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CENTRO DE CIÊNCIAS BIOLÓGICAS E DA SAÚDE
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**IMPACTO DAS ALTERAÇÕES BUCAIS NA QUALIDADE DE VIDA DE PRÉ-
ESCOLARES EM CAMPINA GRANDE-PB**

Monalisa da Nóbrega Cesarino Gomes

CAMPINA GRANDE/ PB

2014

MONALISA DA NÓBREGA CESARINO GOMES

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ESCOLARES EM CAMPINA GRANDE-PB**

Dissertação apresentada ao Programa de Pós-Graduação em Odontologia da Universidade Estadual da Paraíba como parte dos requisitos para obtenção do título de Mestre em Odontologia.

Orientadora: Prof^ª. Dra. Ana Flávia Granville-Garcia

CAMPINA GRANDE/ PB

2014

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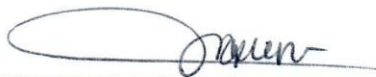
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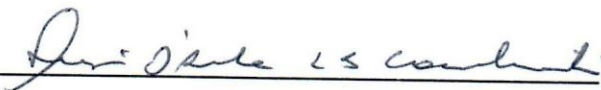
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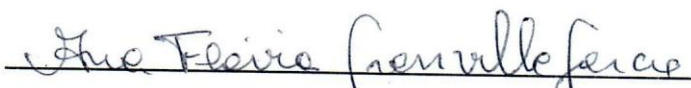
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*“Não importa o que você seja, quem você seja, ou que deseje na vida,
a ousadia em ser diferente reflete na sua personalidade,
no seu caráter, naquilo que você é.*

(...)

*Seja você quem for, tenha sempre como meta, muita força,
muita determinação e sempre faça tudo com muito amor
e com muita fé em Deus, que um dia você chega lá.
De alguma maneira você chega lá.”*

Ayrton Senna

Impacto das alterações bucais na qualidade de vida de pré-escolares em Campina Grande-PB

RESUMO

As alterações bucais apresentam alta prevalência na idade pré-escolar, e para delinear novas políticas de saúde é essencial determinar o impacto dessas alterações nos aspectos funcionais e psicossociais da criança. **OBJETIVO:** O objetivo do presente estudo foi avaliar o impacto das alterações bucais na qualidade de vida relacionada à saúde bucal (QVRSB) de pré-escolares de três a cinco anos de idade e suas famílias, bem como a influência de tais alterações na culpa parental. **MÉTODOS:** Um estudo transversal randomizado de amostra aleatória foi realizado com 843 pré-escolares entre três e cinco anos de idade assistidas em pré-escolas públicas e privadas de Campina Grande-PB, Brasil. Os pais/responsáveis responderam o Brazilian Early Childhood Oral Health Impact Scale (B-ECOHIS) e um questionário sobre dados sociodemográficos e percepção de saúde. O exame clínico foi realizado por três pesquisadores previamente calibrados, com bom grau de concordância intraexaminador ($k=0.85-0.90$) e interexaminador ($k=0.83-0.88$) e foram usados critérios de diagnóstico para cárie dentária, traumatismo dentário (TDI) e má oclusão já estabelecidos na literatura. A regressão hierárquica de Poisson foi utilizada para verificar associações entre as variáveis independentes e QVRSB de acordo com os planos de análise ($\alpha = 5\%$). **RESULTADOS:** A frequência de impacto negativo das alterações bucais na QVRSB foi de 32.1% entre as crianças e 26.2% entre as famílias. As variáveis ser o filho primogênito (RP= 1.430; IC95%: 1.045-1.958), percepção ruim dos pais sobre a saúde bucal da criança (RP= 1.732; IC95%: 1.399-2.145), lesões cavitadas (RP= 2.596; IC95%: 1.982-3.400) e TDI (RP= 1.413; IC95%: 1.161-1.718) estiveram significativamente associados com QVRSB para as crianças; enquanto que percepção ruim dos pais sobre a saúde bucal da criança (RP= 2.116; IC95%: 1.624-2.757), lesões cavitadas (RP= 2.809; IC95%: 2.009-3.926) e tipo de TDI (RP= 2.448; IC95%: 1.288-4.653) estiveram significativamente associados com a QVRSB da família. Em relação à culpa parental, esteve presente em 22.8% da amostra e a percepção ruim dos pais sobre a saúde bucal da criança (RP= 1.980; IC95%: 1.479-2.649), história de dor de dente (RP= 2.427; IC95%: 1.812-3.251), lesões cavitadas (RP= 2.012; IC95%: 1.397-2.896) e

tipo de TDI (RP=1.951; IC95%: 1.099-3.461) estiveram significativamente associados com a culpa parental. **CONCLUSÃO:** Lesões cavitadas e TDI causam impacto negativo na QVRSB de pré-escolares e suas famílias, bem como os pais de crianças com essas condições apresentam uma maior culpa. Além disso, uma pior percepção dos pais sobre a saúde bucal dos filhos e ordem de nascimento foram preditores para um maior impacto na qualidade de vida.

Palavras-chave: qualidade de vida; culpa; cárie dentária; traumatismos dentários; má oclusão; pré-escolar.

Impact of oral diseases on the quality of life of preschool children in the city of Campina Grande-PB

ABSTRACT

Oral diseases are highly prevalent in pre-school age children. In order to develop new health policies, it becomes essential to determine the impact of these conditions on the child's functional and psychosocial features. **OBJECTIVE:** The aim of this study was to evaluate the impact of oral health problems on oral health-related quality of life (OHRQoL) of preschool children aged three to five years and of their families, as well as to assess the influence of such problems on parental guilt. **METHODS:** This was a randomized cross-sectional study comprising a random sample of 843 preschool children aged between three and five years assisted in public and private pre-schools in the city of Campina Grande, PB, Brazil. Parents/guardians answered the Brazilian Early Childhood Oral Health Impact Scale (B-ECOHIS) and a questionnaire on sociodemographic data and health perception. Clinical examination was performed by three calibrated examiners, who achieved good intra-examiner ($k = 0.85-0.90$) and inter-examiner ($0.83-0.88$) agreement levels and were used diagnostic criteria for dental caries, traumatic dental injuries (TDI) and malocclusion already established in the literature. The hierarchical Poisson regression was used to identify associations between the independent variables and OHRQoL according to the levels of analysis ($\alpha = 5\%$). **RESULTS:** The frequency of negative impact of oral health problems on OHRQoL was 32.1% among children and 26.2% among families. The variables oldest child (PR= 1.430, 95%CI: 1.045-1.958), parent's/caregiver's perception of child's oral health as poor (PR= 1.732, 95%CI: 1.399-2.145), cavitated lesions (PR= 2.596; 95%CI: 1.982-3.400) and TDI (PR= 1.413, 95%CI: 1.161-1.718) were significantly associated with the children's OHRQoL; while parent's/caregiver's perception of child's oral health as poor (PR= 2.116, 95%CI: 1.624-2.757), cavitated lesions (PR= 2.809, 95%CI: 2.009-3.926) and type of TDI (PR= 2.448, 95%CI: 1.288-4.653) were significantly associated with the family's OHRQoL. Parental guilt was identified in 22.8 % of the sample and was associated with parent's/caregiver's perception of child's oral health as poor (PR= 1.980, 95%CI: 1.479-2.649), history of toothache (PR= 2.427, 95%CI: 1.812-3.251), cavitated lesions (PR= 2.012, 95%CI: 1.397-2.896) and type of TDI (PR= 1.951,

95%CI: 1.099-3.461). **CONCLUSION:** Cavitated lesions and TDI cause negative impact on OHRQoL of the preschool children and their families. Also, the parents of children with these conditions were found to feel guiltier. Moreover, parent's/caregiver's perception of child's oral health as poor and birth order were predictors for a greater impact on quality of life.

Keywords: quality of life; guilt; dental caries; malocclusion; tooth injuries; preschool child.

LISTA DE ILUSTRAÇÕES

FIGURA 1	Localização geográfica do Estado da Paraíba e da cidade de Campina Grande.....	20
QUADRO 1	Categorização da variável dependente do plano de análise I...	30
QUADRO 2	Definição e categorização das variáveis de interesse do plano de análise I.....	31
QUADRO 3	Definição e categorização das variáveis de caráter exploratório do plano de análise I.....	32
QUADRO 4	Categorização da variável dependente do plano de análise II.....	33
QUADRO 5	Definição e categorização das variáveis de interesse do plano de análise II.....	34
QUADRO 6	Definição e categorização das variáveis de caráter exploratório do plano de análise II.....	35
FIGURA 1 (Artigo 1)	Modelo de análise utilizado no estudo.....	71
FIGURA 1 (Artigo 2)	Modelo de análise utilizado no estudo.....	96

LISTA DE TABELAS

ARTIGO 1	Impacto das condições de saúde bucal na qualidade de vida de pré-escolares e suas famílias: um estudo transversal	
TABELA 1	Frequência das variáveis clínicas analisadas de acordo com dados sócio-demográficos de crianças pré-escolares.....	61
TABELA 2	Prevalência de impacto na qualidade de vida relacionada à saúde bucal e pontuação do B-ECOHIS entre pré-escolares.....	62
TABELA 3	Regressão hierárquica de Poisson para o impacto na QVRSB de crianças e variáveis independentes.....	63
TABELA 4	Regressão hierárquica de Poisson para o impacto na QVRSB da família e variáveis independentes.....	67
ARTIGO 2	Associação entre culpa parental e problemas de saúde bucal em pré-escolares: uma abordagem hierárquica	
TABELA 1	Distribuição de frequência das variáveis sociodemográficas.....	91
TABELA 2	Distribuição de frequência da culpa parental e problemas de saúde bucal.....	92
TABELA 3	Regressão hierárquica de Poisson para a culpa parental e variáveis independentes entre crianças pré-escolares com idade de três a cinco anos.....	93

LISTA DE ABREVIATURAS E SIGLAS

B-ECOHIS – Brazilian Early Childhood Oral Health Impact Scale

CNS – Conselho Nacional de Saúde

COHQOLI – Child Oral Health of Life Instrument

ECOHIS – Early Childhood Oral Health Impact Scale

IBGE – Instituto Brasileiro de Geografia e Estatística

IC – Intervalo de confiança

ICDAS – International Caries Detection and Assessment System

INEP - Instituto Nacional de Estudos e Pesquisas Educacionais

OHRQoL – Oral Health-Related Quality of Life

OMS – Organização Mundial de Saúde

PB – Paraíba

PR – Prevalence Ratio

QVRSB – Qualidade de vida relacionada à saúde bucal

SOHO-5 – Scale of Oral Health Outcomes

SPSS – Statistical Package for the Social Sciences

TDI – Traumatic Dental Injuries

UEPB – Universidade Estadual da Paraíba

VIF – Variance inflation factor

SUMÁRIO

1 CONSIDERAÇÕES INICIAIS	17
2 OBJETIVOS	19
2.1 GERAL	19
2.2 ESPECÍFICOS	19
3 METODOLOGIA	20
3.1 CARACTERIZAÇÃO DA ÁREA DE ESTUDO	20
3.2 DESENHO DO ESTUDO	21
3.3 POPULAÇÃO DE ESTUDO	21
3.4 GRUPO DE ESTUDO E PROCESSO DE SELEÇÃO	21
3.4.1 Cálculo amostral.....	21
3.4.2 Critérios de inclusão.....	22
3.4.3 Critérios de exclusão	23
3.4.4 Calibração.....	23
3.4.5 Estudo-piloto	24
3.5 CONTATO COM AS PRÉ-ESCOLAS.....	24
3.6 CRITÉRIOS DE DIAGNÓSTICO	25
3.6.1 Cárie dentária	25
3.6.2 Traumatismo dentário	26
3.6.3 Má oclusão	26
3.7 COLETA DOS DADOS	27
3.7.1 Instrumentos para coleta dos dados.....	28
3.7.2 Exame clínico.....	29
3.8 ELENCO DE VARIÁVEIS	29
3.8.1 Plano de análise I (Artigo 1)	30

3.8.2 Plano de análise II (Artigo 2)	33
3.9 PRINCÍPIOS ÉTICOS	35
3.9.1 Consentimento das Secretarias Municipal e Estadual de Educação e das Escolas Particulares	35
3.9.2 Termo de Consentimento Livre e Esclarecido	36
3.9.3 Parecer do Comitê de Ética em Pesquisa	36
3.10 PROCESSAMENTO E ANÁLISE DOS RESULTADOS	36
3.11 FLUXOGRAMA	38
4 RESULTADOS	39
ARTIGO 1	40
ARTIGO 2	72
5 CONSIDERAÇÕES FINAIS	98
6 REFERÊNCIAS	100
APÊNDICES E ANEXOS	104

1 CONSIDERAÇÕES INICIAIS

A qualidade de vida tem sido bastante pesquisada desde que uma nova concepção de saúde vem se formando. O conceito de qualidade de vida amplia a visão do profissional de saúde (VIEGAS et al., 2012) e refere-se à percepção do indivíduo de sua posição na vida, no contexto de cultura e sistema de valores nos quais ele vive e em relação aos seus objetivos, expectativas, padrões e preocupações. Dessa forma, é de caráter multidimensional, não estando restrita aos efeitos físicos das doenças (BUCZYNSKI; CASTRO; SOUZA, 2008).

O impacto das alterações bucais na qualidade de vida é denominado qualidade de vida relacionada à saúde bucal (QVRSB). É definido como o impacto dos sintomas e aspectos funcionais, como a experiência de dor e limitação funcional, considera-se também os aspectos psicológicos e sociais no bem-estar do indivíduo, advindos das alterações bucais (LOCKER et al., 2002; LIU; MCGRATH; HÄGG, 2009). Além disso, em pré-escolares, podem afetar o crescimento, socialização, aprendizagem, e também causar impacto na qualidade de vida da família (PAHEL; ROZIER; SLADE, 2007; ALDRIGUI et al., 2011; MARTINS-JÚNIOR et al., 2013; SCARPELLI et al., 2013).

O fornecimento dessas informações sobre o impacto das alterações bucais na QVRSB de pré-escolares contribui para o conhecimento dos aspectos multidimensionais do processo saúde-doença e, com isso, defini-se grupos com níveis mais elevados de necessidades. Assim, permite planejar programas de saúde com estratégias para aumentar a qualidade dos sistemas de saúde, e conseqüentemente implicará na melhoria de serviços oferecidos para as crianças e seus familiares (TESCH; OLIVEIRA; LEÃO, 2007; LEE et al., 2009; MARTINS-JÚNIOR et al., 2013).

O interesse pela qualidade de vida e saúde bucal em crianças e adolescentes vem aumentando (PATEL; TOOTLA; INGLEHART, 2007). Neste sentido, questionários que visam avaliar o impacto das alterações bucais na qualidade de vida tem sido desenvolvidos e adaptados para estes grupos específicos. No entanto, para crianças pré-escolares existem poucos instrumentos, posto que evidências nos campos de desenvolvimento e psicologia da criança indicam que crianças menores de seis anos de idade não são capazes de lembrar com precisão acontecimentos do dia-a-dia, após um período de 24 horas (PAHEL et al., 2007). Dessa forma, considera os pais como

fundamentais na tomada de decisão e no que diz respeito à percepção dos problemas bucais de seus filhos (TESCH; OLIVEIRA; LEÃO, 2008; SCARPELLI et al., 2011)

Atualmente, no Brasil, existem apenas dois instrumentos validados para avaliar a QVRSB de crianças em idade pré-escolar, o “Scale of Oral Health Outcomes” (SOHO-5) que tem sua aplicabilidade confiável apenas para crianças de cinco anos de idade (TSAKOS et al., 2012; ABANTO et al., 2013), e o “Early Childhood Oral Health Impact Scale” (ECOHIS) (TESCH; OLIVEIRA; LEÃO, 2008; SCARPELLI et al., 2011; MARTINS-JÚNIOR, 2012), este último foi desenvolvido inicialmente nos Estados Unidos por Pahel, Rozier e Slade (2007) e, posteriormente, traduzido e adaptado para a língua portuguesa por Tesch, Oliveira e Leão (2008). Esse instrumento pode ser utilizado em crianças de dois a cinco anos de idade e apresenta-se dividido em duas seções: impacto na criança e impacto na família. O ECOHIS usa as opções de resposta dos pais para avaliar a frequência em que a alteração bucal e seu tratamento afeta a QVRSB da criança (PAHEL; ROZIER; SLADE, 2007; SCARPELLI et al., 2011).

Os estudos que avaliam o impacto das alterações bucais na QVRSB de pré-escolares apresentam amostras não randomizadas (KRAMER et al., 2013; MARTINS-JÚNIOR et al., 2013; ABANTO et al., 2014) ou de conveniência (ABANTO et al., 2011; ALDRIGUI et al., 2011; WONG et al., 2011). Além disso, a maioria dos estudos utiliza variáveis dicotômicas (presença/ausência de condições de saúde bucal) (ABANTO et al., 2011; ALDRIGUI et al., 2011; WONG et al., 2011; SCARPELLI et al., 2013). Poucos estudos buscam analisar o impacto das diferentes gravidades de traumatismo dentário (TDI) e os tipos de má oclusão (KRAMER et al., 2013; ABANTO et al., 2014) e todos avaliam a cárie dentária com os critérios da OMS, que não discrimina entre estágios iniciais de cárie dentária e lesões cavitadas. Portanto, esse é o primeiro estudo randomizado que avaliou a gravidade da cárie dentária com base no novo índice de diagnóstico para a cárie dentária (ICDAS-II), juntamente com os diferentes tipos de TDI e má oclusão.

Desse modo, esse estudo teve como objetivo avaliar as repercussões das alterações bucais e fatores associados na qualidade de vida de pré-escolares e suas famílias, bem como a influência de tais alterações na culpa parental. Optou-se pela apresentação da dissertação em forma de artigos científicos, uma vez que constituem uma forma clara e objetiva de divulgação dos resultados das pesquisas junto à comunidade científica.

2 OBJETIVOS

2.1 GERAL

Avaliar as repercussões das alterações bucais e fatores associados na qualidade de vida em pré-escolares e suas famílias, bem como a influência de tais alterações bucais na culpa parental.

2.2 ESPECÍFICOS

Plano de análise I (Artigo 1)

- Verificar o impacto da cárie dentária, do traumatismo dentário e da má oclusão na qualidade de vida de pré-escolares utilizando o *Brazilian Early Childhood Oral Health Impact Scale* (B-ECOHIS).
- Verificar o impacto da cárie dentária, do traumatismo dentário e da má oclusão na qualidade de vida da família dos pré-escolares utilizando o *Brazilian Early Childhood Oral Health Impact Scale* (B-ECOHIS).
- Identificar o impacto das condições sociodemográficas e das percepções de saúde geral e bucal sobre a qualidade de vida relacionada à saúde bucal dos pré-escolares e sua família.

Plano de análise II (Artigo 2)

- Determinar a influência das alterações bucais na culpa parental devido as condições bucais do pré-escolar (Item do B-ECOHIS);
- Identificar fatores sociodemográficos e percepção de saúde geral e bucal associados à culpa parental devido as condições bucais do pré-escolar (Item do B-ECOHIS).

3 METODOLOGIA

3.1 CARACTERIZAÇÃO DA ÁREA DE ESTUDO

O município de Campina Grande está localizado no interior do estado da Paraíba, no agreste paraibano, na parte oriental do Planalto da Borborema (Figura 1). Com uma população estimada de 400,002 habitantes, o município de Campina Grande, apresenta uma área total de 599,6 km² e é um dos principais polos de desenvolvimento econômico do interior do Nordeste. A vigilância sanitária subdivide o município em seis distritos sanitários, visando facilitar a programação local dos serviços de saúde (IBGE, 2012).

O município sedia a Federação das Indústrias do Estado, possui 16 instituições de ensino superior, sendo duas da rede pública. O município conta ainda com várias escolas técnicas e alguns centros de pesquisa, como o Centro Nacional de Pesquisas do Algodão, da Empresa Brasileira de Pesquisa Agropecuária (Embrapa), e a Companhia de Recursos Minerais. Além disso, Campina Grande também tem graves problemas sociais e elevados índices de pobreza, além de um grande número de desempregados e de trabalhadores do setor informal (IBGE, 2012).



Figura 1 Localização geográfica do Estado da Paraíba e da Cidade de Campina Grande.

