THE IMPACT OF EARLY HEAD START ON CHILDREN'S ORAL HEALTH

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ABSTRACT

Jacqueline Marjorie Burgette: The Impact of Early Head Start on Children's Oral Health
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Background. Early Head Start (EHS) is a publicly-funded comprehensive education program for low-income children under three years-old and their families. It is known to improve physical, cognitive and developmental child outcomes over the life course. While EHS impacts general health outcomes, little is known about its effect on oral health. This study assesses the effects of EHS on dental use and oral health-related quality of life (OHRQoL); as well as how the effect of EHS on dental use is modified by parents' health literacy.

Methods. This study examines oral health outcomes in children enrolled in North Carolina EHS programs where staff participated in an educational intervention known as Zero Out Early Childhood Caries (ZOE) and compares these results to Medicaid-matched controls. Parent interviews were conducted at baseline and 24-month follow-up for 1,178 parent-child dyads. Propensity score analysis was used to control for selection bias between the EHS and the control group. Logistic regression, marginalized zero-inflated negative binomial and marginalized semicontinuous two-part modeling with direct adjustment for propensity scores and random effects were used to examine the association between EHS and dental outcomes.

Results. EHS children had increased odds of having any dental visit (aOR=2.5; 95% CI=1.74-3.48) and any preventive dental visits (aOR=2.6; 95% CI=1.84-3.63) compared to non-EHS children. Children in EHS had 1.3 times (95% CI=1.17-1.55) the adjusted mean number of dental visits compared to the children not in EHS. EHS families had a lower odds ratio of having any negative impacts to OHRQoL compared to non-EHS children (aOR=0.65; 95% CI=0.48, 0.87). In the adjusted logit models on the effect of EHS on having any dental visits, the interaction effect between EHS and parent's health literacy was not significant (P>0.05).

Conclusions. This study is the first to demonstrate that EHS provides services that increase child dental use and improve OHRQoL for disadvantaged young children and their families. Moreover, our findings provide evidence that EHS results in similar improvements in dental use regardless of parents' health literacy levels. These results document the effectiveness of comprehensive early education programs in improving dental use and quality of life for low-resource, low-literacy families.

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PREFACE

This dissertation is organized in a non-traditional format, which includes three manuscripts. Chapter 1 provides an introduction to the dissertation, specific aims, and a description of the significance of the research. Chapter 2 provides a literature review and describes the conceptual framework relevant to this dissertation. Chapter 3 describes the methodology used for each of the three studies in this dissertation. Chapters 4, 5, and 6 are the manuscripts for the three studies. These three chapters are intended to stand alone as manuscripts to be submitted for publication and therefore have some redundancies with the earlier chapters and in the papers themselves. Chapter 7 presents a summary of the findings, limitations of the studies, directions for future research, and policy implications.

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LIST OF ABBREVIATIONS

EHS	Early Head Start
GHL	General Health Literacy
NC	North Carolina
OHL	Oral Health Literacy
OHRQoL	Oral Health-related Quality of Life
ZOE	Zero Out Early Childhood Caries

CHAPTER 1. INTRODUCTION

1.1 Background

Early Head Start (EHS) is a national comprehensive early education program for low-income families and children birth to 3 years of age.[1] Large-scale randomized controlled trials of EHS and its predecessor, Head Start, demonstrate that these programs improve short-term health status and long-term social and cognitive development.[2-5] EHS is well-positioned to play an important role in helping reduce existing large oral health disparities in young children in the United States by delivering preventive oral health services to those families at greatest risk for poor oral health.[6] These programs enroll the most disadvantaged of families within their communities and are evaluated against federal performance standards that require that the oral health needs of young children and their families are met. Among the required activities are daily tooth-brushing with fluoridated toothpaste, oral health education, and the determination of a child's oral health status by a dental professional within 90 days of entry into the program. Children with treatment needs must be referred to a dentist for care. Many other EHS standards such as those involving diet can affect oral health.[7]

1.2. Overall Study Purpose and Approach

Although oral health is an integral part of recommended EHS program activities, little is known about program effects on oral health outcomes of children or parents other than some very basic descriptive information on dental use from one national study.[5,8-10] The purpose of this study is to fill this knowledge gap by evaluating the effects of EHS compared to community-matched controls on parent-reported dental use and oral health–related quality of life for low-income children in North Carolina. The literature suggests that there is variation in oral health literacy among low-income parents,[11-13] which may affect their child's oral health status,[14,15] dental care expenditures,[16] and oral health-related quality of life.[17,18] Therefore, this study also examined the modifying effect of parents' health literacy on the effect of EHS on dental use.

Longitudinal data collected as part of an initiative known as Zero Out Early Childhood Caries (ZOE), which was directed toward North Carolina EHS programs, were analyzed to address study aims.[19] Parents of children in EHS (n=479) and community controls (n=699) who were selected from Medicaid enrollment files and matched on child age, preferred language, and resident ZIP code were interviewed in the child's first year of life and approximately 24 months later at the end of the child's EHS program enrollment.

1.3 Specific Aims

All three studies examined the impact of EHS on oral health outcomes using data collected as part of the ZOE study. The specific aims of this study were as follows:

Aim #1: Determine the effectiveness of EHS in increasing parent-reported child use of dental health services for EHS children. I hypothesized that EHS children would have greater dental service use compared to Medicaid-matched children. This hypothesis was based on strong evidence that dental use is increased in older children enrolled in Head Start.[20] Dental use was defined globally as the amount of dental use overall as well as by the treatment type (preventive, treatment, emergency). Marginalized zero-inflated negative binomial modeling with cluster-level-specific random effects was used to examine the association between EHS and amount of dental use. The use of any dental services, a dichotomous outcome, was modeled using logistic regression. Direct adjustment through specification of generalized boosted model propensity scores as a covariate was used to control for EHS program selection criteria for family enrollment and socio-demographic characteristics.

Aim #2: Determine the impact of EHS on oral health-related quality of life for EHS children and their families. I hypothesized that EHS children would have improved oral health–related quality of life (OHRQoL) compared to Medicaid-matched control children as a result of EHS enrollment.[21] Marginalized semicontinuous two-part modeling with cluster-level-specific random effects were used to examine the association between EHS and oral health–related quality of life for children. Direct adjustment via specification of generalized boosted model propensity scores as a covariate was used to control for EHS program selection criteria for family enrollment and socio-demographic characteristics. We also examined whether dental use mediated the relationship between EHS and OHRQoL.

Aim #3: Determine if parents' oral and general health literacy modified the effectiveness of EHS on parent-reported child use of dental health services. Oral health literacy (OHL) is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic oral health information and services needed to make appropriate health decisions and act on them."[22] General health literacy (GHL) similarly is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[23] I hypothesized that parents' OHL and GHL positively modifies the effect of EHS on the child's use of dental health services. This hypothesis is based on previous literature on the effect of parents' literacy on the use of their children's health services for asthma treatment,[24,25] the effect of GHL on general health-related quality of life measures in patients with cancer and chronic disease,[26,27] and the association between parent oral health literacy and child oral health-related quality of life.[17,18] We examined whether the inclusion of an interaction effect between EHS and the health literacy variables modify the association between EHS enrollment and child dental use.

1.4. Summary and Significance

The rationale that underlies the proposed research is that interventions at a young age will overcome challenges to improving health over the life course, especially for parents with low health literacy. These interventions can result in decreased cost of oral disease to families, the health care system, and society. The result of this research will be a better understanding of whether EHS can effectively increase dental use and improve oral health-related quality of life in low-income children. These outcomes are a priority according to the National Institute of Dental and Craniofacial Research's research objectives and are expected to have an important and needed impact because an effective EHS intervention might help curb the crisis in dental caries, the most common chronic disease affecting American children.

EHS has the potential to improve oral health outcomes for thousands of young children who are high risk for dental caries because it: (1) has access to very young children in low-income families, (2) is supported by studies that demonstrate positive short- and long-term impacts in important domains other than oral health, (3) integrates oral health within a comprehensive child development program, (4) is a two-generational program that focuses on both the child and the parent, and (5) has existing oral health performance standards that require effective preventive dental services. Each of these points is considered further in the following paragraphs in the context of potential contributions of this research.

Children in low-income families are at higher risk of experiencing dental caries and gaining access to low-resource families with very young children prior to the onset of early childhood caries is challenging. EHS is a national vehicle to reach children from birth to age three.[28,29] Although it has been shown that Head Start for older children, age 3 to 5, results in improved use of dental care;[20,30] to the author's knowledge, no studies have evaluated the effect of an early childhood educational program from ages birth to 3 years old on oral health outcomes. This study is significant because it determines the effectiveness of a childhood intervention for dental caries targeting children younger than those in previous studies and at an age when guidelines recommend the establishment of a dental home. The results of this study call attention to the importance of improving quality of life through the use of early childhood education programs from age birth to 3 years. This contribution is significant because intervening through an early childhood education program that enrolls thousands of low-resource families can be extended into the Head Start preschool program and may greatly improve oral health.

There is evidence that EHS is associated with positive impacts in areas beyond oral health. The proposed research is significant because it is the first evaluation of the impact of EHS on oral health outcomes. EHS is a well-organized and comprehensive program through which health interventions, such as oral health promotion, can be integrated within a larger program that includes cognitive, social, and emotional interventions in early childhood. EHS focuses on providing services for low-resource families to decrease disparities. The proposed research investigates whether EHS is an effective vehicle to help reduce oral health disparities through targeted oral health services similar to how it improves cognitive, social, emotional, and health outcomes for both the child and the parent.[2,4]

Additionally, EHS is a two-generational program that has the potential to impact ongoing oral health behaviors in the entire family. EHS can have direct effects on both the child and the parent and thus improve children's oral health outcomes. Parents play a pivotal role in children's oral health and care.[31] Two-generation programs provide stimulating, stable, and caring environments for children that can alter their long-term trajectory in positive ways.[2,32-37]

Finally, EHS currently integrates oral health performance standards in its comprehensive strategy to improve children's development in early childhood. These oral health performance standards, which include tooth-brushing, oral health education, and dental screening and referral, are consistent with the spirit of the age 1 dental visit endorsed by the American Academy of Pediatrics, American Dental Association, Academy of General Dentistry, and American Academy of Pediatric Dentistry.[38-40,40]

EHS currently provides oral health services without any scientific evidence of its effect on oral health outcomes. Currently, it is unknown whether EHS elevates the oral health level of enrolled children to that of their community peers. With the findings from this study, we will learn whether oral health is among the outcomes improved as a result of participating in EHS.

The results of this study have implications for policies and programs that target early childhood. This dissertation research addresses the effectiveness of intervening in early childhood to improve oral health, which is important for program evaluation and the development of future policies to improve oral health status and dental use for young children enrolled in EHS. The increasing prevalence of dental caries in young children makes the study both timely and relevant to policy. This study is significant because it can provide actionable evidence to advocate for the inclusion of oral health in new and existing EHS programs for both policy-makers and health practitioners.

CHAPTER 2. LITERATURE REVIEW

2.1. Dental Disease is a Major Public Health Problem for Young Children

Dental caries in early childhood has significant consequences. Not only do untreated dental caries lead to pain and infection, they affect basic vital functions such as eating, speaking, and sleeping, which are imperative to healthy growth and development.[28] The continued high prevalence of dental caries in the primary dentition has implications for long-term oral health because past or current caries experiences are one of the best predictors of future caries among available risk factors.[41,42] Additionally, early childhood caries can affect the immediate and long-term quality of life of the child and family and can have significant social and economic consequences beyond the immediate family.[43,44] Public media also has brought attention to the increasing trend of treating preschool children with severe dental caries in the operating room and the most severe consequence of untreated dental caries: death.[45,46]

Unfortunately, the prevalence of dental caries is high among young children in the United States.[28] Using the National Health and Nutrition Examination Survey (NHANES), Dye and colleagues found that the prevalence of dental caries among American children age 2 to 5 years old significantly increased from 24% in 1988 to 1994 to 28% from 1999 to 2004.[47] The most recent results from NHANES, based on two of the six-year survey cycle, suggest that the caries rate may have stabilized but the prevalence remains high.[48] The prevalence of dental caries in children age 2 to 5 was 23% in 2011–2012, a 5% decline compared to the 1999–2004 data.[48] When the age range is broadened from 2 to 5 years old to 2 to 8 years old, the prevalence of dental caries experience in primary teeth significantly increased from 46% in 1988–1994 to 52%

in 1999–2004, according to NHANES.[49] Similarly, the prevalence of dental caries in this age range, 2 to 8 years old, dropped to 37% in the most recent NHANES data from 2011–2012.[48]

Even though preliminary NHANES results suggest an improvement in childhood dental caries, the prevalence remains high and large disparities continue to be evident among population groups. Among two to four year-olds, untreated primary caries increased from approximately 16% in 1988–1994 to nearly 19% in 1999–2004.[47] In 1999–2004, 20% of decayed and filled teeth of all American children 2 to 5 years of age remained untreated; and the prevalence of untreated decay in children age 2 to 5 years old decreased to 10% in 2011–2012.[47,48,50]

Although childhood dental caries are common in all demographic groups, low-income children both have more dental caries and they are more likely to be left untreated.[28,51,52] In North Carolina, 19% of 2-year-old Medicaid patients attending well-child visits in a large pediatric group practice had cavitated lesions in teeth.[53] The prevalence of untreated decay in primary and permanent teeth in children age 2 to 11 years old in households at 100% of the federal poverty level or less is twice as large compared to those with greater than 200% federal poverty level in both 1988–1994 (37.4% vs. 13.7%, respectively) and 1999–2004 (32.5% vs. 15.1%, respectively).[47]

Dental caries also disproportionately affect minority children.[28,48,52,54] The prevalence of dental caries in primary teeth among children aged 2 to 8 years old was higher for Hispanic (46%) and non-Hispanic black children (44%) compared with non-Hispanic white children (31%).[48] Moreover, dental caries were more likely to go untreated in minority children aged 2 to 8 years old with prevalence of untreated decay significantly higher for both non-Hispanic black (21%) and Hispanic (19%) children compared with non-Hispanic white children (10%).[48]

Dental caries are a major public health problem for young children and national initiatives such as Early Head Start have instituted oral health performance activities that attempt to address this silent epidemic.

2.2. Early Head Start and its Potential Contributions to the Oral Health of Young Children

EHS is a comprehensive, two-generation program that serves high-risk, diverse, and disadvantaged parents and their infants or toddlers up to age 3.[1,4] It is a federally funded and nationally implemented community-based early childhood education program that began in 1995 as an expansion of the long-standing Head Start program. EHS strives to alter child development trajectories by intervening with both the child and the parent, providing direct services for the parent that will indirectly effect the child's development.[55,56] The range of services provided by EHS includes health education, screenings, and referrals to health services, parenting education, and social services.

Early childhood intervention literature often views the parent-child relationship and the family home environment as key agents of change in a young child's life.[56] The health and well-being of young children are inextricably linked to their parents' physical, emotional, and social health, social circumstances, and child-rearing practices.[57,58] At an age when the role of the family is paramount in a child's health and well-being, it is not surprising that there is evidence that two-generation programs provide stimulating, stable, and caring environments for children and can alter the child's long-term trajectory.[2,32-37]

The impact of EHS on cognitive, social, and health outcomes has been debated extensively in the public and scientific press, particularly after the release of the results from a large-scale, national randomized controlled trial: the Early Head Start Research and Evaluation Project (EHSREP).[59,60] The EHSREP is the largest study to date that measures short- and intermediate-term impacts of EHS. In the EHSREP, 17 EHS sites were enrolled purposively.

Mathematica randomized 3,001 families that met the enrollment criteria to EHS and non-EHS.[4] The EHSREP found that 2-year-old children with at least one year of EHS had better cognitive, language, and socio-emotional development than children who did not participate in EHS.[2-4,60] These effects persisted at age 3.[4,60] Additionally, parents of children in EHS had better performance on parenting behaviors such as reading to children, providing language and learning stimulation, spanking less, and providing emotional support.[4,60] Longer-term follow-up of the EHSREP showed that the only positive outcome for EHS that persisted at fifth grade was the social-emotional development of the child, such as decreased peer bullying, attention problems, and delinquency variables.[59] With regards to health, 96% of children in EHS had an ongoing source of medical care and 96% of enrolled children had health insurance at the end of 2010.[61]

EHS is a social program that has performance standards designed to promote a nurturing environment that fosters healthy socio-emotional, physical, and cognitive development for children over the long term.[62] Oral performance standards include daily tooth-brushing with fluoridated toothpaste, oral health education by EHS teachers, and the determination of a child's oral health status by a dental professional within 90 days of entry into the program.[7]

No information is available on the oral health status of EHS children. However, the literature on the prevalence of dental caries suggests that children who have socio-demographic characteristics similar to those enrolled in EHS are at higher risks for dental caries experience and less likely to access dental care.[28,29,51,52,54,63-66] Children usually are enrolled in EHS at an age before the onset of dental caries begins. Thus, EHS is potentially well-suited to promote oral health through the delivery of preventive services and promotion access to these services. This study evaluates whether EHS can successfully address oral health needs and reduce oral health disparities.

With the high prevalence of dental caries in very young children and its serious consequences, early intervention is imperative. To summarize this section, EHS is a comprehensive, early childhood education program that targets both the parent and the child, has federally mandated oral health performance standards, and has evidence of some long-term effects on child behavior and access to health services. These facts provide ample justification for investigating whether oral health may be positively affected by EHS. Combatting dental caries in early childhood through EHS may reverse the increasing trend in dental caries and prevent its costly consequences. Currently, little is known about the effects of EHS participation on oral health outcomes. The next sections review what is known about the effectiveness of comprehensive early education programs, including EHS, on oral health outcomes to be included in this study.

2.3. The Effect of Early Childhood Education Programs on Dental Use

2.3.1. Importance of Dental Use for Young Children

The use of preventive dental services such as sealants[67-70] and topical fluorides[71,72] is effective at preventing dental caries in young children.[64] Key stakeholders have implemented policies to encourage the use of preventive dental care for young children at risk of dental disease. State Medicaid programs cover oral health services as part of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, including the age 1 dental visit.[73] Bright Futures guidelines put forth by the American Academy of Pediatrics recommend oral health services for children including pediatric oral health risk assessments beginning at 6 months old.[40] Primary care providers are reimbursed by Medicaid insurance in most states for providing preventive oral health services, including fluoride varnish, to children within a medical setting beginning at around 12 months of age.[74]

In addition to being effective at reducing the prevalence of dental caries, preventive dental care is cost-effective. An analysis of North Carolina Medicaid claims from 1992 to 1997 found that children who received a preventive dental service before age 1 had lower dental costs over five years compared to children who received their first preventive dental service between ages 2 and 5.[75,76] A more recent analysis of North Carolina Medicaid claims from 1999 to 2006 found that children presumed to be high risk for dental caries (due to dental treatment visits before 18 months of age) had lower dental treatment costs if they received their first dental treatment or tertiary preventive visit before 18 months old compared to those with their first dental visit at 18 to 42 months of age.[77,78] With regards to sealants in particular, a third analysis of North Carolina Medicaid claims from 1985 to 1992 found that sealants placed on the teeth of children at high risk of dental caries resulted in lower dental costs over a five-year period.[79]

Recent studies found improvements in dental use for children nationally; however, it is unclear whether the trends hold for very young children under 3 years old. An analysis of the Medical Expenditure Panel Survey (MEPS) by the American Dental Association Health Policy Institute found a statistically significant increase in dental use among children age 1 to 18 years from 2000 through 2012, with children's dental use being 47.6% in 2012.[80] In another analysis using children age 1 to 20 who were eligible for EPSDT through Medicaid and Children's Health Insurance Program (CHIP), preventive dental services increased from a median of 45% in 2011 to 48% in 2013.[81] Conversely, dental treatment services continued below 25%, from a median of 24% in 2011 and 23% in 2013.[81] The findings of the proposed study will elucidate current levels of dental use for very young children that can be compared with the findings from these previous studies.

2.3.2. Barriers to Dental Use for Young Children in Early Head Start

Access to dental care for young children in Early Head Start is challenging due to factors related to the affordability of dental care and the available dental workforce. The literature documents that a significant barrier to accessing dental care is the family's socioeconomic status. Children in families with higher socioeconomic status have more access to dental care. For example, children who had private dental insurance or who were from families with higher income or education were more likely to receive preventive dental services such as topical fluoride and sealants.[82] Conversely, the likelihood of using dental care and receiving preventive dental care was low in children who were non-Hispanic black or Hispanic, had low family income, and had low education attainment by the head of household.[82] According to the Institute of Medicine (IOM), "In 2008, 4.6 million children did not obtain needed dental care because their families could not afford it."[83] As previously mentioned, these sociodemographic factors are also associated with a higher prevalence of untreated dental caries.[28,51,54]

Although dental insurance, such as Medicaid, generally has a positive impact on preventive dental use for children in the United States,[84] it is not a panacea for access to dental care for families with children under 3 years old. Greater than 90% of families enrolled in EHS are insured by Medicaid.[6] EHS families who have children under 3 years old and Medicaid insurance experience two barriers to accessing dental care due to dental workforce issues: 1) a limited number of dental providers who accept Medicaid insurance,[63-66] and 2) a limited dental workforce trained to see young children and/or dentists who choose not to treat young children.

With regards to the limited dental workforce trained to see young children, the supply of pediatric dentists in the United States was 6,618 in 2011.[85] According to the IOM, "Massachusetts has one pediatric dentist for every 6,000 children age 17 and under (one for every 1,600 children under age 5), but West Virginia has only about one pediatric dentist for every 23,000 children age 17 and under (one for every 6,200 children under age 5)."[83] In North Carolina, young children enrolled in Medicaid continue to face barriers to oral health care because of dental workforce shortages.[86] Dentists who are available to treat young children also may choose not to do so.[63-65,83,87,88] Several studies report that both pediatric and general dentists are reluctant to perform dental examinations or perform treatment on infants before the age of 1.[89-91]

Therefore, EHS promotes the use of dental services and may improve access to dental care, but EHS staff face barriers to effectively gaining access to dental care for EHS families. Accessing dental care will continue to pose challenges for young children, especially those in low-income families.

2.3.3. Data on Dental Use in Early Head Start and Head Start

Currently, it is unknown whether dental use by children is affected by their enrollment in EHS. Oral health outcomes were not a focal point of the EHSREP study, but the limited oral health data from that study showed that EHS did not have a positive effect on dental use compared to non-EHS children.[92] No statistically significant difference was found in the percentage of EHS children (28.3%) who visited a dentist compared to non-EHS controls (26.2%) in the EHSREP.[60] However, children in EHS were found in a non-experimental analysis to have increased dental visits over time, "from 4 percent about 7 months after enrollment (when children were, on average, 10 months old) to 25 percent about 28 months after enrollment (when children were 32 months old, on average)."[92]

It is possible that EHS has an effect on dental use akin to that of Head Start, which is a similar public and comprehensive program for low-income families with the same performance standards for children age 3 to 5 years old. In the Head Start Impact Study (HSIS),[30] a weighted analysis of the 3-year-old cohort showed that 69% of Head Start children received dental care in the first year of enrollment compared to 52% for similar children enrolled in other school readiness initiatives other than Head Start.[20] A similar trend was seen in a weighted analysis of the 4-year-old cohort, in which 73% of Head Start children received dental care in the previous year compared to 57% for similar children enrolled in other school readiness initiatives.[20] Overall, the HSIS reported that children in Head Start were significantly more likely to have used dental services compared to the previous year by 16 to 17 percentage points.[20] Despite the increased dental use among Head Start children age 3 to 5, the use of dental services by children in Head Start was low.[54,93,94]

A finding similar to the HSIS was reported in a South Carolina Head Start Medicaid-matched retrospective cohort study. Martin and colleagues (2012) conducted an analysis of Medicaid claims for 2007 to 2008 and concluded that Head Start children had significantly more visits to dentists than children not enrolled in Head Start ($P<0.001$).[95] The authors report that preventive and diagnostic visits may account for this increase in dental use by Head Start children.

The Office of Head Start reports that "among Head Start preschool-age children, 85% received preventive dental care and 87% have completed a professional dental examination during the 2011-2012 program year."[96] From the results of the HSIS and the Office of Head Start, there is reason to expect that EHS may have an effect on dental use for young children. Families enrolled in EHS are very diverse, and we might expect some of their characteristics to affect the ability of EHS programs to improve oral health outcomes.

2.4. The Effect of Early Childhood Education Programs on Oral Health–Related Quality of Life

Dental conditions can greatly impact a person's quality of life. The United States Surgeon General's report on oral health states that oral diseases and conditions can "undermine self-image and self-esteem, discourage normal social interaction, and cause other health problems and lead to chronic stress and depression as well as incur great financial cost. They may also interfere with vital functions such as eating, swallowing and speaking, and with activities of daily living such as work, school, and family interactions."[28,97]

The physical and psychological influences of oral conditions may have a particular effect on children, who need nutrition and sleep for growth and development, are developing speech, have fewer coping skills for pain and discomfort than adults, and are developing social skills that may be affected by their appearance. In a retrospective chart review on children with severe early childhood caries who underwent sedation or general anesthesia from 1987 to 1991 compared to outpatient surgery patients, 3 year olds with severe early childhood caries weighed approximately 1 kilogram less than children undergoing outpatient surgery. The authors of the chart review posit that this finding may be due to the effect of toothache and infection on eating and sleeping, thereby changing children's overall dietary intake and metabolic processes.[98] The treatment of extensive dental caries for young children also may be associated with high treatment costs and distress to the family, resulting in additional physical and psychological influences on the child.

Oral health–related quality of life (OHRQoL) can be defined as "a multidimensional construct that reflects (among other things) people's comfort when eating, sleeping, and engaging in social interaction; their self-esteem; and their satisfaction with respect to their oral health."[28] The concept of OHRQoL stems from the definition of health from the World Health Organization, which emphasizes the promotion of health as well as the absence of disease. It states, "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."[99]

As an outcome measure, OHRQoL encompasses the presence and absence of disease as well as the impact of that state of health, or lack of health, from the participants' self-report. OHRQoL assesses the impact of oral health problems and related treatment experiences on children and their families. It is a reflection of oral disease and conditions from the family perspective. It can be argued that OHRQoL is an important measure because it is a person-reported outcome that reflects the impact of health or disease on the patient's life as well as the patient's motivation for health-seeking behavior.

A number of OHRQoL instruments have been developed since the 1990s to determine the impact of dental disease and conditions in children on families. One of the more commonly used instruments is the Early Childhood Oral Health Impact Scale (ECOHIS), which was designed to consider impacts that are considered important to parents closely involved in the health and well-being of preschool-aged children.[21] Using the ECOHIS instrument for preschool-aged children, researchers have found the following: (1) dental treatment under general anesthesia is associated with improved OHRQoL in Turkey, Lithuania, the Netherlands, and the United States;[100-103] (2) dental caries is associated with worse OHRQoL in Brazil, the United States, and Hong Kong,[104-108] especially untreated caries;[107] (3) fluorosis has little impact on OHRQoL;[104] (4) traumatic dental injuries may [105,106,109,110] or may not [105,109] be associated with worse OHRQoL in Brazil; (5) malocclusions may[106] or may not[105,110] have an impact on OHRQoL in Brazil; (6) better socioeconomic status is associated with better OHRQoL;[111] and (7) parents' OHL is associated with OHRQoL.[17] Currently, the effect of EHS and other social programs on OHRQoL is unknown. Children in EHS may have improved OHRQoL as a result of daily oral health practices by EHS staff, such as tooth-brushing, oral health education to families, and screenings and referral of children to dental practices.[1]

2.5. The Effect of Parents' Oral Health Literacy on Children's Oral Health Outcomes

Low OHL is associated with low dental use for adults.[94,112,113] According to the IOM, low OHL in the United States creates challenges to recognizing the risk for oral diseases as well as seeking and receiving dental care.[83,113,114] Using national data from the 2003 National Assessment of Health Literacy, only 44% of adults over 16 years of age with less than basic health literacy skills had a dental visit in the preceding year compared with 77% of those with proficient health literacy skills.[94] Only 12% of adults were found in 2003 to have proficient health literacy.[115] According to Holtzman and colleagues (2014), adults who use fewer sources of oral health information, a subset of health literacy skills, are more likely to fail to show for an appointment at a university-based dental clinic.[113] There is evidence to the contrary, however, that the OHL of adults, measured using the Comprehensive Measure of Oral Health Knowledge, was not associated with dental use.[116]

It is unknown whether parents with low OHL have the same low dental health–seeking behavior for their children as they do for themselves. There may be a similar trend of low dental use for children whose parents have low OHL, which can put their children's health at risk. Because low OHL creates obstacles to recognizing the risk for oral diseases as well as seeking and receiving needed care, it is likely that low use of dental care and preventive dental services among children at high risk for dental problems, such as those in EHS, is associated with low OHL.[114]

The literature suggests that there is variation in oral health literacy among parents.[11-13] Evidence is accumulating that levels of OHL among parents can be an important factor in their children's oral health. Low OHL in parents is associated with deleterious oral health behaviors. Therefore, low OHL might pose challenges as a predisposing factor for oral health disparities.[117] Many parents in EHS are particularly vulnerable to having low OHL because they are young and have low educational attainment, both of which are associated with low health literacy.[118] EHS may not be able to overcome the numerous challenges faced by families with low OHL and therefore it might have an attenuating effect for EHS among families with low OHL. However, EHS may have measurable impacts on families with fewer challenges related to OHL, overcoming the barriers that result from moderate OHL. This study will determine whether there is a differential effect of EHS on dental use based on the level of parents' OHL.

2.6. Conceptual Framework

The conceptual framework for this study was adapted from an early education framework proposed in "Direct Effects of Early Childhood Education Programs on Health" by Friedman-Krauss and Barnett (2013) (Figure 2.1). This framework theorizes that early education programs, such as EHS, impact child health outcomes on three levels: direct effects on the child, direct effects on the parent, and long-term effects on the child. EHS has direct effects on the child's health through four pathways: 1) healthy meals and nutrition supplementation, 2) exercise, 3) health screenings and referrals, and 4) health education.[119] EHS has direct effects on the parent that lead to improvements in the child's health through child cognitive development, child social-emotional and self-regulation development, access to health care, and household abuse, injury, and neglect.[119] For example, EHS staff and teachers aid and encourage parents' access to healthcare for the child, which may lead to improvements in the receipt of well-child doctor's visits, immunizations, and dental visits, resulting in improved child health downstream. In addition to the direct effects on the child and parent to improve health during childhood, early childhood educational programs result in long-term health improvements through cognitive and social benefits that are associated with higher educational attainment, leading to increased earning power, having health insurance, and increased use of health information.[119]

In this dissertation research, we focused on two aspects of the early education framework: 1) access to health care as a result of child screening and referral services provided by EHS; and 2) access to health care as a result of education and support of the parent (Figure 2.1).[119] A simplified version of the conceptual model, reflecting the specific aims, is depicted in Figure 2.2. EHS activities connect EHS parent-child dyads with dental providers, which increase dental use in compliance with EHS oral health performance standards (Aim 1). Increased dental knowledge and motivation are expected to lead to improved oral health behaviors and oral health status, which can result in an improved OHRQoL (Aim 2). Parent characteristics such as parents' OHL or GHL modify the effects of EHS on dental use (Aim 3).

