviços de Assistência Domiciliar, Higiene bucal, Saúde bucal, Saliva, Placa dentária, Odontopediatria, Crianças com deficiência.

Abstract

ABSTRACT

Children with Medical Complexity in Home Care Services (CMCHC) have multiple pathologies and present the use of multiple drugs. The systemic commitment of these pediatric patients requires the support of a multi-professional team, being relevant the approach in oral health, giving the close link with the systemic health. Home care in oral health improves access to dental services and should emphasize prevention, promotion, and oral health care that have a positive impact on systemic health. The objective of the study was to evaluate the oral health of CMCHC, as well as the diet habits and oral hygiene performed by caregivers. Additionally, the saliva and dental plaque composition were evaluated considering their possible correlation with oral or systemic health. A cross-sectional study was performed with 56 CMCHC. The caregivers answered a questionnaire about disease diagnosis, clinical history, dental history, and oral hygiene routine. Besides the clinical examination, saliva and dental plaque samples were collected and analyzed by infrared spectroscopy with Fourier transform. Descriptive and bivariate analyses were used, as well as t-Student and Kendall's correlation tests. It could be concluded that: 1- a significant part of the CMCHC presented poor oral hygiene, dental calculus, gingivitis, and gingival hyperplasia; 2- there was a correlation between dental calculus, gingivitis, and gingival hyperplasia, both with the use of antiepileptics and gastrostomy feeding; 3- the CMCHC presented oral alterations, which lack regular dental follow-up; 4- there are differences in salivary and dental plaque composition between CMCHC and healthy children; 5- the CO₂ levels of saliva and dental plaque were correlated with the presence of calculus and gingival hyperplasia.

Keywords: Home Care Services, Oral hygiene, Oral health, Saliva, Dental plaque, Pediatric dentistry, Children with disabilities.

Introdução e Referencial teórico

1. INTRODUÇÃO E REFERENCIAL TEÓRICO

As crianças com complexidade médica (CCM) sob cuidados em âmbito domiciliar têm como características clínicas a presença de multipatologias, estando estas, muitas vezes, em estágio avançado, e ainda fazem o uso de polifármacos.¹ Apresentam dependência de tecnologias para a manutenção da vida, dependência funcional, demandando cuidados diários por parte do cuidador e também da equipe.^{1,2} As CCM fazem parte do grupo de pessoas com deficiência, e embora representem uma pequena fração da população pediátrica, suas demandas em saúde, alto nível de gastos com saúde, e complexidades sistêmica de difícil tratamento torna esse um grupo importante.²

O atendimento domiciliar em saúde conta com uma equipe multiprofissional, a qual trabalha em rede para a promoção em saúde, prevenção de agravos, tratamento de doenças e reabilitação, sendo estes processos realizados em ambiente domiciliar.³ Por estar o paciente em âmbito familiar, o conjunto paciente-cuidador-família goza de autonomia na gerência do cuidado, o que impõe a equipe de saúde um olhar ampliado para garantir a integralidade do cuidado. O principal responsável pelo cuidado do paciente domiciliado é a Equipe Multiprofissional de Atenção Domiciliar (EMAD).⁴ A composição mínima dessa equipe deve conter: médico, enfermeiro, técnico de enfermagem, profissionais de fisioterapia e/ou de assistência social. Tendo ainda uma equipe multiprofissional de apoio (EMAP) com composição mínima de três profissionais de nível superior. O cirurgião dentista pode fazer parte da EMAP, contudo sua participação tem caráter complementar e não obrigatório.⁴

A atenção domiciliar em saúde bucal amplia o acesso das CCM à promoção, prevenção e procedimentos curativos em saúde bucal.⁵ Sendo o cuidador aquele que dispõe de maior tempo junto ao paciente, o impacto da educação em saúde bucal para o cuidador na saúde da criança tende a ser o mais expressivo. As práticas de educação em saúde bucal precisam ser emancipatórias, orientadas para promover autonomia do paciente-cuidador-família.⁶ No domicílio, além da promoção e prevenção é possível realizar procedimentos curativos, reduzindo a necessidade de deslocamento do paciente

ao consultório odontológico.⁷ Por ser um paciente em uso de tecnologias para a manutenção da vida, o acesso a serviços de saúde externos a residência é dificultado devido a frequente necessidade de mobilizar a equipe de saúde e de uma unidade móvel com equipamentos básicos para manter a estabilidade do paciente.⁷

A saúde sistêmica é indissociável da saúde bucal, sendo relevante os cuidados em saúde bucal quando se pensa em promover saúde para as CCM.⁸ A perda de dentes está associada com uma maior mortalidade e piora da qualidade de vida do indivíduo.⁹ A saliva é um espelho dos metabólicos sistêmicos, e junto com o fluido gengival e a placa dental desempenha papel fundamental na manutenção da saúde bucal.¹⁰ Doenças bucais podem predispor a pessoa a doenças crônicas levando a internações hospitalares evitáveis, e também podem afetar a alimentação, a fala, e a qualidade de vida.¹¹ A doença periodontal está associada com doenças cardiovasculares, diabetes, psoríase, artrite reumatóide, alterações na gravidez e doenças respiratórias, sendo o tratamento periodontal um meio efetivo para redução desses agravos.¹²

Portanto, são necessários estudos que avaliem a condição da saúde bucal das crianças com complexidade médica domiciliadas (CCMD), bem como os hábitos de higiene bucal realizados por seus cuidadores, e verificar possíveis correlações entre os fatores da saúde sistêmica e da saúde bucal com a composição de saliva e placa dentária, tendo em vista os aspectos mencionados anteriormente para melhor orientar o cuidado em saúde bucal de crianças desse grupo.

Capítulos

1. CAPÍTULO 1

ARTIGO 1

Oral Health Status of Children Who Require In-Home Medical Care

***Artigo aceito para publicação no Journal of Dentistry for Children, em 13 de agosto de 2020.**

Oral Health Status of Children Who Require In-Home Medical Care

Kamilla França, DDS¹

Merielle Rezende Batista, DDS²

Camila Maria Bullio Fragelli, PhD³

Álex Moreira Herval, DDS, MS, PhD⁴

Luiz Renato Paranhos, DDS, MS, PhD⁵

Robinson Sabino da Silva, DDS, MS, PhD⁶

Priscilla Barbosa Ferreira Soares, DDS, MS PhD⁷

Ana Paula Turrioni, DDS, MS, PhD⁸

¹França and ²Dr. Batista are graduate students, School of Dentistry, Federal University of Uberlândia, Uberlândia, MG, Brazil.

³ Dr. Fragelli is a graduate student, Department of Orthodontics and Children's Clinic, School of Dentistry of Araraquara – São Paulo State University (UNESP), Araraquara, SP, Brazil.

Drs. ⁴Herval and ⁵Paranhos are assistant professors, Department of Community and Preventive Dentistry, ⁷Dr. Soares is assistant professor, Department of Periodontics, and Dr. Turrioni⁸ is assistant professor, Department of Pediatric Dentistry, all in the School of Dentistry, and ⁶Dr. da Silva is assistant professor, Department of Morphology, Physiological Sciences, and Pathology Institute of Biomedical Sciences, , all at the Federal University of Uberlândia, Uberlândia, Minas Gerais, Brazil

Correspond with Dr. Turrioni at apturrioni@ufu.br

ABSTRACT

Purpose: To evaluate the oral health status of children who require in-home medical care their oral hygiene and eating habits, and the association between oral health status and general medical conditions.

Methods: Legal guardians of children who need in-home medical care were interviewed regarding their socioeconomic level and their children's medical and dental history, and oral hygiene habits. An oral exam assessed the children's plaque level, caries experience, and periodontal disease. Descriptive and bivariate analyses were performed.

Results: Fifty-six children participated. Almost 61 percent had never received dental care and 58.9 percent had fair or poor oral hygiene. The most observed oral problems were gingival hyperplasia (46.4 percent), calculus (46.4 percent), and gingivitis (30.3 percent). The use of anticonvulsants and type of food were factors that correlated to calculus, gingivitis, or hyperplasia ($P < 0.05$).

Conclusions: A significant number of children who require in-home medical care presented with deficient oral hygiene and periodontal problems, which were correlated with the use of anticonvulsants and gastrostomy feeding.

KEYWORDS: HOME CARE, ORAL HYGIENE, PEDIATRIC DENTISTRY, CHILDREN WITH DISABILITIES

Patients with systemic health issues may have nutritional problems, decreased salivary flow and reduced ability to protect oral structures, consequently leading to the development of dental caries and periodontal disease.¹⁻³ This process occurs because compromising systemic health triggers an imbalance in the oral microbiota, impairing its essential functions, such as being a barrier against pathogenic microorganisms, modulation of the immune system and degradation of toxic substances.^{2,3} Oral problems can trigger complications, such as cardiovascular disease, endocarditis, alterations in blood glucose levels and respiratory infections, worsening the systemic condition.⁴

Oral health care in patients with systemic disorders increases their quality of life.⁵ For example, routine dental care and good oral hygiene reduce respiratory tract infections.⁶ Studies using molecular biology have shown the association between dental plaque pathogens and incidence of pneumonia in hospitalized and immunocompromised individuals.⁷⁻⁹ Measures to prevent the colonization of respiratory pathogenic microorganisms, such as the use of toothbrushes¹⁰⁻¹² and mouthwashes,¹³⁻¹⁵ help improve the patient's respiratory status. Oral health is also affected by drugs, which often interfere with periodontal tissue.¹⁶ Drug-induced gingival overgrowth elevates the risk of infection and inflammatory complications and hinders oral hygiene.¹⁶ Furthermore, medications and nutritional problems may result in a decrease in salivary flow, decreasing protection against caries and periodontal disease.¹⁷

Although several studies have reported the importance of oral care for patients with health problems and the need for daily care, little data exist on children who require in-home medical care. The purpose of this study was to evaluate the oral health status of children who require in-home medical care, their oral hygiene habits, and the association between their oral health status and systemic health.

METHODS

The cross-sectional study was approved by the Human Research Ethics Committee at the Federal University of Uberlandia, Uberlandia, Minas Gerais, Brazil (protocol number 63903416.0.0000.5152).

The study population was children cared by the Multi-Professional Home Care Team (**EMAD**) of the hospital of the Federal University of Uberlandia, which is responsible for patients in the city of Uberlandia. A dental professional was not part of the team, and the study data were acquired by a dental professional through a project linked to the school of dentistry at the university. In 2017, 119 adult and child patients were monitored by the EMAD. The data were collected from January 2017 to December 2017.

A convenience sample was determined considering inclusion criteria applied to children who needed in-home care. Inclusion criteria were children who in primary or mixed dentition who lived in Uberlandia, and required in-home medical care by the EMAD team. Patients who were not being followed by the EMAD team, who did not live in the city and who had permanent dentition only were excluded.

A single examiner interviewed the legal guardians regarding their child's medical history, dental history, and eating habits. They were asked about the main diagnosis, use of medication, and use of ventilatory support. Patients were classified according to their main diagnosis, following the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10)¹⁸ (1 for nervous system, 2 for circulatory system, 3 for respiratory system, and 4 for congenital malformations, deformations, and

chromosomal abnormalities). Additionally, these children may have multiple comorbidities associated with their main diagnosis. The comorbidities were divided into 1 (changes in the digestive system); 2(diseases of the blood); 3 (respiratory system); 4 (genitourinary system); and 5 (ear, nose and throat system). Regarding dental history, the frequency of dental follow-up, frequency of oral hygiene, method used for oral hygiene, type of toothpaste used, frequency of flossing, and use of mouthwashes were evaluated. Nutritional information was collected using the food frequency questionnaire by Hinnig et al.¹⁹ Data on the caregivers' sex, age, education, and income were also collected

A clinical exam was done to assess the children's plaque level, caries experience, and periodontal disease. Two calibrated examiners performed the clinical evaluations on a stretcher, using a flashlight. The Simplified Oral Hygiene Index (**OHI-S**) to evaluate dental plaque level was used.²⁰ A score between zero and 1.5 represented good oral hygiene, from 1.6 to 2.5 was considered fair, and 2.6 or greater was poor. The decayed, missing, and filled permanent teeth (DMFT) and decayed, missing, and filled primary teeth (dmft) indices were calculated, according to the World Health Organization criteria.²¹ The children were also evaluated for gingival hyperplasia, dental calculus, enamel spots without cavitation, gingival bleeding on brushing, and alterations in the mucosa and dental morphology.