Fonte: <http://www.viagemdeferias.com/mapa/paraiba.gif>

3.2 DESENHO DO ESTUDO

Desenvolveu-se um estudo epidemiológico de base pré-escolar classificado como um estudo do tipo transversal, analítico, que determinou o impacto das alterações bucais (cárie dentária, má oclusão e traumatismo dentário) na qualidade de vida de pré-escolares de três a cinco anos, da cidade de Campina Grande-PB.

Os estudos de corte transversal são importantes, pois permitem analisar a distribuição de um agravo em determinada população, além de serem úteis como base para o planejamento e determinação de necessidades coletivas de tratamento. Apresentam, entre outras vantagens, baixo custo e objetividade dos dados (PEREIRA, 1995, PINTO, 2000).

3.3 POPULAÇÃO DE ESTUDO

Crianças de três a cinco anos, assistidas em pré-escolas públicas e privadas da cidade de Campina Grande-PB. O município apresenta 127 pré-escolas privadas e 122 públicas (estaduais, municipal e federal), perfazendo um total de 12.705 crianças de acordo com o censo escolar 2011.

3.4 GRUPO DE ESTUDO E PROCESSO DE SELEÇÃO

3.4.1 Cálculo amostral

Nesta pesquisa o cálculo amostral foi realizada por meio de procedimento amostral estratificado por Distritos Sanitários e por conglomerados (pré-escolas). Em cada estrato, foi selecionado um número determinado de estabelecimentos, e, em cada pré-escola, foi selecionada uma amostra aleatória proporcional ao número de alunos por pré-escola.

A amostra foi obtida através do cálculo de estimativa de proporção, de acordo com Kirkwood (1996):

$$n = (Z_{1-\alpha})^2 \frac{p(1-p)}{d^2}$$

Onde:

α : nível de significância (95%)

p: prevalência do agravo analisado (50%)

d: erro admissível (4%)

Então:

$\alpha = 95\%$

p = 50%

d = 4%

Deste modo, segundo o cálculo de estimativa de proporções, o tamanho amostral seria de 600 crianças.

O processo de amostragem por conglomerados (*cluster*) altera a precisão das estimativas, já que essas dependem do grau de homogeneidade interna dos conglomerados. Ao se proceder a essa técnica de amostragem, perde-se a homogeneidade, e, portanto, um número mais elevado é requerido para compensar esse aspecto. Essa correção pode ser efetuada de forma simplificada e conservadora: multiplica-se o tamanho da amostra por 1,2 e 2,0. Esse procedimento é denominado efeito de delineamento ou efeito do desenho.

Neste estudo utilizou-se o fator 1,2, sendo a amostra agora estimada em 720 crianças. Porém, torna-se necessário adicionar 20% ao tamanho amostral, para compensar as possíveis perdas. Assim, a amostra final foi constituída de 864 pré-escolares de três a cinco anos.

3.4.2 Critérios de inclusão

- Crianças de três a cinco anos matriculadas em pré-escolas da rede pública e privada de Campina Grande-PB;
- Ausência de doenças sistêmicas e/ou deficiências físicas e de aprendizagem.

3.4.3 Critérios de exclusão

- Presença de um ou mais dentes permanentes em erupção;
- Crianças submetidas a tratamento ortodôntico;
- Acompanhada pelo pai/responsável de outra nacionalidade.

3.4.4 Calibração

A calibração seguiu a metodologia proposta por Peres, Traebert e Marcenes (2001), sendo dividida em duas etapas:

Primeira Etapa: consistiu em um momento teórico no qual foi apresentado o índice utilizado e os critérios de diagnóstico. Imagens das condições que seriam observadas no exame foram projetadas por um minuto, sendo solicitado aos examinadores que diagnosticassem essas alterações. Foi, então, realizado o estudo da ficha clínica e da rotina a ser seguida durante o exame clínico. Esta etapa foi coordenada por especialistas, considerados padrão-ouro no treinamento dos três cirurgiões-dentistas selecionados para o exercício de calibração.

Segunda Etapa: foi a etapa na qual foram conduzidos os exames clínicos, pelos examinadores e pelo padrão ouro, realizados em 50 pré-escolares de três a cinco anos pertencentes a uma pré-escola pública selecionada por sorteio. Estes pré-escolares examinados no exercício de calibração não foram incluídos no estudo principal. O grau de concordância inter-examinador foi testado comparando-se os diagnósticos de cada examinador com o padrão-ouro. Dessas 50 crianças, 30 foram reexaminadas após um intervalo de sete dias para determinação do grau de concordância intra-examinador.

A consistência dos diagnósticos foi medida através do coeficiente *Cohens's kappa* para a obtenção dos valores de concordância a partir da seguinte fórmula:

$$K = \frac{P_o - P_e}{100 - P_e}$$

Onde:

P_o - porcentagem de dentes nos quais houvera concordância diagnóstica.

P_e - porcentagem de concordância esperada.

Os resultados numericamente obtidos representam (BULMAN; OSBORN, 1989):

k igual a zero: baixíssima confiabilidade.

k maior que zero e menor que 0,40: baixa confiabilidade.

k entre 0,41 e 0,60: moderada confiabilidade.

k entre 0,61 e 0,80: substancial confiabilidade.

k acima de 0,81: boa confiabilidade.

Assim, diante da metodologia exposta, os dados obtidos pelo teste de Kappa na calibração realizada variou de 0,83-0,88 na concordância interexaminador e 0,85-0,90 na concordância intraexaminador, representando boa confiabilidade e, desse modo, os três examinadores foram considerados aptos para a realização dos exames clínicos.

3.4.5 Estudo-piloto

Previamente ao estudo principal foi realizado um estudo piloto para testar e avaliar a metodologia proposta para a realização do estudo (realização dos exames clínicos, aplicabilidade do ECOHIS e do questionário sociodemográfico). Este estudo foi realizado em duas pré-escolas, uma pública e uma privada, selecionadas por conveniência e examinadas 20 crianças em cada pré-escola. As crianças não foram incluídas no estudo principal.

A fim de se avaliar a confiabilidade das respostas do questionário foi realizado o teste e re-teste, no qual, o instrumento foi aplicado novamente após um intervalo de sete dias.

3.5 CONTATO COM AS PRÉ-ESCOLAS

As pré-escolas foram localizadas de acordo com os dados fornecidos pelo INEP (Instituto Nacional de Estudos e Pesquisas Educacionais Anísio Teixeira), e foram visitadas inicialmente pela pesquisadora. Neste momento, foram esclarecidos à pessoa responsável pelo estabelecimento os objetivos da pesquisa, as atividades que seriam realizadas na pré-escola e a metodologia do trabalho proposto. Em cada pré-escola

foram apresentadas as aprovações do trabalho pelo Comitê de Ética em Pesquisa e a Autorização da Secretaria de Educação.

3.6 CRITÉRIOS DE DIAGNÓSTICO

3.6.1 Cárie dentária

Foi considerada a presença ou a ausência da cárie dentária e os critérios de diagnósticos seguiram o ICDAS-II (ISMAIL et al., 2007):

0 = Sadio, imediatamente após secagem com ar (5 segundos); sem cárie, manchamento, hipoplasia, desgaste, erosão e outros fenômenos não cariosos.

1 = Imediatamente após secagem com ar, primeira alteração visível no esmalte ou alterações na coloração limitada às áreas de fóssulas e fissuras.

2 = Observação sem secagem, alteração visual distinguível, branca ou colorida, numa extensão que vai além as fóssulas e fissuras.

3 = Ruptura localizada do esmalte, sem dentina visível, descontinuidade na superfície do esmalte. Confirmada com sonda OMS.

4 = Sombra escura subjacente desde a dentina, com ou sem ruptura localizada do esmalte.

5 = Cavidade com dentina exposta na base da cavidade.

6 = Cavidade extensa, visível, em dentina, na base e nas paredes (mais de metade da superfície).

Portanto, presença de cárie dentária foi considerada quando qualquer dente apresentava código ≥ 2 ; ausência de cárie dentária quando todos os dentes receberam código “0”.

Em função da natureza epidemiológica desse estudo os códigos “1” e “2” foram unidos em uma mesma classificação diagnóstica, em virtude da secagem ser feita com gaze e não com jato de ar no escore “1”. Neste estudo foram considerados os dentes com lesões cavitadas aqueles que apresentarem escores iguais ou superiores a “3”, uma vez que é a partir deste ponto que se observa danos estruturais à superfície do esmalte. Foi considerada doença severa quando verificada a presença dos escores “5” e “6”, pois

a partir deste estágio se observa a lesão de cárie com franca cavitação, estendendo-se até a dentina.

3.6.2 Traumatismo dentário

Para o diagnóstico de traumatismo dentário nos incisivos e caninos foi utilizada a classificação de Andreasen et al. (2007) que é destinada a estudos epidemiológicos uma vez que os diagnósticos são realizados sem o auxílio do exame radiográfico. A presença de TDI foi determinada por qualquer tipo de TDI ou alteração de cor:

1. Fratura de esmalte
2. Fratura de esmalte e dentina
3. Fratura coronária complicada
4. Luxação extrusiva
5. Luxação lateral
6. Luxação intrusiva
7. Avulsão
8. Alteração de cor

3.6.3 Má oclusão

Os critérios utilizados para avaliação da oclusão foram baseados no índice de Foster e Hamilton (1969) e Grabowski et al. (2007), descrito abaixo:

Sobremordida: trespasse vertical dos incisivos

- Normal: quando o trespasse vertical dos incisivos não ultrapassar 2mm;
- Sobremordida profunda: quando o trespasse vertical ultrapassar 2mm;
- Mordida aberta anterior: Ausência de contato dos incisivos anteriores estando os posteriores em oclusão.

Sobressaliência: trespasse horizontal dos incisivos

- Normal: distância entre os incisivos superiores e os inferiores no sentido horizontal não ultrapassar 2 mm;

- Sobressaliência aumentada: quando o trespasse horizontal ultrapassar os 2 mm;
- Mordida cruzada anterior: trespasse horizontal negativo.

Mordida Cruzada Posterior

- Os molares superiores ocluem numa relação lingual em relação aos inferiores em oclusão cêntrica.

O pré-escolar que apresentou pelo menos uma das condições de anormalidade indicadas pelo índice, tais como: sobremordida profunda, mordida aberta anterior, sobressaliência aumentada, mordida cruzada anterior e mordida cruzada posterior, foi diagnosticado com presença de má oclusão. Para o diagnóstico de má oclusão a criança permaneceu em oclusão cêntrica.

3.7 COLETA DOS DADOS

A coleta dos dados foi realizada nas instituições selecionadas para o estudo, sendo executada por 3 examinadores calibrados e os dados anotados por assistentes devidamente treinados, no período de outubro de 2011 a abril de 2012.

Para a coleta de dados, primeiramente foi feita a aplicação dos questionários com um dos pais/responsável pelas crianças; e em um segundo momento realizado os exames clínicos daquelas crianças que os pais/responsáveis autorizaram a sua participação no estudo e tenham respondido devidamente o questionário.

O uso de questionários em pesquisa apresenta algumas vantagens em relação à entrevista, como baixo custo, ampla dispersão geográfica, mais tempo para responder às questões e anonimato dos participantes. Essa última vantagem permite uma redução de viés pela remoção da interação do respondente com o entrevistador. As desvantagens dos questionários incluem uma baixa taxa de resposta, viés dos respondentes (pela exclusão de participantes com problemas linguísticos, literários, visuais) e perda por respostas incompletas (PARDAL; CORREIA, 1995).

O exame clínico permite um registro objetivo da condição bucal do examinado assegurando que todas as condições sejam detectadas e diagnosticadas (OMS, 1999).

3.7.1 Instrumentos para coleta dos dados

Para coleta dos dados foram necessários três instrumentos de pesquisa:

- Questionário dirigido aos pais contendo questões relacionadas às condições sociodemográficas e à condição de saúde da criança (APÊNDICE A).
- Questionário B-ECOHIS, também dirigido aos pais/responsáveis (ANEXO A).
- Ficha clínica para anotação dos dados clínicos (APÊNDICE B), contendo a ficha do ICDAS-II (ANEXO B)

O instrumento Early Childhood Oral Health Impact Scale (ECOHIS) foi criado por pesquisadores da Universidade da Carolina do Norte (PAHEL; ROZIER; SLADE, 2007) para avaliar a qualidade de vida relacionada à saúde bucal de crianças na idade pré-escolar. O ECOHIS foi desenvolvido a partir de uma seleção de 13 itens, oriundos dos 36 que compõem o questionário Child Oral Health of Life Instrument (COHQOLI). Esses itens foram considerados os mais relevantes para mensurar o impacto dos problemas bucais sobre a qualidade de vida dos pré-escolares e consideraram as experiências de doenças bucais e tratamentos dentários da vida inteira da criança (TESCH; OLIVEIRA; LEÃO, 2008; SCARPELLI et al., 2011).

A versão brasileira do questionário (B-ECOHIS) foi validada em português do Brasil e já utilizada em estudos anteriores (TESC; OLIVEIRA; LEÃO, 2008; SCARPELLI et al., 2011; MARTINS-JÚNIOR et al., 2012). Esta escala é dividida em duas seções (impacto na criança e impacto na família), com seis domínios e treze itens. Os domínios da seção de impacto na criança são sintomas (um item), funcional (quatro itens), psicológico (dois itens) e interação social e auto-imagem (dois itens). Os domínios da seção de impacto na família são angústia (dois itens) e função da família (dois itens). (TESH; OLIVEIRA; LEÃO, 2008).

As opções de respostas estão elencadas em códigos que variam de 0 a 5, onde, código 0 = nunca, 1 = quase nunca, 2 = às vezes, 3 = com frequência, 4 = com muita frequência, 5= não sei. As respostas referentes ao código 5= “não sei” não são consideradas para análise. Nesse estudo, considerou impacto na QVRSB de crianças e suas famílias quando pelo menos uma resposta "às vezes" foi relatada nos seus itens; e a ausência de impacto quando todas as respostas foram dadas como "nunca" e/ou “quase

nunca” (PAHEL et al., 2007; TESCH; OLIVEIRA; LEÃO, 2008; SCARPELLI et al., 2011).

3.7.2 Exame clínico

Os exames clínicos foram realizados por três cirurgiões-dentistas previamente calibrados, após o retorno dos questionários e termo de consentimento livre e esclarecido. Antes do exame clínico, as crianças realizavam uma escovação supervisionada pelo examinador. Para tal, cada criança recebeu um kit contendo escova de dente, dentrífcio e fio dental para remover a placa bacteriana das superfícies dentárias e facilitar o diagnóstico.

As crianças foram examinadas nas pré-escolas, permanecendo na posição sentada em frente ao examinador, com o auxílio de uma lâmpada portátil posicionada na cabeça do examinador (Petzl Zoom head lamp, Petzl America, Clearfield, UT, USA). Para o exame clínico, os examinadores estavam usando equipamentos de proteção individual, sendo as luvas trocadas a cada exame e o gorro e a máscara a cada turno de exame. Nos exames foram utilizados espelhos bucais estéreis (PRISMA ®, São Paulo, SP, Brasil), sondas de Williams estéreis (OMS-621, Trinity ®, Campo Mourão, PA, Brasil) e gazes dentárias para secar os dentes.

Para a cárie dentária foi utilizado o índice ICDAS-II (ISMAIL et al., 2007), para o traumatismo a classificação de Andreasen et al. (2007) e para a má oclusão foi adotado o índice de Foster e Hamilton (1969) e Grabowski et al. (2007) conforme relatado anteriormente nos critérios de diagnóstico.

3.8 ELENCO DE VARIÁVEIS

O estudo apresenta dois planos de análise. Foi avaliada inicialmente o impacto das alterações bucais (variáveis independentes) na qualidade de vida (variável dependente) e seus fatores associados. Num segundo plano de análise, foi determinada a influência das alterações bucais (variável independente) no sentimento de culpa dos pais/responsáveis (variável dependente). Neste sentido, as variáveis foram classificadas em duas etapas distintas, de acordo com os planos de análise descritos a seguir:

3.8.1 Plano de análise I (Artigo 1)

- **Variável dependente**

A variável dependente eleita nesta etapa da pesquisa são as questões relativas à qualidade de vida. A qualidade de vida foi avaliada pela versão brasileira adaptada transculturalmente do ECOHIS (Early Childhood Oral Health Impact Scale) (TESCH; OLIVEIRA; LEÃO, 2008).

Quadro 1: Categorização da variável dependente do plano de análise I.

VARIÁVEL DEPENDENTE	DOMÍNIOS	CATEGORIZAÇÃO
Impacto na qualidade de vida ECOHIS (TESCH; OLIVEIRA; LEÃO, 2008)	IMPACTO NA CRIANÇA (sintomas, função, psicológico, autoimagem/ interação social)	0. Sem impacto na qualidade e vida 1. Com impacto na qualidade de vida
	IMPACTO NA FAMÍLIA (angústia e função familiar)	0. Sem impacto na qualidade e vida 1. Com impacto na qualidade de vida

- **Variáveis independentes**

As variáveis independentes estão apresentadas de acordo com a seguinte categorização: variáveis de interesse (cárie dentária, traumatismos dentários e má oclusão) e as variáveis de caráter exploratório. No quadro 2 estão apresentadas as variáveis de interesse e no quadro 3 as variáveis de caráter exploratório.

Quadro 2. Definição e categorização das variáveis de interesse do plano de análise I.

TIPO DE VARIÁVEL	DEFINIÇÃO DA VARIÁVEL	AGRUPAMENTO E CATEGORIZAÇÕES
Cárie dentária / ICDAS-II (ISMAIL et al., 2007)	Presença de cárie dentária no exame clínico	0. Ausente 1. Presente
Dentes cavitados	Gravidade da cárie dentária de acordo com a classificação do ICDAS-II (caráter qualitativo)	0.Sem cárie/ mancha branca 1.Dente anterior 2.Dente posterior 3.Dente anterior e posterior
Traumatismo dentário (ANDREASEN et al., 2007)	Presença de traumatismo dentário no exame clínico	0. Ausente 1. Presente
Tipo de traumatismo dentário	Categorização dos traumatismos dentários de acordo com a classificação inglesa (ANDREASEN et al., 2007)	0. Fratura de esmalte 1. Fratura de esmalte e dentina 2. Fratura coronária complicada 3. Luxação extrusiva 4. Luxação lateral 5. Luxação intrusiva 6. Avulsão 7. Alteração de cor
Presença de má oclusão	Presença de má oclusão no exame clínico	0. Ausente 1. Presente
Tipo de má oclusão	Categorização da má oclusão de acordo com a classificação de Foster e Hamilton (1969) e Grabowski et al. (2007)	0. Sobremordida profunda 1. Mordida aberta anterior 2. Sobressaliência aumentada 3. Mordida cruzada anterior 4. Mordida cruzada posterior

Quadro 3 – Definição e categorização das variáveis de caráter exploratório do plano de análise I.

TIPO DE VARIÁVEL	DEFINIÇÃO DA VARIÁVEL	AGRUPAMENTO E CATEGORIZAÇÕES
Sexo	Sexo da criança	0. Feminino 1. Masculino
Idade	Em anos	0. 3 anos 1. 4 anos 2. 5 anos
Tipo de pré-escola	Tipo de pré-escola que a criança está vinculada.	0. Pública 1. Privada
Renda mensal familiar*	Relato do responsável sobre a renda mensal da família.	0. \leq 1 salário mínimo 1. $>$ 1 salário mínimo
Nível de Escolaridade Materna	Relato do responsável sobre a escolaridade da mãe da criança.	0. \leq 8 anos de estudo 1. $>$ 8 anos de estudo
Número de moradores por domicílio	Relato do responsável sobre o número de pessoas que moram com a criança.	0. $<$ 6 pessoas 1. \geq 6 pessoas
Ordem de nascimento da criança	Ordem de nascimento da criança.	0. Único. 1. Mais novo. 2. Mais velho. 3. Do meio.
Idade do responsável	Em anos	0. \leq 30 anos 1. $>$ 30 anos
Percepção de saúde geral da criança	Avaliação da percepção de saúde geral da criança segundo o responsável	0. Muito boa 1. Boa 2. Regular 3. Ruim 4. Muito ruim
Percepção de saúde bucal da criança	Avaliação da percepção de saúde bucal da criança segundo o responsável	0. Muito boa 1. Boa 2. Regular 3. Ruim 4. Muito ruim

*Classificado com base no salário mínimo na época da coleta de dados (R\$ 622,00).

