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Risk factors identification in children with speech disorders: pilot study

Identificação dos fatores de risco em crianças com alteração fonoaudiológica: estudo piloto

ABSTRACT

Purpose: To identify the main risk factors related to children and their parents, associated with speech and language disorders. **Methods:** A prospective descriptive study conducted with 170 children and their parents assisted at a school clinic in the period between March 2010 and July 2012. A protocol was developed for this study in order to identify risk factors for language and speech disorders. Data were tabulated and analyzed using descriptive and inferential statistics by the χ^2 and Student's *t*-test . **Results:** The demographic profile is composed of male children aged between 4 and 5 years old, ethnicity declared by parents as being white, residents of the western region of the city of São Paulo, and whose parents had completed high school. The factors related to family and considered as risks for language impairment were being an only child and having a family history of speech and language disorders. As for the children's health, prematurity, hospitalization for a long period, and the presence of deleterious oral habits were also considered as risk factors. **Conclusion:** The protocol allows establishing the main risk factors related to children with speech and language disorders. It is suggested that children who present with one or more of the aforementioned risk factors should be regularly monitored for speech and language development and, if necessary, referred for early intervention.

RESUMO

Objetivo: Identificar os principais fatores de risco relacionados à criança e seus pais associados às alterações fonoaudiológicas. **Métodos:** Trata-se de um estudo descritivo e prospectivo realizado com 170 crianças e seus respectivos pais atendidas em uma clínica-escola no período de março de 2010 a julho de 2012. Utilizou-se o Protocolo para identificação de fatores de risco para a alteração de linguagem e fala, desenvolvido para este estudo. Os dados foram tabulados e submetidos à análise descritiva e inferencial por meio do χ^2 e Teste t de Student. **Resultados:** O perfil sociodemográfico é de crianças do gênero masculino, com quatro e cinco anos de idade, da raça declarada branca, moradores da região Oeste da cidade de São Paulo e cujos pais tinham ensino médio completo. Os fatores relacionados à família considerados de risco para a alteração de linguagem foram ser filho único e ter antecedentes familiares. Quanto à saúde da criança, a prematuridade, internações por longo período e presença de hábitos orais deletérios também foram considerados fatores de risco. **Conclusão:** O protocolo permite estabelecer os principais fatores de risco fonoaudiológicos em crianças. Sugere-se que as crianças que apresentam um ou mais fatores de risco citados acima devam ser acompanhadas periodicamente quanto ao desenvolvimento da fala e linguagem e, se necessário, encaminhadas para intervenção precoce.

Study carried out at the Laboratory of Speech Language Pathology and Audiology Investigation in Primary Health Attention of the Physical Therapy; Speech Language Pathology and Audiology and Occupational Therapy Department, School of Medicine, Universidade de São Paulo – USP – São Paulo (SP), Brazil.

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INTRODUCTION

Speech Language Pathology and Audiology comprehends individual and collective actions aiming at health promotion, protection, and recovery in aspects concerning language, voice, hearing, and oral motricity. Preventive actions provide support, especially for the management of projects and programs and for their insertion in the management of health services(1).

Knowing about the prevalence, incidence, and risk factors in children aged less than 6 years old with changes in language acquisition and development will decrease the impact on their academic lives, and also on social relations⁽²⁾.

Several studies describe the prevalence and the incidence of language-related changes in children^(3,4). However, only a few point out the risk factors for such changes. Risk factors are aspects of individual behavior or lifestyle, environmental exposure, hereditary, or congenital characteristics associated with a condition related to health^(5,6).

Studies show that racial and socioeconomic variables are prone to communication disorders⁽⁷⁻⁹⁾.

No national references were located concerning the risk factors for different speech language pathology and audiology changes. In this context, the need for studies that identify different types of speech language pathology and audiology changes in children is clear, so that actions connected to public health policies can be effectively conducted based on evidence.

The objective of this study is to identify the main risk factors related to children and their parents associated with speech language pathology and audiology changes.

METHODS

It is a descriptive and prospective study conducted with all the children assisted in the Speech Language Pathology and Audiology Clinic of the Physical Therapy; Speech Language Pathology and Audiology and Occupational Therapy Department of the School of Medicine at Universidade de São Paulo (FMUSP), from March 2010 to July 2012. This study was approved by the Research Ethics Committee of FMUSP, process no. 057/11, and all of the parents/people in charge of the children signed the informed consent.

