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Assessment of intrinsic capacity in the Brazilian older population and the psychometric properties of the WHO/ICOPE screening tool: a multicenter cohort study protocol

Avaliação da capacidade intrínseca da população idosa brasileira e das propriedades psicométricas do instrumento de triagem do ICOPE/OMS: protocolo de estudo de coorte multicêntrico

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Abstract

Introduction: The World Health Organization (WHO) has proposed to monitor intrinsic capacity (IC) in the older population as a public health strategy through the Integrated Care for Older People (ICOPE) program. Although the program has been developed based on solid concepts, scientific evidence on its practical applicability is still scarce.

Objectives: To evaluate IC in Brazilian older adults, its progress over time, and its association with sociodemographic and health factors and outcomes. To evaluate the psychometric properties of the WHO/ICOPE screening tool.

Methods: This is a prospective multicenter cohort study with a 36-month follow-up. We will recruit 3838 people aged ≥60 years, registered in the health care units included in the study by the participating centers. We will collect sociodemographic and health data and will administer tools to assess IC domains, both those provided for in the ICOPE screening tool and the sequence of confirmatory assessments provided for in the program. Participants will be reassessed every 6 months for 36 months.

Expected results: To establish the profile of IC in the study population and to understand its progress and the variables associated with the clinical outcomes of interest. To reveal the diagnostic and psychometric properties of the WHO/ICOPE screening tool. The project is funded by the Brazilian National Council for Scientific and Technological Development (CNPq).

Relevance: Understanding the potential use of the ICOPE public health strategy proposed by the WHO within the scope of the Brazilian Unified Health System (SUS) by integrating several research centers in the field of Geriatrics and Gerontology throughout Brazil.

Keywords: aging; healthy aging; functional status; World Health Organization; quality of life; public health.

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Resumo

Introdução: A Organização Mundial da Saúde (OMS) propõe o monitoramento da capacidade intrínseca (CI) da população idosa como estratégia de saúde pública por meio do Programa ICOPE (*Integrated Care for Older People*). Embora construído com base em conceitos sólidos, a evidência científica sobre a aplicabilidade prática da proposta ainda é escassa.

Objetivo: Avaliar a capacidade intrínseca da população idosa brasileira, sua trajetória e sua associação com variáveis sociodemográficas, de saúde e desfechos. Avaliar as propriedades psicométricas da ferramenta de triagem da estratégia ICOPE da OMS.

Metodologia: Coorte multicêntrica prospectiva com seguimento de 36 meses. Serão recrutadas 3.838 pessoas com 60 anos ou mais, cadastradas nas unidades de saúde incluídas no estudo pelos centros participantes. Serão coletados dados sociodemográficos e de saúde e aplicados instrumentos para avaliação dos domínios da CI, tanto aqueles previstos no instrumento de triagem do ICOPE quanto a sequência de avaliações confirmatórias previstas no programa. Os participantes serão acompanhados semestralmente ao longo de 36 meses.

Resultados esperados: Estabelecer o perfil da CI na população estudada, entender a sua trajetória e as variáveis associadas aos desfechos clínicos avaliados. Revelar as propriedades diagnósticas e o perfil psicométrico da ferramenta de triagem do ICOPE da OMS. O projeto tem financiamento do Conselho Nacional de Desenvolvimento Científico e Tecnológico (CNPq).

Relevância: Compreensão sobre o potencial de utilização da estratégia ICOPE de saúde pública proposta pela OMS no âmbito do Sistema Único de Saúde (SUS) pela integração de diversos centros de pesquisa científica na área de Geriatria e Gerontologia de todo o Brasil.

Palavras-chave: envelhecimento; envelhecimento saudável; estado funcional; Organização Mundial da Saúde; qualidade de vida; saúde pública.

