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Accepted manuscript

Fernandes, I. B., Ramos-Jorge, J., Mourão, P. S., Rodrigues, A. B., Coelho, V. S., Vettore, M. V. & Ramos-Jorge, M. L. (2023). The Impact of Socio-Environmental, Individual, and Biological Factors on Oral Health-Related Quality of Life among Preschool Children: A Cohort Study with 3-Year Follow-Up. Caries Research, 1-15. https://doi.org/10.1159/000529908

Published in: Caries Research

DOI: https://doi.org/10.1159/000529908

AURA: https://hdl.handle.net/11250/3066169

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Available: 09. March 2024

Title: The impact of socio-environmental, individual and biologic factors on oral health-related quality of life among preschool children: a cohort study with 3-year follow-up

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Short Title: Oral health and quality of life of preschoolers

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Keywords: early childhood caries, child, quality of life, longitudinal study
DOI: 10.1159/000529908

Abstract

This study assessed impact of socio-environmental, individual, and biological factors on the worsening and severe worsening of oral health-related quality of life (OHRQoL) among preschoolers and their families. A cohort study was conducted in Diamantina, Brazil, with 151 children between 1 and 3 years of age and their mothers, who were evaluated at baseline (2014) and re-evaluated after 3 years (2017). The children were clinically examined to assess the presence of dental caries, malocclusion, dental trauma, and enamel defects. The mothers answered the Early Childhood Oral Health Impact Scale (B-ECOHIS) and a questionnaire addressing individual characteristics of the child and socio-environmental factors. Extensive caries found in the follow-up (relative risk [RR] = 1.91; 95% confidence interval [CI] = 1.26–2.91) and failure to undergo the dental treatment recommended at baseline (RR = 2.49; 95% CI = 1.62–3.81) were associated with worsening of OHRQoL over 3 years. An increase in the number of children in the household (RR = 2.95; 95% CI = 1.06–8.25), occurrence of extensive caries in the follow-up (RR = 2.06; 95% CI = 1.05–4.07), and failure to undergo the dental treatment recommended at baseline (RR = 3.68; 95% CI = 1.96–6.89) were associated with a severe worsening of OHRQoL. In conclusion, the risk of worsening and severe worsening of OHRQoL was higher in preschoolers with extensive caries at follow-up and among those who did not undergo dental treatment. Furthermore, severe worsening of OHRQoL was also impacted by an increase in the number of children in the household.

Introduction

Oral health-related quality of life (OHRQoL) is a multidimensional construct involving subjective measurement of the impact of oral disorders on daily functioning and on the status of emotional, psychological, and social well-being [Sischo and Broder, 2011]. The assessment of OHRQoLemerged from a contemporary understanding of the importance of including measures that acknowledge patient's perspectives and experiences related to their oral health in conjunction with clinical data [Locker and Allen, 2007]. Therefore, there has been an increase in the adoption of a comprehensive assessment of oral health in epidemiological studies involving the combination of normative and subjective measures, including the measurement of OHRQoL [Paula et al., 2013]. The Wilson and Cleary conceptual model of interrelationships between the components that constitute health-related quality of life proposes that biological, individual, and environmental characteristics may affect individuals' perceptions of their quality of life [Wilson and Cleary, 1995]. The relationship between oral health problems and OHRQoL in preschool children has been investigated predominantly in cross-sectional studies [Borges et al., 2017; Zaror et al., 2018; Nora et al., 2018; Zaror et al., 2022]. The evaluation of OHRQoL is particularly important in this age group since oral health problems may have a harmful effect on children's growth, development, learning abilities, and socialization [Perazzo et al., 2017]. In children, poor oral health is also capable of having negative impact on the daily routine of their families' lives [Fernandes et al., 2017]. Previous studies have demonstrated the association between socio-environmental characteristics and oral diseases, with the latter having been associated with a negative impact on quality of life [Thomson et al., 2002; Fisher-Owens et al., 2007; Kumar et al., 2014; Chaffee et al., 2017; Fernandes et al., 2017; Perazzo et al., 2017; Nora et al., 2018]. There have been arguments favoring dental treatment as a possible means of reducing the impact of oral diseases on quality of life [Aimée et al., 2019]. Improvements in OHRQoL after dental treatment may not last if the individuals involved continue to be exposed to the same risk factors that led to the impact on their quality of life. Thus, improvement in environmental conditions appears to be of paramount importance for reducing oral diseases and their impact on quality of life. However, longitudinal studies to assess the possible influence of changes in socio-environmental factors over time on OHRQoL are needed to test this hypothesis. The importance of identifying nonclinical factors that affect the relationship between dental clinical variables and OHRQoL is emphasized, not only for the purpose of establishing effective interventions [Wilson and Cleary, 1995] but also because the onset

and progression of oral conditions are influenced by behavioral factors, socioeconomic status, and social and economic policies [Thomson et al., 2002; Fisher-Owens et al., 2007]. Thus, in dental research, the assessment of socio-environmental factors, including socioeconomic conditions and home environment, could support the development of policies and intersectoral actions directed toward providing a healthy psychosocial environment for children's development [Locker and Allen, 2007]. Recently, there has been more research investigating the role of socio-environmental factors in preschool children's oral health. These factors could be addressed in health promotion and protective policies with the aim of reducing inequalities in health [Paula et al., 2013; Chaffee et al., 2017]. Despite recommendations for the development of longitudinal studies to investigate the influence of social and environmental determinants on OHRQoL in preschool children [Kumar et al., 2014], these studies have not focused on this objective. To date, epidemiological studies have used the longitudinal design to examine the responsiveness of OHRQoL assessment tools in dental intervention studies [Aimée et al., 2019] and in studies assessing the relationship between presence, progression, and incidence of dental caries and OHRQoL [Guedes et al., 2016b; Piva et al., 2018; Guedes et al., 2018a; Benelli et al., 2022]. Empirical studies on the influence of social and socio-environmental factors on oral health are essential to enhance the knowledge on this topic and consequently to support evidence-based oral health promotion strategies and outline public health priorities. Thus, the aim of this study was to prospectively evaluate whether socio-environmental, individual, and biological factors impact worsening and severe worsening of OHRQoL among preschool children over time.

Material and Methods

Ethical aspects

The study was approved by the Human Research Ethics Committee of the Federal University of Vales do Jequitinhonha e Mucuri, Brazil. All mothers were informed about the objectives of the study and signed a term of free and informed consent before data collection began. This study was reported according to the "Strengthening the Reporting of Observational Studies in Epidemiology" guidelines.

