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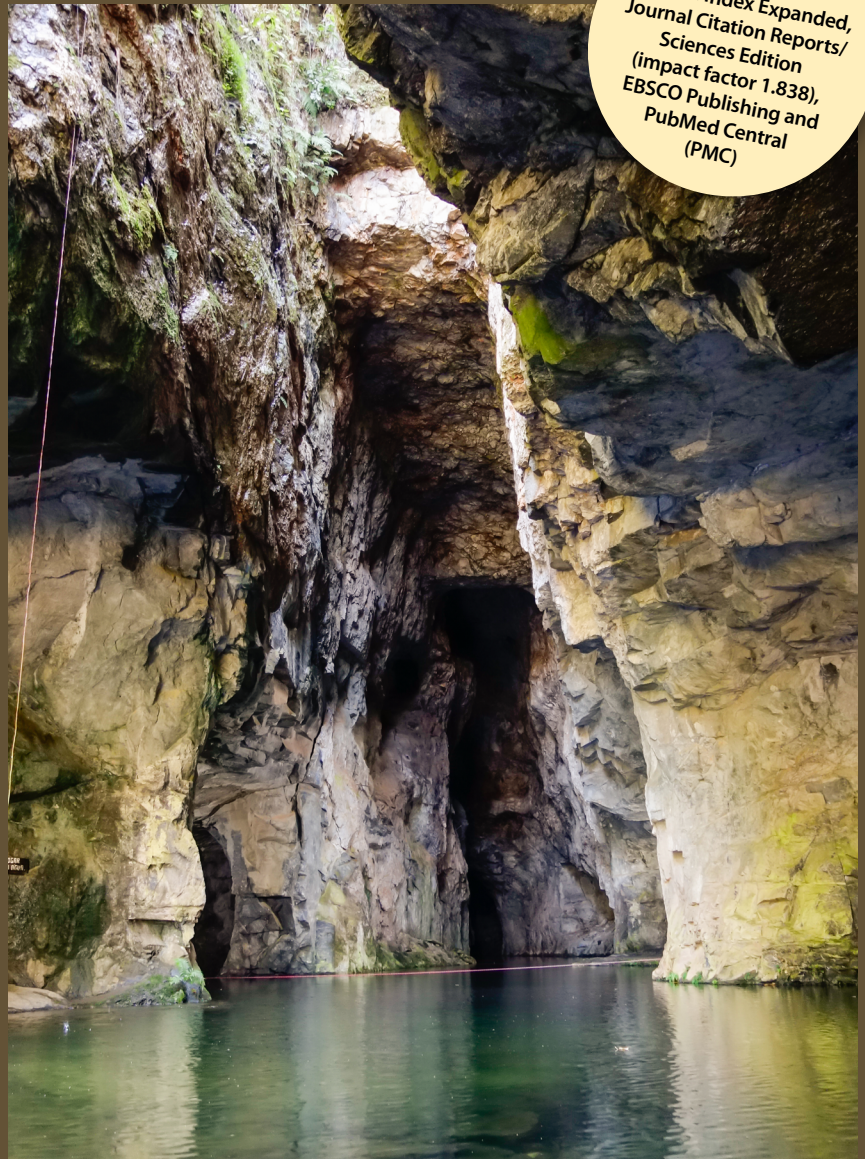
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- Exploring the effect of the structural model of active aging on the self-assessment of quality of life among older people: a cross-sectional and analytical study



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# Organ donation consent after death

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Most countries where organ transplants are performed, defined laws exist to address different legal aspects of these procedures, particularly concerning consent for organ donation after death.<sup>1</sup>

The authorization for organ removal for transplantation purposes raises controversial debates, considering its profound ethical and moral implications. It examines core societal values and reflects on fundamental rights, such as respect for human dignity, including the right to personality and autonomy of self-determination.

Every individual possesses the freedom to decide regarding certain actions concerning their body according to their own conscience. However, these decisions must be made within certain boundaries to uphold fundamental rights. In Brazil, an individual's autonomy over their own body is included in three articles of the Constitution. Article 1 emphasizes the principle of human dignity; Article 5 outlines the right to life and the right to freedom; and Article 199 addresses the ability to waive parts of the human body.<sup>2</sup>

## Classification of consent for organ donation after death

Consent for organ donation is typically classified into four categories: informed consent, mandatory choice, presumed consent, and compulsory removal. Informed consent, mandatory choice, and presumed consent are used in a vast majority of countries, although with variations.<sup>3,4</sup> However, compulsory removal, which involves the mandatory removal of viable organs for transplantation from deceased individuals, is not legally permissible in any country. Unlike other types of consent, compulsory removal does not involve obtaining formal consent as it renders consent unnecessary.

## Informed consent

This approach requires explicit consent from individuals during their lifetime and/or from their family members after death. It is widely regarded as the most ethical approach and upholds principles of autonomy, voluntarism, and altruism. Under this system, organs are not removed without explicit consent, and individuals have the opportunity to benefit others without any personal benefit.<sup>4,5</sup>

In countries following this system, such as those that prioritize the principle of autonomy, individuals make their decision and register it through a donor registry (opting-in). When individuals have not registered, the decision lies with their family members.<sup>5,6</sup> However, in countries such as Brazil, the family has the exclusive decision-making authority immediately after death.<sup>7</sup> Other countries with greater restrictions on donation, such as Japan and South Korea, require authorization from both the individual during their lifetime and from family members after death.<sup>8</sup>

From a bioethical standpoint, many scholars advocate that a donation should only be considered valid if it was the explicit wish of the deceased individual, rather than relying solely on the family's decision. However, others argue that offering the possibility of donation to the family can provide a way to relieve their suffering by adding a noble act to the tragedy of losing a loved one.

