

Developing Ice Cream for Mucositis Management and Improving the Nutritional Support for Pediatric Cancer Patients

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Desenvolvimento de um Sorvete para Prevenção e Tratamento da Mucosite e Suporte Nutricional a Pacientes Pediátricos com Câncer

Desarrollo de Helados para el Manejo de la Mucositis y del Soporte Nutricional a Pacientes Pediátricos con Cáncer

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ABSTRACT

Introduction: Mucositis is one of the main complications of cancer treatment, associated with several nutritional limitations and the ability to cause secondary infections. Cryotherapy is a low-cost treatment consistent with clinical practice guidelines for treating patients with mucositis. **Objective:** To develop and evaluate the acceptance of ice cream for the prevention and treatment of mucositis and nutritional support of pediatric cancer patients. **Method:** Based on knowledge about the side effects of chemotherapy (especially in oral and gastrointestinal mucositis) and the nutritional needs of pediatric cancer patients, a literature search for ingredients that could meet the study's objectives was undertaken. Food Technology Laboratory of the São Paulo State University (Unesp), Botucatu campus, and in partnership with *Sorvetes Naturais* ice cream shop in the municipality of Botucatu-SP, produced the ice cream. An acceptance test was applied in ten patients undergoing cancer treatment and 30 individuals in the control group using the 5-point mixed facial hedonic scale. **Results:** The final formula consisted of semi-skimmed lactose-free milk, extra virgin coconut oil, oat flour, honey, chamomile, Fortini® food supplement, demerara sugar, and stabilizer/emulsifier. 90% of patients undergoing cancer treatment rated the final product as "liked" or "loved it," compared to 63% of the control group. **Conclusion:** Development of an ice cream that met the objectives of the study was possible through the choice of its composition. Honey and chamomile can favor the prevention of mucositis, and other ingredients offer the caloric density and protein supply.

Key words: mucositis/prevention & control; cryotherapy; nutritional status; ice cream; neoplasms.

RESUMO

Introdução: A mucosite é uma das principais complicações do tratamento oncológico, está associada a várias limitações nutricionais e é capaz de causar infecções secundárias. A crioterapia é uma forma de tratamento de baixo custo, consistente com as diretrizes de prática clínica para o cuidado de pacientes com mucosite. **Objetivo:** Desenvolver e avaliar a aceitação de um sorvete para prevenção e tratamento da mucosite e para suporte nutricional de pacientes pediátricos com câncer. **Método:** Baseado no conhecimento sobre os efeitos colaterais da quimioterapia (especialmente na mucosite oral e gastrointestinal) e nas necessidades nutricionais do paciente oncológico pediátrico, buscou-se, na literatura, por ingredientes que pudessem alcançar os objetivos do estudo. O sorvete foi produzido no Laboratório de Tecnologia de Alimentos da Universidade Estadual Paulista (Unesp), campus de Botucatu, e em parceria com a sorveteria *Sorvetes Naturais* no município de Botucatu-SP. Foi realizado teste de aceitação com dez pacientes em tratamento oncológico e com 30 indivíduos do grupo controle usando a escala hedônica facial mista de 5 pontos. **Resultados:** A fórmula final consistiu em leite sem lactose semidesnatado, óleo de coco extravirgem, farinha de aveia, mel, camomila, suplemento alimentar Fortini®, açúcar demerara e estabilizante/emulsificante. Dos pacientes em tratamento oncológico, 90% classificaram o produto final em "gostei" ou "adorei", comparado com 63% do grupo controle. **Conclusão:** O desenvolvimento de um sorvete que alcançasse os objetivos do estudo foi possível por meio da escolha da sua composição. O mel e a camomila podem favorecer a prevenção da mucosite, e outros ingredientes oferecem densidade calórica e oferta proteica.

Palavras-chave: mucosite/prevenção & controle; crioterapia; estado nutricional; sorvetes; neoplasias.