2.7. New Contributions

This research is innovative in several important aspects. This study will be the first to determine: 1) any improvements in oral health outcomes (dental use and oral health–related quality of life) resulting from enrollment in EHS from ages birth to 3 years old; and 2) the effects of parent's health literacy in EHS families. Further, in the absence of ethical randomization, this study addresses selection bias by measuring a plethora of known characteristics of families enrolled in the EHS program during data collection and uses that information in an innovative way to balance those characteristics between the EHS and non-EHS groups during data analysis. For these purposes, we used generalized boosted model propensity scores, which are based partly on information collected during parent interviews on known EHS program selection criteria for enrollment into the program. Finally, this study employed a novel statistical count data model, marginalized zero-inflated negative binomial regression, and a novel statistical continuous model, marginalized semicontinuous two-part modeling; both of which yield overall treatment effects directly from the model parameters. Each of these innovations is described in more detail in the following paragraphs.

The first innovative aspect of the research proposed is that it evaluated improvements in oral health outcomes (dental use and OHRQoL) following an early childhood educational program. Despite the increased dental use among Head Start children age 3 to 5, the overall use of dental services by children in Head Start was low and gains compared to their peers disappeared with age.[54,93] This present study evaluated whether there was a similar trend in younger children, from ages birth to 3 years old, enrolled in EHS. This research is innovative, in our opinion, because it evaluates the oral health outcomes of a national public early childhood education program, EHS, designed to reduce cognitive, social, and health disparities for which effects are unknown.

The second innovative aspect of the research undertaken in this dissertation is that it is the first study to evaluate whether the parent's baseline OHL or GHL alters dental outcomes in EHS families. This research determined whether parent's health literacy modified the effect of EHS on the child's dental use. The effect of the EHS intervention may be modified by parent's health literacy; therefore, health literacy might need to be taken into account to properly evaluate the effectiveness of EHS or to fully achieve desired outcomes. Moreover, EHS was evaluated to determine if it can overcome the challenges of poor health literacy.

Finally, three of the methods used in this dissertation research involved innovative applications of state-of-the-art, contemporary statistical procedures: 1) generalized boosted model propensity scores to address selection bias; 2) marginalized zero-inflated negative binomial modeling with random effects; and 3) marginalized semicontinuous two-part modeling with random effects.

To address the potential for selection bias in this study, we analyzed the selection criteria used by EHS programs and designed the questionnaire so that we could measure these variables in both groups and thus control for them in the analysis. We balanced the characteristics that EHS programs use to select families into their programs, which were known causes of selection bias, using generalized boosted model (GBM) propensity scores.[120,121] Although GBM propensity score analysis has been used in health services research, this will be the first application in dentistry or early education research. The positive results from our application of GBM propensity score analysis provides another possible option for researchers who might be faced with analyzing unbalanced data from non-randomized trials. These options are significant because lack of randomization is a wide-spread challenge in dental research, particularly evaluation of public health practice and early childhood education programs. The research in this study is innovative, in our opinion, because it evaluates the effect of the early childhood education program, EHS, using modern statistical techniques to address selection bias that are currently overlooked in dentistry and early education research.

This dissertation employed two recently developed analytical models that are new to dental research: marginalized zero-inflated negative binomial modeling for count data and marginalized two-part semicontinuous modeling for continuous data. In particular, this study presents the first applications of the marginalized zero-inflated negative binomial model with random effects and the marginalized generalized gamma two-part model for semicontinuous data. Moreover, marginalized two-part semicontinuous modeling (with or without random effects) have not hitherto been published in dental research. The research presented in this dissertation was innovative, in our opinion, because it evaluates the effect of the early childhood education program, EHS, using modern statistical techniques to determine overall treatment effects in a manner that is conceptually beneficial to and computationally convenient for dentistry and early education research.

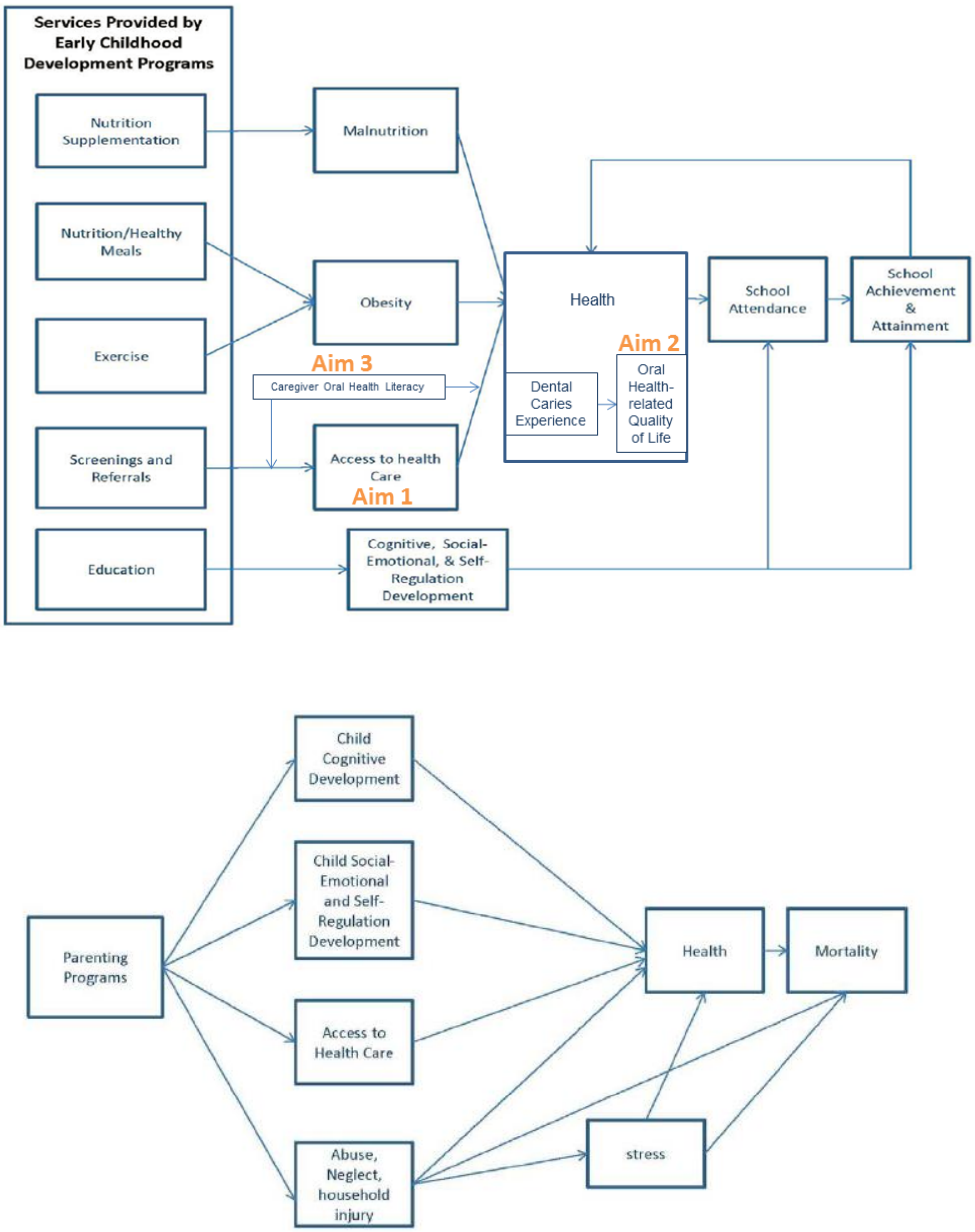

Figure 2.1. Conceptual framework.

Adopted from Friedman-Krauss and Barnett's "Direct Effects of Early Childhood Education Programs on Health" (2013).[119]

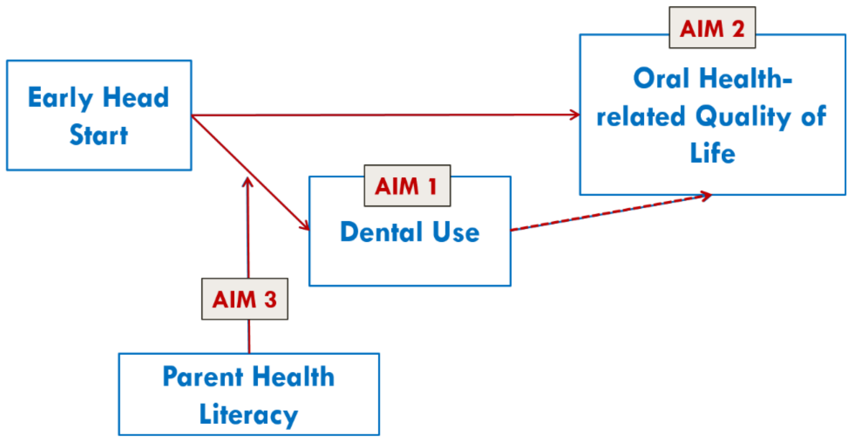

Figure 2.2. Conceptual model on the relationship between Early Head Start, parent-reported dental use, oral health–related quality of life, and parent health literacy.

CHAPTER 3. METHODS

3.1. Overview of Methods

The goal of this research was to determine the effect of Early Head Start (EHS) on oral health outcomes among low-income children enrolled in this program. Each of the study aims analyzed data collected as part of the Zero Out Early Childhood Caries (ZOE) study, a National Institutes of Health (NIH)–funded EHS research initiative in North Carolina. EHS is a community-based, statewide network that serves racial and ethnically diverse families with disadvantaged children age birth to 3 years old in 26 programs in 44 of North Carolina's 100 counties (Figure 3.1).

To determine the effect of the EHS intervention on oral health, Aim 1 examined the relationship between EHS enrollment and parent-reported dental use using logit and marginalized zero-inflated negative binomial regression models with generalized boosted model propensity scores as a covariate and cluster-level-specific random effects (Table 3.1) (Chapter 3.5). Aim 2 studied the effect of EHS enrollment on early childhood-related OHRQoL using logit and marginalized semicontinuous two-part models with generalized boosted model propensity scores as a covariate and cluster-level-specific random effects (Table 3.1) (Chapter 3.6). Aim 3 added an interaction term between EHS and parent oral and general health literacy to the model developed in Aim 1 because we hypothesize that children of parents with low health literacy may have smaller gains in dental use by participating in EHS (Table 3.1). In all, we conducted data analyses to study dental use, OHRQoL, and the modifying effect of parents' health literacy using data from the ZOE study.

3.2. Research Design

The primary data source, ZOE, was used to examine the effect of EHS on oral health outcomes of young children. The ZOE study was quasi-experimental, in which the EHS group was compared with the matched control group of children not enrolled in EHS. The research design was a non-randomized, pretest-posttest nested cohort control group cluster trial. The "treatment" for the EHS group included education of EHS staff to bolster their awareness of and adherence to oral health education, dental screening and referral, and child classroom tooth brushing, as specified in existing early education and federal EHS performance standards.

Parents of children enrolled in the study and of community control children were interviewed when children were on average about 9 months of age and at EHS program end about 24 months after baseline interviews. Primary data collection provided variables specific to the research questions. Each of the study aims included an analysis of primary data collected as part of the ZOE study. Almost all aims used a pre-post 24-month longitudinal prospective study design to determine the effects of EHS (Table 3.1).

3.3. Data Sources

Each of the study aims used data collected as part of the ZOE study. The sampling strategy for ZOE involved three stages: (1) enroll EHS programs, (2) enroll parent-child dyads within EHS programs, and (3) enroll community-matched parent-child dyads to serve as controls. In stage one, all North Carolina EHS programs were invited to participate, and all EHS programs except one were enrolled into the study. The sample design yielded parent-child dyads clustered within 25 of the 26 EHS programs in the state and in approximately 50 of the 80 EHS centers. In stage two, parents of EHS children younger than 19 months of age from all participating EHS programs were enrolled through direct recruitment by the research team. In stage three, Medicaid-enrolled children of the same age and language residing in the same geographic area (ZIP codes) as already enrolled EHS parent-child dyads were recruited as the control group through direct mailings from the North Carolina Medicaid program.

Because the ZOE intervention involved nearly all North Carolina EHS programs and many programs did not have excess applications that could be waitlisted, the control group was selected from a non-EHS population. Families enrolled in EHS were drawn from a low-income population, of which greater than 90% are insured by Medicaid.[6] Because the comparison group lived in the same locale as the children receiving the EHS intervention, the comparison group was an appropriate ethical alternative to denying EHS in a randomized experimental design. The proposed study used community-matched controls based on age, language and residential code to control for the potential for selection bias resulting from the quasi-experimental design of the ZOE study.

Parents were interviewed at two time points: 1) baseline, before the child turned 19 months of age, and 2) follow-up, when the child was as close to 36 months of age as possible and about ready to age out of the EHS program. On average, follow-up interviews took place approximately 24 months after baseline interviews. The variables of interest, dental use and OHRQoL, were included within the one-hour, in-person interviews at both baseline and 24-month follow-up. OHL and GHL were measured at baseline.

Baseline English and Spanish questionnaires were administered, as appropriate, to parents of children in EHS and non-EHS controls from September 2010 to July 2012 (N=1,561). The total baseline sample consisted of 634 parent-child dyads from EHS programs and 927 non-EHS controls. Follow-up interviews were completed from November 2012 to March 2014 (N=1,178). The total follow-up sample consisted of 479 parent-child dyads from EHS programs and 699 non-EHS controls.

3.3.1. Zero Out Early Childhood Caries (ZOE) Staff Targeted Education Activities

The primary aim of ZOE was to assess the impact of EHS program participation on oral health outcomes of children after all teachers and other staff in these programs had been trained in basic oral health strategies required by performance standards and in techniques to effectively communicate oral health messages to families.

Training in effective communication with families was provided for 176 EHS staff in every EHS program in North Carolina by two experts in motivational interviewing (MI). Knowledge of MI was self-assessed before and after training using a 10-point scale. Results demonstrated improved baseline knowledge scores after introductory training (Pretest= 6.9, Post-test = 7.8; $p<0.001$). Application of MI skills was self-assessed before and after training using written responses to Miller's Helpful Response Questionnaire (1–5 scale with greater and equal to three as MI adherent). Participants had improved scores in Miller's Helpful Response Questionnaire but lacked adherence to MI (Pretest= 1.2, Post-test = 2.5; $p<0.001$). As a result, EHS staff were not always able to demonstrate practical skill application of MI in their daily routines working with EHS families.

Oral health training was provided for 400 EHS teachers and staff by the Preschool Oral Health Coordinator for the North Carolina Division of Public Health through a collaboration with the North Carolina state health department. The curriculum specifically covered the importance of oral health during pregnancy, the importance of baby teeth, steps for a healthy smile, establishing a classroom tooth-brushing program, and the importance of oral health preventive services during well-visits at a medical practice. Assessments completed at the end of each session showed high levels of knowledge acquisition for participants (89% of staff scored 100%), and in their readiness to make changes in the way they teach oral health to young children and families (mean=7.8 on a 1–10 "not ready" to "ready" scale).

This training gave EHS teachers and staff an enhanced awareness of existing early education performance standards from early education and childcare guidelines and the federal performance standards for EHS programs. The goal of the ZOE training was full implementation of the EHS performance standards for oral health to provide the best case scenario for the effect of EHS on oral health outcomes.

3.4. Overview of Data Analysis

3.4.1. Aim 1: The Impact of Early Head Start on Dental Use for Children Under 3 Years Old

For Aim 1, we tested the hypothesis that EHS improves dental use compared to non-EHS children over time. Our rationale was that EHS provides screening and referral services for oral health. The primary outcome of this study, overall dental use by the child, was analyzed as both a binary and count variable in separate analyses. When defined as a binary variable, overall dental use was determined by a positive response to the question of the parent at follow-up, "Has your child ever been to a dentist or dental clinic?" When defined as a count variable, the number of lifetime dental visits for the child was determined using parent self-report at the follow-up interview. Additional outcomes of this study, preventive, treatment, and emergency dental use by the child were analyzed as binary variables in separate analyses.

We used logistic regression models to examine the effect of EHS on dental use with separate models for each type of dental use (overall, preventive, treatment, emergency). We used a marginalized zero-inflated negative binomial model with random effects to estimate the marginal mean increment in number of overall dental visits for EHS compared to non-EHS children, which accounts for over-dispersed distributions of counts with a significant number of zeros (Chapter 3.5).[122] The benefit of using a marginalized model over a traditional zero-inflated model is that it parameterizes the covariate effects directly on the overall mean, providing interpretable covariate effects on the overall mean.[122-124]

For all analytical models in this study, we controlled for baseline dental need, baseline dental use, and directly adjusted for a generalized boosted model propensity score covariate.[125]

We controlled for clustering of subjects within EHS programs (n=25). These clusters correspond to geographic areas (ZIP codes) where EHS and non-EHS study participants reside. Non-EHS parent-child dyads were selected from the same residential ZIP code as enrolled EHS parent-child dyads. Fewer than 3% of non-EHS parent-child dyads (n=19/699, 2.7%) resided in ZIP codes without any EHS enrolled parent-child dyads, so they were assigned to an EHS program using the closest ZIP code to ensure that all EHS and non-EHS participants had a treatment group comparator in the same cluster.

The impact of EHS on oral health outcomes was estimated in random effects models to increase statistical efficiency of the parameter estimates compared to fixed effects. A similar random effects approach to adjusting for the effect of clustering was used by Young and colleagues (2007) on a dataset similar to ZOE, a nonrandomized clustered design.[126]

3.4.2. Aim 2: Enrollment in EHS, Pediatric Dental Use, and Oral Health–Related Quality of Life

For Aim 2, we hypothesized that EHS children would have improved oral health–related quality of life compared to non-EHS children because EHS has the potential to both reduce dental disease and facilitate access to dental providers. As a sub aim to Aim 2, we hypothesized that dental use mediated the effect of EHS on OHRQoL based on the results of Aim 1 in which EHS has a strong positive impact on dental use.

OHRQoL was measured using the Early Childhood Oral Health Impact Scale (ECOHIS), a 0–52 point scale with higher scores indicating worse OHRQoL. Using a logit model, we estimated the effect of EHS on OHRQoL prevalence, defined as the probability of having any negative impact on OHRQoL at 24-month follow-up (ECOHIS≥1). Mediation analysis for dental use was performed on the logit model using the counterfactual framework analysis (Chapter 3.7). We used a marginalized two-part semicontinuous model with random effects to estimate the effect of EHS on OHRQoL severity, defined as the overall mean ECOHIS scores at follow-up.[127-129]

For all analytical models in this study, we controlled for baseline ECOHIS score and survey language and directly adjusted for a generalized boosted model propensity score covariate.[125] We also included a random effect for the 25 EHS programs in a manner similar to Aim 1.

3.4.3. Aim 3: The Influence of Health Literacy on the Effectiveness of Early Head Start's Improving Children's Dental Use

For Aim 3, we hypothesized that parents' health literacy would modify the effectiveness of the EHS intervention on parent-reported child dental use. We posited that parents with better health literacy will gain greater benefit from the EHS program compared to parents with lower health literacy, thus attenuating the EHS effect on use.

We used two measures of health literacy: one general measure for health and another specific to oral health. GHL was measured using the continuous-variable Short Assessment of Health Literacy—Spanish and English (SAHL-S&E), an 18-item word recognition test of comprehension.[130] OHL was measured using the continuous-variable Oral Health Literacy Assessment (OHLA), which is a 30-point word recognition test available in both Spanish (OHLA-S) and English (OHLS-E). The OHLA-S and OHLA-E are valid and reliable when used separately but likely do not measure the same underlying construct and scores are not considered to be equivalent.[131] Analyses were performed for English- and Spanish-speakers separately for both measures of health literacy. They were also performed for the combined sample using the GHL measure because scores have been shown to be equivalent using item response theory, a modern psychometric analytical technique.[130]

In the moderation analysis, we tested whether an added interaction effect between parent's health literacy and EHS was a significant predictor of dental use in a logit model that estimated the effect of EHS enrollment on the probability of having an overall dental visit (Aim 1), controlling for baseline dental use, dental need, and a propensity score covariate. We also included a random effect for the 25 EHS programs in a similar manner to Aim 1.

The following three sections provide a detailed overview of the methods used in this dissertation that are novel to dental research. Aims 1 and 3 employed marginalized zero-inflated negative binomial modeling with random effects to study the impact of EHS on the count variable, dental use (Section 3.5). A marginalized semicontinuous two-part model with random effects was used in Aim 2 to study the impact of EHS on the continuous variable, OHRQoL (Section 3.6). Finally, we performed a causal mediation analysis using the counterfactual framework of causal inference to evaluate whether dental use was a mediator in the relationship between EHS and OHRQoL found in Aim 2 (Section 3.7).

3.5. Marginalized Zero-Inflated Negative Binomial Model with Random Effects

The first part of the marginalized zero-inflated negative binomial (MZINB) model is similar to the first part of the traditional zero-inflated negative binomial model

$$\log\left[\frac{\psi_{ij}}{1-\psi_{ij}}\right] = \gamma_0 + \gamma_1 x_{1i} + \gamma_2 x_{2ij} + \gamma_3 x_{3ij} + \gamma_4 x_{4ij} + c_i$$

where ψ_{ij} is the probability of an excess zero for the *j*th child in the *i*th EHS program cluster conditional on the cluster-specific effect, c_i. In this model x_{1i} is the EHS enrollment indicator, x_{2ij} = indicates needed dental care at baseline, x_{3ij} denotes any dental visits at baseline (dichotomous), and x_{4ij} is the estimated propensity score. Finally, c_i are mean zero, normally distributed random effects.

The second part of the MZINB model is

$$\log(\nu_i) = \alpha_0 + \alpha_1 x_{1i} + \alpha_2 x_{2ij} + \alpha_3 x_{3ij} + \alpha_4 x_{4ij} + d_i$$

where ν_{ij} is the overall mean number of dental visits for the *j*th child in the *i*th EHS program cluster conditional on the cluster-specific effect, d_i. Furthermore, (c_i,d_i) are assumed to be bivariately normally distributed with the variance

$$\Sigma = \begin{pmatrix} \sigma_1^2 & \rho\sigma_1\sigma_2 \\ \rho\sigma_1\sigma_2 & \sigma_2^2 \end{pmatrix}$$

where σ_1 and σ_2 are standard deviations of c_i and d_i, respectively, and ρ is their correlation. Note that the overall (marginal) mean ν_{ij} is related to the traditional zero-inflated count regression model latent class mean μ_{ij} of children believed to be at-risk for having dental visits via $\nu_{ij} = (1 - \psi_{ij})\mu_{ij}$.[132] Unlike traditional zero-inflated count regression models, the regression coefficients in the second part of the MZINB model have the same interpretations as in one-part Poisson regression or negative binomial regression as log incident rate ratios in the overall population. In the MZINB, the role of the first model part is to account for extra-variation in the outcome counts due to excess zeros. The γ-coefficients are not of interest.

3.6. Marginalized Semicontinuous Two-part Model with Random Effects

The first part of the marginalized semicontinuous two-part model with random effects[127-129] is similar to the first part of the traditional semicontinuous two-part model[133]

$$\log\left[\frac{\Pi_{ij}}{1-\Pi_{ij}}\right] = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2ij} + \beta_3 x_{3ij} + \beta_4 x_{4ij} + b_i \qquad \text{(EQN 1)}$$

where π_{ij} is the probability of having of any negative impact to OHRQoL (ECOHIS≥1) at follow-up for the *j*th child in the *i*th EHS program cluster conditional on the cluster-specific effect, b_i. In particular, b_i is a normally distributed random effect for each EHS program cluster (N=25) where $b_i \sim N\,(0, \sigma_1^2)$. The EHS cluster-specific odds ratio, e^{β_1}, is the odds of having any negative impact to OHRQoL (ECOHIS≥1) by a child in EHS relative to the odds for a child not in EHS, conditional on the EHS and non-EHS child being from the same geographic area.

The second part of the marginalized semicontinuous two-part model is

$$\log\,(\nu_i) = \alpha_0 + \alpha_1 x_{1i} + \alpha_2 x_{2ij} + \alpha_3 x_{3ij} + \alpha_4 x_{4ij} + d_i \qquad \text{(EQN 2)}$$

where ν_{ij} is the overall mean ECOHIS score for the *j*th child in the *i*th EHS program cluster conditional on the cluster-specific effect, d_i. We assume that ECOHIS score has a generalized gamma distribution.[129] Furthermore, (b_i,d_i) are assumed to be bivariately normally distributed with the variance

$$\Sigma = \begin{pmatrix} \sigma_1^2 & \rho\sigma_1\sigma_2 \\ \rho\sigma_1\sigma_2 & \sigma_2^2 \end{pmatrix}$$

where σ_1 and σ_2 are standard deviations of b_i and d_i, respectively, and ρ is their correlation. The EHS cluster-specific mean ratio, e^{α_1}, is the multiplicative increase in mean OHRQoL for a child in EHS relative to the mean OHRQoL for a child not in EHS, conditional on the EHS and non-EHS child being from the same geographic area.

3.7. Causal Mediation Analysis Using the Counterfactual Framework of Causal Inference

Mediation analysis is growing in popularity as a way to understand causal pathways, particularly as new analytical approaches and tools become available to the scientific community. However, some of the newer methods used in this study have not gained widespread use, even though these new methods resolve some of the shortcomings of older methods. Moreover, there is no consensus among the research community on a preferred approach to mediation analyses.

We tested whether any dental use mediated the relationship between EHS and OHRQoL prevalence with a single mediation model using causal mediation analysis.[134] This mediation approach was performed because it is not limited to a particular statistical model and therefore is applicable to a wide range of situations.[134] In our study, it allowed for the analysis of overall dental use as a mediator using the full logistic regression model specified in the Aim 1 study for any negative impact to OHRQoL with random effects.

Causal mediation analysis uses a counterfactual framework of causal inference, in which each individual has four potential outcomes: A) outcome if treated and mediator if the individual had been treated; B) outcome if treated and mediator if control; C) outcome if control and mediator if treated; and D) outcome if control and mediator if control. Of these four potential outcomes, we only observe one for each person in the dataset.

The mediation effect was measured using three parameters: average causal mediation effect (ACME), average direct effects (ADE) and total effects.[134,135] The ACME is the indirect effect of the treatment (EHS) on the outcome (OHRQoL) through the mediating variable (dental use).[136] Using the above four potential outcomes, the ACME is A minus B or C minus D, averaged over the sample of interest.

The ADE is the effect of the treatment (EHS) on the outcome (OHRQoL) while holding the mediator (overall dental use) constant at the level that would be realized under the treatment (EHS or non-EHS) participation. Using the four potential outcomes, the ADE is A minus C or B minus D.

The total effect is the sum of the average causal mediation and average direct effects.[134] Using the four potential outcomes, the total effect is A minus D, which is any negative impact to OHRQoL to an individual in the EHS group if they had the dental use of themselves in the EHS group minus any negative impact to OHRQoL to an individual in the Non-EHS group if they had the dental use of themselves in the Non-EHS group. For the total effect, the dental use for the EHS (non-EHS) outcomes are that which would result from being in the EHS (non-EHS) group.

Table 3.1. Summary of Study Design

Aim	Objective	Design	Outcome (variable)	Outcome (type)	Model[†]
#1a	**Dental Use:** Overall	Quasi-experimental Pre-Post	Any *overall* dental visits	Binary	Logistic Regression
			Number of *overall* dental visits	Count	Marginalized zero-inflated Negative Binomial
#1b	**Dental Use:** Preventive	Quasi-experimental Pre-Post	Any *preventive* dental visits	Binary	Logistic Regression
#1b	**Dental Use:** Treatment	Quasi-experimental Pre-Post	Any *dental treatment* visits	Binary	Logistic Regression
#1b	**Dental Use:** Emergency	Quasi-experimental Pre-Post	Any *emergency* dental visits	Binary	Logistic Regression
#2	**Oral Health-related Quality of Life**	Quasi-experimental Pre-Post	ECOHIS Prevalence	Binary	Logistic Regression
			ECOHIS Severity	Semi-continuous	Generalized Gamma Marginalized Semicontinuous two-part
#2a	**Oral Health-related Quality of Life** Test whether dental use is a mediator between EHS and Oral Health-related Quality of Life	Quasi-experimental Pre-Post	ECOHIS Prevalence	Binary	Causal Mediation Analysis
#3	**Parent Health Literacy** Add interaction effect of EHS intervention and baseline *health literacy*[‡] on Aim 1a (dental use)	Quasi-experimental Pre-Post	Any *overall* dental visits	Binary	Logistic Regression
			Number of *overall* dental visits	Count	Marginalized zero-inflated Negative Binomial

[†]All models will employ a random effect for each of the EHS program clusters (N=25) and direct adjustment for generalized boosted model propensity scores as a covariate.
[‡]Health Literacy was measured using the following literacy instruments: Oral Health Literacy Assessment and the Short Assessment of Health Literacy.
EHS = Early Head Start
ECOHIS = 13-item Early Childhood Oral Health Impact Scale

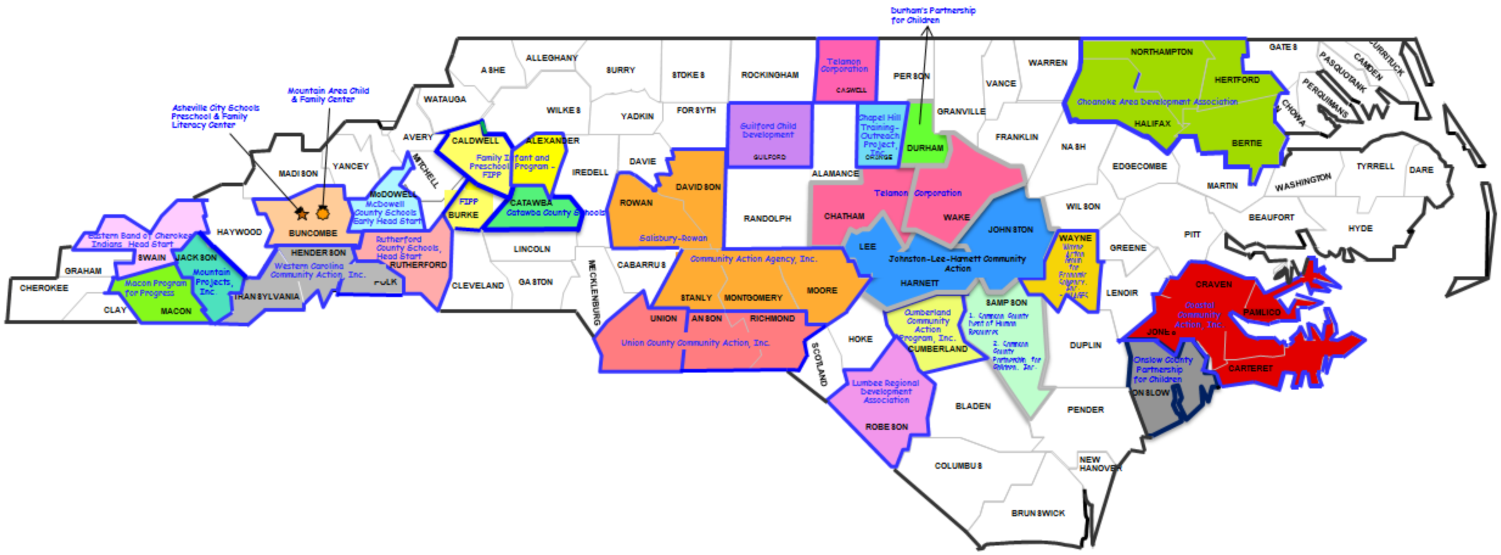

Figure 3.1. County locations of North Carolina Early Head Start Programs (N=25) in the Zero Out Early Childhood Caries (ZOE) study.