Individuals

One hundred and seventy children participated in this study, as well as their respective parents/responsible parties, who searched for speech language pathology and audiology care in the referred school clinic.

The inclusion criteria were: age group until 5 years old and complaints related to hearing, voice, speech, language, and orofacial myofunctional system.

Material and procedures

At the speech language pathology and audiology screening, the protocol to identify risk factors for language and speech-related changes (PIFRAL) was used. The protocol was developed by the authors of this article specifically for this research, based on previous studies concerning the risk factors for communication (2,10,11).

PIFRAL is a form with 29 items addressed to parents/ responsible parties (Chart 1) and comprehends sociodemographic (age, gender, declared ethnicity, and schooling of the children; age, schooling, and profession of the parents; location of residence), and family questions (number of siblings, order of birth, twinning, time spent with children, and language used in the house), as well as information on pre, peri, and postnatal periods and the temper of the child.

In the clinical routine of the Laboratory of Speech Language Pathology and Audiology Investigation in Primary Health Attention, the parents/responsible parties of children assisted at screening were asked to answer the PIFRAL form, individually.

Chart 1. Protocol to identify risk factors for language and speech-related changes

3	
Risk factor protocol	
Name:	Number:
1. Age:	

- 2. Gender:
- 3. Ethnicity:
- Speech language pathology and audiology complaint:
- 5. Age at the onset of speech language pathology and audiology
- 6. Are there cases of family members with the same difficulty or other hearing or communcative changes? Which ones?
- Child's schooling:
- 8. Parents' schooling:
- 9. Parents' profession:
- 10. Number of siblings and their age:
- 11. Order of birth:
- 12. Twinning:
- 13. Parents' age:
- 14. Age of the mother at birth:
- 15. Mother tongue and language spoken at home:
- 16. How much time parents spend with their children:
- 17. Child's temper:
- 18. Neighborhood of residence:
- 19. Socioeconomic status:
- 20. Did the mother present prenatal intercurrences?
- 21. Did the mother use drugs, medicines, alcohol, or smoked during pregnancy?
- 22. Was the child born premature or with low weight?
- 23. Was the APGAR score lower than 4 at the first minute and lower than 6 at the fifth minutes of life?
- 24. Was the child hospitalized?
- 25. What are the child's health conditions? Does he or she have any diagnosed disease?
- 26. Has the child undergone a hearing test? Does the child have difficulties hearing?
- 27. Does the child present difficulties to feed or motor facial problems?
- 28. Does the child present or has presented with oral habits? For how long?
- 29. Has the child ever seen or suffered any type of violence (robbery, fights, missing family members, abuse, negligence, etc.)?

Data analysis

The collected data were quantitative and qualitative. More specifically, variables concerning the educational aspects were categorized as "up to incomplete high school" and "from complete high school on"; variables on socioeconomic status were subdivided according to the Brazilian Association of Research Companies⁽¹²⁾; those of occupational classification considered the Brazilian Occupation Classification⁽¹³⁾; and those concerning the temper of the child were categorized according to Klein and Linhares⁽¹⁴⁾.

Data were tabulated and submitted to descriptive and inferential analysis by the χ^2 test in order to describe the possible variations in the studied group, according to the stipulated variables. The Student's *t*-test was also used to verify the statistical significance among the studied variables.

RESULTS

The mean time between perceiving the problem and performing the speech language pathology and audiology screening was 16 months, and the onset of the complaint occurred after 33 months of life, on an average.

Sociodemographic profile of the participants

Mostly, there were children aged 4–5 years old (30.0%), male (69.4%) whose ethnicity was declared as white by the parents (63.5%) (Table 1). The prevalent level of kinship of the informer was the mother (90.0%), and the dominant socioeconomic level was B1 (R\$ 4,558.00–8,098.00) and B2 (R\$ 2,327.00–4,557.00) (24.1% each).