RESUMEN

Introducción: La mucositis es una de las principales complicaciones del tratamiento del cáncer, asociada a varias limitaciones nutricionales y la capacidad de causar infecciones secundarias. La crioterapia es una forma de tratamiento de bajo costo consistente con las guías de práctica clínica para el cuidado de pacientes con mucositis. **Objetivo:** Desarrollar y evaluar la aceptación de un helado para la prevención y tratamiento de la mucositis y para el apoyo nutricional de pacientes pediátricos con cáncer. **Método:** Con base en el conocimiento sobre los efectos secundarios de la quimioterapia (especialmente en la mucositis oral y gastrointestinal) y las necesidades nutricionales de los pacientes con cáncer pediátrico, buscamos en la literatura ingredientes que pudieran lograr los objetivos del estudio. El helado fue producido en el Laboratorio de Tecnología de Alimentos de la Universidad Estatal de São Paulo (Unesp), campus de Botucatu y en sociedad con la heladería *Sorvetes Naturais* del municipio de Botucatu-SP. Se realizó una prueba de aceptación con diez pacientes en tratamiento oncológico y 30 individuos del grupo control utilizando la escala hedónica facial mixta de 5 puntos. **Resultados:** La fórmula final estuvo compuesta por leche semidesnatada sin lactosa, aceite de coco virgen extra, harina de avena, miel, manzanilla, complemento alimenticio Fortini®, azúcar demerara y estabilizante/emulsionante. El 90% de los pacientes en tratamiento contra el cáncer calificaron el producto final como "me gustó" o "me encantó", en comparación con el 63% del grupo de control. **Conclusión:** El desarrollo de un helado que cumpliera con los objetivos del estudio fue posible a través de la elección de su composición. La miel y la manzanilla pueden favorecer la prevención de la mucositis y otros ingredientes ofrecen densidad calórica y aporte proteico.

Palabras clave: mucositis/prevencción & control; crioterapia; estado nutricional; helados; neoplasias.

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INTRODUCTION

In 2020, childhood cancer corresponded to 1.4% of all malignant tumours globally, with more than 100,000 deaths. In Brazil, in this same year, there were approximately 2,700 deaths¹. Pediatric cancer patients represent a risk group for malnutrition, and about 6% to 50% may present malnutrition at diagnosis and after treatment^{2,3}. Malnutrition can result in adverse outcomes such as decreased tolerance to treatment, increased susceptibility to infections, and reduced survival⁴. Apparently, an adequate nutritional status is necessary for pediatric cancer patients⁵.

Cancer treatment has been related to the high occurrence of gastrointestinal symptoms, such as nausea, vomiting, constipation, diarrhoea, xerostomia and taste changes⁶. Chart 1 summarises the general recommendations for nutritional management according to treatment^{7,8} adverse effects. Among them, oral and gastrointestinal mucositis stands out as an inflammatory condition. The incidence varies from 15 to 100% and is more prevalent in patients undergoing high doses of chemotherapy, head and neck radiotherapy or hematopoietic stem cell transplantation (HSCT). In these groups, 70 to 100% develop mucositis⁹⁻¹² which results in severe discomfort that impair the patient's ability to eat and speak¹³. In addition, xerostomia, dysgeusia, secondary infections, and low water and food intake may result in dehydration and malnutrition. Oral pain is also associated with difficulty to chew and swallow¹⁴.

Oral mucositis is an important limiting factor to the treatment because it can change or suspend the antineoplastic treatment, interfering with disease control, survival, increasing length of stay and hospital expenses¹⁵⁻¹⁷. It is noticeable that mucositis negatively affects patients' quality-of-life¹⁸. Gastrointestinal mucositis is a general acute clinical problem with rapid onset of diarrhea (usually within 24 to 48 hours of treatment), abdominal pain, nausea, vomiting, anorexia, and in more severe cases, weight loss, dehydration and sepsis¹⁹⁻²³.

Oral cryotherapy consists of cooling the mouth using ice, iced water, ice cream or popsicles and continuous replacement of fresh ice during cytotoxic treatment²⁴. This treatment reduces blood flow to the oral mucosa and decreases exposure to chemotherapeutic agents^{25,26}. Cryotherapy is a low-cost therapeutic choice and practically of universal access, with high efficacy and simple applicability^{27,28}. The mucositis study group of the Multinational Association of Supportive Care in Cancer and the International Society of Oral Oncology recommends 30 minutes of cryotherapy in patients receiving 5-fluorouracil chemotherapy, high doses of