CHAPTER 4. AIM 1: THE IMPACT OF EARLY HEAD START ON DENTAL USE FOR CHILDREN UNDER 3 YEARS OLD

4.1. Overview

We examined the effect of North Carolina (NC) Early Head Start (EHS)—a federal early education program for children under three years old and their families—on children's dental use. We performed a quasi-experimental study, aiming to enroll all eligible children (n=1,458) in all EHS programs in NC (n=26) and compare them with children of the same age, language, and residential neighborhoods randomly selected from Medicaid files. We interviewed 479 EHS and 699 non-EHS parent-child dyads at baseline when the child averaged 9 months old and at 24-month follow-up. Using logit models, we estimated the effect of EHS on the probability of having a dental visit (overall, preventive, treatment, emergency). We used a marginalized zero-inflated negative binomial model to estimate the mean increment in number of overall dental visits for EHS compared to non-EHS children. We controlled for baseline dental need and dental use, a propensity score covariate, and included random effects to account for clustering within EHS programs. Over 24 months, 81% (388/479) of EHS children and 59% (413/699) of non-EHS children had a dental visit (P<0.01). In adjusted logit models, EHS children had an increased odds of having any dental visit (OR=2.5; 95% CI=1.74-3.48) and having a preventive dental visit (OR=2.6; 95% CI=1.84-3.63) compared to non-EHS children. Children in EHS had 1.3 times the adjusted mean number of dental visits compared to the children not in EHS (95% CI=1.17-1.55). This study is the first to demonstrate that EHS provides services that increase dental use for disadvantaged young children.

4.2. Introduction

The Centers for Disease Control and Prevention recommends dental services during early childhood "to improve the health of infants, children, and adolescents and promote healthy lifestyles that will enable them to achieve their full potential."[137] Similarly, the Institute of Medicine (IOM) states that "improving access to oral health care is a critical and necessary first step to improving oral health outcomes and reducing disparities."[83] The use of preventive dental care for young children at risk of dental disease is encouraged by key stakeholders such as State Medicaid programs, which cover oral health services as part of the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit.[73] Not only are preventive dental services, such as sealants[67-70] and topical fluorides,[71,72] effective at preventing dental caries in children they also are associated with reduced dental expenditures.[138]

Despite the risk of dental caries in young children and the documented benefits of early preventive dental care, the use of dental services by children, particularly very young children from low-income families, is very low.[82] In 2009, only 7.6% of children from birth to age 2 used any type of dental care, and only 1.7% had a preventive dental visit.[82] According to the IOM, "In 2008, 4.6 million children did not obtain needed dental care because their families could not afford it."[83] Not surprisingly, socioeconomically vulnerable children had a higher prevalence of untreated dental caries.[28,51,54] Recent evidence suggests that the use of dental services is increasing beyond historically low levels, however how this trend is affecting young children is not clear and significant structural barriers remain for children in this age group obtaining recommended preventive and treatment services.[80,81]

Evidence suggests that social programs targeting disadvantage families, such as Medicaid; Special Supplemental Nutrition program for Women, Infants and Children (WIC); and Head Start, all established in the 1960s, improve dental use.[30,139,140] Yet limited evidence is available about whether Early Head Start (EHS), a program established in the 1990s, might contribute to improved dental use. EHS is a national comprehensive early education program for low-income families and young children (birth to 3 years of age).[1] This program potentially has an important role in promoting dental use because it targets families at greatest risk for poor oral health,[6] provides comprehensive family services and support, improves social and cognitive development long term,[2-5] and operates according to comprehensive federal performance standards that integrate oral health.[7] These oral health performance standards (tooth-brushing with fluoridated toothpaste, oral health education, determination of a child's oral health status by a dental professional within 90 days of entry into the program) are consistent with the spirit of the age 1 dental visit endorsed by professional organizations.[38-40]

Although oral health is an integral part of recommended EHS program activities, little is known about program effects on oral health outcomes of children.[5,8-10] One national study implemented soon after the EHS program was established found no difference in dental use between children enrolled in EHS and comparison non-EHS children.[60,92] The purpose of this study is to determine the effects of EHS compared to Medicaid-enrolled, community-matched controls on parent-reported dental use for children in North Carolina. We hypothesize that compared to non-EHS children, EHS children will have greater use of overall, preventive, and treatment dental services while enrolled in the program. We examine the association between EHS and type of dental use (overall, preventive, treatment, emergency) as well as the association between EHS and the mean increment in number of overall dental visits.

4.3. Methods

4.3.1. Study Design and Data Source

The study used data collected as part of the Zero Out Early Childhood Caries (ZOE) study, a 24-month longitudinal prospective study undertaken to estimate the effect of enrollment in EHS on oral health outcomes in young children. The ZOE study is quasi-experimental, in which the EHS group is compared with the matched control group of children not enrolled in EHS (Figure 4.1).

Teachers and staff in participating EHS programs received training to bolster awareness of EHS performance standards and help facilitate their implementation. Training in effective communication with families was provided by two experts in motivational interviewing to 176 EHS staff in NC EHS programs. Oral health training was provided for 400 EHS teachers and staff by the Preschool Oral Health Coordinator for the Division of Public Health, North Carolina Department of Health and Human Services. The curriculum covered oral health during pregnancy; the importance of baby teeth; steps for a healthy smile; strategies and techniques for establishing a classroom tooth-brushing program; and the importance of early preventive dental visits, including oral health preventive services available during well-child visits at medical practices. The goal of this intervention was to promote maximum implementation of the federal EHS oral health performance standards but with a minimal and practical intervention. The study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill and by the NC Head Start State Collaboration Office.

4.3.2. Sample

The sampling strategy for ZOE involved three stages: (1) enrollment of EHS programs, (2) enrollment of parent-child dyads within EHS programs, and (3) enrollment of community-matched parent-child dyads to serve as controls. In stage one, all North Carolina EHS programs were invited to participate, and all except one were enrolled. In stage two, parents of EHS children younger than 19 months from all participating EHS programs were recruited by the research team. Five criteria were used for enrollment of EHS and non-EHS parent-child dyads: 1) child <19 months old; 2) parent >18 years old; 3) interviewee is the primary caregiver; 4) no plans to move from the county or, in the case of an EHS subject, withdraw from EHS; and 5) parent speaks English or Spanish fluently. Additional enrollment criteria for non-EHS parents were the following: 6) never had a child in EHS; 7) never participated in the EHS prenatal program; 8) never volunteered for EHS; and 9) never worked for EHS. In stage three, Medicaid-enrolled children of the same age, language, and ZIP code as already enrolled EHS parent-child dyads were recruited as the control group through direct mailings from the North Carolina Medicaid program. The design and implementation of the sample yielded EHS and non-EHS parent-child dyads clustered within 25 of the 26 NC EHS programs and in approximately 50 of the 80 EHS centers.

4.3.3. Procedures

Trained interviewers administered structured, in-person interviews to parents at two time points: 1) baseline (child <19 months old), and 2) follow-up (~24 months after baseline interviews), which coincided with children aging out of the EHS program at 36 months old. The outcome variable of interest, dental use, was included within the one-hour, in-person interviews at both baseline and follow-up. English and Spanish questionnaires were administered, as appropriate, to parents of children in EHS and non-EHS controls. Baseline interviews were conducted from September 2010 to July 2012, with follow-up interviews completed from November 2012 to March 2014.

4.3.4. Conceptual Framework

The conceptual framework for this study is adapted from an early education framework proposed in "Direct Effects of Early Childhood Education Programs on Health" by Friedman-Krauss and Barnett (2013).[119] In our study, we focus on two aspects of the early education framework related to the direct effects on the child and parent: 1) access to health care as a result of screening and referral services facilitated or provided by EHS; and 2) access to health care as a result of education and support of the parent. EHS activities connect EHS parent-child dyads with dental providers, which might increase dental use in compliance with EHS oral health performance standards.

4.3.5. Measures

The main independent variable, Early Head Start (EHS) enrollment, was supplied by EHS staff and confirmed by the parent at the baseline enrollment screening and interview. It was treated as a binary variable in the analysis.

The dependent variable, overall dental use by the child, was analyzed as both a binary and count variable in separate analyses. When defined as a binary variable, overall dental use was determined by a positive response to the question of the parent at follow-up, "Has your child ever been to a dentist or dental clinic?" When defined as a count variable, the number of lifetime dental visits for the child was determined using parent self-report at the follow-up interview.

The type of dental visit was determined by the question, "What dental treatments has your child received during his or her lifetime?" Preventive dental use was defined as "routine check-up" or "fluoride or other preventive treatments" in addition to open-ended responses such as "cleaning." Treatment dental use was defined as "fillings for a cavity or toothache" or "tooth pulled" in addition to open-ended responses such as "caps." Emergency dental use was based on the reported reason for either the first dental visit or lifetime dental use being "emergency visit for an injury;" a visit was also considered an emergency if the parent volunteered responses such as "fell and broke front tooth."

We included two baseline covariates in the analyses because of their potential impact on future dental use: dental need and dental use from birth to time of baseline interview. Dental need was self-reported by the parent as a binary variable, determined as a positive response to the question, "During your child's life, has he or she ever needed dental care or check-ups?"

Dental use was self-reported by the parent as a binary variable, determined as a positive response to the question, “Has your child ever been to a dentist or dental clinic?”

4.3.6. Data Analyses

We used an “intent to treat” approach in which the treatment indicator (EHS) was as-assigned. We used descriptive statistics to explore the distribution of both the children’s and parents’ demographic characteristics by EHS enrollment, exposure to early childhood programs for the control group, and the exposure to social programs (EHS, Head Start, Medicaid) for both the EHS and non-EHS groups. Descriptive statistics and graphics were also used to describe the distribution of the number of dental visits. Before modeling the relationship between EHS and dental use, we examined the unadjusted relationship between EHS enrollment and having one or more dental visits (overall, preventive, treatment, and emergency). For all analytical models in this study, we controlled for baseline dental need, baseline dental use, and directly adjusted for a generalized boosted model propensity score covariate, which was based on 47 socio-demographic factors and the enrollment criteria for EHS programs (Appendix 1, Appendix 2, Appendix 3).[125]

We controlled for clustering of subjects within EHS programs (n=25). These clusters correspond to geographic areas (ZIP codes) where EHS and non-EHS study participants reside. Non-EHS parent-child dyads were selected from the same residential ZIP code as enrolled EHS parent-child dyads. Fewer than 3% of non-EHS parent-child dyads (n=19/699, 2.7%) resided in ZIP codes without any EHS enrolled parent-child dyads; so, they were assigned to an EHS program using the closest ZIP code to ensure that all EHS and non-EHS participants had a treatment group comparator in the same cluster.

The impact of EHS on oral health outcomes was estimated in random effects models to increase statistical efficiency of the parameter estimates. A similar random effects approach to adjusting for the effect of clustering was used by Young and colleagues (2007) on a dataset similar to ZOE, a nonrandomized clustered design.[126] With the exception of emergency visits that were infrequent, random effects were used to control for clustering within each of the 25 Early Head Start programs.

4.3.7. Logistic Regression Models of any Visits and by Type

We used logit maximum likelihood estimation models to examine the effect of the binary independent variable, EHS, on dental use. The categories for dental use (overall, preventive, treatment, emergency) were not mutually-exclusive. Therefore, separate models were used for each type of use to examine the association between EHS and type of dental use. The dichotomous models were employed to understand potential differences in any use versus no use between the EHS and non-EHS groups. An example of modeling the EHS intervention effect on dental use using logistic regression is the following:

$$\log\left[\frac{P_{ij}}{1-P_{ij}}\right] = \beta_0 + \beta_1 x_{1i} + \beta_2 x_{2ij} + \beta_3 x_{3ij} + \beta_4 x_{4ij} + b_i$$

where $P_{ij} = E(Y_{ij} \mid b_i)$, the expected value (probability) of receipt of children's dental services at 24-month follow-up for the *j*th child in the *i*th EHS program cluster.

x_{1i} = Early Head Start enrollment (treatment indicator, dichotomous)

x_{2ij} = Any needed dental care at baseline (dichotomous)

x_{3ij} = Any dental visits at baseline (dichotomous)

x_{4ij} = Generalized boosted model propensity score (continuous)

b_i = Normally-distributed random effect for each EHS program cluster (N=25)

where $b_i \sim N(0, \sigma_b^2)$

We estimate the EHS cluster-specific odds ratio, e^{β_1}, to be the odds of receipt of dental services by a child in EHS relative to the odds or receipt for a child not in EHS, conditional on the EHS and non-EHS child being from the same geographic area.

Additionally, the marginal effect of EHS was determined using the method of recycled predictions, which generated the average predicted probabilities of having a dental visit after changing all observations to being enrolled in EHS, and repeating the process after changing all observations to not being enrolled in EHS.[141] The continuous independent variable, propensity score, passed two tests for model misspecification: Pregibon's Link Test and Hosmer and Lemeshow's goodness-of-fit test. Standard errors and 95% confidence intervals for the marginal percentage point difference were calculated using the delta method. Data analyses for the logit models were conducted using STATA 14 (StataCorp LP, College Station, TX).

4.3.8. Count Model for Number of Visits of Any Type

We used a marginalized zero-inflated negative binomial model with random effects to estimate the marginal mean increment in number of overall dental visits for EHS compared to non-EHS children as described in Chapter 3.5.[122] The benefit of using a marginalized zero-inflated negative binomial model over a traditional zero-inflated model is that it parameterizes the covariate effects directly on the overall mean, provides interpretable covariate effects on the overall mean, accounts for overdispersed distributions of counts with a significant number of zeros, and avoids the conceptual and interpretation pitfalls of zero-inflated models in dental research.[122-124] While both are two-part models, the difference between the marginalized zero-inflated negative binomial count model and the traditional zero-inflated count model is that the former models the overall mean of the mixture distribution of negative binomial counts and added zeros while the latter models the mean negative binomial count from the 'susceptible class' of children who are said to be at-risk for having dental visits. Our model extends the marginalized zero-inflated negative binomial for independent counts[122] to allow for clustering while also extending the marginalized zero-inflated Poisson model with random effects[132] to allow for overdispersion (counts with extra-Poisson variation). Data analyses for the count model were performed using SAS/STAT® version 9.4 (SAS, 2013) (Appendix 4).

4.4. Results

We enrolled 60% (n=634) of an estimated 1,054 eligible participants of the targeted age enrolled in NC EHS programs and 9% (n=927) of the 9,967 Medicaid-enrolled children in the sample frame. Follow-up interviews were completed with 479 parent-child dyads from EHS programs and 699 non-EHS controls, resulting in a 75% follow-up rate for both groups (Figure 4.1).

Baseline characteristics of the EHS and non-EHS children were similar for gender, age, enrollment in public health insurance, and physical, learning, or mental health limitations; however, more children in EHS had been homeless and were minority race and ethnicity compared to children not enrolled in EHS (Table 4.1). EHS and non-EHS parents' baseline characteristics were similar with respects to gender, age, language, nativity, receipt of government benefits (unemployment, WIC, social security), and full- or part-time employment status; however, more parents of EHS children were single or never married, had less education, received food stamps, received childcare subsidy, received housing assistance, were enrolled in Medicaid, and were in school or training compared to parents whose children were not enrolled in EHS (Table 4.2).

Children in both the EHS and non-EHS groups had exposure to early childhood education (Table 4.3, Table 4.4). Of the 699 non-EHS control children in the ZOE study, 240 (34%) reported at follow-up to have participated in a child care, preschool or day care program that was not EHS (Table 4.3). Of these non-EHS children, 9% (n=61) participated in EHS over the follow-up period, with a mean enrollment time of approximately 10 months (Table 4.3). Although few non-EHS parents were enrolled in the EHS prenatal program (2%, n=15), 23% (n=119) participated in Head Start themselves as children (Table 4.3). At follow-up, 67% (n=321) of EHS children were still enrolled in EHS and 7% (n=50) of the non-EHS children were enrolled in EHS (Table 4.4). Children in both groups were enrolled in Head Start at the time of the 24-month follow-up (EHS: 8%, n=38; non-EHS: 5%, n=33).

At the follow-up interview, significantly more EHS than non-EHS children had an overall dental visit (81% vs. 68%, unadjusted OR = 3.5, 95% CI: 2.6, 4.6) (Table 4.5). When controlling for the baseline dental need, having had a dental visit at baseline, and the propensity score covariate, children enrolled in EHS had a higher odds of having a dental visit that those not in EHS within the same cluster (aOR=2.46, 95% CI: 1.7, 3.5) (Table 6). When describing these results in terms of marginal effects, EHS enrollment was associated with a 17.2 percentage point increase in the probability of having at least one dental visit compared to children not enrolled in EHS (95% CI: 10.7, 23.6).

Similarly, significantly more EHS than non-EHS children had a preventive dental visit (79% vs. 56%, unadjusted OR = 3.4, 95% CI: 2.6, 4.6) (Table 4.5). When controlling for the baseline dental need, having had a dental visit at baseline, and the propensity score covariate, children enrolled in EHS had a higher odds of having a preventive dental visit compared to the children not enrolled in EHS in the same cluster (aOR=2.59, 95% CI: 1.8, 3.6) (Table 4.6). With respect to marginal effects, EHS enrollment was associated with a 19.0 percentage point increase in the probability of having at least one preventive dental visit compared to children not enrolled in EHS (95% CI: 12.4, 25.6).

The number of children with treatment or emergency dental visits was less than 10% for both the EHS and non-EHS children (Table 4.5). No differences were found between children in the EHS and non-EHS groups with regards to adjusted estimates for treatment or emergency dental visits (OR 0.7, 95% CI: 0.40, 1.11 and OR –0.2, 95% CI: –1.25, 0.79 respectively) (Table 4.6). When describing these results in terms of marginal effects, EHS enrollment was associated with a three percentage point decrease in the probability of having at least one treatment dental visit compared to children not enrolled in EHS and a 0.4 percentage point decrease in the probability of having at least one emergency dental visit compared to children not enrolled in EHS (95% CI: –6.8, 0.8 and 95% CI: –2.3, 1.5, respectively).

By the time of the follow-up interview, children in EHS had more dental visits than non-EHS children (2.0 vs. 1.7, $P<0.01$) (Figure 4.2). After adjusting for baseline dental need, having a baseline dental visit, and the propensity score covariate, the mean number of dental visits among children in EHS was 1.35 (95% CI=1.17, 1.55) times the mean number of dental visits among children not enrolled in EHS within the same cluster (Table 4.7).

4.5. Discussion

This study is the first to demonstrate that EHS increases overall dental use for disadvantaged young children. Importantly, this increase is found for preventive visits, rather than treatment or emergency visits. Children in EHS not only have a greater odds of having a preventive dental visit, but also have more dental visits on average compared to similar disadvantaged children who are not enrolled in EHS. Notably, Medicaid-enrolled children in the control group had high use of preventive dental care (56%) compared to the 45–48% observed nationally in the Medicaid population.[81] Thus, the magnitude of improvements in preventive dental use for children in EHS (79%) is even more impressive. This increase in preventive oral care service use can contribute to long-term oral health outcomes.

Our study expands the literature on the impact of EHS on oral health outcomes beyond the 2002 Early Head Start Research and Evaluation Project (EHSREP), a large-scale, national randomized controlled trial that measured short- and intermediate-term impacts of EHS, and to our knowledge, the only other study on the effects of EHS enrollment on oral health.[4,59,60] Although oral health outcomes were not a focal point of the EHSREP study, the limited oral health data included in the study showed that EHS did not have a significant effect on dental use.[60,92] Unlike the EHSREP, we observed a significant and positive effect on dental use among children in EHS. This difference may reflect two important aspects of the time period (EHSREP collected data in 1996-1999): 1) the EHS was a new program beginning to develop performance standards and may not have prioritized oral health referral systems; and 2) professional guidelines for the age of the recommended first dental visit were evolving from age 3 to age 1 year. Additionally, the EHSREP study did not provide EHS programs additional training for oral health services as was done in the ZOE study in NC.

Our findings are similar to a large randomized controlled trial of Head Start, a public and comprehensive program similar to EHS for low-income children aged 3–5 years. The Head Start Impact Study (HSIS)[30] found that 69% of Head Start 3-year-old children received dental care in the first year of enrollment compared to 52% among similar children enrolled in school readiness initiatives other than Head Start.[20] A similar trend was seen in the 4 year-old cohort (73% vs. 57%).[20] Overall, the HSIS reported differences in magnitude that were similar to what we observed: 16 to 17 percentage points greater use of oral health services.[20]

A finding similar to the HSIS study was reported in a South Carolina Head Start Medicaid-matched retrospective cohort study.[95] Notably, although Head Start for children aged 3 to 5 years has been shown to improve use of dental care,[20,30] ours is the first study to observe the effect of an early childhood educational program from ages birth to 3 years old on dental use. The finding of increased preventive visits, but not treatment or emergency visits, is consistent with previous studies that show an association between early dental visits and reduced dental expenditures.[138]

Although children in EHS had more dental visits than non-EHS children (2.0 vs. 1.7), the number of dental visits over the two-year study period was less than recommended in professional guidelines set forth by the American Academy of Pediatric Dentistry, which is commonly a preventive dental visit every six months for a total of four visits during a two-year period.[142] Accordingly, the average child in EHS received half of the recommended preventive dental visits, and the average non-EHS child received even fewer dental visits in the ZOE study.

Interpreting the number of dental visits in this study is challenging because we do not have information about the clinical status of each child or the specific reason for each visit. Although the majority of children received preventive dental care, the larger number of dental visits in the EHS group compared to the non-EHS group can reflect more dental treatment, a positive outcome in a high-risk, high-need group of children. However, this outcome also can signal the failure of preventive services.

Marginalized negative binomial regression models were used for the first time in dental research to estimate the multiplicative increase in the mean number of dental visits among children in EHS relative to the mean number among children not enrolled in EHS. This model performed similarly to the traditional zero-inflated negative binomial model with respect to the Akaike information criterion (4340.1 and 4338.4, respectively). Furthermore, the sign and magnitude of their respective differential EHS effects were similar (data not shown). Nonetheless, the interpretations of these different model types are distinct. The marginalized negative binomial regression model was selected for analysis because interest was in the effect of EHS participation on the mean number of dental visits in the overall population of North Carolina children and not in some unobserved sub-group (i.e., latent class) of children assumed to be not-at-risk for having dental visits.

4.5.1. Limitations

There are several limitations to this study. First, lack of random assignment of parent-child dyads to EHS and control groups can result in biased effect estimates. However, we used a Medicaid-matched control group and used propensity scores during data analysis to overcome this limitation (Appendix 1, Appendix 2, Appendix 3). Second, the strong effect of EHS on preventive dental use may have been attenuated by the study design. We relied on self-reported data, which may overestimate preventive dental use.[143] However, this overestimation of the treatment effect resulting from self-report may be balanced by cross-over, that is children in the non-EHS group participated in alternative early childhood education programs and parent-child dyads in the control group participated in the EHS treatment. Such crossover leads to an underestimation of the effect of EHS on dental use. Third, it is possible that the models used in this study are subject to endogeneity, such as omitted variable bias.

Fourth, the oral health effects of EHS may be dependent on the type of EHS program, length of enrollment in EHS, and other characteristics of EHS programs that were not included in the models. EHS programs are heterogeneous, and the participation of each family in EHS is unique. Previous research on the effect of EHS has found variation based on the type of EHS program (home-based, center-based, mixed between home and center).[4] In this study, approximately 50% of children in EHS at baseline were enrolled in a home-based EHS program. This figure is comparable to national estimates, with 45% of families enrolled in home-based EHS in 2010.[61] It is possible that home-based EHS programs may have a greater or lesser effect on oral health compared to center-based EHS programs. Similarly, the family's length of enrollment in EHS and characteristics of EHS programs themselves (teachers, facilities, location, resources) may result in effect variation. EHS program design effects that may influence the EHS exposure, and therefore have an effect on the relationship between EHS and dental use.

Finally, the study was conducted in North Carolina. Notably, given dental service use by NC children receiving Medicaid insurance is higher than other states, our finding of an effect may underestimate the impact of EHS in other states with lower dental use in children on Medicaid.

4.5.2. Public Health Implications

This study answers an important question that has significant implications for children's oral health: whether early education programs can improve public health among our most vulnerable citizens. We conclude that comprehensive early childhood education programs like Early Head Start can increase dental use for the most disadvantaged children. To our knowledge, this is the first study to provide evidence that an early childhood program enrolling children younger than 3 years of age can increase preventive dental service use. Our findings suggest that programs such as EHS can address oral health disparities. Future research is needed to identify the attributes of EHS programs that are associated with improved children's dental use and, ultimately, oral health status. Identifying these attributes can inform the design of future federal and state programs that target vulnerable children and families.

4.5.3. Conclusion

Access to dental services for low-resource families with very young children prior to the onset of early childhood caries is challenging. EHS is a national program that can reach children from birth to age three.[28,29] Our findings illustrates that intervening in early childhood is effective at improving dental use. This finding is particularly timely and relevant, not only because of the high prevalence of dental caries in young children but also because EHS has been providing oral health services without evidence on its effectiveness in improving oral health outcomes. With full implementation of existing oral health performance standards, children in EHS can rise to even higher levels of preventive dental use compared to their peers.

Table 4.1. Baseline Child Characteristics of the ZOE Study Population, by Early Head Start (EHS) and Non–Early Head Start (Non-EHS) Groups

Characteristic	Overall n (N=1178)	Overall %*	EHS n (n=479)	EHS %	Non-EHS n (n=699)	Non-EHS %	p-value†
Age (months) [mean, SD (range)]	10.5, 4.7 (0-19)		10.6, 4.8 (0-19)		10.3, 4.6 (1-19)		0.297
Gender							0.246
Male	608	51.6%	257	53.7%	351	50.2%	
Female	570	48.4%	222	46.3%	348	49.8%	
Race and ethnicity							0.000
Non-Hispanic White	341	28.9%	84	17.5%	257	36.8%	
Non-Hispanic Black	313	26.6%	177	37.0%	136	19.5%	
Non-Hispanic Native American	19	1.6%	11	2.3%	8	1.1%	
Non-Hispanic Other, Single Race/Ethnicity	8	0.7%	1	0.2%	7	1.0%	
Non-Hispanic Other, Multiple Races/Ethnicities	113	9.6%	36	7.5%	77	11.0%	
Hispanic	378	32.1%	166	34.7%	212	30.3%	
Missing	6	0.5%	4	0.8%	2	0.3%	
Enrolled in public health insurance							0.441
Yes	1161	98.6%	470	98.1%	691	98.9%	
No	16	1.4%	8	1.7%	8	1.1%	
Missing	1	0.1%	1	0.2%	0	0.0%	
Physical, learning, or mental health limitations							0.159
Yes	43	3.7%	22	4.6%	21	3.0%	
No	1121	95.2%	453	94.6%	668	95.6%	
Don't know	14	1.2%	4	0.8%	10	1.4%	
Ever been homeless or not had a regular place to live							0.006
Yes	35	3.0%	22	4.6%	13	1.9%	
No	1140	96.8%	455	95.0%	685	98.0%	
Don't know	3	0.2%	2	0.4%	1	0.1%	
Number of children in the household under 5 years-old [mean, SD (range)]	1.6, 0.8 (1-7)		1.8, 1.0 (1-7)		1.4, 0.6 (1-5)		<0.001
Number of children in the household between 5 and 17 years-old [mean, SD (range)]	0.8, 1.1 (0-6)		1.0, 1.2 (0-6)		0.7, 1.1 (0-5)		0.0008
Number of adults in the household over 17 years-old [mean, SD (range)]	2.2, 1.0 (0-9)		2.1, 1.0 (0-7)		2.2, 1.0 (1-9)		0.0040

N=number of subjects in stratum, SD=standard deviation, *Due to rounding, percentages may not add to exactly 100%.

†The p-values are for chi-square tests or t-tests comparing EHS and non-EHS groups. For the chi-square test, "don't know" and "missing" values were excluded, and categories were combined if the expected count for a particular cell was less than five to satisfy the test's assumptions.