Study design

A prospective cohort study was conducted to collect data at baseline and after a 3-year time interval of follow-up of preschool children and their mothers in the city of

Diamantina, southeastern region, Brazil. Diamantina has a total of 45,880 inhabitants. Among them, 3,013 were between 0 and 4 years of age, according to the 2010 census [Instituto Brasileiro de Geografia e, 2010].

Clinical training and calibration

Training and calibration were undertaken by two clinical examiners (IBF and RGL) before data collection in each time interval. Training in the use of dental indices was provided by an experienced clinician using photographs of dental clinical conditions (dental caries, enamel defects, malocclusion, and traumatic dental injuries). Two examiners and an experienced clinician were submitted to test-retest the reliability of the dental clinical measures in a sample of 30 children over a 7-day period. The minimum Kappa coefficient for intra-examiner and inter-examiner calibration at baseline was 0.86 and 0.83, respectively. The minimum Kappa coefficient for intra-examiner and inter-examiner calibration at follow-up was 0.81 and 0.85, respectively.

Pilot study

Initially, a pilot study was conducted with 40 children and their mothers involving the application of questionnaires and dental clinical examinations to test the data collection procedures and to obtain information for sample size calculation of the main study. The pilot study had 1-year follow-up period. As there was no need to change the methods, the participants of the pilot study were included in the main study.

Sample size calculation

As a starting point to check the sample size needed for this study, the sample size calculation was performed considering the parameters obtained during the pilot study. OpenEpi, version 3, Open Source calculator — SSCohort (http://www.openepi.com2.5) was used to calculate the sample size. Assuming a 71% proportion of worsening quality of life among exposed individuals (children from families who had an income of less than two minimum wages or high income at baseline and low income at follow-up) and a 46% proportion of worsening of quality of life among unexposed individuals, with 80% power and 5% type I error probability, a study to detect a relative risk (RR) of 1.5 would require 130 participants. A further 21 participants were invited in each group, assuming a dropout rate of 32%, resulting in a final sample of 172 children. After finishing the study, the study power for multiple regression was calculated using the statistical calculator using the statistical calculator available at https://www.danielsoper.com/statcalc.

Selection criteria and sampling procedures

At baseline, eligible children were those aged from 1 to 3 years, whose mothers were the main caregivers. Children with any chronic systemic disease reported by their parents were excluded. The mothers were invited to bring their children to the postgraduate dental clinic of the Federal University of Vales do Jequitinhonha e Mucuri for data collection. The baseline data were gathered from a representative sample of 308 children aged 1 to 3 years, who participated in a populationbased epidemiological survey conducted in the city of Diamantina in 2014. The participants were randomly selected from all children in the abovementioned age group, who attended any public health services in the city for vaccination in 2014. The list of vaccinated children in 2014 was provided by the municipal secretary of health. The vaccination coverage rate was 94.7% in the city of Diamantina in 2014 (data obtained from the Brazilian health care system). The 3-year follow-up data collection was performed in the period between January and May 2017 when 172 children aged 4 to 6 years were randomly selected from the baseline sample. Participants' parents were contacted by telephone or in home visits to book the appointments for follow-up interviews and dental examinations.

Data collection

During the individual interviews with the mothers, structured questionnaires were used to collect socio-environmental and individual characteristics and OHRQoL of the children and their families at both baseline and follow-up. In both periods, the children and their mothers were submitted to dental clinical examinations performed by two trained and calibrated dentists using artificial light and dental chairs after dental prophylaxis. In both periods, the examinations were carried out by the same examiners using an identical data collection protocol at the dental clinic of the Federal University of Vales do Jequitinhonha e Mucuri. The examiners were re-trained and re-calibrated before the 3-year followup data collection occurred.

Data collection was performed according to the following sequence at baseline and follow-up. Initially, the mothers answered the questionnaires, and soon afterward, dental clinical examinations were performed. Then the mothers were informed about their oral health status and the dental status of their children. Those with treatment needs were referred to the dental clinic of the Federal University of Vales do Jequitinhonha e Mucuri. Dental treatment was recorded at follow-up consultation only when the dental treatment that had been recommended at baseline had been completed.

Socio-Environmental and Individual Characteristics

Age and sex of the children were considered individual data. Maternal educational level was measured using the following categories: 1 = stable high education (≥13 years of schooling), 2 = increased schooling (low education at baseline and high education at follow-up), stable low education (5 MMW), 2 = increased income (low income at baseline and high income at follow-up), 3 = stable low income (< 2 MMW), 4 = reduced income (high income at baseline and low income at follow-up). Family structure was categorized as follows: 1 = stable nuclear (parents living together)/non-nuclear status (parents living separately), 2 = changed from nuclear to nonnuclear or from non-nuclear to nuclear between baseline and follow-up. Number of children in the household: 1 = stable, 2 = increased, 3 = decreased. The latter category was not used since no family experienced a reduction in the number of children (e.g., death).

Dental Clinical Status

Biological data of the children at baseline included dental caries, malocclusion, traumatic dental injuries, and enamel defects. Dental caries was assessed using the International Caries Detection & Assessment System (ICDAS-II) [International Caries Detection and Assessment System Coordinating Committee, 2012]. Each dental surface was coded as 1 = absence of extensive dental caries (ICDAS codes from 0 to 4) and 2 = presence of extensive dental caries (ICDAS codes 5 and 6). Traumatic dental injuries were measured according to the criteria proposed by Andreasen et al. [Andreasen et al., 2018]. Crown discoloration was also considered. Traumatic dental injuries were dichotomized as the absence or presence of dental trauma. Malocclusion was recorded if the child presented at least one of the following clinical conditions [Foster and Hamilton, 1969; Grabowski et al., 2007]: anterior open bite, posterior crossbite, overjet >3 mm, anterior crossbite, or deep open bite. When the child did not have opposing teeth in occlusion, the condition was categorized as not having malocclusion. The occurrence of enamel defects, including diffuse opacity, demarcated opacity, or enamel hypoplasia, was assessed according to the Developmental Defects of Enamel Index [Federation Dentaire Internationale: Commission on Oral Health Research and Epidemiology, 1992].

Children's follow-up dental measures included the incidence of extensive dental caries and incidence of caries or caries progression that were obtained by comparing ICDAS-II measures between baseline and follow-up. Incidence of extensive dental caries was registered when at baseline the child had presented at least one sound tooth that was subsequently diagnosed with extensive caries (ICDAS ≥5) at follow-up. Incidence of caries or caries progression was recorded according to ICDAS-II when one of the

following clinical situations was observed: code 0 at baseline and score >0 at follow-up; dental caries code 1–2 (initial dental caries) at baseline and code ≥3 at follow-up; dental caries code 3–4 (established dental caries) at baseline and code ≥5 at follow-up; dental caries code 5–6 (extensive dental caries) at baseline and pulp involvement or tooth loss due to caries at follow-up. It was also recorded whether the child had received dental treatment (yes/no) between baseline and follow-up.

