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Original Article

Economic Impact of the Implementation of a PCDT for Cow Protein Allergy – CMPA in the State of Rio Grande do Norte

Impacto Econômico da Implementação de um PCDT de Alergia à Proteína da Vaca – APLV no Estado do Rio Grande do Norte

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ABSTRACT

Introduction: Cow's milk protein allergy (CMPA) is one of the most common food allergies in childhood, affecting children under 3 years old. In Brazil, prevalence ranges from 1% to 5.4%, with a significant impact on the Unified Health System (SUS) due to the high costs of special formulas used in treatment. The implementation of Clinical Protocols and Therapeutic Guidelines (CPTG) has proven to be an efficient strategy for managing CMPA. **Objective**: To report the experiences of the state of Rio Grande do Norte in implementing the CPTG for CMPA and to analyze the economic impact associated with providing special formulas. **Methods**: This descriptive study was based on data from government reports and scientific literature from 2019 to 2023. Costs related to the provision of special formulas and the impact of the COVID-19 pandemic on demand were evaluated. The analysis included historical trends in care and inflation-adjusted economic calculations. **Results**: From 2019 to 2023, there was an increase in the demand for special formulas and associated costs, driven by the pandemic and price volatility. However, administrative strategies reduced costs related to judicial demands by up to 50%. In 2023, 595 patients were enrolled in state programs, with significant growth in coverage and treatment access. **Conclusion**: The implementation of public policies such as CPTGs for CMPA in the Rio Grande do Norte proved cost-effective, expanding access and optimizing public spending. Investments in early diagnosis and efficient administrative management are essential to improve clinical and economic outcomes.
Keywords: Cow Protein Allergy; Clinical protocols and therapeutic guidelines; Economic Impact.

RESUMO

Introdução: A alergia à proteína do leite de vaca (APLV) é uma das alergias alimentares mais comuns na infância, afetando crianças menores de 3 anos. No Brasil, a prevalência varia de 1% a 5,4%, com grande impacto no Sistema Único de Saúde (SUS) devido aos altos custos das fórmulas alimentares especiais utilizadas no tratamento. A implementação de Protocolos Clínicos e Diretrizes Terapêuticas (PCDT) tem se mostrado uma estratégia eficiente para o manejo da APLV. **Objetivo:** Relatar a experiência do estado do Rio Grande do Norte na implementação do PCDT de APLV e analisar o impacto econômico associado ao fornecimento de fórmulas alimentares especiais. **Métodos**: Trata-se de um estudo descritivo baseado em dados de relatórios governamentais e literatura científica, abrangendo o período de 2019 a 2023. Foram avaliados os custos associados ao fornecimento de fórmulas alimentares e o impacto da pandemia de COVID-19 sobre a demanda. A análise incluiu a evolução histórica de atendimentos e cálculos econômicos ajustados pela inflação. **Resultados**: Entre 2019 e 2023, observou-se aumento na demanda por fórmulas alimentares especiais e nos custos associados, impulsionado pela pandemia e pela volatilidade dos preços. Apesar disso, estratégias administrativas reduziram os custos relacionados às demandas judiciais em até 50%. Em 2023, 595 pacientes foram cadastrados nos programas estaduais, com incremento significativo na cobertura e no acesso ao tratamento. **Conclusão**: A implementação de políticas públicas como o PCDT de APLV no Rio Grande do Norte demonstrou ser custo-efetiva, ampliando o acesso e otimizando os gastos públicos. Investimentos em diagnóstico precoce e gestão administrativa eficiente são fundamentais para melhorar os desfechos clínicos e econômicos.
Palavras-chave: Alergia à Proteína da Vaca; Protocolos clínicos e diretrizes terapêuticas; Impacto econômico.

Introduction

Cow's Milk Protein Allergy (CMPA) is one of the most common food allergies in childhood, affecting mostly children under 3 years of age. It is characterized by an adverse reaction mediated by specific immune mechanisms that occur in sensitized individuals after the ingestion or contact with cow's milk proteins, such as casein and lactoglobulin. Symptoms vary from mild to severe, including urticaria, vomiting, diarrhea, abdominal pain, and, in extreme cases, anaphylactic shock. These adverse reactions are mediated by IgE antibodies and/or T cells.[1,2]