Chart 1. Summary of the general recommendations for adverse effects-based nutritional management

| |
|--|
| Oral mucositis |
| <ul style="list-style-type: none"> • Modify the consistency of the diet according to the mucositis grade • Eat food at room temperature • Intake softer and more pasty foods • Offer oral supplement in case of insufficient nutritional support |
| Nausea and vomiting |
| <ul style="list-style-type: none"> • In case of poor nutritional support, associate hypercaloric and hyperproteic oral nutritional therapy, palatable to the patient, fractionated into small servings, at room temperature or frozen • Avoid drinking liquids during meals, using them in small amounts at intervals, preferably iced (example: popsicle) |
| Diarrhea |
| <ul style="list-style-type: none"> • Avoid foods rich in lactose, gluten and sucrose • Low insoluble fiber and high soluble fiber diet |
| Anorexia |
| <ul style="list-style-type: none"> • Increase the caloric and protein density of foods • Fractioned hypercaloric/hyperproteic diets in small portions • Prefer high calorie drinks • Introduce hypercaloric and hyperproteic oral supplements at intervals |
| Xerostomia |
| <ul style="list-style-type: none"> • Prefer moistened foods, add sauces to preparations • Chew and suck ice made from water, coconut water and fruit juice or popsicles |

melphalan, with or without total body irradiation, and is a requirement for HSCT^{29,30}.

The aim of the present study was to develop and evaluate the acceptance of ice cream popsicle for the prevention and treatment of mucositis and for nutritional support of pediatric cancer patients. In addition to cryotherapy, the development of the ice cream also attempted to meet the following goals: 1) develop a lactose-free product to assist in the management of diarrhea (a side effect of chemotherapy or secondary to gastrointestinal mucositis) and allow its use in lactose intolerant children; 2) support the nutritional supply during cancer treatment; 3) contribute to the management of nausea and xerostomia; 4) use ingredients that assist the prevention and treatment of mucositis.

METHOD

The study was developed in two phases. The first phase consisted in the elaboration of the ice cream. The

second phase comprehended the acceptability test with a small number of children and adolescents without mucositis. Data collection for the second phase of the study was carried out between October and December 2020, comprising a total of 40 children: 30 in the control group and 10 in the cancer group. The cancer group was undergoing oncological treatment at the *Hospital das Clínicas da Faculdade de Medicina de Botucatu* (SP), either hospitalized or in outpatient consultation. Participants of the control group met the inclusion and exclusion criteria (mentioned below), being present in the same hospital as patients' companions, in outpatient care or inpatients. A hospital was chosen for data collection of the control group because the study was being conducted during the COVID-19 pandemic.

The Institutional Review Board of "*Hospital das Clínicas da Faculdade de Medicina de Botucatu* (SP), Unesp" approved the study (CAAE: 30450420.3.0000.5411), and the informed consent form was signed.

PHASE 1. ICE CREAM ELABORATION

The ice cream popsicle was developed by a nutritionist, a food engineer and a pediatric dentist, based on the existing knowledge of chemotherapy-related side effects (primarily oral and gastrointestinal mucositis) and the nutritional needs of pediatric oncology patients. The main references used and the description of the ingredients chosen to prepare the ice cream are presented in Chart 2³¹⁻³⁷. The final formula consisted of semi-skimmed

lactose-free milk (Italac[®], Goiás, Brazil), extra virgin coconut oil (Siamar[®], São Paulo, Brazil), whole oat flour (Quaker[®], Paraná, Brazil), honey (Alvorada[®], São Paulo, Brazil), chamomile (in bulk), Fortini[®] Food Supplement (Danone[®], Minas Gerais, Brazil), demerara sugar (Guarani[®], São Paulo, Brazil), emulsifier/stabilizer (Marvi[®], São Paulo, Brazil). The product was developed at the Food Technology Laboratory of Horticulture Department of the Sao Paulo State University (Unesp), Brazil and in partnership with the ice cream shop *Sorvetes Naturais* in Botucatu, São Paulo, Brazil.

All the ingredients were weighed on a culinary scale and crushed in a mixer. 24 shaped popsicles were processed by an industrial popsicle machine for around 25 to 50 minutes at a temperature ranging from -24 to -30 degrees Celsius. Each popsicle was individually packed, sealed and stored in a freezer. The Dietbox[®] Software was used for popsicle nutritional calculation.

