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Fine motor skills and expressive language: a study with children with congenital hypothyroidism

Habilidade motora fina e linguagem expressiva em crianças com hipotireoidismo congênito

ABSTRACT

Purpose: To screen the global development of children with and without congenital hypothyroidism and to investigate the association between fine motor skills and expressive language development in both groups. **Methods:** This is a prospective study of a cohort of children diagnosed with Congenital Hypothyroidism and monitored in a reference service for congenital hypothyroidism of a public hospital and of children without this disorder. The screening was performed using the Bayley Scales of Infant Development III in the cognitive, gross and fine motor skills, and receptive and expressive language domains. The children's performance was expressed in three categories: competent, and non-competent. **Results:** We screened 117 children with average age of 21 months diagnosed with Congenital Hypothyroidism at birth, with the Thyroid Stimulating Hormone (TSH) level normalized during screening, and 51 children without the condition. The children with Congenital Hypothyroidism presented lower performance in gross and fine motor skills upon comparison between the two groups, and no differences were found in the cognitive and receptive and expressive language domains. The association between fine motor skills and language persisted in the group with Hypothyroidism, demonstrating that the interrelationship of skills is present in all individuals, although this group is two times more likely to present expressive language impairment when fine motor skills are already compromised. **Conclusion:** In the development process, both skills – motor and expressive language – might be associated and/or dependent on each other in the sample assessed.

RESUMO

Objetivo: Triar o desenvolvimento global de crianças com e sem hipotireoidismo congênito e investigar a associação entre as habilidades motora fina e de linguagem expressiva nesses dois grupos. **Método:** Trata-se de um estudo prospectivo de uma coorte de crianças com hipotireoidismo congênito, diagnosticadas e acompanhadas em um serviço de referência em triagem neonatal de um hospital público e de crianças sem essa disfunção. A triagem foi realizada por meio das Escalas Bayley de Desenvolvimento Infantil III, nos domínios cognitivo, motor grosso e fino e de linguagem receptiva e expressiva. O desempenho das crianças foi expresso em competente e não competente. **Resultados:** Foram triadas 117 crianças com Hipotireoidismo Congênito diagnosticado pelo teste do pezinho, com o nível de Hormônio Tireotrófico (TSH) normalizado no momento da avaliação e 51 sem essa doença, ambos os grupos com idade média de 21 meses. As crianças com Hipotireoidismo Congênito apresentaram um desempenho pior nas habilidades motora grossa e fina quando realizada a comparação entre os dois grupos e não houve diferença nas áreas cognitiva e de linguagem receptiva e expressiva. A associação entre motricidade fina e linguagem persiste no grupo com a doença, demonstrando que há uma inter-relação dessas habilidades, sendo que o grupo com hipotireoidismo apresenta duas vezes mais chances de alterações na linguagem expressiva quando a motricidade fina já estiver comprometida. **Conclusão:** No processo de desenvolvimento, ambas as habilidades, linguagem expressiva e motricidade fina, podem estar associadas e/ou dependentes uma da outra nesta amostra avaliada.

Study carried out at Centro de Investigação em Pediatria – CIPED - Campinas (SP), Brazil.

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INTRODUCTION

Congenital hypothyroidism (CH) is defined as a condition of thyroid hormone (TH), thyroxine (T4), and triiodothyronine (T3) deficiency present at birth, which causes generally reduced metabolic processes. These hormones are vital for growth, maturation and organogenesis of the central nervous system (CNS), and appropriate development depend on them for the critical period between fetal life and 2 years of age^(1,2). The absence of hormones causes impairment of different areas of the brain, affecting the posterior parietal cortex, responsible for spatial awareness; the inferior temporal lobes, responsible for identification of objects; the caudate nucleus, associated with attention; the hippocampus, associated with memory. There have also been reports of hearing impairment^(3,4). In addition, there may still be deficiencies in the perception, cognitive, linguistic, social, and self-care areas, as well as impairments in language, speech and comprehension acquisitions, among others^(5,6).

Maturation of the nervous system allows for progressive learning of abilities in general. In children with congenital hypothyroidism examined between 7 and 14 years of age, a significantly poorer performance was found in gross and fine motor functions, and the researchers concluded that problems with fine motor skills may be associated with visuomotor and visuospatial changes, besides problems with memory and attention⁽⁷⁾.