Table 1. Characterization of the 170 children who participated in this study

Demographic information	Classification	Frequency	%
	0-12 months	1	0.6
	1-2 years old	12	7.1
Age group	2-3 years old	26	15.3
	3-4 years old	47	27.6
	0-12 months 1 0 1 1-2 years old 12 7. 2-3 years old 26 15 3-4 years old 47 27 4-5 years old 84 49 Male 118 69 Female 52 30 White 108 63 Yellow 3 1. Brown 37 21 Black 22 12 Mother 153 90 ween the Father 11 6 child Grandmother 5 2 Aunt 1 0 A1 4 2 A2 9 5 B1 41 24 Status C1 29 17 C2 39 22 D 7 4	49.4	
Gender	Male	118	69.4
	Female	52	30.6
	White	108	63.5
Ethnicity	1-2 years old 12 2-3 years old 26 3-4 years old 47 4-5 years old 84 Male 118 Female 52 White 108 Yellow 3 Brown 37 Black 22 Mother 153 een the Father 11 Carandmother 5 Aunt 1 A1 4 A2 9 B1 41 B2 41 C1 29 C2 39	1.8	
Lumerty	Brown	37	21.8
	Black	22	12.9
	Mother	153	90.0
Kinship level between the	Father	11	6.5
informer and the child	Grandmother	5	2.9
	Aunt	1	0.6
	A1	4	2.4
	A2	9	5.3
	B1	41	24.1
Socioeconomic status*	B2	41	24.1
Socioeconomic status	C1	29	17.1
	C2	39	22.9
	D	7	4.1
	E	4	2.4

^{*}According to the Brazilian Association of Research Companies.

Most of the children in this study attended school (76.5%) and most of the mothers (56.5%) and fathers (46.5%) were aged between 28 and 38 years old, men being significantly older (p<0.001) than women.

Mean age of the mothers at the child's birth was 29 years old (minimum of 18 years old, maximum of 44 years old; mean of 33 years old). Most of them (85.5%) and the fathers (82.4%) had completed high school, and the distribution of schooling did not differ between mothers and fathers (p=0.453).

There was a higher percentage of mothers (38.8%) in the category "does not work", and only 3.0% of the fathers in the same situation. Categories were reassembled so that statistical analysis could take place: Position 1 (involving categories 0–2, including members of the armed forces, public power, and professionals of sciences and arts); Position 2 (categories 3–5, including medium-level technicians, workers of the administrative sector, and salespeople); Position 3 (categories 6–9, consisting of farming, industrial, and repair/maintenance workers); and the position "does not work", including unemployed and retired people as well as those working in the household (Table 2).

Concerning the geographic matter, 61.2% of the participants lived in the city of São Paulo, and 67.3% of them lived in the West region. Among those who did not live in the city, 40.9% were from Osasco.

Factors related to family

Out of the 170 participants, 87 (51.2%) were the only child. From the 83 who had siblings, most of them (31.76%) were the youngest. It was observed that 4.1% were twins. Most of the parents (48.2%) spend from four to eight hours a day with the children, and most of the families (98.2%) spoke Brazilian Portuguese.

Factors related to the children's health

The frequency of risk factors in this population was organized according to the period of occurrence: pre, peri, or postnatal, concerning isolated and associated factors. The Student's *t*-test was used to demonstrate the statistically significant difference among the studied variables (Table 3).

Table 2. Characterization of parents' occupation

	Position	Frequency	%	χ^2	DF	p-value		
	1	22	12.9					
	2	66	38.8					
Mother	3	16	9.4					
	Does not	66	38.8					
	work			71.571	3	<0.001*		
	1	26	15.9	7 1.57 1	3	<0.001		
	2	84	51.2					
Father	3	49	29.9					
	Does not	5	3.0					
	work							
*Significant results (n<0.05) = v								

Significant results (p<0.05) – χ

Caption: DF = degree of freedom

In the prenatal period, 31.2% of the children did not present risk factors. The predominant ones were the presence of family history and intercurrences during pregnancy, and each of these had 38.2% of occurrence. At a lower percentage, there was use of drugs and medicines, consumption of alcohol, or smoking during pregnancy (24.7%). Intercurrences (p<0.001) and family history (p<0.001) are significant for this population

In the perinatal period, 75.9% of the children did not present risk factors. The prematurity factor is significant (p<0.001) in comparison to other factors: low weight at birth and APGAR below 4 in the 1st minute and below 6 in the 5th minute in this group.