INTRODUCTION

Accelerated population aging will profoundly affect economies and health systems around the world.[1] In Brazil, the number of people aged 60 years and older increased from 22.3 million (11.3% of the population) in 2012 to 31.2 million (14.7%) in 2022, and projections for 2050 indicate that there will be more than 65 million people aged ≥60 years, which will correspond to 30% of the country's population.[2,3] The adoption of measures capable of preserving the health and functional status of older people and of reducing the number of care-dependent individuals, is a major challenge that should be urgently debated. In response to this reality, the World Health Organization (WHO) developed the Integrated Care for Older People (ICOPE) strategy, aiming to create actions to promote healthy aging, characterized by helping people maintain functional ability throughout the lifespan.[4]

Functional ability is defined as the "health-related attributes that enable people to be and to do what they have reason to value."[4] These attributes include intrinsic capacity (IC), which is the combination of the individual's physical and mental capacities (including psychological capacity), and the interaction of IC with the environment a person inhabits.[4]

To achieve this goal, the WHO has proposed to monitor the older person's progress across the 6 domains of IC (mobility, cognition, vitality, psychological capacity, vision, and hearing), thus allowing the adoption of targeted measures to reverse, stabilize, or delay possible losses in each domain.[5]

The ICOPE was designed to be delivered in 5 steps. This pathway starts with the administration of a screening tool (step 1; Table 1) to assess

TABLE 1. World Health Organization ICOPE Screening Tool.

Domain	Tests	Assess fully any domain with a checked circle
Cognitive decline	Remember 3 words: "flower", "door", "rice" (for example) Orientation in time and space: What is the full date today? Where are you now (home, clinic, etc.)? Recalls the 3 words?	◯ Wrong to either question or does not know ◯ Cannot recall all 3 words
Limited mobility	Chair rise test: Rise from chair 5 times without using arms. Did the person complete 5 chair rises within 14 seconds?	◯ No
Malnutrition	Weight loss: Have you unintentionally lost more than 3 kg over the last 3 months? Appetite loss: Have you experienced loss of appetite?	◯ Yes ◯ Yes
Visual impairment	Do you have any problems with your eyes: difficulties in seeing far, reading, eye diseases or currently under medical treatment (e.g. diabetes, high blood pressure)?	◯ Yes
Hearing loss	Hears whispers (whisper test); or Screening audiometry result is 35 dB or less; or Passes automated app-based digits-in-noise test	◯ No
Depressive symptoms	Over the past 2 weeks, have you been bothered by: feeling down, depressed, or hopeless? little interest or pleasure in doing things?	◯ Yes ◯ Yes

Adapted from: Integrated Care for Older People (ICOPE). Guidance for person-centered assessment and pathways in primary care. Geneva: World Health Organization; 2019.

potential declines in IC, which must be evaluated in detail (step 2) with validated tools used in clinical practice.[6] The next step is to design a personalized care plan (step 3) including affordable, evidence-based measures and to monitor cases over time (step 4). Step 5 refers to the recommended actions to offer support to caregivers and engage communities in caring for the older population, preventing ageism.[5]

The concept of IC and its 6-domain construct underpin the WHO proposal and have already been studied in different populations.[7-12] The predictive ability of the ICOPE screening tool and its association with negative outcomes have also been explored in studies using retrospective data to simulate each of its components.[13,14] However, the tool still lacks proper evaluation of its applicability and psychometric properties, which are the gateway to the program, in real-world scenarios, by prospective studies.[15] The WHO has acknowledged the limited evidence on the topic in its latest report on the ICOPE implementation pilots, so the organization itself encourages and supports scientific initiatives in this regard.[16]

Given these considerations, an interprofessional and interdisciplinary group of researchers specializing in human aging proposed the Project ICOPE Brazil with the aim of analyzing the characteristics of IC in Brazilian older adults in each of the domains of IC, as well as its progress over time, its relationship with sociodemographic and health factors, and its association with health outcomes.[17] Moreover, we will be able to evaluate the psychometric properties of the screening tool proposed by the WHO program, notably its sensitivity, specificity, accuracy, and predictive ability to measure IC in Brazilian older adults.