Table 4.2. Baseline Parent Characteristics of the ZOE Study Population, by Early Head Start (EHS) and Non–Early Head Start (Non-EHS) Groups

	Overall		**EHS**		**Non-EHS**		**p-value**†
Characteristic	n (N=1178)	%*	n (n=479)	%	n (n=699)	%	
Age (years) [mean, SD (range)]	28.2, 7.1 (18-70)		27.9, 7.1 (18-70)		28.5, 7.1 (18-62)		0.176
Male	26	2.2%	9	1.9%	17	2.4%	0.529
Race and ethnicity							<0.001
Non-Hispanic White	417	35.4%	115	24.0%	302	43.2%	
Non-Hispanic Black	321	27.2%	177	37.0%	144	20.6%	
Non-Hispanic Native American	27	2.3%	16	3.3%	11	1.6%	
Non-Hispanic Other, Single Race/Ethnicity	10	0.8%	1	0.2%	9	1.3%	
Non-Hispanic Other, Multiple Race/Ethnicity	56	4.8%	24	5.0%	32	4.6%	
Hispanic	342	29.0%	143	29.9%	199	28.5%	
Missing	5	0.4%	3	0.6%	2	0.3%	
Spanish Language	290	24.6%	124	25.9%	166	23.7%	0.403
Nativity							0.347
United States	855	72.6%	343	71.6%	512	73.2%	
Mexico	230	19.5%	102	21.3%	128	18.3%	
Central America	62	5.3%	20	4.2%	42	6.0%	
Other	31	2.6%	14	2.9%	53	7.6%	
Marital Status							<0.001
Single/Never Married	564	47.9%	261	54.5%	303	43.3%	
Married/Common Law Marriage/Cohabitate	534	45.3%	184	38.4%	350	50.1%	
Separated/Divorced/Widowed	75	6.4%	30	6.3%	45	6.4%	
Other/Missing	5	0.4%	4	0.8%	1	0.1%	
Education							0.014
Some high school or less	324	27.5%	151	31.5%	173	24.7%	
High school graduate or GED	303	25.7%	126	26.3%	177	25.3%	
Some college or 2-year college degree	438	37.2%	167	34.9%	271	38.8%	
English: 4 year college degree or more, Spanish: 6 year college degree or more	111	9.4%	34	7.1%	77	11.0%	

Don’t know/Missing	2	0.2%	1	0.2%	1	0.1%	
Government Support							
Welfare, Work First, TANF, cash assistance	103	8.7%	62	12.9%	41	5.9%	<0.001
Unemployment benefits or disability insurance	177	15.0%	80	16.7%	97	13.9%	0.183
Food Stamps	814	69.1%	381	79.5%	433	61.9%	<0.001
Special Supplemental Food Program for Women, Infants, and Children	1062	90.2%	434	90.6%	628	89.8%	0.589
Child support/Alimony	159	13.5%	81	16.9%	78	11.2%	0.004
Child care subsidy or Education assistance	186	15.8%	106	22.1%	80	11.4%	<0.001
Housing assistance	127	10.8%	78	16.3%	49	7.0%	<0.001
Social Security	163	13.8%	68	14.2%	95	13.6%	0.772
Medicare or Medicaid	980	83.2%	383	80.0%	597	85.4%	0.026
Medicaid	520	44.1%	234	48.9%	286	40.9%	0.005
Employment							
Full Time (30+ hours/week)	236	20.0%	104	21.7%	132	18.9%	0.227
Part Time	211	17.9%	78	16.3%	133	19.0%	0.234
Looking for work	325	27.6%	143	29.9%	182	26.0%	0.144
In school/training	259	22.0%	132	27.6%	127	18.2%	<0.001
Keeping House	765	64.9%	301	62.8%	464	66.4%	0.228

N=number of subjects in stratum, SD=standard deviation, *Due to rounding, percentages may not add to exactly 100%.
†The p-values are for chi-square tests or t-tests comparing EHS and non-EHS groups. For the chi-square test, “don’t know” and “missing” values were excluded, and categories were combined if the expected count for a particular cell was less than five to satisfy the test’s assumptions.

Table 4.3. Description of Exposure to Early Childhood Programs for the Non–Early Head Start (Non-EHS) Group in the ZOE Study Population (N=699)

	Baseline		**24-month Follow-up**	
Characteristic	n	%	n	%
Child Characteristics				
Enrollment in a non-EHS Childcare				
Yes	113	16.2%	240	34.3%
No	585	83.7%	458	65.5%
Missing (b) / Don't know (f)	1	0.1%	1	0.1%
Program Type				
Child care, Preschool, or Day care Center	73	10.4%	164	23.5%
Family-based child care outside of the home	11	1.6%	4	0.6%
Nanny or Relative childcare inside the home	2	0.3%	1	0.1%
Other	1	0.1%	0	0.0%
Don't know	0	0.0%	1	0.1%
Missing	612	87.6%	529	75.7%
Enrolled in a non-EHS Childcare at 24-month Follow-up				
Yes	87	12.4%	172	24.6%
No	26	3.7%	71	10.2%
Missing (b) / Don't know (f)	586	83.8%	456	65.2%
Enrollment in EHS				
Yes			61	8.7%
No			626	89.6%
Don't know			12	1.7%
Months of Enrollment in EHS [mean, SD (range)] n=61			9.6, 7.9 (0-30)	
Parent Characteristics				
Enrollment in EHS Prenatal Program				
Yes			15	2.1%
No			672	96.1%
Don't know			12	1.7%
Volunteered or Worked at EHS				
Yes			47	6.7%
No			652	93.3%
Heard of EHS or Head Start				
Yes	526	75.3%		
No	171	24.5%		
Don't know	1	0.1%		
Missing	1	0.1%		
Enrollment in Head Start as a Child, Among Those Who Heard of EHS or Head Start (n=526)				
Yes	119	22.6%		
No	368	70.0%		
Don't know	39	7.4%		
Familiarity with EHS or Head Start, Among Those Who Heard of EHS or Head Start (n=526)				
Very familiar	82	15.6%		
Somewhat familiar	218	41.4%		
Not very familiar	225	42.8%		
Don't know	1	0.2%		

n= number of subjects in stratum, SD=standard deviation.
b=baseline interview, f=24-month follow-up

Table 4.4. Description of Exposure to Early Childhood Programs and Public Health Insurance for the ZOE Study Population at 24-month follow-up, by Early Head Start (EHS) and non–Early Head Start (non-EHS) Groups

	Overall		**EHS**		**Non-EHS**		**p-value**†
Characteristic	n (N=1178)	%	n (n=479)	%	n (n=699)	%	
EHS Enrollment at 24-month Follow-up							0.211
Yes	371	31.5%	321	67.0%	50	7.2%	
No	175	14.9%	158	33.0%	17	2.4%	
Don't know	632	53.7%	0	0.0%	632	90.4%	
Head Start Enrollment at 24-month Follow-up							<0.001
Yes	71	6.0%	38	7.9%	33	4.7%	
No	786	66.7%	120	25.1%	666	95.3%	
Missing	321	27.2%	321	67.0%	0	0.0%	
Enrollment in public health insurance such as Medicaid, Health Check, Health Choice, or the State Children's Health Insurance Plan							<0.001
Both Baseline and Follow-up	1105	93.8%	462	96.5%	643	92.0%	
Baseline Only	51	4.3%	5	1.0%	46	6.6%	
Follow-up Only	2	0.2%	1	0.2%	1	0.1%	
Neither Baseline nor Follow-up	14	1.2%	7	1.5%	7	1.0%	
Missing	6	0.5%	4	0.8%	2	0.3%	

n=number of subjects in stratum, SD=standard deviation.
†The p-values are for chi-square tests comparing EHS and non-EHS groups. For the chi-square tests, "don't know" and "missing" values were excluded, and categories were combined if the expected count for a particular cell was less than five to satisfy the test's assumptions. The chi-square test for enrollment in public health insurance was performed on the following three categories: Both Baseline and Follow-up, Either Baseline and Follow-up, and Neither Baseline nor Follow-up.

Table 4.5. Unadjusted Analysis on the Impact of Early Head Start (EHS) Enrollment on Overall, Preventive, Treatment, and Emergency Dental Use After 24 Months.

Number of Parent-child Dyads who Self-reported at Least One Dental Visit	Overall (N=1178)	EHS (n=479)	Non-EHS (n=699)	OR (95% CI)[§]
Overall	801 (68%)	388 (81%)	413 (59%)	3.5 (2.6, 4.6)
Preventive	773 (66%)	380 (79%)	393 (56%)	3.4 (2.6, 4.6)
Treatment	103 (8%)	40 (8%)	63 (9%)	0.9 (0.6, 1.4)
Emergency	24 (2%)	8 (2%)	16 (2%)	0.7 (0.3, 1.7)

[§]Odds ratio estimate with 95% confidence interval for the unadjusted random intercept models. A random effect was used to adjust for clustering within each of the 25 EHS programs.

Table 4.6. Logit Models on the Effect of Early Head Start Enrollment on Having One or More Dental Visit (N=1,178)

	Overall	**Preventive**	**Treatment**	**Emergency**
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Early Head Start	2.46** (1.74, 3.48)	2.59** (1.84, 3.63)	0.67 (0.40, 1.11)	–0.23 (–1.25, 0.79)
Needed Any Dental Care at Baseline	8.26** (3.90, 17.49)	7.09** (3.60, 13.99)	1.91* (1.09, 3.36)	1.57** (0.67, 2.47)
Any Dental Visits at Baseline	2.68* (1.19, 6.01)	2.49* (1.15, 5.38)	3.05** (1.47, 6.34)	0.95 (–0.58, 2.48)
Propensity Score	2.41* (1.02, 5.73)	1.89 (0.82, 4.39)	2.00 (0.56, 7.12)	–2.28 (–5.05, 0.48)
Constant	0.96 (0.63, 1.47)	0.91 (0.61, 1.37)	0.07** (0.04, 0.12)	–3.34** (–4.28, –2.40)
Random Effect, σ_b	0.65 (0.43, 0.98)	0.60 (0.39, 0.92)	0.29 (0.10, 0.84)	NA

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval

Note: With the exception of emergency visits that were infrequent, models included random effects for each of the 25 Early Head Start program clusters.

Table 4.7. Marginalized Zero-Inflated Negative Binomial Model on the Effect of Early Head Start (EHS) on the Mean Increment in Dental Visits (N=1,178)

	Parameter	Parameter Estimate	Model-based Standard Error	Empirical Standard Errors	Odds Ratio†	95% Confidence Interval†
Probability of Having an Excess Dental Visit						
EHS	α_1	–1.23**	0.22	0.25	0.29	0.19, 0.46
Propensity Score	α_2	0.029	0.56	0.56	1.03	0.32, 3.29
Needed Dental Care at Baseline	α_3	–4.98	7.78	11.45	0.01	0.00, 66529.45
Had a Dental Visit at Baseline	α_4	–1.20*	0.45	0.66	0.30	0.12, 0.77
Constant	α_0	–0.59**	0.20	0.26	0.55	0.37, 0.84
Overall Mean Number of Dental Visits					Rate Ratio†	
EHS	β_1	0.30**	0.068	0.063	1.35	1.17, 1.55
Propensity Score	β_2	0.30	0.16	0.16	1.35	0.98, 1.87
Needed Dental Care at Baseline	β_3	0.53**	0.040	0.061	1.69	1.56, 1.84
Had a Dental Visit at Baseline	β_4	0.42**	0.089	0.090	1.52	1.26, 1.83
Constant	β_0	0.31**	0.092	0.090	1.36	1.13, 1.65
Random Effects variance components						
Standard deviation of excess zeros intercept	σ_1	0.69**	0.13	0.014		
Standard deviation of mean model intercept	σ_2	0.28**	0.061	0.054		
Correlation of random intercepts	ρ	–0.94**	0.078	0.061		
Overdispersion parameter	φ	0.039	0.019	0.023		

* P<0.05, ** P<0.01, CI=confidence interval, †Odds ratios, rate ratios and confidence intervals are based on the model's empirical standard errors.

Note: Models included random effects for each of the 25 EHS program clusters.

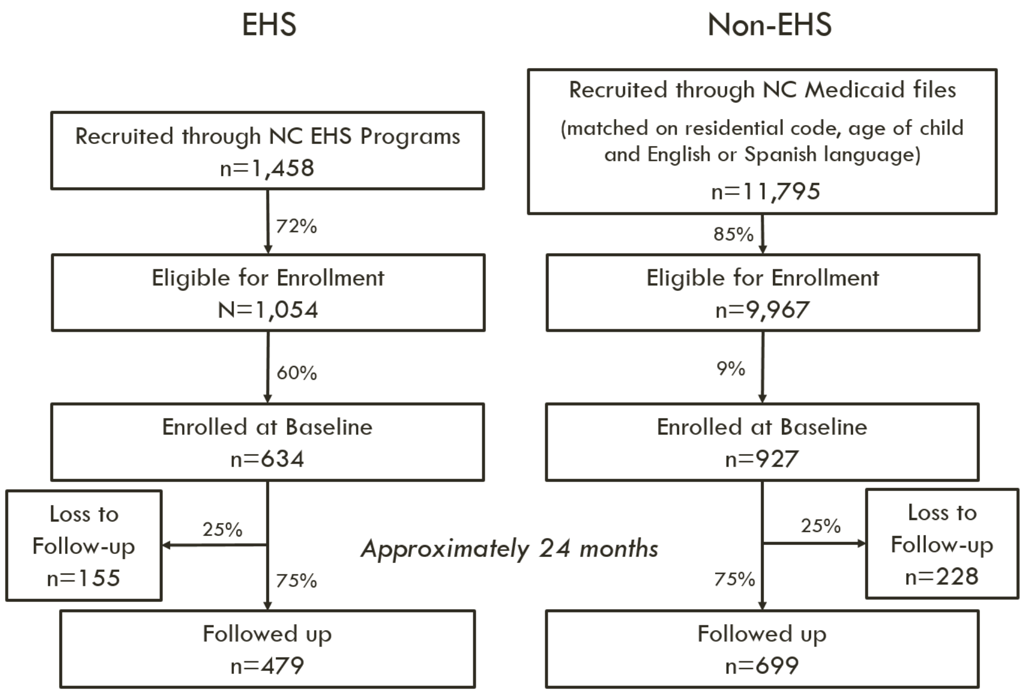

Figure 4.1. Data collection for the Zero Out Early Childhood Caries study by EHS group.

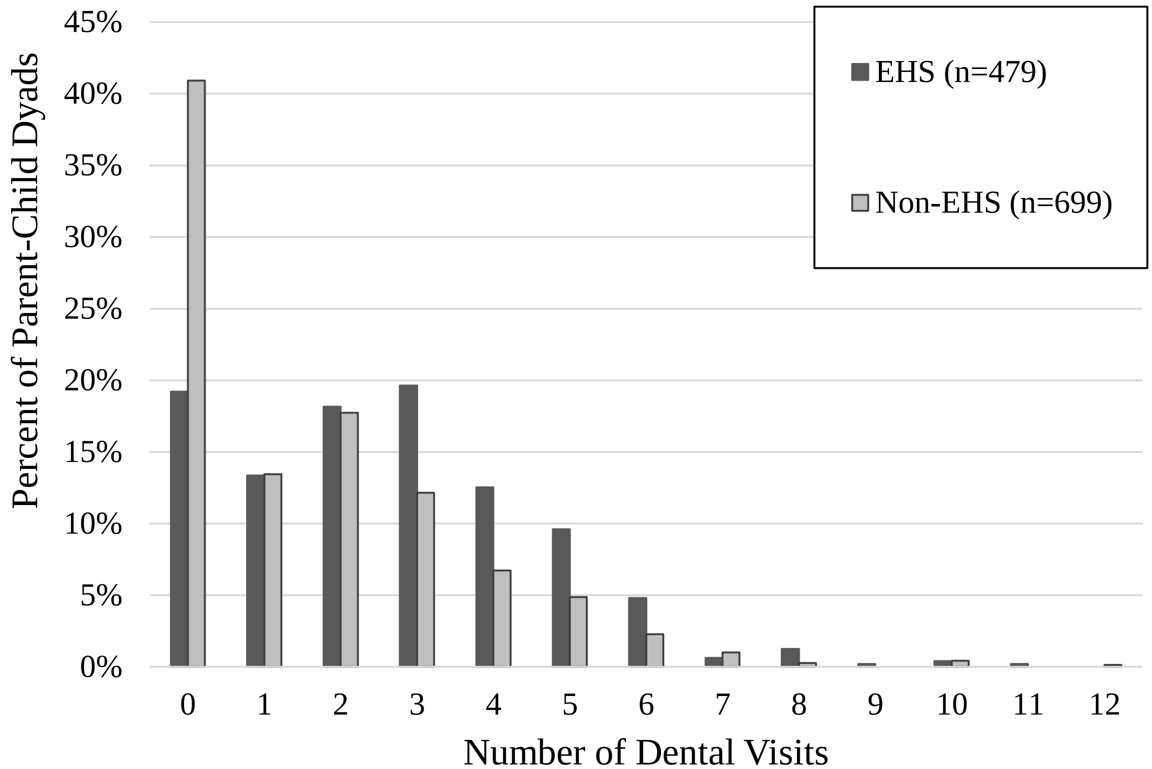

Figure 4.2. Percent distribution of the number of dental visits by EHS group.

Total Sample: N=1,178, mean 2.0 (SD=2.0), median 2, Range 0-12. *EHS Group:* n=479, mean 2.6 (SD=2.0), median 2, Range 0-11. *Non-EHS Group:* n=699, mean 1.7, (SD=2.0), median 1, Range 0-12.

CHAPTER 5. AIM 2: ENROLLMENT IN EHS, PEDIATRIC DENTAL USE AND ORAL HEALTH-RELATED QUALITY OF LIFE

5.1. Overview

The lives of young children and their families can be disrupted by dental disease and its treatment. We examined the effect of North Carolina Early Head Start (EHS) on oral health-related quality of life (OHRQoL) and tested whether dental use mediates the relationship between EHS and OHRQoL. We interviewed caregivers of 479 EHS and 699 Medicaid-matched children at baseline when the child was 9 months old and 24 months later. OHRQoL was measured using the Early Childhood Oral Health Impact Scale (ECOHIS), a 0–52 point scale with higher scores indicating worse OHRQoL. Using a logit model, we estimated the effect of EHS on OHRQoL prevalence, defined as the probability of having any negative impact on OHRQoL at 24-month follow-up (ECOHIS≥1). Mediation analysis for dental use was performed on the logit model using the counterfactual framework analysis. We used a marginalized two-part semicontinuous model to estimate the effect of EHS on OHRQoL severity, defined as the overall mean ECOHIS scores at follow-up. For all models, we included random effects for the EHS program clusters and controlled for baseline ECOHIS, survey language (English, Spanish) and a propensity score covariate derived from socio-demographic characteristics and EHS enrollment criteria. At 24-month follow-up, the unadjusted prevalence [EHS=37% (172/468), non-EHS=45% (312/688)] and severity [EHS=1.59 (SE=3.34), non-EHS=2.11 (SE=3.85)] of ECOHIS scores were significantly different between EHS and non-EHS families (*P*<0.05). In the adjusted logit model, EHS families had lower odds of having any negative impacts to their OHRQoL compared to non-EHS children (OR=0.65; 95% CI=0.48, 0.87). In the mediation analysis, any dental use had a mediation effect in the undesired direction with a 2% increase in the probability of any negative impact to OHRQoL (95% CI=0.72%, 3.6%). Even with the higher dental use by EHS participants, the probability of any negative impact to OHRQoL was eight percentage points lower if an individual were moved from the Non-EHS group to the EHS group (95% CI= –14%, –1.2%). The ratio of adjusted mean severity scores for EHS to Non-EHS children was not statistically significant (Mean Ratio=0.82; 95% CI=0.59, 1.15). This study is the first to demonstrate that families with young children enrolled in EHS report improved OHRQoL compared to similar disadvantaged families. EHS participation significantly reduced the odds of having any negative impacts to OHRQoL, an important finding due to its high prevalence. Dental use plays a role in the relationship between EHS and OHRQoL. These results call attention to both the effectiveness of improving quality of life for low-resource families through early childhood education program.

5.2. Introduction

Oral health–related quality of life (OHRQoL) can be defined as “the impact of oral disorders on aspects of everyday life that are important to patients and persons, with those impacts being of sufficient magnitude, whether in terms of severity, frequency or duration, to affect an individual’s perception of their life overall.”[144] OHRQoL is not only “the absence of negative impacts of oral conditions on social life,” but also “a positive sense of dentofacial self-confidence.”

According to the World Health Organization, “oral health affects general health by causing considerable pain and suffering and by changing what people eat, their speech and their quality of life and well-being.”[145] The physical and psychological influences of oral conditions may have a particularly negative effect on children, who need nutrition and sleep for growth and development, are developing speech, have fewer coping skills for pain and discomfort than adults, and are developing social skills that may be affected by their appearance.[28,97] Dental caries, the most common dental disease in childhood, is associated with worse OHRQoL,[104-108,146] especially when it is left untreated.[107]

The treatment of extensive dental caries for young children can be associated with high treatment costs and distress to the family, resulting in additional physical and psychological influences on the child and family.[28,97] Studies have found that dental treatment under general anesthesia is associated with improved OHRQoL,[100-103] but outcomes can vary according to characteristics of families seeking treatment. For example, both socioeconomic status and oral health literacy are associated with OHRQoL.[17,111] The impact of clinical conditions on OHRQoL also can extend beyond treatment itself to the process of accessing treatment, which in and of itself can have a negative impact on low-income families.[9,147]

Early Head Start (EHS) is a national social program designed to improve the lives of low-income families and children birth to 3 years of age.[1] Given its target population, EHS may well improve OHRQoL of families at greatest risk for poor oral health[6] because it provides comprehensive family services and support; improves social and cognitive development long-term;[2-5] and operates according to comprehensive Federal performance standards that integrate oral health.[7] Yet, to the authors' knowledge, the effect of EHS on OHRQoL has not been examined, other than a single cross-sectional analysis using data from the current study.[148]

The purpose of this study is to evaluate whether participation in EHS has an impact on the OHRQoL; we hypothesize that EHS will improve the OHRQoL in these at-risk children.[104-108] In addition, we examine whether dental use mediates the effect of EHS on OHRQoL. We expected dental use to mediate the effect of EHS on OHRQoL because of previous work in which we observed a relationship between EHS and improved dental use (Aim 1) and the existing literature on the association of dental treatment with changes in OHRQoL.[100-103] We hypothesize that EHS activities connect EHS parent-child dyads with dental providers, which may increase dental use in compliance with EHS oral health performance standards, reduce oral health symptoms and improve function thereby helping to improve OHRQoL.

5.3. Methods

5.3.1. Overview of Study Design and Data Source

We used data collected as part of the Zero Out Early Childhood Caries (ZOE) study, a pre-post 24-month longitudinal prospective non-randomized study to determine the effect of EHS on oral health outcomes of young children. In the ZOE study, the EHS group is compared with a control group of Medicaid-enrolled children not enrolled in EHS. Teachers and staff in EHS programs received minimal training in oral health and communication techniques to bolster awareness of EHS performance standards and facilitate their implementation. The study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill and by the NC Head Start State Collaboration Office.

5.3.2. Study Population

Subjects were recruited using a three-step process described in detail in a previous publication:[148] (1) enrollment of EHS programs, (2) enrollment of parent-child dyads within EHS programs, and (3) enrollment of community-matched parent-child dyads to serve as controls. In Step 1, all North Carolina EHS programs were invited to participate; all except one were enrolled. In Step 2, parents of EHS children <19 months of age from all participating EHS programs were recruited by the research team. In Step 3, Medicaid-enrolled children of the same age, language, and ZIP codes and their parents were recruited as the control group through direct mailings from the North Carolina Medicaid program. Our final sample included EHS and non-EHS parent-child dyads clustered within 25 of the 26 North Carolina EHS programs.

Trained personnel conducted in-person, computer-assisted, structured interviews with parents of eligible children at baseline and approximately 24 months later (the time children aged out of the EHS program). The outcome variable of interest, OHRQoL, was included within the one-hour interviews at both baseline and follow-up. Interviews were conducted in English or Spanish, as appropriate.

5.3.3. Conceptual Framework

We used a general health-related quality of life conceptual model developed by Ferrans and colleagues (2005) to study the impact of EHS on OHRQoL.[149] In this model, both individual and environmental characteristics affect factors (biological function, symptoms, functional status, and general health perceptions) that lead to health-related quality of life. We consider early childhood education programs to be part of the environmental characteristics domain that can affect health-related quality of life for the child. For example, EHS provides multiple services for the child and parent (e.g., education, nutrition, tooth-brushing and dental healthcare referrals) that can impact symptoms, functional status and general health perceptions for the child. These direct effects on the child and family are support by an early education and childcare framework proposed by Friedman-Krauss and Barnett.[119]

5.3.4. Variables

The main independent variable, Early Head Start (EHS) enrollment, was supplied by EHS staff and confirmed by the parent at the baseline enrollment screening and interview. It was treated as a binary variable in the analysis.

The dependent variable, OHRQoL, was measured using the 13-item Early Childhood Oral Health Impact Scale (ECOHIS), the most frequently used scale for assessing OHRQoL among preschool children and families.[21,111] ECOHIS items queried parents about the frequency of lifetime impacts of dental problems or treatments as: 0 = never; 1 = hardly ever; 2 =

occasionally; 3 = often; 4 = very often. The total score across the 13 items ranged from 0 (best) to 52 (worst) OHRQoL. In addition, separate sub-scores were calculated for the 9 items related to the child (range from 0 to 36) and 4 family impact items (range from 0 to 16).[21] We excluded observations with missing responses to > 2 child items or 1 family item (n=22); otherwise, we performed simple imputation of the average of the remaining items for missing values (baseline n=128, follow-up n=49).

The dental literature recommends the use of the following parameters when studying OHRQoL: prevalence, severity and extent.[150-157] These three scoring formats provide complimentary information that can improve the interpretation of quality of life data. ECOHIS prevalence is defined as the probability of having any negative impacts on OHRQoL at follow-up (ECOHIS≥1). ECOHIS severity is defined as the mean of all individual ECOHIS scores at follow-up. ECOHIS extent is defined as the mean of individual ECOHIS scores at follow-up conditional on having any negative OHRQoL impacts (ECOHIS≥1) at follow-up.

We included two baseline covariates in the models because of their potential impact on follow-up OHRQoL: baseline ECOHIS score and survey language. The Spanish language version of ECOHIS has not been as widely used or tested for its psychometric properties as the English version, but its construct validity and internal consistency was demonstrated in a previous study.[158] A cross-sectional analysis of baseline interviews in the ZOE study found language to have an influence on OHRQoL scores, with Spanish-speaking parents reporting a lower severity of ECOHIS impacts.[148] Because of differences between the Spanish- and English-speaking families in the baseline scores, we included interview language (Spanish or English) in the analyses for the current study.

The potential mediator, overall dental use, was a binary variable defined as a positive response to the question of the parent, “Has your child ever been to a dentist or dental clinic?” determined at follow-up.

5.3.5. Analytical approach

We used descriptive statistics to explore the distribution of the children’s demographic characteristics by EHS enrollment and describe the distribution of the overall ECOHIS scores by EHS group.

Overview of Regression Modeling. We used an as-assigned “intent to treat” analysis of EHS because it is more generalizable and estimates the impact of EHS policies as implemented. For all analytical models, we controlled for clustering of subjects within EHS programs (n=25) and estimated the impact of EHS on OHRQoL using random effects models. Because of the random effect, prevalence is defined on the aggregate residential ZIP code level as the probability that a representative child in EHS (or Non-EHS) in a residential code has any negative impact to OHRQoL. We controlled for baseline OHRQoL severity, survey language, and directly adjusted for a generalized boosted model propensity score covariate.[125]

5.3.6. Logistic Regression Model for Any Negative Impact to OHRQoL

We used logistic regression with random effects to examine the effect of the binary independent variable, EHS, on ECOHIS prevalence at follow-up (ECOHIS≥1). The model (EQN 1 of Chapter 3.6) has the following independent variables:

x_{1i} = Early Head Start enrollment (treatment indicator, dichotomous)

x_{2ij} = any negative impact to OHRQoL (ECOHIS≥1) at baseline (dichotomous)

x_{3ij} = Survey language (dichotomous: Spanish, English)

x_{4ij} = Generalized boosted model propensity score (continuous)

We estimate the EHS cluster-specific odds ratio, e^{β_1}, to be the odds of having any negative impact to OHRQoL (ECOHIS≥1) by a child in EHS relative to the odds for a child not in EHS, conditional on the EHS and non-EHS child being from the same geographic area.

Additionally, the marginal effect of EHS was determined using the method of recycled predictions, which generated the average predicted probabilities of having any negative impact to OHRQoL after changing all observations to being enrolled in EHS, and repeating the process after changing all observations to not being enrolled in EHS.[141] Standard errors and 95% confidence intervals for the marginal percentage point difference were calculated using the delta method. The continuous independent variable, propensity score, passed two tests for model misspecification: Pregibon's Link Test and Hosmer and Lemeshow's goodness-of-fit test. Data analyses for the logit models were conducted using STATA 14 (StataCorp LP, College Station, TX).

5.3.7. Mediation Test for Overall Dental Use

We tested whether any dental use mediated the relationship between EHS and OHRQoL prevalence with a single mediation model based on EQN (1) using causal mediation analysis in Chapter 3.6.[134] This mediation approach was performed because it is not limited to a particular statistical model and therefore is applicable to a wide range of situations.[134] In our study, it allowed for the analysis of overall dental use as a mediator using the full logistic regression model for any negative impact to OHRQoL with random effects (Chapter 3.7).

The mediation effect was measured using three parameters: average causal mediation effect (ACME), average direct effects (ADE) and total effects. The ACME is the indirect effect of the treatment (EHS) on the outcome (ECOHIS prevalence) through the mediating variable (dental use).[136] The ADE is the effect of the treatment (EHS) on the outcome (ECOHIS prevalence) while holding the mediator (dental use) constant at the level that would be realized under the treatment (EHS or non-EHS) participation. The total effect is sum of the average causal mediation and average direct effects.[134] We used the software, mediation, version 4.4.5,[135] which is freely available as an R package at the Comprehensive R Archive Network and has been used in the literature for mediation analyses.[159-163] Confidence intervals were obtained using bootstrap resampling with 1,000 replications.

5.3.8. Two-Part Model for Overall Mean ECOHIS Score

We used a marginalized semicontinuous two-part model with random effects to estimate the effect of EHS on ECOHIS severity scores at follow-up.[127-129] The two-part model couples the logistic model for any negative impact to OHRQoL in the previous section with an exponential model to assess covariate effects on overall mean ECOHIS, thus providing straightforward interpretation while accounting for skewed distributions such as those with a significant number of zeros.[128] This study is the first application of the marginalized semicontinuous two-part model with random effects. The difference between the marginalized semicontinuous two-part model and the traditional semicontinuous two-part model is that the former models the overall mean of ECOHIS that includes zeros while the latter models the mean of ECOHIS of the positive responses only. Our model, described in Chapter 3.6, combines the marginalized semicontinuous two-part model[128] with random effects[127] for a continuous outcome in the second part of the model having a generalized gamma distribution.[129] Maximum likelihood estimation of the semicontinuous model was performed using SAS/STAT® version 9.4 (SAS, 2013) as described in Appendix 5.

5.4. Results

The study enrolled 1,567 child-parent dyads, an estimated 60% of the eligible EHS sample and 9% of the non-EHS comparison sample. Follow-up interviews were completed with

468 parent-child dyads from EHS programs and 688 non-EHS controls. Baseline characteristics of the EHS and non-EHS children were similar with respect to age, gender, enrollment in public health insurance, and physical, learning, or mental health limitations; however, more children in EHS had been homeless and were minority race and ethnicity compared to children not enrolled in EHS (Table 5.1). On average, children in EHS also had a greater number of children in the household and fewer adults in the household compared to non-EHS children (Table 5.1).