3.8.2 Plano de análise II (Artigo 2)

- **Variável dependente**

A variável dependente do plano de análise II foi a questão relativa ao sentimento de culpa dos pais/responsáveis no questionário ECOHIS (Early Childhood Oral Health Impact Scale). Essa questão faz parte do domínio de angústia do impacto na família (TESCH; OLIVEIRA; LEÃO, 2008). Para analisar os dados, as respostas sobre a culpa parental serão dicotomizadas em ausência (incluindo apenas a opção de resposta "nunca") e presença de culpa (incluindo as opções de resposta restantes: “quase nunca”, “às vezes”, “com frequência” e “com muita frequência”) (CARVALHO et al., 2012).

Quadro 4. Categorização da variável dependente do plano de análise II.

VARIÁVEL DEPENDENTE	DOMÍNIOS	CATEGORIZAÇÃO
Questão relativa à culpa parental do questionário ECOHIS (CARVALHO et al., 2012)	Sentimento de culpa dos pais/responsáveis devido alterações bucais das crianças.	1. Ausência 2. Presença

- **Variáveis independentes**

As variáveis independentes serão apresentadas de acordo com a seguinte categorização: variáveis de interesse e variáveis de caráter exploratório. No quadro 5 serão apresentadas as variáveis de interesse e no quadro 6 as variáveis de caráter exploratório.

Quadro 5. Definição e categorização das variáveis de interesse do plano de análise II.

TIPO DE VARIÁVEL	DEFINIÇÃO DA VARIÁVEL	AGRUPAMENTO E CATEGORIZAÇÕES
História de dor de dente	História de dor de dente da criança	0. Ausente 1. Presente
Cárie dentária / ICDAS-II (ISMAIL et al., 2007)	Presença de cárie dentária no exame clínico	0. Ausente 1. Presente
Dentes cavitados	Gravidade da cárie dentária de acordo com a classificação do ICDAS-II (caráter qualitativo)	0. Sem cárie/ mancha branca 1. Dente anterior 2. Dente posterior 3. Dente anterior e posterior
Traumatismo dentário (ANDREASEN et al., 2007)	Presença de traumatismo dentário no exame clínico	0. Ausente 1. Presente
Tipo de traumatismo dentário	Categorização dos traumatismos dentários de acordo com a classificação inglesa (ANDREASEN et al., 2007)	0. Fratura de esmalte 1. Fratura de esmalte e dentina 2. Fratura coronária complicada 3. Luxação extrusiva 4. Luxação lateral 5. Luxação intrusiva 6. Avulsão 7. Alteração de cor
Presença de má oclusão	Presença de má oclusão no exame clínico	0. Ausente 1. Presente
Tipo de má oclusão	Categorização da má oclusão de acordo com a classificação de Foster e Hamilton (1969) e Grabowski et al. (2007)	0. Sobremordida profunda 1. Mordida aberta anterior 2. Sobressaliência aumentada 3. Mordida cruzada anterior 4. Mordida cruzada posterior

Quadro 6 – Definição e categorização das variáveis de caráter exploratório do plano de análise II.

TIPO DE VARIÁVEL	DEFINIÇÃO DA VARIÁVEL	AGRUPAMENTO E CATEGORIZAÇÕES
Sexo	Sexo da criança	0. Feminino 1. Masculino
Idade	Em anos	0. 3 anos 1. 4 anos 2. 5 anos
Tipo de pré-escola	Tipo de pré-escola que a criança está vinculada.	0. Pública 1. Privada
Renda mensal familiar*	Relato do responsável sobre a renda mensal da família.	0. ≤ 1 salário mínimo 1. > 1 salário mínimo
Escolaridade materna	Relato do responsável sobre a escolaridade da mãe da criança.	0. ≤ 8 anos de estudo 1. > 8 anos de estudo
Idade do responsável	Em anos	0. ≤ 30 anos 1. > 30 anos
Percepção de saúde geral da criança	Avaliação da percepção de saúde geral da criança segundo o responsável	0. Muito boa 1. Boa 2. Regular 3. Ruim 4. Muito ruim
Percepção de saúde bucal da criança	Avaliação da percepção de saúde bucal da criança segundo o responsável	0. Muito boa 1. Boa 2. Regular 3. Ruim 4. Muito ruim

*Classificado com base no salário mínimo na época da coleta de dados (R\$ 622,00).

3.9 PRINCÍPIOS ÉTICOS

3.9.1 Consentimento das Secretarias Municipal e Estadual de Educação e das Escolas Particulares

Após a definição dos instrumentos de pesquisa e elaboração do projeto, este foi encaminhado à Secretaria Municipal de Educação e à Secretaria Estadual de Educação para análise e obtenção do consentimento, a fim de possibilitar a realização da pesquisa nas pré-escolas de Campina Grande-PB.

Após a assinatura por parte dos Secretários Municipal (APÊNDICE C) e Estadual de Educação (APÊNDICE D), das cartas de anuência, o projeto foi encaminhado ao Comitê de Ética em Pesquisa da Universidade Estadual da Paraíba (UEPB).

Para obtenção da autorização nas pré-escolas particulares, foi solicitada à responsável técnica das pré-escolas a assinatura de uma carta de anuência (APÊNDICE E), na qual foram explicados os objetivos do estudo e os procedimentos a serem realizados nas pré-escolas.

3.9.2 Termo de Consentimento Livre e Esclarecido

Diante do estabelecido pela resolução 196/96 (CNS), foi enviado um Termo de Consentimento Livre e Esclarecido (APÊNDICE F) a todos os pais/responsáveis pelas crianças participantes do estudo. Este termo teve a finalidade de apresentar os objetivos do estudo, a ausência de riscos e danos aos participantes; e de obter a autorização dos mesmos para a execução da pesquisa.

3.9.3 Parecer do Comitê de Ética em Pesquisa

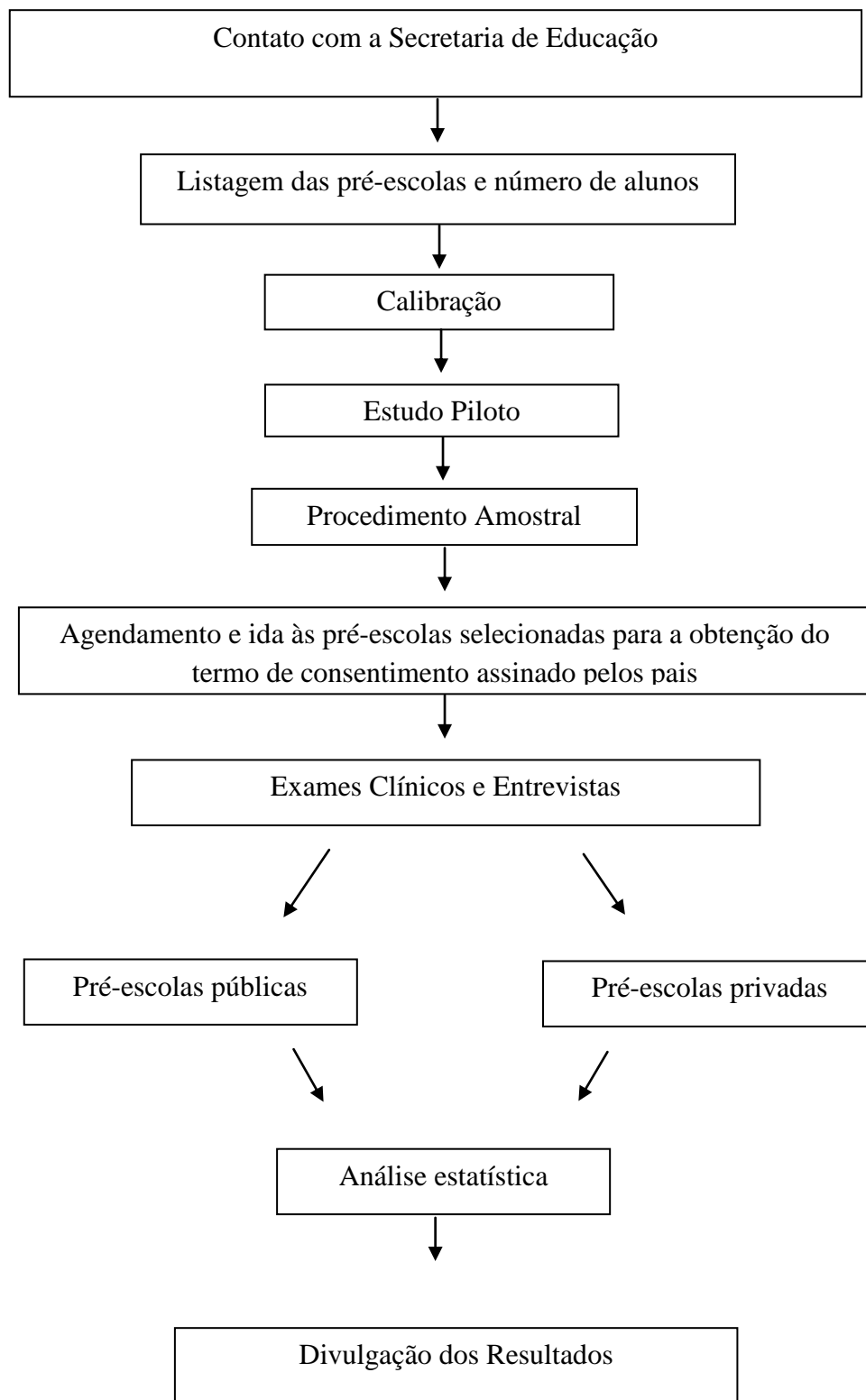
De acordo com a resolução 196/96 do Conselho Nacional de Saúde (CNS), de 10 de outubro de 1996, o projeto de pesquisa foi submetido à análise e aprovação pelo Comitê de Ética em Pesquisa da UEPB, sob o protocolo de número do CAAE 0046.0.133.000-11 (ANEXO C).

3.10 PROCESSAMENTO E ANÁLISE DOS RESULTADOS

Inicialmente estatísticas descritivas foram realizadas para caracterizar a amostra. A análise de regressão de Poisson bivariada com variância robusta foi utilizada para determinar as associações entre a variável dependente e as variáveis independentes de acordo com o plano de análise ($p < 0,05$). O modelo multivariado seguiu uma abordagem hierárquica de determinantes distais para proximais realizadas em três níveis: (1) sociodemográficas, (2) percepção de saúde e (3) alterações bucais (VICTORA et al., 1996). Um procedimento backward foi usado para selecionar as

variáveis que tenham alcançado um valor de $p < 0,20$ na análise bivariada, bem como variáveis consideradas determinantes epidemiológicos, de cada nível. As variáveis com valor de $p < 0,05$ na análise ajustada foram mantidas no modelo final de regressão. Interações entre cárie dentária, TDI e má oclusão foram testadas através do teste de Wald para heterogeneidade. Os valores do fator de inflação da variância (VIF) foram calculados para realizar um diagnóstico de colinearidade entre os preditores do modelo ajustado. A organização dos dados e as análises estatísticas foram realizadas utilizando o programa Statistical Package for Social Sciences (SPSS for Windows, version 20.0, SPSS Inc, Chicago, IL, USA).

3.11 FLUXOGRAMA



4 RESULTADOS

Como descrito anteriormente, o presente trabalho foi dividido em dois artigos. Desse modo, os resultados serão apresentados conforme a apresentação de cada artigo.

ARTIGO 1

Periódico: Health and Quality of Life Outcomes

Fator de impacto: 2,27 / Qualis Odontologia A2

Artigo formatado segundo as normas de publicação do periódico (ANEXO D)

Impact of oral health conditions on the quality of life of preschool children and their families: A cross-sectional study

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Abstract

Background: Dental caries, traumatic dental injury (TDI) and malocclusion are common oral health conditions among preschool children and can have both physical and psychosocial consequences. Thus, it is important to measure the impact of oral health conditions on the oral health-related quality of life (OHRQoL) of children. The aim of the present study was to assess the impact of oral health conditions on the OHRQoL of preschool children and their families.

Methods: A preschool-based, cross-sectional study was carried out with 843 preschool children in the city of Campina Grande, Brazil. Parents/caregivers answered the Brazilian version of the Early Childhood Oral Health Impact Scale and a questionnaire addressing socio-demographic data as well as the parent's/caregiver's perceptions regarding their child's health. Clinical exams were performed by three researchers who had undergone a calibration process for the diagnosis of dental caries, TDI and malocclusion ($K=0.83-0.85$). Hierarchical Poisson regression was employed to determine the strength of associations between oral health conditions and OHRQoL ($\alpha=5\%$). The multivariate model was run on three levels obeying a hierarchical approach from distal to proximal determinants: 1) socio-demographic data; 2) perceptions of health; and 3) oral health conditions. **Results:** The prevalence of negative impact from oral health conditions on OHRQoL was 32.1% among the children and 26.2% among the families. The following variables were significantly associated with a negative impact on OHRQoL among the children: birth order of child (PR=1.430; 95% CI: 1.045-1.958), parent's/caregiver's perception of child's oral health as poor (PR=1.732; 95% CI: 1.399-2.145), cavitated lesions (PR=2.596; 95% CI: 1.982-3.400) and TDI (PR=1.413; 95% CI: 1.161-1.718). The following variables were significantly associated with a negative impact on OHRQoL among the families: parent's/caregiver's perception of child's oral health as poor (PR=2.116; 95% CI: 1.624-2.757), cavitated lesions (PR=2.809; 95% CI: 2.009-3.926) and type of TDI (PR=2.448; 95% CI: 1.288-4.653). **Conclusion:** Cavitated lesions and TDI exerted a negative impact on OHRQoL of the preschool children and their families. Parents'/caregivers' perception of their child's oral health

as poor and the birth order of the child were predictors of a greater negative impact on OHRQoL.

Key words: Quality of life; Dental caries; Malocclusion; Tooth injuries; Preschool child.

Background

Oral health conditions can have a negative impact on the functional, social and psychological wellbeing of young children and their families, causing pain and discomfort for the child [1,2]. Assessing the impact of oral health on the life quality of children can improve communication between patients, parents and the dental team and can provide an outcome measure for clinicians to assess the quality of care. Moreover, the evaluation of oral health-related quality of life (OHRQoL) can assist in the assessment of treatment needs, the prioritisation of care and the evaluation of the outcomes of treatment strategies and initiatives [3-5].

The interest in the assessment of OHRQoL among children has grown in recent years, which is a major improvement, as children in many communities around the world are affected by dental caries, traumatic dental injury (TDI) and malocclusion [2,4-9]. Recent studies carried out in Brazil have shown high prevalence rates of adverse oral conditions, especially in areas with social inequalities, such as the area in which the present study was conducted [10-12].

The Early Childhood Oral Health Impact Scale (ECOHIS) was developed to assess the impact of oral health conditions on the quality of life of preschool children (aged 2 to 5 years) and their families and has been validated in Portuguese for use on Brazilian populations [1,13,14]. This scale is a proxy measure that considers parents/caregivers to be fundamental in the treatment decision-making process and perceptions regarding children's oral health conditions [1,13]. Moreover evidence in the fields of child development and psychology indicates that children less than six years of age are incapable of accurately recalling day-to-day events after more than 24 hours [15].

Studies evaluating the impact of oral health conditions on OHRQoL are often based on non-randomised [5-7] convenience samples [9,16,17]. Moreover, most studies use dichotomised variables (presence/absence of oral health conditions) [2,9,16,17]. Few studies have stratified the variables based on the severity of TDI and types of malocclusion [5,7] and all studies have evaluated dental caries using the WHO criteria, which does not discriminate cavitated dental caries and the initial stages of dental caries (e.g., white spots). No study in the literature has evaluated the severity of dental caries based on new diagnostic index for dental caries: the International Caries Detection and Assessment System (ICDAS), which is an internationally accepted caries detection system that allows the assessment of initial carious lesions (white spots) on the enamel and active lesions in the dentine. This system is based on the combined knowledge of the clinical appearance of the lesion, whether the lesion is in a plaque stagnation area and tactile sensation (texture) when a round-tipped probe is gently drawn across the surface of the tooth [18,19]. No study has evaluated the impact of white spots and cavitations on OHRQoL. Furthermore, the present investigation is a unique representative, randomised study with a two-stage sampling method and hierarchical analysis to evaluate the impact of the severity of TDI, type of malocclusion, white spots and cavitated dental caries on OHRQoL.

The aim of the present study was to evaluate the impact of oral health conditions on the OHRQoL of preschool children aged three to five years and their families in a representative, preschool-based sample.

Methods

Sample characteristics

A cross-sectional study was carried out involving a randomly selected sample of 843 male and female children aged three to five years enrolled in private and public preschools in the city of Campina Grande, Brazil. The participants were selected from a total population of 12,705 children in this age group. Campina Grande (estimated population: 386,000) is an

industrialised city in northeast Brazil and is divided into six administrative districts. The city has a Human Development Index of 0.72 [20].

The percentage distribution of three-to-five-year-old preschool children in each administrative district was calculated from information provided by the municipal Board of Education. To ensure representativeness, the sample was stratified according to administrative district and type of institution (two-phase sampling method). Preschools were randomly selected from each administrative district in the first phase and preschool children were randomly selected from each preschool in the second phase. Sample distribution was proportional to the total population enrolled in private and public preschools in each administrative district of the city. The sample size was calculated based on a 4% margin of error, a 95% confidence level and a correction factor of 1.2 to compensate for the design effect [21]. As the prevalence of impact on OHRQoL was unknown, a prevalence rate of 50% was considered to increase the power and because this value gives the largest sample regardless of the actual prevalence [22]. Eighteen of the 127 public preschools and 15 of the 122 private preschools were randomly selected. The minimum sample size was estimated at 720 preschool children, to which an additional 20% was added to compensate for possible losses, giving a total sample of 864 preschool children.

The present study received approval from the Human Research Ethics Committee of the State University of Paraíba (Brazil) under process number 00460133000-11 in compliance with Resolution 196/96 of the Brazilian National Health Council. All participants' rights were protected. Parents/caregivers read and signed a statement of informed consent prior to the children's participation.

Eligibility criteria

To be included in the study, the children needed to be between three and five years of age, enrolled in a preschool and free of systemic diseases (based on the reports of the parents/caregivers). Only reports of parents/caregivers were considered for systemic disease; no systemic examination was conducted. The exclusion criteria were the presence of one or more

erupted permanent teeth, a history of orthodontic treatment and caregivers not fluent in Brazilian.

Training and calibration exercise

The training and calibration exercise consisted of two steps (theoretical and clinical). The theoretical step involved a discussion of the criteria for the diagnosis of dental caries, TDI, malocclusion and an analysis of photographs. A specialist in paediatric dentistry (gold standard in this theoretical framework) coordinated this step, instructing three general dentists on how to perform the examination. The clinical step was performed at a randomly selected preschool that was not part of the main sample. Each dentist examined 50 previously selected preschool children between three and five years of age. Inter-examiner agreement was tested by comparing each examiner ($K = 0.83$ to 0.88). After a seven-day interval, the examinations were performed a second time for the determination of intra-examiner agreement ($K = 0.85$ to 0.90). Data analysis involved Cohen's Kappa coefficient on a tooth-by-tooth basis. As the Kappa coefficients were very good [23], the examiners were considered capable of conducting the epidemiological study.

Pilot study

A pilot study was conducted to test the methodology and comprehension of the questionnaires. The children in the pilot study ($n = 40$) were not included in the main sample. As there were no misunderstandings regarding the questionnaires or the methodology, no changes to the data collection process were deemed necessary.

Non-clinical data collection

The acquisition of the non-clinical data involved the administration of the Brazilian version of the Early Childhood Oral Health Impact Scale (B-ECOHIS) and questionnaires addressing socio-demographic data and parents'/caregivers' perceptions regarding their child's

health. Parents/caregivers were previously contacted to attend a meeting at the preschools, at which they were informed regarding the objectives of the study. Parents/caregivers who agreed to participate signed a statement of informed consent and were then instructed to answer the B-ECOHIS and a questionnaire addressing socio-demographic data. For the B-ECOHIS, the parents/caregivers were instructed to consider the child's entire lifetime experience of oral health conditions and treatment. All questionnaires were filled out by the parents/caregivers and returned at the end of the meeting.