METHODS

Study design

A multicenter cohort study with a 36-month follow-up. We will perform a baseline assessment, with reassessments via teleconsultation at 6, 18, and 30 months and in-person reassessments at 12, 24, and 36 months. The variables collected in each of the described stages are summarized in Table 2.

Population

People aged ≥60 years who are users of the public health system, registered in the participating primary health care units, and domiciled in their respective coverage area.

Health care units

Each research center will be able to determine which primary health care units will be selected for the inclusion of

TABLE 2. Baseline and follow-up assessments.

Procedures	Baseline In-person	6 months Teleconsultation	12 months In-person	18 months Teleconsultation	24 months In-person	30 months Teleconsultation	36 months In-person
ICOPE ST	✓	✓	✓	✓	✓	✓	✓
Baseline questionnaire	✓						
Follow-up questionnaire		✓	✓	✓	✓	✓	✓
Charlson index	✓		✓		✓		✓
Barthel ADL	✓	✓	✓	✓	✓	✓	✓
Lawton IADL	✓	✓	✓	✓	✓	✓	✓
CFS	✓	✓	✓	✓	✓	✓	✓
FRAIL	✓	✓	✓	✓	✓	✓	✓
SARC-F	✓	✓	✓	✓	✓	✓	✓
HHIE-S	✓	✓	✓	✓	✓	✓	✓
MMSE	✓		✓		✓		✓
GDS-15	✓		✓		✓		✓
MNA	✓		✓		✓		✓
IPAQ_	✓		✓		✓		✓
WHOQOL-BREF	✓		✓		✓		✓
SPPB	✓		✓		✓		✓
TGUG	✓		✓		✓		✓
Handgrip strength	✓		✓		✓		✓
Visual acuity	✓		✓		✓		✓
Audiometry	✓		✓		✓		✓
Sample collection*	✓						
Anthropometry	✓		✓		✓		✓
Otoscopy	✓						
Blood pressure	✓		✓		✓		✓
BIA*	✓						
DEXA*	✓						

ICOPE ST: ICOPE screening tool; ADL: activities of daily living; IADL: instrumental activities of daily living; CFS: Clinical Frailty Scale; HHIE-S: Hearing Handicap Inventory for the Elderly – Screening Version; MMSE: Mini-Mental State Examination; GDS-15: 15-item Geriatric Depression Scale; MNA: Mini Nutritional Assessment; IPAQ: International Physical Activity Questionnaire; WHOQOL-BREF: abbreviated World Health Organization Quality of Life questionnaire; SPPB: Short Physical Performance Battery; TGUG: Timed Get Up and Go; BIA: bioelectrical impedance analysis; DEXA: dual energy X-ray absorptiometry.

participants according to the reality of each site (logistic feasibility, physical structure, resources, partnership with the participating center, etc.), as long as the study recruitment protocol is respected.

Coordinating center

The Project ICOPE Brazil will involve the participation of academic medical centers from the 5 regions of the country and will be coordinated by the Medical School of Universidade de São Paulo (FMUSP).

Participating centers

- South region: Hospital de Clínicas de Porto Alegre, Universidade Federal do Rio Grande do Sul (HCPA-UFRGS); and Universidade Federal de Santa Catarina (UFSC).
- Southeast region: FMUSP, Ribeirão Preto Medical School (FMRP), Universidade de São Paulo Nursing School (EEUSP); Ribeirão Preto Nursing School, Universidade de São Paulo; School of Medical Sciences of Minas Gerais (FCM-MG), Botucatu