5.4.1. Effect of EHS on ECOHIS Prevalence

At 24-month follow-up interview (children were ~36 months), ECOHIS prevalence (ECOHIS≥1) was lower for EHS compared to non-EHS families (37% vs. 45%, $P<0.01$), indicating that EHS families were less likely to experience negative impacts on their OHRQoL (Table 5.2). We found a statistically significant difference at follow-up in the unadjusted prevalence between EHS and non-EHS groups for overall child impact scores, child symptoms, child psychology and parent distress (Table 5.2).

When controlling for baseline ECOHIS score, survey language and the propensity score covariate, children enrolled in EHS had a lower odds of having any negative impacts to their OHRQoL compared to non-EHS families within the same cluster (aOR=0.65; 95% CI=0.48, 0.87) (Table 5.3). When describing these results in terms of marginal effects, EHS enrollment was associated with a 10.0 percentage point (95% CI: –16.8, –3.2) decrease in the probability of having any negative impact to OHRQoL compared to children not enrolled in EHS.

5.4.2. Dental Use as a Mediator of EHS Effect on Any Negative Impact to OHRQoL

The outcome (ECOHIS≥1 at follow-up) used in the mediator analysis is binary, so all estimated effects are expressed as the increase in probability that the participant reports any negative impact to OHRQoL at follow-up. The estimated total effect was –0.078 (95% CI= –0.14, –0.012). Thus, on average, the probability of any negative impact to OHRQoL is eight percentage points lower if the individual were moved from the Non-EHS group to the EHS group (Table 5.4, Figure 5.1, Figure 5.2).

The estimated ACME was 0.02 (95% CI= 0.0072, 0.036), which indicates that, on average, the probability of any negative impact to OHRQoL is two percentage points higher if everyone had the dental use they would have received if enrolled in EHS versus not being in EHS, if all other aspects of their treatment assignment were unchanged (Table 5.4, Figure 5.1, Figure 5.2). According to the ACME averaged within the Non-EHS group, an individual in the Non-EHS who is changed only to receive the dental use they would have had if they were in EHS (but receives no other aspects of EHS exposure) would have their probability of any negative impact to OHRQoL increase by 2 percentage points on average (Table 5.4).

The estimated ADE was –0.099 (95% CI= –0.17, –0.031), which can be interpreted as follows: On average, the probability of any negative impact to OHRQoL is ten percentage points lower if the individual were moved from the Non-EHS group to the EHS group, while keeping dental use fixed at the level that would be experienced if the individual retained their original treatment status (Table 5.4, Figure 5.1, Figure 5.2). For the ADE averaged specifically within the Non-EHS group, if an individual's dental use were held constant at the observed value, but the treatment group were changed to EHS in all other respects, then the probability of any negative impact to OHRQoL would be ten percentage points lower on average (Table 5.4).

5.4.3. Effect of EHS on ECOHIS Severity

The plot of the distribution of the ECOHIS scores at follow-up for the EHS and non-EHS groups are displayed in Figure 5.3. At follow-up, families in EHS had lower ECOHIS severity scores than non-EHS families (1.59 vs. 2.11, $P<0.05$) (Table 5.2). From baseline to follow-up, ECOHIS severity decreased from 3.53 (SE=4.64) to 1.90 (SE=3.66) (Table 5.2). Although the overall severity decreased over time, several domains remained relatively unchanged: child function, overall family score and parent distress (Table 5.2).

Differences between EHS and non-EHS groups were found in unadjusted severity scores for child impacts overall and for child symptoms and child psychology domains ($P<0.05$) (Table 5.2). Similar to prevalence, parent distress differed between the EHS and non-EHS groups ($P<0.05$) (Table 5.2). After adjusting for baseline ECOHIS score, survey language and the propensity score covariate, overall mean ECOHIS severity scores among children in EHS were not significantly different from those among children not enrolled in EHS within the same cluster (adjusted mean ratio=0.82; 95% CI=0.59, 1.15) (Table 5.5). Similarly, there was no significant difference between the EHS and non-EHS groups in adjusted ECOHIS extent scores (aRR=0.017; 95% CI= -0.18, 0.21) (Table 5.6).

5.5. Discussion

The current study has three important findings. First, families with children enrolled in EHS experience fewer negative impacts on OHRQoL from their children's dental disease than their counterparts not enrolled in EHS. Second, dental use, which is improved through EHS participation, mediated some of the EHS intervention effects on OHRQoL, but in an unexpected way: worse indirect effect but not of sufficient size to counterbalance the direct effect of EHS on improved OHRQoL. Finally, the average number of impacts from child dental experiences are similar in EHS and non-EHS groups.

5.5.1. Effect of EHS on OHRQoL

EHS participation significantly reduced the odds of having any negative impacts to OHRQoL. This finding is important because of the high prevalence of negative impacts to OHRQoL observed in this study: 37% in EHS families and 45% in non-EHS families. The influence of EHS on ECOHIS can be explained by the theoretical pathways put forth in the conceptual model proposed by Ferrans and colleagues (2005): EHS staff provide a supportive environment that reduces oral health-related symptoms, and improves functional status and general health perceptions for the child. This supportive environment includes daily oral health practices by EHS staff, such as tooth-brushing, oral health education to families, and support services to facilitate and encourage child visits to dental practices.[1]

The plot of the distribution of the ECOHIS scores at follow-up is different for the EHS and non-EHS groups. Notably, there is a difference in the proportion of EHS and non-EHS families with an ECOHIS score of 0, which explains the unadjusted and adjusted difference in ECOHIS prevalence (ECOHIS$\geq$1) between the EHS and non-EHS groups (Figure 5.3). While the severity scores are different between the EHS and non-EHS groups in the unadjusted analysis, this difference is no longer statistically significant in the adjusted analysis. The absence of a statistically significant difference in the adjusted severity scores between EHS and non-EHS children may reflect the low overall mean scores at follow-up when the children were approximately 36 months old. The unadjusted mean ECOHIS scores were less than 3 for both the EHS and non-EHS groups while the ECOHIS score has a range from 0 to 52. This result shows that families in this study reported a small number of negative impacts to OHRQoL.

Low ECOHIS severity scores are preferred because they indicate fewer and less severe impacts of oral health problems. The low scores observed in this study are particularly noteworthy considering that the study sample was drawn from a non-care-seeking Medicaid population. Low ECOHIS severity scores also were found in other non-care seeking populations of children slightly older than those in this study.[17,164]

While the impact of dental problems on OHRQoL was generally low, one notable trend is that the mean ECOHIS score decreased from 3.53 per child overall at the baseline interview to

1.90 per child 24 months later. Similarly, another study observed a decrease in OHRQoL severity but over an 11-month period, for children birth to 6 years in Australia.[165,166] Some potential explanations for a decrease in scores for young children may be related to teething as infants, decreased worry and distress in parents as they obtain more information and experience in child rearing, and less constant caretaking by the parent with the child's enrollment in childcare programs.

5.5.2. Dental Use as a Mediator of EHS Effect on OHRQoL

Previously we found that EHS enrollment had a positive effect on dental use (Aim 1). In the current study, we extend those findings by examining whether dental use mediates the effect of EHS on OHRQoL. The overall ACME in the mediation analysis showed that dental use was a statistically significant and positive mediator on the impact of EHS on the prevalence of OHRQoL impacts.

A number of studies might provide insights into the unexpected findings about the mediation effect of dental use. Most studies of treatment effects on OHRQoL in young children are those in which severe disease is treated in a tertiary care center.[100-102,165-167] Based on these studies, we expected a reduction in the probability of negative impacts with dental use. Qualitative studies provide insights into our unexpected results because they can reveal parents' opinions about the entire dental care experience, not just the dental visit itself. For example, parents in one study described being misunderstood and unfairly judged for how they balanced their demanding lives with their sincere but frustrating efforts to care for their children's teeth.[9] In another study, parents described negative experiences when obtaining dental care for their child, such as time spent searching for dental providers, the availability of limited appointment times, difficulty with transportation, long waiting times on the day of the appointment, and judgmental, disrespectful, and discriminatory behavior because of their race and public assistance status.[147]

In a quantitative study on the effect of preventive dental care on OHRQoL, Nelson and colleagues (2015) found that over a third of parents with children under 3 years old reported that their children experienced severe distress during preventive dental visits consisting of an examination, cleaning and fluoride treatment.[168] Similarly, the association between dental treatment and an increased burden on the OHRQoL for children and families was found in a cross-sectional survey of low-income parents of 3-year-old children (N=973) in 20 counties in North Carolina using the ECOHIS instrument.[169] Treatment of those with moderate-to-high caries experience was associated with higher mean ECOHIS scores compared to those without treatment.[169]

Strategies should be considered to help prevent negative impacts from dental visits. We can improve the quality of dental care that young children in EHS receive. For example, providing dental care in a patient-centered and culturally acceptable manner, consistent with recommended characteristics of a dental home, may help avoid the negative impacts to OHRQoL observed by Mofidi and colleagues (2009).[9] EHS programs can develop interventions including acclimation and preparation for in-office dental use targeted to parents of very young children to help reduce the negative impacts of dental visits. One example is a dental counterpart to existing home-visiting programs within early childhood education programs that provide medical and psychosocial services during pregnancy and up to two years postpartum for first-time mothers who are generally young, unmarried and have low socioeconomic status.[170] Additional interventions may take inspiration from other childhood health promotion activities, such as vaccination campaigns, in which infants and toddlers are expected to experience negative outcomes, like a fever, following vaccination that can affect their short-term quality of life. More research is needed to better understand the causes of negative impacts of dental use on families with very young children and how early childhood education programs, such as EHS, can provide services and support to help mitigate the negative impact of child dental use on families.

We found that that overall dental use does not account for all of the relationship between EHS enrollment and ECOHIS scores. The ADE and total effect of EHS on ECOHIS scores were both negative and statistically significant, resulting in an overall improvement in OHRQoL despite the negative role that overall dental use plays in mediating the relationship between EHS and OHRQoL (Table 5.4, Figure 5.1). We tested a single mediator model in this study; however, multiple processes are likely to be responsible for the improved OHRQoL resulting from EHS enrollment. The additional oral health and supportive services provided by EHS likely compensated for the effect of use and resulted in an overall positive effect on OHRQoL. Additional research is needed to identify and understand the factors and pathways that contribute to these finding.

5.5.3. Limitations

We note several limitations of our study. First, we could not randomize families; however, we, used a Medicaid-matched control group and propensity scores to reduce the potential for biased estimates of effect. Second, the study was conducted in a single state. However, it is important to note that we did not enroll a health care-seeking population; therefore it likely includes parents who may not have wanted to bring their child to the dentist and families who may not value oral health.

Third, although we used a validated instrument to measure oral health-related quality of life (ECOHIS), few studies have evaluated the performance of ECOHIS in longitudinal studies,[165,166] and the equivalence of the English and Spanish ECOHIS scores has not been established. A previous study suggested some differences in ECOHIS between English- and Spanish-speaking samples.[148] Moreover, no studies have defined a minimal important difference (MID) in ECOHIS scores. One strength of the ECOHIS instrument is that it is parent-reported, which makes it likely that the differences between the EHS and non-EHS groups are meaningful differences to the parent.

Mediation analysis is growing in popularity as a way to understand causal pathways, particularly as new analytical approaches and tools become available to the scientific community. However, some of the newer methods such as the causal mediation analysis framework used in this study have not gained widespread popularity, even though these new methods resolve some of the shortcomings of older methods. Even so, our findings are similar to that of the mediation effect using the classic Baron and Kenny approach (Figure 5.4).[171]

5.5.4. Conclusion

OHRQoL is one of the cornerstones of dental health care because it influences health-seeking behavior and health practices. It is especially important in early education and childcare studies, in which participating low-income families face major challenges in everyday life. Federally-funded social programs, such as EHS, represent a critical structure through which benefits can be delivered to socioeconomically and clinically vulnerable families.

We found that families with children in EHS experienced a lower prevalence of negative OHRQoL impacts at the end of their child's enrollment compared to families with children not enrolled in EHS. While the observed total effect of EHS suggests improvements in the prevalence of OHRQoL, we also found that OHRQoL was negatively affected by one of the successes of the EHS program: child dental use. Although the direction of the effect was as expected, we also found that severity scores were not affected by EHS enrollment at a statistically significant level. These results call attention to both the effectiveness of improving quality of life for low-resource families through early childhood education programs as well as the need for future research to reduce the potential for negative impacts of dental use on children and families.

Table 5.1. Baseline Child Characteristics of the ZOE Study Population, by Early Head Start (EHS) and non–Early Head Start (Non-EHS) Groups

Characteristic	Overall		EHS		Non-EHS		p-value†
	n (N=1156)	%*	n (n=468)	%	n (n=688)	%	
Age (months) [mean, SD (range)]	10.5, 4.7 (0-19)		10.6, 4.8 (0-19)		10.4, 4.6 (1-19)		0.351
Gender							0.226
Male	600	51.9%	253	54.17%	347	50.4%	
Female	556	48.1%	215	45.9%	341	49.6%	
Race and ethnicity							<0.001
Non-Hispanic White	335	29.0%	82	17.5%	253	36.8%	
Non-Hispanic Black	311	26.9%	177	37.8%	134	19.5%	
Non-Hispanic Native American	19	1.6%	11	2.4%	8	1.2%	
Non-Hispanic Other, Single Race/Ethnicity	7	0.6%	0	0.0%	7	1.0%	
Non-Hispanic Other, Multiple Races/Ethnicities	110	9.5%	35	7.5%	75	10.9%	
Hispanic	369	31.9%	160	34.2%	209	30.4%	
Missing	5	0.4%	3	0.6%	2	0.3%	
Language							0.633
English	873	75.5%	350	74.8%	523	76.0%	
Spanish	283	24.5%	118	25.2%	165	24.0%	
Enrolled in public health insurance							0.441
Yes	1140	98.6%	460	98.3%	680	98.8%	
No	16	1.4%	8	1.7%	8	1.2%	
Physical, learning, or mental health limitations							0.160
Yes	41	3.5%	21	4.5%	20	2.9%	
No	1103	95.4%	444	94.9%	659	95.8%	
Don't know	12	1.0%	3	0.6%	9	1.3%	
Ever been homeless or not had a regular place to live							0.002
Yes	33	2.9%	22	4.7%	11	1.6%	
No	1121	97.0%	445	95.1%	676	98.3%	
Don't know	2	0.2%	1	0.2%	1	0.1%	
Number of children in the household under 5 years-old [mean, SD (range)]	1.6, 0.8 (1-7)		1.8, 1.0 (1-7)		1.4, 0.6 (1-5)		<0.001

Number of children in the household between 5 and 17 years-old [mean, SD (range)]	0.8, 1.1 (0-5)	1.0, 1.2 (0-5)	0.7, 1.1 (0-5)	0.0014
Number of adults in the household over 17 years-old [mean, SD (range)]	2.2, 1.0 (0-9)	2.1, 1.0 (0-7)	2.2, 1.0 (1-9)	0.0044

N=number of subjects in stratum, SD=standard deviation, *Due to rounding, percentages may not add to exactly 100%.
†The p-values are for chi-square tests or t-tests comparing EHS and non-EHS groups. For the chi-square test, “don’t know” and “missing” values were excluded, and categories were combined if the expected count for a particular cell was less than five to satisfy the test’s assumptions.

Table 5.2. Characteristics of the Oral Health–Related Quality of Life Scale, Early Childhood Oral Health Impact Scale (ECOHIS), for the ZOE Study Population at Baseline and 24-month Follow-up

ECOHIS Instrument and Subscale (No. Items)	**Overall** (N=1,156)		**EHS** (n=468)		**Non-EHS** (n=688)	
	Prevalence‡	Severity§	Prevalence‡	Severity§	Prevalence‡	Severity§
24-month Follow-up						
Overall scale (13)∞∞*	484 (42%)	1.90 (3.66)	172 (37%)	1.59 (3.34)	312 (45%)	2.11 (3.85)
Child overall (9)∞∞*	429 (37%)	1.32 (2.63)	150 (32%)	1.11 (2.43)	279 (41%)	1.46 (2.75)
Child symptoms (1)∞∞*	279 (24%)	0.38 (0.75)	93 (20%)	0.31 (0.70)	186 (27%)	0.42 (0.78)
Child function (4)	175 (15%)	0.36 (1.17)	72 (15%)	0.31 (1.00)	103 (15%)	0.40 (1.28)
Child psychological (2)∞∞*	260 (22%)	0.50 (1.09)	83 (18%)	0.41 (1.01)	177 (26%)	0.57 (1.13)
Child self-image (2)	51 (4%)	0.08 (0.42)	21 (4%)	0.08 (0.40)	30 (4%)	0.07 (0.43)
Family overall (4)	234 (20%)	0.58 (1.45)	83 (18%)	0.48 (1.30)	151 (22%)	0.65 (1.54)
Parent distress (2)∞*	146 (13%)	0.33 (1.02)	45 (10%)	0.25 (0.87)	101 (15%)	0.39 (1.11)
Family function (2)	157 (14%)	0.25 (0.72)	59 (13%)	0.24 (0.73)	98 (14%)	0.26 (0.71)
Baseline						
Overall scale (13)∞*	648 (56%)	3.53 (4.64)	242 (52%)	3.13 (4.52)	406 (59%)	3.80 (4.70)
Child overall (9)∞*	637 (55%)	3.05 (3.81)	237 (51%)	2.71 (3.75)	400 (58%)	3.28 (3.83)
Child symptoms (1)∞∞**	535 (46%)	1.01 (1.24)	192 (41%)	0.90 (1.23)	343 (50%)	1.09 (1.24)
Child function (4)	189 (16%)	0.35 (1.00)	80 (17%)	0.36 (1.00)	109 (16%)	0.34 (1.00)
Child psychological (2)∞∞**	533 (46%)	1.47 (1.94)	192 (41%)	1.28 (1.88)	341 (50%)	1.61 (1.97)
Child self-image (2)	137 (12%)	0.21 (0.68)	50 (11%)	0.18 (0.60)	87 (13%)	0.24 (0.72)
Family overall (4)	209 (18%)	0.48 (1.28)	75 (16%)	0.42 (1.23)	134 (23%)	0.52 (1.31)
Parent distress (2)∞*	181 (16%)	0.36 (1.00)	59 (14%)	0.29 (0.91)	122 (18%)	0.41 (1.06)
Family function (2)	76 (7%)	0.12 (0.50)	33 (7%)	0.13 (0.54)	43 (6%)	0.11 (0.47)

EHS=Early Head Start
‡Prevalence: ≥1 impacts (number of observations, percentage)
§Severity: Mean sum of scores (standard error)
∞P<0.05 for chi-square test comparing the prevalence of ≥1 impacts between the EHS and non-EHS groups.
∞∞P<0.01 for chi-square test comparing the prevalence of ≥1 impacts between the EHS and non-EHS groups.
*P<0.05 for t-test comparing the severity (mean ECOHIS score) between the EHS and non-EHS groups.
**P<0.01 for t-test comparing the severity (mean ECOHIS score) between the EHS and non-EHS groups.

Table 5.3. Logit Models on the Effect of Early Head Start Enrollment on Any Impact to Follow-up Oral Health–Related Quality of Life (ECOHIS† Score ≥1) (N=1,156)

	OR (95% CI)
Early Head Start	0.65** (0.48, 0.87)
Baseline Oral Health-Related Quality of Life†	1.07** (1.04, 1.10)
English	1.58** (1.16, 2.15)
Propensity Score	1.08 (0.51, 2.31)
Constant	0.33** (0.22, 0.52)
Random Effect, σ_b	0.24 (0.12, 0.49)

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval

†Oral Health-Related Quality of Life was measured using the Early Childhood Oral Health Impact Scale (ECOHIS), which is a 0-52 continuous variable with a higher score indicating worse Oral Health-Related Quality of Life and a score of 0 indicating no negative impact to Oral Health-Related Quality of Life. This covariate was coded as a dichotomous variable for having any negative impact to Oral Health-Related Quality of Life at baseline (ECOHIS≥1).

Note: Models included random effects for each of the 25 Early Head Start program clusters.

Table 5.4. Causal Mediation Analysis for the Mediating Effect of Any Dental Use in the Association between Early Head Start (EHS) Enrollment on Any Impact to Follow-up Oral Health-Related Quality of Life (OHRQoL)† (N=1,156)

	Estimate (95% CI)
Total Effect‡	–0.078* (–0.14, –0.012)
ACME§ (Average Across EHS and Non-EHS groups)	0.020** (0.0072, 0.036)
ACME (Non-EHS)	0.021** (0.0074, 0.038)
ACME (EHS)	0.020** (0.0069, 0.035)
ADE∞ (Average Across EHS and Non-EHS groups)	–0.99** (–0.17, –0.031)
ADE (Non-EHS)	–0.98** (–0.16, –0.031)
ADE (EHS)	–0.99** (–0.17, –0.031)

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval
†Oral Health-Related Quality of Life was measured using the Early Childhood Oral Health Impact Scale (ECOHIS), which is a 0-52 continuous variable with a higher score indicating worse Oral Health-Related Quality of Life and a score of 0 indicating no negative impact to Oral Health-Related Quality of Life. Therefore, any negative impact to OHRQoL is an ECOHIS Score ≥1.
‡Total Effect: The sum of the average causal mediation and average direct effects.
§Average Causal Mediation Effect (ACME): The indirect effect of the treatment (EHS) on the outcome (OHRQoL) through the mediating variable (overall dental use).
∞Average Direct Effect (ADE): The effect of the treatment (EHS) on the outcome (OHRQoL) while holding the mediator (overall dental use) constant at the level that would be realized under the treatment (EHS or non-EHS) participation.
Note: The model included random effects for each of the 25 Early Head Start program clusters and adjusted for baseline ECOHIS score, survey language and the propensity score covariate.

Table 5.5. Generalized Gamma Marginalized Semicontinuous Two-Part Model† on the Effect of Early Head Start (EHS) on the Overall Mean Early Childhood Oral Health Impact Scale (ECOHIS) Score (N=1,156)

	Parameter	Parameter Estimate	Model-based Standard Error	Empirical Standard Errors	Exponentiation of Parameter∞	95% Confidence Interval∞
Probability of Having an Any Impacts (ECOHIS≥1)					**Odds Ratio**	
EHS	α_1	–0.36*	0.15	0.14	0.70*	0.52, 0.94
ECOHIS Score at Baseline	α_2	0.63**	0.13	0.14	1.88**	1.41, 2.51
English	α_3	0.35*	0.16	0.17	1.42*	1.00, 2.01
Propensity Score	α_3	0.22	0.38	0.29	1.25	0.69, 2.27
Constant	α_0	–0.93**	0.21	0.20	0.39**	0.26, 0.59
Overall Mean ECOHIS Score					**Mean Ratio**	
EHS	β_1	–0.19	0.13	0.16	0.82	0.59, 1.15
ECOHIS Score at Baseline	β_2	0.43**	0.11	0.11	1.54**	1.24, 1.92
English	β_3	0.13	0.14	0.16	1.14	0.82, 1.59
Propensity Score	β_4	–0.04	0.32	0.33	0.96	0.48, 1.92
Constant	β_0	0.34	0.21	0.19	1.40	0.95, 2.07
	Σ	0.82**	0.03	0.03		
	κ	–0.32*	0.14	0.15		
	ρ	0.93**	0.12	0.06		
	θ_1	0.27*	0.09	0.09		
	θ_2	0.28*	0.09	0.12		

* $P<0.05$, ** $P<0.01$

†Note: ECOHIS with random effects for each of the 25 EHS clusters. Akaike Information Criterion 3866.5, Log Likelihood 3836.5.

∞For model with empirical standard errors.

Table 5.6. Extent† of the Oral Health–Related Quality of Life Scale, Early Childhood Oral Health Impact Scale (ECOHIS), for the ZOE Study Population at Baseline and 24-Month Follow-Up

ECOHIS Instrument and Subscale (No. Items)	**Overall** (N=484)	**EHS** (n=172)	**Non-EHS** (n=312)
24-month Follow-up			
Overall scale (13)	4.54 (4.48)	4.34 (4.30)	4.65 (4.58)
Child overall (9)	3.56 (3.27)	3.47 (3.19)	3.60 (3.32)
Child symptoms (1)	1.56 (0.71)	1.57 (0.72)	1.56 (0.71)
Child function (4)*	2.39 (2.06)	2.03 (1.74)	2.65 (2.24)
Child psychological (2)	2.24 (1.17)	2.33 (1.15)	2.20 (1.18)
Child self-image (2)	1.70 (1.12)	1.69 (0.96)	1.72 (1.23)
Family overall (4)	2.86 (1.95)	2.71 (1.86)	2.95 (2.00)
Parent distress (2)	2.63 (1.49)	2.56 (1.39)	2.66 (1.54)
Family function (2)	1.83 (0.95)	1.86 (1.09)	1.81 (0.86)
Baseline			
Overall scale (13)	6.30 (4.57)	6.07 (4.65)	6.44 (4.52)
Child overall (9)	5.54 (3.54)	5.36 (3.69)	5.64 (3.45)
Child symptoms (1)	2.19 (0.86)	2.18 (0.94)	2.19 (0.81)
Child function (4)	2.12 (1.53)	2.10 (1.51)	2.13 (1.56)
Child psychological (2)	3.20 (1.62)	3.12 (1.70)	3.25 (1.58)
Child self-image (2)	1.81 (1.00)	1.57 (0.96)	1.89 (1.01)
Family overall (4)	2.66 (1.81)	2.65 (1.88)	2.67 (1.77)
Parent distress (2)	2.32 (1.38)	2.31 (1.39)	2.32 (1.38)
Family function (2)	1.80 (0.86)	1.88 (0.93)	1.74 (0.82)

EHS=Early Head Start
†Extent: Mean number (standard error) among those with ≥1 impacts
*P<0.05 for t-test comparing the mean ECOHIS score between the EHS and non-EHS groups among those with ≥1 impacts.
Note: After adjusting for baseline ECOHIS score, survey language and the propensity score covariate, overall mean ECOHIS extent scores among children in EHS were not significantly different from those among children not enrolled in EHS within the same cluster (aRR=0.017; 95% CI= -0.18, 0.21).

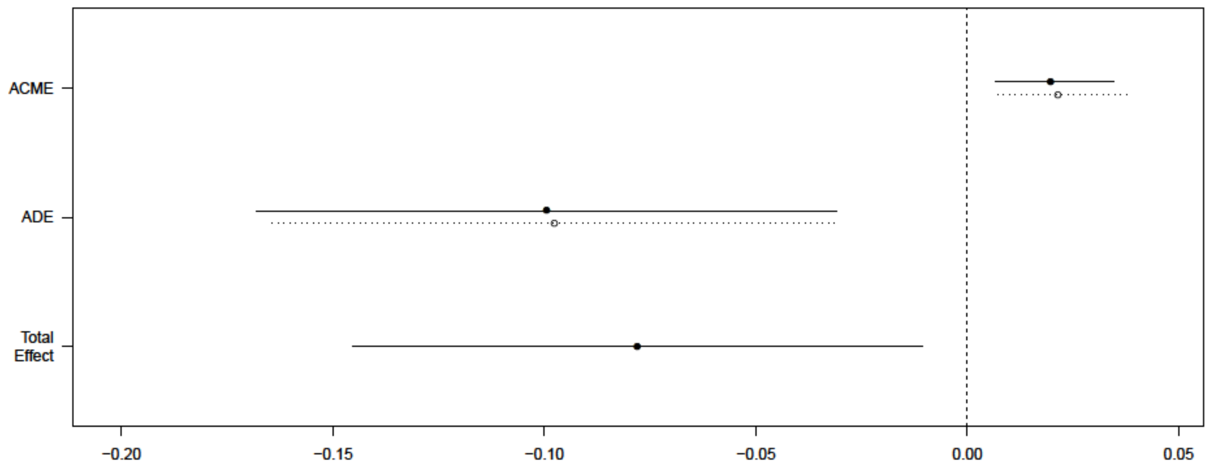

Figure 5.1. Causal mediation analysis using the average causal mediation effect (ACME), average direct effect (ADE), and total effect.

Circles represent estimates. Bars represent 95% confidence intervals. Filled circles and solid bars represent the Early Head Start group. Open circles and dashed bars represent the Non-Early Head Start group.

Average Causal Mediation Effects (ACME) $\bar{\delta}(t)$

$\delta i(t) \equiv Yi(t, Mi(1)) - Yi(t, Mi(0))$

Estimate of individual treatment effect =
Individual OHRQoL outcome in EHS group with the dental use mediator as if in the EHS group
– Individual OHRQoL outcome in EHS group with the dental use mediator as if in the Non-EHS group

Average individual treatment effects
(Average Treatment Effect on the Treated)

EHS Group
Estimate=0.020
95% CI=0.0067, 0.035
p=<0.001

Estimate of individual treatment effect =
Individual OHRQoL outcome in Non-EHS group with the dental use mediator as if in the EHS group
– Individual OHRQoL outcome in Non-EHS group with the dental use mediator as if in the Non-EHS group

Average individual treatment effects
(Average Treatment Effect on the Untreated)

Non-EHS Group
Estimate=0.021
95% CI=0.0072, 0.038
p=<0.001

Overall
Estimate=0.02
95% CI=0.0069, 0.036
p=<0.001

Average Direct Effects (ADE) $\bar{\zeta}(t)$

$\zeta i(t) \equiv Yi(1, Mi(t)) - Yi(0, Mi(t))$

Estimate of individual treatment effect =
Individual OHRQoL outcome in EHS group with the dental use mediator as if in the EHS group
– Individual OHRQoL outcome in Non-EHS group with the dental use mediator as if in the EHS group

Average individual treatment effects
(Average Treatment Effect on the Treated)

EHS Group
Estimate= –0.099
95% CI= –0.17, –0.031
p=0.01

Estimate of individual treatment effect =
Individual OHRQoL outcome in EHS group with the dental use mediator as if in the Non-EHS group
– Individual OHRQoL outcome in Non-EHS group with the dental use mediator as if in the Non-EHS group

Average individual treatment effects
(Average Treatment Effect on the Untreated)

Non-EHS Group
Estimate= –0.098
95% CI= –0.16, –0.030
p=0.01

Overall
Estimate= –0.099
95% CI= –0.17, –0.031
p=0.01

Total Effect: $\tau_i \equiv Y_i(1, M_i(1)) - Y_i(0, M_i(0))$
Estimate= –0.078; 95% CI= –0.15, –0.010; p=0.02
Estimate of individual treatment effect =
Individual OHRQoL outcome in EHS group with the dental use mediator as if in the EHS group
– Individual OHRQoL outcome in Non-EHS group with the dental use mediator as if in the Non-EHS group
Then, average the individual treatment effects

Figure 5.2. Figurative depiction of the causal mediation analysis using the average causal mediation effect (ACME), average direct effect (ADE), and total effect.