The data were tabulated and analyzed using the SPSS 18.0 software (IBM Corp., Armonk, NY, USA). The data were analyzed descriptively, identifying the means and standard deviations or relative and absolute frequencies, according to the type of variable under analysis. The variables of medical and dietary history that showed the highest frequencies were included in the bivariate analysis, and the outcome was the variable of oral condition. Spearman's correlation coefficient and contingency coefficient C were used for this analysis. Correlations statistically significant were confirmed assessing the power of test (**PT**) for cross-sectional studies.

RESULTS

All 56 children monitored by EMAD participated in the study, with 41 boys (73.2 percent). The participants' ages ranged between four and 14 years, with a mean of 6.3 years (standard deviation [SD]: ± 2.1 years). There were 41 boys (73.2 percent). The age distribution included 21 children aged four to six years old (37.5 percent), 15 children seven to nine years old (26.8 percent), 18 children 10 to 12 years old (32.1 percent), and two children 13 to 14 years old (3.6 percent). Most caregivers were women (N 54, 96.4 percent) between 34 to 44 years (N = 29; 51.8 percent). As for education, 64.2 percent (N = 36) had completed high school, 28.5 percent (N 16) had higher education, and 7.1 percent (N four) had a vocational education (high school level). Regarding family income, 82.1 percent (N 46) received up to US \$497.38 per month, 14.3 percent (N equals eight) between US \$497.38 and US \$746.07, and 3.6 percent (N equals two) received at least US \$994.79, according to the Brazilian minimum monthly wage values at the time.

The most prevalent main diagnosis (Table 1) concerned the nervous system (N 31, 55.3 percent). Regarding the associated comorbidities, 21.4 percent (N equals 12) of patients presented only one comorbidity and 31 patients (55.3 percent) had two or more. The most common comorbidity was related to the digestive system (44.6 percent, Table 1). The most frequent medication was anticonvulsants - sodium valproate, carbamazepine, phenytoin and phenobarbital (N 30; 53.6 percent). Seventy-five percent of the children had an exclusively gastrostomy tube.

Table 2 shows the means and standard deviations of the food groups represented in portions per day and grams consumed by the participants. The foods with the highest average were infant formula (287.2 g per day ± 33.4 SD), milk and dairy products (172.4 g per day ± 20.4), and fruits (150.1 g per day ± 23.1).

Most caregivers performed oral hygiene for their children once a day or more (N 45; 80.4 percent), sometimes or less than once a day (N 6; 10.7 percent), or never (N 5; 8.9 percent). As for toothbrushing method, 64.3 percent (N 36) used a manual toothbrush, 26.7 percent (N 15) used gauze, 12.5 percent (N 7) used dental floss, and 62.6 percent (N

35) used a toothpaste with more than 1,000 ppm of fluoride. Thirty-four children (60.7 percent) had never received dental care. Only 41.1 percent (N 23) had good oral hygiene, 30.4 percent (N 17) had fair oral hygiene, and 28.5 percent (N 16) had poor oral hygiene. There was a low caries experience overall (DMFT 0.28 ± 0.08 and dmft 0.08 ± 0.10), and 41.1 percent (N 23) had an enamel stain, and 3.5 percent had alterations in the oral mucosa, such as aphthous ulcers and coated tongue. Forty-six percent (N 26) had calculus, 30.3 percent (N 17) presented bleeding during toothbrushing, and 46.4 percent (N 26) had hyperplastic gingiva. The Kappa intra- and inter-examiner reliability scores were 0.85.

Table 3 shows the results of the bivariate analysis between the oral health condition and systemic issues. The OHI-S outcome variable did not show statistically significant correlations with the independent variables analyzed. Furthermore, the variables corresponding to oral hygiene habits and diet did not present a significant correlation to the oral changes found. The presence of dental calculus was correlated to the use of anticonvulsants (*Correlation coefficient [C]*=0.474; *P*<0.001; Power of Test [PT] 62.1 percent), digestive system alterations (*C*=0.424; *P*=0.024; PT 46.3 percent), gastrostomy feeding (*C*=0.501; *P*=0.000; PT 96.5 percent), and respiratory system alterations (*C*=0.385; *P*=0.049; PT 2.5 percent). For gingivitis, there was a statistically significant correlation with the use of anticonvulsants (*C*=0.430; *P*=0.027; PT 61.5 percent), invasive mechanical ventilation (*C*=0.459; *P*=0.035; PT_{a/bc} 25.8 percent; PT_{b/ac} 2.5 percent), and gastrostomy feeding (*C*=0.453; *P*=0.016; PT 97.9 percent). Gingival hyperplasia showed a statistically significant correlation with the presence of nervous system alterations (*C*=0.414; *P*=0.005; PT 70.3 percent), with the use of anticonvulsants (*C*=0.508; *P*<0.001; PT 76.4 percent), and gastrostomy feeding (*C*=0.453; *P*=0.016; PT 97.9 percent).

DISCUSSION

Optimal oral hygiene, especially in hospitalized patients or those with systemic diseases, prevents complications resulting from the use of mechanical ventilation or tracheostomy.^{13,21}

The main result of this study was a correlation between dental calculus, gingivitis, and gingival hyperplasia with the use of anticonvulsants and gastrostomy feeding. Furthermore, the children presented poor oral hygiene overall, low frequency of flossing and lack of dental care. Optimal oral hygiene, especially in hospitalized patients or those with systemic diseases, prevents complications resulting from the use of mechanical ventilation or tracheostomy, such as respiratory diseases.^{13,21}

The high prevalence of anticonvulsant use may be explained by the characteristics of the sample that mainly include nervous system disorders, such as convulsions and epileptic seizures. The phenytoin used by the patients in this study isolated or in association with other anticonvulsants have a known correlation with gingival hyperplasia,^{22,23} which was reinforced by the present study in CMCHM. Phenobarbital, sodium valproate and carbamazepine are not supported in the literature to cause gingival hyperplasia.

In hospitalized adult patients, dental calculus and tracheostomy ventilation have shown a positive correlation with the development of pneumonia.²⁴ This is because calculus and tracheostomy act as reservoirs of bacteria with the potential to colonize the lower airways.²⁴ These data reinforce the importance of dental care in preventing complications from the use of mechanical ventilation.¹

The consumption of healthy foods in this cohort was high, which may be explained by the presence of the nutritionist in the multidisciplinary team. However, there was clear consumption of foods rich in sucrose, even in patients whose only food route was gastrostomy. According to the caregivers, sugary foods were used to help in times of constipation and/or support of normal intestinal flow.²⁵⁻⁻²⁷ It is important to highlight that all patients who had a gastrostomy (53.6%) were fed exclusively via the g-tube.

It is not surprising that the patients had a low caries experience because their diet, although high in sucrose, was given directly into the gastrostomy tube bypassing the oral cavity. The same effect was observed in the study by Hidas et al.,²⁸ in which hospitalized children fed by gastrostomy had no caries experience. Similarly, the study by Cardona-Soria et al.²⁹ evaluating children with cerebral palsy showed that patients with gastrostomy have a reduced caries experience but a high prevalence of periodontal

disease. However, these patients showed high levels of biofilm accumulation, gingivitis, and dental calculus. The justification could be related to functional dependence, absent or deficient chewing and self-cleaning movements, complexity of the patient's general health status, drug use and salivary composition alteration.^{4,16,30,31} Additionally, due to difficulties in care, caregivers who lack knowledge or guidance may not perform oral hygiene care efficiently.³²

The lack of access to dental care and oral hygiene by the children included in the study is concerning. These patients present calculus, gingival hyperplasia, gingivitis, functional dependence, and systemic complications. Mainly, the lack of oral hygiene reduces the elimination of microorganisms, which may lead respiratory diseases through the aspiration of saliva.^{16,28, 33-35} Therefore, it is crucial to educate not only caregivers but also physicians and nurses about the importance of oral care. Thus, the participation of the oral health professional in comprehensive health care is important to prevent respiratory and oral problems that will affect the patient's quality of life negatively.³⁶ As there was no oral health professional in the current multiprofessional team caring for the patients in this study, an oral health team composed of dental faculty, dental students and graduate students was established.

Caregivers' socioeconomic status and perceptions of oral health may influence their children's access to dental services and the children's oral health.³⁷ In addition to that, it is known that a higher level of knowledge about oral health by caregivers has a positive impact on the oral health of their children.³² The caregivers in this study had the low level of education and low socioeconomic status, which certainly affect the understanding of the importance of good oral health care for their children.^{32,37}

The present study is not without limitations. The small sample size and the sampling process may have interfered with data inference. However, the authors calculated the PT of variables with correlation to statistical significance, which makes the interpretation of the results clearer. Another limitation concerns the cross-sectional study design, which does not allow for determining cause-effect.

CONCLUSIONS

Based on the results of this study, the following conclusions can be made:

1. A significant number of children who require in-home medical care presented with deficient oral hygiene, dental calculus, gingivitis, and gingival hyperplasia.
2. A correlation between dental calculus, gingivitis, and gingival hyperplasia was evidenced by the use of anticonvulsants (phenytoin) and gastrostomy feeding.

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Table 1. Medical History Data of the Sample by Sex

	Male		Female		Total	
	N	%	N	%	N	%
Main diagnosis						
Nervous system	19	33.9	12	21.4	31	55.3
Circulatory system	4	7.1	1	1.8	5	8.9
Respiratory system	10	17.8	1	1.8	11	19.6
Congenital malformations, deformations and chromosomal abnormalities	8	14.4	1	1.8	9	16.2
Associated comorbidities						
Diseases of the blood	6	10.7	7	12.5	13	23.2
Respiratory system	9	16.0	2	3.6	11	19.6
Genitourinary system	5	8.9	3	5.4	8	14.3
Digestive system	18	32.1	7	12.5	25	44.6
Otorhinolaryngological	5	8.9	8	14.3	13	23.2
Types of ventilation						
Invasive mechanical ventilation	18	32.2	12	21.4	30	53.6
Oxygen therapy	17	30.3	2	3.6	19	33.9
None	6	10.7	1	1.8	7	12.5
Feeding mechanism						
Gastrostomy	30	53.6	12	21.4	42	75.0
Oral	11	19.6	3	5.4	14	25.0
Drugs						
Anticonvulsant	18	32.2	12	21.4	30	53.6
Vitamin	17	30.3	4	7.2	21	37.5
Laxative	10	17.8	9	16.1	19	33.9
Antiulcer	8	14.2	7	12.5	15	26.7
Bronchodilator	6	10.7	6	10.7	12	21.4
Anxiolytic	11	19.3	1	2.1	12	21.4
Antihypertensive	6	10.7	4	7.1	10	17.8
Muscle relaxant	8	14.4	1	1.8	9	16.2

Antibiotic	2	3.6	3	5.3	5	8.9
Anti-inflammatory	4	7.1	1	1.8	5	8.9
Other medicines	9	16.2	1	1.8	10	17.9

Table 2. Food Groups Consumed by Sample in Portions Per Day and Grams Per Day

Food groups	Portions per day		Grams per day	
	Average	±Standard deviation	Average	±Standard deviation
Fruits	2.8	±0.8	150.1	±23.1
Cereals, bread, and pastas	2.5	±0.5	140.0	±10.2
Milk and derivatives	3.1	±0.2	172.4	±20.4
Vegetables	1.7	±0.3	65.4	±10.5
Beans and grains	2.1	±0.3	94.1	±25.6
Infant formula	5.5	±1.1	287.2	±33.4
Sweets	0.3	±0.1	4.5	±1.1
Meats	2.2	±0.6	90.4	±12.3

Table 3. Correlations Between Systemic Issues and Medications and Calculus, Gingivitis, and Gingival Overgrowth