Thyroid hormones regulate the terminal differentiation process, neuronal migration and cerebral myelination. Myelination deficiencies can be observed in the brain, visual and auditory cortex, hippocampus, and cerebellum - areas for which there are reports of developmental delays. With impaired development, the central and peripheral nervous systems have an important role in functional behaviors and motor production of speech. The voluntary movements skill depends on the pyramidal system (cerebral cortex, corticobulbar and corticospinal tracts), and coordination of the action of speaking originates in the Broca's area of the dominant hemisphere, below and after the precentral motor cortex. The extrapyramidal system mediates automatic muscle activity (posture, muscle tone, and movements that support and accompany voluntary movements), the basal ganglia are responsible for postural plans and programs and are supporting components of motor activity, while the cerebellar system coordinates and executes smooth goal-directed movements⁽⁸⁾.

CH occurs in 1:2000 to 4000 live births and is twice more common among girls. It is a major preventable cause of mental retardation and neuropsychomotor developmental delay (NPMD)⁽⁹⁾. Diagnosis at early age and immediate initiation of adequate treatment are key factors in the evolution of the disease and prevention of sequelae. However, considering that other factors such as adherence to treatment and proper administration of drugs influence the success of treatment, it is necessary to monitor NPMD as a strategy for early detection of developmental delays. Early detection allows timely intervention in habilitation and rehabilitation - a relevant procedure, considering new knowledge on cerebral plasticity, particularly in the child's first years of life, as a way to reduce or prevent neurological sequelae.

Monitoring of NPMD can be done through NPMD screening scales, which is a fast evaluation procedure designed to identify children who need to be referred for further evaluation. It is important that monitoring of development be based on reliable assessment scales with proven sensitivity, to detect infants with impairments, and proven specificity, to identify infants with typical development⁽¹⁰⁾.

Given that the major alterations in children with CH are focused on several areas, but particularly in motor⁽⁷⁾ and language skills⁽¹¹⁻¹³⁾, the objectives of this study were to screen the global development of children with and without congenital hypothyroidism and to investigate the relationship between fine motor skills and expressive language skills in these two groups.

METHODS

This is a prospective, cross-sectional study of a cohort of children with congenital hypothyroidism (CH) seen at the outpatient clinic for congenital hypothyroidism of Serviço de Referência em Triagem Neonatal [Neonatal Reference Screening Service] of Universidade Estadual de Campinas (SRTN/UNICAMP), and of a cohort of children not diagnosed with CH, who attend Centro de Estudos e Pesquisas em Reabilitação "Prof. Dr. Gabriel Porto"/Cepre, [Center for Study and Research in Rehabilitation Prof. Dr. Gabriel Porto] of Faculdade de Ciências Médicas of Universidade Estadual de Campinas for hearing screening (Evoked Otoacoustic Emissions), as well as of children from two day care facilities in the city of Piracicaba.

A total of 168 children from both genders participated in the study, of which 117 composed the CH group (CHG) and 51, the comparative group (CG). The children with CH, with an average age of 22 (\pm 12) months, were selected on the dates of consultation at the outpatient clinic between March 2011 and December 2012.

Inclusion criteria for the CHG were: children with congenital hypothyroidism seen at outpatient clinics, aged between 1 and 42 months, living in the areas covered by SRTN/UNICAMP (municipalities of Departamento Regional de Saúde (DRS) of Campinas, São João Boa Vista and Piracicaba), whose parents or legal guardians agreed to participate in the study and signed the Informed Consent.

Inclusion criteria for the CG were: children aged between 1 and 42 months, who were invited to attend neonatal hearing screening and presented normal responses at screening, without risk indicators for developmental disabilities, or children attending day care facilities in the city of Piracicaba, with no complaints of hearing problems and development impairments, whose parents or legal guardians signed the Informed Consent.

Exclusion criteria for the Comparative Group were: children diagnosed with NPMD delays enrolled or not in (re)habilitation programs specific for developmental disabilities, children who presented a score <7 on the Apgar Scale at the 5th minute, children with low birth weight (<2500 g), gestational age <35 weeks and neurological impairments, syndromes, autistic traits and/or hearing complaints.

This study was approved by the Research Ethics Committee 1008/2011 of Universidade Estadual de Campinas.

For the application of the Bayley Scales of Infant and Toddler Development III - Screening test (BSITD III)⁽¹⁴⁾, we considered the age on the date of assessment, preferably carried out on the same day of the visit to the outpatient clinic, or of sample collection.