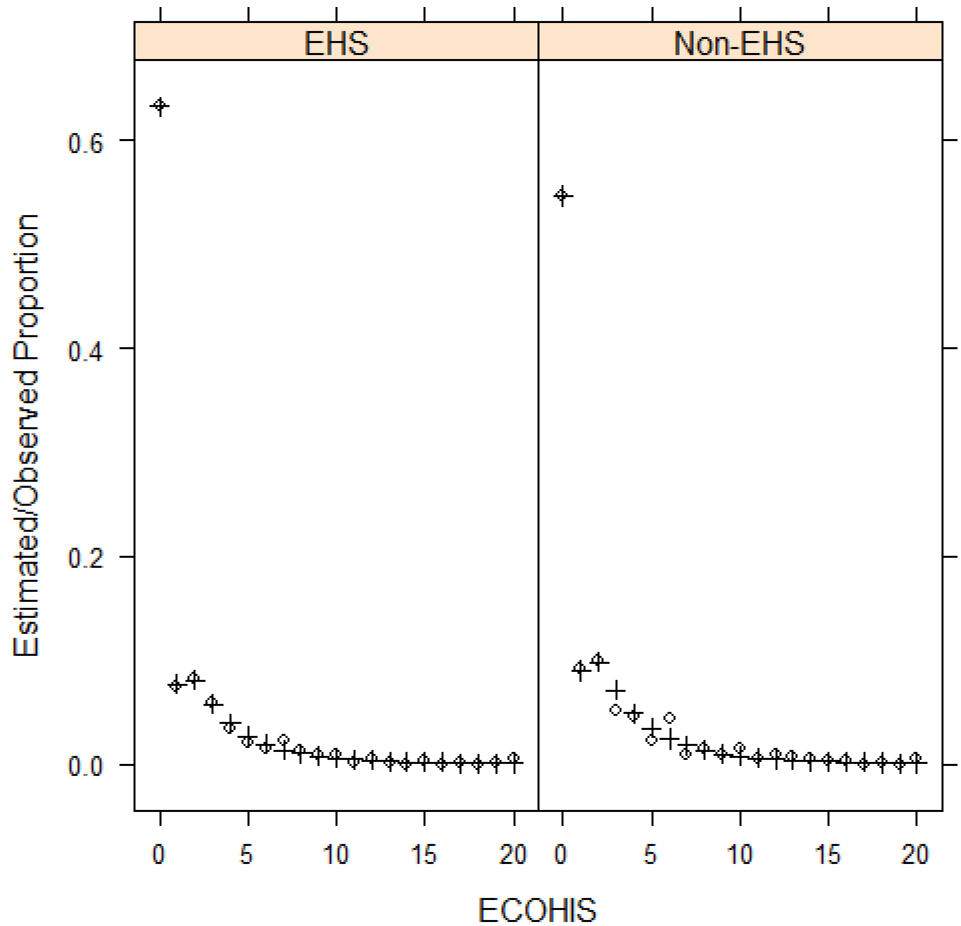

Figure 5.3. Proportion of Early Head Start (EHS) and non-EHS with each Early Childhood Oral Health Impact Scale (ECOHIS) score (N=1,156).

ECOHIS scores at 20 represent all higher observations (total seven participants). Circles represent the observed values and Pluses represent the estimated values using the Generalized Gamma Marginalized Semicontinuous Two-part Model.

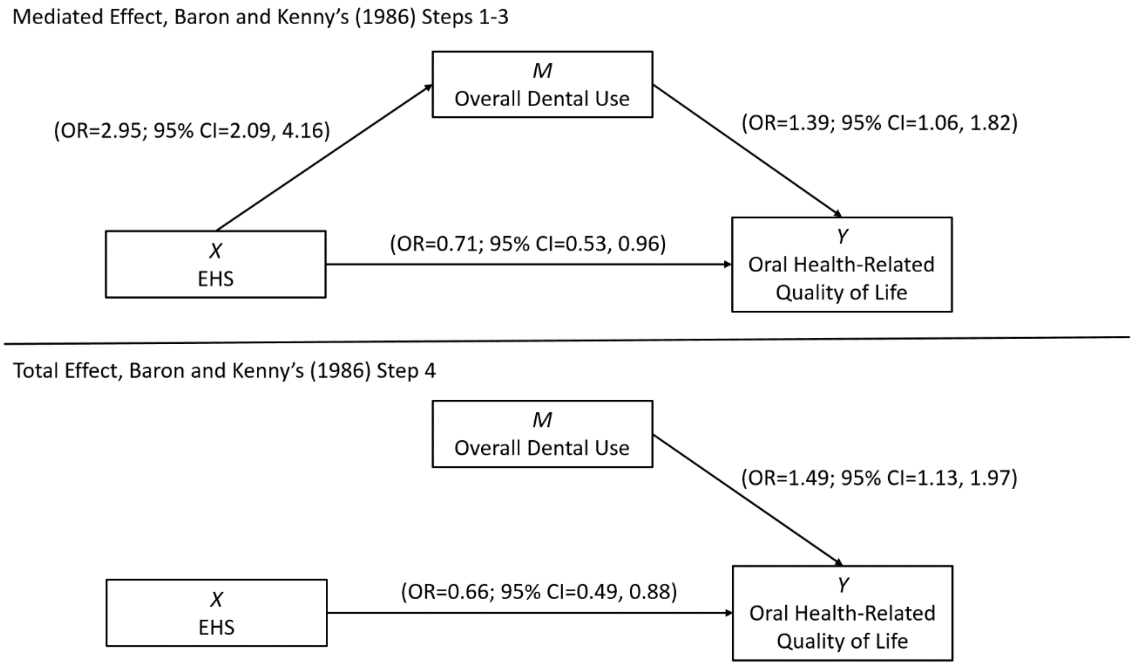

Figure 5.4. Mediation analysis using the Baron and Kenny's (1986) Steps for Mediation.[171]

The top panel illustrates the mediated effect of independent variable *X* (EHS) on dependent variable *Y* (Oral Health-Related Quality of Life) through mediating variable *M* (Overall Dental Use), Baron and Kenny's (1986) Steps 1-3. The bottom panel illustrates the total effect of independent variable *X* (EHS) and the mediating variable *M* (Overall Dental Use) on dependent variable *Y* (Oral Health-Related Quality of Life), Baron and Kenny's (1986) Step 4. OR=odds ratio, CI=confidence interval

CHAPTER 6. AIM 3: THE INFLUENCE OF HEALTH LITERACY ON THE EFFECTIVENESS OF EARLY HEAD START'S IMPROVING CHILDREN'S DENTAL USE

6.1. Overview

We examined the moderating effect of parents' oral health literacy (OHL) and parents' general health literacy (GHL) on the relationship between enrollment in North Carolina Early Head Start (EHS) and children's use of dental services. Parents with higher OHL or GHL may harness greater benefit from the EHS program compared to parents with lower health literacy. We interviewed 479 EHS and 699 Medicaid-matched caregiver-child dyads at baseline when the child was an average of ten months old and 24 months later. OHL was measured using the Oral Health Literacy Assessment. GHL was measured using the Short Assessment of Health Literacy. In the moderation analysis, we tested in separate analyses whether the interaction effects between EHS and parents' OHL or GHL were significant predictors of dental use in a logit model that estimated the effect of EHS enrollment on the probability of having a dental visit, controlling for baseline dental use, dental need and a propensity score covariate. Thirty-two percent of parents in the EHS group had low OHL compared to 22% of parents in the Non-EHS group ($P<0.01$). For GHL, 19% of parents in EHS had low literacy compared to 12% of parents in the Non-EHS group ($P<0.01$). In the adjusted logit models analyzing the effect of EHS on having a dental visit, the interaction term between EHS and parent's health literacy variables were not significant ($P>0.05$). Parents in EHS have a higher prevalence of low OHL and GHL compared to non-EHS parents. Neither parents' OHL nor parents' GHL were moderators for the relationship between

EHS and dental use. The results provide evidence that EHS results in similar improvements in dental use regardless of parent's health literacy levels.

6.2. Introduction

General health literacy (GHL) is defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."[23] Nationally, only 12% of the U.S. adult population had proficient health literacy in 2003.[115] Low GHL is associated with poor access to medical care, increased hospitalizations and fewer preventive visits.[24]

Oral health literacy (OHL) is defined similarly to GHL, but the most common definition specifically limits "information and services" to "oral health."[22] Low OHL among parents is an important determinant of children's oral health.[11-13] It is associated with deleterious childcare oral health behaviors, including nighttime bottle use and lack of daily brushing,[13] lower oral health knowledge,[13] increased dental caries in children,[14,15] worse caregiver-reported oral health status,[13,15,172] elevated emergency dental care expenditures for their children,[16] and worse oral health-related quality of life.[17,18] Its role in oral health has been recognized in a causal model of early childhood caries,[173] by the United States Department of Health and Human Services' (US DHHS) multiagency national action plan to improve health literacy[174] and by the US DHHS Oral Health Strategic Framework that specifies goals for federal agencies for 2014–2017.[175]

Health literacy is a complex construct, requiring a range of skills to communicate and function within the health system. It is possible that many of the skills required to access and use information may be common to both medical and dental health care systems. Although OHL and GHL are conceptually different, they are highly correlated and underlying constructs being measured by each have not been fully identified in available measurement instruments.[116,176,177] Further, study of GHL and OHL might be context specific. They both may be important for studying oral health in social programs that include comprehensive services that integrate medical and dental services. A GHL instrument has been used successfully in a study on oral health outcomes in a Head Start population.[178]

Health-related interventions often target individuals and families with low literacy in an attempt to help them achieve good health. Systematic reviews demonstrate varying levels of success in achieving desired outcomes.[179-181] These studies often assume low-literacy based on sociodemographic characteristics of the study population or include measures of health literacy as confounders to control for experimental group imbalances.[182] Less frequent are studies in which actual health literacy levels are measured and their modifying effects on the effectiveness of health interventions tested.[178] A recent publication identified only a few such studies.[183] The direction of moderation effects for health literacy was unclear: greater for participants with low literacy in one study,[184] inconsistent across different outcomes in some,[185-188] and not different by literacy levels in others.[189-192]

We undertook a study known as Zero Out Early Childhood Caries (ZOE) to determine the effects of Early Head Start (EHS) enrollment on oral health outcomes.[1] Previously, we showed that being enrolled in EHS had a strong positive effect on dental use of children younger than 3 years of age (Aim 1). However, that and other studies of older children in Head Start document that all enrolled children do not have the recommended number of dental visits or receive comprehensive care. It is unknown whether the effect of EHS on dental use is influenced by parents’ OHL or GHL. Many parents in EHS are particularly vulnerable to having low health literacy because they are young and have low incomes and education attainment, which are associated with low health literacy.[118]

We hypothesized that parents' low health literacy can have an attenuating effect on the impact of EHS on oral health outcomes such as dental use. The purpose of this study was to determine: (1) the OHL and GHL levels of EHS and non-EHS parents; and (2) whether OHL and GHL influences the effectiveness of EHS in improving parent-reported child use of dental health services.

6.3. Methods

6.3.1. Overview of Study Design and Data Source

The study used data collected as part of the ZOE study, a pre-post 24-month longitudinal prospective non-randomized study. The ZOE study is quasi-experimental, in that the oral health outcomes of young children in the EHS program were compared with a control group of children not enrolled in EHS. Teachers and staff in EHS programs received minimal training in oral health and communication techniques to bolster awareness and implementation of EHS federal performance standards. The study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

6.3.2. Study Population and Data Collection Procedures

Subjects were recruited to the study through a three-step process described in detail in a previous publication:[148] (1) enrollment of EHS programs, (2) enrollment of parent-child dyads within EHS programs, and (3) enrollment of community-matched parent-child dyads to serve as controls. In step one, all North Carolina EHS programs were invited to participate, and all except one were enrolled. In step two, parents of EHS children younger than 19 months of age from all participating EHS programs were recruited by the research team. In step three, Medicaid-enrolled children of the same age, language, and geographic area (ZIP codes) as enrolled EHS parent-child dyads were recruited as the control group through direct mailings from the North

Carolina Medicaid program. The sample yielded EHS and non-EHS parent-child dyads clustered within 25 of the 26 EHS programs in the state.

Parents were interviewed by trained interviewers using in-person computer-assisted, structured interview techniques at baseline (mean child age = 10 months) and approximately 24 months later, which coincided with the end of the EHS program (children were ~36 months old). The outcome of interest, dental use, was derived from a question included in both baseline and follow-up interviews. The potential moderator variables, OHL and GHL, were measured at baseline. English and Spanish questionnaires were administered, as appropriate.

6.3.3. Conceptual Framework

We used a health literacy conceptual model developed by Nutbeam to guide our study.[193] In this model, health literacy is a "risk" in which tailored information, education and communication can improve access to health care and productive interaction with health care professionals. Additionally, health literacy is an "asset" that can lead to the development of skills conducive to navigating the health care system. This model recognizes the impact that low literacy can have on health outcomes from engaging in social programs. Thus, EHS may be a vehicle to improve child oral health outcomes by accommodating parents' health literacy levels. The direct effects of EHS on the child's dental use is supported by an early education and childcare framework proposed by Friedman-Krauss and Barnett.[119]

6.3.4. Measures

The main independent variable, EHS enrollment, was a binary variable (enrolled, not enrolled) supplied by EHS staff and confirmed by the parent at baseline. The dependent variable, overall dental use by the child, was analyzed as both a binary and count variable in separate analyses. The binary outcome was determined by a positive response at follow-up to the question: “Has your child ever been to a dentist or dental clinic?” The count variable was the number of lifetime dental visits for the child using parent self-report at the follow-up interview.

We tested the potential for both health literacy specific to oral health, OHL, and GHL to moderate the effectiveness of EHS. OHL was measured using the Spanish (OHLA-S) and English (OHLA-E) Oral Health Literacy Assessment instruments, which are 30-item word recognition and comprehension tests related to oral health.[131,194] Each OHLA item is assigned a score of 1 when the results of pronunciation and association tests are both correct. If either of the results are incorrect, the score for that particular item is assigned a 0. The overall OHLA-E or OHLA-S score is the sum of correct items, for a possible score of 0 to 30, with higher scores representing better OHL. OHLA-E and OHLA-S were not equivalent in one study.[131]

GHL was measured using the Short Assessment of Health Literacy – Spanish and English (SAHL-S&E), 18-item word recognition and comprehension tests scored similarly to the OHLA instruments.[130] SAHL-S&E scores have been shown to be equivalent for English and Spanish speakers.[130] The number of correct items provides a continuous score ranging from 0 to 18.

We included two baseline covariates in the models because of their potential impact on future dental use: dental need and dental use between birth and the baseline interview. Dental need was self-reported by the parent as a binary variable, determined as a positive response to the question, “During your child’s life, has he or she ever needed dental care or check-ups?” Dental use was also a binary variable determined as parents’ positive response to the question, “Has your child ever been to a dentist or dental clinic?”

6.3.5. Analytical Approach

Descriptive Analyses. We used descriptive statistics to describe the distribution of the children’s demographic characteristics and parent OHL and GHL by EHS group.

Unadjusted Analyses. We examined the unadjusted relationship between EHS and dental use, stratified by parent's OHL and GHL. These unadjusted analyses were performed for Spanish- and English-speaking parents both separately and in aggregate. The prevalence of any dental use by literacy levels was also depicted in graphs for both the EHS and non-EHS groups and by interview language. We performed the Breslow-Day test for homogeneity of the odds ratio to determine whether the odds ratios for dental use are different across two strata: low health literacy or not low health literacy. We considered $P < 0.05$ as statistically significant.

Adjusted Binary Models. We analyzed the association between EHS and dental use with multivariate logistic regression. Models included an interaction term between health literacy (low and not low) and EHS to test for the moderating effect of health literacy. When used as an interaction term, OHLA was treated as a binary variable for low OHL, which was defined as the lowest quintile of the sample (OHLA score ≤13). When used as an interaction term, SAHL-S&E was treated as a binary variable for low health literacy (SAHL≤14).[130] In addition to EHS group, literacy level and their interaction term, we included baseline dental use, baseline dental need and a generalized boosted model propensity score covariate[125] in logit models as *a priori* confounders. In the GHL models, in which English- and Spanish-speakers were combined, a covariate for survey language was included in the models. In all models except the adjusted count model with the interaction effect between EHS and parent low OHL, we controlled for clustering of subjects within EHS programs and estimated the impact of EHS on OHRQoL using random effects models.

Adjusted Count Models. We used a marginalized zero-inflated negative binomial count model to examine whether parent OHL or GHL moderated the relationship between EHS and the number of dental visits. We included interaction terms defined in the same manner and with the same covariates as in the adjusted logit models. The analyses for the English- and Spanish-speaking participants were performed independently. For GHL, analyses were also performed in aggregate.

6.4. Results

The study enrolled 1,567 child-parent dyads, an estimated 60% of the eligible EHS sample and 9% of the non-EHS comparison sample. Follow-up interviews were completed with 468 parents from EHS programs and 688 non-EHS controls. Baseline characteristics of the EHS and non-EHS children were similar with respect to age, gender, enrollment in public health insurance, and physical, learning, or mental health limitations; however, more children in EHS had been homeless and were minority race and ethnicity compared to children not enrolled in EHS (Table 6.1). On average, children in EHS also had a greater number of children and fewer adults in the household compared to non-EHS children (Table 6.1).

6.4.1. Dental Use

The prevalence of any dental use was significantly higher in the EHS group compared to the non-EHS group overall and when stratified by language (Table 6.2: Overall sample: EHS=81%; Non-EHS=59%, $P<0.01$. English-speaking sample: EHS=78%; Non-EHS=55%, $P<0.01$. Spanish-speaking sample: EHS=89%; Non-EHS=71%, $P<0.01$). Similarly, there was a significant difference in the mean number of dental visits between children in the EHS and Non-EHS groups overall and when stratified by language ($P<0.01$) (Table 6.2: Overall sample: EHS=2.58; Non-EHS=1.66, $P<0.01$. English-speaking sample: EHS=2.22; Non-EHS=1.44, $P<0.01$. Spanish-speaking sample: EHS=3.62; Non-EHS=2.36, $P<0.01$).

6.4.2. Prevalence of Low Oral Health Literacy

Overall, 26.3% of the study sample had low OHL, but it varied by EHS group and language. A greater percentage of parents in the EHS group had low OHL (OHLA≤13) than parents in the Non-EHS group (32% vs. 22%, *P*<0.01) (Table 6.3, Figure 6.1). When stratified by language, 18% (n=53/290) of the Spanish speakers had low OHL compared to 29% (n=257/888) of English speakers (*P*<0.01) (Table 6.2, Figure 6.1). In the stratified samples by language, there remained a difference between the prevalence of low OHL between the EHS and non-EHS groups among the English-speakers (*P*<0.01), but not among the Spanish-speakers (*P*>0.05) (Table 6.2).

6.4.3. Moderating Effect of Oral Health Literacy

No difference was observed in the prevalence of dental use between parent-child dyads with and without low parent OHL; this relationship was found in both the EHS and Non-EHS groups for English or Spanish speakers (*P*>0.05) (Figure 6.2A, Table 6.2: English-speaking EHS sample: Low OHL=78%, Not Low OHL=79%, *P*>0.05; English-speaking Non-EHS sample: Low OHL=56%, Not Low OHL=55%, *P*>0.05. Spanish-speaking EHS sample: Low OHL=86%, Not Low OHL=90%, *P*>0.05. Spanish-speaking Non-EHS sample: Low OHL=60%, Not Low OHL=73%, *P*>0.05). No evidence of effect modification of the parents' low OHL-dental use relationship depending on EHS status was detected in the stratified analysis (Overall B-D χ^2 *P*=0.91; English-speaking sample B-D χ^2 *P*=0.81; Spanish-speaking sample B-D χ^2 *P*=0.77). In the adjusted logit model on the effect of EHS on having any dental visits, the interaction effect between EHS and parent OHL level did not have a significant effect on having any dental visits among English or Spanish speakers (Table 6.4: English aOR= 0.93; 95% Cl: 0.46, 1.89; Spanish aOR= 0.92; 95% Cl: 0.18, 4.83).

We found no difference in the mean number of dental visits between parent-child dyads where the parent had low OHL in the EHS (Table 6.2). In the adjusted count model, the interaction term between EHS and low parent OHL was not significant among English or

Spanish speakers (Table 6.5: English aRR=1.01; 95% CI: 0.76, 1.35; Spanish aRR=1.11; 95% CI: 0.64, 1.91).

6.4.4. Prevalence of Low General Health Literacy

A greater percentage of parents in the EHS group had low GHL (SAHL≤14) than parents in the Non-EHS group (19% vs. 12%, $P<0.01$) (Table 6.6, Figure 6.3). When stratified by language, 29.3% (n=85/290) of the Spanish speakers had low GHL compared to 10.4% (n=92/888) of English speakers ($P<0.01$) (Table 6.6, Figure 6.3). In the stratified samples by language, there remained a difference between the prevalence of low GHL between the EHS and non-EHS groups among the English-speakers ($P<0.01$), but not among the Spanish-speakers ($P>0.05$) (Table 6.6).

6.4.5. Moderating Effect of General Health Literacy

No difference was observed in the prevalence of dental use between parent-child dyads with and without low parent GHL; this relationship was found in both the EHS and Non-EHS groups for English or Spanish speakers ($P>0.05$) (Figure 6.2B, Table 6.6: EHS sample: Low=82%, Not Low=81%, $P>0.05$. Non-EHS sample: Low=63%, Not Low=58%, $P>0.05$). No evidence of effect modification of the parents' low GHL-dental use relationship depending on EHS group status was detected in the stratified analysis (B-D χ^2 $P=0.78$). In the adjusted logit model, the interaction effect between EHS and low parent GHL did not have a significant effect on having any dental visits (aOR=0.95; 95% CI: 0.57, 1.59) (Table 6.7).

We found no difference in the mean number of dental visits between parent-child dyads where the parent had low GHL in the EHS; however, there was a significant difference in low GHL in the Non-EHS group (Table 6.6: EHS sample: Low=2.73, Not Low=2.55, $P>0.05$. Non-EHS sample: Low=2.10, Not Low=1.59, $P<0.01$). In the adjusted count model, the interaction between EHS group and low parent GHL was not significant (aRR=0.88; 95% CI: 0.72, 1.09)

(Table 6.8). We also modeled the English and Spanish speakers separately; for the EHS-low parent GHL interaction effect, we found similar results in the logistic regression (Table 6.9) and count models (Table 6.10).

6.5. Discussion

This study builds on positive findings about the effectiveness of EHS in promoting use of dental services by enrolled children. The current study is the first investigation to examine the prevalence of low health literacy among parents whose children are enrolled in EHS, and its impact on the relationship between enrollment and child dental use. We had two important findings. First, a greater proportion of parents with young children enrolled in EHS have low OHL and GHL compared to similar disadvantaged families, particularly among English-speakers. Second, neither parents' OHL nor GHL moderated the effectiveness of EHS on improving child dental use. This finding suggests that improvements in children's dental use are not attenuated by whether or not the parent has low health literacy.

6.5.1. Parent's Oral Health Literacy

EHS parents had a higher prevalence of low OHL compared to their Medicaid-enrolled peers. This finding is consistent with literature showing that low-income, first-time mothers, younger parents, and those with lower educational attainment have poorer OHL.[11,118] In our study population, the families in the EHS group had less education, were more likely to be minority race and ethnicity and received more government support compared to the non-EHS group.

Spanish-speaking families had a higher prevalence of dental use compared to English-speaking families in both the EHS and non-EHS groups. This finding may be an indication that the OHLA instrument was a valid representation of OHL because there was a significantly lower prevalence of low OHL (OHLA≤13) in the Spanish-speaking sample compared to the English-speaking sample.

6.5.2. Parent's General Health Literacy

We found a greater percentage of Spanish-speaking parents had low GHL compared to English-speaking parents; this is opposite from our results with OHL. Lee and colleagues (2010) also reported a higher prevalence of low GHL in Spanish speakers and a lower prevalence of low GHL in English speakers in an adult, hospital-based population.[130] We expected that both GHL and OHL would have a similar trend since they are measuring similar constructs. A likely explanation for this finding is that the OHLA and SAHL are measuring different constructs or that the Spanish-speaking sample has better OHL than GHL.

6.5.3. Absence of Moderation Effect by General Health Literacy and Oral Health Literacy

We expected that low health literacy might pose challenges to accessing dental care in this low-income study population that would be difficult for EHS programs to overcome with available resources.[117] This premise was based on previous literature, which reports an association between parents' GHL and their children's use of health services for problems such as asthma.[24,25] Although the literature has not reached a consensus on the modifying effect of health literacy on intervention effectiveness,[183-192] we anticipated that there might be a differential effect of EHS on dental use based on the level of parents' health literacy, either OHL or GHL. We expected that child dental use would be significantly lower in EHS families where parents had low health literacy, comparable to levels in the Non-EHS group and that the interaction term between parent OHL and EHS would be significant in our analyses.

However, our hypothesis was disproven. The treatment effect for EHS on dental use did not differ for parents with and without low health literacy. This finding implies that EHS is able to accommodate parents with low health literacy resulting in more dental use among the low-literacy EHS parents compared to non-EHS parents who had better literacy levels. In other words, EHS may overcome challenges to using oral health information to make dentist appointments by connecting EHS families with dental providers for all families regardless of OHL or GHL. One explanation for this effect is that EHS staff and teachers may use the same universal communication techniques for every family in an approach that assumes a low level of literacy.

Another explanation for this null result is that the OHLA instrument may not have the sensitivity to identify families with low OHL among a low-income sample. The OHLA scores have a bell-shaped distribution and the OHLA instrument does not have a cut-off for low OHL that is validated by oral health behaviors or outcomes in either English (OHLA-E) or Spanish (OHLA-S) (Figure 2, Figure 3). However, the null results for the modifying effect of literacy are similar when using both the OHLA and SAHL instruments, which has a left-skewed distribution designed to identify families with low GHL and has an established cut-off for low GHL.[130]

The use of both GHL and OHL instruments in this study resulted in similar results for the primary finding on the moderation effect of health literacy; however, they yielded dissimilar results related to the relative prevalence of low literacy in English- and Spanish-speakers. Our findings did not depend on the type health literacy instrument we used for the main effect, yet the results highlighting the need to tailor the health literacy instruments to the needs of the study and emphasize that GHL and OHL are not interchangeable. For our study, the inclusion of a GHL instrument was appropriate for two reasons: 1) psychometrically, the GHL instrument was more developed and amenable to the diverse cultural and language backgrounds of the study population compared to the OHL instrument; and 2) the EHS treatment is a comprehensive social program that includes social, medical, and cognitive outcomes beyond of scope of oral health.

Previous studies on health literacy and oral health outcomes also have used a GHL instrument or developed a combined GHL-OHL instrument for reasons specific to their study needs.[178,195]

These results fill the gap in our knowledge about OHL and GHL levels in EHS families and whether parents' health literacy modifies the significant and positive impact that EHS has on dental use. Our findings are consistent with some of the literature on the moderating effect of GHL;[183,189-192] however our results, in which we did not find a significant moderating effect for health literacy on EHS impacts, differs from the effectiveness of a health literacy–related intervention in an early childhood education program.[182]

Currently, some evidence suggests that intensive interventions can improve health outcomes among low health literacy populations.[179-182] In a systematic review, Sheridan and colleagues (2011) found that intensive self-management interventions reduced emergency department visits and hospitalizations and reduced disease severity.[180] Similarly, the oral health services provided by EHS staff may overcome challenges posed by low health literacy and mitigate the effects of low health literacy in a similar manner. This possibility is particularly evident in this study related to children's dental use, in which EHS families have a higher prevalence of children's dental use while also having a higher prevalence of low OHL and GHL compared to non-EHS families. In other words, the oral health services provided by EHS can support families with different levels of literacy as they navigate the health system in order to obtain, process, and understand basic oral health information and access oral health services, thereby overcoming some of the obstacles presented by this health literacy gap.

6.5.4. Limitations

There are several limitations of this study, including lack of randomization of EHS enrollment, endogeneity, and lack of generalizability. We used a Medicaid-matched control group and propensity scores during data analysis to reduce the potential for biased estimates of effect.

Another limitation of this study is that the validity of the results are dependent on the psychometric properties of the OHLA and SAHL-S&E instruments as applied in this study population. OHLA-S and OHLA-E are valid and reliable when used separately but appear to measure different underlying OHL constructs.[131] Thus, scores for English- and Spanish-speakers cannot be used in an analysis that ignores language, effectively reducing the sample size available for analysis. We made efforts to address this limitation by conducting a psychometric study using Item Response Theory to identify a single set of reliable and valid items out of the 30 OHLA items that would similarly measure OHL in English and Spanish speakers. We identified 12 items that loaded on two latent factors in both English and Spanish, and were free from differential item functioning. However, similar to a previous study, predictive and convergent validity tests of the two separate factors yielded mixed results.[130,131] Being unsuccessful in creating a subset of OHLA items that measured the same construct in English- and Spanish-speakers, we proceeded with using the previously validated and reliable OHLA-E and OHLA-S 30-items instruments.

6.5.5. Future Research

Future research is needed to develop an OHL instrument that provides equivalent assessments for the OHL of English and Spanish speakers. Additional research also is needed to study the influence of OHL and GHL on other child dental outcomes, such as oral hygiene practices, which may be more susceptible to modification by a parent’s OHL or GHL levels. Additionally, future research is needed on the direct impact of health literacy on dental outcomes, such as dental use and oral hygiene practices, among young children under 3 years old. The study of health literacy and dental outcomes among a more socioeconomically diverse sample might also provide useful insights into the function of OHL and the relationships among literacy and oral health outcomes.

6.5.6. Conclusions

Access to dental services for low-resource families with very young children is challenging, particularly so in families where parents have low health literacy. EHS is a national program that can reach children from birth to age 3.[28,29] Our findings not only illustrate that more parents in EHS have low OHL and GHL than those not enrolled in EHS but also that comprehensive early childhood education programs like EHS can improve dental use for families if the parent has low health literacy. To our knowledge, this is the first study to provide evidence that an early childhood education program enrolling children younger than 3 years of age can have similar improvements for parents with and without low health literacy.