	Calculus			Gingivitis			Gingival Overgrowth		
	N (%)		Correlation	N (%)		Correlation	N (%)		Correlation/P
	Yes	No	/P-value	Yes	No	/P-value	Yes	No	-value
Nervous system									
Yes	20 (35.71)	11 (19.64)	0.294	13 (23.21)	18 (32.14)	0.213	21 (37.50)	10 (17.85)	0.414*
No	10 (17.85)	15 (26.78)	<i>P</i> =0.067	10 (17.85)	15 (26.78)	<i>P</i> =0.199	5 (8.92)	20 (35.71)	<i>P</i>=0.005
Anticonvulsant									
Yes	22 (39.28)	8 (14.28)	0.474	19 (33.92)	11 (19.64)	0.430	24 (42.28)	6 (10.71)	0.508
No	7 (12.50)	19 (33.92)	<i>P</i>=0.000	5 (8.92)	21(37.50)	<i>P</i>=0.027	6 (10.71)	20 (35.71)	<i>P</i>=0.000
Antiulcer									
Yes	7 (12.50)	8 (14.28)	0.163	6 (10.71)	9 (16.07)	0.192	8 (14.28)	7 (12.50)	0.100
No	20 (35.71)	21 (37.50)	<i>P</i> =0.347	13 (23.21)	27 (48.21)	<i>P</i> =0.308	19 (33.92)	22 (39.28)	<i>P</i> =0.540
Laxative									
Yes	11 (19.64)	8 (14.28)	0.014	5 (8.92)	14 (25.00)	0.120	9 (16.07)	10 (17.85)	0.043
No	17 (30.35)	20 (35.71)	<i>P</i> =1.000	16 (28.57)	21 (37.50)	<i>P</i> =0.482	16 (28.57)	21 (37.50)	<i>P</i> =1.000
Vitamin									
Yes	10 (17.85)	11 (19.64)	0.018	4 (7.14)	17 (30.35)	0.123	10 (17.85)	11 (19.64)	0.054
No	17 (30.35)	18 (32.14)	<i>P</i> =1.000	14 (25.00)	22 (39.28)	<i>P</i> =0.512	16 (28.57)	19 (33.92)	<i>P</i> =0.761

Type of ventilation

None	6 (10.71)	1 (1.78)		2 (3.57)	5 (8.92)		1 (1.78)	6 (10.71)	
Oxygen therapy	8 (14.28)	11 (19.64)	0.262	16 (28.57)	3 (5.35)	0.459	5 (8.92)	14 (25.00)	0.306
Mechanical ventilation	15 (26.78)	15 (26.78)	<i>P</i> =0.244	15 (26.78)	15 (26.78)	<i>P</i>=0.035	15 (26.78)	15 (26.78)	<i>P</i> =0.119

Gastric change

Yes	20 (35.71)	5 (8.92)	0.424	15 (26.78)	10 (17.85)	0.258	17 (30.35)	9 (16.07)	0.391
No	8 (14.28)	23 (41.07)	<i>P</i>=0.024	11 (19.64)	20 (35.71)	<i>P</i> =0.43	11 (19.64)	20 (35.71)	<i>P</i> =0.073

Respiratory change

Yes	9 (16.07)	2 (3.57)	0.385	6 (10.71)	5 (8.92)	0.213	6 (10.71)	5 (8.92)	0.213
No	10 (17.85)	35 (62.50)	<i>P</i>=0.049	20 (35.71)	25 (44.64)	<i>P</i> =0.625	22 (39.28)	23 (41.07)	<i>P</i> =0.625

Feeding mechanism

Oral	1 (1.78)	13 (23.21)	0.501	1 (1.78)	13 (23.21)	0.453	1 (1.78)	13 (23.21)	0.453
Gastrostomy	32 (56.14)	10 (17.85)	<i>P</i>=0.000	33 (58.92)	9 (16.07)	<i>P</i>=0.016	33 (58.92)	9 (16.07)	<i>P</i>=0.016

* Bolded values represent correlation with statistical significance.

2. CAPÍTULO 2

ARTIGO 2

Oral Health and Salivary and Dental Plaque Composition in Children with Medical Complexity Who Require in Home Medical Care: A Cross Sectional Investigation

***Artigo a ser enviado para o periódico INTERNATIONAL JOURNAL OF PAEDIATRIC DENTISTRY**

Oral health, saliva and dental plaque in Children with Medical Complexity

Student - Kamilla França - França K - kamillafranca@gmail.com¹

Student - Guilherme Telini Cintra - Cintra GT - guilhermetc2000@hotmail.com¹

Student - Léia Cardoso de Sousa - Cardoso-Sousa L - leiacardosos92@gmail.com²

Prof. Dr. Álex Moreira Herval - Herval AM - alexmherval@gmail.com³

Prof. Dr. Robinson Sabino da Silva - Sabino-Silva R - robinsonsabino@gmail.com²

Prof^a. Dr^a. Ana Paula Turrioni - Turrioni AP- apturrioni@ufu.br¹

¹ Department of Pediatric Dentistry, School of Dentistry, Federal University of Uberlândia, Uberlândia, MG, Brazil.

² Institute of Biomedical Sciences, Departments of Morphology, Physiological Sciences, and Pathology, Federal University of Uberlândia, Uberlândia, MG, Brazil.

³ Department of Community and Preventive Dentistry, School of Dentistry, Federal University of Uberlândia, Uberlândia, MG, Brazil.

CORRESPONDING AUTHOR:

Prof^a. Dr^a. Ana Paula Turrioni - Turrioni A.P

Department of Pediatric Dentistry, School of Dentistry, Federal University of Uberlândia, Uberlândia, MG, Brazil.

Av. Pará 1720, Umuarama.

ZIP code: 38400902, Uberlândia, MG, Brazil

E-mail: apturrioni@ufu.br

Telephone number: +55-16-3301-64

Oral Health and Salivary and Dental Plaque Composition in Children with Medical Complexity Who Require in Home Medical Care: A Cross Sectional Investigation

SUMMARY

Background: The data on oral health of children with medical complexity who require in home medical care (CMCHM), are scarce even with the confirmed impact of oral health deficiency on systemic health. **Aim:** To assess the oral health of CMCHM, compare salivary and dental plaque (DP) composition between CMCHM and control group (CG), and correlate with oral and general health factors. **Design:** This cross-sectional study was performed with 56 CMCHM. The caregivers answered a questionnaire on disease diagnosis, medical history, dental history, and oral hygiene routine. Besides the clinical examination, saliva and DP were collected and analyzed by Fourier transform infrared spectroscopy. The Student t and Kendall correlation tests were used. **Results:** It was observed a prevalence of gingival hyperplasia (46.4%). As for salivary composition, it was observed that CMCHM presented a higher amount of lipids and collagen and a lower amount of CO₂ and carbohydrates than the group of CG ($p < 0.05$). The CO₂ in saliva and DP presented a positive correlation to the presence of calculus and gingival hyperplasia. **Conclusions:** The CMCHM presented oral comorbidities. There was a difference in salivary and DP composition between CMCHM and CG, and this composition was correlated to calculus and hyperplasia.

Keywords: Home care services; Oral health; Saliva; Dental plaque; Children with disabilities.

INTRODUCTION

It is estimated that 13 million children between 0 and 14 years old have severe disabilities and require special health care ¹. Some of them are considered high complexity for presenting a high degree of functional dependence, which makes caregivers responsible for feeding, mobility, administering medication, and especially performing body and oral hygiene ². Home care services is an alternative for monitoring and promoting health care, adapting to the needs of these patients and their family members ³.

Oral health in home care aims to prevent and monitor oral problems using regular clinical examinations, anticipatory instructions, and curative treatment when required, to contribute to the establishment of general health and encourage caregivers regarding oral hygiene ^{2,3}. The data on oral health of children with medical complexity who require in home medical care (CMCHM) are scarce even with the confirmed impact of oral health deficiency on systemic health ⁴. Molecular biology can prove the association between the pathogens in dental plaque and the incidence of pneumonia in hospitalized and immunocompromised individuals ⁵.

Oral problems may cause systemic complications and have been associated with cardiovascular diseases, endocarditis, change in glycemic levels, and respiratory infections. They may also aggravate the general health condition and increase comorbidities in patients ⁴. Oral health is obtained and maintained by factors that extrapolate the functional condition of teeth and stomatognathic structures, and the clinical status of oral health is related to the quality of life and levels of biological and psychosocial functions in children ⁶.

Systemic changes are common in CMCHM and, similar to oral changes, they can lead to changes in the microbiota and the concentrations of proteins, inorganic compounds, and salivary flow ⁷. It is known that dental plaque plays a direct role in the demineralization-remineralization process and the composition of oral microflora ⁸. Children with carious lesions have shown dental plaque with lower concentrations of inorganic components ⁹. Moreover, the influence of the type of organism composing dental plaque on the occurrence of nosocomial pneumonia in lung disease patients has stood out, considering it serves as a

pathogen reservoir that may colonize the respiratory system ¹⁰.

Dental plaque accumulation and an increased number of microorganisms in saliva may be expected when there is a low salivary secretion rate ¹¹. Saliva is used for disease diagnosis, prognosis, and follow-up. Tests using this type of fluid are considered non-invasive, practical, and low-cost, serving for diagnosing systemic syndromes and disorders ¹². Moreover, salivary biomarkers have been studied for the diagnosis and prognosis of oral diseases such as periodontitis ¹³.

The CMCHM may present specific salivary and dental plaque changes when compared to a control group of healthy patients, and such changes may be correlated to the oral and systemic conditions of these patients. Thus, this study hypothesizes that CMCHM present high indexes of oral problems and biochemical changes in saliva and dental plaque when compared to a control group and that there is a correlation between the variables related to oral health and the ones related to salivary and plaque composition. Therefore, this study aims to assess the oral health of CMCHM, compare salivary and dental plaque (DP) composition between CMCHM and control group (CG), and correlate oral and general health factors of CMCHM to salivary and DP composition.

MATERIAL AND METHODS

Study design and ethical aspects

This is a cross-sectional observational study developed with CMCHM (n=56). From these total, it was possible to collect data on salivary and dental plaque composition in 31 CMCHM. Those data were compared to a control group - CG (n=15) and correlated to the oral and general health data. The project was approved by the Human Research Ethics Committee of the local institution (Approval protocol: 63903416.0.0000.5152). The data were collected only after obtaining informed consent from the children's caregivers.

Study context

The study was performed with CMCHM assisted at a public home care service. This service consists of multidisciplinary teams (physicians, nurses, nutritionists, physiotherapists, physical education professionals, social workers,

nursing technicians, and administrative assistants) who care for dehospitalization patients. The teams are complemented by dental professionals through an extension project linked to the University. The data were collected between January and December 2018.

Study participants

The study all included children in high medical complexity care assisted regularly by a multi-professional team of the public home care service, in the age group of 4 to 14 years (n=56), whose legal guardians had signed written consent. There was no sample loss, which may be attributed to the close follow-up of patients and family members performed by the multi-professional team. Therefore, the entire universe of children in this condition residing in the city selected for the study was assessed for medical and dental history and oral health conditions.

For the analysis of salivary and dental plaque composition, the sample collection was possible for only 31 out of the 56 patients. Besides these, 15 patients from the control group were included. This group consisted of children with average age and sex ratio similar to the CMCHM, who did not use medications regularly, were not diagnosed with general or oral health morbidities, and were healthy from medical and dental (absence of dental caries, visible dental biofilm, calculus, gingival hyperplasia, and periodontal disease) standpoints. The patients from the control group were selected in appointments at the Pediatric Dentistry Prevention Clinic of the School of Dentistry of the Federal University of Uberlândia (UFU), MG, Brazil. It is worth noting that the sample size used in the present analysis agrees with previous studies published, which assessed salivary samples of non-disabled patients or with medical complexity, focusing on oral diseases ^{14,15}.

Data measuring

Saliva and dental plaque collection

The patients provided unstimulated saliva, which was collected between 2 and 5 p.m., reducing the influence of the circadian rhythm. Moreover, the collection took place at least two hours after the last meal or oral hygiene. The

salivary material was collected with an individual sterile rectal probe (discarded at the end of the procedure) on the floor of the tongue in the oral cavity. The probe was coupled to an electric and portable low-power secretion aspirator (Aspiramax MA 520, NS, São Paulo, Brazil) so that one end was in contact with the oral cavity of the patient and the other end was inside a 15-mL Falcon tube, preventing the contamination of the sample collected. During saliva collection and transport, the 15-mL Falcon tubes were maintained cooled. The collection occurred until obtaining 2 mL of fluid without surpassing 15 minutes of collection time per patient. The samples were centrifuged at 10,000 rpm for 10 minutes at 4°C. The supernatant was stored in a freezer at -80°C until processing.

The dental plaque was collected from the buccal surfaces of permanent first molars and deciduous second molars using a dental explorer and the material collected was transferred to Eppendorfs with deionized water and stored in a freezer at -80°C until processing.

For analyzing saliva and dental plaque, the Fourier transform infrared spectrometer (FTIR) was applied to regions with an electromagnetic spectrum between 4000 cm^{-1} and 400 cm^{-1} . This technique allowed identifying with high accuracy the C-H, O-H, and N-H protein terminations, lipid composition, and glycidic compounds. A portion of 2 μL of saliva and dental plaque was applied on the FTIR crystal and dried for two minutes and 30 seconds, then the sample spectra were acquired. All analyses were performed in triplicate. Thirty-two scans were performed to obtain the profile of each sample with a resolution of 4 cm^{-1} .