### Mandatory choice

Mandatory choice requires that all competent adults must decide in advance whether they wish to donate their organs for transplantation after death. The decision, labeled as either “donor” or “non-donor,” is recorded on an identity document or driver’s license.<sup>4,9</sup>

Advocates of this approach argue that it can boost consent, preserve altruism values, and eliminate the need for family approval. Moreover, this approach provides the possibility to increase the pool of potential donors, by mandating that all competent adults make a decision.<sup>4</sup>

However, the chief disadvantage lies in the requirement for all adults to make the definitive decision and officially record their status as either a “donor” or “non-donor.” Not all individuals may feel adequately prepared or informed to make such a significant decision, which is considered coercive and an invasion of privacy.<sup>9,10</sup>

For instance, in Sweden, the implementation of the National Register of Donors and Non-Donors in 1996, and the first 300,000 records revealed that 52% opted to register as donors, whereas 48% selected the non-donor status.<sup>11</sup>

Similar trends were observed in Brazil from January 1998 to October 2000 when mandatory choice was implemented, although without the support of medical entities and society. A consultation by the Brazilian Association of Organ Transplants performed in the identification institutes and traffic departments from January 1998 to December 1999 found that 51.2% of people were against the donation of their organs after death.<sup>1</sup>

These results suggest that forcing people to make a decision may have adverse effects, as the majority opt not to donate. Although opinion polls consistently indicate support for donation exceeding 70%, mandatory registration records indicate that only approximately 50% opt to be donors after death.<sup>9,10</sup> Therefore, the implementation of mandatory choice did not sufficiently increase the “donors” rate, where it was used, to justify the moral, social, and financial costs.<sup>8</sup> Education and public awareness are more important than a mandatory choice system.

### Presumed consent

In presumed consent, individuals are assumed donors unless during their lifetime, they do not express opposition to the donation of their organs after death. This system operates based on non-donor registration, implying that individuals must actively opt out if they do not wish to be donors.<sup>1,2,12</sup>

Under strong presumed consent, the lack of a record indicating the individual’s refusal to donate results in their organs being removed for transplantation, regardless of the family’s wishes.

Under weak presumed consent, donation is assumed unless there is a specific objection from the individual while alive and from family members immediately after their death.

Proponents argue that presumed consent prevents family members from having to make the decision about donation at an emotionally difficult time, when they are grieving. This implies an increase in the consent rate.<sup>13</sup> However, this has been questioned, as many families feel comforted by organ donation, stating that “*the death was not in vain.*” Presumed donation removes altruism and denies this possibility for the family.<sup>14</sup>

Presumed consent is deemed ethically acceptable under certain conditions:<sup>1</sup>

1. Universal acknowledgment of the law within the population
2. Easy registration of donation denial
3. Respect for the decision made

Some bioethics experts advocate that the absence of objection cannot be considered as consent. They view organ removal without explicit consent as a violation of the autonomy over one’s body and dignity.<sup>12,14,15</sup> Others consider this system ethical, as failure to register the objection (with adequate possibilities to do so) can be interpreted as implied consent.<sup>13,16,17</sup>

Despite only approximately 5% of the eligible population opting out of donation, opinion polls indicate that 20% to 30% are against donations.<sup>18</sup> The ethical point is that a person may not register their opposition for various reasons and cannot be implied to have consented.<sup>12,14,15</sup>

There is no conclusive evidence to suggest that presumed consent increases organ donation, as indicated by the examples of the two countries with the highest donation rates:

- In Spain, which has presumed consent in legislation, the family is consulted and must authorize the removal of the organs in all situations (presumed consent in law but informed in practice). Although presumed consent has been in place since 1979, the significant increase in donation rates began in 1989, when hospital transplant coordinators became involved in the search for donors.<sup>19</sup>
- In the United States, the decision regarding organ donation is typically made by the individual during their lifetime. If no decision was made, the family decides after death. Organ procurement organizations, which are highly professional and work with goals, are a common model there.<sup>20</sup>

In Latin America, several countries have adopted presumed consent over the last 15 years and have not increased donation rates, as it does not increase organ donation alone.<sup>14</sup>

### Compulsory removal of organs from deceased people

The compulsory removal of organs from deceased individuals without requiring permission, also known as **Organ Conscription** or **Routine Salvaging**,<sup>21,22,23</sup> is not formally used in any country.

Proponents of this approach argue for the principle of distributive justice, asserting that all individuals who die with usable organs should contribute, and all patients who need them can benefit, without depending on altruism or voluntarism. They advocate for the perspective that human organs should be considered a societal asset with society assuming possession of them after death.<sup>23,24</sup>

The chief argument against compulsory removal is that it infringes upon individual autonomy, and society's rights override individual rights, which makes it unacceptable.