The B-ECOHIS is used for the evaluation of parents'/caregivers' perceptions regarding the impact of oral health conditions on the OHRQoL of preschool children and their families. This measure has been employed in previous studies [1,13,14] and is divided into two sections (Child Impact and Family Impact), with a total of six subscales and 13 items. The subscales on the Child Impact section are symptoms (1 item), function (4 items), psychology (2 items) and self-image/social interaction (2 items). The subscales on the Family Impact section are parental distress (2 items) and family function (2 items). Each item has six response options: 0 = never; 1 = hardly ever; 2 = sometimes; 3 = often; 4 = very often; and 5 = "I don't know". Questionnaires with two or more unanswered items on the Child Impact section or one or more unanswered item on the Family Impact section were considered incomplete and were excluded from the analysis. The scores are totalled for each section ("don't know" responses are not counted). The total score ranges from 0 to 36 points on the Child Impact section and 0 to 16 points on the Family Impact section, with higher scores indicating greater impact [1,13]. In the present study, negative impact on child and family OHRQoL was recorded when at least one response of "sometimes", "often" or "very often" was chosen, whereas responses of "never" and "hardly ever" were considered indicative of an absence of negative impact, as recommended by the creators of the original ECOHIS [15].

The following socio-demographic variables were analysed: sex and age of child; parent's/guardian's age; mother's schooling; number of residents in the home; child's birth

order among siblings; type of preschool (public or private); and monthly household income (categorised based on the monthly minimum salary in Brazil, which was equal to US\$312.50).

Parent's/caregiver' perceptions regarding their child's general and oral health status were evaluated based on answers to the following question: In general, how would you describe your child's general health/oral health? The response options were 1) very good, 2) good, 3) fair, 4) poor and 5) very poor. For statistical purposes, these answers were dichotomised as good (codes 1 and 2) and poor (codes 3, 4 and 5) [2].

Clinical data collection

After the return of the questionnaires and signed statement of informed consent, clinical examinations were performed at the preschools by three dentists who had undergone the training and calibration exercise. Prior to the exam, each child received a kit containing a toothbrush, toothpaste and dental floss to remove bacterial plaque from the teeth and facilitate the diagnosis. The child was then seated in front of the examiner. Light was provided by a portable lamp positioned on the examiner's head (Petzl Zoom head lamp, Petzl America, Clearfield, UT, USA). The dentists used individual protection equipment, a sterilised mouth mirror (PRISMA ®, São Paulo, SP, Brazil), sterilised Williams probe (WHO-621, Trinity ®, Campo Mourão, PA, Brazil) and gauze to dry the teeth.

Dental caries was diagnosed using the International Caries Detection and Assessment System (ICDAS II) [18], which is a scoring system ranging from 0 (absence of dental caries) to 6. Due to the epidemiological nature of the present study, code 1 was not used, as drying of the teeth was performed with gauze rather than compressed air. Code 2 was used for white spots and codes ≥ 3 determined different degrees of cavitation. For statistical purposes, dental caries was dichotomised as absent (code 0) or present (code ≥ 2) [18]. Untreated dental caries was also considered in the evaluation of the impact of cavitated lesions in OHRQoL. This variable was categorised as absent/white spot (codes 0 and 2), cavitated anterior teeth (codes ≥ 3), cavitated posterior teeth (codes ≥ 3), cavitated anterior and posterior teeth (codes ≥ 3).

TDI was diagnosed as enamel fracture, enamel + dentine fracture, complicated crown fracture, extrusive luxation, lateral luxation, intrusive luxation and avulsion [24]. A visual inspection was also made of tooth colouration. TDI was recorded in the presence of any type of TDI or tooth discolouration. Malocclusion was recorded in the presence of at least one of the following conditions: increased overbite (> 2 mm), increased overjet (> 2 mm), anterior open bite, anterior crossbite and posterior crossbite [25,26]. Following the exam, a fluoridated varnish was applied to the teeth and children with dental caries or other dental needs were sent for treatment.

Statistical analysis

Descriptive statistics were first performed to characterise the sample. The chi-square test was used to test associations between oral health conditions and socio-demographic data and the Bonferroni correction was used for variables with more than two categories. Bivariate Poisson regression analysis with robust variance was used to determine associations between the independent variables and negative impact on the OHRQoL of the preschool children and their families ($p < 0.05$). The multivariate model obeyed a hierarchical approach from distal to proximal determinants: 1) socio-demographic data, 2) parent's/caregiver's perception of child's health and 3) oral health conditions (Figure 1) [27]. The backward stepwise procedure was used to incorporate variables that achieved a p-value < 0.20 in the bivariate analysis as well as variables considered epidemiological determinants on each level. Variables with a p-value < 0.05 in the adjusted analysis were maintained in the final regression model. Interactions among dental caries, TDI and malocclusion were tested using Wald's test. Variance inflation factors were calculated to determine the existence of collinearity among the predictors in the adjusted model. The data were organised and analysed with the aid of the Statistical Package for Social Sciences (SPSS for Windows, version 20.0, SPSS Inc, Chicago, IL, USA).

Results

A total of 843 pairs of preschool children and their parents/caregivers participated in the present study, corresponding to 97.5% of the total determined by the sample size calculation. The loss of 21 children was due to a lack of cooperation during the exam ($n= 6$), incomplete questionnaires ($n = 11$) and absence from preschool on the days scheduled for the clinical examinations ($n = 4$).

Table 1 displays the oral health conditions distributed according to the socio-demographic data of the sample. The chi-square test revealed that, among the three oral conditions, only cavitated lesions were significantly associated with age, type of school, mother's schooling and monthly household income. More children with cavitated lesions were aged five years (56.8%), studied at public preschools (58.6%), had mothers with \leq eight years of schooling (62.4%) or came from families that earned up to the minimum wage (61.1%) compared to children with white spots or without dental caries. Parents'/caregivers' perceptions of general and oral health were poor among 81.0% and 66.5% of the sample, respectively.

The prevalence of negative impact on OHRQoL was 32.1% among the children and 26.2% among the families. Scores of 0 (floor effect) were found on 58.6% and 69.6% of the Child Impact and Family Impact sections of the B-ECOHIS, respectively (i.e., 58.6% and 69.6% of the parents/caregivers reported no impacts). No ceiling effect was found for either section (i.e., scores of 36 and 16 on the Child and Family Impact sections, respectively). The maximum score was 31 on the Child Impact section and 14 on the Family Impact section (Table 2). Table 2 also displays the mean, standard deviation, median, minimum and maximum total B-ECOHIS scores and subscales scores. The items with the highest means were "reported pain", "felt guilty" and "been upset".

In the final hierarchical Poisson regression model, the following variables were significantly associated with a negative impact on OHRQoL among the children: child's order of birth, parent's/caregiver's perception of child's oral health as poor, cavitated dental caries and TDI (Table 3). The following variables were significantly associated with a negative impact

on OHRQoL among the families: parent's/caregiver's perception of child's oral health as poor, cavitated dental caries and greater severity of TDI (Table 4).

Discussion

The present study evaluated the impact of dental caries, TDI and malocclusion on the OHRQoL of preschool children using the Brazilian Portuguese version of the ECOHIS. The occurrence of cavitated lesions and TDI was found to cause a negative impact on the OHRQoL of preschool children and their families, whereas different types of malocclusion did not have this effect. Another finding that should be stressed was that the mere presence of dental caries (code ≥ 2) did not have an impact on OHRQoL, but cavitated lesions (code ≥ 3) exerted an impact on the quality of life of the preschool children and their families. Moreover, this is the first study to perform a hierarchical approach, which stratifies the impact of the severity of TDI, different types of malocclusion, different stages of dental caries and the teeth affected as risk factors that exert an influence on quality of life. Such an approach allows an analysis of interrelationships among factors rather than making the strict statistical associations commonly found in multivariate methods [27].

Cavitated lesions were associated with OHRQoL among the children and families due to the fact that parents/caregivers recognise an oral health problem when it becomes evident or when it is manifested in the form of pain [28,29]. Indeed, the parents/caregivers reported greater impact on the items "reported pain", "difficulty drinking hot or cold beverages", "difficulty eating some foods" and "been irritable". These findings indicate symptoms related to more serious oral health problems, such as untreated dental caries [30]. Severe dental caries can result in parents/caregivers missing days of work and greater financial expenditures as well as feelings of guilt, with a consequent negative impact on the OHRQoL of the family [17,28]. Moreover, the greater participation of women in the job market and consequent reduction in the role mothers play in raising their children [31] may have contributed to the greater frequency of the

items “felt guilty” and “been upset”, as suggested in previous studies [2,8,17]. It should be stressed that dental caries was diagnosed in the present study using the criteria of the ICDAS-II, which detects the early manifestations of this condition [18]. This may explain why the presence of dental caries when considering data on white spots was not associated with OHRQoL, as such lesions often go unperceived by parents/caregivers and do not cause pain. Cavitated teeth have been associated to a negative impact on OHRQoL in previous investigations [2,5,6,17,29], although the location of the lesions was not evaluated in the studies cited. Cavitated lesions on anterior teeth were not associated with a negative impact on OHRQoL, likely due to the nature of these lesions, which were not very severe, and the lesser importance given to aesthetics in the age group analysed [32]. However, when posterior teeth and both posterior and anterior teeth were analysed, significant associations were found with a negative impact on OHRQoL, possibly because cavities on posterior teeth are generally more severe and associated with reports of pain and difficulty eating [28,30].

Cavitated lesions were associated with socio-demographic variables (lower income, lower educational level of the mother, enrolment at a public preschool and children aged five years) in comparison to children with white spots or without dental caries. This demonstrates the importance of socio-demographic data regarding the use of dental services [33,34]. Some studies have found a greater frequency of impact on the OHRQoL of preschool children from families with a lower socioeconomic status [2,6,17]. However, no socioeconomic variable remained associated with the negative impact on quality of life in the present investigation, which is in agreement with data reported in a previous study [5]. This finding suggests that oral health conditions can exert an impact on the quality of life of children regardless of one's socioeconomic status.

While a previous investigation found an association between malocclusion and impact on OHRQoL [5], the majority of studies found no such association [2,7,9,17,35], which is in agreement with the present findings. However, TDI had a negative impact on the OHRQoL of the preschool children and cases of avulsion and/or luxation were predictors of a negative

impact on the OHRQoL of the families. This type of oral health problem may require a considerable amount of time on the part of the family due to the urgency of relieving the pain symptoms and the limitations that may arise [5,9,28]. Parents/caregivers generally perceive a negative impact on quality of life when clinical signs are involved, such as tooth discolouration, which can exert a psychosocial impact on the child [8]. However, some studies have found no association between TDI and OHRQoL [2,8,17]. This may be due to the type of TDI considered in the analysis, as negative impact generally only occurs in more serious cases [7,9,28].

Birth order of the child was a predictor of a greater negative impact on OHRQoL among the children, likely because financial resources and attention from parents/caregivers are shared among the siblings as more children are born into the family [36,37]. Indeed, a greater frequency of dental caries is found among children in large families [38].

Parents'/caregivers' perception of their child's oral health was associated with a negative impact on the OHRQoL of both the children and families. Perceptions of parents/caregivers regarding their child's oral health plays an important role in the determination of the negative impact on OHRQoL [39], as the health of preschool children depends on parental/caregiver knowledge regarding health care [40].

The present study has the limitations inherent to the cross-sectional design and the answers on the questionnaires may have been subject to information bias. However, a number of measures were taken to diminish the occurrence of such bias, such as the use of a validated questionnaire and the execution of a pilot study. Thus, it is possible to extrapolate the findings, since the present investigation was a representative, preschool-based study. Longitudinal studies are needed to clarify the relationship of causality and allow establishment of public policies aimed at reducing the impact of oral health conditions on the OHRQoL of preschool children and their families.

Conclusion

Cavitated lesions on anterior and posterior teeth, traumatic dental injuries and parents'/caregivers' perception of their child's oral health as poor are determinants of a negative impact on the OHRQoL of preschool children and their families. While white spots were not associated with impact on OHRQoL, it is important to treat such cases to prevent the progression to cavitation.

List of abbreviations

OHRQoL: oral health-related quality of life; TDI: traumatic dental injury; ECOHIS: Early Childhood Oral Health Impact Scale; B-ECOHIS: Brazilian version of the Early Childhood Oral Health Impact Scale; ICDAS: International Caries Detection and Assessment System

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MCG was responsible for the analysis and interpretation of the data, helped the statistical analysis and drafted the manuscript. TCAPS was responsible for the conception and study design, acquisition and interpretation of data. EMMBC performed data acquisition and drafted the manuscript. CCM performed the analysis and interpretation of the data and a critical review of the manuscript. AFGG was responsible for conception design, analysis and interpretation of the data and a critical review of the manuscript. SMP was responsible for the conception and study design and performed the final critical review. All authors read and approved the final manuscript.

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Legends

Table 1 – Frequency of clinical variables according to socio-demographic data of preschool children analysed

Table 2 – Prevalence of impact on oral health-related quality of life and B-ECOHIS scores among preschool children

Table 3 – Hierarchical Poisson regression for impact on OHRQoL of children and independent variables

Table 4 – Hierarchical Poisson regression for impact on OHRQoL of family and independent variables

Figure 1 - Analysis model used in the study

Table 1 – Frequency of clinical variables according to socio-demographic data of preschool children analysed

Variable	Dental caries			TDI		Malocclusion	
	Absent*	White spots*	Cavitations*	Absent	Present	Absent	Present
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Sex							
Female	125 (30.7) ^A	82 (20.1) ^A	200 (49.1) ^A	275 (67.9) ^A	130 (32.1) ^A	141 (34.8) ^A	264 (65.2) ^A
Male	158 (36.2) ^A	76 (17.4) ^A	202 (46.3) ^A	278 (64.1) ^A	156 (35.9) ^A	152 (35.0) ^A	282 (65.0) ^A
Age							
3 years	107 (38.9) ^A	61 (22.2) ^A	107 (38.9) ^B	176 (64.0) ^A	99 (36.0) ^A	85 (30.9) ^A	190 (69.1) ^A
4 years	103 (30.8) ^A	69 (20.7) ^A	162 (48.5) ^B	226 (68.2) ^A	106 (31.9) ^A	115 (34.6) ^A	217 (65.4) ^A
5 years	73 (31.1) ^A	28 (12.0) ^A	133 (56.8) ^B	151 (65.1) ^A	81 (34.9) ^A	93 (40.1) ^A	139 (59.9) ^A
Type of preschool							
Public	111 (24.3) ^A	78 (17.1) ^A	267 (58.6) ^B	305 (67.3) ^A	148 (32.7) ^A	163 (36.0) ^A	290 (64.0) ^A
Private	172 (44.4) ^A	80 (20.7) ^A	135 (34.9) ^B	248 (64.2) ^A	138 (35.8) ^A	130 (33.7) ^A	256 (66.3) ^A
Mother's schooling							
≤ 8 years of study	100 (25.8) ^A	46 (11.9) ^A	242 (62.4) ^B	262 (68.1) ^A	123 (31.9) ^A	133 (34.5) ^A	252 (65.5) ^A
> 8 years of study	183 (40.5) ^A	111 (24.6) ^A	158 (35.0) ^B	289 (64.1) ^A	162 (35.9) ^A	160 (35.5) ^A	291 (64.5) ^A
Monthly household income							
≤ 1 minimum salary	108 (24.4) ^A	64 (14.5) ^A	270 (61.1) ^B	299 (68.0) ^A	141 (32.0) ^A	166 (37.7) ^A	274 (62.3) ^A
> 1 minimum salary	157 (43.4) ^A	84 (23.2) ^A	121 (33.4) ^B	229 (63.6) ^A	131 (36.4) ^A	113 (31.4) ^A	247 (68.6) ^A
TOTAL	283 (33.6)	158 (18.7)	402 (47.7)	553 (65.9)	286 (34.1)	293 (34.9)	546 (65.1)

* Chi-square test with Bonferroni correction; Different capital letters denote significantly different results ($p < 0.05$).

Table 2 – Prevalence of impact on oral health-related quality of life and B-ECOHIS scores among preschool children

Subscales, Items	SCORE		Minimum-	Impact
	Mean \pm SD	Median	Maximum	N (%)
ECOHIS total (0 - 52)	3.60 \pm 6.10	0	0 - 38	349 (41.4)
Child Impact	2.41 \pm 4.41	0	0 - 31	271 (32.1)
Reported pain	0.61 \pm 0.99	0	0 - 4	195 (23.1)
Had difficulty drinking hot or cold beverages	0.36 \pm 0.82	0	0 - 4	110 (13.1)
Had difficulty eating some foods	0.37 \pm 0.85	0	0 - 4	112 (13.3)
Had difficulty pronouncing words	0.22 \pm 0.72	0	0 - 4	66 (7.8)
Missed preschool, day care or school	0.13 \pm 0.49	0	0 - 3	34 (4.1)
Had trouble sleeping	0.20 \pm 0.64	0	0 - 4	56 (6.6)
Been irritable or frustrated	0.31 \pm 0.78	0	0 - 4	95 (11.3)
Avoided smiling or laughing	0.11 \pm 0.49	0	0 - 4	26 (3.1)
Avoided talking	0.10 \pm 0.45	0	0 - 4	27 (3.2)
Family Impact	1.23 \pm 2.31	0	0 - 14	221 (26.2)
Been upset	0.41 \pm 0.92	0	0 - 4	126 (15.0)
Felt guilty	0.49 \pm 0.97	0	0 - 4	157 (18.7)
Taken time off work	0.17 \pm 0.59	0	0 - 4	56 (6.7)
Financial impact	0.16 \pm 0.60	0	0 - 4	46 (5.4)

Table 3 – Hierarchical Poisson regression for impact on OHRQoL of children and independent variables

Variable	Impact on child's					
	OHRQoL		Bivariate		Multivariate	
	Present n(%)	Absent n(%)	Unadjusted PR* p-value	Unadjusted PR* (95% CI)	Adjusted PR † p-value	Adjusted PR † (95% CI)
Sex						
Female	132(32.4)	275(67.6)	0.864	1.017(0.836-1.238)	-	-
Male	139(31.9)	297(68.1)		1.00	-	-
Age						
3 years	71(25.8)	204(74.2)		1.00	-	-
4 years	95(28.4)	239(71.6)	0.470	1.102(0.847-1.433)	-	-
5 years	105(44.9)	129(55.1)	<0.001	1.738(1.360-2.222)	-	-
1st level						
Type of preschool						
Public	171(37.5)	285(62.5)	<0.001	1.451(1.181-1.784)	-	-
Private	100(25.8)	287(74.2)		1.00	-	-
Mother's schooling						
≤ 8 years of study	153(39.4)	235(60.6)	<0.001	1.510(1.239-1.841)	-	-
> 8 years of study	118(26.1)	334(73.9)		1.00	-	-
Monthly household income						
≤ 1 minimum salary	177(40.0)	265(60.0)	<0.001	1.686(1.357-2.094)	-	-
> 1 minimum salary	86(23.8)	276(76.2)		1.00	-	-
Parent's/guardian's age						
≤ 30 years	139(32.9)	283(67.1)	0.456	1.079(0.883-1.319)	-	-
> 30 years	123(30.5)	280(69.5)		1.00	-	-

Number of residents in**home**

< 6	214(30.6)	485(69.4)		1.00	-	-
≥ 6	53(41.1)	76(58.9)	0.014	1.342(1.061-1.697)	-	-

Birth order

Only child	60(22.8)	203(77.2)		1.00		1.00
Oldest child	50(40.7)	73(59.3)	<0.001	1.782(1.309-2.425)	0.025	1.430(1.045-1.958)
Middle child	38(36.5)	66(63.5)	0.006	1.602(1.143-2.243)	0.316	1.183(0.852-1.641)
Youngest child	121(34.7)	228(65.3)	0.002	1.520(1.166-1.981)	0.106	1.228(0.957-1.575)

2nd level**Perception of general****health**

Good	201(29.6)	479(70.4)		1.00	-	-
Poor	70(44.0)	89(56.0)	<0.001	1.489(1.207-1.838)	-	-