It is estimated that the prevalence of CMPA in developed countries ranges from 0.5% to 3% in children during the first year of life.[3] In Brazil, a multicenter study found a prevalence of 5.4% and an incidence of 2.2% in children under 24 months of age.[4] Another national survey using the oral food challenge test (OFC) identified a prevalence of 1% in children aged 4 to 23 months and 0.09% in children aged 24 to 59 months.[5]

In Brazil, the management of this condition is supported by specific clinical guidelines, such as the Clinical Protocol and Therapeutic Guidelines (PCDT), designed to standardize medical care, facilitate access to appropriate treatments, and improve patients' quality of life. However, the PCDT for CMPA, approved by CONITEC[6] in 2022, has not yet been implemented nationwide. Given that CMPA affects a particularly vulnerable population, some state health departments have taken the initiative to develop and implement their own local protocols, as exemplified by the implementation of the CMPA PCDT in Rio Grande do Norte.[7,8] This represents an important step toward ensuring access to specialized formulas while considering regional specificities and financial constraints. There are, however, few documented experiences in the Brazilian literature regarding the implementation of CMPA PCDTs.[9,10]

The present article aims to report the experience of the state of Rio Grande do Norte in providing care for patients with CMPA and to analyze the economic impact associated with the supply of specialized dietary formulas.

Methods

A descriptive study was conducted on the implementation of the CMPA PCDT in the state of Rio Grande do Norte, including the analysis of official documents, financial reports, and scientific literature on CMPA management and its impact on reducing legal claims related to treatment access. Economic values were expressed in Brazilian Reais (R$) per year.

The cost savings achieved through administrative procurement versus judicial demands were calculated based on the difference in average cost per patient, considering factors such as treatment duration, volume of distributed formulas, and inflation adjustments. Data were obtained from governmental reports and local monitoring databases, covering service delivery and expenditures between 2019 and 2023. The analysis included:

Historical Series: evolution in the number of patients served and formulas distributed;

Cost Calculation: total expenditures adjusted for inflation and compared annually;

Inclusion/Exclusion Criteria: confirmed CMPA diagnosis, maximum age of 24 months, and regular clinical monitoring;

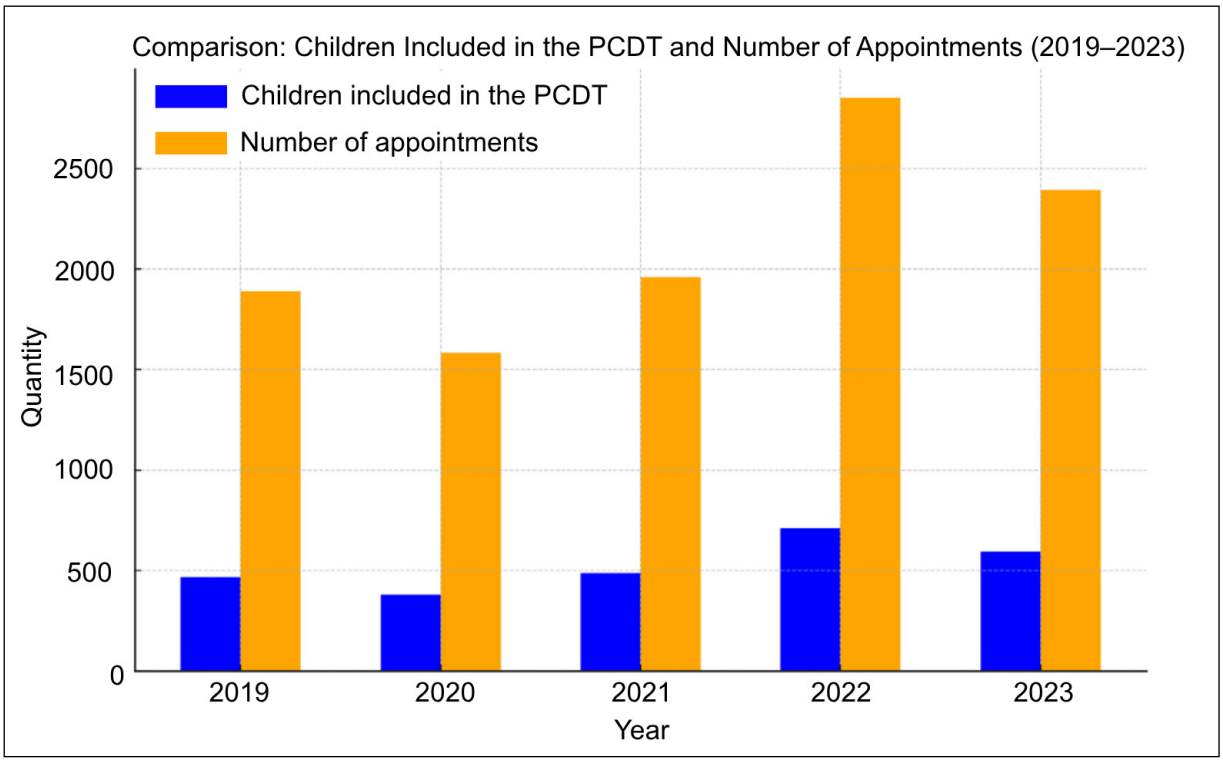
Data Analysis: means, percentage variations, and the impact of the COVID-19 pandemic were assessed to interpret observed trends.