Medical School – Universidade Estadual Paulista "Júlio de Mesquita Filho" (Unesp); Universidade do Estado do Rio de Janeiro (UERJ); Universidade Federal de Minas Gerais (UFMG); Universidade Federal de Alfenas (Unifal); Universidade Federal de Juiz de Fora (UFJF); Universidade Federal dos Vales do Jequitinhonha e Mucuri (UFVJM); and Universidade Federal do Triângulo Mineiro (UFTM).
- Midwest region: Universidade Federal do Mato Grosso (UFMT).
- Northeast region: Universidade Federal do Rio Grande do Norte (UFRN); Universidade Federal do Ceará (UFC); Universidade Federal de Sergipe (UFSE); Universidade Federal de Pernambuco (UFP); Fundação Universidade de Pernambuco (FUPE); and Universidade Estadual do Sudoeste da Bahia (UESB).
- North region: Universidade Federal do Amazonas (UFAM) and Universidade Federal do Pará (UFPA).

Sample size calculation

The sample size was calculated to detect differences in the incidence of functional decline between robust older people and those with loss of IC identified by the ICOPE screening tool (power of 80% and alpha error of 1%, with a prevalence of estimated IC loss of 10% among participants at baseline), and resulted in a minimum of 202 individuals per participating center and a total sample size of 3838 older people (considering the participation of 23 research centers and 19 planned collection sites). This number of participants will also be sufficient to perform the psychometric analyses, for which the sample size calculation follows a different rationale.[18,19]

Inclusion criteria

- People aged ≥60 years, with no age limit;
- Being registered (with available contact information) in the participating health care units;
- Being available to go in person to the data collection sites for the assessments.

Exclusion criteria

- Inability to access the data collection site;
- Severe neurologic and/or cognitive abnormalities that preclude an interaction with the evaluators to complete the proposed tests and data collections;
- Advanced serious illness or under palliative care: Clinical Frailty Scale (CFS)[20] score of 8 (severely frail) or 9 (terminally ill).

Enrollment

We will generate a random order from the lists of users registered in each of the health care units included in the project to invite participants, ensuring randomization of the entry sequence and equal opportunity for participation. We will invite people to participate via telephone or home visit, following the order of the randomization list, until the minimum expected number of participants in each of the centers is reached. Centers enrolling participants from 2 or more health care units to reach the minimum expected sample size of 202 participants are required to consolidate the lists of users from these units into a single list prior to randomization.

Procedures

All older people who agree to participate in the study will be required to present in person to the collection site, determined by each participating center, to sign the informed consent form (ICF). After obtaining written informed consent, data will be collected using the Research Electronic Data Capture (REDCap) platform.[21] The research teams at each center, properly trained to apply the protocol, will conduct the assessments. Identification and contact data will be collected and the WHO/ICOPE screening tool will be administered.[5] Participants will then respond to a standard questionnaire, with questions about sociodemographic status, use of electronic devices (smartphones, computers, etc.), Internet use, and health-related issues.

We will apply tools to assess comorbidities (Charlson index[22]), functional status (Barthel[23] and Lawton[24] scales), and frailty (CFS,[20] FRAIL scale,[25] and SARC-F scale[26]). We will use the tools suggested by the WHO for detailed assessment of each IC domain (step 2)[5]: Mini-Mental State Examination — MMSE[27] (cognition); 15-item Geriatric Depression Scale — GDS-15[28] (mood); Mini Nutritional Assessment — MNA[29] (nutrition); Short Physical Performance Battery — SPPB[30] (mobility); visual acuity using a Snellen chart (vision); and audiometry (hearing). We will also assess physical activity level (International Physical Activity Questionnaire— IPAQ,[31] short version), quality of life (WHOQOL-BREF),[32] and hearing disability using the Hearing Handicap Inventory for the Elderly – Screening Version (HHIE-S),[33] in addition to mobility and strength tests (Timed Get Up and Go — TGUG[34] and measurement of handgrip strength using a dynamometer[35]). Participants will also undergo anthropometric measurements, otoscopy, and blood pressure measurement.

Depending on the availability of each center, additional tests will be performed: blood and urine collection for laboratory tests and biobanking (which will allow future analysis of potential biomarkers), bioelectrical impedance analysis, and whole-body densitometry (to assess body composition).