Medical and dental history and clinical oral examination

A single researcher collected data regarding disease diagnosis, medical history, dental history, and oral hygiene routine, through the report of caregivers. The following variables were collected regarding medical history: medical diagnosis - Patients were classified according to their main diagnosis, following the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) (1 for nervous system, 2 for circulatory system, 3 for respiratory system, and 4 for congenital malformations, deformations, and chromosomal abnormalities), type of ventilation and feeding,

and list of medications used. As for dental history, frequency of oral hygiene, the method used for oral hygiene, type of dentifrice used, and frequency of dental floss use were assessed.

Oral hygiene was assessed using the Simplified Oral Hygiene Index (OHI-S). The scores from the OHI-S, which mean result ranges from 0 to 3, were categorized. Means between 0 and 1.5 indicated good oral hygiene, between 1.6 and 2.5 indicated regular oral hygiene, and higher than 2.6 indicated poor oral hygiene. Such assessment occurred before the dental professional performed oral hygiene in the children.

After obtaining the OHI-S, the professional performed oral hygiene with a manual toothbrush, fluoridated dentifrice, and gauze. The other clinical assessments involved the variables of decayed, missing, and filled teeth index (DMFT) for the permanent dentition, and for the deciduous dentition (dmft), calculus (presence or absence), gingival hyperplasia (presence or absence), intrinsic stains (presence or absence), gingival bleeding during toothbrushing (presence or absence), mucosal changes (presence or absence), and changes in the dental morphology (presence or absence) were assessed. For the examination, an oral mirror #5 (Golgran, São Caetano do Sul, SP, Brazil) and a WHO probe (Golgran, São Caetano do Sul, SP, Brazil) were used, both previously sterilized.

Two previously calibrated examiners performed the OHI-S and DMFT/dmft indexes and assessed the other clinical oral characteristics, at home, aided by ambient light and a flashlight. (Kappa intra- and inter-examiners > 0.85). All participants and caregivers were instructed on oral hygiene care according to age group and the oral health problems mentioned were treated in the extension project in home pediatric dentistry.

Statistical analysis

The data were computed in spreadsheets and levels were attributed to scores for all variables-answers studied to allow a quantitative analysis in the statistical software SPSS, version 18.0. After verifying normal data distribution, the Student t-test was used to compare the group of CG versus CMCHM, and

the Kendall correlation test was used to verify potential associations between the variables of salivary and DP composition and the variables of the oral and general health of the sample. The spectra obtained in the analysis of saliva and DP in FTIR were normalized by the vector method and, later, the baseline was corrected. The mean profile and band areas were obtained with the Opus 6.5 software (Bruker Optics, Reinstetten, Germany) and the original data were plotted in the Origin Pro 9.0 software (OriginLab, Northampton, MA, USA) for a detailed analysis.

RESULTS

Regarding age, 21 (37.5%) children were in the age group of 4 to 6 years, 15 (26.8%) from 7 to 9 years, 18 (32.1%) from 10 to 12 years, and two (3.6%) from 13 to 14 years, with a prevalence of the male sex (n=41; 73.2%). The changes in nervous system was the most prevalent type of medical diagnosis (n=31; 55.3%). As for the use of medications, the most frequent ones were antiepileptics (n=30; 53.5%). Table 1 presents the general characteristics of children in high complexity care included in the study, oral hygiene habits, and oral health conditions of this population.

Regarding oral hygiene habits, it was observed that most children performed oral hygiene once a day or more (n=45; 80.4%) and used a manual toothbrush (n=36; 64.3%). Most children in high complexity care had never used dental floss (n=49; 87.5%) and 35 (62.6%) children used fluoridated dentifrice with more than 1000 ppm of fluorine. A great portion of the children (n=34; 60.7%) had never had a dental follow-up.

The classification obtained by the OHI-S showed that 33 children (58.9%) presented regular or poor oral hygiene. As for oral diseases, low caries experience was found (dmft 0.08 ± 0.10 and DMFT 0.28 ± 0.08).

Table 2 shows the values found for each representative peak of the molecular groups assessed by FTIR in the saliva and DP samples.

The data presented in Table 2 regarding salivary composition showed that patients in high complexity care presented a higher amount of lipids and collagen and a lower amount of CO₂ and carbohydrates than the group of healthy patients

($p < 0.05$). The other peaks did not present a statistical difference between both groups ($p > 0.05$).

As for DP composition, it was observed that CMCHM presented a higher amount of CO_2 than the group of CG ($p < 0.05$). The other peaks did not present a statistical difference between both groups ($p > 0.05$).

Figure 1 shows that the molecular groups in saliva with a significant statistical difference in the absorption range between the groups of CG and CMCHM were lipids, CO_2 , collagen, and carbohydrates.

Table 3 shows the correlation values between the variables studied.

There was a moderate positive correlation between the CO_2 of DP and the presence of changes in nervous system, frequency of oral hygiene, and calculus. The CO_2 of saliva showed a weak positive correlation to changes in nervous system and the presence of gingival hyperplasia and a moderate positive correlation to the frequency of oral hygiene. The collagen in saliva presented a weak positive correlation with neuronal deficiency and the use of antiepileptics. The other independent variables and salivary and DP components did not present significant correlations.

DISCUSSION

Saliva and DP are two components whose analysis becomes important when there is a need for establishing relationships between the general and oral health status of individuals^{12,16}. Saliva is the representation of systemic metabolites and is used for diagnosing several diseases¹². DP defines oral microbiota and works in the demineralization-rem mineralization process of dental structures.^{8,16} The results of the present study provide a significant contribution to establish preventive and/or curative measures for the oral health of CMCHM, considering they present the prevalence of oral diseases and changes in salivary and DP composition, which were correlated to changes in general or oral health.

The low caries experience found in CMCHM were expected because most children were fed by gastrostomy tube and this may have reflected in the reduction of salivary carbohydrate in these children. One of the possible explanations may be related to the lower concentration of salivary CO_2 , which

produces higher alkalinity in the medium. Saliva with basic pH is associated with caries protection and a higher calcification of DP ¹⁷. The sample studied also presented a high prevalence of gingival bleeding and hyperplasia, and the increase in lipids observed in the saliva samples of CMCHM may be associated with periodontal disease. In the literature, lipids are linked to oxidative stress and inflammatory mediation ¹⁸, which reinforces their potential relationship with the development of pathologies in the periodontal region. Regarding DP composition, there were no possible changes associated with periodontal problems but the high levels of supragingival plaque and calculus are related to progressive periodontal disease ¹⁹. In the CMCHM group studied, a significant portion of the sample presented calculus and OHI-S indicating moderate or poor oral hygiene.

The highest prevalence of calculus and gingivitis (Bleeding on toothbrushing) observed in CMCHM is concerning because this change is associated with chronic obstructive pulmonary disease ²⁰. Moreover, the periodontal problem and DP in CMCHM may resonate systemically, increasing the risk of aspiration pneumonia, especially in children with enteral nutrition and respiratory problems ²¹. The control of supragingival and subgingival plaque in this group forms the base for the treatment of periodontal disease and it may contribute to reducing systemic comorbidities.

The increase in CO₂ in the DP of CMCHM indicates a favorable environment for the proliferation of anaerobic bacteria, which are associated with periodontal disease and the increased risk of mortality by aspiration pneumonia ^{8,10}. The highest frequency of oral hygiene in this study was associated with the reduction of CO₂ in DP, suggesting that the disarray in plaque favors CO₂ removal. It is worth noting that this study did not assess the microbiota of CMCHM, whereas the literature reports that elderly patients who use enteral nutrition presented an increase in pathogenic bacteria ²². Moreover, other factors (e.g., systemic factors) interfere with salivary and dental plaque composition ¹⁸, hence further research is required for explaining the changes in salivary and dental plaque composition that are related to the oral condition or the physiological condition of the body.

Regarding sex, there is a high association between male sex and the risk

of major morbidities in the first years of life, especially in low-weight premature babies ²³. Furthermore, changes in nervous system linked to chromosome x, considering that recessive sex-linked inheritance transmitted by female carriers ultimately affects the male sex, contributes to greater involvement of diseases in this group ²⁴. These factors may justify the higher rate of male CMCHM (n=41; 73.2%) observed in this study. The higher frequency of changes in nervous system as a diagnosis for the CMCHM studied exposes the challenging work of dentists, who need to educate and care for children with different types of nervous impairment. The study showed a high level of respiratory support and gastrostomy use, which compromises the self-care of these children, making caregivers determinant factors for achieving oral health ²⁵. Dental professionals must make an effort to educate the family, especially caregivers, regarding habits that interfere with the general and oral health of the child.

Considering the complexity of the systemic condition and the daily demands of patients in home care, caregivers often find it difficult to perform tasks such as oral hygiene and diet control ²⁶. Education directed to oral hygiene is a prevention tool in public health, and when instructed and followed-up by an oral health professional, prevents the appearance of diseases, painful processes, and tooth loss ²⁷. It is, therefore, the responsibility of oral health professionals to encourage caregivers and educate them on the importance of oral health and how it may interfere with systemic health.

The patients of the present study also presented high frequency for the use of antiepileptics. The use of antiepileptics is associated with excessive gingival growth, which is linked to the abnormal activity of the fibroblast and consequently the excessive production of collagen in the tissue. However, the literature does not report the effect of antiepileptics on salivary collagen concentration ²⁸. This study presented a reduction in salivary collagen concentration in CMCHM when using antiepileptics and when the patient presented neuronal deficiency.

Dental home care services is already a reality and finds its purpose in the context of family care, but its reach is still limited ²⁹, justifying the sample number of this study: 56 children. Promoting dental home care services for CMCHM

requires using strategies that provide a trust bond and mutual responsibilities between dentists and patients and their family members, thus obtaining cooperation for proposals to improve oral health. Dental home care services for CMCHM must be inserted in a multi-professional team, which should establish effective and close communication, producing knowledge and maximizing the success of patient and family care ²⁹. Moreover, this type of assistance reverses the access route to oral health, in which the professional is active and goes to the patient, having the opportunity to promote health education and establish preventive actions in the family environment ³⁰.

As for the characteristics of saliva, DP, and oral health, it was concluded that: 1- The CMCHM presented oral changes and lack of a regular dental follow-up; 2- There was a difference in salivary and DP composition between CMCHM and Cg; and 3- The levels of CO₂ in plaque and saliva were correlated to the presence of calculus and gingival hyperplasia.

Bullet Points:

- The children with medical complexity presented oral changes – calculus, bleeding on toothbrushing, gingival hyperplasia - and lack of a regular dental follow-up;
- There was a difference in salivary and dental plaque composition - CO₂, Carbohydrates, Lipids, Collagen - between children with medical complexity and control group;
- The CO₂ saliva and dental plaque were correlated to the presence of calculus and gingival hyperplasia.

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Table 1: Absolute and relative frequencies of the variables related to general characteristics (CMCHM), oral hygiene habits, and oral changes found.

	Total	
	N	%
Medical diagnosis		
Nervous system	31	55.3
Circulatory system	5	8.9
Respiratory system	11	19.6
congenital malformations, deformations, and chromosomal abnormalities	9	16.2
Type of ventilation		
Invasive mechanical ventilation	30	53.6
Oxygen therapy	19	33.9
None	7	12.5
Feeding route		
Gastrostomy	42	75.0
Oral route	14	25.0
Type of medication		
Antiepileptic	30	53.5
Vitamin	21	37.5
Laxative	19	33.9
Antiulcerative	15	26.7
Bronchodilator	12	21.4
Anxiolytic	12	21.4
Antihypertensive	10	17.8
Muscle relaxant	9	16.1
Antibiotic	5	8.9
Anti-inflammatory	5	8.9
Other medications	10	17.8
Toothbrushing frequency		
Never	5	8.9
Less than one toothbrushing per day	6	10.7
One toothbrushing per day	13	23.2
More than one toothbrushing per day	32	57.2
Toothbrushing methods		
Manual toothbrush	36	64.3
Gauze	18	32.1
Finger brush	1	1.8
Dental floss	7	12.5
Use of dentifrice		
Adult fluoridated toothpaste	35	62.6
Low fluorine concentration	2	3.5
No dentifrice	19	33.9

Oral hygiene classification (OHI-S)		
Good	23	41.1
Regular	17	30.4
Poor	16	28.5
Oral Clinical Findings		
Calculus	26	46.4
Bleeding on toothbrushing	17	30.3
Gingival hyperplasia	26	46.4
Mucosal change	2	3.5
Dental morphology change	1	1.8
Intrinsic stains	23	41.1

Table 2: Salivary and bacterial plaque composition of children with medical complexity who require in home medical care (CMCHM) and healthy children (HC), assessed by FTIR.