For preterm infants, adjusted age was calculated according to the formula: [Chronological age – (40 weeks – gestational age)]. The following criteria were used: four weeks for a month, and seven days for a week. Age was adjusted until the child reached 24 months of chronological age.

Gestational age was obtained from the Child Health Record regardless of the method used to estimate GA. Children born with GA below 37 weeks were considered preterm infants⁽¹⁵⁾.

The Bayley Scales of Infant and Toddler Development III - Screening test BSITD III (14) are intended to screen children with up to 42 months of age for development impairments, and are among the most widely used scales in the area of child development evaluation, providing reliable, valid and accurate results of the child's developmental state^(10,14,16). The evaluations were performed by members of Grupo Interdisciplinar de Avaliação do Desenvolvimento Infantil (GIADI) [Interdisciplinary Group for Child Development Assessment], with proper training to apply the screening and diagnostic scales of BSITD III. The evaluations were carried out in one of the rooms at Centro de Investigação em Pediatria (CIPED) [Paediatrics Investigation Center].

The BSITD III are composed of five different subtests: cognitive, receptive language, expressive language, gross and fine motor skills. Each subtest has a certain point of entry consistent with the child's chronological or adjusted age. At each item, the children are given a score of zero or one. Zero refers to the child who did not perform the item or failed to meet the criteria established by the test, while one refers to the child who met the criteria established by the test, presenting adequate performance at the item. All subtests are performed with the child using reversal and discontinue rules to ensure administration of the most appropriate items for each of them. The test is discontinued after four consecutive zeros⁽¹⁴⁾.

A raw score is obtained for each subtest at the end of screening, which classifies the child into one of three categories: competent (low risk of delay), emerging risk, and at-risk. The children classified by screening in the emerging risk and at-risk categories must be re-assessed. In case risk of neuropsychomotor development impairments are confirmed, children are referred to reference services in their cities⁽¹⁴⁾.

The assessments were carried out in a large and well-lit room. All children were assessed in the presence of parents, and the evaluations were performed by an examiner and monitored by an observer. The average time of application of items in the screening scale varied between 15 and 30 minutes. When the child's response did not safely reflect their ability, due to crying or sleepiness, the assessment was interrupted and resumed as soon as the discomfort was resolved⁽¹⁴⁾.

The test application requires a standardized evaluation form and the following standardized materials contained in the original test kit: rattle, bell, rim tied to synthetic cord, colored sugar balls, flask with lid, transparent box with opening, cup with handle, three plastic cups, rubber toy, set of seven ducks (three large, three small and one heavy), shoelaces, three metal spoons, white paper, scissors, red crayon, picture book, story book, 12 cubes, ball, ladder, plastic doll, and two trays with fitting toys.

The data recorded in the assessment guides were transcribed and saved in the file extensions for the Statistical Package for Social Sciences for Personal Computer (SPSS/PC), Version 16.0, and were subsequently revised in order to detect and correct possible typos. Continuous variables were expressed by measures of central tendency and dispersion, and the categorical variables, as frequency. For the analysis between groups CHG and CG, performance in the different domains was dichotomized into competent or non-competent (including emerging risk and at-risk classifications). In order to test the association between the proportion of participation in the performance categories and the groups with CH and comparative group, we used the Pearson Qui-square test. A level of significance of 5% was considered in the statistical tests. The univariate and multivariate logistic regression analysis was also used to study the association.

RESULTS

A total of 168 children were screened, where 117 composed the group with congenital hypothyroidism (CHG) and 51, the group without the condition (Comparative Group, CG). The average age of children on the day of assessment was 22 months and 11 days, gestational age of 39 weeks. Weight between groups was statistically significant, and the weight of the comparative group was greater (Table 1).

A difference in weight at birth was found between the groups. Nevertheless, all children in both groups presented appropriate weight at birth (≥ 2500 g), as described in the research methodology. With regard to gestational age, it was observed that 4 (4% of children in the CHG and 3 (9.4%) in the CG were preterm, with 36 weeks.

The groups were homogeneous in terms of male and female gender distribution (Table 2).

The results obtained from the Bayley Scales of Infant and Toddler Development showed that only one child was classified as at-risk, which led us to a new regrouping for statistical analysis. Thus, results were presented as competent (normal classification) and non-competent (emerging and at-risk classification).