Follow-up and schedule

Six follow-up reassessments are planned to occur at 6, 18, and 30 months via teleconsultation and at 12, 24, and 36 months at the research center. All procedures planned for each follow-up assessment, as well as the baseline assessment, are listed in Table 2. The Research Ethics Committee of the Coordinating Center approved the Project ICOPE Brazil (CAAE 71672723.5.1001.0068). A UFRGS pilot project for participant recruitment and baseline analysis in the city of Porto Alegre, state of Rio Grande do Sul, in the format of the Project ICOPE Brazil, was approved by the Research Ethics Committee (CAAE 57139721.3.0000.5327), and the inclusion of the first participants began in April 2023.

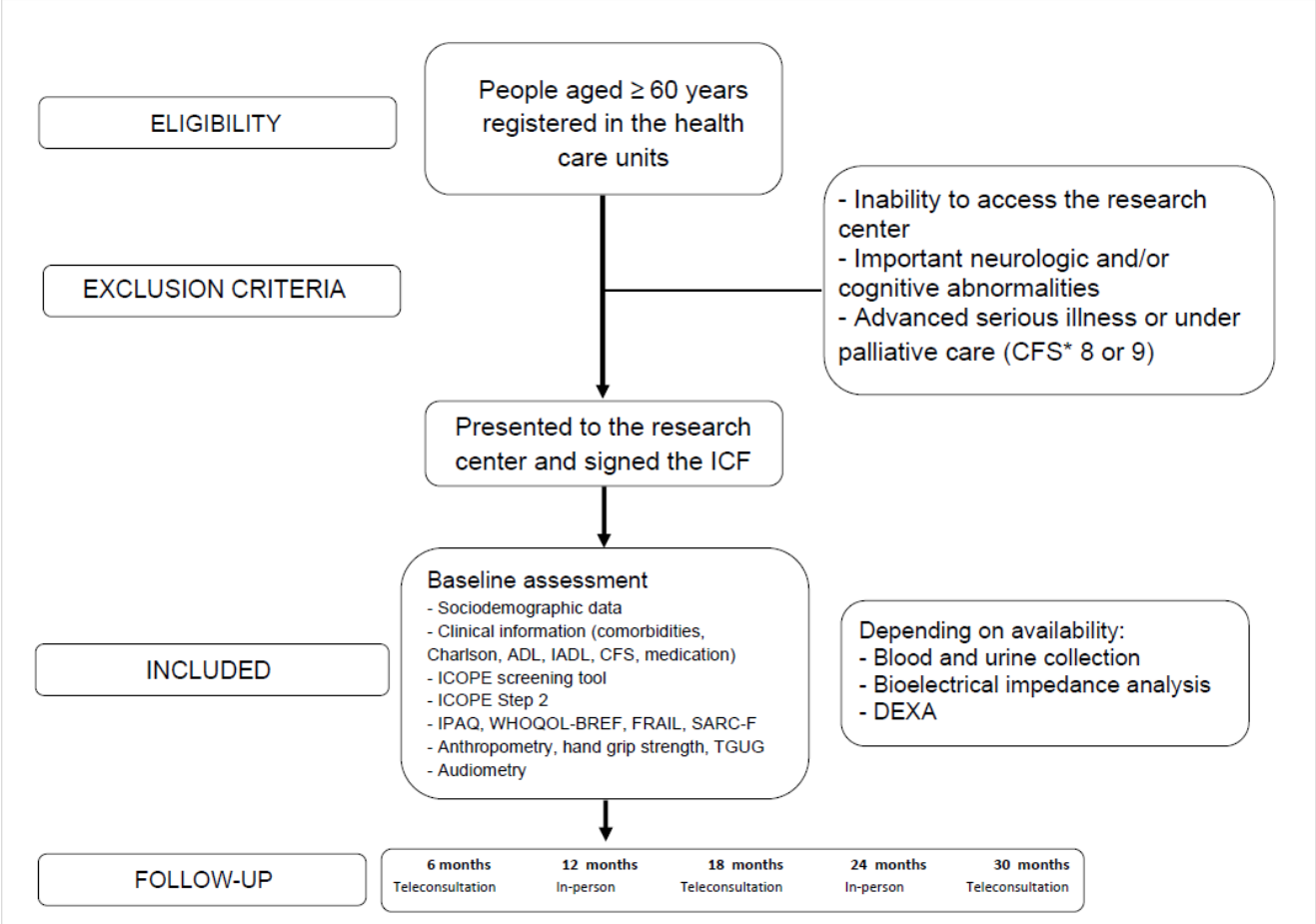
The study flow diagram is shown in Figure 1.