Peak (wavelength cm ⁻¹)	Molecular group	HC (n=15) area (a.u)	CMCHM (n=31) area (a.u)	p-value
SALIVA				
1 (2986)	Lipids	0.00 (0.00)**	0.01 (0.001)	<0.0001*
2 (2960)	Lipids	0.06 (0.02)	0.07 (0.02)	0.0320*
3 (2919)	Lipids	0.07 (0.07)	0.15 (0.11)	0.0027*
4 (2325)	CO ₂	0.50 (0.50)	0.06 (0.14)	0.0008*
5 (1641)	Proteins (Amide I)	6.03 (0.76)	5.58 (0.77)	0.0769
6 (1551)	Proteins (Amide II)	1.39 (0.86)	1.82 (0.64)	0.0686
7 (1454)	Collagen	0.26 (0.07)	0.23 (0.08)	0.2125
8 (1401)	Collagen	0.43 (0.17)	0.31 (0.12)	0.0144*
9 (1312)	Proteins (Amide III)	0.01 (0.03)	0.01 (0.02)	0.1197
10 (1242)	Collagen	0.15 (0.05)	0.11 (0.06)	0.0258*
11 (1076)	Carbohydrates	3.52 (0.54)	2.74 (0.73)	0.0010*
12 (986)	Carbohydrates	0.15 (0.09)	0.04 (0.06)	0.0001*
BACTERIAL PLAQUE				
1 (2990)	Lipids	0.04 (0.02)	0.03 (0.03)	0.422
2 (2946)	Lipids	0.29 (0.12)	0.23 (0.15)	0.327
3 (2864)	Lipids	0.05 (0.02)	0.06 (0.03)	0.424
4 (2387)	CO ₂	0.03 (0.03)	0.16 (0.18)	0.030*
5 (2349)	CO ₂	0.04 (0.04)	0.09 (0.08)	0.117
6 (1764)	Proteins	0.02 (0.02)	0.01 (0.01)	0.283
7 (1723)	Proteins	2.72 (0.24)	2.76 (0.88)	0.902
8 (1586)	Proteins (Amide II)	1.60 (0.56)	1.49 (0.62)	0.649
9 (1479)	Collagen	0.17 (0.08)	0.13 (0.05)	0.167
10 (1426)	Collagen	0.26 (0.10)	0.20 (0.10)	0.212
11 (1335)	Proteins (Amide III)	0.03 (0.01)	0.02 (0.01)	0.522
12 (1272)	Collagen	0.35 (0.10)	0.27 (0.15)	0.183
13 (1182)	Carbohydrates	0.04 (0.02)	0.03 (0.03)	0.406

* Statistically significant differences between groups, Student t-test, p<0.05.

** Values represent the mean (standard deviation) of each group.

Table 3: Correlation values between the variables studied after applying the Kendall correlation test.

	Kendall correlation coefficient							
	Peak 4 (bacterial plaque) CO2	Peak 1 (saliva) Lipids	Peak 2 (saliva) Lipids	Peak 3 (saliva) Lipids	Peak 4 (saliva) CO2	Peak 8 (saliva) Collagen	Peak 10 (saliva) Collagen	Peak 12 (saliva) Carbohydrates
Neuronal deficiency	0.487* p=0.042	-0.004 p=0.979	-0.226 p=0.178	-0.018 p=0.916	0.314 p=0.043	0.066 p=0.693	-0.377 p=0.023	0.408 p=0.117
Antiepileptics	0.268 p= 0.375	0.018 p=0.916	-0.279 p=0.096	0.229 p=0.170	0.176 p=0.315	-0.136 p=0.414	-0.386 p=0.020	0.136 p=0.425
Frequency of oral hygiene	-0.605 p=0.029	-0.039 p=0.801	0.161 p=0.292	0.135 p=0.372	-0.352 p=0.027	-0.080 p=0.599	0.197 =0.192	-0.050 p=0.746
Feeding route	0.476 p=0.124	0.093 p=0.583	0.092 p=0.583	0.132 p=0.429	-0.197 p=0.259	0.101 p=0.543	0.162 p=330	0.00 p=1.00
Feeding frequency	0.309 p=0.304	-0.219 p=0.179	-0.055 p=0.732	0.091 p=0.569	0.128 p=0.445	-0.146 p=0.362	-0.136 p=0.393	0.075 p=0.645
OHI-S	0.103 p=0.737	0.220 p=0.172	0.359 p=0.225	0.205 p=0.197	-0.131 p=0.431	0.095 p=0.550	0.095 p=0.550	-0.090 p=0.579
Calculus	0.478 p=0.048	0.245 p=0.149	0.060 p=0.718	0.009 p=0.959	0.167 0.340	0.099 p=0.554	-0.171 p=0.304	0.088 p=0.604
Hyperplasia	-0.021 p=0.947	-0.087 p=0.606	-0.073 p=0.662	0.137 p=0.410	0.306 p=0.040	-0.026 p=0.877	-0.188 p=0.258	0.257 p=0.132
Type of ventilation	0.047 p=0.840	0.070 p=0.663	-0.054 p=0.735	-0.019 p=0.904	-0.232 p=0.164	-0.076 p=0.629	0.103 p=0.515	0.170 p=0.295

*Values in bold represent a statistically significant correlation (p<0.05).

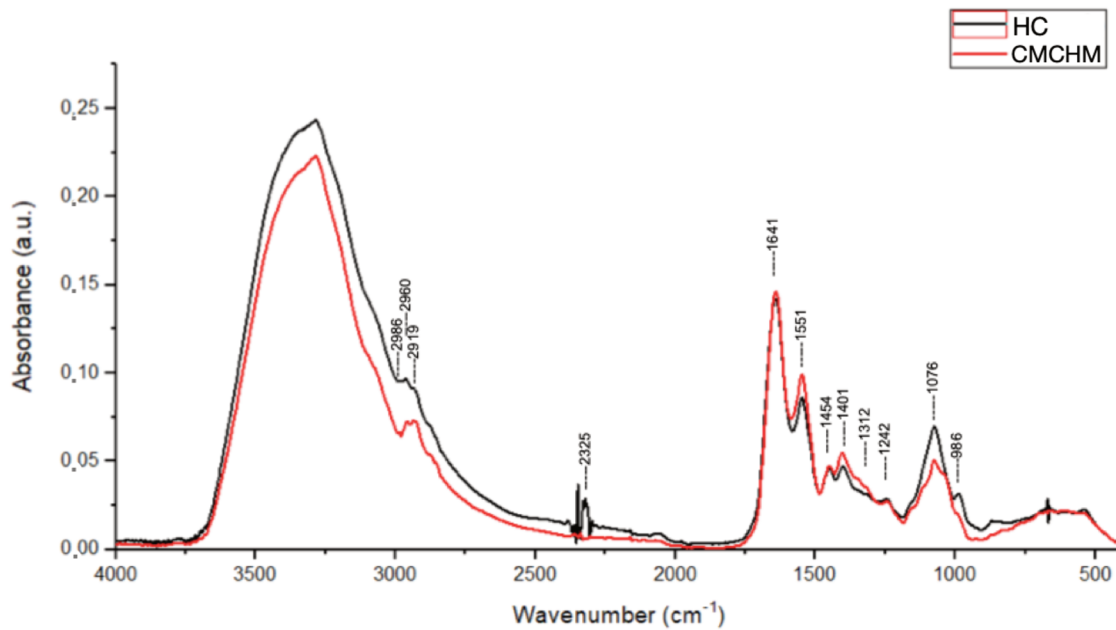


Figure 1. Wavelength absorption range (a.u.) obtained by FTIR, which characterizes each molecular group found in the saliva of the control group of healthy children (HC) and children with medical complexity who require in home medical care (CMCHM). (2986) (2960) (2919) lipids, (2325) CO₂, (1641) proteins - amide I, (1551) proteins - amide II, (1312) proteins - amide III, (1076) (986) carbohydrates, (1454) (1401) (1242) collagen.

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Anexos

Normas do Periódico 1

Journal of Dentistry for Children

instructions for authors | 2020 1

AAPD Instructions for Authors

Pediatric Dentistry

Pediatric Dentistry is the official publication of the American Academy of Pediatric Dentistry, the American Board of Pediatric Dentistry and the College of Diplomates of the American Board of Pediatric Dentistry. It is published bi-monthly and is internationally recognized as the leading journal in the area of pediatric dentistry. The journal promotes the practice, education and research specifically related to the specialty of pediatric dentistry. This peer-reviewed journal features scientific articles, case reports, and abstracts of current pediatric dental research.

Journal of Dentistry for Children

The *Journal of Dentistry for Children (JDC)* is an internationally renowned journal whose publishing dates back to 1934. Published three times a year, *JDC* promotes the practice, education and research specifically related to the specialty of pediatric dentistry. It covers a wide range of topics related to the clinical care of children, from clinical techniques of daily importance to the practitioner, to studies on child behavior and growth and development. *JDC* also provides information on the physical, psychological and emotional conditions of children as they relate to and affect their dental health.

This peer-reviewed journal features scientific articles, case reports, and abstracts of current pediatric dental research.

Introduction

Manuscripts that are selected for publication promote the practice, education and research for the specialty of pediatric dentistry. Manuscripts are considered for publication only if the article, or any part of its essential substance, tables or figures have not been or will not be published in another journal or are not simultaneously submitted to another journal.

The statements, opinions, and advertisements are solely those of the individual authors, contributors, editors, or advertisers, as indicated. Published manuscripts do not necessarily represent the views of the editor, the AAPD Communications Department, or the American Academy of Pediatric Dentistry organization.

Types of Manuscripts

Type of manuscript must be one of the following: *Meta- Analyses/Systematic Reviews, Scientific Studies, Case Reports, or Literature Reviews (JDC only), Letters to the Editor, Editorials and Brief Communications*. Authors submitting manuscripts are expected to follow these instructions before submissions will be accepted for review consideration.

Scientific Studies

Full-length manuscript not to exceed 3,500 words (including structured *Abstract, Introduction, Methods, Results, Discussion, Conclusions, and Acknowledgments*; excluding *References and Figure Legends*). The structured abstract should be no longer than 200 words and contain the following sections: *Purpose, Methods, Results, and Conclusions*.

The *Introduction* section should include only pertinent references. The *Methods* section should be sufficiently detailed to replicate the study. The *Results* section should include only results and not discussion of the data. The *Discussion* section should discuss the results, of the present study and compare them to the existing knowledge base. The *Conclusions* section should consist of succinct, numbered statements that are supported by the results of the study. They should not repeat the *Results* section.

Maximum Figures: 4 • Maximum Tables: 3 or viceversa.

*** Authors desiring to have more figures or tables than provided in the Table above MUST agree to electronic publication of their manuscript, and must select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts.**

Letters to the Editor & Responses to the Letter to the Editor

Full-length manuscript not to exceed 1000 words; excluding References.

Editorials

Full-length manuscript not to exceed 1,000 words; excluding *References and Figure Legends*.

Maximum Figures: 2 • Maximum Tables: 2 or viceversa.

Brief Communications

Full-length manuscript not to exceed 2,000 words (including structured *Abstract*; excluding *References and Figure legends*). The structured Abstract should be no longer than 150 words. The scope of this style submission is for concise scientific studies and not intended to be a substitute for literature review.

Manuscript Submission

All new manuscripts must be submitted to AAPD's online sub-mission and review website, ScholarOne Manuscripts; *Pediatric Dentistry* at: "http://mc.manuscriptcentral.com/pediadent"; *JDC* at: "http://mc.manuscriptcentral.com/jdentchild". Authors who do not yet have an

account on the website should click the 'Create Account' link on the upper right-hand corner of the welcome page and follow the step-by-step process to open an account. On the dashboard page, authors should select the Author Center. In the Author Center, they should click the 'Click here to submit a new manuscript' link.

If you already have an account, enter your user ID and password and log in.

Manuscript submission guidelines for *Pediatric Dentistry* follow the 'uniform requirements for manuscripts submitted to biomedical journals' which have been developed by the International Committee of Medical Journal Editors (ICMJE). Please visit the ICMJE website at: "http://www.icmje.org/manuscript_1prepare.html" for more information.