The incidences of traumatic dental injuries and malocclusions were obtained by comparing measurements between baseline and follow-up. Children without history of dental trauma at baseline and presenting at least one tooth with dental trauma at follow-up were classified as incidence of a case of dental trauma. Incidence of malocclusion was registered when the child presented no characteristic of malocclusion at baseline and had at least one occlusal deviation at follow-up.

Oral Health-Related Quality of Life

The Brazilian version of the B-ECOHIS was used to evaluate OHRQoL of the children and their families [Martins-Junior et al., 2012]. The self-reported questionnaire has 13 items encompassing six domains: symptoms, functional aspects, psychological aspects, self-image/social interaction, parental distress, and family functioning. The response format is a 6- point Likert scale from “never” (score = 0), “rarely” (score = 1), “sometimes” (score = 2), “often” (score = 3), “very often” (score = 4) to “I don’t know.” If any participant answered “don’t know” to one or more items, the participant was excluded from the study. The total score ranges from 0 to 52, and a higher B-ECOHIS score indicates worse quality of life. In the pilot study, an increase in the average B-ECOHIS score was found from baseline to follow-up. Thus, the outcomes measured were worsening of OHRQoL and severe worsening of OHRQoL between baseline and follow-up. Children with at least one-unit increase in the B-ECOHIS score were classified as worsening of quality of life. Children with reduction in the B-ECOHIS scores between baseline and follow-up and those with zero scores in both periods were the reference group. Severe worsening of OHRQoL was assessed according to the minimal importance difference method determined by calculating one-half of the standard deviation (SD) of the baseline score. Participants reporting differences of ECOHIS scores ≥2.1 and < 0.20) in the severe worsening of quality of life and the reference groups, respectively [Masood et al., 2014].

Theoretical Model

In this study, an adapted version of the conceptual model of Wilson and Cleary [1995] was used considering biological and physiological factors (e.g., enamel defects, incidence of malocclusion, incidence of traumatic dental injury, incidence of severe caries, incidence of caries/caries progression), individual characteristics and socio-environmental factors (e.g., sex and child's age at baseline, maternal educational level, family income, family structure, and number of children in the household), and selfreported oral health outcome measures (OHRQoL) (Fig. 1). Furthermore, dental treatment was considered a separate level, taking into account the importance of controlling this variable in longitudinal studies.

Statistical Analysis

The statistical analysis was conducted using the Statistical Package for the Social Sciences (SPSS for Windows, version 22.0, SPSS Inc., Chicago, USA). The frequencies and mean (SD) values of socio-environmental characteristics, individual factors, biological and physiological factors at baseline were presented for all participants who completed the study and those lost during the follow-up. Comparisons of the independent variables between the abovementioned groups were made by using $\chi 2$ and Mann-Whitney tests. Effect sizes were also calculated. Unadjusted associations of independent variables with worsening of OHRQoL and severe worsening of OHRQoL were estimated through RRs and respective 95% confidence intervals (CIs). Multivariate Poisson regression with robust variance using hierarchical models was used to evaluate the associations of socio-environmental characteristics, individual factors, biological and physiological variables, and dental access with worsening of OHRQoL and severe worsening of OHRQoL. Independent variables that were significant at 20% ($p < 0.20$) in the unadjusted analysis were retained in the multivariate analysis. Additionally, "gender, age, and family income" were included in the adjusted model due to the importance of these variables in the theoretical model. The independent variables were selected using the stepwise forward method in four statistical models according to the theoretical framework. The first level consisted of socio-environmental characteristics and individual factors. The second level included biological and physiological factors, and the third level included dental access. Variables that remained statistically significant at 5% ($p \leq 0.05$) and those important for the theoretical model were retained in the analysis for adjustment in the final model. RRs with 95% CI and p values were estimated in each model. The VIF between 5 and 10 was adopted to identify multicollinearity between independent variables. The VIF values of all variables were below 2.0, suggesting no multicollinearity.

Results

There were 172 participants at baseline and 151 in the cohort at follow-up. Twenty-one children (12.2%) were lost between baseline and 3-year follow-up due to change of home address and change of contact telephone number (Fig. 2).

The mean age of the children at baseline and follow-up was 28.5 months (SD = 10.8) and 66.6 months (SD = 11.9), respectively. Baseline socio-environmental, biological and physiological, and individual measures of the participants who completed the follow-up data collection phase and those who were lost during follow-up are summarized in Table 1. Approximately half of the study sample consisted of girls. Maternal educational level predominantly ranged between 9 and 12 years of schooling, and the majority of participants received less than 2 monthly minimum wages. The prevalence of malocclusion, dental trauma, and extensive dental caries at baseline was 45.0%, 23.2%, and 27.8%, respectively (Table 1). Only 2% of children had complicated dental trauma.

The mean B-ECOHIS score increased from 3.1 (DP = 4.2) at baseline to 4.1 (DP = 5.7) at follow-up, representing worsening of OHRQoL. Fifty-seven children (37.7%) experienced worsening of OHRQoL (B-ECOHIS increase ≥1) between baseline and 3-year follow-up. Severe worsening of OHRQoL (B-ECOHIS increased ≥2.1) was observed among 39 children (25.8%). None of the participants answered “don’t know” to one or more items of ECOHIS at baseline and follow-up. Table 2 presents data on worsening and severe worsening of OHRQoL by the independent variables. Those children with incidence of extensive caries, incidence of caries/caries progression, and those who did not have dental treatment had a higher frequency of worsening of OHRQoL and severe worsening of OHRQoL.

Table 3 presents the unadjusted analysis and the Poisson regression models of the association of socioenvironmental, individual, biological and physiological, and dental access variables with worsening of OHRQoL. The increase in maternal educational level between baseline and follow-up, incidence of extensive dental caries, incidence of caries/caries progression, and not having dental treatment were associated with a higher risk of worsening of OHRQoL in the unadjusted analysis. In the final adjusted model, children who had no dental treatment had higher risk of worsening of OHRQoL than those who had dental treatment (RR = 2.49; 95% CI: 1.62–3.81). The risk for worsening of OHRQoL was 1.86 times higher among children with extensive new dental caries

lesions (RR = 1.91; 95% CI: 1.26–2.91) than those without any extensive new dental caries lesions. All models showed an adequate fit (Omnibus test: $p < 0.001$).