Perception of oral health

Good	120(21.4)	440(78.6)		1.00		1.00
Poor	151(53.5)	131(46.5)	<0.001	2.499(2.062-3.029)	<0.001	1.732(1.399-2.145)

3rd level**Dental caries**

Absent	46(16.3)	237(83.7)		1.00	-	-
Present	225(40.2)	335(59.8)	<0.001	2.472(1.862-3.281)	-	-

Cavitated lesions

Absent/white spots	77(17.5)	364(82.5)		1.00		1.00
Cavitated anterior teeth	17(29.3)	41(70.7)	0.024	1.679(1.072-2.628)	0.146	1.422(0.885-2.287)
Cavitated posterior teeth	82(44.6)	102(55.4)	<0.001	2.552(1.970-3.307)	<0.001	2.011(1.518-2.664)
Cavitated anterior and posterior teeth	95(59.4)	65(40.6)	<0.001	3.401(2.675-4.323)	<0.001	2.596(1.982-3.400)

TDI						
Absent	168(30.4)	385(69.6)		1.00		1.00
Present	100(35.0)	186(65.0)	0.173	1.151(0.940-1.409)	0.001	1.413(1.161-1.718)
Type of TDI						
Discolouration	38(39.2)	59(60.8)	0.071	1.285(0.979-1.688)	-	-
Avulsion and/or luxation	4(36.4)	7(63.6)	0.661	1.193(0.542-2.628)	-	-
Enamel + dentine fracture	16(38.1)	26(61.9)	0.276	1.250(0.836-1.868)	-	-
Enamel fracture and without trauma	210(30.5)	479(69.5)		1.00	-	-
Malocclusion						
Absent	95(32.4)	198(67.6)	0.827	1.023(0.833-1.258)	-	-
Present	173(31.7)	373(68.3)		1.00	-	-
Anterior crossbite						
Absent	256(31.5)	557(68.5)		1.00	-	-
Present	9(39.1)	14(60.9)	0.413	1.243(0.739-2.090)	-	-
Anterior open bite						
Absent	201(31.1)	446(68.9)		1.00	-	-
Present	58(32.8)	119(67.2)	0.663	1.055(0.830-1.341)	-	-
Posterior crossbite						
Absent	229(31.3)	503(68.7)		1.00	-	-
Unilateral	30(32.3)	63(67.7)	0.848	1.031(0.754-1.411)	-	-
Bilateral	5(55.6)	4(44.4)	0.058	1.776(0.980-3.217)	-	-
Increased overbite						
Absent	224(33.6)	442(66.4)	0.009	1.518(1.112-2.073)	-	-
Present	35(22.2)	123(77.8)		1.00	-	-
Increased overjet						
Absent	144(30.6)	326(69.4)		1.00	-	-

Present	121(33.1)	245(66.9)	0.455	1.079(0.884-1.317)	-	-
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*Unadjusted Poisson regression for independent variables and impact on child's quality of life

** Variables incorporated in multivariate model ($p < 0.20$): sex, age, type of preschool, mother's schooling, monthly household income, number of residents in home, child's birth order, parent's/caregiver's perception of child's general health, parent's/caregiver's perception of child's oral health, dental caries, untreated dental caries, traumatic dental injury, type of traumatic dental injury, malocclusion, posterior crossbite and increased overbite

*** For dental caries, the cut-off point was code ≥ 2 ; for cavitated lesions, absent/white spots (codes ≤ 2) and cavitated tooth (codes ≥ 3) were considered

† Hierarchical Poisson regression: Level 1 adjusted for child's characteristics and socio-demographic variables; Level 2 adjusted for child's characteristics, socio-demographic variables and parent's/caregiver's perception of child's health; Level 3 adjusted for child's characteristics, socio-demographic variables, parent's/caregiver's perception of child's health and oral health problems (dental caries, traumatic dental injuries and malocclusion)

Table 4 – Hierarchical Poisson regression for impact on OHRQoL of family and independent variables

Variable	Impact on family's					
	OHRQoL		Bivariate		Multivariate	
	Present	Absent	Unadjusted PR*		Adjusted PR †	
	n(%)	n(%)	p-value	(95% CI)	p-value	(95% CI)
Sex						
Female	106(26.0)	301(74.0)		1.00	-	-
Male	115(26.4)	321(73.6)	0.913	1.013(0.807-1.270)	-	-
Age						
3 years	66(24.0)	209(76.0)		1.00	-	-
4 years	85(25.4)	249(74.6)	0.681	1.060(0.802-1.402)	-	-
5 years	70(29.9)	164(70.1)	0.133	1.246(0.935-1.662)	-	-
1st level						
Type of preschool						
Public	131(28.7)	325(71.3)	0.074	1.235(0.980-1.557)	-	-
Private	90(23.3)	297(76.7)		1.00	-	-
Mother's schooling						
≤ 8 years of study	117(30.2)	271(69.8)	0.019	1.311(1.045-1.644)	-	-
> 8 years of study	104(23.0)	348(77.0)		1.00	-	-
Monthly household income						
≤ 1 minimum salary	132(29.9)	310(70.1)	0.023	1.318(1.039-1.673)	-	-
> 1 minimum salary	82(22.7)	280(77.3)		1.00	-	-
Parent's/guardian's age						
≤ 30 years	120(28.4)	302(71.6)	0.080	1.232(0.975-1.557)	-	-
> 30 years	93(23.1)	310(76.9)		1.00	-	-

Number of residents in**home**

< 6	176(25.2)	523(74.8)		1.00	-	-
≥ 6	43(33.3)	86(66.7)	0.046	1.324(1.005-1.744)	-	-

Birth order

Only child	55(20.9)	208(79.1)		1.00	-	-
Oldest child	39(31.7)	84(68.3)	0.020	1.516(1.068-2.152)	-	-
Middle child	27(26.0)	77(74.0)	0.290	1.241(0.832-1.853)	-	-
Youngest child	98(28.1)	251(71.9)	0.046	1.343(1.006-1.792)	-	-

2nd level**Perception of general****health**

Good	157(23.1)	523(76.9)		1.00	-	-
Poor	61(38.4)	98(61.6)	<0.001	1.662(1.307-2.113)	-	-

Perception of oral health

Good	88(15.7)	472(84.3)		1.00		1.00
Poor	133(47.2)	149(52.8)	<0.001	3.001(2.389-3.770)	<0.001	2.116(1.624-2.757)

3rd level**Dental caries**

Absent	35(12.4)	248(87.6)		1.00	-	-
Present	186(33.2)	374(66.8)	<0.001	2.686(1.928-3.742)	-	-

Cavitated lesions

Absent/white spots	55(12.5)	386(87.5)		1.00		1.00
Cavitated anterior teeth	14(24.1)	44(75.9)	0.013	1.935(1.152-3.252)	0.079	1.586(0.949-2.651)
Cavitated posterior teeth	73(39.7)	111(60.3)	<0.001	3.181(2.345-4.315)	<0.001	2.380(1.679-3.372)
Cavitated anterior and posterior teeth	79(49.4)	81(50.6)	<0.001	3.959(2.954-5.306)	<0.001	2.809(2.009-3.926)

TDI

Absent	143(25.9)	410(74.1)		1.00	-	-
Present	74(25.9)	212(74.1)	0.996	1.001(0.786-1.274)	-	-

Type of TDI

Discolouration	32(33.0)	65(67.0)	0.080	1.322(0.968-1.805)	0.054	1.326(0.995-1.766)
Avulsion and/or luxation	4(36.4)	7(63.6)	0.352	1.457(0.660-3.217)	0.006	2.448(1.288-4.653)
Enamel + dentine fracture	9(21.4)	33(78.6)	0.614	0.858(0.474-1.554)	0.877	1.048(0.582-1.885)
Enamel fracture and without trauma	172(25.0)	517(75.0)		1.00		1.00

Malocclusion

Absent	81(27.6)	212(72.4)	0.386	1.110(0.877-1.405)	-	-
Present	136(24.9)	410(75.1)		1.00	-	-

Anterior crossbite

Absent	207(25.5)	606(74.5)		1.00	-	-
Present	9(39.1)	14(60.9)	0.107	1.537(0.911-2.593)	-	-

Anterior open bite

Absent	166(25.7)	481(74.3)	0.950	1.009(0.759-1.341)	-	-
Present	45(25.4)	132(74.6)		1.00	-	-

Posterior crossbite

Absent	548(74.9)	184(25.1)		1.00	-	-
Unilateral	27(29.0)	66(71.0)	0.408	1.155(0.821-1.625)	-	-
Bilateral	5(55.6)	4(44.4)	0.009	2.210(1.216-4.017)	-	-

Increased overbite

Absent	185(27.8)	481(72.2)	0.006	1.688(1.164-2.449)	-	-
Present	26(16.5)	132(83.5)		1.00	-	-

Increased overjet

Absent	128(27.2)	342(72.8)	0.298	1.133(0.896-1.432)	-	-
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Present	88(24.0)	278(76.0)	1.00	-	-
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*Unadjusted Poisson regression for independent variables and impact on family's quality of life

** Variables incorporated in multivariate model ($p < 0.20$): sex, age, type of preschool, mother's schooling, monthly household income, parent's/guardian's age, number of residents in home, child's birth order, parent's/caregiver's perception of child's general health, parent's/caregiver's perception of child's oral health, dental caries, untreated dental caries, traumatic dental injury, type of traumatic dental injury, malocclusion, anterior crossbite, posterior crossbite and increased overbite

*** For dental caries, the cut-off point was code ≥ 2 ; for cavitated lesions, absent/white spots (codes ≤ 2) and cavitated tooth (codes ≥ 3) were considered

† Hierarchical Poisson regression: Level 1 adjusted for child's characteristics and socio-demographic variables; Level 2 adjusted for child's characteristics, socio-demographic variables and parent's/caregiver's perception of child's health; Level 3 adjusted for child's characteristics, socio-demographic variables, parent's/caregiver's perception of child's health and oral health problems (dental caries, traumatic dental injuries and malocclusion)

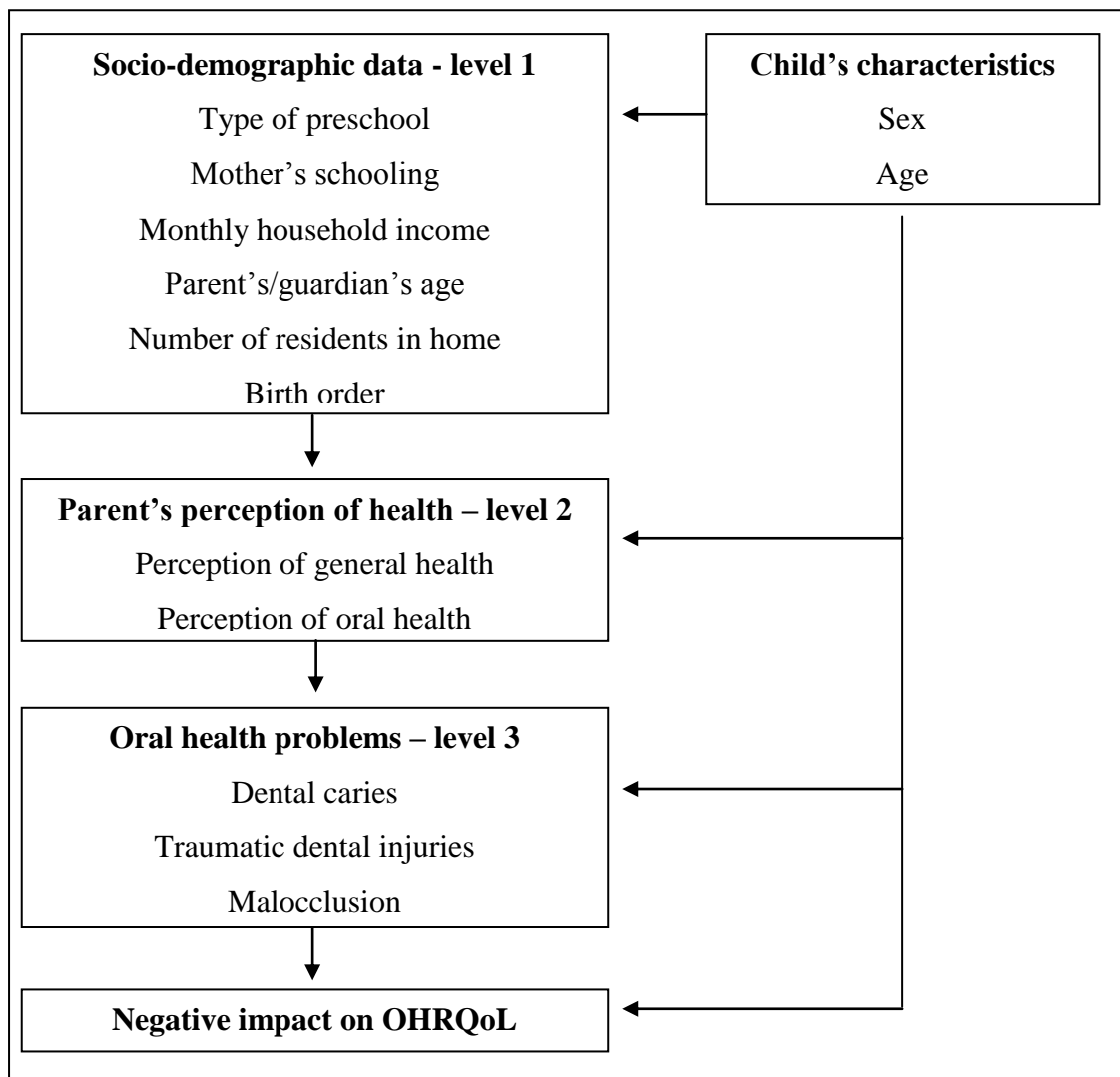


Figure 1 - Analysis model used in the study

ARTIGO 2

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Association between parental guilt and oral health problems in preschool children: A hierarchical approach

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ABSTRACT

Background: Dental caries, traumatic dental injury (TDI) and malocclusion can play an important role in the emergence of parental guilt, since parents feel responsible for their child's health. The aim of the present study was to evaluate the influence of oral health problems among preschool children on parental guilt. **Methods:** A preschool-based, cross-sectional study was carried out with 832 preschool children between three and five years of age in the city of Campina Grande, Brazil. Parents/caregivers answered the Brazilian version of the Early Childhood Oral Health Impact Scale (B-ECOHis). The item "parental guilt" was the dependent variable. Questionnaires addressing socio-demographic variables (child's sex, child's age, parent's/caregiver's age, mother's schooling, type of preschool and household income), history of toothache and health perceptions (general and oral) were also administered. Clinical exams for dental caries, TDI and malocclusion were performed by three dentists who had undergone a training and calibration exercise (Kappa: 0.83-0.90). Poisson hierarchical regression was used to determine the significance of associations between parental guilt and oral health problems ($\alpha = 5\%$). The multivariate model was carried out on three levels using a hierarchical approach from distal to proximal determinants: 1) socio-demographic aspects; 2) health perceptions; and 3) oral health problems. **Results:** The frequency of parental guilt was 22.8%. The following variables were significantly associated with parental guilt: parental perception of child's oral health as poor (PR= 1.980; 95% CI: 1.479-2.649), history of toothache (PR= 2.427; 95% CI: 1.812-3.251), cavitated lesions (PR= 2.012; 95% CI: 1.397-2.896), avulsion/luxation (PR= 1.951; 95% CI: 1.099-3.461) and tooth discoloration (PR= 1.534; 95% CI: 1.162-2.025). **Conclusion:** Based on the present findings, parental guilt increases with the occurrence of oral health problems that require treatment, such as dental caries and TDI of greater severity. Parental perceptions of poor oral health in their children and history of toothache were predictors of greater feelings of parental guilt.

Keywords: guilt; dental caries; tooth injuries; malocclusion; preschool child.

INTRODUCTION

Despite advances in the prevention and treatment of oral health problems, high prevalence rates of dental caries (1,2), traumatic dental injury (TDI) (3,4) and malocclusion (5,6) continue to be found among preschool children. These conditions can have a negative impact on the oral health-related quality of life (OHRQoL) of the family (7-9), since parents feel responsible for their child's oral health (10). Indeed, parents play an important role in the oral health status of children and in seeking dental care (11,12) and therefore tend to express feelings of guilt when their child exhibits oral health problems and/or treatment needs (7,13). Thus, parental guilt can be defined as an emotional state aroused by actions or intentions that are perceived as incorrect (14).

A number of factors are considered determinants of the emergence of parental guilt, such as less time available for raising children and care delegated to third parties due to the need to work outside the home as well as a lack of knowledge on oral health care and the presence of oral health problems (10,15,16). It is believed that many oral health problems can be reduced or even avoided when parents/caregivers have access to information on oral health (17,18).

Studies on this issue are rare and conducted with non-representative samples of children who require dental care (16,19). Parents feel accountable when their children exhibit oral health problems at an early age (16,19) and the likelihood of feeling guilty increases with the severity of dental caries in children (16). Knowledge on parental feelings regarding their child's oral health is important to improving oral health and OHRQoL among children and their families. Such knowledge can contribute to the establishment of public policies aimed at improving oral health care among preschool children (17,20), especially when considering the deficient health care found in Brazil (12,21). The aim of the present study was to evaluate the influence of oral health problems in preschool children on parental guilt in a representative, preschool-based sample.

METHODS

Ethical Considerations

The present study received approval from the Human Research Ethics Committee of the State University of Paraíba (Brazil) (process number: 00460133000-11) in compliance with Resolution 196/96 of the Brazilian National Health Council. All participants' rights were protected. Caregivers read and signed a statement of informed consent prior to the children's participation.

Sample characteristics

A cross-sectional study was carried out involving a random sample of 832 male and female children aged three to five years enrolled at private and public preschools in the city of Campina Grande, Brazil. The participants were selected from a total population of 12,705 children in this age group. Campina Grande (population: 386,000) is an industrialized city in northeast Brazil and is divided into six administrative districts. The city has a Human Development Index of 0.72 (22).

The percentage distribution of three-to-five-year-old preschool children in each administrative district was calculated from information provided by the municipal Board of Education. To ensure representativeness, the sample was stratified according to administrative district and type of institution (two-phase sampling method). Preschools were randomly selected from each administrative district in the first phase and preschool children were randomly selected from each preschool in the second phase. Sample distribution was proportional to the total population enrolled in private and public preschools in each administrative district of the city. The sample size was calculated based on a 4% margin of error, a 95% confidence level and a correction factor of 1.2 to compensate for the design effect (23). As the prevalence of parental guilt was unknown, a prevalence rate of 50% was considered to increase the power and because this value gives the largest sample regardless of the actual prevalence (24). Eighteen of the 127

public preschools and 15 of the 122 private preschools were randomly selected. The minimum sample size was estimated at 720 preschool children, to which an additional 20% was added to compensate for possible losses, giving a total sample of 864 preschool children.

Eligibility criteria

To be included in the study, the children needed to be between three and five years of age, enrolled in a preschool and free of systemic diseases (based on the reports of the parents/caregivers). Only reports of parents/caregivers were considered for systemic disease; no systemic examination was conducted. The exclusion criteria were the presence of one or more erupted permanent teeth, a history of orthodontic treatment, caregivers not fluent in Brazilian Portuguese and incomplete questionnaires.

Training and calibration exercise

The training and calibration exercise consisted of two steps (theoretical and clinical). The theoretical step involved a discussion of the criteria for the diagnosis of dental caries, TDI and malocclusion and an analysis of photographs. A specialist in pediatric dentistry (gold standard in this theoretical framework) coordinated this step, instructing three general dentists on how to perform the examination. The clinical step was conducted at a randomly selected preschool that was not part of the main sample. Each dentist examined 50 previously selected children between three to five years of age. Inter-examiner agreement was tested by comparing each examiner with the gold standard ($K = 0.85$ to 0.90). A seven-day interval was respected between clinical examinations for the determination of intra-examiner agreement ($K = 0.85$ to 0.90). Data analysis involved Cohen's Kappa coefficient on a tooth-by-tooth basis. As Kappa coefficients were very good (25), the examiners were considered capable of performing the epidemiological study.

Pilot study

A pilot study was conducted to test the methodology and comprehension of the questionnaires. The children in the pilot study (n = 40) were not included in the main sample. As there were no misunderstandings regarding the questionnaires or the methodology, no changes to the data collection process were deemed necessary.