Statistical analysis

To characterize the sample and variables of interest, we will present measures of central tendency and dispersion depending on data distribution. The baseline variables will be expressed as mean (SD) for continuous variables and as absolute and relative frequencies for categorical variables. To analyze comparisons of variables between groups, we will use the chi-square test for categorical variables and Student's t test for independent samples, with Levene's test for equality of variances, for continuous variables. To test univariate and multivariate associations, the prevalence ratios of the factors under study with the loss of IC will be calculated using modified Poisson regression with robust variance estimation.

Regarding risk analyses for the incidence of outcomes during follow-up, we will use a Cox regression model and outcome-free survival analysis by comparing Kaplan-Meier curves.

We will perform analyses for internal structure and relationships with other variables to provide validity evidence. We will analyze the internal structure validity evidence using exploratory and confirmatory factor analysis. The predictive



CFS: Clinical Frailty Scale; ICF: informed consent form; ADL: activities of daily living; IADL: instrumental activities of daily living; ICOPE: Integrated Care for Older People; IPAQ: International Physical Activity Questionnaire; WHOQOL-BREF: abbreviated World Health Organization Quality of Life questionnaire; TGUG: Timed Get Up and Go; DEXA: dual energy X-ray absorptiometry.

FIGURE 1. Flow diagram of study participants.

relationship analysis will test the performance and accuracy of the ICOPE screening tool in detecting and predicting clinical outcomes (IC decline, functional decline, falls, hospitalization, and mortality) at different time points (6, 12, 18, 24, 30, and 36 months) by using receiver operating characteristic (ROC) curve analysis with Delong test.

Ethics

The study procedures were designed to meet current recommendations for research involving human participants, notably Resolution No. 466/12 and the Circular Letter of the Brazilian National Research Ethics Committee (CONEP) for research in virtual environments. All participants will be informed of the study procedures and will be invited to sign an ICF, approved by the research ethics committees of each participating center and by CONEP. The researchers will evaluate the test results, and those that are significantly altered will be communicated to the participants and/or family members with the respective instructions. The results of the tests and assessments will be made available to participants at the end of the study. The biological material will be used in accordance with the ethical standards established in Ordinance No. 2201/2011 of the Brazilian Ministry of Health and in Resolution No. 441/2011 of the Brazilian National Health Council referring to biorepositories and biobanks of human biological material for research purposes.

Data management plan

We developed the data management plan on the DMPTool platform. Data collection and management procedures will be carried out entirely on the REDCap platform.[21] To increase data storage security, registered researchers will receive access-level permissions. The data will be anonymized and de-identified for analysis.

Relevance

The Project ICOPE Brazil is aligned with similar initiatives that are underway in countries such as Spain,[36] Andorra,[36] France,[37] and China,[38] which also evaluate the WHO's public health strategy to face the challenges related to population aging. The ICOPE approach emerges as an important tool to promote healthy aging by preserving the health and improving the quality of life of older people, which may result in a reduced number of care-dependent people. The ICOPE Brazil is the first study to evaluate the WHO strategy on a national scale using a multicenter, longitudinal initiative and will obtain its data by randomly selecting community-dwelling older people rather than by convenience sampling. The functional capacity required to allow in-person assessments at the collection sites (a study inclusion criterion) should result in the inclusion of more robust older adults, a population in which screening for functional decline seems to make the most sense. The sensitivity and specificity data of the ICOPE screening tool will elucidate its potential for use in decision-making by health care teams.