PHASE 2. EVALUATION OF ACCEPTABILITY OF THE ICE CREAM

The overall acceptability of the ice cream was evaluated through a 5-point hedonic scale (loved, liked, indifferent, did not like, hated). The criteria for evaluating acceptance of the ice cream as percentages of the expressions "loved" and "liked" were added and classified as 70% (High), between 50 and 70% (Medium), between 30 to 50% (Low), and less than 30% (Very Low)^{38,39}. The cancer group included ten patients without mucositis, and the inclusion criteria were: aged 5 to 15 years old; cancer

Chart 2. Description of the ingredients used for ice cream preparation

| Ingredient | Description for use |
|-------------------------------------|---|
| Lactose-free semi-skimmed milk | Contribute to the nutritional value and management of diarrhea due to gastrointestinal mucositis or a side effect of the chemotherapy protocol. In children, chemotherapy has been shown to reduce the absorption of lactose ³¹ |
| Chamomile infusion at 2.5% | A significant reduction of oral mucositis was found after the use of chamomile resulting in lower incidence, severity and duration, which indicates the effectiveness of this ingredient ³² . A randomized study concluded that the occurrence of oral mucositis was lower in patients submitted to chamomile infusion ³³ cryotherapy |
| Lactose-free nutritional supplement | A lactose-free nutritional supplement for children was used to complement the energy, protein, and micronutrient supply and improve the palatability of the final product. In the final formula, the supplement Fortini [®] vanilla flavour was used |
| Honey | Honey can reduce the severity of chemotherapy and radiotherapy induced oral mucositis. Also, pain in the oral cavity can be relieved after honey treatment. Honey can be a cost-effective way to limit oral mucositis and can find high acceptance by patients and their caregivers. Also, as an adjuvant in sweetening, improving palatability and assisting in energy supply ^{34,35} |
| Oatmeal flour | A good source of soluble dietary fibre, especially beta-glucan, with excellent functional and nutritional properties ³⁶ |
| Coconut oil | More than 50% of the fat in coconut oil is medium chain fatty acids (MCFA), which are transported to the liver similar to carbohydrates. It provides energy faster as they are not re-esterified within the intestinal mucosa, being bound and transported directly with albumin in the blood. They represent an option for lipid absorption in patients whose fat absorption mechanisms are impaired ³⁷ |

diagnosis through conventional methods; undergoing cancer treatment. The control group consisted in 30 children and adolescents from the outpatient clinic and pediatric ward aged 5 to 15. The exclusion criteria for both groups were allergy or intolerance to any of the ingredients of the product developed, chronic digestive symptoms, diagnosis of diabetes, or other pathologies that result in altered blood glucose.

All the participants underwent nutritional assessment. Weight was collected with a calibrated digital scale and height with a vertical stadiometer. With these data, the Body Mass Index (BMI), the height for age (H/A), weight for age (W/A) and BMI for age (BMI/A) were obtained. Gender, age and type of cancer were collected from the medical records of “Hospital das Clínicas da Faculdade de Medicina de Botucatu”.

Clinical data were compiled into a single database and analyzed using GraphPad Prism version 7.00 for Windows (GraphPad Software, San Diego, CA). The Kolmogorov-Smirnov test was used to verify normal distribution and to define the tests as parametric and non-parametric. The median and interquartile ranges were used for clinical variables. Categorical variables were presented as counts (n) and percentages (%) and analyzed using Fisher’s exact test. Statistical tests were two-tailed, and values of $p < 0.05$ were considered statistically significant.

RESULTS

Vanilla was the final predominant flavour of the ice cream developed. Table 1 presents the nutritional information of a popsicle developed and the percentage of daily nutritional requirements reached with the intake of a popsicle by a ten-year-old girl with weight and height in the 50th percentile. A 10-year-old female child (sex randomly assigned) was chosen as a reference of nutritional needs to compose Table 1, because the age is similar to the median among the study participants. Assuming that the patient in cryotherapy will need approximately four units of popsicles/day, good energy and protein supply are achieved according to the daily nutritional needs of a ten-year-old girl.

Table 2 presents the comparison between the nutritional information of the popsicle developed in this study with a commercial popsicle manufactured by Kibon, (Fruttare coco®)⁴⁰ because it was manufactured with milk, without icing, or other characteristics different from the one elaborated with known and accessible nutritional components. The popsicle developed has low caloric value, practically twofold the volume of protein and less saturated fat than the commercial popsicle.