In China, thousands of prisoners sentenced to death have had, or have, their organs removed after death for transplantation purpose. This situation is absolutely unacceptable, considering that a select few individuals (prisoners sentenced to death) have their organs compulsorily removed and a minimal portion of society receives these organs (those who pay for them).<sup>8</sup>

### Evolution of consent in Brazil

The first three transplant laws in Brazil, dating back to 1963,<sup>25</sup> 1968,<sup>26</sup> and 1992<sup>27</sup> used the concept of "informed consent," considering the patient's authorization while alive or of family members after death. Over the years, subtle changes were made. In all cases the family was consulted and it decided regarding the donation, as it was not possible to register individuals' preferences for organ donation after death.

The hemodialysis tragedy in Caruaru in 1996, which resulted in numerous deaths owing to poisoning, encouraged a group of chronic kidney disease patients to ask the National Congress for measures favorable to transplantation. Senator Darcy Ribeiro worked to approve a new transplant law that would increase donations. On February 4, 1997, without any discussions with society and medical entities, Law 9,434<sup>28</sup> was approved to come into effect from 1998, changing the form of consent from *informed* to *strong presumed*. However, this law did not take effect, as the non-donor registry was not created. One month later, in March 1997, Decree n° 2,170 was approved,<sup>29</sup> using mandatory choice, and required all adults to express their choice as "donor" or "non-donor," when obtaining or renewing their identity or driver documents, with strong opposition from society and medical entities.

There were two types of consent in practice: mandatory choice for those opting to be "non-donors" and informed consent for those opting to be "donors," decided by medical professionals.

As it was highly opposed by the population, the mandatory choice was repealed in October 2000.<sup>30</sup> Subsequently, in March 2001, a new law was enacted, returning to the informed consent system, with the exclusive decision of family members. The registers of "donor" or "non-donor" in the documents lost their value.<sup>7</sup>

Large sections of the media and population and some health professionals misunderstood that presumed consent was the rule between 1998 and 2000. An opinion poll conducted by Datafolha

in January 1998, and compared with that of April 1995, revealed that the intention to donate organs decreased from 75% to 63%. It may be because of the media affirming in 1997 that presumed consent would be in force from 1998 onward, which caused fear among the population. This indicates that despite not being used, this form of consent reduced the population's positive perception of donation.<sup>1</sup>

### CONCLUSION

Although a bill advocating for presumed consent is pending in the Chamber of Deputies in Brazil, maintaining informed consent appears to be more suitable. This entails establishing a voluntary donor registry, where individuals can register in the presence of witnesses. The registry should be legally valid and under the control by the Judiciary, allowing for revocation if desired. The State Transplant Center should only access this registry after the individual's death.<sup>1</sup>

The informed consent legislation could be articulated as follows: "Unless explicitly stated during the donor's lifetime in the donor registry, the removal of organs, tissues and parts of the human body will require the authorization from family members."

These modifications aim to uphold informed consent to its fullest extent, preserving society's trust in the transplant program. Although the foundation is robust, enhancements are necessary to maximize benefits for the maximum number of patients respecting while adhering to ethical principles.<sup>6</sup>

It is noteworthy that in Brazil, states with equal legislation and financing have achieved donor rate above 40 per million people (pmp), among the highest in the world. Conversely, some states have a rate below 10 pmp.<sup>31</sup> This variance suggests that the decisive factor in the increase in donation and transplantation is not the form of consent adopted. Other important challenges, such as failure to identify potential donors, lack of logistics for evaluating potential donors and removing organs, and the limited use of removed organs, cause or increase the imbalance between demand and the number of transplants performed. Therefore, effective planning, organizational improvements, logistical enhancements, and educational initiatives can be more effective than changing the form of consent. Such measures can enhance efficiency, avoid public distrust, and reduce conflicts with family members.<sup>6</sup>

There is no universal method of consent, and the success of any transplant program cannot be attributed to legislation alone. If that were the case, all countries would follow the same. Moreover, effective laws should conform to what is accepted by society and not attempt to change society through coercion. The relation between the form of consent and donation rate is not straightforward, suggesting that the laws governing organ donation are more of a legal and philosophical challenge than a crucial factor in obtaining organs.<sup>1</sup>

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# Global research trends related to coronavirus disease 2019 and the aged: a bibliometric analysis

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## ABSTRACT

**BACKGROUND:** A bibliometric analysis covering only the production of original studies or considering world production until 2022 has yet to be conducted. The creation and advancement of vaccines have also influenced research priorities, demonstrating the need for a new approach to this subject.

**OBJECTIVES:** To analyze worldwide scientific production related to coronavirus disease 2019 (COVID-19) and the aged and to describe what has already been produced.

**DESIGN AND SETTING:** Bibliometric analysis with a quantitative approach.

**METHOD:** The search terms "COVID-19," "SARS-CoV-2," "Aged," and "Elderly" were used to retrieve articles from the Web of Science database. A total of 684 articles were included in the analysis. Data were imported into RStudio Desktop Software and linked to R Software. The Bibliometrix R package and VOSviewer software were used for analysis.