As to the postnatal period, 81.2% of the children presented risk factors, and this period concentrates the highest occurrence of risk factors. Deleterious oral habits were significant (p<0.001) in relation to all of the other factors in the same period: hospital stay, genetic changes or syndrome, neurological and psychiatric pathology, chronic disease and exposure to some sort of violence. Also in the postnatal period, when analyzing the second item with higher occurrence, longer hospital stays, we observe significant difference (p<0.001) in relation to others, which presented lower occurrence in the same period.

It is interesting to notice that in the three periods, the isolated risk factor appears most frequently when compared with associated factors. So, this period concentrates the highest occurrence of risk factors. The affective and shy tempers were more common (69.4 and 27.6%, respectively), followed by difficult (18.8%), aggressive (12.9%), and fearful (11.2%).

Association between diagnostic hypothesis and study variables

Aiming to establish an association between diagnostic hypothesis and the other variables in the study, only for this analysis, participants presenting with two or more diagnostic hypotheses were exclude from the sample. Therefore, after crossing the diagnostic hypothesis with the other variables, the number of participants is 125. The "diagnostic hypothesis" was categorized as: language-related change characteristic of autism spectrum; changes in acquisition and/or development of receptive and/or expressive language; phonological disorder; changes in the orofacial myofunctional system; language-related change characteristic of neurological syndrome or impairment; and voice change. All of the diagnoses were obtained after a complete speech language pathology and audiology evaluation, and, when necessary, conducted by a multidisciplinary team (geneticist, neurologist, psychiatrist etc.). The male gender was predominant in all of the categories, as statistically confirmed (Table 4).

Due to the irregular distribution of diagnostic hypotheses in the different categories (temper, age, schooling and profession of the parents, order of children's birth, spoken language,

Table 3. Information on risk factors in the pre, peri, and postnatal periods of the 170 children

Period	Diels foretone	No		Yes		Could not tell		
	Risk factors	Frequency	%	Frequency	%	Frequency	%	p-value
	Family history (language-related change)	104	61.2	65	38.2	1	0.6	
Dropotol	Use of drugs, medicines, alcohol,	128	75.3	42	24.7	0	0.0	<0,001*
Prenatal	or smoking during pregnancy			42		U		<0,001
	Intercurrences	105	61.8	65	38.2	0	0.0	
Perinatal	Prematurity	136	80.0	34	20.0	0	0.0	
	Low birth weight	153	90.0	17	10.0	0	0.0	
	APGAR below 4 on the 1st minute and	166	97.6	4	2.4	0	0.0	-0.001*
	below 6 on the 5 th minute							<0,001*
Postnatal	Hospital admissions	108	63.5	62	36.5	0	0.0	
	Genetic alteration or syndrome	149	87.6	21	12.4	0	0.0	
	Neurological or psychiatric pathology	136	80.0	34	20.0	0	0.0	<0,001*
	Chronic disease	139	81.8	31	18.2	0	0.0	
	Exposure to some type of violence	139	81.8	30	17.6	1	0.6	
	Deleterious oral habits	84	49.4	86	50.6	0	0.0	

^{*}Significant results (p<0.05) -Student's t-test

Table 4. Association between diagnostic hypothesis and gender

		LCCAS	CADREL	PD	COMS	LCCNSI	VC	Total	χ^2	DF	p-value
Gender	Male	28	17	26	9	6	6	92			
	Female	5	6	7	2	8	5	33	11.855	5	0.037*
Total		33	23	33	11	14	11	125			

^{*}Statistical difference (p<0.05) – χ^2 .

Caption: LCCAS = language-related change characteristic of autism spectrum; CADREL = changes in acquisition and/or development of receptive and/or expressive language; PD = phonological disorder; COMS = changes in the orofacial myofunctional system; LCCNSI = language-related change characteristic of neurological syndrome or impairment; VC = voice change; DF = degree of freedom.

location of residence, and pre, peri and postnatal factors), it was not possible to apply the statistical test to conclude whether or not there was an association between these variables and each of the diagnostic hypothesis, as performed with the speech language and audiology changes as a whole and aforementioned.

DISCUSSION

This study aimed to identify the main risk factors related to the children and their parents associated with speech language pathology and audiology changes.

Ninety percent of the informers were the mothers of the children (Table 1), and most of them (38.8%) were housewives (Table 2), and spend more than four hours a day with the child, thus being more available to accompany them in medical appointments.

However, this fact does not guarantee the quality of the time spent in situations of mother-child interaction. Most of the women did not report playing with their children, or telling them stories, for instance. Time is spent with physical care: food, hygiene, and transportation.