Author Information

The author must include each author's name, earned academic degrees, professional title (such as 'associate professor', 'chair'), work affiliations, complete address, telephone and fax numbers, and email address. These can be uploaded to the site as a Microsoft Word Document (it is recommended that statements from all authors be placed in a single document). No honorary designations such as 'FRCS', 'FICD', 'Diplomate', should be listed.

A submission with more than one author implies that each author has significant intellectual contribution to the submission. Only individuals who have made a significant contribution to the study or manuscript should be listed as authors. Contributors who do not meet the criteria for authorship, such as individuals who provided only technical help or writing assistance, should be listed in the *Acknowledgments* section at the end of the manuscript. The corresponding author should submit the

following statement for each author (fill in the blanks): The responsibility of _____ was to _____.

Authors (including authors of letters to the editor) are responsible for disclosing all financial and personal relationships that might bias their work. If such conflicts exist, the authors must provide additional detail in the appropriate text box during online submission. Funding sources for the work being submitted must be disclosed in the *Acknowledgments* section of the manuscript.

Authors should express their own findings in the past tense and use the present tense where reference is made to existing knowledge, or where the author is stating what is known or concluded. Footnotes should be avoided and their content incorporated into the text. The editors reserve the right to revise the wording of papers in the interest of the journal's standards of clarity and conciseness.

Author and institution blinded submissions will be selected by the Editor or Section Editors to be sent to at least two reviewers. The corresponding author may submit the names and email addresses of up to four qualified potential reviewers for their manuscript. These individuals (as well as requests to exclude reviewers) will be considered by the editorial membership. Preferred reviewers should not be colleagues at the contributors' institution or present or former research partners.

Manuscripts will be published in English, using American spelling. Manuscripts must be submitted with proper English grammar, syntax, and spelling. Before submitting a manuscript for consideration authors may consider using a

professional editing service such as: “<http://www.journalexperts.com>”. AAPD does not endorse such service and use of such service has no relation with acceptance of a manuscript for publication.

Two versions of the manuscript must be uploaded, one version containing all the author information and one version without any information identifying the authors or their institutions (in the text as well as the Title page. The title page of the manuscript must provide the following data of the contents complying with the criteria for specific types of submissions as described:

Abstract: number of words _____.

Body of text (excluding *Abstract*, *Acknowledgments*, *References*, Figures and Tables): number of words _____.

Number of tables: _____.

Number of figures: _____.

Tables should appear at the end of the main document, while photos, photomicrographs and graphs are to be sub-mitted as separate files (.jpg or .tif format only). Do not embed tables, photos, figures or graphics in the text of the manuscript. Each table and figure should have a number (if more than one) and title included with appropriate footnotes (and figure legend for figures). Prior to submission, the corresponding author must guarantee that the article has not been published and is not being considered for publication elsewhere.

Manuscript Preparation

Authors are advised to review several recently published articles to familiarize themselves with proper format and requirements.

Title: Titles should be as brief as possible while clearly convey-ing the main point or purpose of the article. The manuscript title is limited to 20 words or less, and a short title limited to five words or less must also be submitted. All submissions, in-cluding titles and subheads, are subject to change during the editing process.

Short Title: Also refered as a ‘Running Head’, must be a brief but comprehensive phrase of what the paper is all about, or a brief version of the title of the paper. not to exceed 50 characters.

Keywords: A maximum of five keywords must be submitted. Authors should ensure that the keywords appear in the title and/or abstract and that they are PubMed searchable.

Abstract: All submissions must include an abstract. An abstract should be brief, providing the reader with a concise but com-plete summary of the paper. Generalizations such as ‘methods were described’ should not be used. Meta-Analyses/Systematic Reviews and Scientific Studies should have a structured abstract of no more than 200 words with the following sections: *Purpose*, *Methods*, *Results* and *Conclusions*. Case Reports, Literature Re-views (*JDC* only) and Brief Communications should have an unstructured abstract of no more than 150 words.

Introduction: The introduction should provide the context for the article, the objective of the study, and should state the hypothesis or research question

(purpose statement), how and why the hypothesis was developed, and why it is important. It should generally not exceed two or three paragraphs.

Methods: The methods section should include as appropriate, a detailed description of the study design or type of analysis and dates and period of study; condition, factors, or disease studied; details of sample (e.g., study participants and the setting from which they were drawn); method of random sequence generation in detail (coin flip, random table, etc.); method of allocation concealment in detail (opaque envelopes, sequential numbered drug containers, etc); description of treatment providers; whether providers and participants were blinded; inclusion and exclusion criteria; intervention(s), if any; outcome measures; method of blinding of outcome assessors; method of standardization and calibration of outcome assessors, including kappa statistics; and statistical analysis.

Results: The results reported in the manuscript should be specific and relevant to the research hypothesis. Characteristics of the study participants should be followed by presentation of the results, from the broad to the specific. The Results section should not include implications or weaknesses of the study, but should include validation measures if conducted as part of the study. Results should not discuss the rationale for the statistical procedures used.

Discussion: The discussion section should be a formal consideration and critical examination of the study. The research question

or hypothesis should be addressed in this section, and the results should be compared to and contrasted with the findings of other studies. New results not previously reported in the *Results* cannot appear first in the Discussion. (Note: A lengthy reiteration of the results should be avoided.) The study's limitations and the generalizability of the results should be discussed, as well as mention of unexpected findings with suggested explanations. The type of future studies needed, if appropriate, should be mentioned.

Conclusion: The conclusion should help the reader understand why the research should matter to them after they have finished reading the paper. Conclusions should be numbered, succinct statements that are supported by the results of the study. They should not repeat the Results section.

Acknowledgment: Funding and other sources of support must be disclosed in the acknowledgment section. Personal acknowledgments should be limited to appropriate professionals who have contributed intellectually to the paper but whose contribution does not justify authorship.

References: References are a critical element of a manuscript and serve three primary purposes—documentation, acknowledgment, and directing or linking the reader to additional resources. Authors bear primary responsibility for all reference citations. References should be numbered consecutively with superscript Arabic numerals in the order in which they are cited in the text. A list of all references should appear at the end of the paper in numeric order as they are cited in the text. Journal abbreviations are those used by Index Medicus. The reference style to use is the recent edition of the American Medical Association Manual of Style.

The following are sample references:

Journal

For journals, list all authors when there are six or fewer; when there are seven or more, list the first three, then 'et al.' Page numbers should be included where possible. For example: 12-8, 191-5, 347-51.

Bogert TR, García-Godoy F. Effect of prophylaxis agents on the shear bond strength of a fissure sealant. *Pediatr Dent* 1992;14(1):50-1.

Book

Bixler D. Genetic aspects of dental anomalies. In: McDonald RE, Avery DR, eds. *Dentistry for the Child and Adolescent*. 5th ed. Philadelphia: CV Mosby Co.; 1987:90-116.

The Reference Manual of Pediatric Dentistry

For Clinical Practice Guidelines, do not use the reference manual but rather the original source that it was published in. When referencing other documents in this manual, use the latest publication for example:

American Academy of Pediatric Dentistry. **TITLE**. *The Reference Manual of Pediatric Dentistry*. Chicago, Ill.: American Academy of Pediatric Dentistry; 2019:page range.

Other articles, report, or monograph issued by a committee, institution, society, or government agency

Medicine for the public: Women's health research Bethesda, Md.: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health; 2001. DHHS publication 02-4971.

World Wide Web

All websites and web articles (**URLs**) must be listed in the reference section at the end of the manuscript with the last date that the URL was accessed in parenthesis. DO NOT include links to websites in the text.

Authors should provide direct references to original sources whenever possible. Avoid using abstracts or literature reviews as references. If possible, avoid references to papers accepted but not yet published. If such a citation is necessary, these papers should be cited as being 'In press', and verification that they have been accepted for publication must be provided. Where possible, references of easily accessible material are preferable to dissertations, theses, and other unpublished documents.

Authors should avoid citing 'personal communication' unless it provides essential information not available from a public source. Personal communications should not be numbered, but should be cited in the text as follows: (G. Seale, DDS, oral communication, January 2019). Authors should obtain written permission and confirmation of accuracy from the source of a personal communication; this permission should be uploaded in ScholarOne as a supplementary document at the time of manuscript submission. Authors should verify the accuracy of all references and are responsible for ensuring that no cited

reference contains material that was retracted or found to be in error subsequent to its publication.

Editorial Style

Text formatting:

Manuscripts should be submitted as Office 2010 Microsoft Word format (.docx); Word .doc files are also accepted. No paper copy will be accepted.

Double space all text.

Use basic fonts such as Arial, Courier, Helvetica no smaller than 11 points.

Units of measure: Authors should express all quantitative values in the International System of Units

(**SI units**) unless reporting English units from a cited reference. Figures and tables should use SI units, with any necessary conversion factors given in legends or footnotes. For most cases spell out numbers under 10, and use numerals for numbers 10 and above — this applies to all ages, days of the month, degrees of temperature, dimensions, percentages; proportions, scores, serial numbers, speeds, sums of money, time of day, and percent values. Numbers beginning a sentence should be spelled out. Report percentages to one decimal place (i.e., XX.X percent) when sample size is ≥ 200 . Laboratory data values should be rounded to the number of digits that reflects the precision of the results and the sensitivity of the measurement procedure.

Statistical tests: The results of all statistical comparisons should be reported to include the statistical test value and the associated *P*-value and confidence interval, if appropriate. Except when one-sided tests are required by study design, such as in non inferiority trials, all reported *P*-values should be two-sided. In general, *P*-values larger than 0.01 should be reported to two decimal places, those between 0.01 and 0.001 to three decimal places; *P*-values smaller than 0.001 should be reported as $P < 0.001$. Results in the abstract and the paper generally should include estimates of effect size and 95 percent confidence intervals (95% CI), not just *P*-values or statements that a difference was statistically significant.

Tooth names: The complete names of individual teeth should be given in full in the text of articles using the following convention: [(primary/permanent), (maxillary/mandibular), (right/ left), (central/lateral or first/second/third), (tooth type)]. Examples: 'primary maxillary right first molar', 'permanent mandibular first molars', but 'mandibular right second pre-molar'. In tables these names may be abbreviated by the Universal system (A-T for primary teeth, 1-32 for permanent teeth).

Commercially-produced materials: Any mention of commercially produced materials, instruments, devices, software, etc., must be followed by the name of the manufacturer and the manufacturer's location in parentheses. Example: '... in an Excel spreadsheet (Microsoft, Inc, Redmond, Wash., USA).'

Abbreviations: Abbreviations should be used to make manuscripts more concise. The first time an abbreviation appears, it should be placed in bold in

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The following categories constitute the editorial actions that may be taken on a manuscript:

Rejection: The flaws that lead to this decision generally center on substantive or methodological issues. A manuscript is usually rejected because: it is outside the area of coverage of the journal; it contains serious flaws of design, methodology, analysis, or interpretation; or it is judged to make only a limited novel contribution to the field.

Revision: Manuscripts may have publication potential but are not yet ready for final publication. The study as presented may not merit acceptance as is but may warrant consideration after substantive revision (e.g., reorganizing the conceptual structure, conducting additional experiments, or modifying analyses). The action editor will give the author an invitation to revise and resubmit for another round of reviews (usually with the same reviewers). An editor cannot

guarantee acceptance of a revised manuscript, but authors who respond flexibly and attend closely to suggested revisions enhance their chances for an acceptance. Authors must include a detailed cover letter outlining their responses to the revisions. Revisions **must be submitted using Track Changes** so the original with the sections deleted can be seen along with the new text.

Acceptance: When the reviewers and Editor have determined the revision is acceptable the author receives a letter of acceptance specifying an approximate time frame for anticipated publication. Once a manuscript is accepted, it enters the production phase of publication. At this point, no further changes can be made by the author other than those suggested by the copy-editor.

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AAPD Manuscript Submission Checklist

This checklist applies specifically to original research articles, yet much of it will apply to submission of other manuscript types, as well. Please see the section 'Types of Manuscripts' in the Instructions for Authors for complete information.