Results

In 2020, despite an 18.58% decrease in the number of patients served, total costs increased by 13.35%, primarily due to inflationary pressures. The administrative approach adopted in Rio Grande do Norte has proven to be a cost-effective strategy: the cost per patient managed administratively is, on average, 50% lower than that of patients assisted through judicial demands. This difference stems from strict control over treatment duration and periodic reassessment, which reduce waste and promote the rational use of public resources.

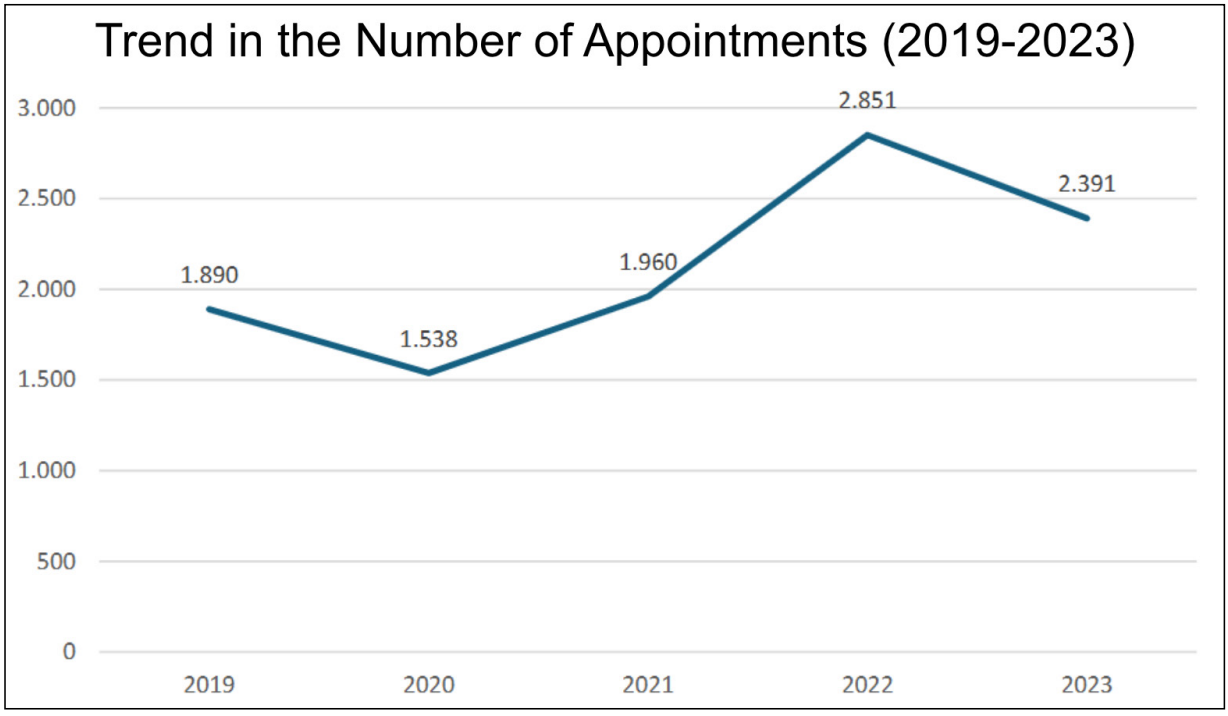
In 2023, a total of 595 patients were enrolled in the program and monitored at the designated reference centers. For contextual understanding, Figures 1, 2, and 3 present data on children enrolled and assisted by the State Health Secretariat's CMPA program in Rio Grande do Norte.