Non-clinical data collection

The collection of the non-clinical data involved one item on the family distress subscale of the Brazilian version of the Early Childhood Oral Health Impact Scale (B-ECOHIS) and questionnaires addressing socio-demographic data, health perceptions and history of toothache. Parents/caregivers were previously contacted to attend a meeting at the preschools, at which they were informed regarding the objectives of the study. Parents/caregivers who agreed to participate signed a statement of informed consent and were then instructed to answer the B-ECOHIS and a questionnaire addressing socio-demographic data. For the B-ECOHIS, the parents/caregivers were instructed to consider the child's entire lifetime experience of oral health conditions and treatment. All questionnaires were filled out by the parents/caregivers and returned at the end of the meeting.

The B-ECOHIS addresses the perceptions of parents/caregivers regarding the impact of oral health problems on the quality of life of preschool children and their families. This scale is divided into two sections (Child Impact and Family Impact), containing six subscales and thirteen items. Parental guilt was evaluated using the family distress subscale (26,27). The item on parental guilt has demonstrated satisfactory internal consistency and reliability (28). For statistical purposes, parental guilt was dichotomized as absent (only the response option "never") and present (remaining response options: "hardly ever", "sometimes", "often" and "very often"). "Don't know" responses were not counted (16).

The following socio-demographic data were analyzed: child's sex, child's age, parent's/caregiver's age, mother's schooling, type of preschool (public or private) and

household income (classified based on the monthly minimum wage in Brazil, which was equal to US\$312.50).

Perceptions of the children's general health and oral health were investigated using the following questions: How would you describe your child's overall health/oral health status in general? The response options were 1) very good, 2) good, 3) fair, 4) poor and 5) very poor. For statistical purposes, perceptions were dichotomized as good (responses of "very good" and "good") and poor (responses of "fair", "poor" and "very poor") (9).

Clinical data collection

After the return of the questionnaires and signed statement of informed consent, the clinical exams were performed by three dentists who had undergone the training and calibration exercise. Prior to the exam, the children cleaned their teeth under the supervision of the examiner. For such, each child received a kit containing a toothbrush, toothpaste and dental floss to remove bacterial plaque from the tooth surfaces and facilitate the diagnosis. The children were examined at the preschools in a sitting position in front of the examiner. Lighting was provided by a portable headlamp (Petzl Zoom head lamp, Petzl America, Clearfield, UT, USA). The dentists used individual protection equipment, a sterile mouth mirror (PRISMA ®, São Paulo, SP, Brazil), sterile Williams probe (WHO-621, Trinity ®, Campo Mourão, PA, Brazil) and dental gauze to dry the teeth.

Dental caries was diagnosed using the International Caries Detection and Assessment System (ICDAS II) (29). This index has codes ranging from 0 (absence of dental caries) to 6. Due to the epidemiological nature of the present study, code 1 was not used, as drying of the teeth was performed with gauze rather than compressed air. Code 2 is used for white spots and codes equal to or greater than 3 determine different degrees of cavitation. Dental caries was recorded as present when any tooth had a code of ≥ 2 and absent when all teeth received code 0 (29). Untreated dental caries was also considered in the evaluation of the impact of cavitated lesions in OHRQoL. This variable was categorized as absent/white spot (codes 0 and 2),

cavitated anterior teeth (codes ≥ 3), cavitated posterior teeth (codes ≥ 3), cavitated anterior and posterior teeth (codes ≥ 3).

TDI was classified as enamel fracture, enamel + dentin fracture, complicated crown fracture, extrusive luxation, lateral luxation, intrusive luxation and avulsion (30). A visual evaluation of tooth coloration was also performed. TDI was recorded as present when any type of injury or tooth discoloration was diagnosed. Malocclusion was recorded when at least one of the following conditions was found: deep overbite (> 2 mm), increased overjet (> 2 mm), anterior open bite, anterior crossbite and posterior crossbite (31,32). After the exam, a fluoridated varnish was applied to all teeth and children with dental caries or other dental needs were sent for treatment.

Statistical analysis

Descriptive analysis was performed to characterize the sample. Bivariate Poisson regression analysis with robust variance was used to determine the significance of associations between the independent variables and parental guilt ($p < 0.05$). The multivariate model followed a hierarchical approach from distal to proximal determinants on three levels: (1) socio-demographic data; (2) health perceptions; and (3) oral health problems (Figure 1) (33). On each level, the backward stepwise method was used for the selection of variables having with a p-value < 0.20 in the bivariate analysis as well as variables considered epidemiological determinants. Variables with a p-value < 0.05 in the adjusted analysis were maintained in the final regression model. Interactions among dental caries, TDI and malocclusion were tested using Wald's test. Variance inflation factors were calculated to test collinearity among the predictors in the adjusted model. The Statistical Package for Social Sciences (SPSS for Windows, version 20.0, SPSS Inc, Chicago, IL, USA) was used for the statistical analyses.

RESULTS

A total of 832 pairs of parents/caregivers and their children participated in the present study, corresponding to 96.7% of the total determined by the sample calculation. The loss of 32 pairs was due to a lack of cooperation on the part of the child during the clinical examination (n = 6), incomplete questionnaires (n = 11), absence from preschool on the days scheduled for the examinations (n = 4) and “don’t know” responses on the B-ECOHIS item addressing parental guilt (n = 11).

Tables 1 and 2 display the frequency distribution of the socio-demographic data, parental guilt and oral health problems. The majority of children was of the masculine sex, had 4 years and enrolled in preschools publics. The majority of families had a household income less than or equal one minimum salary, mother’s schooling greater than eight years of study, and parent’s age less than or equal to 30 years (Table 1). The prevalence of parental guilt was 22.8%. A total of 66.5% of the children had dental caries, 34.1% were diagnosed with TDI and 65.3% had malocclusion (Table 2).

In the bivariate analysis, the following independent variables were associated with parental guilt: age of child, parental perception of child’s general health and oral health as poor, history of toothache, dental caries, cavitated lesions, types of TDI, posterior crossbite and deep overbite. However, only parental perception of child’s oral health as poor (PR= 1.980; 95% CI: 1.479-2.649), history of toothache (PR= 2.427; 95% CI: 1.812-3.251), cavitated lesions (PR= 2.012; 95% CI: 1.397-2.896) and TDI types avulsion/luxation (PR= 1.951; 95% CI: 1.099-3.461) and tooth discoloration remained (PR= 1.534; 95% CI: 1.162-2.025) in the final hierarchical Poisson regression model (Table 3).

DISCUSSION

The present study was carried out to investigate the association between parental guilt and oral health problems (dental caries, TDI and malocclusion). The occurrence of toothache, cavitated lesions and complicated TDI was found to cause guilt among the parents/caregivers of

preschool children, whereas different types of malocclusion did not. To the best of our knowledge, only two studies have focused on parental guilt in relation to oral health problems (16,19). However, the studies cited were conducted with non-representative samples of children who required dental care (16) and were treated under general anesthesia (19). Moreover, this is the first study to consider the impact of the severity of TDI, different types of malocclusion, different stages of dental caries and the teeth affected in relation to parental guilt.

The frequency of parental guilt in the present sample was 22.8%. This feeling can arise when parents feel accountable for their children's problems (14) and therefore admit the need to change behavior related to oral health (19). The literature reports similar rates of parental guilt regarding the oral health problems of children (20.0 to 24.0%) (9,34,35). However, one study found a rate of only 4.2%, which was likely due regular visits to the dentist and consequently lower prevalence of oral health problems (8). Indeed, prevalence rates vary across countries/regions as well as in consequence of the age group analyzed and diagnostic criteria employed.

The frequency of parental guilt was greater among parents/caregivers who expressed a perception of their child's oral health as poor. Studies have demonstrated that parental perceptions are associated with clinical characteristics, as children with dental caries are more prone to having their oral health status rated as poor (17,36,37). As parents/caregivers are responsible for their child's health care and admit that oral health problems can be avoided, the perception of poor oral health may cause feelings of guilt (10,19). Moreover, the perception of poor oral health is associated with dental treatment needs in preschool children (17).

The fact that cavitated lesions was associated with parental guilt may be explained by the identification on the part of parents/caregivers of pain symptoms and difficulty eating certain foods (38), as occurs with untreated dental caries on posterior teeth. Although dental health professionals explain the main methods for preventing dental caries (39), many parents fail to put these methods into daily practice (16,20). In such cases, parents/caregivers often feel accountable (10,11) and worry about their child's future opportunities in life (20). Parental guilt

with regard to cavitated lesions further demonstrates the negative impact of this oral health problem on quality of life (7-9,38).

Complicated TDIs, such as avulsion/luxation and tooth discoloration, were associated with parental guilt. Feelings of guilt regarding avulsion/luxation may be attributed to pain, functional limitations and irritability on the part of the child, which are often found in cases of complicated TDIs (8). These injuries can lead to the dislocation of a tooth and pulp involvement, which is a cause of concern for parents/caregivers (20). Moreover, TDI can result in tooth discoloration, which exerts an impact on dental esthetics and psychosocial aspects in children (40), with consequent feelings of guilt on the part of parents/caregivers. It should be stressed that, despite the high prevalence rates of dental caries (66.5%) and TDI (34.1%) (2,4), only those of greater severity were associated with parental guilt, demonstrating that feelings of guilt arise when oral health problems in children are clearly identifiable (19).

Despite the high prevalence rate of malocclusion (65.3%), this variable was not significantly associated with parental guilt, likely due to the fact that this type of oral health problem does not cause pain and does not exert an impact on the OHRQoL of preschool children and their families (7,9,40). Moreover, the association between malocclusion and nonnutritive sucking habits is often not clear to parents, who generally attribute this oral health problem solely to heredity (16). The lack of information combined with the high prevalence rate of malocclusion underscores the importance of drafting public policies aimed at educating parents/caregivers regarding the prevention and treatment of malocclusion, as parental knowledge is fundamental to the oral health of children (41).

A history of toothache was associated with parental guilt, further demonstrating the value of this factor. Previous studies report that this aspect is one of the main reasons for seeking dental treatment in this phase of life (42,43). It appears that only oral conditions that cause pain, such as cavitated lesions and complicated TDI, are predictors of parental guilt and parents commonly accept the absence of pain in their children to be a sign of good oral health

(16). Indeed, toothache and functional limitations are aspects that exert a greater influence on OHRQoL in preschool children (20,27,35).

The present study has the limitations inherent to the cross-sectional design, which preempts inferences regarding causality and temporal relationships between variables; thus, longitudinal studies should be conducted to investigate this issue. The possibility of recall bias is also a concern when working with questionnaires. However, measures were taken to minimize this bias, such as the use of a validated questionnaire and the execution of a pilot study. The fact that this study was a preschool-based investigation with a randomly selected, representative sample allows the possibility of extrapolating the findings to the population in the age group analyzed.

CONCLUSION

Based on the present findings, parental guilt is mediated by oral health problems of greater severity in preschool children, such as untreated dental caries and complicated TDI, due to the association with pain symptoms. The recognition of parental guilt can assist in the drafting of public health policies aimed at reestablishing OHRQoL among preschool children and their families and encouraging changes in behavior toward healthier habits, as parents/caregivers have a direct influence on the oral health of their children.

List of abbreviations

OHRQoL: oral health-related quality of life; TDI: traumatic dental injury; ECOHIS: Early Childhood Oral Health Impact Scale; B-ECOHIS: Brazilian version of the Early Childhood Oral Health Impact Scale; ICDAS: International Caries Detection and Assessment System

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

MCG was responsible for the analysis and interpretation of the data, helped the statistical analysis and drafted the manuscript. TCAPS was responsible for the conception and study design, acquisition and interpretation of data. MAC performed data acquisition and drafted the manuscript. CCM performed the analysis and interpretation of the data and a critical review of the manuscript. AFGG was responsible for conception design, analysis and interpretation of the data and a critical review of the manuscript. SMP was responsible for the conception and study design and performed the final critical review. All authors read and approved the final manuscript.

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LEGENDS

Table 1 - Frequency distribution of socio-demographic variables

Table 2 - Frequency distribution of parental guilt and oral health problems

Table 3 - Hierarchical Poisson regression for parental guilt and independent variables among preschool children aged three-to-five years

Figure 1 - Analysis model used in the study

Table 1 - Frequency distribution of socio-demographic variables

Variable	Frequency	
	n	%
Sex		
Male	430	51.7
Female	402	48.3
Age		
3 years	273	32.8
4 years	328	39.4
5 years	231	27.8
Type of preschool		
Public	450	54.1
Private	382	45.9
Mother's schooling		
≤ 8 years of study	379	45.7
>8 years of study	450	54.3
Monthly household income		
≤ 1 minimum salary	435	54.9
> 1 minimum salary	358	45.1
Parent's/guardian's age		
≤ 30 years	416	51.1
> 30 years	398	48.9
TOTAL	832	100.0

Table 2 - Frequency distribution of parental guilt and oral health problems

Variable	Frequency	
	n	%
Parental guilt		
Absent	642	77.2
Present	190	22.8
History of toothache		
No	569	68.4
Yes	263	31.6
Dental caries		
Absent	279	33.5
Present	553	66.5
TDI		
Absent	548	65.9
Present	284	34.1
Malocclusion		
Absent	289	34.7
Present	543	65.3
TOTAL	832	100.0

Table 3 - Hierarchical Poisson regression for parental guilt and independent variables among preschool children aged three-to-five years

Variable	Parental guilt		Bivariate		Multivariate	
	Yes	No	Unadjusted PR*		Adjusted PR †	
	n(%)	n(%)	p-value	(95% CI)	p-value	(95% CI)
Sex						
Female	88(21.9)	314(78.1)		1.00	-	-
Male	102(23.7)	328(76.3)	0.530	1.084(0.843-1.392)	-	-
Age						
3 years	53(19.4)	220(80.6)		1.00		
4 years	65(19.8)	263(80.2)	0.901	1.021(0.737-1.413)	-	-
5 years	72(31.2)	159(68.8)	0.003	1.605(1.179-2.186)	-	-
1st level						
Type of preschool						
Private	79(20.7)	303(79.3)		1.00	-	-
Public	111(24.7)	339(75.3)	0.174	1.193(0.925-1.538)	-	-
Mother's schooling						
≤ 8 years of study	98(25.9)	281(74.1)	0.065	1.265(0.985-1.623)	-	-
>8 years of study	92(20.4)	358(79.6)		1.00	-	-
Monthly household income						
≤ 1 minimum salary	110(25.3)	325(74.7)	0.128	1.223(0.944-1.586)	-	-
> 1 minimum salary	74(20.7)	284(79.3)		1.00	-	-
Parent's/guardian's age						
≤ 30 years	101(24.3)	315(75.7)	0.210	1.178(0.911-1.524)	-	-
> 30 years	82(20.6)	316(79.4)		1.00	-	-
2nd level						

Perception of general**health**

Good	136(20.2)	537(79.8)		1.00	-	-
Poor	51(32.9)	104(67.1)	<0.001	1.628(1.243-2.134)	-	-

Perception of oral health

Good	71(12.8)	485(87.2)		1.00		1.00
Poor	119(43.3)	156(56.7)	<0.001	3.389(2.623-4.377)	<0.001	1.980(1.479-2.649)

3rd level**History of toothache**

No	72(12.7)	497(87.3)		1.00		1.00
Yes	118(44.9)	145(55.1)	<0.001	3.546(2.750-4.571)	<0.001	2.427(1.812-3.251)

Dental caries

Absent	28(10.0)	251(90.0)		1.00	-	-
Present	162(29.3)	391(70.7)	<0.001	2.919(2.007-4.245)	-	-

Cavitated lesions

Absent/ white spots	48(11.0)	389(89.0)		1.00		1.00
Cavitated anterior teeth	12(20.7)	46(79.3)	0.030	1.884(1.065-3.331)	0.264	1.370(0.788-2.381)
Cavitated posterior teeth	63(35.6)	114(64.4)	<0.001	3.240(2.324-4.518)	<0.001	2.012(1.397-2.896)
Cavitated anterior and posterior teeth	67(41.9)	93(58.1)	<0.001	3.812(2.759-5.268)	0.006	1.696(1.161-2.477)

TDI

Absent	126(23.0)	422(77.0)	0.882	1.020(0.783-1.329)	-	-
Present	64(22.5)	220(77.5)		1.00	-	-

Type of TDI

Tooth discoloration	32(33.7)	63(66.3)	0.005	1.567(1.142-2.151)	0.003	1.534(1.162-2.025)
Avulsion/luxation	4(36.4)	7(63.6)	0.195	1.692(0.764-3.746)	0.022	1.951(1.099-3.461)
Enamel + dentin fracture	7(16.7)	35(83.3)	0.471	0.776(0.388-1.548)	0.577	0.796(0.358-1.772)

Enamel fracture or no trauma	147(21.5)	537(78.5)		1.00		1.00
Malocclusion						
Absent	68(23.5)	221(76.5)	0.728	1.047(0.807-1.358)	-	-
Present	122(22.5)	421(77.5)		1.00	-	-
Anterior crossbite						
Absent	181(22.5)	625(77.5)		1.00	-	-
Present	8(34.8)	15(65.2)	0.135	1.549(0.872-2.750)	-	-
Anterior open bite						
Absent	144(22.4)	498(77.6)		1.00	-	-
Present	42(24.0)	133(76.0)	0.659	1.070(0.792-1.445)	-	-
Posterior crossbite						
Absent	154(21.2)	571(78.8)		1.00	-	-
Unilateral	29(31.2)	64(68.8)	0.024	1.468(1.052-2.048)	-	-
Bilateral	5(55.6)	4(44.4)	0.002	2.615(1.434-4.770)	-	-
Deep overbite						
Absent	160(24.2)	500(75.8)	0.047	1.464(1.005-2.132)	-	-
Present	26(16.6)	131(83.4)		1.00	-	-
Increased overjet						
Absent	112(24.1)	352(75.9)	0.302	1.144(0.886-1.478)	-	-
Present	77(21.1)	288(78.9)		1.00	-	-

* Unadjusted Poisson regression for independent variables and parental guilt.

** Variables incorporated into multivariate model ($p < 0.20$): sex, age, type of preschool, mother's schooling, monthly household income, perception of general health, perception of oral health, history of toothache, dental caries, untreated dental caries, TDI, type of TDI, malocclusion, anterior crossbite, posterior crossbite and deep overbite.

† Hierarchical Poisson regression: Level 1 adjusted by characteristics of child and socio-demographic data; Level 2 adjusted by characteristics of child, socio-demographic data and health perception; Level 3 adjusted by characteristics of child, socio-demographic data, health perception and oral health problems (dental caries, TDI and malocclusion).