Table 6.1. Baseline Child Characteristics of the ZOE Study Population, by Early Head Start (EHS) and non–Early Head Start (Non-EHS) Groups

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Characteristic	EHS (n=479) %	non-EHS (n=699) %	p-value†
Age (months) [mean, SD (range)]	10.6, 4.8 (0-19)	10.3, 4.6 (1-19)	0.297
Gender			0.246
Male	53.7%	50.2%	
Female	46.3%	49.8%	
Race and ethnicity			0.000
Non-Hispanic White	17.5%	36.8%	
Non-Hispanic Black	37.0%	19.5%	
Non-Hispanic Native American	2.3%	1.1%	
Non-Hispanic Other, Single Race/Ethnicity	0.2%	1.0%	
Non-Hispanic Other, Multiple Races/Ethnicities	7.5%	11.0%	
Hispanic	34.7%	30.3%	
Missing	0.8%	0.3%	
Language			0.403
English	74.1%	76.3%	
Spanish	25.9%	23.7%	
Enrolled in public health insurance			0.441
Yes	98.1%	98.9%	
No	1.7%	1.1%	
Missing	0.2%	0.0%	
Physical, learning, or mental health limitations			0.159
Yes	4.6%	3.0%	
No	94.6%	95.6%	
Don't know	0.8%	1.4%	
Ever been homeless or not had a regular place to live			0.006
Yes	4.6%	1.9%	
No	95.0%	98.0%	
Don't know	0.4%	0.1%	
Number of children in the household under 5 years-old [mean, SD (range)]	1.8, 1.0 (1-7)	1.4, 0.6 (1-5)	<0.001
Number of children in the household between 5 and 17 years-old [mean, SD (range)]	1.0, 1.2 (0-6)	0.7, 1.1 (0-5)	0.0008
Number of adults in the household over 17 years-old [mean, SD (range)]	2.1, 1.0 (0-7)	2.2, 1.0 (1-9)	0.0040

N=number of subjects in stratum, SD=standard deviation, *Due to rounding, percentages may not add to exactly 100%.

†The p-values are for chi-square tests or t-tests comparing EHS and non-EHS groups. For the chi-square test, "don't know" and "missing" values were excluded, and categories were combined if the expected count for a particular cell was less than five to satisfy the test's assumptions.

Table 6.2. Overall Dental Use at 24-Month Follow-Up in the Zero-Out Early Childhood Caries Study, by Early Head Start (EHS) and Parent's Oral Health Literacy

Group	**Parent Oral Health Literacy**[∞]	**Overall Dental Use** (n, %)	**Number of Overall Dental Visits** (Mean, SD, Range)	**Parent Oral Health Literacy**[∞]	**Overall Dental Use** (n, %)	**Number of Overall Dental Visits** (Mean, SD, Range)	**Parent Oral Health Literacy**[∞]	**Overall Dental Use** (n, %)	**Number of Overall Dental Visits** (Mean, SD, Range)
	Overall (N=1,178)			**English** (n=888)			**Spanish** (n=290)		
EHS	Low *(n=154)*	122 (79%)	2.45 (SD=2.06) Range=0-11	Low *(n=126)*	98 (78%)[‡]	2.25 (SD=1.95) Range=0-8	Low *(n=28)*	24 (86%)	3.36 (SD=2.33) Range=0-11
	Not Low *(n=325)*	266 (82%)	2.64 (SD=1.99) Range=0-10	Not Low *(n=229)*	180 (79%)[‡]	2.20 (SD=1.79) Range=0-10	Not Low *(n=96)*	86 (90%)	3.70 (SD=2.06) Range=0-10
	Both *(n=479)*	388 (81%)[‡]	2.58[†] (SD=2.01) Range=0-11	Both *(n=355)*	278 (78%)[‡]	2.22[†] (SD=1.84) Range=0-10	Both *(n=124)*	110 (89%)[‡]	3.62[†] (SD=2.12) Range=0-11
Non-EHS	Low *(n=156)*	88 (56%)	1.54 (SD=1.86) Range=0-10	Low *(n=131)*	73 (56%)[‡]	1.44 (SD=1.76) Range=0-10	Low *(n=25)*	15 (60%)	2.04 (SD=2.30) Range=0-7
	Not Low *(n=543)*	324 (60%)	1.69 (SD=1.92) Range=0-12	Not Low *(n=402)*	221 (55%)[‡]	1.44 (SD=1.76) Range=0-10	Not Low *(n=141)*	103 (73%)	2.42 (SD=2.15) Range=0-12
	Both *(n=699)*	412 (59%)[‡]	1.66[†] (SD=1.90) Range=0-12	Both *(n=533)*	294 (55%)[‡]	1.44[†] (SD=1.76) Range=0-10	Both *(n=166)*	118 (71%)[‡]	2.36[†] (SD=2.17) Range=0-12

[∞]Oral Health Literacy Assessment (OHLA). Low Parent Oral Health Literacy was defined as the lowest quintile of OHLA scores (OHLA ≤13).
[†]Significant difference between the EHS and Non-EHS groups at the 0.01 significance level using a t-test.
[‡]Significant difference between the EHS and Non-EHS groups at the 0.01 significance level using the chi-squared test.
Note: There was no significant evidence of effect modification of the parent oral health literacy-dental use relationship depending on EHS status at the 0.05 significance level using the Breslow-Day test for homogeneity of the odds ratio: Overall, *P*=0.91; English, *P*=0.81; Spanish, *P*=0.77.

Table 6.3. Parent Oral Health Literacy Separated by Quintile, As Measured Using the Oral Health Literacy Assessment (OHLA) in the Zero-Out Early Childhood Caries Study, by Early Head Start (EHS)

OHLA Quintile	**Overall (N=1,178)** (n, %)	**EHS (n=479)** (n, %)	**Non-EHS (n=699)** (n, %)
Q1: 0-13 (Mean 10.47, SD 2.89, Median 11)*	310 (26.3%)	154 (32.2%)	156 (22.3%)
Q2: 14-15 (Mean 14.54, SD 0.50, Median 15)	207 (17.6%)	76 (15.9%)	131 (18.7%)
Q3: 16-17 (Mean 16.44, SD 0.50, Median 16)	224 (19.0%)	88 (18.4%)	136 (19.5%)
Q4: 18-20 (Mean 18.84, SD 0.81, Median 19)	250 (21.2%)	101 (21.1%)	149 (21.3%)
Q5: 21-30 (Mean 23.25, SD 2.15, Median 23)*	187 (15.9%)	60 (12.5%)	127 (18.2%)

SD=standard deviation.
Oral Health Literacy Assessment (OHLA) has an overall Mean 16.13, SD 4.65, and Median 16.
*Chi-square test between EHS and non-EHS groups is significant at the 0.01 significance level.
Note: Unequal numbers of individuals in the quintiles reflect many parents having the same OHLA score.

Table 6.4. Logit Models on the Effect of Early Head Start Enrollment on Any Dental Visits With and Without Early Head Start-Oral Health Literacy Interaction Effect, by English- and Spanish-Speaking Samples

	Any Dental Visits			
	English-speakers (n=888)		**Spanish-speakers** (n=290)	
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Early Head Start	2.56** (1.73, 3.81)	2.62** (1.67, 4.13)	2.39* (1.11, 5.16)	2.47* (1.06, 5.79)
Had a Dental Visit at Baseline	3.08* (1.18, 8.03)	3.09* (1.18, 8.06)	1.77 (0.36, 8.64)	1.72 (0.35, 8.39)
Needed Dental Care at Baseline	8.75** (3.87, 19.78)	8.76** (3.88, 19.79)	8.04* (1.05, 61.79)	8.44* (1.09, 65.00)
Propensity Score	2.38 (0.91, 6.19)	2.38 (0.91, 6.22)	1.39 (0.16, 11.75)	1.53 (0.18, 13.11)
Low Parent Oral Health Literacy†	--	1.01 (0.66, 1.56)	--	0.61 (0.23, 1.60)
Interaction Effect between Early Head Start and Low Parent Oral Health Literacy†	--	0.93 (0.46, 1.89)	--	0.92 (0.18, 4.83)
Constant	0.81 (0.52, 1.26)	0.81 (0.51, 1.27)	2.33 (0.92, 5.94)	2.42 (0.95, 6.18)
Random Effect, σ_b	0.63 (0.41, 0.96)	0.63 (0.41, 0.96)	0.60 (0.26, 1.42)	0.57 (0.23, 1.42)

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval
†Oral Health Literacy Assessment (OHLA). Low Parent Oral Health Literacy was defined as the lowest quintile of OHLA scores (OHLA ≤13).
Note: Models included random effects for each of the 25 Early Head Start program clusters.

Table 6.5. Marginalized Zero-Inflated Negative Binomial Model on the Effect of Early Head Start (EHS) on the Mean Increment in Dental Visits with EHS-Oral Health Literacy Interaction Effect, by English- and Spanish-Speaking Samples

		English-speakers (n=888)		**Spanish-speakers** (n=290)	
	Parameter	Exponentiation of the Parameter	95% CI†	Exponentiation of the Parameter	95% CI†
Probability of Having an Excess Dental Visit		**Odds Ratio**		**Odds Ratio**	
EHS	α_1	0.33**	0.16, 0.67	0.32*	0.11, 0.91
Propensity Score	α_2	1.79	0.22, 2.80	1.58	0.15, 16.51
Needed Dental Care at Baseline	α_3	0.04	0.00, 4.20	0.10	0.01, 1.69
Had a Dental Visit at Baseline	α_4	0.44	0.11, 1.76	0.82	0.12, 5.44
Low Parent Oral Health Literacy‡	α_5	1.02	0.61, 1.71	2.25	0.85, 5.94
Interaction Effect between EHS and Low Parent Oral Health Literacy‡	α_6	1.15	0.40, 3.32	0.78	0.12, 4.92
Constant	α_0	0.68	0.42, 1.08	0.28*	0.10, 0.77
Overdispersion parameter	φ				
Overall Mean Increment in Dental Visits		**Rate Ratio**		**Rate Ratio**	
EHS	β_1	1.31**	1.10, 1.56	1.31*	1.07, 1.61
Propensity Score	β_2	1.25	0.86, 1.83	1.63	0.93, 2.86
Needed Dental Care at Baseline	β_3	1.93**	1.66, 2.23	1.38**	1.13, 1.69
Had a Dental Visit at Baseline	β_4	1.53**	1.19, 1.96	1.38*	1.03, 1.85
Low Parent Oral Health Literacy‡	β_5	0.98	0.78, 1.23	0.80	0.50, 1.26
Interaction Effect between EHS and Low Parent Oral Health Literacy‡	β_6	1.01	0.76, 1.35	1.11	0.64, 1.91
Constant	β_0	1.25**	1.06, 1.48	1.97**	1.53, 2.52

* P<0.05, ** P<0.01, CI=confidence interval, †Odds ratios and confidence intervals based on model with empirical standard errors.

‡Oral Health Literacy Assessment (OHLA). Low Parent Oral Health Literacy was defined as the lowest quintile of OHLA scores (OHLA ≤13).

Note: Models did not include random effects for each of the 25 EHS program clusters.

Table 6.6. Overall Dental Use at 24-Month Follow-Up in the Zero-Out Early Childhood Caries Study, by Early Head Start (EHS) and Parent's General Health Literacy

Group	Parent Health Literacy∞	Overall Dental Use (n, %)	Number of Overall Dental Visits (Mean, SD, Range)	Parent Health Literacy∞	Overall Dental Use (n, %)	Number of Overall Dental Visits (Mean, SD, Range)	Parent Health Literacy∞	Overall Dental Use (n, %)	Number of Overall Dental Visits (Mean, SD, Range)
	Overall (N=1,178)			**English** (n=888)			**Spanish** (n=290)		
EHS	Low *(n=90)*	74 (82%)	2.73 (SD=1.99) Range=0-8	Low *(n=50)*	40 (80%)‡	2.36 (SD=1.91) Range=0-7	Low *(n=40)*	34 (85%)	3.20 (SD=2.00) Range=0-8
	Not Low *(n=389)*	314 (81%)	2.55 (SD=2.02) Range=0-11	Not Low *(n=305)*	238 (78%)‡	2.20 (SD=1.83) Range=0-10	Not Low *(n=84)*	76 (90%)	3.82 (SD=2.16) Range=0-11
	Both *(n=479)*	388 (81%)‡	2.58† (SD=2.01) Range=0-11	Both *(n=355)*	278 (78%)‡	2.22† (SD=1.84) Range=0-10	Both *(n=124)*	110 (89%)‡	3.62† (SD=2.12) Range=0-11
Non-EHS	Low *(n=87)*	55 (63%)	2.10* (SD=2.14) Range=0-10	Low *(n=42)*	24 (57%)‡	1.74 (SD=2.08) Range=0-10	Low *(n=45)*	31 (69%)	2.44 (SD=2.16) Range=0-7
	Not Low *(n=612)*	357 (58%)	1.59* (SD=1.86) Range=0-12	Not Low *(n=491)*	270 (55%)‡	1.41 (SD=1.73) Range=0-10	Not Low *(n=121)*	87 (72%)	2.33 (SD=2.18) Range=0-12
	Both *(n=699)*	412 (59%)‡	1.66† (SD=1.90) Range=0-12	Both *(n=533)*	294 (55%)‡	1.44† (SD=1.76) Range=0-10	Both *(n=166)*	118 (71%)‡	2.36† (SD=2.17) Range=0-12

∞Short Assessment of Health Literacy (SAHL). Low Parent Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).
*Significant difference between the number of overall dental visits at the 0.01 significance level using a t-test.
†Significant difference between the EHS and Non-EHS groups at the 0.01 significance level using a t-test.
‡Significant difference between the EHS and Non-EHS groups at the 0.01 significance level using the chi-squared test.
Note: There was no significant evidence of effect modification of the parent health literacy-dental use relationship depending on EHS status at the 0.05 significance level using the Breslow-Day test for homogeneity of the odds ratio : Overall, P=0.78; English, P=0.95; Spanish, P=0.59.

Table 6.7. Logit Models on the Effect of Early Head Start Enrollment on Any Dental Visits With and Without Early Head Start-General Health Literacy Interaction Effect (N=1,178)

	Any Dental Visits	
	OR (95% CI)	OR (95% CI)
Early Head Start	2.53** (1.79, 3.59)	2.54** (1.76, 3.69)
Had a Dental Visit at Baseline	2.65* (1.17, 5.99)	2.64* (1.17, 5.98)
Needed Dental Care at Baseline	8.45** (3.98, 17.91)	8.45** (3.98, 17.91)
Survey Language	0.56** (0.39, 0.79)	0.55** (0.38, 0.79)
Propensity Score	2.10 (0.89, 4.99)	2.12 (0.89, 5.04)
Low Parent General Health Literacy†	--	0.95 (0.57, 1.59)
Interaction Effect between Early Head Start and Low Parent General Health Literacy†	--	0.98 (0.43, 2.20)
Constant	1.60 (0.96, 2.66)	1.61 (0.96, 2.71)
Random Effect, σ_b	0.58 (0.38, 0.90)	0.58 (0.38, 0.90)

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval
†Short Assessment of Health Literacy (SAHL). Low Parent Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).
Note: Models included random effects for each of the 25 Early Head Start program clusters.

Table 6.8. Marginalized Zero-Inflated Negative Binomial Model on the Effect of Early Head Start (EHS) on the Mean Increment in Dental Visits with EHS-General Health Literacy Interaction Effect (N=1,178)

	Parameter	Exponentiation of Parameter	95% CI†
Probability of Having an Excess Dental Visit		**Odds Ratio**	
EHS	α_1	0.31**	0.19, 0.54
Had a Dental Visit at Baseline	α_2	0.40	0.18, 0.89
Needed Dental Care at Baseline	α_3	0.04	0.00, 2.83
Survey Language	α_4	1.26	0.66, 2.43
Propensity Score	α_5	0.86	0.26, 2.83
Low Parent General Health Literacy‡	α_6	1.14	0.62, 2.10
Interaction Effect between EHS and Low Parent General Health Literacy‡	α_7	0.96	0.34, 2.75
Constant	α_0	0.47*	0.28, 0.78
Overall Mean Number of Dental Visits		**Rate Ratio**	
EHS	β_1	1.36**	1.20, 1.55
Had a Dental Visit at Baseline	β_2	1.46**	1.22, 1.76
Needed Dental Care at Baseline	β_3	1.69**	1.55, 1.84
Survey Language	β_4	0.69**	0.59, 0.82
Propensity Score	β_5	1.35	0.98, 1.86
Low Parent General Health Literacy‡	β_6	1.07	0.87, 1.31
Interaction Effect between EHS and Low Parent General Health Literacy‡	β_7	0.88	0.72, 1.09
Constant	β_0	1.79**	1.48, 2.15
Random Effects variance components			
Standard deviation of excess zeros intercept	σ_1		
Standard deviation of mean model intercept	σ_2		
Correlation of random intercepts	ρ		
Overdispersion parameter	φ		

* P<0.05, ** P<0.01, CI=confidence interval, †Odds ratios, rate ratios and confidence intervals are based on the model's empirical standard errors.

‡Short Assessment of Health Literacy (SAHL). Low Parent Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).

Note: Models included random effects for each of the 25 EHS program clusters.

Table 6.9. Logit Models on the Effect of Early Head Start Enrollment on Any Dental Visits With and Without Early Head Start-General Health Literacy Interaction Effect, by English- and Spanish-Speaking Samples

	Any Dental Visits			
	English-speakers (n=888)		**Spanish-speakers** (n=290)	
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Early Head Start	2.56** (1.73, 3.81)	2.50** (1.66, 3.78)	2.39* (1.11, 5.16)	2.86* (1.13, 7.26)
Had a Dental Visit at Baseline	3.09* (1.18, 8.03)	3.08* (1.18, 8.03)	1.76 (0.36, 8.64)	1.61 (0.32, 8.05)
Needed Dental Care at Baseline	8.75** (3.87, 19.78)	8.75** (3.87, 19.78)	8.04* (1.05, 61.79)	8.05* (1.05, 61.96)
Propensity Score	2.38 (0.92, 6.19)	2.37 (0.91, 6.19)	1.39 (0.16, 11.75)	1.64 (0.19, 14.23)
Low Parent General Health Literacy†	--	0.99 (0.50, 1.95)	--	0.92 (0.41, 2.06)
Interaction Effect between Early Head Start and Low Parent General Health Literacy†	--	1.21 (0.42, 3.44)	--	0.59 (0.14, 2.54)
Constant	0.81 (0.52, 1.26)	0.81 (0.52, 1.27)	2.34 (0.92, 5.94)	2.27 (0.88, 5.85)
Random Effect, σ_b	0.63 (0.41, 0.96)	0.63 (0.41, 0.97)	0.60 (0.26, 1.42)	0.61 (0.26, 1.43)

* P<0.05, ** P<0.01, OR=odds ratio, CI=confidence interval
†Short Assessment of Health Literacy (SAHL). Low Parent Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).
§The covariates, "Had a Dental Visit at Baseline" and "Needed Dental Care at Baseline" were dropped due to collinearity. Sixteen observations were dropped because 11 participants with needed dental care at baseline had an overall dental visit and 6 participants with a dental visit at baseline had an overall dental visit.
Note: Models included random effects for each of the 25 Early Head Start program clusters.

Table 6.10. Marginalized Zero-Inflated Negative Binomial Model on the Effect of Early Head Start (EHS) on the Mean Increment in Dental Visits, by English- and Spanish-Speaking Samples

		English-speakers (n=888)		**Spanish-speakers** (n=290)	
	Parameter	Estimate	95% CI	Estimate	95% CI
Probability of Having an Excess Dental Visit		**Odds Ratio**		**Odds Ratio**	
EHS	$\exp(\alpha_1)$	0.28**	0.12, 0.67	0.32*	0.11, 0.91
Had a Dental Visit at Baseline	$\exp(\alpha_2)$	0.35	0.06, 1.98	0.82	0.12, 5.44
Needed Dental Care at Baseline	$\exp(\alpha_3)$	0.04	0.00, 1.95	0.10	0.01, 1.69
Propensity Score	$\exp(\alpha_4)$	0.63	0.12, 3.38	1.58	0.15, 16.52
Low Parent General Health Literacy‡	$\exp(\alpha_5)$	1.22	0.51, 2.90	2.25	0.85, 5.94
Interaction Effect between EHS and Low Parent General Health Literacy‡	$\exp(\alpha_6)$	0.95	0.11, 7.99	0.78	0.12, 4.92
Constant	$\exp(\alpha_0)$	0.61	0.32, 1.16	0.28*	0.10, 0.77
Overall Mean Number of Dental Visits		**Rate Ratio**		**Rate Ratio**	
EHS	$\exp(\beta_1)$	1.37**	1.16, 1.61	1.31*	1.07, 1.61
Had a Dental Visit at Baseline	$\exp(\beta_2)$	1.56**	1.21, 2.02	1.38*	1.03, 1.85
Needed Dental Care at Baseline	$\exp(\beta_3)$	1.93**	1.64, 2.26	1.38**	1.13, 1.69
Propensity Score	$\exp(\beta_4)$	1.32	0.89, 1.94	1.63	0.93, 2.86
Low Parent General Health Literacy‡	$\exp(\beta_5)$	1.15	0.80, 1.65	0.80	0.50, 1.26
Interaction Effect between EHS and Low Parent General Health Literacy‡	$\exp(\beta_6)$	0.83	0.53, 1.29	1.11	0.64, 1.91
Constant	$\exp(\beta_0)$	1.20	0.98, 1.48	1.97**	1.53, 2.52
Random Effects		**Variance Component**			
Standard deviation of excess zeros intercept	σ_1	0.53**	0.13		
Standard deviation of mean model intercept	σ_2	0.25**	0.05		
Correlation of random intercepts	ρ	–1.00**	0.27		
Overdispersion parameter	φ	0.07	0.04		

* P<0.05, ** P<0.01, CI=confidence interval.

‡Short Assessment of Health Literacy (SAHL). Low Parent Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).

Note: Model for English-speaking sample included random effects for each of the 25 EHS program clusters.

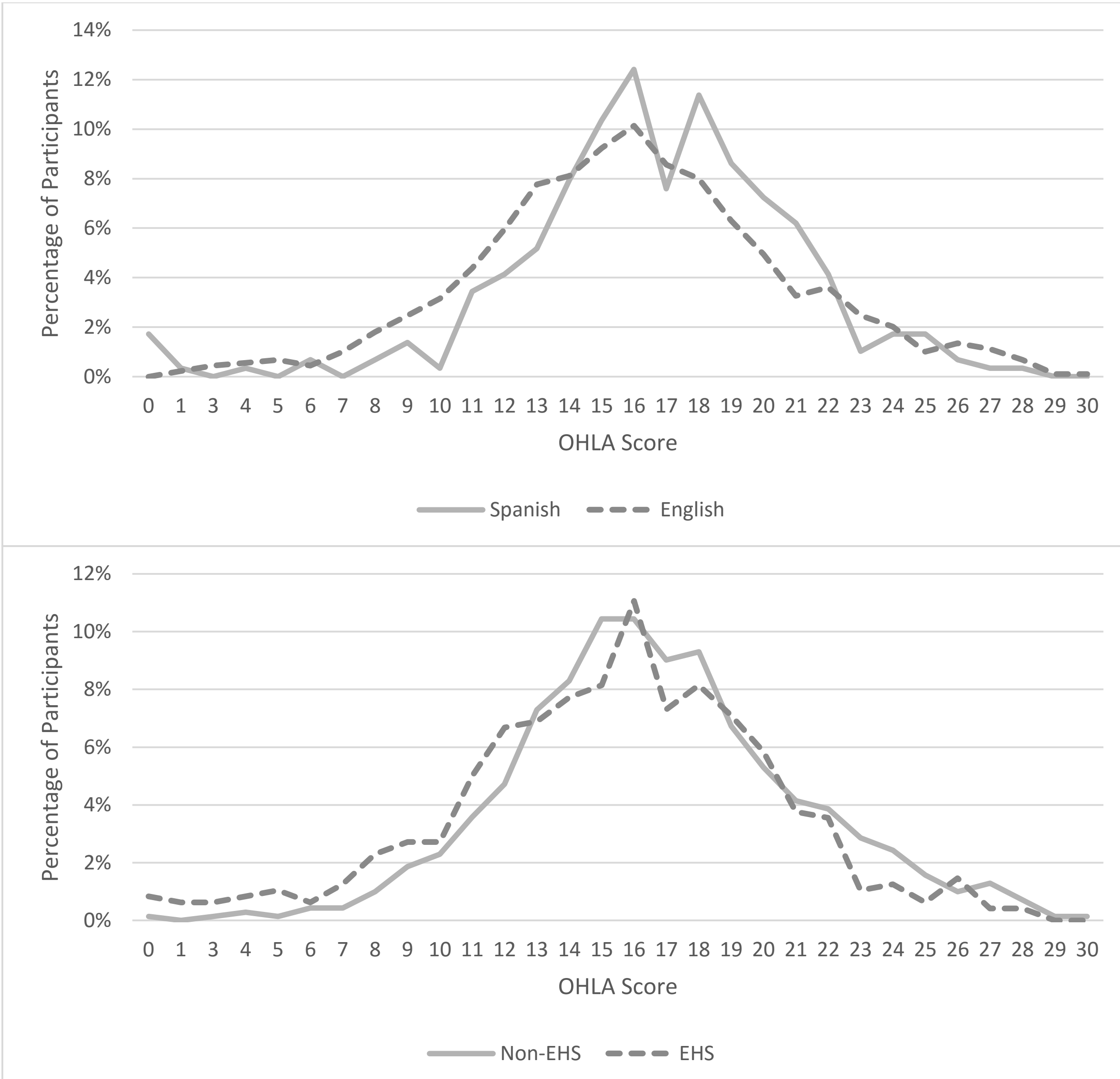

Figure 6.1. Parent oral health literacy as measured by the Oral Health Literacy Assessment (OHLA) instrument, by Spanish and English language and by Early Head Start (EHS) and Non–Early Head Start (Non-EHS) groups (N=1,178).

Low Parent Oral Health Literacy was defined as the lowest quintile of OHLA scores (OHLA ≤13).

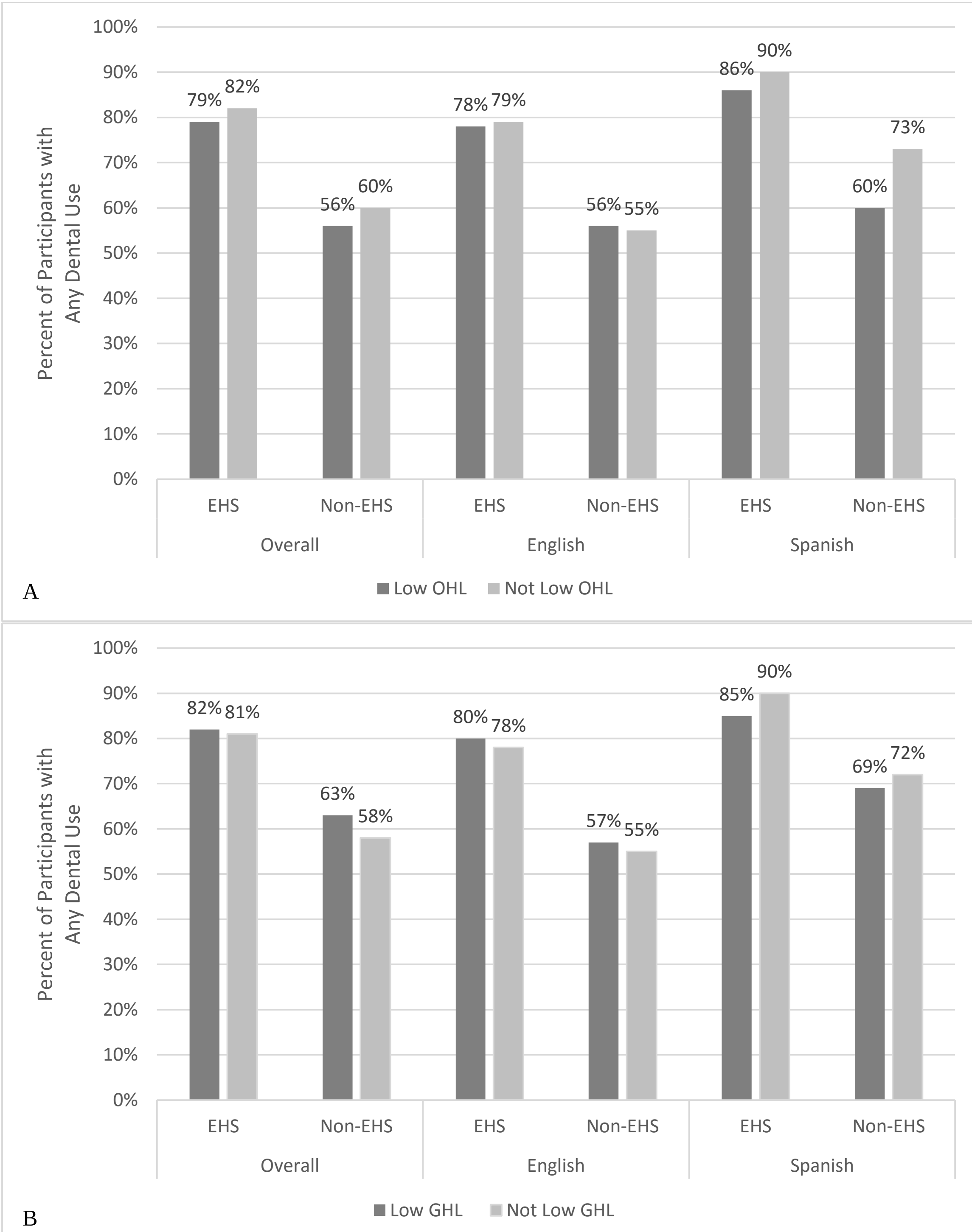

Figure 6.2. Percent pediatric dental use by heath literacy level, EHS group, and language (N=1,178).

A. Parent Oral Health Literacy (OHL) was measured using the Oral Health Literacy Assessment (OHLA) Instrument. Low Parent OHL was defined as the lowest quintile of OHLA scores (OHLA ≤13). B. Parent General Health Literacy (GHL) was measured using the Short Assessment of Health Literacy (SAHL) Instrument. Low Parent GHL was defined as a SAHL score of 14 and under (SAHL ≤14).