Table 3 presents the global results on the development of the children in both groups. A statistically significant difference was observed in the gross and fine motor skills between the groups, and there was no difference in the cognitive area and receptive and expressive language area.

However, upon comparing the results of both groups and performing association between the children classified as

competent and non-competent as to the Bayley Scales, in the fine motor and expressive language skills, an actual association was observed, as shown in Table 4.

Upon analysis of the CHG and CG data separately, among the children who were competent and non-competent as to the

Bayley Scales in fine motor and expressive language skills, we observed an association between the two skills only in the CHG (p-value = 0.0493), presenting 2.3 times more chances of language alterations (Table 5). The CG did not present any differences between the two skills.

Table 1. Characteristics of children in the CHG and CG in terms of weight at birth, gestational age and age on the date of assessment

	Group	n	Mean (SD)	Median	Minimum	Maximum	p-value
Weight at Birth (g)	CHG	117	3254.40 (412.69)	3235	2510	4350	0.032*
	CG	51	3413.06 (419.31)	3405	2565	4945	
Gestational age (weeks)	CHG***	102	39.06	39	34.57	42	0.819**
	CG***	46	38.9	39	36.00	42	
Chronological age (months)	CHG	117	22.46 (11.71)	24.23	2.2	41.4	0.734**
	CG	51	21.45 (11.53)	17.47	7.30	42.7	

*Student's t test; **Mann-Whitney U test; ***missing data for the children's part. The statistically significant data (expressed by the value of p) is highlighted in bold
Caption: CHG: congenital hypothyroidism group; CG: control group

Table 2. Characterization of gender, male and female, of groups CHG and CG

	Child's Gender		Value of p
	CHG	CG	
Female	41 (35.0%)	23 (45.1%)	0.217*
Male	76 (65.0%)	28 (54.9%)	

*Qui-square statistical test

Caption: CHG: congenital hypothyroidism group; CG: control group

Table 3. Comparison of groups CHG and CG in all domains of Bayley's Scales

Skill	Group	Competent	Non-competent	Total	Value of p
Gross motor skills	CHG	85 (73.3%)	31 (26.7%)	116 (100%)	0.014*
	CG	46 (90.2%)	5 (9.8%)	51 (100%)	
Fine motor skills	CHG	87 (74.4%)	30 (25.6%)	117 (100%)	0.020*
	CG	46 (90.2%)	5 (9.8%)	51 (100%)	
Cognitive	CHG	91 (77.8%)	26 (22.2%)	117 (100%)	0.112*
	CG	45 (88.2%)	6 (11.8%)	51 (100%)	
Receptive language	CHG	92 (78.6%)	25 (21.4%)	117 (100%)	0.072*
	CG	46 (90.2%)	5 (9.8%)	51 (100%)	
Expressive communication	CHG	76 (65%)	41 (35%)	117 (100%)	0.605*
	CG	31 (60.8%)	20 (39.2%)	51 (100%)	

*Qui-square statistical test. The statistically significant data (expressed by the value of p) is highlighted in bold

Caption: CHG: congenital hypothyroidism group; CG: comparative group

Table 4. Association between competent and non-competent children in fine motor skills and expressive language for the two groups, CHG and CG. n=168

Fine motor skills	Expressive language		Value of p
	Non-competent	Competent	
	Competent	Competent	
	18 (29.5%)	17 (15.9%)	0.037*
	43 (70.5%)	90 (84.1%)	

*Qui-square statistical test. The statistically significant data (expressed by the value of p) is highlighted in bold

Table 5. Associations between competent and non-competent children with regard to fine motor skills and language, using logistic regression, for the two groups (CHG and CG)

Fine motor skills	Association: fine motor skills x expressive language - CHG				
	Expressive language		Value of p*	OR**	CI***
	Competent	Non-competent			
Competent	61 (52.14%)	26 (22.22%)	0.0493	2,346	1,003:5,490
Non-competent	15 (12.82%)	15 (12.82%)			
Total	76 (64.96%)	41 (35.04%)			
Fine motor skills	Association: fine motor skills x expressive language - CG				
	Expressive language		Value of p	OR	CI
	Competent	Non-competent			
Competent	29 (56.86%)	17 (33.33%)	0.3291	2,559	0.338:16,880
Non-competent	2 (3.92%)	3 (5.88%)			
Total	31 (60.78%)	20 (39.22%)			