The association between severe worsening of OHRQoL and socio-environmental, individual, biological and physiological, and dental access variables is summarized in Table 4. In the unadjusted Poisson regression, severe worsening of OHRQoL was associated with increase in maternal educational level, between baseline and followup, increase in number of children in the household, incidence of extensive dental caries, incidence of caries/ caries progression, enamel defects, and not having dental treatment. The multivariate model showed the increase in the number of children in the household (RR = 2.95; 95% CI: 1.06–8.25), extensive new dental caries lesions (RR = 2.06; 95% CI: 1.05–4.07), and not having dental treatment (RR = 3.68; 95% CI: 1.96–6.89) increased the risk of severe worsening of OHRQoL. All models showed an adequate fit (Omnibus test: $p < 0.001$). The final sample size of 151 participants included in the regression analysis would lend a power of 89% to detect statistically significant effects size of at least 0.15 (medium effect size) for multiple regression with 12 predictors and 5% level of significance [Cohen et al., 2003].

Discussion

The present longitudinal study evaluated whether socio-environmental, individual, and biological factors influence the worsening and severe worsening of OHRQoL in preschool children. In this study, children from families who experienced an increase in the number of children in the household during follow-up had a higher risk of severe worsening of OHRQoL. Among the biological and physiological variables, incidence of extensive dental caries and lack of dental treatment increased the risk of worsening and severe worsening of OHRQoL among children.

Age and sex were treated as independent determinants of worsened OHRQoL and were not associated in the present investigation. Females are generally more sensitive to the perception of their own problems and appearance than males [Pavithran et al., 2020]. Thus, there may be an overestimation of morbidities in females [van Wijk and Kolk, 1997], who tend to report a worse OHRQoL than males. With increasing age, children develop the abstraction of thinking and the concept of self-image. In addition, they increase their ability to communicate with their parents and to report the impact of their oral condition on the OHRQoL [Hetherington et al., 1999]. However, preschoolers may have less ability to communicate. This explains the lack of association between both age and sex with the outcomes evaluated in the present investigation. It is possible that at

preschool age, the difference between the sexes does not impact the children's ability to report.

The increase in maternal educational level between baseline and follow-up was a meaningful determinant of worsening quality of life in the crude analysis. However, maternal educational level was no longer a predictor of poor OHRQoL when dental treatment was included in the analysis. Previous studies have suggested that maternal education was a relevant factor of mother's perception of their children's OHRQoL [Chaffee et al., 2017; Rai and Tiwari, 2018]. There are two possible explanations for this finding. The first emphasizes the role of educational level in access to health information that results in the adoption of healthy behaviors, such as those related to eating and hygiene habits [Ferreira et al., 2007]. Previous research has shown the relationship between maternal behaviors and children's OHRQoL [Pereira et al., 2020]. The second explanation refers to the maternal perception of oral health conditions and their impact on their children's OHRQoL. Mothers with lower education usually have limited access to health information. Thus, they tend to acknowledge oral problems less frequently, resulting in a positive perception of their children's quality of life.

Making use of dental services can reduce inequalities in oral health among children and attenuate the influence of socio-environmental factors on children's oral health problems [Goettems et al., 2012]. Thus, access to dental care could possibly reduce oral health inequalities among children with mothers from different educational backgrounds. Our findings on the influence of not having dental treatment on worsening of quality of life and the lack of association between maternal educational level and OHRQoL outcomes emphasize the importance of expanding access to dental care to improve OHRQoL.

The increase in the number of children in the household was an important risk factor for severe worsening of OHRQoL after adjusting for children's age, incidence of caries/caries progression, incidence of extensive caries, dental treatment, among other variables. Previous studies have shown the association between larger families and children's worse OHRQoL Kumar et al., 2014]. Parents of larger families may perceive greater impact on their quality of life and on their children's OHRQoL. The lack of time to pay attention and devote time to many children and financial issues related to providing dental care to them might explain this finding.

In this study, the occurrence of extensive new dental caries, according to ICDAS clinical scoring system, increased the risk of worsening and severe worsening of

OHRQoL. Similarly, a previous study has reported that preschool children with new dental caries on four or more dental surfaces had 2.2 greater risk of poorer OHRQoL than those who did not have new dental caries over a 2-year period [Guedes et al., 2018b]. Another study investigated the influence of the presence of caries lesions in early life on OHRQoL years later and verified that the presence of cavitated caries in teeth after 3 years of life was a predictor of adverse impacts on OHRQoL after 6 years of age [Benelli et al., 2022]. This finding indicated the strong impact of dental caries in the long term and the importance of preventive and oral health promotion actions directed toward younger children to reduce the development of dental caries and the harmful consequences.

The inclusion of non-cavitated caries lesions may have contributed to the smaller difference in the report of impact on quality of life. Therefore, the association between incidence of caries/caries progression and decline in OHRQoL was weaker than expected and the association between these variables was not significant in the multivariate analysis. A previous study has shown that after 2 years, initial caries lesions in children had no greater impact on their OHRQoL than it had on the OHRQoL of children without caries lesions [Guedes et al., 2016b]. Despite this, the importance of evaluating early carious lesions has been demonstrated, as these lesions may result in a higher risk for caries after 2 years of follow-up [Guedes et al., 2018b].

The incidence of malocclusion and traumatic dental injuries was not associated with worsening or severe worsening of OHRQoL in the 3-year period. Similar to our findings, previous systematic reviews have shown that uncomplicated dental trauma and malocclusion were not associated with the negative impact of these clinical conditions on children's quality of life [Kragt et al., 2016; Lopez et al., 2019]. In the population studied, only 2% of the children had an incidence of complicated dental trauma, which could explain this absence of association. Furthermore, the influence of occlusal deviations on children's OHRQoL may occur in older children, such as those aged 8 years or older [Kragt et al., 2016]. The concomitant evaluation of malocclusion, traumatic dental injuries, and dental caries in this study allowed a more comprehensive understanding of the possible influence of these clinical conditions on children's OHRQoL in the long term. Therefore, the role of the incidence of dental caries on OHRQoL in preschool children has suggested priorities in oral health care planning at both individual and population levels to improve children's oral health.