Figure 1. Evolution in the Number of Children with CMPA Included and Assisted in the Dispensing Program through Administrative Processes of the Rio Grande do Norte State Health Department (2019-2023*)



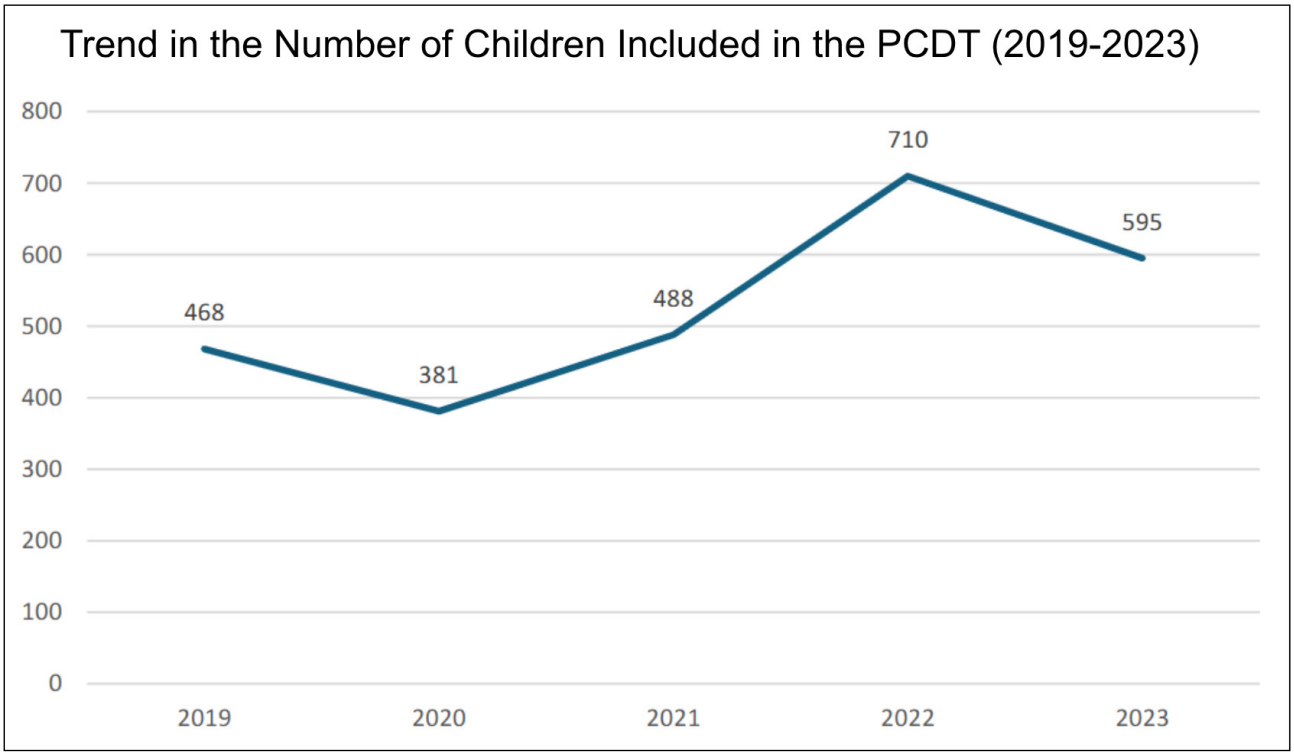
Source: Central Unit of Therapeutic Agents (UNICAT), Rio Grande do Norte (RN). *2023: January-August.

Figure 2. Evolution in the Number of Appointments for Children with CMPA in the Dispensing Program through Administrative Processes of the Rio Grande do Norte State Health Department (2019-2023*)



Source: Central Unit of Therapeutic Agents (UNICAT), Rio Grande do Norte (RN). *2023: January-August.

Figure 3. Evolution in the Number of Children with CMPA Included in the Dispensing Program through Administrative Processes of the Rio Grande do Norte State Health Department (2019-2023*)



Source: Central Unit of Therapeutic Agents (UNICAT), Rio Grande do Norte (RN). *2023: January-August.

Over the past five years, a decline of 18.58% in patient care was observed in 2020, corresponding to the first wave of the COVID-19 pandemic. However, in 2021, despite ongoing pandemic challenges, there was a significant increase of 28.08% compared with 2020 and 4.27% compared with 2019. In 2022, the number of patients increased by 45.49% compared with 2021. By 2023, even considering the partial data (January-August 2023), a marked increase in service demand was already evident, continuing the growth trend observed in previous years.