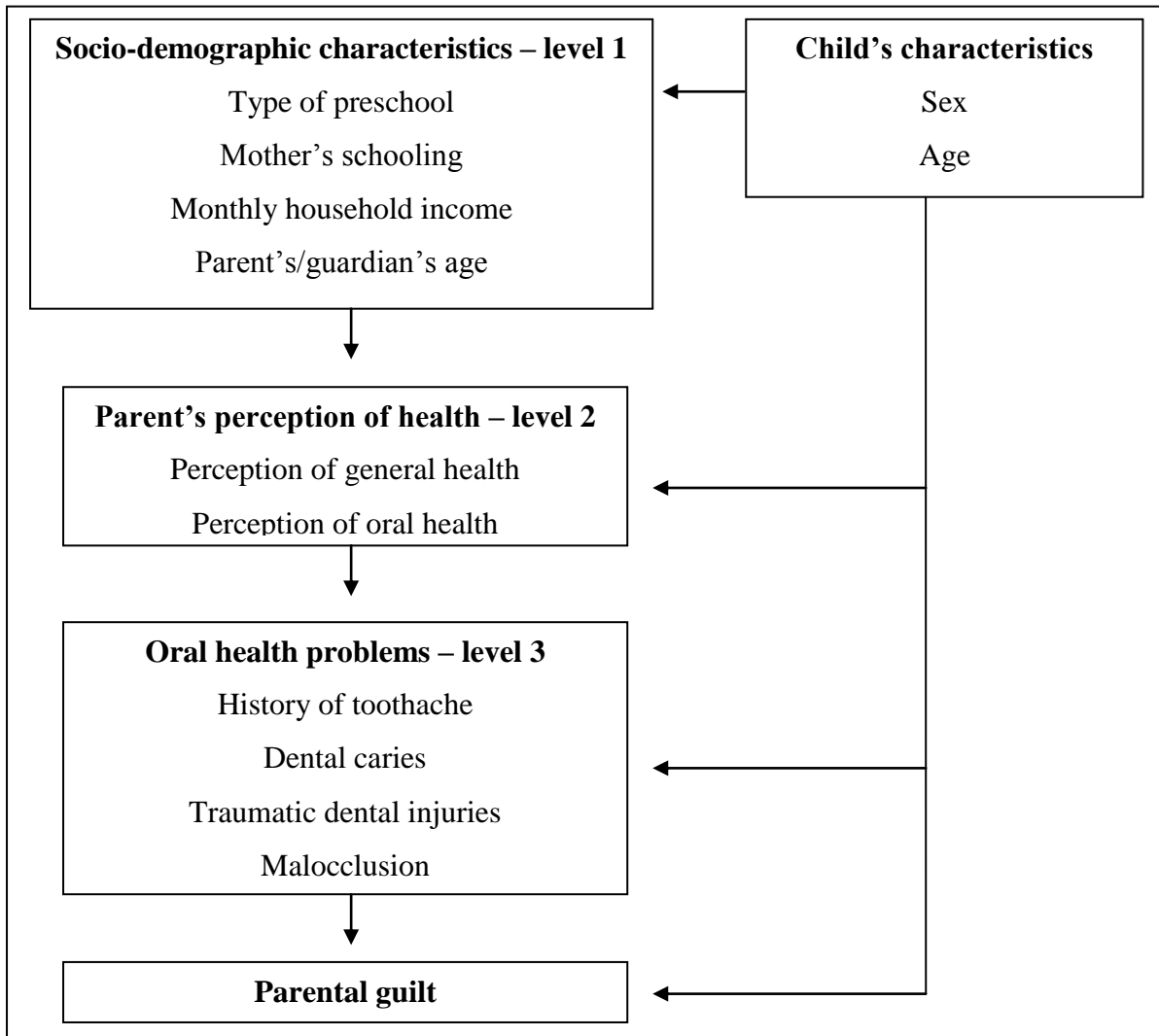


Figure 1 - Analysis model used in the study

5 CONSIDERAÇÕES FINAIS

Os indicadores de qualidade de vida são importantes em decisões para alocação de recursos e planejamento de estratégias de atenção à saúde. Assim, ao compreender as repercussões das alterações bucais na qualidade de vida das crianças em idade pré-escolar, torna-se possível a reestruturação das práticas e a elaboração de programas de promoção de saúde muito mais adequados e específicos para cada grupo.

Devido à temporalidade da permanência dos dentes decíduos, muitos pais acreditam que problemas bucais na infância não trazem maiores consequências às crianças. A saúde bucal dos pais pode também refletir sobre a importância e cuidados com a saúde bucal dos filhos. Dessa forma, a falta de conhecimento sobre a denteição decídua contribui para que os cuidados preventivos não sejam uma prioridade nessa idade. (HILTON et al., 2007). Além disso, a cobertura dos programas de saúde pública não abrange a primeira infância, e dessa forma as alterações bucais nessas crianças muitas vezes resulta em dor e limitações funcionais (LEE et al., 2010).

Os resultados desse estudo contribuem para evidenciar que as alterações bucais que necessitam de tratamento como lesões cavitadas e TDI, bem como a percepção ruim dos pais sobre a saúde bucal dos filhos são determinantes para um impacto na QVRSB dos pré-escolares e suas famílias, sendo também fatores que contribuem para o surgimento da culpa parental. A cárie dentária é a doença crônica mais prevalente na infância (PATEL et al., 2007; GOETTEMS et al., 2011) e implica em limitações para as famílias, uma vez que as crianças apresentam dor, dificuldades na mastigação, além de distúrbios durante o sono, o que resulta em dias de trabalho perdidos pelos pais. Referindo-se especificamente ao TDI, é necessário que se avaliem quais os tipos dessa alteração podem causar repercussão na QVRSB dos pré-escolares, devido à urgência para resolução da sintomatologia dolorosa e das limitações funcionais que podem ocasionar os casos de maior gravidade (ALDRIGUI et al., 2011; ABANTO et al., 2012).

Quanto à má oclusão, observa-se que a mesma não implica em repercussão negativa na qualidade de vida de pré-escolares, o que justifica o fato da estética não interferir na qualidade de vida nessa fase, bem como más oclusões em dentes posteriores serem imperceptíveis aos pais. Além disso, muitos pais não reconhecem as

consequências estéticas, psicológicas e financeiras que a má oclusão pode produzir em idades mais avançadas, dessa forma os pais não demonstram sentimentos de culpa. Então, pode-se concluir que a dor e desconforto sejam mais relevantes, fazendo com que alterações bucais como a cárie dentária e TDI complicados possam exercer maior influência na qualidade de vida em pré-escolares e suas famílias. No entanto, vale salientar que mesmo a má oclusão não exercendo influência negativa na qualidade de vida de pré-escolares, merece atenção nesta fase, por tratar-se de uma guia para o desenvolvimento da dentição permanente (PETRÉN; BONDEMARK; SÖDERFELDT, 2003; GÓIS et al., 2008)

Assim, a implantação de ações de cuidados em saúde bucal em pré-escolares deve ser vista como essencial, uma vez que poderá levar a uma melhora expressiva na qualidade de vida da população. E uma compreensão integral sobre o papel das alterações bucais na vida dos pré-escolares e suas famílias, permite ampliar as informações que servirão de base para construção de políticas públicas em saúde bucal.

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APÊNDICES E ANEXOS

APÊNDICE A Questionário Dirigido aos Pais



Programa de Pós-Graduação em Odontologia

QUESTIONÁRIO DIRECIONADO AOS PAIS/RESPONSÁVEIS

IDENTIFICAÇÃO:

01. Nome da criança: _____
02. Sexo: () menina () menino 03. Dia do aniversário da criança: ____/____/____
04. Nome do responsável pela criança _____
05. Pré-escola: _____ 06. Pública () Particular ()
07. Você é que parente da criança? (MARQUE COM UM X)
- () Mãe () Pai () Irmão (ã) () Tio (a) () Avô (ó) () Vizinho (a)
- () Amigo (a) () Outro. Qual? _____
08. Qual a idade do responsável pela criança: _____
09. A criança é:
- () filho(a) único(a) () filho(a) mais novo(a) () filho(a) mais velho(a) () filho (a) do meio

DADOS SOBRE A FAMÍLIA DA CRIANÇA

10. A mãe da criança estudou até quando? (MARQUE COM UM X)
- () não estudou
- () 1ª a 4ª série incompleta () 1ª a 4ª série completa
- () 5ª a 8ª série incompleta () 5ª a 8ª série completa
- () 1º ao 3º ano científico incompleto () 1º ao 3º ano científico completo
- () ensino superior incompleto () ensino superior completo
11. Somando a sua renda com as das pessoas que moram com você, quanto é aproximadamente, a RENDA MENSAL DA SUA FAMÍLIA? (incluir salários-mínimos, Bolsa família, Seguro desemprego, “bicos”) Valor R\$ _____ () Não tem renda
12. Quantas pessoas moram na casa da criança (contando com ela)? _____

DADOS SOBRE A CRIANÇA

13. O que você acha da saúde geral de sua criança?
- () muito boa () boa () regular () ruim () muito ruim
14. O que você acha da saúde da boca de sua criança?
- () muito boa () boa () regular () ruim () muito ruim

APÊNDICE B Ficha clínica

Universidade Estadual da Paraíba
Departamento de Odontologia

FICHA CLÍNICA

Nº _____ Examinador: _____
Pré-escola: _____ Pública () Particular ()
Responsável pela criança na pré-escola: _____
Pertencente ao distrito sanitário: _____

Dados Pessoais:

Nome da criança: _____
Sexo: () menina () menino
Dia, mês e ano em que a criança nasceu: ____/____/____ Idade: ____ (em meses)
Nome da mãe, pai, ou responsável: _____

Exame Clínico:**TRAUMATISMO**

55	54	53	52	51	61	62	63	64	65
85	84	83	82	81	71	72	73	74	75

Tipo de trauma:

0. Sem trauma
1. Fratura de esmalte
2. Fratura de esmalte e dentina
3. Fratura coronária complicada
4. Luxação extrusiva
5. Luxação lateral
6. Luxação intrusiva
7. Avulsão
8. Alteração de cor

MÁ OCLUSÃO

01. *Overjet*:

() Ideal () Aumentado () Topo-a-topo () Cruzado

02. *Overbite*:

() Ideal () Reduzido () Mordida aberta anterior () Aumentado

03. Mordida Cruzada posterior:

() Ausente () Unilateral, lado _____ () Bilateral

APÊNDICE C Consentimento da Secretaria Municipal de Educação



UNIVERSIDADE ESTADUAL DA PARAÍBA
CENTRO DE CIÊNCIAS BIOLÓGICAS E DA SAÚDE
Departamento de Odontologia

CARTA DE ANUÊNCIA

Exmo. Sr. Secretário Municipal de Educação.

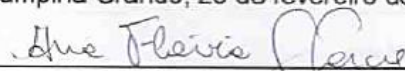
Nós, Ana Flávia Granville-Garcia e Edja Maria de Melo Brito Costa, pesquisadoras responsáveis, objetivamos realizar uma pesquisa para dissertação de mestrado intitulada "Avaliação das repercussões das alterações bucais na qualidade de vida em pré-escolares de 36 a 60 meses de Campina Grande-PB".

Solicitamos, por gentileza, sua autorização para examinar pré-escolares de 36 a 60 meses e entrevistar suas mães/responsáveis. Informamos que a realização deste trabalho não trará custos para as instituições e, na medida do possível, não iremos interferir na operacionalização e/ou nas atividades cotidianas das mesmas. Salientamos, ainda que em retorno, forneceremos os resultados desta pesquisa para a Secretaria de Educação.

Esclarecemos que tal autorização é uma pré-condição bioética para execução de qualquer estudo envolvendo seres humanos, sob qualquer forma ou dimensão, em consonância com a resolução 196/96 do Conselho Nacional de Saúde.

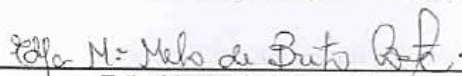
Atenciosamente,

Campina Grande, 28 de fevereiro de 2011



Ana Flávia Granville-Garcia

Profª do programa de pós-graduação em odontologia da UEPB



Edja Maria de Melo Brito Costa

Profª do programa de pós-graduação em odontologia da UEPB

Autorizo



Exmo. Prof. Flávio Romero Guimarães

Secretário de Educação do Município de Campina Grande-PB

APÊNDICE D Consentimento da Secretaria Estadual de Educação



UNIVERSIDADE ESTADUAL DA PARAÍBA
Departamento de Odontologia

CARTA DE ANUÊNCIA

Ilma Sra. Claubete Ludugério,

Estamos realizando uma pesquisa que tem como título: “Alterações Bucais: Prevalência, Fatores Associados e Impacto na Qualidade de Vida de Pré-Escolares de Campina Grande-PB” com o objetivo de avaliar a condição de saúde bucal, em relação a cárie dentária, maloclusão e traumatismo, bem como suas possíveis causas e a repercussão dessas condições com a qualidade de vida de crianças de 36 a 60 meses. Esta pesquisa será realizada por professores da Universidade Estadual da Paraíba, alunos de mestrado e de graduação e tem finalidade acadêmica.

O estudo será realizado mediante exame clínico da criança, o qual apresenta baixo risco ou desconforto à criança e apenas será realizado se a mesma e seu pai/mãe/responsável permitir. Também será realizada aplicação de questionário aos pais ou responsáveis, sendo que este questionário não apresenta quaisquer tipos de risco ou desconforto, exceto o tempo gasto para responder as questões (cerca de 15 minutos).

Salienta-se que todas as informações obtidas serão guardadas e resguardadas, não sendo revelada sob qualquer pretexto a identificação das crianças e dos respondentes. Deixamos claro, desde já, que não haverá nenhuma forma de benefício financeiro ou pessoal para os pesquisadores, nem para as instituições.

Solicitamos então, por gentileza, sua autorização para examinar essas crianças e entrevistar suas mães/pais/responsáveis. Informamos que, na medida do possível, não iremos interferir na operacionalização e/ou nas atividades cotidianas das escolas/creches, nem das crianças. Será feita aplicação de Flúor nas crianças, como também serão fornecidos Kits para escovação. Salientamos, ainda que em retorno, forneceremos os resultados desta pesquisa para a Secretaria de Educação.

Esclarecemos que tal autorização é uma pré-condição bioética para execução de qualquer estudo envolvendo seres humanos, sob qualquer forma ou dimensão, em consonância com a resolução 196/96 do Conselho Nacional de Saúde.

Atenciosamente,

Campina Grande, 8 de agosto de 2011

Ana Flávia Granville-Garcia
Profª do programa de pós-graduação em odontologia da UEPB

Edja Maria de Melo Brito Costa
Profª do programa de pós-graduação em odontologia da UEPB

Autorizo

Claubete L. Pereira
Chefe do NUAGE da Terceira
Gerência Regional de Educação
Coordenadora da Inspeção de Ensino da 3ª Região

1557068
88416064.

APÊNDICE E Consentimento das Escolas Particulares



UNIVERSIDADE ESTADUAL DA PARAÍBA
CENTRO DE CIÊNCIAS BIOLÓGICAS E DA SAÚDE

CARTA DE ANUÊNCIA

Exmo(a). Sr(a). Diretor(a).

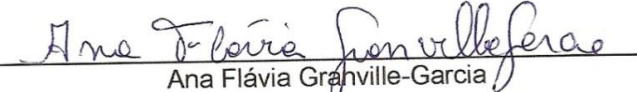
Eu, Ana Flávia Granville-Garcia, pesquisadora responsável, juntamente com minha equipe, objetivamos realizar uma pesquisa para dissertação de mestrado intitulada "Avaliação das repercussões das alterações bucais na qualidade de vida em pré-escolares de 36 a 60 meses de Campina Grande-PB".

Solicitamos, por gentileza, sua autorização para examinar pré-escolares de 36 a 60 meses e entrevistar suas mães/responsáveis. Informamos que a realização deste trabalho não trará custos para as instituições e, na medida do possível, não iremos interferir na operacionalização e/ou nas atividades cotidianas das mesmas. Salientamos, ainda que em retorno, forneceremos os resultados desta pesquisa para a sua escola posteriormente.

Esclarecemos que tal autorização é uma pré-condição bioética para execução de qualquer estudo envolvendo seres humanos, sob qualquer forma ou dimensão, em consonância com a resolução 196/96 do Conselho Nacional de Saúde.

Atenciosamente,

Campina Grande, ____ de _____ de 2011.



Ana Flávia Granville-Garcia

Profª do programa de pós-graduação em odontologia da UEPB

Autorizo

Diretor (a) / Responsável pela escola

APÊNDICE F Termo de Consentimento Livre e Esclarecido

Programa de Pós-Graduação em Odontologia

Termo de Consentimento Livre e Esclarecido

Prezado (a) Senhor (a), responsável, pedimos o favor de dedicar alguns minutos do seu tempo para ler este comunicado.

Estamos realizando uma pesquisa que tem como título: “Avaliação das repercussões das alterações bucais na qualidade de vida em pré-escolares de três a cinco anos de Campina Grande-PB”. Esta pesquisa tem finalidade acadêmica. Será realizada mediante aplicação de um questionário aos pais dos pré-escolares, sendo que este procedimento não apresenta quaisquer tipos de risco ou desconforto, exceto o tempo gasto para responder as questões (cerca de 15 minutos); e exame clínico da criança, o qual apresenta baixo risco ou desconforto a mesma e apenas será realizado se ela permitir. Salienta-se que todas as informações obtidas serão guardadas e resguardadas, não sendo revelada sob qualquer pretexto a identificação das crianças e dos respondentes. Deixamos claro, desde já, que não haverá nenhuma forma de benefício financeiro ou pessoal, e que esta declaração de concordância em participar do estudo poderá ser retirada a qualquer época, não acarretando em danos. A sua colaboração, autorizando no quadro abaixo a realização do exame e da entrevista, é importante para avaliar a necessidade de realização de programas de saúde bucal. Esclarecemos que sua participação é decorrente de sua livre decisão após receber todas as informações que julgarem necessárias. Você não será prejudicado de qualquer forma caso sua vontade seja de não colaborar, até mesmo onde haja submissão à autoridade. Se quiser informações sobre nosso trabalho, por favor, ligue para Ana Flávia Granville-Garcia, professora responsável pela pesquisa no telefone 33153300, ou então, fale com ela pessoalmente na Av. das Baraúnas, s/n Bodocongó, no horário comercial de 2ª a 6ª feiras. Esperamos contar com o seu apoio, desde já agradecemos.

Ana Flávia Granville-Garcia (Pesquisadora Responsável)

AUTORIZAÇÃO

Após ter sido informado sobre as características da pesquisa: “Avaliação das repercussões das alterações bucais na qualidade de vida em pré-escolares de três a cinco anos de Campina Grande-PB”, autorizo a realização do exame clínico na criança e entrevista em:

Campina Grande, ___ de _____ 2012

Responsável _____ RG _____



ANEXO A Instrumento B-ECOHIS

Universidade Estadual da Paraíba
Departamento de Odontologia

Instrumento ECOHIS**Questionário sobre a Qualidade de Vida Relacionada à Saúde Bucal de Crianças na Idade Pré-Escolar**

“Problemas com dentes, boca, ou maxilares (ossos da boca) e seus tratamentos, podem afetar o bem-estar e a vida diária das crianças e suas famílias. Para cada uma das seguintes questões perguntadas pelo entrevistador, por favor, indique no quadro de opções de respostas a que melhor descreve as experiências da sua criança ou a sua própria. Considere toda a vida da sua criança, desde o nascimento até agora, quando responder cada pergunta”.

Sua criança já sentiu dores nos dentes, na boca ou nos maxilares (ossos da boca)?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já teve dificuldade de beber bebidas quentes ou frias devido a problemas com os dentes ou tratamentos dentários?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já teve dificuldade para comer certos alimentos devido a problemas com os dentes ou tratamentos dentários?

6. Nunca
7. Quase nunca
8. Às vezes
9. Com frequência
10. Com muita frequência

11. Não sei

Sua criança já teve dificuldade de pronúncias qualquer palavra devido a problemas com os dentes ou tratamentos dentários?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já faltou à creche, jardim de infância ou escola devido a problemas com os dentes ou tratamentos dentários.

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já teve dificuldades em dormir devido a problemas com os dentes ou tratamentos dentários.

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já ficou irritada devido a problemas com os dentes ou tratamentos dentários.

6. Nunca
7. Quase nunca
8. Às vezes
9. Com frequência
10. Com muita frequência
11. Não sei

Sua criança já evitou sorrir ou rir devido a problemas com os dentes ou tratamentos dentários.

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já evitou falar devido a problemas com os dentes ou tratamentos dentários.

0. Nunca
1. Quase nunca

2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Você ou outra pessoa da família já ficou aborrecida devido a problemas com os dentes ou tratamentos dentários de sua criança?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Você ou outra pessoa da família já se sentiu culpada devido a problemas com os dentes ou tratamentos dentários de sua criança?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Você ou outra pessoa da família já faltou trabalho devido a problemas com os dentes ou tratamentos dentários de sua criança?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

Sua criança já teve problemas com os dentes ou fez tratamentos dentários que causaram impacto financeiro na sua família?