**RESULTS:** Most articles were published in 2020. These were produced by 4,937 authors and published in 379 journals. The keyword most used by the authors was "COVID-19." Publications from 77 countries were obtained. China had the highest article production ranking, and Spain collaborated the most. The articles addressed the implications of the pandemic on the aged, the relationship between vaccination in the aged, and the implications for the disease itself.

**CONCLUSION:** Further research should be conducted, mainly concerning vaccines and vaccination of the aged, owing to the need for and importance of immunization in this risk group, including assessing the long-term effects of vaccines.

## INTRODUCTION

On March 11, 2022, with the alarming spread and severity of coronavirus disease 2019 (COVID-19), the World Health Organization (WHO) assessed it as a pandemic. The WHO Director-General emphasized the magnitude of the new disease and the need to adopt governmental and societal approaches to create comprehensive strategies to prevent infections, save lives, and minimize the impact.<sup>1</sup>

With the continuation of the pandemic, based on WHO data from December 12, 2022, COVID-19 caused 645,084,824 confirmed cases worldwide, resulting in 6,633,118 deaths.<sup>2</sup> This extension occurred due to the emergence of variants of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) virus, such as the Omicron, Alpha, Beta, Gamma, and Delta variants. However, despite creating vaccines to prevent COVID-19, other forms of prevention are still necessary, such as using masks and hand hygiene, especially for risk groups such as older adults.<sup>4,5</sup>

Thus, since the beginning of the pandemic, the Centers for Disease Control and Prevention have stated that the aged are at a greater risk of developing hospital complications, extended hospital stays, and high mortality rates.<sup>6</sup>

Several factors require attention regarding the aged, as many belong to nursing homes or long-term institutions. For example, there is a need for strategies to prevent or impede virus transmission in these places.<sup>7</sup> In addition to the occurrence of chronic diseases in this group, favoring hospitalization, health problems related to mental health can also occur, which has been affected by isolation, family distancing, or concerns about COVID-19.<sup>8,9</sup>

Parallel to this situation, through a bibliometric analysis of scientific literature, it is possible to identify what is being addressed in existing publications in a specific area or topic through a

quantitative analysis of articles in each field so that their results can support the realization of future studies.<sup>10</sup>

A bibliometric analysis covering only the production of original studies or contemplating world production until 2022 is yet to be conducted.<sup>11,12</sup> Additionally, the creation and advancement of vaccines have also influenced research priorities, demonstrating the need for a new approach to the subject.<sup>5</sup>

## OBJECTIVE

This study analyzed worldwide scientific production related to COVID-19 and the aged and described what has already been produced.

## METHODS

### Research design

This bibliometric analysis used a quantitative approach. Bibliometrics is a discipline that seeks to measure scientific and social activity and predict trends through literature analysis conducted using the following steps: research design, a compilation of bibliometric data, data analysis, data visualization, and interpretation of results.<sup>13,14</sup>

### Data-gathering period

A search for scientific articles was conducted using an advanced query in the Web of Science™ (WoS) database on October 31, 2022. WoS is among the most reliable and comprehensive databases for bibliometric studies, allowing the tracking of ideas across disciplines and a time of nearly 1.9 billion references cited in more than 171 million records.<sup>15</sup>

### Selection criteria

The included studies met the following criteria: original research on COVID-19 and the aged, without language restrictions, and published until October 31, 2022. As exclusion criteria: articles that deviated from the research scope, review articles, opinion articles, reflection articles, editorials, and case studies.

### Data-gathering

Before starting the research, the descriptors “COVID-19,” “SARS-CoV-2,” and “Aged” were obtained in the Medical Subject Headings (MeSH), including the alternative descriptor “Elderly” often used to refer to the aged in the scientific literature. To ensure precise and targeted outcomes while minimizing false positives, the present research focused exclusively on the articles using the following search strategy: “TI=((“COVID-19” OR “SARS-CoV-2”) AND (“Aged” OR “Elderly”)).”

The search yielded 1,466 articles; 968 had early or open access after filtering the originals. To ensure the inclusion of articles on

the target topic and reduce false positives, the researchers read all titles and excluded those unrelated to COVID-19 and the aged. The remaining 684 contained all available information downloaded in text file format for analysis.

### Data processing and analysis

The recovered data was imported into RStudio Desktop Software, version:2022.07.1 (© Posit Software, Massachusetts, United States, 2022), linked to R Software, version:4.2.1 (The R Foundation, Vienna, Austria, 2022). For analysis, the following were used: the Bibliometrix R package (© K-Synth Srl, Academic Spin-Off of the University of Naples Federico II, Naples, Italy, 2022), its graphical web interface, Biblioshiny, and VOSviewer Software, version:1.6.18 (© Centre for Science and Technology Studies, Leiden University, Leiden, The Netherlands, 2022).<sup>16,17</sup>

In summary, the analysis allowed data visualization for later interpretation. The results encompassed various aspects, including the number of articles published annually, scientists’ productivity (Lotka’s Law of 1926),<sup>18</sup> the dispersion of scientific knowledge through journals (Bradford Law of 1934),<sup>18</sup> the topics addressed, the most cited manuscripts, the origin of the articles, and collaborations among researchers based on their countries of origin.