Studies have demonstrated the responsiveness of the ECOHIS questionnaire for detecting changes in OHRQoL after dental interventions since improvements in quality

of life have been identified after dental treatment among preschool children [Novaes et al., 2017; Aimée et al., 2019; Milani et al., 2021]. Likewise, in the present study, children who had no dental treatment within the 3-year period of study exhibited a worsening and a severe worsening of OHRQoL, irrespective of the incidence of dental caries. Our findings were in agreement with those from a previous study reporting that children who did not visit a dentist on a regular basis had worse OHRQoL in adulthood [Aimée et al., 2019]. The higher incidence of caries or caries progression among children who had not undergone dental treatment may explain this finding. Untreated dental caries lesions tend to progress, especially in children who already have caries [Guedes et al., 2016a], and the impact of dental caries progression on OHRQoL has been reported in preschoolers [Piva et al., 2018]. It should be emphasized that all children evaluated at baseline were booked for preventive or curative dental treatment at the postgraduate dental clinic of the Federal University of Vales do Jequitinhonha e Mucuri. Moreover, the sample was composed of a population with considerable dental treatment needs. Future studies should investigate the possible causes of and barriers related to non-adherence to free dental treatment in the population studied. In the present study, in addition to verifying the reduction in B-ECOHIS scores, we calculated the minimal important difference for OHRQoL measures. The latter was defined as severe worsening of OHRQoL. Minimal important difference is the smallest difference in score in the domain of interest that is considered clinically meaningful and allows researchers to interpret these findings from the patient's perspective and not only from a statistical point of view [Masood et al., 2014]. If a significant change in health status occurs due to a disease or a condition or after implementation of an intervention, patient should be able to perceive this change and acknowledge it as an important change [Masood et al., 2014].

The study involved children aged from 1 to 3 years. Consequently, the present findings should not be applied to children of other age groups. At baseline, the prevalence of extensive dental caries (ICDAS ≥5) was nearly 30%, despite the fact that only children in their early childhood were included in the study. This suggested a population at high risk for the incidence of caries or caries progression. Thus, the implications of our findings should not be extrapolated to children at low risk for dental caries.

Some limitations of the present study should be considered. The severity of malocclusion and dental trauma was not considered in the analysis due to the low prevalence of severe conditions in the population studied. Furthermore, disqualification bias may possibly have occurred due to reporting bias in some situations. This may have

happened because mothers of children with extensive caries might report OHRQoL differently from mothers of children with no extensive caries, as they might have felt that this could increase the chances of their children receiving dental treatment earlier. To minimize this bias, all mothers were informed that the child would be referred for treatment. Losses to follow-up can negatively influence the validity of longitudinal studies and jeopardize the interpretation of the findings. In this study, over 80% of the sample was re-assessed at the 3-year follow-up, which may be considered an acceptable follow-up response rate. Although socio-environmental, individual, and biological and physiological factors did not differ between participants who were lost in the follow-up and the sample analyzed, the former included a higher proportion of children from poor families, with fewer cases of malocclusion, traumatic dental injures, and severe dental caries than those who were analyzed. Thus, selection bias might have underestimated some of the associations between these variables and OHRQoL outcomes.

This study presented relevant findings; however, the effect sizes were generally small and this demonstrates the importance of longitudinal studies being performed on larger samples. Moreover, future studies that investigate the determinants of the impact on OHRQoL using longitudinal design should involve children with low and moderate risk of dental caries.

The present study pointed out the importance of increasing oral health professionals' understanding of risk factors for quality of life in preschool children. Our findings must be acknowledged in the planning of specific preventive and oral health promotion strategies during early childhood to improve children's OHRQoL in the short and long term. Therefore, young children must be one of the target age groups of oral health programs.

In conclusion, the risk of worsening and severe worsening of OHRQoL in preschool children was significantly higher among those who did not receive the recommended dental treatment and those who had extensive new dental caries lesions within the 3-year period. The risk of severe worsening of OHRQoL in preschool children was also higher among children from families that had an increase in the number of children in the household.

Acknowledgments

We show our appreciation to the members of Babies Oral Health Group (BOHG) for promoting, organizing, and conducting all procedures related to this study and others. We would like to thank the Postgraduate Program in Dentistry at the Federal University of Minas Gerais.

Statement of Ethics

This study received approval from the Human Research Ethics Committee of the Universidade Federal dos Vales do Jequitinhonha e Mucuri, Brazil (protocol number 1.921.084). Written informed consent was obtained from the parents.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

Funding Sources

This study was financed in part by Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – Brasil (Capes), the Research Foundation of the State of Minas Gerais (FAPEMIG), and the National Council for Scientific and Technological Development (CNPQ), Brazil.

Author Contributions

Izabella Barbosa Fernandes was responsible for collecting patient data, for statistical analysis, and writing the manuscript. Priscila Seixas Mourão, Angélica Beatriz Rodrigues, and Valéria Silveira Coelho were responsible for collecting patient data and writing the manuscript. Joana Ramos Jorge was responsible for statistical analysis, the critical review of the manuscript, and orientation of the work. Mário Vianna Vettore was responsible for writing the manuscript and for the critical review of the manuscript. Maria Letícia Ramos-Jorge was responsible for the critical review of the manuscript and orientation of the work. All authors discussed and approved the final version of this article. Data

Availability Statement

Data supporting the results in this paper were not archived in a public repository. The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request. All data generated or analyzed during this study are included in this article. Further inquiries can be directed to the corresponding author.