Perspectives

The Project ICOPE Brazil aims to produce relevant results that will allow a better understanding of the role of IC and its domains in the aging process. Cooperation with international research centers that are centers of excellence in the field, such as the *Gérontopôle* of the University of Toulouse and its INSPIRE platform[39] for translational research on aging, as well as joint work with the Pan American Health Organization (PAHO) and WHO will allow us to contribute to the improvement of the ICOPE strategy. Furthermore, the initiative will strengthen scientific integration between researchers and research centers in Geriatrics and Gerontology in Brazil, creating opportunities for new partnerships and projects in favor of the Brazilian older population.

DECLARATIONS

Conflict of interest

RAL, RBGM, RELFR, KP and PJFVB declare that they are part of the GGA editorial board. The other authors declare that they have no conflict of interest.

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Authors' Contribution

EF: project administration, conceptualization, data curation, writing – first draft, writing – review & editing, funding acquisition, resources, supervision. RAL: project administration, conceptualization, writing – first draft, writing – review & editing, methodology, supervision. VPO: project administration, data curation, conceptualization, writing – first draft, writing – review & editing, methodology, supervision. RGBM: project administration,

formal analysis, conceptualization, data curation, writing – first draft, writing – review & editing, methodology, supervision. RELFR: project administration, formal analysis, conceptualization, writing – first draft, writing – review & editing, methodology, supervision. ALB: conceptualization, writing – review and editing. ACCM: conceptualization, writing – review and editing. AAOL: conceptualization, writing – review and editing. ACRL: conceptualization, writing – review and editing. AMN: conceptualization, writing – review and editing. AF: conceptualization, writing – review and editing. CSSC: conceptualization, writing – review and editing. CRCX: conceptualization, writing – review and editing. DSF: conceptualization, writing – review and editing. DCCA: conceptualization, writing – review and editing. FR: conceptualization, writing – review and editing. HR: conceptualization, writing – review and editing. JLFS: conceptualization, writing – review and editing. JSRF: conceptualization, writing – review and editing. JMAM: conceptualization, writing – review and editing. JAOC: conceptualization, writing – review and editing. JEP: conceptualization, writing – review and editing. JCM: conceptualization, writing – review and editing. JMP: conceptualization, writing – review and editing. JPS: conceptualization, writing – review and editing. KP: conceptualization, writing – review and editing. LSMP: conceptualization, writing – review and editing. LK: conceptualization, writing – review and editing. MSP: conceptualization, writing – review and editing. NMCA: conceptualization, writing – review and editing. NKCL: conceptualization, writing – review and editing. NCPA: conceptualization, writing – review and editing. OLSA: conceptualization, writing – review and editing. PJFVB: conceptualization, writing – review and editing. PSB: conceptualization, writing – review and editing. RCFJ: conceptualization, writing – review and editing. ROG: conceptualization, writing – review and editing. RSA: conceptualization, writing – review and editing. RRDC: conceptualization, writing – review and editing. RAPR: conceptualization, writing – review and editing. SLAS: conceptualization, writing – review and editing. TN: conceptualization, writing – review and editing. WCRF: conceptualization, writing – review and editing. WJF: conceptualization, writing – review and editing, supervision.

Ethical approval and informed consent

The Project was approved by the Research Ethics Committee of the Coordinating Center, under number CAAE 71672723.5.1001.0068.

Reporting guidelines

In accordance with Spirit 2013 Recommendations for clinical studies.

Data availability statement

The data that support the findings of this study will be available on request from the project steering committee, and members of research groups linked to the study and NAPENV members will have priority access.

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