Five patients of the cancer group had acute lymphoblastic leukemia, two had acute myeloid leukemia, two had Ewing’s sarcoma and one had optic pathway

Table 1. Popsicle nutrition facts

| Nutritional information 70 g serving (1 popsicle) | | |
|---|------------------|-------|
| Energy value | 88 kcal | 6% |
| Carbohydrates | 12 g | 7% |
| Proteins | 2.5 g | 7% |
| Total fat | 3.0 g | 6% |
| Cholesterol | Does not contain | ** |
| Polyunsaturated fat | 0.3 g | ** |
| Monounsaturated fat | 1.0 g | ** |
| Saturated fat | 1.3 g | ** |
| Trans fat | Does not contain | ** |
| Dietary fibre | 0.2 g | 1.4% |
| Sodium | 44 mg | 3.6% |
| Vitamin A (retinol) | 17 mcg | 2.8% |
| Vitamin B9 (folic acid) | 7.0 mcg | 2.3% |
| Potassium | 40 mg | 0.88% |
| Magnesium | 4.1 mg | 1.7% |
| Calcium | 75 mg | 5.8% |
| Selenium | 1.3 mcg | 3.2% |
| Vitamin C (ascorbic acid) | 4.6 mg | 10% |
| Phosphorus | 24 mg | 2% |
| Zinc | 0.40 mg | 5% |

(%) Daily reference values, based on Reference Daily Intake for children aged 9 to 13 years.

(**) Daily values not established.

Table 2. Comparison of popsicles nutritional information

| | Popsicle produced for this study 70 g serving | Commercial popsicle (Kibon Fruttare Coco®) 70 g serving |
|---------------|---|---|
| Energy value | 88 kcal | 98 kcal |
| Carbohydrates | 12 g | 16 g |
| Proteins | 2.5 g | 1.3 g |
| Total fat | 3.0 g | 3.0 g |
| Saturated fat | 1.3 g | 1.3 g |

glioma. Table 3 shows no significant difference between the baseline characteristics, and the popsicle acceptability test for children and adolescents. The percentage found in the acceptability test for “loved + liked” for the cancer group and control group were 90% and 63%, respectively.

Some participants reported they were uncomfortable with oat flour added to the ice cream. One child of the control group negatively associated the texture of oatmeal with coconut fruit. Another participant from the same

Table 3. Baseline characteristics of children and adolescents submitted to the popsicle acceptability test

| Baseline Characteristics | Control group (n=30) | Cancer group (n=10) | p-value < |
|-------------------------------|------------------------------|------------------------|-----------|
| | Median (interquartile range) | | |
| Female, n (%) | 13 (43) | 5 (50) | 0.77 |
| Age (years) | 9.8 (8.1-11.7) | 10.8 (6.9-12.7) | 0.50 |
| Nutritional assessment | | | |
| Weight/Age (z score) | 0.6 (-0.7-1.5) | 1.03 (-0.22-1.96) | 0.61 |
| Height/Age (z-score) | 0.5 (-0.2-1.3) | 0.26 (-0.15-1.32) | 0.78 |
| BMI†, kg/m ² | 18.1 (16.2-22.2) | 17.6 (16.9-23.9) | 0.74 |
| BMI/Age (z score) | 0.7 (-0.2-1.3) | 0.85 (-0.40-1.90) | 0.78 |
| BMI/Age (z score ≥ 1.0 n) (%) | 14 (47) | 5 (50) | 1.0 |
| Acceptability (n) | | | |
| Loved | 12 | 4 | 0.99 |
| Liked | 7 | 5 | 0,10 |
| Indifferent | 9 | 0 | NA* |
| Did not like | 2 | 1 | NA* |
| Hated | 0 | 0 | NA* |
| Loved + Liked | 19 | 9 | 0.20 |

Captions: NA* = not analysed; BMI† = body mass index.

z-score: statistical measure for a value's relationship to the mean of a group of values.

group mentioned “oat taste” negatively impacting the acceptance. One child of the cancer group reported not liking the colour of the popsicle.

DISCUSSION

The current study developed a therapeutic ice cream with combinations of energy, proteins, carbohydrates and fat that could favour cryotherapy and support the nutritional status. The acceptability was high in children and adolescents undergoing cancer treatment.