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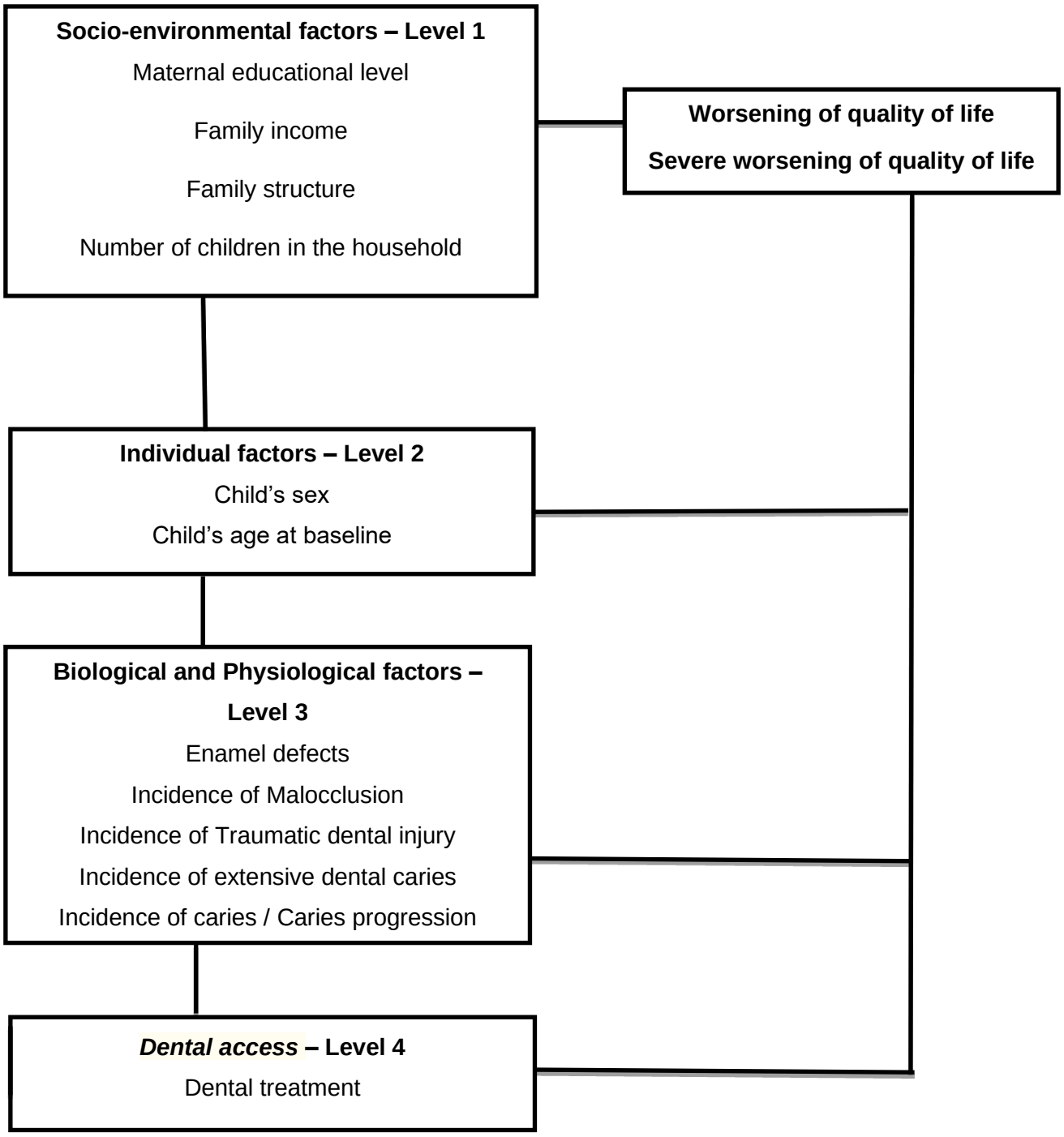

Fig. 1. Hierarchical conceptual framework used in the Poisson regression analysis.

Fig. 2. Flowchart of the study.

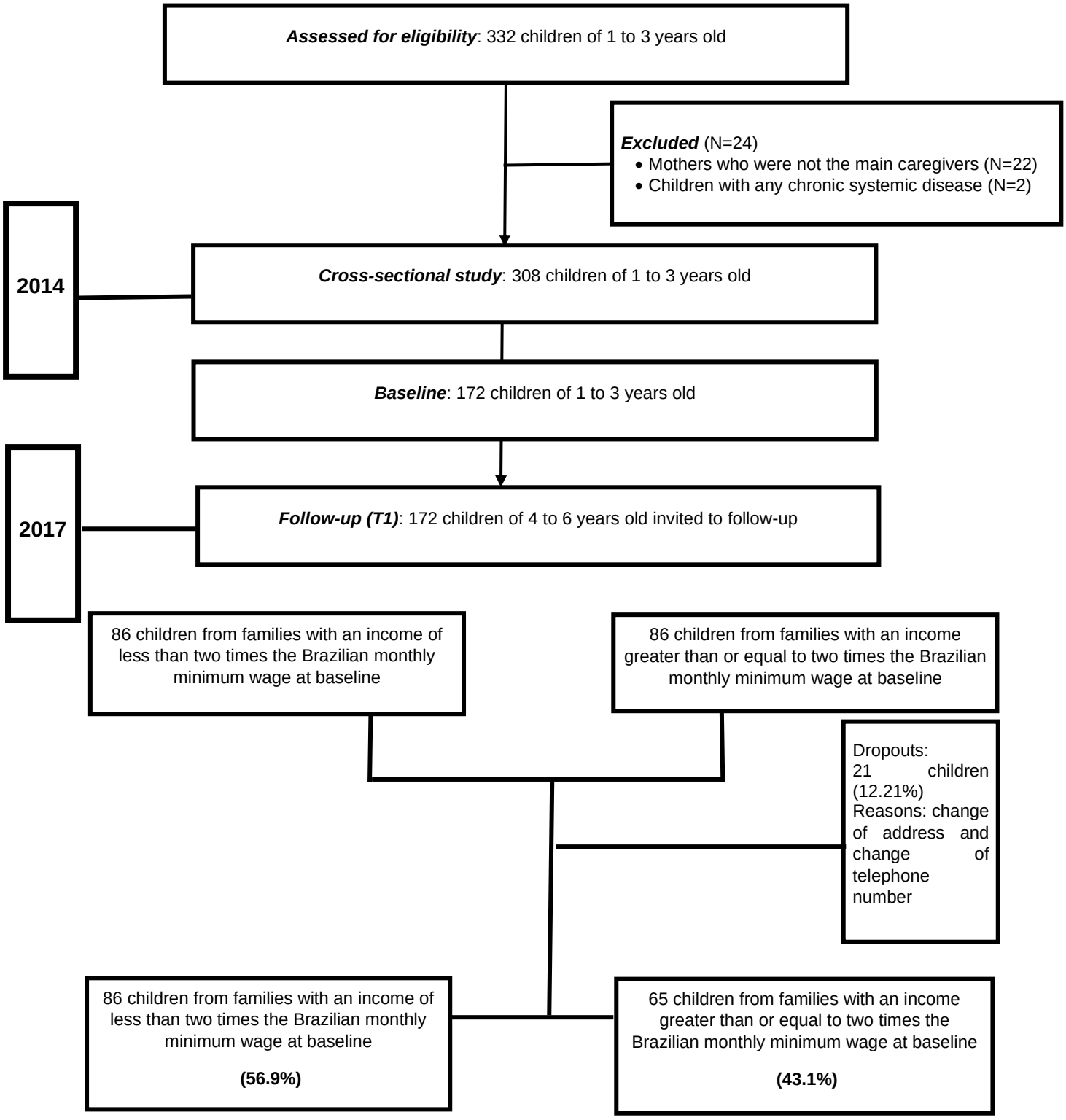

Table 1. Baseline characteristics between follow-up and drop-out participants.