0. Nunca
1. Quase nunca
2. Às vezes
3. Com frequência
4. Com muita frequência
5. Não sei

ANEXO B Ficha ICDAS-II

I.D. Circ. _____ Escola _____ Examinador _____ Data _____

Idade _____ Gênero _____ Anotador _____ Peso _____ Taman _____

Código Dental

S – Saudável
 U – Não erupcionado
 E – Exfoliado (>60 meses)
 X – Perdido por cárie
 Dentes anteriores – (6-59 meses)
 Posteriores (6-71 meses)
 T – Perdido por trauma
 R – Resto radicular
 N – Não aplicável
 C – Cárie
 P – Exposição pulpar
 F – Fístula

Código ICDAS -lesões

0- hígido
 2- não cavitada (seca e úmida)
 3- ruptura localizada no esmalte
 4- **sombra cinzenta de dentina**
 5- cavidade com dentina visível
 6- cavidade extensa

Superior Direito

código dente	55			54			53			52			51		
	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES
Mesial															
Oclusal															
Distal															
Vestib															
Lingual															

Superior Esquerdo

código dente	61			62			63			64			65		
	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES
Mesial															
Oclusal															
Distal															
Vestib															
Lingual															

Inferior Direito

código dente	85			84			83			82			81		
	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES
Mesial															
Oclusal															
Distal															
Vestib															
Lingual															

Inferior Esquerdo

código dente	71			72			73			74			75		
	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES	LES	Ativ	RES
Mesial															
Oclusal															
Distal															
Vestib															
Lingual															

Código de Atividade

1- não ativa
 2- ativa

Código Restauração

(0 – Nada)
 1 - Selante parcial
 2 - Selante completo
 3 - Rest. dcor do dente
 4 - Amálgama
 5- Corona aço/policarb.
 6 – Corona **ouro/ porcelana**
 7 - Rest. perdida
 8 - Rest. temporária
 9 - Outra

OBSERVAÇÕES:

*Resinas, compómeros, ionômeros, etc

ANEXO C Parecer do Comitê de Ética em Pesquisa

**UNIVERSIDADE ESTADUAL DA PARAÍBA-UEPB
PRÓ-REITORIA DE PÓS-GRADUAÇÃO E PESQUISA- PRPGP
COMITÊ DE ÉTICA EM PESQUISA ENVOLVENDO SERES HUMANOS
COMPROVANTE SISNEP**

Andamento do projeto - CAAE - 0046.0.133.000-11

Título do Projeto de Pesquisa				
Avaliação das repercussões das alterações bucais na qualidade de vida em pré-escolares de 36 a 60 meses de Campina Grande-PB				
Situação	Data Inicial no CEP	Data Final no CEP	Data Inicial na CONEP	Data Final na CONEP
Aprovado no CEP	15/03/2011 14:44:02	30/03/2011 15:00:43		

Descrição	Data	Documento	Nº do Doc	Origem
1 - Envio da Folha de Rosto pela Internet	28/02/2011 11:24:33	Folha de Rosto	FR406207	Pesquisador
3 - Protocolo Aprovado no CEP	30/03/2011 15:00:43	Folha de Rosto	0046.0.133.000-11	CEP
2 - Recebimento de Protocolo pelo CEP (Check-List)	15/03/2011 14:44:02	Folha de Rosto	0046.0.133.000-11	CEP

UNIVERSIDADE ESTADUAL DA PARAÍBA
PRÓ-REITORIA DE PÓS-GRADUAÇÃO E PESQUISA
COMITÊ DE ÉTICA EM PESQUISA


 Profª Dra. Doralúcia Pedrosa de Araújo
 Coordenadora do Comitê de Ética em Pesquisa

ANEXO D Normas de publicação da revista Health and Quality of Life Outcomes

Instructions for authors

Research Articles

[Submission process](#) | [Preparing main manuscript text](#) | [Preparing illustrations and figures](#) | [Preparing tables](#) | [Preparing additional files](#) | [Style and language](#)

See '[About this journal](#)' for descriptions of different article types and information about policies and the refereeing process.

Submission process

Manuscripts must be submitted by one of the authors of the manuscript, and should not be submitted by anyone on their behalf. The submitting author takes responsibility for the article during submission and peer review.

Please note that *Health and Quality of Life Outcomes* levies an article-processing charge on all accepted Research Articles; if the submitting author's institution is a [BioMed Central member](#) the cost of the article-processing charge may be covered by the membership (see [About](#) page for detail). Please note that the membership is only automatically recognised on submission if the submitting author is based at the member institution.

To facilitate rapid publication and to minimize administrative costs, *Health and Quality of Life Outcomes* prefers [online submission](#).

Files can be submitted as a batch, or one by one. The submission process can be interrupted at any time; when users return to the site, they can carry on where they left off.

See below for examples of [word processor](#) and [graphics file formats](#) that can be accepted for the main manuscript document by the online submission system. Additional files of any type, such as [movies](#), animations, or [original data files](#), can also be submitted as part of the manuscript.

During submission you will be asked to provide a cover letter. Use this to explain why your manuscript should be published in the journal, to elaborate on any issues relating to our editorial policies in the '[About Health and Quality of Life Outcomes](#)' page, and to declare any potential competing interests. You will be also asked to provide the contact details (including email addresses) of potential peer reviewers for your manuscript. These should be experts in their field, who will be able to provide an objective assessment of the manuscript. Any suggested peer reviewers should not have published with any of the authors of the manuscript within the past five years, should not be

current collaborators, and should not be members of the same research institution. Suggested reviewers will be considered alongside potential reviewers recommended by Editorial Board members or other advisers.

Assistance with the process of manuscript preparation and submission is available from [BioMed Central customer support team](#).

We also provide a collection of links to useful tools and resources for scientific authors on our [Useful Tools](#) page.

File formats

The following word processor file formats are acceptable for the main manuscript document:

Microsoft word (DOC, DOCX)

Rich text format (RTF)

Portable document format (PDF)

TeX/LaTeX (use [BioMed Central's TeX template](#))

DeVice Independent format (DVI)

TeX/LaTeX users: Please use [BioMed Central's TeX template](#) and BibTeX stylefile if you use TeX format. During the TeX submission process, please submit your TeX file as the main manuscript file and your bib/bbl file as a dependent file. Please also convert your TeX file into a PDF and submit this PDF as an additional file with the name 'Reference PDF'. This PDF will be used by internal staff as a reference point to check the layout of the article as the author intended. Please also note that all figures must be coded at the end of the TeX file and not inline.

If you have used another template for your manuscript, or if you do not wish to use BibTeX, then please submit your manuscript as a DVI file. We do not recommend converting to RTF.

For all TeX submissions, all relevant editable source must be submitted during the submission process. Failing to submit these source files will cause unnecessary delays in the publication procedures.

Preparing main manuscript text

General guidelines of the journal's style and language are given [below](#).

Overview of manuscript sections for Research Articles

Manuscripts for Research Articles submitted to *Health and Quality of Life Outcomes* should be divided into the following sections (in this order):

[Title page](#)

[Abstract](#)

[Additional non-English language abstract](#)

[Keywords](#)

[Background](#)

[Methods](#)

[Results and discussion](#)

[Conclusions](#)

[List of abbreviations used \(if any\)](#)

[Competing interests](#)

[Authors' contributions](#)

[Authors' information](#)

[Acknowledgements](#)

[Endnotes](#)

[References](#)

[Illustrations and figures \(if any\)](#)

[Tables and captions](#)

[Preparing additional files](#)

The **Accession Numbers** of any nucleic acid sequences, protein sequences or atomic coordinates cited in the manuscript should be provided, in square brackets and include the corresponding database name; for example, [EMBL:AB026295, EMBL:AC137000, DDBJ:AE000812, GenBank:U49845, PDB:1BFM, Swiss-Prot:Q96KQ7, PIR:S66116].

The databases for which we can provide direct links are: EMBL Nucleotide Sequence Database ([EMBL](#)), DNA Data Bank of Japan ([DDBJ](#)), GenBank at the NCBI ([GenBank](#)), Protein Data Bank ([PDB](#)), Protein Information Resource ([PIR](#)) and the Swiss-Prot Protein Database ([Swiss-Prot](#)).

You can [download a template](#) (Mac and Windows compatible; Microsoft Word 98/2000) for your article.

For reporting standards please see the information in the [About](#) section.

Title page

The title page should:

provide the title of the article

list the full names, institutional addresses and email addresses for all authors

indicate the corresponding author

Please note:

the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study"

abbreviations within the title should be avoided

Abstract

The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the [CONSORT extension for abstracts](#).

Additional non-English language abstract

An additional non-English language abstract can be included within the article. The additional abstract should be placed after the official English language abstract in the submitted manuscript file and should not exceed 350 words. Please ensure you indicate the language of your abstract. In addition to English, we can support German, Spanish, French, Norwegian and Portuguese abstracts.

Keywords

Three to ten keywords representing the main content of the article.

Background

The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate

why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

Methods

The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

For studies involving human participants a statement detailing ethical approval and consent should be included in the methods section. For further details of the journal's editorial policies and ethical guidelines see ['About this journal'](#).

For further details of the journal's data-release policy, see the policy section in ['About this journal'](#).

Results and discussion

The Results and discussion may be combined into a single section or presented separately. Results of statistical analysis should include, where appropriate, relative and absolute risks or risk reductions, and confidence intervals. The Results and discussion sections may also be broken into subsections with short, informative headings.

Conclusions

This should state clearly the main conclusions of the research and give a clear explanation of their importance and relevance. Summary illustrations may be included.

List of abbreviations

If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations can be provided, which should precede the competing interests and authors' contributions.

Competing interests

A competing interest exists when your interpretation of data or presentation of information may be influenced by your personal or financial relationship with other people or organizations. Authors must disclose any financial competing interests; they should also reveal any non-financial competing interests that may cause them embarrassment were they to become public after the publication of the manuscript.

Authors are required to complete a declaration of competing interests. All competing interests that are declared will be listed at the end of published articles. Where an author gives no competing interests, the listing will read 'The author(s) declare that they have no competing interests'.

When completing your declaration, please consider the following questions:

Financial competing interests

In the past five years have you received reimbursements, fees, funding, or salary from an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? Is such an organization financing this manuscript (including the article-processing charge)? If so, please specify.

Do you hold any stocks or shares in an organization that may in any way gain or lose financially from the publication of this manuscript, either now or in the future? If so, please specify.

Do you hold or are you currently applying for any patents relating to the content of the manuscript? Have you received reimbursements, fees, funding, or salary from an organization that holds or has applied for patents relating to the content of the manuscript? If so, please specify.

Do you have any other financial competing interests? If so, please specify.

Non-financial competing interests

Are there any non-financial competing interests (political, personal, religious, ideological, academic, intellectual, commercial or any other) to declare in relation to this manuscript? If so, please specify.

If you are unsure as to whether you, or one your co-authors, has a competing interest please discuss it with the editorial office.

Authors' contributions

In order to give appropriate credit to each author of a paper, the individual contributions of authors to the manuscript should be specified in this section.

According to [ICMJE guidelines](#), An 'author' is generally considered to be someone who has made substantive intellectual contributions to a published study. To qualify as an author one should 1) have made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) have been involved in drafting the manuscript or revising it critically for important intellectual content; 3) have given final approval of the version to be published; and 4) agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.

We suggest the following kind of format (please use initials to refer to each author's contribution): AB carried out the molecular genetic studies, participated in the sequence alignment and drafted the manuscript. JY carried out the immunoassays. MT participated in the sequence alignment. ES participated in the design of the study and performed the statistical analysis. FG conceived of the study, and participated in its design and coordination and helped to draft the manuscript. All authors read and approved the final manuscript.

All contributors who do not meet the criteria for authorship should be listed in an acknowledgements section. Examples of those who might be acknowledged include a person who provided purely technical help, writing assistance, or a department chair who provided only general support.

Authors' information

You may choose to use this section to include any relevant information about the author(s) that may aid the reader's interpretation of the article, and understand the standpoint of the author(s). This may include details about the authors' qualifications, current positions they hold at institutions or societies, or any other relevant background information. Please refer to authors using their initials. Note this section should not be used to describe any competing interests.

Acknowledgements

Please acknowledge anyone who contributed towards the article by making substantial contributions to conception, design, acquisition of data, or analysis and interpretation of data, or who was involved in drafting the manuscript or revising it critically for important intellectual content, but who does not meet the criteria for authorship. Please also include the source(s) of funding for each author, and for the manuscript preparation. Authors must describe the role of the funding body, if any, in design, in the collection, analysis, and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. Please also acknowledge anyone who contributed materials essential for the study. If a language editor has made significant revision of the manuscript, we recommend that you acknowledge the editor by name, where possible.

The role of a scientific (medical) writer must be included in the acknowledgements section, including their source(s) of funding. We suggest wording such as 'We thank Jane Doe who provided medical writing services on behalf of XYZ Pharmaceuticals Ltd.'

Authors should obtain permission to acknowledge from all those mentioned in the Acknowledgements section.

Endnotes

Endnotes should be designated within the text using a superscript lowercase letter and all notes (along with their corresponding letter) should be included in the Endnotes section. Please format this section in a paragraph rather than a list.

References

All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

Only articles, datasets, clinical trial registration records and abstracts that have been published or are in press, or are available through public e-print/preprint servers, may be cited; unpublished abstracts, unpublished data and personal communications should not be included in the reference list, but may be included in the text and referred to as "unpublished observations" or "personal communications" giving the names of the involved researchers. Obtaining permission to quote personal communications and unpublished data from the cited colleagues is the responsibility of the author. Footnotes are not allowed, but endnotes are permitted. Journal abbreviations follow Index Medicus/MEDLINE. Citations in the reference list should include all named authors, up to the first 30 before adding '*et al.*'..

Any *in press* articles cited within the references and necessary for the reviewers' assessment of the manuscript should be made available if requested by the editorial office.

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Examples of the *Health and Quality of Life Outcomes* reference style

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Article within a journal supplement

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In press article

Kharitonov SA, Barnes PJ: **Clinical aspects of exhaled nitric oxide.** *Eur Respir J*, in press.

Published abstract

Zvaifler NJ, Burger JA, Marinova-Mutafchieva L, Taylor P, Maini RN: **Mesenchymal cells, stromal derived factor-1 and rheumatoid arthritis [abstract].** *Arthritis Rheum* 1999, **42**:s250.

Article within conference proceedings

Jones X: **Zeolites and synthetic mechanisms.** In *Proceedings of the First National Conference on Porous Sieves: 27-30 June 1996; Baltimore.* Edited by Smith Y. Stoneham: Butterworth-Heinemann; 1996:16-27.

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Ponder B, Johnston S, Chodosh L (Eds): **Innovative oncology.** In *Breast Cancer Res* 1998, **10**:1-72.

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Complete book

Margulis L: *Origin of Eukaryotic Cells.* New Haven: Yale University Press; 1970.

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Hunninghake GW, Gadek JE: **The alveolar macrophage**. In *Cultured Human Cells and Tissues*. Edited by Harris TJR. New York: Academic Press; 1995:54-56. [Stoner G (Series Editor): *Methods and Perspectives in Cell Biology*, vol 1.]

Book with institutional author

Advisory Committee on Genetic Modification: *Annual Report*. London; 1999.

PhD thesis

Kohavi R: **Wrappers for performance enhancement and oblivious decision graphs**. *PhD thesis*. Stanford University, Computer Science Department; 1995.

*Link / URL***The Mouse Tumor Biology**

Database [<http://tumor.informatics.jax.org/mtbwi/index.do>]

Link / URL with author(s)

Corpas M: **The Crowdfunding Genome Project: a personal genomics community with open source values** [<http://blogs.biomedcentral.com/bmcblog/2012/07/16/the-crowdfunding-genome-project-a-personal-genomics-community-with-open-source-values/>]

Dataset with persistent identifier

Zheng, L-Y; Guo, X-S; He, B; Sun, L-J; Peng, Y; Dong, S-S; Liu, T-F; Jiang, S; Ramachandran, S; Liu, C-M; Jing, H-C (2011): **Genome data from sweet and grain sorghum (*Sorghum bicolor*)**. *GigaScience*. <http://dx.doi.org/10.5524/100012>.

Clinical trial registration record with persistent identifier

Mendelow, AD (2006): **Surgical Trial in Lobar Intracerebral Haemorrhage**. *Current Controlled Trials*. <http://dx.doi.org/10.1186/ISRCTN22153967>

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There is no explicit limit on the length of articles submitted, but authors are encouraged to be concise.

Health and Quality of Life Outcomes will not edit submitted manuscripts for style or language; reviewers may advise rejection of a manuscript if it is compromised by grammatical errors. Authors are advised to write clearly and simply, and to have their article checked by colleagues before submission. In-house copyediting will be minimal. Non-native speakers of English may choose to make use of a copyediting service.

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Type the text unjustified, without hyphenating words at line breaks.

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Units

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ANEXO E Normas de publicação da revista BMC Public Health

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Research articles

[Criteria](#) | [Submission process](#) | [Preparing main manuscript text](#) | [Preparing illustrations and figures](#) | [Preparing tables](#) | [Preparing additional files](#) | [Style and language](#)

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[Background](#)

[Methods](#)

[Results and discussion](#)

[Conclusions](#)

[List of abbreviations used](#) (if any)

[Competing interests](#)

[Authors' contributions](#)

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The title page should:

provide the title of the article

list the full names, institutional addresses and email addresses for all authors

indicate the corresponding author

Please note:

the title should include the study design, for example "A versus B in the treatment of C: a randomized controlled trial X is a risk factor for Y: a case control study"

abbreviations within the title should be avoided

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The Abstract of the manuscript should not exceed 350 words and must be structured into separate sections: **Background**, the context and purpose of the study; **Methods**, how the study was performed and statistical tests used; **Results**, the main findings; **Conclusions**, brief summary and potential implications. Please minimize the use of abbreviations and do not cite references in the abstract. **Trial registration**, if your research article reports the results of a controlled health care intervention, please list your trial registry, along with the unique identifying number (e.g. **Trial registration**: Current Controlled Trials ISRCTN73824458). Please note that there should be no space between the letters and numbers of your trial registration number. We recommend manuscripts that report randomized controlled trials follow the [CONSORT extension for abstracts](#).

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The Background section should be written in a way that is accessible to researchers without specialist knowledge in that area and must clearly state - and, if helpful, illustrate - the background to the research and its aims. Reports of clinical research should, where appropriate, include a summary of a search of the literature to indicate why this study was necessary and what it aimed to contribute to the field. The section should end with a brief statement of what is being reported in the article.

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The methods section should include the design of the study, the setting, the type of participants or materials involved, a clear description of all interventions and comparisons, and the type of analysis used, including a power calculation if appropriate. Generic drug names should generally be used. When proprietary brands are used in research, include the brand names in parentheses in the Methods section.

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All references, including URLs, must be numbered consecutively, in square brackets, in the order in which they are cited in the text, followed by any in tables or legends. Each reference must have an individual reference number. Please avoid excessive referencing. If automatic numbering systems are used, the reference numbers must be finalized and the bibliography must be fully formatted before submission.

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All web links and URLs, including links to the authors' own websites, should be given a reference number and included in the reference list rather than within the text of the manuscript. They should be provided in full, including both the title of the site and the URL, in the following format: **The Mouse Tumor Biology Database** [http://tumor.informatics.jax.org/mtbwi/index.do]. If an author or group of authors can clearly be associated with a web link, such as for weblogs, then they should be included in the reference.

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Article within a journal supplement

Orengo CA, Bray JE, Hubbard T, LoConte L, Sillitoe I: **Analysis and assessment of ab initio three-dimensional prediction, secondary structure, and contacts prediction.** *Proteins* 1999,**43**(Suppl 3):149-170.

In press article

Kharitonov SA, Barnes PJ: **Clinical aspects of exhaled nitric oxide.** *Eur Respir J*, in press.

Published abstract

Zvaifler NJ, Burger JA, Marinova-Mutafchieva L, Taylor P, Maini RN: **Mesenchymal cells, stromal derived factor-1 and rheumatoid arthritis [abstract].** *Arthritis Rheum* 1999, **42**:s250.

Article within conference proceedings

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Book chapter, or article within a book

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Whole issue of journal

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Complete book

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Monograph or book in a series

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Book with institutional author

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PhD thesis

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Dataset with persistent identifier

Zheng, L-Y; Guo, X-S; He, B; Sun, L-J; Peng, Y; Dong, S-S; Liu, T-F; Jiang, S; Ramachandran, S; Liu, C-M; Jing, H-C (2011): **Genome data from sweet and grain sorghum (*Sorghum bicolor*)**. *GigaScience*. <http://dx.doi.org/10.5524/100012>.

Clinical trial registration record with persistent identifier

Mendelow, AD (2006): **Surgical Trial in Lobar Intracerebral Haemorrhage**. Current Controlled Trials. <http://dx.doi.org/10.1186/ISRCTN22153967>

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