## RESULTS

The sample comprised 684 articles, of which 17.5% (n = 120) were published in 2020, 43.9% (n = 300) in 2021, and 38.6% (n = 264) in 2022. Articles were produced by 4 937 different authors, with 93.5% of the authors present in only one article (**Figure 1A**). Moreover, the articles were published in 379 scientific journals, emphasizing 29 articles on the Bradford nucleus, comprising 226 articles (**Figure 1B**).

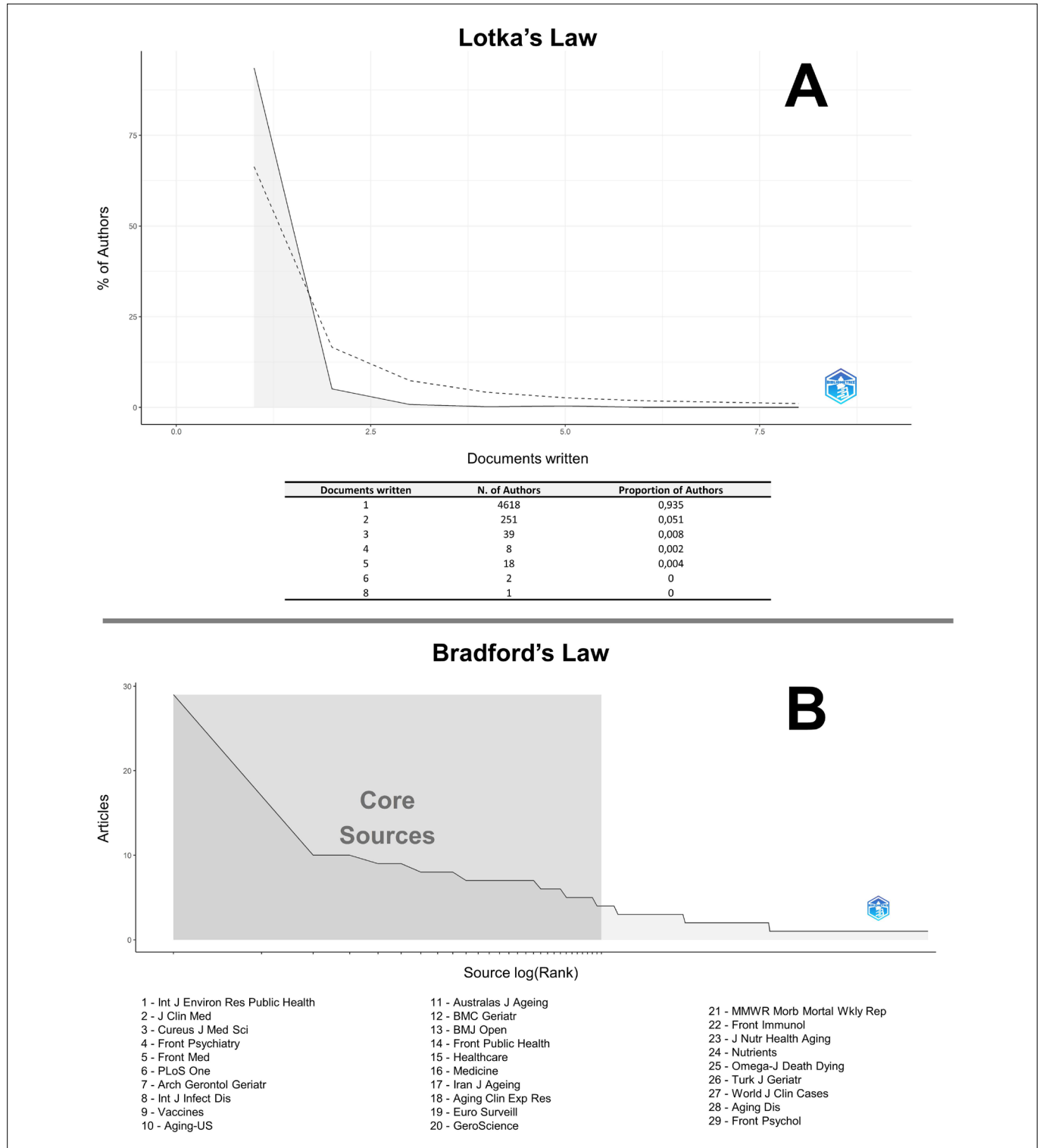
**Figure 2** shows the 49 keywords most frequently used by the authors (frequency ≥ 6). The authors used 3,212 keywords with 1,571 words. The most frequent keywords were: “COVID-19” (n = 439), “Elderly” (n = 160), and “SARS-CoV-2” (n = 86). Other words that stood out were: “mortality,” “older adults,” “pandemic,” “depression,” “coronavirus,” “mental health,” “aged,” “frailty,” and “anxiety.”

Considering the co-occurrence of terms in frequency ≥ 10 and relating the title to the abstract, 397 terms were found from 14,170 expressions. **Figure 3** shows 60% (n = 238) of the most relevant terms. The VOSviewer Software divides the terms into three main clusters, identified by the colors red, blue, and green. Noteworthy, the size of the item’s circle or node is proportional to the number of times a given item appears.

The evaluated articles had an average citation count of 7.7%, using 18 434 references. In ranking the most cited articles (**Table 1**), the number of citations ranged from 223 to 53. Such articles have been published in 17 journals, 13 in 2020 and five in 2021.