Information was put together concerning the fathers of the participants, since the studies point out to the relevancy of factors related to them for development^(4,15). It is known that the more communicative participation of the fathers in developing and learning stages of the child's life, the higher the chances this child will develop according to the expected for his or her age⁽¹⁶⁾.

It was observed that the mean age of mothers when their children were born was of 29 years old, which indicated that women are postponing maternity. Studies report that the age of the mother in the gestation period can be considered as a risk factor for speech language and audiology changes, as in the case of syndromes⁽⁴⁾. The age group of the participants ranged from 1 to 5 years old, mostly 4–5 years (49.4%). Studies conducted previously also point out to the prevalence of preschoolers in the identification of language-related changes⁽¹⁷⁻²⁰⁾.

In this sample, most of the participants were boys (69.4%), corroborating national and international literature^(2-4,18). The fact of being male was considered as an important risk factor for language-related changes, which was justified by the slow maturation of the nervous system among boys, which leads to more vulnerability to changes in general, and also by the influence of testosterone, which stops cell death and makes the proper connections difficult, so it can have a negative effect on the development of areas involved with the language skills of these participants⁽²¹⁾.

Concerning ethnicity or self-declared skin color, white was prevalent (63.5%). No articles were found relating this characteristic to speech language and audiology changes. In Brazil, we found the miscegenation of several races and ethnicities, and, in this context, it was observed that some parents had doubts at the time of classification, and were based on the color of the children to choose. Most of the subjects presented an affective (27.6%) and shy (69.4%) temper. According to performed studies, more affective behaviors can have a positive influence on aspects related to development, but further studies are

necessary concerning the relationships between individual and environmental variables⁽¹⁴⁾. In relation to shyness, it is possible to infer that it is a reflex of the speech language and audiology change, or a barrier to new experiences, which is an extremely important aspect of childhood development.

The greater occurrence of being the only child was observed (51.2%), followed by younger children (31.8%), which indicates that the order of birth may influence speech and language development⁽¹⁹⁾. Some studies pointed out some limitations in social skills, higher incidence of problematic behaviors, and therapeutic interventions during the childhood of the only child. On the other hand, these aspects have been attributed to excessive monitoring and parental overprotection. An only child becomes both the target of high parental expectations, usually oriented to the first-born, and receives typical favors and care, as the youngest child⁽⁶⁾.

In relation to the youngest children, a hypothesis to be considered is the division of time the mother spends with each child after the birth of a new baby: she does not have the same enthusiasm and time in comparison to when she had fewer children. Another hypothesis is that parents have the tendency to infantilize the youngest child for a longer period of time, which makes the "motherese" to remain for longer than expected. Therefore, the individual is not recognized enough for his or her accomplishments⁽²²⁾, such as pronouncing a word properly, for instance, so, it may lead this person to give up trying to pronounce correctly due to the lack of positive reinforcement.

There was a higher frequency of individuals in classes B1 and B2 (48.2%), whose monthly income ranges from R\$ 2,327.00 to 8,098.00. However, classes C2 and C1 (40%) are very close. Socioeconomic status is able to increase the risk for speech language and audiology changes. However, its real impact on the development of speech and language is not conclusive, so further research is necessary in this aspect⁽¹⁹⁾. It is worth to mention that the socioeconomic disadvantage has been pointed out as a risk factor for development, because the child who lives in a poor environment is more prone to living with violence, in a high-risk neighborhood, family instability, and deprivation of stimuli that can result in behavioral and socialization problems, thus affecting learning and language development.

It was observed that most of the kids participating in this study (61.2%) live in the city of São Paulo, more specifically in the West zone, where the Speech Language Pathology and Audiology Clinic of FMUSP is located. In this region, there is only one hired Speech Language Pathologist to assist the population of six Basic Health Units, besides two Speech Language Pathologists of the Family Health Support Center. The need to hire more professionals with this specialty is clear due to the major demand of services of this nature.

The variables bilingualism and twinning will not be considered as risk factors for the language-related changes in this study, since only three participants spoke a language other than Portuguese, and seven children had a twin sibling. Therefore, the low number of individuals does not allow generalizations. However, it is known that language acquisition among twins is atypical⁽²³⁾, and that bilingual children present less lexical

variation and longer time for lexical access in relation to monolingual ones⁽²⁴⁾.