Submission Documents

- Submit manuscript in .doc or .docx format.
- Manuscript is double spaced.
- Used basic fonts such as Arial, Courier, Helvetica no smaller than 11 points.
- Two versions of the manuscript are to be uploaded, one version containing all the author information and one version without any information identifying the authors or their institutions (blinded).
- Tables appear at the end of the main document, while photos, photomicrographs and graphs are to be submitted as separate files (.jpg or .tif format only).
- IRB approval, informed consent (verbal or written), HIPAA compliance (if from the United States), and/or animal care committee must be included with the submission.
- IRB approval letters must be in English, on official IRB letterhead, and over an official signature of the IRB approval agent.
- For **Randomized Clinical Trials (RCT)**: Studies that are RCTs should consider CONSORT guidelines and checklist available at: "www.consort-statement.org" in the organization of the submission. This document can be added as a supplemental file in ScholarOne.
- For **Cohort Studies**: Studies that are observational cohort, case-controlled and cross-sectional studies should use the STROBE checklist addressing the guidelines available at: "www.strobe-statement.org/index.php?id=available-checklists" in the organization of the submission. This document can be added as a supplemental file in ScholarOne.

Short Title

- A brief but comprehensive phrase summarizing the paper.

Keywords

- Five words that appear in the title/abstract, and searchable in PubMed.

Abstract

- The abstract is brief, providing the reader with a concise yet complete summary of the paper.
- Date range of study should be given.
- Number of patients/animals (including age and gender, if appropriate) should be given.
- Various groups, including controls, described.
- Procedures performed should be described.
- Specifics of evaluation should parallel the results portion of the abstract.
- Abstract results parallel abstract methods.
- Abstract results contain quantitative data along with statistical significance.
- Abstract conclusions can be drawn from the results of the study.

Introduction

- Provides context for the article.
- Provides objective of the study.
- Provides a clear purpose/hypothesis.
- Does not exceed two or three paragraphs.

Methods

- As appropriate, includes a detailed description of the study design or type of analysis.
- As appropriate, includes dates and period of study.
- As appropriate, includes condition, factors, or disease studied.
- As appropriate, includes details of sample (e.g., study participants and the setting from which they were drawn).
- As appropriate, includes method of random sequence generation in detail (coin flip, random table, etc.)
- As appropriate, includes method of allocation concealment in detail (opaque envelopes, sequential numbered drug containers, etc.)
- As appropriate, includes a description of treatment providers.

Continued on next page

- As appropriate, includes whether providers and participants were blinded.
- As appropriate, includes inclusion and exclusion criteria.
- As appropriate, includes intervention(s), if any.
- As appropriate, includes outcome measures.
- As appropriate, includes method of blinding of outcome assessors.
- As appropriate, includes method of standardization and calibration of outcome assessors, including kappa statistics.
- As appropriate, includes statistical analysis.

Results

- Clearly mirrors methods; used subtitles if needed. Check for consistency in data in text, tables, and figures.
- Report the results of the statistical analysis for all variables collected and analyzed, not just for those which exhibited statistical or near statistical significance.
- Text and Tables must stand alone.

Discussion

- State pertinent new findings, and do not repeat results.
- How did your results differ from other relevant literature?
- Do not cite tables or figures in the Discussion. These should be introduced in the methods and results sections.
- Do not cite new results not previously reported in the Results. All results the author wishes to discuss must have first been presented in the Results section of the manuscript.
- Describe limitations of your study in the paragraph just before your Conclusions. Include itemization of limitations of any incomplete data.
- Describe the type of future studies needed, if appropriate.

Conclusions

- Synthesis of key points.
- List and number using Arabic numerals.
- Conclusions should be supported by data.
- Numbered succinct statements.

References

- Call out references in order they appear in text.
- Adhere to AAPD guidelines.
- Verify accuracy of your references.

Tables

- Adhere to AAPD Maximum requirements according to Type of Manuscript.
- Include title for each table.
- Numbers correspond to numbers in text.
- Define abbreviations below each table.

Figures

- Adhere to AAPD maximum requirements according to type of manuscript.
- Image resolution, after cropping to the area of interest, should be a minimum 300-600 dpi.
- Figures should be submitted individually as .jpg or .tif files.
- Figures should be numbered in Arabic numerals in the order of the first citation in the text.
- Legends for each figure must be printed on a separate page.
- Figure legends should clearly define findings on each figure, with labels mentioned in the caption if they are used in the figure.
- If based on individual subject, caption should include subject age and gender.

NOTE: Authors desiring to have more Figures or Tables, MUST agree with the electronic publication of their manuscript and select this preference. Each separate chart, graph or photograph will be counted as a separate figure. Figures grouped together will be counted as their individual parts. See examples on page 2.

Normas do Periódico 2

International Journal of Paediatric Dentistry

Author Guidelines

Sections

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1. SUBMISSION

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International Journal of Paediatric Dentistry publishes papers on all aspects of paediatric dentistry including: growth and development, behaviour management, diagnosis, prevention, restorative treatment and issue relating to medically compromised children or those with disabilities. This peer-reviewed journal features scientific articles, reviews, case reports, short communications and abstracts of current paediatric dental research. Analytical studies with a scientific novelty value are preferred to descriptive studies. Case reports illustrating unusual conditions and clinically relevant observations are acceptable but must be of sufficiently high quality to be considered for publication; particularly the illustrative material must be of the highest quality.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

i. Original Articles

Divided into: Summary, Introduction, Material and methods, Results, Discussion, Bullet points, Acknowledgements, References, Figure legends, Tables and Figures arranged in this order.

- **Summary** should be structured using the following subheadings: Background, Hypothesis or Aim, Design, Results, and Conclusions and should be less than 200 words.
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- **Discussion** section presents the interpretation of the findings. This is the only proper section for subjective comments and reference to previous

literature. Avoid repetition of results, do not use subheadings or reference to tables in the results section.

- **Bullet Points:** Authors will need to provide no more than 3 'key points' that summarise the key messages of their paper to be published with their article. The key points should be written with a practitioner audience in mind under the heading: *Why this paper is important to paediatric dentists.

References: Maximum 30.

vi. Letters to the Editor

Should be sent directly to the editor for consideration in the journal.

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Parts of the Manuscript

The manuscript should be submitted in separate files: title page; main text file; figures.

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 - ii. A short running title of less than 50 characters;
 - iii. The full names of the authors and a statement of author contributions, e.g. Author contributions: A.S. and K.J. conceived the ideas; K.J. and R.L.M. collected the data; R.L.M. and P.A.K. analysed the data; and A.S. and K.J. led the writing;
 - iv. The author's institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
 - v. Acknowledgments;
 - vi. Word count (excluding tables)

Authorship

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Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

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As papers are double-blind peer reviewed the main text file should not include any information that might identify the authors.

The main text file should be presented in the following order:

- i. Title, abstract and key words;
- ii. Main text;
- iii. References;
- iv. Tables (each table complete with title and footnotes);
- v. Figure legends;
- vi. Appendices (if relevant).

Figures and supporting information should be supplied as separate files.

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Sample references follow:

Journal *article*

1. King VM, Armstrong DM, Apps R, Trott JR. Numerical aspects of pontine, lateral reticular, and inferior olivary projections to two paravermal cortical zones of the cat cerebellum. *J Comp Neurol* 1998;390:537-551.

Book

2. Voet D, Voet JG. *Biochemistry*. New York: John Wiley & Sons; 1990. 1223 p.

Internet

document

3. American Cancer Society. *Cancer Facts & Figures* 2003. <http://www.cancer.org/downloads/STT/CAFF2003PWSecured.pdf> Accessed March 3, 2003

Tables

Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

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Legends should be concise but comprehensive – the figure and its legend must be understandable without reference to the text. Include definitions of any symbols used and define/explain all abbreviations and units of measurement.

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- GenBank: www.ncbi.nlm.nih.gov/genbank

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Author Guidelines Updated 22 November, 2019

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: CONDIÇÃO DE SAÚDE BUCAL EM CRIANÇAS DE ALTA COMPLEXIDADE ATENDIDAS EM DOMICÍLIO OU SOB INTERNAÇÃO HOSPITALAR

Pesquisador: Ana Paula Turrioni Hidalgo

Área Temática:

Versão: 1

CAAE: 14970819.9.0000.5152

Instituição Proponente: FACULDADE DE ODONTOLOGIA

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.458.873

Apresentação do Projeto:

Segundo os pesquisadores:

"Estudos têm demonstrado que pessoas com deficiência (PD), quando comparadas aquelas sem deficiência e de mesma idade, apresentam uma maior prevalência de cárie, maior número de dentes extraídos e não tratados e uma doença periodontal mais severa.

E necessário a verificação do como esses fatores se inter-relacionam gerando saúde ou doença, e de como interferem na saúde bucal para que se direcione as ações de prevenção e tratamento. E ainda, se o acesso ao cirurgião dentista é determinante para saúde bucal de crianças de alta complexidade (CAC).

HIPÓTESES

A Saúde bucal de pacientes pediátricos de alta complexidade atendidos em domicílio é superior quando comparada aos pacientes sob internação hospitalar e inferior quando comparada ao grupo de pacientes sem deficiência.

- Os fatores de comportamento, biológicos e socioeconômicos estão altamente correlacionados com o estado de saúde bucal dos pacientes de alta complexidade atendidos em domicílio ou sob internação hospitalar.

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Amostra:

Os participantes serão os pacientes pediátricos(4 a 12 anos):1-acompanhados pelo Serviço de Atendimento Domiciliar do Hospital de Clínicas da Universidade Federal de Uberlândia(SAD-HC-UFU), 2-admitidos na Enfermaria de Pediatria-HC-UFU e que apresentam algum tipo de deficiência e 3-em atendimento ambulatorial nas Clínicas de Odontopediatria da Faculdade de Odontologia da Universidade Federal de Uberlândia-FOUFU. A amostra será selecionada por conveniência, segundo os critérios de inclusão e exclusão estabelecidos. Em 2018, 68 crianças foram atendidas pelo SAD, fato que torna este grupo limitante na composição da amostra. Por conseguinte, todos pacientes acompanhados pelo SAD comporão o universo amostral, e a quantidade observada nesse seguimento tornar-se-á referência para pareamento nos demais grupos.Serão coletados dados referentes ao sexo, idade, diagnóstico da deficiência, história médica, hábitos de higiene oral e informações nutricionais, por meio do relato dos pais/responsáveis. Especificamente quanto aos hábitos de higiene bucal, serão avaliadas as seguintes variáveis: frequência de acompanhamento odontológico, frequência de higiene bucal, método utilizado para higiene bucal, tipo de dentifrício utilizado, frequência do uso de fio dental e uso de colutórios. As informações nutricionais serão coletadas por meio da aplicação do questionário de frequência alimentar (Hinnigl et al; 2014). Todos os participantes receberão orientações quanto aos cuidados de higiene oral de acordo com a faixa etária. Além de informações sobre gênero, nível de escolaridade e renda familiar dos pais/cuidadores.

O material salivar será coletado por meio de aspiração do fluido presente nesta região utilizando um sugador portátil de baixa potência (Aspiramax MA 520, NS, São Paulo, Brasil). A placa bacteriana será coletada das superfícies vestibulares dos primeiros molares superiores, utilizando uma sonda exploradora. As amostras serão armazenadas em freezer -70oC até o momento do processamento. A determinação de biomarcadores salivares e do biofilme dentário por meio de FTIR permite identificar com grande acurácia as terminações C-H, O-H e N-H de proteínas, a composição lipídica e compostos glicídicos. A avaliação dos picos permitirá a determinação de proteínas totais, Imunoglobulina A e de cortisol salivar. A higiene oral será avaliada utilizando os critérios do Índice de Higiene Oral simplificado (IHO-S) (Greene e Vermillion, 1964) definidos com os seguintes escores de 0 a 3, para presença de placa bacteriana e cálculo. Serão avaliadas as superfícies vestibulares dos elementos 11/ 51, 31/ 71, 16/ 55, 26/ 65 e linguais dos elementos 36/ 75 e 46/ 85. Após a avaliação do IHO-S, será realizada higiene oral em cada criança de acordo com a idade e métodos de higiene de escolha. Após higiene oral, será realizada o índice de dentes cariados, perdidos e obturados (CPO-D) para dentição completa permanente (Who, 1997) ou o

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Bairro: Santa Mônica

CEP: 38.408-144

UF: MG

Município: UBERLANDIA

Telefone: (34)3239-4131

Fax: (34)3239-4131

E-mail: cep@propp.ufu.br

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índice de dentes cariados, esfoliados e obturados (ceo-d) para a dentição decidua ou dentadura mista (Who, 1997). As demais avaliações clínicas envolverão as variáveis: grau de hiperplasia gengival de acordo com o estudo de Angelopoulos e Goaz (1972), manchas no esmalte sem cavitação (presença ou ausência), sangramento gengival pelo respectivo índice (ISG) desenvolvido por Loe e Silness (1963) citado por Loe et al, alteração na mucosa (presença ou ausência) e alteração na morfologia dentária (presença ou ausência). Para o exame serão utilizados espelho bucal Nº 5 (Golgran, São Caetano do Sul, SP, Brasil) e sonda OMS (Golgran, São Caetano do Sul, SP, Brasil), ambos previamente esterilizados.