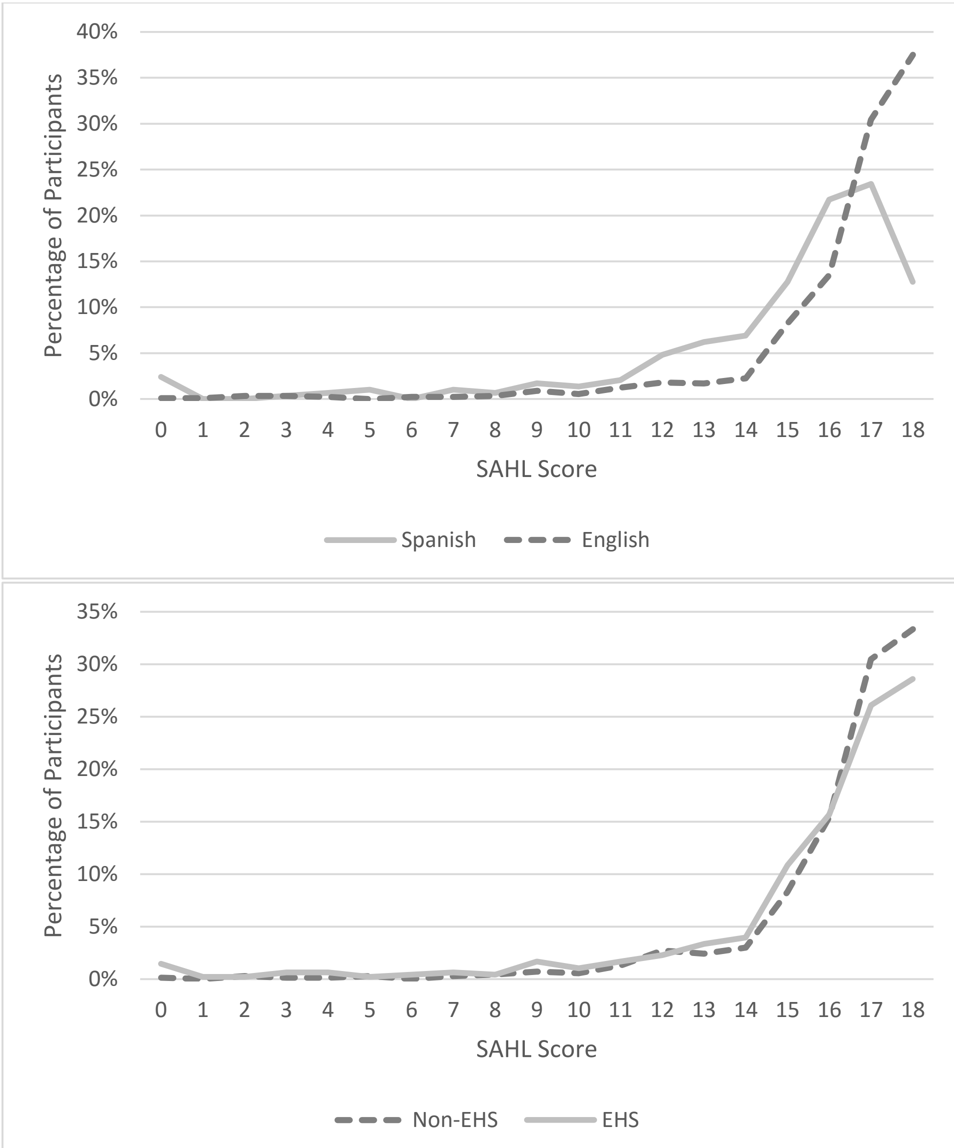

Figure 6.3. Parent General Health Literacy as measured by the Short Assessment of Health Literacy (SAHL) Instrument, by Spanish and English language and by Early Head Start (EHS) and Non-Early Head Start (Non-EHS) Groups (N=1,178).

Low Parent General Health Literacy was defined as a SAHL score of 14 and under (SAHL ≤14).

CHAPTER 7. SUMMARY, LIMITATIONS, AND IMPLICATIONS

EHS is a comprehensive, two-generation early education program that serves high-risk, racially diverse, and disadvantaged families and their children up to 3 years of age. Because programs preferentially enroll the most disadvantaged of families within the targeted communities, they are well-positioned to address the high burden of oral disease in young children at greatest risk for poor oral health. Our study population consisted predominantly of minority families (64%) with a large percentage born outside the United States (27% of parents born in 27 countries). EHS programs are expected to implement daily classroom tooth-brushing with fluoridated toothpaste, provide oral health education for children and family members, and ensure that each child's oral health status is evaluated by a dental professional within 90 days of EHS enrollment.

This dissertation examined the impact of the EHS program on oral health outcomes. First, we evaluated its impact on the use of dental services for children. Then, we examined the impact of EHS on OHRQoL and evaluated whether child dental use mediated the relationship between EHS and OHRQoL. Finally, we tested whether the effect of EHS on child dental use was modified by parent's general or oral health literacy. This concluding chapter summarizes the main findings from the three studies, discusses limitations of each study, and describes policy implications and recommendations for future research.

7.1. Aim 1: The Impact of Early Head Start on Dental Use for Children under 3 Years Old

Our research found that children enrolled in EHS had 2.5 times the odds of having one or more dental visits of any type and 2.6 times the odds of having one or more preventive dental visits compared to non-EHS children. We conclude from these findings that early childhood education programs can increase dental use for the most disadvantaged children in the state, particularly preventive dental services so critical to diverting disease before onset in young children. To our knowledge, this is the first study to show that the goal of improving dental use can be successfully integrated into an early childhood program that includes cognitive, social and emotional interventions. We show that incorporating oral health into an early education and childcare program is an effective way to address inequities in use of dental services.

7.2. Aim 2: Enrollment in EHS, Pediatric Dental Use and Oral Health–Related Quality of Life

This study had three important findings. First, it demonstrated that families with children enrolled in EHS experienced fewer negative impacts on OHRQoL from their children's dental disease experiences than those families with children not enrolled in EHS. Dental use, which was improved through EHS participation, mediated some of the EHS intervention effects on OHRQoL, but in an unexpected direction. This indirect effect resulted in worse OHRQoL but was not of sufficient size to counterbalance the direct effect of EHS on improved OHRQoL. Finally, we found that the average number of impacts from child dental experiences are lower in EHS than non-EHS groups but the difference is not large enough to be of scientific importance or meaningful to parents.

These results call attention to both the effectiveness of improving quality of life for low-resource families through early childhood education program as well as the need for future research to reduce the potential for negative impacts of dental use on children and families.

7.3. Aim 3: The Influence of Health Literacy on the Effectiveness of Early Head Start's Improving Children's Dental Use

Our research filled the gap in knowledge about general and oral health literacy levels in EHS families, and whether parents' health literacy modifies the significant and positive impact that EHS has on dental use. We demonstrated that a larger proportion of parents with young children enrolled in EHS report low general and oral health literacy compared to similar disadvantaged families, particularly among English-speakers. Second, parent's oral and general health literacy did not moderate the effectiveness of the EHS interventions on dental use. This finding suggests that improvements in children's dental use was not attenuated by whether or not the parent had low health literacy. EHS programs were able to improve dental use and even achieve higher rates than other low-income children in the face of this high prevalence of low literacy. These results are particularly timely and relevant, not only because of the high prevalence of dental caries in young children, but also because low health literacy plays a critical role in oral health disparities.

7.4. Limitations

This dissertation research has several limitations. First, we could not randomize families; but used a Medicaid-matched control group and propensity scores to reduce the potential for biased estimates of effect. Second, the study was conducted in a single state and results might not generalize to other states. However, it is important to note that we did not enroll a health care-seeking population; therefore it likely includes parents who may not have wanted to take their child to the dentist and families who may not value oral health.

Third, we relied on self-reported data, which may overestimate preventive dental use.[143] However, the potential overestimation of the EHS effects may be counterbalanced by cross-over, that is children in the non-EHS group participated in EHS and alternative early childhood education programs. Such crossover could lead to an underestimation of the effect of EHS on dental use.

Fourth, the oral health effects of EHS may depend on the type of EHS program (home, center, mixed), length of enrollment in EHS, and other characteristics of EHS programs (teachers, facilities, location, resources) that were not considered in our analysis. The EHSREP found that the effects of home-based EHS programs on non-dental outcomes to be different than center-based or mixed EHS programs.[4] EHS programs are heterogeneous and their characteristics can influence the EHS exposure and have an effect on the relationship between EHS and dental outcomes.

Finally, the validity of the results dependent on the properties of our research instruments. Although we used a validated instrument to measure oral health–related quality of life (ECOHIS) in Aim 2, few studies have evaluated the performance of ECOHIS in longitudinal studies of English-speaking parents,[165,166] and equivalence of ECOHIS scores between the English and Spanish speakers has not been established. A previous study suggested that some differences might exist between ECOHIS scores when administered to English- and Spanish-speaking samples.[148] Moreover, there are no studies that define a clinically important difference in ECOHIS scores. One strength of the ECOHIS instrument is that it is parent-reported, which indicates that it is likely that the differences between the EHS and non-EHS groups are meaningful differences to the parent. For Aim 3, the validity of the results are dependent on the psychometric properties of the OHLA and SAHL-S&E instruments as applied in this study population. Currently, no cut-off for low OHL using OHLA has been published, so we used an arbitrary cut-off for low OHL based on the lowest quintile of OHLA scores.

7.5. Future Research

Results of research conducted as part of this dissertation suggest several needs for future research: 1) to identify aspects of EHS that result in improved access to care; 2) to establish the minimally important difference for ECOHIS; 3) to evaluate the direct impact of health literacy on child oral health outcomes; 4) to elucidate the reasons for the negative mediating effect of dental use on the impact of EHS on improving OHRQoL; 5) to determine if an oral health intervention in EHS contributes to the improvement in child oral health outcomes; and 6) to improve the measurement of oral health outcomes related to early childhood dental research. Each of these future research areas is described in more detail in the following paragraphs.

Additional research is needed to identify the attributes of EHS programs that are associated with children's improved dental use and, ultimately, whether they lead to improvements in clinical and psychosocial oral health outcomes. Identifying these attributes and the pathways through which they affect outcomes can inform the design of future federal and state early education programs that target vulnerable preschool-aged children and their families.

With regards to OHRQoL, future research is needed to determine whether the difference in any OHRQoL impact between the EHS and non-EHS groups is clinically significant by establishing a minimally important difference for ECOHIS. A previous study estimated the MID for ECOHIS scores among parents of older children to be 2.7, far exceeding differences for scores obtained in the current study.[104]

Future research is needed to study the modifying impact of general and oral health literacy on other child dental outcomes, such as oral hygiene practices including tooth-brushing. These modifiable health outcomes may be more susceptible to the effects of health literacy on the effectiveness of social programs such as EHS than was found for dental use in this study. Additionally, future research is also needed on the direct impact of health literacy on dental outcomes, such as dental use, among young children under 3 years old.

Although the observed total effect of EHS suggests improvements in the prevalence of OHRQoL, we also found that OHRQoL was negatively affected by child dental use. First, further research is needed to validate this finding for young children. Second, more research is needed to better understand the causes of negative impacts of dental use on families with very young children to identify steps that can be taken to mitigate the negative effects of early childhood dental visits. Using the current data set, a future analysis can compare the self-rated experiences for families with and without early dental experiences, especially related to particular dental home characteristics, such as family-centered, compassionate and culturally effective dental care.

Specific to EHS, more research is needed to better understand the causes of negative impacts of dental use on families with very young children and how early childhood education programs such as EHS can provide services and support to help mitigate the negative impact of dental use by young children on families. For example, ensuring that enrolled children have access to dental care that is family-centered and culturally acceptable, consistent with a dental home, may help avoid the negative impacts to OHRQoL observed by Mofidi and colleagues (2009).[9] EHS programs can develop and evaluate interventions, including acclimation and preparation for in-office dental use, targeted to parents of very young children to help reduce the negative impacts of dental visits.

In the current study, teachers and staff in participating EHS programs received training in children's oral health to bolster awareness of EHS performance standards and help facilitate their implementation. The goal of this intervention was to promote maximum implementation of the federal EHS oral health performance standards, but with a minimal and practical intervention. Future research is needed to elucidate whether this additional training for EHS teachers and staff contributed to the observed impacts of EHS on oral health outcomes, or if the effects of EHS are robust to variations in EHS adherence to the oral health performance standards.

Finally, future research is needed to improve the measurement of oral health outcomes used in early childhood dental research. Regarding OHRQoL, future research is needed to establish the comparability between the English and Spanish ECOHIS. Regarding health literacy, an OHL instrument that can be used for English and Spanish speakers is needed. Also, future research is needed to establish a validated cut-off for low OHL.

7.6. Policy Implications

The increasing prevalence of tooth decay and growing diversity in young children in North Carolina makes this study both timely and relevant to policy. Understanding the relationship between EHS and improved access to dental services is an important step toward addressing the epidemic of dental caries. Our research shows that North Carolina EHS is helping to address childhood caries, the most common chronic disease affecting young children, by improving use of preventive dental services. Our results also provide evidence of effectiveness and guidance for the inclusion of oral health promotion in policies and programs that target the considerable number of children who participate in private early childhood programs, not just the federally sponsored EHS program. State officials are making plans for the dissemination of preventive oral health guidelines tested in this project to the larger group of public and private early childhood programs.

Our study was also an evaluation of a federal program that was implemented in the state of North Carolina. Although we do not know the degree to which the EHS performance standards were implemented or our efforts to reduce selection bias were entirely successful, we found that families with children enrolled in EHS were better off compared to families with children who were not enrolled in EHS. The findings from this study indicate that disadvantaged families with young children benefit from being enrolled in comprehensive early education programs. Currently, EHS only serves about four percent of eligible infants and toddlers.[61] This study provides evidence not only for the continuation but the expansion of comprehensive early education programs for children under 3 years old.

APPENDIX 1. TWENTY-FIVE SOCIO-DEMOGRAPHIC VARIABLES INCLUDED IN PROPENSITY SCORE ANALYSES

Child and Parent Socio-demographic Variables		**EHS** Mean (SD) or %	**Non-EHS** Mean (SD) or %	**Non-EHS with GBM weight** Mean (SD) or %
1	Child Age in months	10.4 (4.9)	10.1 (4.6)	10.1 (4.8)
2	Child Gender			
	Male	55%	51%	51%
	Female	45%	49%	49%
3	Survey language			
	English	76%	76%	74%
	Spanish	24%	24%	26%
4	Parent race and ethnicity			
	Non-Hispanic White	25.3%	43.0%*	25.4%
	Non-Hispanic African American	36.7%	20.6%*	34.3%
	Non-Hispanic Native American	3.3%	1.6%	2.1%
	Non-Hispanic Other single race and ethnicity	0.2%	1.2%*	0.5%
	Non-Hispanic Other multiple race and ethnicity	5.0%	5.1%	5.5%
	Hispanic	29.0%	28.2%	31.8%
	Missing	0.5%	6.8%	0.4%
5	Child race and ethnicity			
	Non-Hispanic White	18.5%	35.6%*	20.0%
	Non-Hispanic African American	35.6%	19.5%*	34.1%
	Non-Hispanic Native American	2.4%	1.1%	1.7%
	Non-Hispanic Other single race and ethnicity	0.2%	0.9%	0.4%
	Non-Hispanic Other multiple race and ethnicity	8.3%	11.8%	8.6%
	Hispanic	34.2%	30.9%	34.9%
	Missing	0.8%	8.8%	0.4%
6	Parent place of birth			
	US and Puerto Rico	73.5%	73.1%	71.5%
	Mexico	20.1%	18.1%	21.0%
	South America	0.5%	0.3%	0.2%
	Central America	0.2%	0.6%	0.2%
	Caribbean	0.3%	0.2%	0.3%
	Asia	3.8%	6.1%	5.5%
	Europe	0.9%	0.4%	0.6%
	Middle East	0%	0.2%	0.2%
	Africa	0%	0.2%	0.2%
	Other	0.6%	0.6%	0.3%
	Missing	0.2%	0%	0%

7	Multiple birth, such as twins or triplets			
	Yes	3.1%	2.5%	4.2%
	No	96.4%	97.3%	95.6%
	Don't know	0%	0%	0%
	Missing	0.5%	0.2%	0.2%
8	Brothers or sisters			
	Yes	77.7%	63.4%*	74.8%
	No	22.0%	36.5%*	25.1%
	Don't know	0%	0%	0%
	Missing	0.3%	0.1%	0.1%
9	Interviewee relationship			
	Mother	94.2%	95.6%	95.3%
	Father	2.5%	2.2%	2.0%
	Grandparent	2.4%	1.0%	1.6%
	Legal Guardian	0.5%	0.5%	0.6%
	Foster Parent	0%	0.3%	0.2%
	Other	0.3%	0.4%	0.3%
	Missing	0.2%	0%	0%
10	Interviewee is biological mother			
	Yes	99.8%	99.8%	99.7%
	No	0.2%	0.2%	0.3%
	Missing	5.8%	4.4%	4.7%
11	Interviewee gender			
	Male	2.5%	2.6%	2.4%
	Female	97.5%	97.4%	97.6%
	Missing	0.2%	0%	0%
12	Number of member in household younger than 5 years	1.78 (0.91)	1.42* (0.68)	1.67 (0.80)
	Missing	0.2%	0%	0%
13	Number of member in household between 5 and 17 years-old	0.87 (1.14)	0.74 (1.04)	0.82 (1.09)
	Missing	0.9%	0.2%	0.3%
14	Number of member in household older than 17 years including self	2.08 (0.96)	2.26 (0.95)	2.13 (1.01)
	Missing	0.3%	0%	0%
15	Interviewee nativity			
	Within United States	26.6%	27.1%	28.7%
	Outside United States	3.4%	2.9%	1.3%
	Missing	0.2%	0%	0%
16	Interviewee year immigrated to US	2000.5 (6.5)	2001.3 (5.1)	2000.5 (5.3)
	Missing	73.8%	73.4%	72.1%
17	Language spoken at home			
	English	72.8%	72.4%	70.5%

	Spanish	25.1%	24.4%	27.4%
	Other	1.7%	3.2%	2.0%
	Missing	0.3%	0%	0%
18	Interviewee marital status			
	Single/Never Married	54.9%	44.4%*	52.9%
	Married/Common Law Marriage/Live with Partner	38.5%	48.1%	39.3%
	Separated/Divorced/Widowed	6.0%	7.3%	7.5%
	Other	0.5%	0.2%	0.3%
	Missing	0.2%	0%	0%
19	Interviewee total years of school completed	11.9 (3.2)	12.4 (3.2)	11.9 (3.2)
	Missing	0.2%	0%	0%
20	Interviewee highest level of education			
	Some high school or less	31.2%	26.3%	31.5%
	High school graduate or GED	30.1%	26.5%	26.6%
	Some college or 2-year college degree	32.2%	36.5%	33.7%
	College degree or more	6.3%	10.6%	8.1%
	Missing	0.2%	0.1%	0%
21	Interviewee currently enrolled in Medicaid			
	Yes	49.9%	56.1%	49.6%
	No	49.3%	43.2%	50.0%
	Don’t know	0%	0%	0%
	Missing	0.8%	0.6%	0.4%
22	Interviewee has another type of insurance that pays for dental care			
	Yes	10.5%	13.4%	10.3%
	No	39.2%	43.0%	39.9%
	Don’t know	0%	0%	0%
	Missing	50.2%	43.5%	49.8%
23	Interviewee type of dental insurance			
	Government Program	0.8%	0.4%	0.4%
	Private Insurance	8.5%	10.5%	8.1%
	Other	1.1%	2.5%	1.8%
	Missing	89.6%	86.6%	89.7%
24	Child enrolled in a public health insurance program such as Medicaid, Health Check, Health Choice, or the State Children’s Health Insurance Plan			
	Yes	98.1%	99%	99.2%
	No	1.9%	1%	0.8%
	Missing	0.3%	0%	0%
25	Child has another type of insurance that covers dental care			
	Yes	41.7%	44.4%	35.5%
	No	58.3%	55.6%	64.5%

SD = standard deviation   *Effect size is greater than 0.2.

APPENDIX 2. TWENTY-TWO EARLY HEAD START (EHS) SELECTION CRITERIA INCLUDED IN PROPENSITY SCORE ANALYSES

	Early Head Start Selection Criteria	**EHS** Mean (SD) or %	**Non-EHS** Mean (SD) or %	**Non-EHS with GBM weight** Mean (SD) or %
1	Physical, learning, or mental health limitations			
	Yes	4.2%	3.3%	4.1%
	No	94.8%	95.5%	95.1%
	Don't know	0%	0%	0%
	Missing	0.9%	1.2%	0.8%
2	Household member has a physical, learning, or mental health limitation			
	Yes	16.8%	14.1%	14.9%
	No	82.6%	85.2%	84.6%
	Don't know	0%	0%	0%
	Missing	0.6%	0.8%	0.5%
3	Household member receives Welfare, Work First, TANF or general cash assistance?			
	Yes	12.2%	6.7%	11.2%
	No	86.7%	92.2%	87.5%
	Don't know	0%	0%	0%
	Missing	1.1%	1.2%	1.3%
4	Household member receives unemployment benefits or disability insurance?			
	Yes	16.3%	14.9%	13.0%
	No	82.9%	84.2%	86.3%
	Don't know	0%	0%	0%
	Missing	0.8%	0.9%	0.7%
5	Household member receives Food Stamps?			
	Yes	19.9%	34.9%*	21.6%
	No	79.1%	64.9%*	78.3%
	Don't know	0%	0%	0%
	Missing	0.9%	0.1%	0.1%
6	Household member receives WIC - Special Supplemental Food Program for Women, Infants, and Children?			
	Yes	91.0%	90.0%	92.6%
	No	9.0%	10.0%	7.4%
	Missing	0.3%	0%	0%
7	Household member receives Child support or alimony?			
	Yes	16.8%	12.2%	14.5%
	No	82.3%	87.6%	85.3%
	Don't know	0%	0%	0%
	Missing	0.9%	0.2%	0.1%

8	Household member receives Child care subsidy or education assistance?			
	Yes	21.4%	10.4%*	18.4%
	No	76.3%	89.2%*	81.0%
	Don't know	0%	0%	0%
	Missing	2.4%	0.3%	0.6%
9	Household member receives Housing assistance?			
	Yes	16.8%	7.4%*	13.6%
	No	82.1%	92.3%*	86.2%
	Don't know	0%	0%	0%
	Missing	1.1%	0.3%	0.2%
10	Household member receives Social Security: disability, retirement or survivor's benefits?			
	Yes	14.4%	13.9%	14.0%
	No	84.9%	85.6%	85.6%
	Don't know	0%	0%	0%
	Missing	0.6%	0.5%	0.4%
11	Household member receives Medicare or Medicaid?			
	Yes	17.9%	13.3%	16.2%
	No	81.3%	86.3%	83.4%
	Don't know	0%	0%	0%
	Missing	0.8%	0.3%	0.4%
12	Household member receives Workers compensation?			
	Yes	0.5%	0.8%	0.7%
	No	98.7%	99.2%	99.3%
	Don't know	0%	0%	0%
	Missing	0.8%	0%	0%
13	Household member receives Veteran's benefits?			
	Yes	1.4%	2.4%	2.7%
	No	98.3%	97.4%	97.2%
	Don't know	0%	0%	0%
	Missing	0.3%	0.2%	0.2%
14	Household member receives other type of public or governmental support?			
	Yes	3.9%	2.9%	2.3%
	No	94.8%	95.7%	96.4%
	Don't know	0%	0%	0%
	Missing	1.3%	1.4%	1.3%
15	Child ever been homeless or not had a regular place to live			
	Yes	3.8%	2.6%	2.8%
	No	95.8%	97.3%	97.1%
	Don't know	0%	0%	0%
	Missing	0.5%	0.1%	0.2%

16	Working full time (30 hours per week or more)			
	Yes	20.8%	18.6%	19.3%
	No	79.2%	81.4%	80.7%
	Missing	0.3%	0%	0%
17	Working part-time			
	Yes	16.4%	18.3%	18.3%
	No	83.6%	81.7%	81.7%
	Missing	0.3%	0%	0%
18	Looking for work			
	Yes	32.8%	28.6%	30.8%
	No	67.2%	71.4%	69.2%
	Missing	0.3%	0%	0%
19	Laid off from work			
	Yes	4.3%	6.0%	5.7%
	No	95.7%	94%	94.3%
	Missing	0.3%	0%	0%
20	In school / training			
	Yes	27.1%	18%*	22.5%
	No	72.9%	82%	77.5%
	Missing	0.3%	0%	0%
21	Keeping house			
	Yes	61.1%	65.5%	64.3%
	No	38.9%	34.5%	35.7%
	Missing	0.3%	0%	0%
22	Other work			
	Yes	6.6%	9.0%	8.1%
	No	93.4%	91%	91.9%
	Missing	0.3%	0%	0%

SD = standard deviation *Effect size is greater than 0.2.

APPENDIX 3. BASELINE CHARACTERISTICS THAT WERE IMBALANCED BETWEEN THE EHS AND NON-EHS GROUPS PRIOR TO PROPENSITY SCORE ANALYSES

Socio-demographic Variable	*On average, EHS Group had:*
Brothers or sisters	More brothers and sisters
Number in household under 5 years-old	More people under 5 years-old in the household
Parent marital status	More single/never married parents
Parent race and ethnicity: Non-Hispanic White	Fewer non-Hispanic White parents
Parent race and ethnicity: Non-Hispanic African American	More non-Hispanic African American parents
Parent race and ethnicity: Non-Hispanic single other race	Fewer non-Hispanic single other race parents
Child race and ethnicity: Non-Hispanic White	Fewer non-Hispanic White children
Child race and ethnicity: Non-Hispanic African American	More non-Hispanic African American children
Early Head Start Selection Criteria	*On average, EHS Group had:*
Does any of your household receive Food Stamps?	Received more Food Stamps
Does any of your household receive Child care subsidy or education assistance?	Received more child care subsidy or education assistance
Does any member of your household receive Housing assistance?	Received more housing assistance
Parent in school or training	More parents in school or training

APPENDIX 4. SAS CODE FOR THE MARGINALIZED ZERO-INFLATED NEGATIVE BINOMIAL MODELING WITH RANDOM EFFECTS

```
* MZINB: Use random effects to adjust for clustering of EHS programs (n=25);
title "marginalized ZINB model with RE clusters and model-based SEs from NLMIXED";
proc nlmixed data= duse absxconv=0.00001;
parms a0=-0.2908 a1_ehs=-0.9109 a2=-0.7196 a3=-2.7893 a4=-0.9806 phi=0.06 /* from
traditional ZINB model estimates*/
   b0= 0.2925 b1_ehs= 0.2624 b2= 0.4277 b3= 0.5652 b4= 0.4560 /* use NB regr
estimates*/
       sigma1 1 rho -0.2 sigma2 1; /*use NB regr estimates*/
linpinfl = a0 + u1 + a1_ehs*ehs + a2*ps + a3*needcare + a4*Boverallvisit;
psi = 1/(1+exp(-linpinfl)); /*inflation probability for excess zeros*/
nu = exp(b0 + u2 + b1_ehs*ehs + b2*ps + b3*needcare + b4*Boverallvisit); /*nu is the
marginal mean*/
mu = nu/(1-psi); /*transformation from marginal mean to susceptical class mean*/
alpha = 1/phi;
theta = 1/(1+(mu/alpha));
if numvisit=0 then loglike =log(psi + (1-psi)*(theta**alpha));
else loglike = log(1-psi) + lgamma(numvisit+alpha) - lgamma(alpha)
             + numvisit*log(1-theta)+alpha*log(theta) - lgamma(numvisit+1);
model numvisit ~ general(loglike);
random u1 u2 ~ Normal([0, 0], [sigma1*sigma1, rho*sigma1*sigma2, sigma2*sigma2])
subject=ProCluster;
estimate 'exp(ehs)' exp(b1_ehs);
ODS output ParameterEstimates=MZINBre_mb;
run;

* MZINB with RE clusters and empirical SEs;
title "marginalized ZINB model with RE clusters and empirical SEs from NLMIXED";
proc nlmixed data= duse absxconv=0.00001 empirical;
parms a0=-0.2908 a1_ehs=-0.9109 a2=-0.7196 a3=-2.7893 a4=-0.9806 phi=0.06
   b0= 0.2925 b1_ehs= 0.2624 b2= 0.4277 b3= 0.5652 b4= 0.4560
       sigma1 1 rho -0.2 sigma2 1;
linpinfl = a0 + u1 + a1_ehs*ehs + a2*ps + a3*needcare + a4*Boverallvisit;
psi = 1/(1+exp(-linpinfl));
nu = exp(b0 + u2 + b1_ehs*ehs + b2*ps + b3*needcare + b4*Boverallvisit);
mu = nu/(1-psi);
alpha = 1/phi;
theta = 1/(1+(mu/alpha));
if numvisit=0 then loglike =log(psi + (1-psi)*(theta**alpha));
else loglike = log(1-psi) + lgamma(numvisit+alpha) - lgamma(alpha)
             + numvisit*log(1-theta)+alpha*log(theta) - lgamma(numvisit+1);
model numvisit ~ general(loglike);
random u1 u2 ~ Normal([0, 0], [sigma1*sigma1, rho*sigma1*sigma2, sigma2*sigma2])
subject=ProCluster;
estimate 'exp(ehs)' exp(b1_ehs);
ODS output ParameterEstimates=MZINBre_emp;
run;
```

APPENDIX 5. SAS CODE FOR THE MARGINALIZED SEMICONTINUOUS TWO-PART MODEL WITH RANDOM EFFECTS

```
title "Generalized Gamma Marginalized Two-part model with RE clusters and
empirical SEs from NLMIXED";
proc nlmixed data=eco maxiter=10000 tech=nrridg empirical;
bounds 0<sigma;
parms a0 = -0.7335 a1_ehs = -0.32733 a2 = 0.0645 a3 = 0.3749 a4 = 0.0405
      b0 = 1.3187 b1_ehs= -0.0339 b2= 0.0334 b3= 0.0393 b4= 0.0201
      sigma=0.8196 kappa=-0.2259 theta1=0.2 theta2=0.1247 rho=0.25;
linbin = a0 + z1 + a1_ehs*ehs + a2*ECOHISscoreB1 + a3*English + a4*ps;
binprob = exp(linbin)/(1+exp(linbin)); /* probability ECOHISscoreF > 0 */
eta=abs(kappa)**(-2);
mu = b0 + z2+ b1_ehs*ehs + b2*ECOHISscoreB1 + b3*English + b4*ps
      - log(binprob) - (sigma*log((kappa)**2))/kappa-log(GAMMA(1/((kappa)**2)
      + sigma/kappa)) + log(GAMMA(1/((kappa)**2)));
if ECOHISscoreF1=0 then loglik=log(1-binprob);
else if ECOHISscoreF1>0 then do;
      u = SIGN(kappa)*(log(ECOHISscoreF1)-mu)/sigma;
loglik=log(binprob)+eta*log(eta)-log(sigma)-log(ECOHISscoreF1)
      - log(GAMMA(eta))-.5*log(eta) + u*sqrt(eta)-eta*exp(abs(kappa)*u);
end;
model ECOHISscoreF1~general(loglik);
random z1 z2 ~ Normal([0, 0], [theta1*theta1, rho*theta1*theta2,
      theta2*theta2]) subject=ProCluster;
ECOHISscoreF1pred=exp(b0+b1_ehs*ehs+b2*ECOHISscoreB1+b3*ps);
predict ECOHISscoreF1pred out=mtpgg_pred;
run;
```

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