Considering the studied sample, the risk factors of the pre, peri, and postnatal periods were analyzed (Table 3) and the intercurrences during the gestation period presented statistically significant rates, in accordance with other researchers⁽²⁰⁾. According to the Ministry of Health⁽²⁵⁾, the main objective of prenatal care is to "assist the women from the beginning of the pregnancy, ensuring the birth of a healthy child at the end of gestation, and guaranteeing maternal and neonatal well-being".

In this period, the statistically significance occurrence of family history among children with speech language and audiology changes was observed. As reported in other studies, family history has a great influence on the onset of speech language and audiology changes in the following generations^(2,9,11,19). The impact of family history may be related to genetic or environmental influences, or to a combination of both.

Also in the prenatal period, there is a risk factor related to the consumption of drinks, drugs, alcohol, or smoke during gestation. Several studies mention the impact caused by the use of substances that are harmful to the fetus, such as tobacco, drugs, and alcohol^(26,27), which may interfere in fetal development, leading to future harmful changes also concerning the child's language development.

The significant risk factor in the perinatal period was prematurity, corroborating previous studies which state that the delay in physiological and neurobiological maturation caused by prematurity damages aspects of neuronal plasticity (very active at this period), thus changing the development of several aspects, including language^(2,10,28,29).

In the postnatal period, the statistically significant risk factor was the existence of deleterious oral habits, followed by long periods of hospital stay. Deleterious oral habits are negative for the formation and the functionality of phonoarticulatory organs⁽³⁰⁾; at the same time, hospital admissions affect the emotional picture of the child. Both aspects (physical and emotional) are inter-related with speech and language development, and the association of postnatal risk factors may seriously influence language development⁽⁴⁾.

It has been observed that speech language and audiology complaints usually begin at an age of 33 months. The mean time between noticing the problem and performing speech language pathology and audiology screening was 16 months, that is, when the children attend speech language pathology and audiology screening, they are 4 years old. This fact indicates that the period considered as being ideal for oral language acquisition and development (receptive and expressive), due to greater neuronal plasticity, has passed, and the consequences on the quality of life will be more influential if there is a long delay to begin speech language pathology and audiology intervention⁽⁴⁾.

This study did not aim at analyzing the different diagnostic hypotheses or at establishing an epidemiological profile of the studied population, but to conduct an analysis of causality and risk. However, it is worth to mention there was an irregular distribution of such hypotheses, which does not allow the statistical analysis relating each diagnostic hypothesis to a specific risk factor, except for gender, thus confirming that the male

gender presents more risks of speech language and audiology changes (p=0.037), regardless of the pathology, corroborating international studies^(2,4,17) (Table 4).

CONCLUSION

The sociodemographic profile of the participants who searched for care in the public school-clinic is composed of families with children living in the West region of São Paulo and in the city of Osasco, belonging to the male gender, aged between 4 and 5 years old, who attend school, and are declared as being white. Parents belonged to the socioeconomic levels B1 and B2, with complete high school, whose occupation was medium-level technicians, working in administrative services, and as salespeople. As for the mothers, mean age at the time of gestation was 29 years old. PIFRAL proved to be a simple tool, which assists in the unrestrained identification of risk factors for speech language pathology and audiology changes, including all the different areas of hearing and language.

It was observed that the interval between the suspicion of change and the performance of screening is still relatively high, so more attention is required for this fact with the objective of early diagnosis and intervention.

The risk factors identified among children with speech language and audiology changes, who participated in this study and demonstrated statistical significance are:

being male, only child, having history of speech language pathology and audiology changes in the family, intercurrences during pregnancy, prematurity, deleterious oral habits, and long postnatal admissions.

Children presenting one or more of the aforementioned risk factors should be periodically followed-up for the development of communication (speech, voice, language, hearing and orofacial motricity), and, if necessary, referred to early intervention.

A bigger sample of children with speech language pathology and audiology changes is necessary, as well as their relationship with the control group, so that there is more understanding concerning the risk factors and their relationship with the different speech language pathology and audiology diagnoses.

*GMDS was in charge of data collection and tabulation; MIVC accompanied collection and collaborated with data analysis; DRMA was responsible for the project and study design, as well as the general orientation of the stages of execution and elaboration of the manuscript.

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