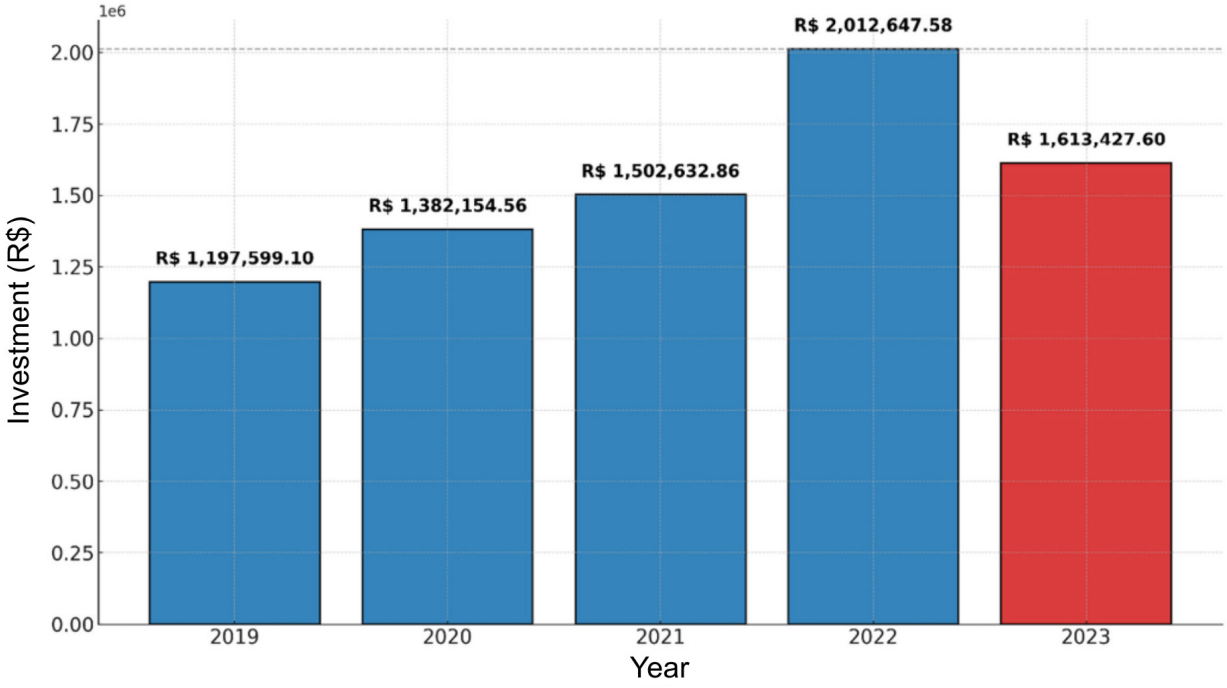
In addition, Figure 4 presents data on direct costs associated with the procurement of special formulas between 2019 and 2023 (2023: January-August). A rising trend in formula acquisition costs was observed, mirroring the increase in service demand — except for 2020, when there was a notable rise in healthcare supply costs despite a decrease in patient care, due to the COVID-19 pandemic. For 2023, projections indicated a strong growth trajectory and expansion of access and care for patients diagnosed with Cow's Milk Protein Allergy (CMPA).

Discussion

The provision of specialized dietary formulas for patients with Cow's Milk Protein Allergy (CMPA) has significant economic implications for the Brazilian Unified Health System (SUS). These formulas, often imported and high-cost, represent an ongoing financial burden. According to recent data, the average annual cost per patient may exceed R$ 5,000.00, depending on the prescribed formula and the severity of the condition.[11]

Between 2019 and 2023, the increase in acquisition costs was driven by both the growth in demand and the volatility of international input prices. The COVID-19 pandemic further exacerbated this situation, raising global prices for pharmaceutical and food products.[11] The development of public policies that integrate efficient management, continuous monitoring, and expanded access to specialized formulas is essential to optimize spending and improve clinical outcomes. Studies suggest that investments in preventive strategies, such as educational campaigns and early diagnosis, can lead to substantial long-term savings.[3]

Figure 4. Public Investment by the State of Rio Grande do Norte for the Acquisition of Formulas for the Treatment of CMPA from 2019 to 2023*



Source: Central Unit of Therapeutic Agents (UNICAT), Rio Grande do Norte (RN). *2023: January-August.