The ice cream developed is lactose-free and it can be used in patients with intolerance to this disaccharide or with diarrhea. It can be offered instead of standard cryotherapy as a way to prevent mucositis, complement the nutritional supply, help manage other symptoms (nausea, anorexia, xerostomia and diarrhea) and humanize the treatment.

The studies mentioned below have also reconciled cryotherapy associated with other ingredient(s) that could bring additional benefits to therapy alone. A randomized study³³ comparing cryotherapy only with chamomile-based infusion cryotherapy concluded that the chamomile group had less pain, oral mucositis was mild, there were no oral ulcerations, was well tolerated, and without toxicity. In another study⁴¹, honey ice cubes significantly reduced the occurrence of chemotherapy-induced oral mucositis

in pediatric cancer patients. In a study⁴² that compared pure ice with flavoured ice, a higher frequency of nausea was found in flavoured ice.

New products designed for the oncological public were developed to improve food acceptance by oral route⁴³⁻⁴⁶. Trindade et al.⁴³ used a fortified ice cream dough for head and neck cancer patients and reported that the availability of foods that could effectively play the role of conventional supplements that were also tasty and familiar would immediately improve their quality-of-life.

Many considered ice cream a popular food, affirming it is a welcome addition to their daily diet⁴³. A study identifying demands at mealtimes and food preferences of hospitalized patients with haematological cancer found that fruits and ice cream were the most desired foods and their combination could improve caloric intake and sensory pleasure⁴⁷. Vieira et al.⁴⁶ developed an ice cream with three flavours as a therapeutic strategy for cancer patients, resulting in high acceptance in both control and cancer groups.

Food has a primordial function, as it relates to the nice and pleasant memories that specific food preparations provoke in the lives of human beings. The importance of food does not change the onset of a severe illness. In a situation of not being able to eat, food is perceived more for its lack or difficulties than for its presence and pleasure⁴⁸. Eating already known foods, such as ice cream,

can provide a sense of autonomy and normality⁴⁷. Thus, in addition to the study objectives, the elaboration of an ice cream contributed to rescue the pleasure with food, combining food the patients already know with benefits for cancer treatment.

Eating behaviours are influenced by intrinsic genetics, age, gender, and environmental factors, such as family, community, society and peers⁴⁹. Humans generally have innate positive responses to sweet and salty and negative responses to bitter tastes⁵⁰. Children are predisposed to prefer foods with high caloric density, reject new foods, and learn associations between food flavours and the consequences after eating⁵¹. Due to the negative association of the final texture with oats, despite their benefits, considering the pros and cons, it was suggested a formula without oat flour or adding another soluble fibre. Add colour is a suggestion to increase public interest in consuming the product.

The study has several strengths: developing a lactose-free popsicle with high acceptance, with ingredients that can help to prevent mucositis (such as honey and chamomile) and complement nutritional intake. In addition, it contributes to manage nausea, xerostomia, inappetence, and the humanization of treatment. The limitations are the small sample, especially in the cancer group, restricting the interpretation of the nutritional status assessment and popsicle acceptance since a more significant number of patients would increase the power of the study.

The effectiveness of offering products matched to the individuals' nutritional demands affected by cancer is increasing^{45,46}. Developing strategies to fulfil a therapeutic role and collaborating to achieve other goals is welcome. The benefits of honey, chamomile and other compounds need to be addressed in future studies as they are essential to prevent childhood cancer mucositis. It is believed that for patients with diagnosis impacting so many areas, the possibility to submit to cryotherapy with a food that is already known and that can contribute to nutrient intake allows a patient-centered therapeutic strategy with such unique needs.

CONCLUSION

The development of an ice cream that met the study's objectives was possible through the choice of its composition. Honey and chamomile may favour the prevention of mucositis, and other ingredients provide caloric density and protein supply. However, different ingredients can be utilized for the same purpose as there is no single way to combine cryotherapy with nutritional supply.

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CONTRIBUTIONS

All the authors contributed substantially to the study design, acquisition, analysis and interpretation of the data, wording and critical review. They approved the final version to be published.

DECLARATION OF CONFLICT OF INTERESTS

There is no conflict of interests to declare.

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