Authors from 77 countries participated in the articles, as recognized by the Bibliometrix. **Figure 4A** shows the countries that produced the most, considering the co-occurrence of these countries in the address list of each author, and that, consequently, may be present

more than once. China occupied the top position of production by being present 373 times, followed by Italy with 329, the United States with 262, Spain with 246, and France with 204 registrations. Countries such as Germany, Australia, Brazil, and Japan also stand out.



**Figure 1.** (A) Productivity of scientists according to Lotka's Law. (B) Dispersion of scientific knowledge according to Bradford's Law.



**Table 1.** Ranking of the most cited articles on COVID-19 and the aged

Rank	Authors (year), Journal	Title	Total citations
1	Wu et al. (2021), Lancet Infect Dis <sup>19</sup>	Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy adults aged 60 years and older: a randomised, double-blind, placebo-controlled, phase 1/2 clinical trial	223
2	Liu et al. (2020), Complement Ther Clin Pract <sup>20</sup>	Respiratory rehabilitation in elderly patients with COVID-19: A randomized controlled study	202
3	Liu et al. (2020), Eur J Clin Nutr <sup>21</sup>	Prevalence of malnutrition and analysis of related factors in elderly patients with COVID-19 in Wuhan, China	149
4	Tenforde et al. (2021), MMWR Morb Mortal Wkly Rep <sup>22</sup>	Effectiveness of Pfizer-BioNTech and Moderna vaccines against COVID-19 among hospitalized adults aged ≥65 years – United States, January-March 2021	132
5	Ioannidis et al. (2020), Environ Res <sup>23</sup>	Population-level COVID-19 mortality risk for non-elderly individuals overall and for non-elderly individuals without underlying diseases in pandemic epicenters	124
6	Daoust (2020), PLoS One <sup>24</sup>	Elderly people and responses to COVID-19 in 27 Countries	116
7	Covino et al. (2020), Geriatr Gerontol Int <sup>25</sup>	Clinical characteristics and prognostic factors in COVID-19 patients aged ≥80 years	86
8	Gorrochategi et al. (2020), Am J Geriatr Psychiatry <sup>26</sup>	Stress, anxiety, and depression in people aged over 60 in the COVID-19 outbreak in a sample collected in Northern Spain	68
9	Fulzele et al. (2020), Aging Dis <sup>27</sup>	COVID-19 virulence in aged patients might be impacted by the host cellular microRNAs abundance/profile	66
9	Gou et al. (2020), Gerontology <sup>28</sup>	Clinical characteristics of elderly patients with COVID-19 in Hunan Province, China: a multicenter, retrospective Study	66
10	Brandén et al. (2020), Lancet Healthy Longev <sup>29</sup>	Residential context and COVID-19 mortality among adults aged 70 years and older in Stockholm: a population-based, observational study using individual-level data	62
11	Poloni et al. (2020), EClinicalMedicine <sup>30</sup>	Prevalence and prognostic value of Delirium as the initial presentation of COVID-19 in the elderly with dementia: an Italian retrospective study	61
11	Moline et al. (2021), MMWR Morb Mortal Wkly Rep <sup>31</sup>	Effectiveness of COVID-19 vaccines in preventing hospitalization among adults aged ≥65 years – COVID-NET, 13 States, February-April 2021	61
12	Van Jaarsveld (2020), Front Psychiatry <sup>32</sup>	The effects of COVID-19 among the elderly population: a case for closing the digital divide	59
13	Abouhashem et al. (2020), Antioxid Redox Signal <sup>33</sup>	Is low alveolar type II cell SOD3 in the lungs of elderly linked to the observed severity of COVID-19?	58
14	Jang and Rhee (2020), Int J Infect Dis <sup>34</sup>	Three cases of treatment with nafamostat in elderly patients with COVID-19 pneumonia who need oxygen therapy	54
15	Jung et al. (2021), Crit Care <sup>35</sup>	The impact of frailty on survival in elderly intensive care patients with COVID-19: the COVIP study	53
15	Gallè et al. (2021), Vaccines (Brasel) <sup>36</sup>	Acceptance of COVID-19 vaccination in the elderly: a cross-sectional study in Southern Italy	53

**Figure 4 B** shows the collaborations, with Spain standing out for collaborating with 53 countries, France with 49 countries, and Italy with 55 countries. United Kingdom, Germany, the United States, Israel, and Poland collaborated with 51, 50, 56, 41, and 39 countries, respectively.