Variables	Follow-ups n (%)	Drop-out n (%)	p-value*	Total n (%)
Maternal educational level				
≥ 13 years of study	47 (31.1)	7 (33.3)	0.819	54 (31.4)
9 to 12 years of study	88 (58.3)	12 (57.2)		100 (58.1)
< 9 years of study	16 (10.6)	2 (9.5)		18 (10.5)
Family income				
≥ *two times the BMMW*	65 (43.0)	8 (38.1)	0.668	73 (42.4)
< *two times the BMMW*	86 (57.0)	13 (61.9)		99 (57.6)
Family structure				
Nuclear	105 (69.5)	14 (66.7)	0.790	119 (69.2)
Non-nuclear	46 (30.5)	7 (33.3)		53 (30.8)
Number of children in the household				
One	76 (50.3)	11 (52.4)	0.861	87 (50.6)
> 1	75 (49.7)	10 (47.6)		85 (49.4)
Child's sex				
Female	80 (53.0)	14 (66.7)	0.238	94 (54.7)
Male	71 (47.0)	7 (33.3)		78 (45.3)
Child's age				
1 year old	57 (37.7)	8 (38.1)	0.978	65 (37.8)
2 years old	45 (29.8)	6 (28.6)		51 (29.7)
3 years old	49 (32.5)	7 (33.3)		56 (32.6)
Malocclusion				
Absence	83 (55.0)	14 (66.7)	0.311	97 (56.4)
Presence	68 (45.0)	7 (33.3)		75 (43.6)
Traumatic dental injury				
Absence	116 (76.8)	14 (66.7)	0.310	130 (75.6)
Presence	35 (23.2)	7 (33.3)		42 (24.4)
Extensive dental caries				
Absence	109 (72.2)	13 (61.9)	0.331	122 (70.9)
Presence	42 (27.8)	8 (38.1)		50 (29.1)
Mean B-Ecohis score (SD)	3.11 (4.19)	3.18 (2.04)	0.214	

BMMW, Brazilian monthly minimum wage; SD, standard deviation. *p values refer to $\chi 2$ test for categorical variables and Mann-Whitney test for the continuous variable.

Table 2. Frequency distribution and association between independent variables and worsening and severe worsening of quality of life (n=151).

Variables	Worsening of quality of life		p-value[a]	Effect size[b]	Severe worsening of quality of life		p-value[a]	Effect size[b]
	No n (%)	Yes n (%)			No n (%)	Yes n (%)		
Child's sex								
Female	47 (58.8)	33 (41.3)	0.346	0.077	58 (72.5)	22 (27.5)	0.618	0.041
Male	47 (66.2)	24 (33.8)			54 (76.1)	17 (23.9)		
Child's age								
1 year old	40 (70.2)	17 (29.8)	0.160	0.115	45 (78.9)	12 (21.1)	0.262	0.092
2 years old	26 (57.8)	19 (42.2)			33 (73.3)	12 (26.7)		
3 years old	26 (57.1)	21 (42.9)			34 (69.4)	15 (30.6)		
Maternal educational level								
Maintained high	88 (65.2)	47 (34.8)	0.132	0.123	103 (76.3)	32 (23.7)	0.196	0.106
Increased	1 (14.3)	6 (85.7)			3 (42.9)	4 (57.1)		
Maintained low	5 (55.6)	4 (44.4)			6 (66.7)	3 (33.3)		
Family income								
Maintained high	33 (62.3)	20 (37.7)	0.664	0.035	40 (75.5)	13 (24.5)	0.693	0.032
Increased	13 (68.4)	6 (31.6)			15 (78.9)	4 (21.1)		
Maintained low	42 (62.7)	25 (37.3)			48 (71.6)	19 (28.4)		
Reduced	6 (50.0)	6 (50.0)			9 (75.0)	3 (25.0)		
Family structure								
Maintained nuclear / non-nuclear status	65 (61.3)	41 (38.7)	0.717	0.029	80 (75.5)	26 (24.5)	0.576	0.046
Changed from nuclear to non-nuclear or from non-nuclear to nuclear during assessments	29 (64.4)	16 (35.6)			32 (71.1)	13 (28.9)		
Number of children in the household								
Maintained	92 (63.0)	54 (37.0)	0.297	0.085	110 (75.3)	36 (24.7)	0.076	0.144
Increased	2 (40.0)	3 (60.0)			2 (40.0)	3 (60.0)		
Enamel defects								
Absence	65 (67.0)	32 (33.0)	0.106	0.132	77 (79.4)	20 (20.6)	0.050	0.160
Presence	29 (53.7)	25 (46.3)			35 (64.8)	19 (35.2)		
Incidence of Malocclusion								
Absence	57 (64.8)	31 (35.2)	0.450	0.061	66 (75.0)	22 (25.0)	0.784	0.022
Presence	37 (58.7)	26 (41.3)			46 (73.0)	17 (27.0)		
Incidence of Traumatic dental injury								
Absence	75 (60.5)	49 (39.5)	0.337	0.078	92 (74.2)	32 (25.8)	0.990	0.001
Presence	19 (70.4)	8 (29.6)			20 (74.1)	7 (25.9)		
Incidence of extensive caries								
Absence	68 (74.7)	23 (25.3)	**<0.001**	0.317	77 (84.6)	14 (15.4)	**<0.001**	0.294
Presence	26 (43.3)	34 (56.7)			35 (58.3)	25 (41.7)		
Incidence of caries / Caries progression								
Absence	79 (68.1)	37 (31.9)	**0.007**	0.220	93 (80.2)	23 (19.8)	**0.002**	0.250
Presence	15 (42.9)	20 (57.1)			19 (54.3)	16 (45.7)		
Dental treatment								
Yes	87 (73.7)	31 (26.3)	**<0.001**	0.448	101 (85.6)	17 (14.4)	**<0.001**	0.493
No	7 (21.2)	26 (78.8)			11 (33.3)	22 (66.7)		

a $\chi 2$ test. bEffect size based on Eta: 0.1 for small; 0.3 for medium; 0.5 for large.

Table 3. Unadjusted and adjusted Poisson regression analysis on the association between independent variables and worsening of quality of life (n=151).