*Chi-square test; **Odds ratio; ***Confidence interval. The statistically significant data (expressed by the value of p) is highlighted in bold

DISCUSSION

In the present study, no significant difference was observed with regard to gender in the congenital hypothyroidism and comparative groups. The literature, however, states that CH is more frequent among females, although this research verified the presence of more boys than girls. This may have happened because the period of data collection for the survey was limited and, therefore, from March 2011 to December 2012, more boys were submitted to assessment by chance. A study carried out in the Brazilian states of Rondônia and Acre, by means of interviews with parents of children with CH, found data similar to ours, with more male children⁽¹⁷⁾. Similarly, there was no statistically significant difference between the groups with regard to the children's gestational and chronological age on the day of assessment. However, a difference was observed between the two groups in relation to weight at birth, although the same exclusion criteria (low weight, prematurity, etc.) were used, i.e. all of them had weight above 2500 g.

As to performance on the Bayley Scales, the children presented a significant difference as to gross and fine motor skills, where a higher number of the latter was found in the group with CH. Such accounts are also confirmed by one study⁽¹⁸⁾ that assessed 107 children, 72 in the group with CH, and 35 in the control group, as to motor and cognitive skills. As a result, it was observed that, when comparing the groups, the children with CH obtained a very low score in the fine motor skills, balance and language areas.

Another study⁽¹⁾ described the neurological evolution of patients with CH, reporting that out of 37 patients examined, 9 presented some level of impairment - 5 with neuropsychomotor delay from 2 to 3 months -, one patient presented left-side hemiparesis, and 2 presented normal neuropsychomotor development.

Gulshan⁽¹⁹⁾ reported the following percentage of children with their respective impairments, upon assessing 59 children with CH in early treatment: 10% presented impairment in gross motor skills, 13% in fine motor skills, and 6% in cognitive function. In addition, 96% presented normal hearing, and 82.6%, normal language development. In children undergoing treatment at a later stage (21), 57%, 71%, and 66% presented delayed gross and fine motor skills and cognitive function, respectively; 26% presented some kind of hearing impairment; and 76%, delayed language, indicating the importance of early treatment initiation.

With regard to the Bayley Scales tests, this study verified that the children in the CG presented impairment in fine motor skills (5 children) and expressive language (20 children), as well as the ones with CH, with 30 children presenting alterations in fine motor skills and 41, in expressive language. Nevertheless, upon association between the two groups and the two areas, we observed that the children in the group with congenital hypothyroidism presented 2.3 times more chances to present impairment in expressive language when impairment in fine motor skills is already present.

The same results were presented by Gibim⁽²⁰⁾, who assessed, by means of the Bayley Scales for Child Development, the motor performance of 90 children, 50 of those with CH and 40, without CH. As a result, an association of fine motor skills between the groups and risk indication was obtained. The study also demonstrated that children with congenital hypothyroidism were 4.36 times more prone to presenting impairment in fine motor skills. Another study in this same line of research⁽²¹⁾ assessed 65 children, 33 with CH and 32 without the condition, demonstrating no association between the groups in terms of fine and gross motor skills, receptive and expressive language, and cognition. However, results indicated risk for the group with CH in all areas.

Therefore, it can be observed that motor alterations are present in several research studies involving children with CH⁽⁴⁾. In the literature, there are also many works indicating that the language area would be the most affected in children with CH^(5,21,22). A literature review performed by Muñoz et al.⁽²²⁾ observed that, although there are several articles about the language of children with CH, there is still controversy as to the results obtained. Our research detected alterations in language associated with motor impairments.

Language acquisition and development play a central role during the first years of life, and by screening their development it is possible to assess the integrity of several neural subsystems, among them hearing and motor articulation⁽²³⁾. Language acquisition must be dealt with as an important barometer for success in integrative tasks. Whenever a child presents difficulty with language acquisition, other areas may be involved, due to its multidetermined nature. Thus, a possible hormonal alteration involved in the maturation of motor skills may have implications on language acquisition as a consequence, causing impairments and possibly interfering with the development of communication skills⁽²⁴⁾. In this vein, this study confirms such alterations in both populations, i.e. language impairments are observed in children with CH undergoing treatment and in children without gland dysfunction, but only the group with CH presented association between fine motor skills and expressive language.