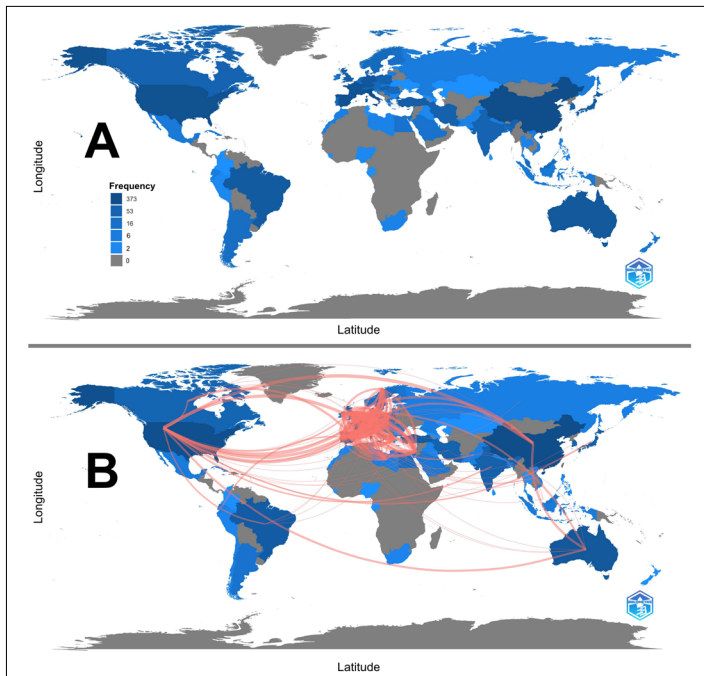
## DISCUSSION

This bibliometric analysis of research related to COVID-19 and the aged covered the original production from 2020 to October 2022, based on data retrieved from WoS. Regarding production, articles increased by approximately 26.4% from 2020 to 2021 and decreased by approximately 5.4% from 2021 to 2022. The increase in publications from 2020 to 2021 may have occurred because of the creation of vaccines, which began to be approved

on January 5, 2021, and led to extensive scientific production related to the subject.<sup>1,4</sup>

Most authors have published only one article on this topic. Therefore, according to Lotka's law, this area must be consolidated. This law estimates that approximately 60% of authors will produce a single document, and a third of the literature will be produced by a tenth of the most productive authors.<sup>18</sup>

Moreover, the percentage of authors who produced only one article may be even more significant than what was identified. Notably, a high number of authors was noted in some articles, and there was a lack of standardization of citations of authors' names, including the similarity of names. Such findings make it impossible to identify and make inferences about the most productive ones.



**Figure 4.** (A) Co-occurrence of countries in the address list of each author. Color targeting includes gray (no posts) and blue (with posts). (B) Collaboration between producing countries. The red lines represent collaborations, with the thickness indicating the number of co-publications.

The “International Journal of Environmental Research and Public Health” (2021, Journal Citation Reports™:4,614) published the most significant number of articles on the subject (29 in total), which may be correlated with the fact that the journal is multidisciplinary, comprehensive, and composed of 20 main sections. The second journal with the most publications was the “Journal of Clinical Medicine” (2021, Journal Citation Reports™:4,964), with 17 publications; in its scope, it is defined as a comprehensive journal that accepts clinical and pre-clinical research, as well as also encourages the publication of negative results, so that other researchers do not have to repeat the experiments that other people have already performed.

The third place was occupied by two other journals, one related to psychiatry and the other related to general health, each publishing ten articles. Thus, the authors preferred to publish their studies in a broad scope because, of the scientific journals that comprised the Bradford nucleus, only 10 had a specific scope for geriatrics, gerontology, or aging.

Keywords can summarize the focus of articles and determine research trends based on the analysis of these words.<sup>37</sup> In the current research, the authors’ keywords mainly addressed the name of the disease and its variations, the name of the virus, problems related to the pandemic and the disease, factors that make the aged more susceptible, and words related to vaccines or vaccination.

Several names were used to refer to the aged, such as “Elderly,” “Older adults,” “Aged,” “Aging,” “Elderly patients,” “Elderly population,” “Older people,” “Elderly people,” “Age,” “Geriatrics.” Noteworthy, such a diversity of names made it difficult to initially filter the articles, thus recommending the standardization of “Aged,” the primary term according to MeSH, or its alternative term, “Elderly.”

According to the terms of the titles and abstracts of the articles, three topics were addressed: 1 (red) implications of the pandemic on the aged, which triggered psychological problems such as depression and anxiety; 2 (blue) the relation of vaccine or vaccination in the aged; and 3 (green) implications of the disease itself, causing hospitalization to death, mainly in the studied population.

Regarding the most-cited articles, despite being recent, vaccines have already received many citations. Its effectiveness was addressed in three of the most cited articles, and the fourth addressed vaccination acceptance.

The most-cited article was a randomized, double-anonymized, placebo-controlled clinical trial. The main result was vaccine tolerance in healthy adults 60 years, with live SARS-CoV-2 neutralizing antibody responses not being reduced in this population. It is noteworthy that this is the first report of an inactivated SARS-CoV-2 vaccine (CoronaVac) tested in the aged (aged  $\geq 60$  years).<sup>19</sup>

The second most cited article stated that six-week respiratory rehabilitation could improve respiratory function, quality of life, and anxiety in aged patients with COVID-19, with a slight significant improvement in depression in this public.<sup>20</sup> The third study identified a high prevalence of malnutrition in aged patients with COVID-19 and concluded that nutritional support should be reinforced during treatment, especially for those with diabetes mellitus, low calf circumference, or low albumin.<sup>21</sup>

Other most-cited articles addressed the clinical characteristics and factors predisposing older adults to the worsening of COVID-19 and the occurrence of psychological symptoms resulting from the pandemic or the disease itself.

Based on the researchers’ origins, China ranked first in article production. This finding is due to the onset of COVID-19 transmission in this location, resulting in diverse types of research being carried out to elucidate the disease.<sup>38,39</sup> Notably, China had fewer collaborations than other countries, such as Spain, demonstrating that most of its articles covered only national territory.