The state of Rio Grande do Norte has adopted its own strategies for managing patients with CMPA. The implementation of a **Conduct Adjustment Agreement (TAC)**[8] in 2006 highlights the importance of partnerships between governments and judicial institutions to ensure equitable access to treatment. This access-promoting strategy becomes even more relevant considering that the implementation of the CMPA Clinical Protocol and Therapeutic Guidelines (PCDT) by the **Ministry of Health (MS)**[6] has faced structural and logistical challenges in Rio Grande do Norte. A lack of financial resources, shortage of specialized professionals, and limited access to appropriate technologies hinder universal coverage. However, these limitations also create opportunities for public-private partnerships.

This study showed that investment by the state of Rio Grande do Norte grew consistently from 2019 to 2022, with the largest increase in 2022 (+33.94%). In 2023, there was a significant reduction, which may indicate budget adjustments or greater spending efficiency. Despite the reduction, the 2023 investment level remained higher than the average between 2019 and 2022, which encompassed the COVID-19 pandemic period.

Moreover, the local context of Northeastern states requires a careful analysis of healthcare infrastructure conditions, including professional training, access to medications, and health service coverage. Another relevant aspect concerns family awareness and nutritional education, which play a crucial role in treatment effectiveness. Despite the aforementioned challenges, there is pragmatic evidence that implementing a standardized local care pathway for CMPA patients in Rio Grande do Norte can reduce the incidence of severe complications and improve quality of life. Well-established experiences in other Brazilian states have demonstrated that the use of appropriate hypoallergenic formulas and specialized follow-up are essential to ensure the recovery and healthy development of affected children.[11]

As an example of the diversity among existing models for providing formulas to CMPA patients, Table 1 summarizes a comparison of programs implemented in two state health departments in the Northeast Region, focusing on management struc-

ture, coverage, main formulas, challenges, and strengths. In Maranhão, more than 10,000 children have been assisted since the creation of the Special Milk Program in 2005.[9]

Table 1: Comparison of Pharmaceutical Assistance Programs for Patients with CMPA in the States of Rio Grande do Norte and Maranhão

Component	Maranhão	Rio Grande do Norte
Managment	SES-MA	SESAP via UNICAT
Coverage	Regionalized	More centralized
Main Fomulas	Amino acid-based, hydrolyzed, soy	Amino acid-based, hydrolyzed, soy
Challenges	Logistics, procurement delays	Centralization, rising costs
Strengths	Regional expansion	Regional expansion

Source: Prepared by the authors.

It is important to highlight some limitations of this study. First, the analysis is based on data from a single Brazilian state, which prevents direct comparisons with results from other regions or studies. In addition, effectiveness data of the program were not directly assessed, although the study still provides empirical evidence of the impact of these initiatives. Nonetheless, this research fills an important knowledge gap by documenting a successful public policy implementation experience that ensures access to evidence-based technologies. This aligns with recent assessments by CONITEC,[6] which reaffirmed the clinical and economic value of such interventions. Most importantly, this study sheds light on the role of the state health department's pharmaceutical services, which have promoted rational access to these technologies in contrast to access via judicial demands.

Conclusion

Cow's Milk Protein Allergy (CMPA) is a condition that demands continuous attention from public health authorities due to its significant impact on both the SUS budget and affected families. The experience of Rio Grande do Norte provides valuable insights into the implementation of cost-effective public policies. Investing in awareness campaigns, early diagnosis, and efficient administrative management can improve clinical outcomes and reduce healthcare costs.

Authors' Contributions

BSO and LAC: Conceptualization and project design; manuscript writing; responsibility for all aspects of the text, ensuring the accuracy and integrity of every part of the work. JMBP and TAVS: Data collection and manuscript writing. LAC, JMBP, TAVS, and ELC: Data analysis and interpretation. LAC, JMBP, TAVS, and ELC: Critical review and editing of the manuscript; final approval of the version to be published.

Conflicts of Interest

This study was made possible through funding from Danone. Bruno dos Santos de Oliveira is an employee of Danone. The authors declare that these potential conflicts of interest did not influence the interpretation of the results.

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Data Availability Statement

All data relevant to the study are included in this article.

Responsible editor

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