With this impaired development, deficiencies may occur in the perceptive, cognitive, linguistic, social, and self-care areas. With regard to language, in this research, children with CH did not present significant impairment in expressive and receptive language when compared to the group without CH, but were classified as non-competent in receptive language skills in 21.4% of the cases, and in expressive language, in 35% of the cases. In fact, we consider as non-competent the children found in the emerging risk and at-risk classifications, with only one child having been classified as at-risk and the remainder, at emerging risk. Reports from other studies indicate that children may present language delay, phonological alterations, among others⁽⁵⁾. A bibliographical review carried out in 2008 showed that, in 14 papers that assessed language in children with CH, 11 reported the presence of different impairments, such as:

delayed speech, oral comprehension difficulties, speech and language disorders and morphosyntactic impairment⁽²¹⁾.

In 2000, researchers assessed hearing of 75 children with CH. Only one of them had had a previous hearing test and, of the total, 20% of them presented conductive or sensorineural hearing loss. Among these children, the ones aged between three, five and seven years presented delayed speech⁽¹⁷⁾. This aspect can also be observed in the study that interviewed parents of children with CH in order to verify language complaints. Among them, the most cited were: delayed oral language, exchange errors in speech, unintelligible speech, agitated behavior and delayed acquisition of oral language. Impairments in language comprehension are more frequent when diagnosis and beginning of treatment take place at a later stage⁽²⁵⁾.

Another study that aimed to identify speech-language manifestations in children with CH showed that 80% of individuals assessed presented speech and language impairments, and 93.3%, in understanding requests⁽¹⁷⁾. Gejão et al.⁽¹³⁾, pointed out that children with CH and phenylketonuria are at risk of alteration in developmental skills (motor, cognitive, linguistic, adaptive, and social). Socio-linguistic alterations were observed mainly after pre-school age, and patients with CH had more cognitive and language deficits.

Researchers questioned the period of thyroid hormone action on brain development, through clinical observations and experimental findings, pointing out that 20% of CH cases presented mild sensorineural hearing loss, and suggested that fine motor skills, hearing, hearing processing, increased selective attention and memory deficits are more sensitive to postnatal hormone deficiency⁽²⁶⁾.

In this study, 15 (12.82%) children with CH were classified as at emerging risk in both fine motor skills and language, which did not occur with children without CH, who were classified as at emerging risk in expressive language. This fact draws attention due to the interrelationship between the two skills, where one can influence the other's development.

There is also considerable consensus on the fact that the course of language development reflects an interaction of factors in at least five domains: social, perceptual, and cognitive, conceptual, and linguistic processing, indicating the great power of language over child development⁽²³⁾. Such information is supported by the literature on the fact that acquisition of language by children occurs along with other skills in the sensorimotor domain⁽⁸⁾. In this sense, it can be understood that any alteration that occurs at the beginning of gestation can interfere with and/or delay fine motor maturation, and may also have consequences on the process of expressive language acquisition⁽²³⁾. This aspect can also be observed in the study that interviewed parents of children with CH in order to verify language complaints. Among them, the most cited were: delayed oral language, exchange errors in speech, unintelligible speech, agitated behavior and delayed acquisition of oral language. Language impairments are more frequent when diagnosis and beginning of treatment take place at a later stage⁽²⁰⁾.

CONCLUSION

With this study, it was possible to verify that children with congenital hypothyroidism who present fine motor skill impairments are twice as likely to present impairment in expressive language. Fine motor skills and expressive language may be dependent on each other in the developmental process, particularly in children with endocrine alterations.

The importance and necessity of studies with a population of children with congenital hypothyroidism, especially in the first years of life, is noteworthy, so that the process of family orientation and rehabilitation occurs at an early stage.

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Author contributions

RCF participated in the study conception and design, data collection, analysis, and interpretation, and in the final writing; DCCS participated in the study conception and design, data analysis and interpretation, and final writing, as well as in the final appraisal of the version to be published; MMFG participated in the study conception and design, data analysis and interpretation, and in the final writing, as well as in the final appraisal of the version to be published; MPCO participated in data collection and analysis; CTMS participated in data analysis and interpretation, as well as in the final appraisal of the version to be published; VD participated in data collection, analysis, and interpretation; MCMPL participated in the study conception and design, data analysis and interpretation, and final writing, as well as in the final appraisal of the version to be published.