Variables	Model 1 RR unadjusted (95% CI)	Model 2 RR adjusted[a] (95% CI)	Model 3 RR adjusted[b] (95% CI)	Model 4 RR adjusted[c] (95% CI)
Maternal educational level				
Maintained high	1	1	1	1
Increased	2.46 (1.68-3.60)*	2.53 (1.43-4.48)*	2.37 (1.26-4.46)*	1.89 (0.96-3.74)
Maintained low	1.28 (0.59-2.75)	1.24 (0.55-2.75)	1.20 (0.63-2.28)	0.93 (0.49-1.79)
Family income				
Maintained high	1	1	1	1
Increased	0.84 (0.40-1.77)	0.84 (0.40-1.78)	0.82 (0.41-1.65)	0.97 (0.48-1.95)
Maintained low	0.99 (0.62-1.57)	0.85 (0.49-1.47)	0.66 (0.41-1.07)	0.58 (0.36-1.12)
Reduced	1.32 (0.68-2.57)	1.25 (0.63-2.48)	1.18 (0.56-2.43)	1.03 (0.52-2.04)
Family structure				
Maintained nuclear / non-nuclear status	1			
Changed from nuclear to non-nuclear or from non-nuclear to nuclear during assessments	0.92 (0.58-1.46)			
Number of children in the household				
Maintained	1			
Increased	1.62 (0.77-3.42)			
Child's sex				
Female	1	1	1	1
Male	0.82 (0.54-1.24)	0.84 (0.56-1.26)	0.74 (0.48-1.13)	0.78 (0.52-1.16)
Child's age				
1 year old	1	1	1	1
2 years old	1.42 (0.84-2.39)	1.20 (0.66-2.16)	1.01 (0.69-1.85)	0.94 (0.56-1.57)
3 years old	1.44 (0.86-2.40)	1.27 (0.75-2.16)	1.13 (0.69-1.85)	1.07 (0.67-1.70)
Enamel defects				
Absence	1		1	1
Presence	1.40 (0.94-2.10)		1.26 (0.84-1.90)	1.15 (0.77-1.73)
Incidence of Malocclusion				
Absence	1			
Presence	1.02 (0.68-1.54)			
Incidence of Traumatic dental injury				
Absence	1			
Presence	1.08 (0.67-1.73)			
Incidence of extensive caries				
Absence	1		1	1
Presence	2.24 (1.48-3.40)*		2.09 (1.38-3.18)*	1.91 (1.26-2.91)*
Incidence of caries / Caries progression				
Absence	1		1	1
Presence	1.79 (1.21-2.65)*		1.47 (0.95-2.27)	1.12 (0.71-1.77)
Dental treatment				
Yes	1			1
No	2.99 (2.11-4.26)*			2.49 (1.62-3.81)*

RR, relative risk; 95% CI, 95% confidence intervals. *$p < 0.05$. [a] Adjusted for mother's schooling, family income, child's sex, and child's age. [b]Adjusted for mother's schooling, family income, child's sex, child's age, incidence of extensive caries, and incidence of caries/caries progression. c Adjusted for mother's schooling, family income, child's sex, child's age, incidence of extensive caries, incidence of caries/caries progression, and dental treatment.

Table 4. Unadjusted and adjusted Poisson regression analysis on the association between independent variables and severe worsening of quality of life (n=151).

Variables	Model 1 RR unadjusted (95% CI)	Model 2 RR adjusted[a] (95% CI)	Model 3 RR adjusted[b] (95% CI)	Model 4 RR adjusted[c] (95% CI)
Maternal educational level				
Maintained high	1	1	1	1
Increased	2.41 (1.19-4.90)*	2.29 (0.94-5.53)*	2.39 (0.99-5.75)	1.75 (0.70-2.12)
Maintained low	1.41 (0.53-3.72)	1.36 (0.46-3.99)	1.49 (0.62-3.57)	1.04 (0.51-2.12)
Family income				
Maintained high	1	1	1	1
Increased	0.86 (0.32-2.31)	0.87 (0.34-2.24)	0.84 (0.35-2.03)	0.98 (0.36-2.65)
Maintained low	1.16 (0.63-2.12)	1.08 (0.53-2.22)	0.87 (0.46-1.64)	0.68 (0.37-1.25)
Reduced	1.02 (0.34-3.02)	1.01 (0.34-2.97)	0.97 (0.32-2.90)	0.79 (0.29-2.18)
Family structure				
Maintained nuclear / non-nuclear status	1			
Changed from nuclear to non-nuclear or from non-nuclear to nuclear during assessments	1.18 (0.67-2.08)			
Number of children in the household				
Maintained	1	1	1	1
Increased	2.43 (1.13-5.25)*	2.63 (1.14-6.07)*	3.15 (1.37-7.25)*	2.95 (1.06-8.25)*
Child's sex				
Female	1	1	1	1
Male	0.87 (0.50-1.50)	0.91 (0.54-1.55)	0.77 (0.46-1.29)	0.89 (0.54-1.46)
Child's age				
1 year old	1	1	1	1
2 years old	1.27 (0.63-2.55)	1.06 (0.48-2.34)	0.76 (0.36-1.60)	0.67 (0.32-1.44)
3 years old	1.45 (0.75-2.80)	1.36 (0.67-2.75)	1.06 (0.56-1.99)	1.03 (0.60-1.77)
Enamel defects				
Absence	1		1	1
Presence	1.71 (1.01-2.91)*		1.58 (0.91-2.73)	1.35 (0.75-2.43)
Incidence of Malocclusion				
Absence	1			
Presence	0.94 (0.55-1.63)			
Incidence of Traumatic dental injury				
Absence	1			
Presence	0.72 (0.35-1.50)			
Incidence of extensive caries				
Absence	1		1	1
Presence	2.71 (1.54-4.78)*		2.38 (1.33-4.26)*	2.06 (1.05-4.07)*
Incidence of caries / Caries progression				
Absence	1		1	1
Presence	2.31 (1.38-3.85)*		1.92 (1.16-3.16)*	1.23 (0.71-2.14)
Dental treatment				
Yes	1			1
No	4.63 (2.80-7.64)*			3.68 (1.96-6.89)*

RR, relative risk; 95% CI, 95% confidence intervals. *$p < 0.05$. Variables included in the multivariate analysis due to $p < 0.20$: number of children in the household and enamel defects. [a]Adjusted for mother's schooling, family income, number of children in the household, child's sex, and child's age. [b]Adjusted for mother's schooling, family income, number of children in the household, child's sex, child's age, incidence of extensive caries, incidence of caries/caries progression, and enamel defects. [c]Adjusted for mother's schooling, family income, number of children in the household, child's sex, child's age, incidence of extensive caries, incidence of caries/caries progression, enamel defects, and dental treatment.