Critérios de Inclusão no Estudo:

Pacientes pediátricos, de 4 a 12 anos, acompanhados pelo SAD-HC-UFU, admitidos na Enfermaria de Pediatria-HC-UFU e que apresentam algum tipo de deficiência e em atendimento ambulatorial na Clínica de Pediatria-FOUFU, cujos pais/responsáveis concordem em participar da pesquisa por meio da assinatura do Termo de consentimento livre e esclarecido – TCLE.

Critérios de Exclusão no Estudo:

Pacientes com idade diferente da faixa etária estabelecida (de 4 a 12 anos).

Pacientes com deficiência, em uso de medicamento ou com alguma alteração sistêmica atendidos na Clínica de Pediatria-FOUFU.

Pacientes sem deficiência admitidos no SAD ou Enfermaria de Pediatria do Hospital de Clínicas de Uberlândia.

Objetivo da Pesquisa:

Objetivo Primário:

Avaliar a condição de saúde bucal de CAC atendidos em domicílio ou sob internação hospitalar e correlacionar fatores de comportamento, biológicos e socioeconômicos com os possíveis problemas de saúde bucal.

Objetivos Secundários:

Avaliar e comparar a condição de saúde bucal de CAC atendidos em domicílio, sob internação hospitalar e pacientes sem deficiência por meio dos índices de higiene oral simplificado, CPO-D/ceo-d, índice de sangramento gengival e índice de hiperplasia gengival.

Correlacionar fatores de comportamento (dieta, hábitos de higiene bucal, uso de medicamentos),

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biológicos (placa bacteriana e saliva) e socioeconômicos com os possíveis problemas de saúde bucal de CAC atendidos em domicílio ou sob internação hospitalar.

Avaliação dos Riscos e Benefícios:

Segundo os pesquisadores:

Riscos: Há o risco de identificação do participante, entretanto o pesquisador se compromete em resguardar os dados pessoais dos indivíduos participantes, não sendo eles em hipótese alguma identificados nas diversas fases da pesquisa. Para evitar a identificação do participante, os dados pessoais serão substituídos por códigos e nomes fictícios.

Com o objetivo de minimizar o risco de identificação dos pacientes, será atribuído um código numérico para cada participante, o qual será utilizado para anotações nos instrumentos de coleta de dados. Além disso, nenhum dado que favoreça a identificação dos pacientes será coletado (ex: nome, número de documento, endereço).

Benefícios: O benefício esperado é evidenciar e difundir alternativas ao atendimento ambulatorial que atendam as necessidades e limitações das CAC e seus familiares, contribuindo com o estabelecimento de protocolo de atendimento para esse grupo. Identificação de hábitos prejudiciais para a saúde bucal e direcionamento da intervenção odontológica para as necessidades mais urgentes, através da quantificação da influência dos hábitos de higiene e alimentar e uso de medicamentos pelas CAC e nível educacional e econômico de pais/responsáveis. Além de impacto direto na saúde bucal dos participantes por meio de instrução de higiene oral e acompanhamento odontológico personalizado.

Comentários e Considerações sobre a Pesquisa:

Estudo com objetivo de avaliar a condição de saúde bucal das crianças de alta complexidade (CAC) atendidas em domicílio ou sob internação hospitalar e correlacionar fatores de comportamento, biológicos e socioeconômicos com os possíveis problemas de saúde bucal. Será realizada avaliação da composição salivar e placa bacteriana, Índice de Higiene Oral Simplificado (IHO-S), e exame clínico bucal. Será aplicado um questionário contendo dados sobre história médica, hábitos de higiene bucal e nutricionais das crianças e gênero, nível de escolaridade e renda familiar dos pais/cuidadores. Análise estatística será utilizada para verificar possíveis associações entre as variáveis ($p < 0,05$). Os pesquisadores esperam contribuir para a determinação de protocolo de cuidados bucais para CAC, minimizando o surgimento de doenças bucais, além da redução do impacto de problemas bucais a nível sistêmico.

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Considerações sobre os Termos de apresentação obrigatória:

O TCLE está adequado, dirigido aos responsáveis pelos menores de forma clara e concisa. Explica como será realizado o questionário e o procedimento da coleta da saliva.

Os termos obrigatórios também estão adequados.

Conclusões ou Pendências e Lista de Inadequações:

De acordo com as atribuições definidas na Resolução CNS 466/12, o CEP manifesta-se pela aprovação do protocolo de pesquisa proposto.

O protocolo não apresenta problemas de ética nas condutas de pesquisa com seres humanos, nos limites da redação e da metodologia apresentadas.

Considerações Finais a critério do CEP:

Data para entrega de Relatório Parcial ao CEP/UFU: Junho de 2020.

Data para entrega de Relatório Final ao CEP/UFU: Junho de 2021.

OBS.: O CEP/UFU LEMBRA QUE QUALQUER MUDANÇA NO PROTOCOLO DEVE SER INFORMADA IMEDIATAMENTE AO CEP PARA FINS DE ANÁLISE E APROVAÇÃO DA MESMA.

O CEP/UFU lembra que:

a- segundo a Resolução 466/12, o pesquisador deverá arquivar por 5 anos o relatório da pesquisa e os Termos de Consentimento Livre e Esclarecido, assinados pelo sujeito de pesquisa.

b- poderá, por escolha aleatória, visitar o pesquisador para conferência do relatório e documentação pertinente ao projeto.

c- a aprovação do protocolo de pesquisa pelo CEP/UFU dá-se em decorrência do atendimento a Resolução CNS 466/12, não implicando na qualidade científica do mesmo.

Orientações ao pesquisador :

- O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado (Res. CNS 466/12) e deve receber uma via original do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.
- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado e descontinuar o estudo somente após análise das razões da descontinuidade pelo CEP que o aprovou (Res. CNS 466/12), aguardando seu parecer, exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade de regime oferecido a um dos

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grupos da pesquisa que requeiram ação imediata.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo (Res. CNS 466/12). É papel de o pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.
- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprobatório do CEP, para serem juntadas ao protocolo inicial (Res.251/97, item III.2.e).

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1364218.pdf	03/06/2019 13:40:23		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.doc	03/06/2019 13:40:05	Ana Paula Turrioni Hidalgo	Aceito
Declaração de Instituição e Infraestrutura	declaracao_coparticipante.pdf	03/06/2019 13:38:36	Ana Paula Turrioni Hidalgo	Aceito
Folha de Rosto	Folha_de_rosto.pdf	29/05/2019 15:34:00	Ana Paula Turrioni Hidalgo	Aceito
Outros	Links_para_acesso_ao_Curriculo.docx	25/05/2019 09:28:44	Ana Paula Turrioni Hidalgo	Aceito
Outros	Instrumento_de_Coleta.docx	25/05/2019 09:27:30	Ana Paula Turrioni Hidalgo	Aceito
Projeto Detalhado / Brochura Investigador	ProjetoMestrado_20_05_19.docx	25/05/2019 09:24:38	Ana Paula Turrioni Hidalgo	Aceito
Declaração de Pesquisadores	equipe.pdf	25/05/2019 09:23:43	Ana Paula Turrioni Hidalgo	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

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Não

UBERLANDIA, 17 de Julho de 2019

Assinado por:
Karine Rezende de Oliveira
(Coordenador(a))

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TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Prezado(a) senhor(a), o(a) menor, pelo qual o(a) senhor(a) é responsável, está sendo convidado(a) para participar da pesquisa intitulada “**Avaliação da saúde bucal e sua correlação com fatores biológicos e cognitivos em crianças atendidas pelo Serviço de Atenção Domiciliar da Universidade Federal de Uberlândia**”, sob a responsabilidade dos pesquisadores Profa. Dra. Ana Paula Turrioni, Prof. Dr. Robinson Sabino da Silva e o Fisioterapeuta Vinícius Pafume de Oliveira.

Nesta pesquisa nós estamos buscando avaliar as condições de saúde bucal de crianças atendidas pelo Serviço de Atendimento Domiciliar oferecido pela Universidade Federal de Uberlândia (SAD-UFU), bem como correlacionar fatores biológicos e cognitivos com a saúde bucal destes pacientes.

O Termo de Consentimento Livre e Esclarecido será obtido pelo pesquisador Profa. Dra. Ana Paula Turrioni anteriormente a aplicação dos questionários, durante as visitas domiciliares.

Na participação do(a) menor, ele(a) será submetido a exame clínico odontológico para avaliação da higiene bucal e presença de cárie. Durante o exame clínico será realizada a limpeza bucal com escova, pasta dental com flúor e gaze. Também serão dadas orientações quanto aos cuidados de higiene bucal. Anteriormente aos exames clínicos, serão coletados 2 mL de saliva utilizando um sugador portátil de baixa potência. Também será coletado um pequeno conteúdo da placa dental (restos de alimento) localizada na superfície dos dentes.

Em nenhum momento o(a) menor será identificado(a). Os resultados da pesquisa serão publicados e ainda assim a sua identidade será preservada.

O(A) menor não terá nenhum gasto e ganho financeiro por participar na pesquisa.

Os riscos, da participação do(a) menor na pesquisa, consistem na possibilidade de identificação do participante. Com o objetivo de minimizar o risco de identificação, será atribuído um código numérico para cada participante, o qual será utilizado para anotações nos instrumentos de coleta de dados. Além disso, nenhum dado que favoreça a identificação será coletado para uso na pesquisa (ex: nome, número de documento, endereço). Os benefícios serão resultados importantes para a sociedade, pois a partir do estudo, será possível desenvolver estratégias de promoção de saúde que possam favorecer as condições de saúde bucal e geral dos pacientes pediátricos atendidos pelo SAD-UFU, com impacto direto em sua qualidade de vida.

O(A) menor é livre para deixar de participar da pesquisa a qualquer momento sem nenhum prejuízo ou coação.

Uma via original deste Termo de Consentimento Livre e Esclarecido ficará com o(a) senhor(a), responsável legal pelo(a) menor.

Qualquer dúvida a respeito da pesquisa, o(a) senhor(a), responsável legal pelo(a) menor, poderá entrar em contato com: Profa. Dra. Ana Paula Turrioni no telefone (34) 3225-8146, endereço: Av. Pará, s/ no Bloco 2G, sala 02, Campus Umuarama – Uberlândia – MG, CEP 38405-320. Poderá também entrar em contato com o CEP - Comitê de Ética na Pesquisa com Seres Humanos na Universidade Federal de Uberlândia: Av. João Naves de Ávila, nº 2121, bloco A, sala 224, Campus Santa Mônica – Uberlândia –MG, CEP: 38408-100; fone: 34-32394131. O CEP é um colegiado independente criado para defender os interesses dos participantes das pesquisas em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos conforme resoluções do Conselho Nacional de Saúde.

Uberlândia, dede 201.....

Assinatura dos pesquisadores

Eu, responsável legal pelo(a) menor _____ consinto na sua participação no projeto citado acima, caso ele(a) deseje, após ter sido devidamente esclarecido.

Responsável pelo(a) menor participante da pesquisa

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation	Page No
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	2
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	3-4
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	4-5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	4-5
Bias	9	Describe any efforts to address potential sources of bias	--
Study size	10	Explain how the study size was arrived at	3-4
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	--
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	5
		(b) Describe any methods used to examine subgroups and interactions	5
		(c) Explain how missing data were addressed	--
		(d) If applicable, describe analytical methods taking account of sampling strategy	--
		(e) Describe any sensitivity analyses	--
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	5
		(b) Give reasons for non-participation at each stage	--
		(c) Consider use of a flow diagram	--
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	5-7
		(b) Indicate number of participants with missing data for each variable of interest	--
Outcome data	15*	Report numbers of outcome events or summary measures	5-7
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	--

		(b) Report category boundaries when continuous variables were categorized	--
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	--
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	--
Discussion			
Key results	18	Summarise key results with reference to study objectives	7
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	9-10
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7-10
Generalisability	21	Discuss the generalisability (external validity) of the study results	9-10
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	--

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.