Another important finding relates to the nine countries that produced the most, comprising the list of the Human Development Report and classified as countries with very high or high human development. Specifically, they are countries that invest in essential universal services, such as health and education, which leads to the production of knowledge, whether by health agencies or researchers at universities.<sup>40</sup>

The limitations were how the bibliometric survey was conducted, including using a single database, and the rigor of the search adopted by contemplating only the titles of the articles. Another limitation was the non-standardization of authors' names, which, owing to the similarity of names, may have influenced Lotka's law.

However, the database used is a selective, structured, and balanced database with complete citation links and improved meta-data that support a wide range of information purposes, allowing the development of scientometrics.<sup>41</sup> Regarding the search by title, studies have already described that it allows the recovery and specificity of the articles, generating minimal losses compared to the search that includes all fields.<sup>42,43</sup>

## CONCLUSION

When observing the results of the present bibliometric analysis on scientific production related to COVID-19 and the aged, it is noted that the production of new articles increased from 2020 to 2021 but has already started to decrease. Thus, the main topics addressed in the articles were the implications of the pandemic on the aged, which triggered psychological problems such as depression and anxiety; the relationship between the vaccine or vaccination in the aged; and the implications of the disease itself, which can lead to hospitalization or even death, especially in the studied population. The most-cited article, with 223 citations, addressed one of the topics already described: vaccine effectiveness (CoronaVac) in the older adult population.

Thus, synthesizing the research patterns related to COVID-19 and the international population can provide valuable insights into future research areas and perspectives. Thus, considering the current context of the COVID-19 pandemic, it is suggested that further research be conducted, mainly related to vaccines and vaccination of the aged, owing to the need for and importance of immunization in this risk group as well as the need to assess the long-term effects of vaccines.

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# Validation and calibration of the Food Consumption Frequency Questionnaire for pregnant women

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## ABSTRACT

**BACKGROUND:** Few food frequency questionnaires (FFQ) have been validated for pregnant women, particularly those in small- and medium-sized cities in different regions of Brazil.

**OBJECTIVES:** To validate and calibrate a semiquantitative FFQ for pregnant women.

**DESIGN AND SETTING:** The study was validated with a sample of 50 pregnant women ( $\geq 18$  years) enrolled in Brazilian prenatal services.

**METHODS:** An FFQ and a 24-hour recall were used to evaluate dietary intake. Dietary variables were tested for normality and log-converted when asymmetrical. Pearson's Correlation Coefficient was used to validate the questionnaire. Linear regression was applied to extract calibration factors. All variables underlying the consumption analysis were adjusted for energy.

**RESULTS:** The mean age of the pregnant women was 26 years  $\pm$  6.2 years; 58% were in their first trimester, and 30% were identified as overweight/obese. The Pearson correlation analysis results indicated that the FFQ overestimated energy and nutrient intake, whose coefficients ranged from -0.15 (monounsaturated fat) to 0.50 (carbohydrate). Adjusting for energy reduced the mean values of intake coefficients, which now ranged from -0.33 (sodium) to 0.96 (folate). The calibration analysis results indicated variation in the coefficients from -0.23 (sodium) to 1.00 (folate). Calibration produced satisfactory coefficients for the FFQ compared with the reference standard for energy, macronutrients, monounsaturated fat, cholesterol, vitamins B12/C, folate, sodium, iron, and calcium.

**CONCLUSIONS:** After validating and calibrating tests, we observed that the FFQ was adequately accurate for assessing the food consumption of the pregnant women in this study.

## INTRODUCTION

Currently, researchers in nutritional epidemiology have made efforts to identify evaluation methods and analysis techniques to obtain precise and accurate food consumption data during different life stages, considering cultural conditions, the complexity of factors associated with human food, and peculiarities of regional and local contexts. This task requires the development of methodological instruments for qualitative-quantitative assessments to understand the role of food and nutrients in the occurrence of health- and disease-related events.<sup>1</sup>

Instruments available to assess food consumption are likely to have measurement errors, producing biased dietary intake estimates.<sup>2-4</sup> Among these instruments, the 24-hour Recall Questionnaire (24hR) and the Food Frequency Questionnaire (FFQ) are widely employed in population studies in their quantitative or semi-quantitative versions. While the 24hR characterizes the food and beverage consumption in the 24 hours before the interview,<sup>2-4</sup> the FFQ assesses an individual's customary diet in a specific period. One advantage of these methods is their low cost, which allows the assessment of a more significant number of individuals, thereby enabling effective association of dietary patterns with outcomes of interest. Thus, these instruments have been used to estimate risk trends for the consumption of nutrients per degree of exposure to different intake levels.<sup>1,5-7</sup>

The FFQ, specifically, is widely used to evaluate the dietary habits and consumption patterns of people from different sociocultural and economic contexts.<sup>8,9</sup> In the absence of a gold standard method to achieve these goals, existing methods should be adapted and validated for specific populations to understand food consumption patterns and reliably minimize associated errors. This validation involves comparing the nutrient intake estimates obtained by the test method with those of a standard, using different statistical analyses.<sup>2,10</sup> Furthermore, calibrating the instrument

is essential to reduce or eliminate bias in the underestimation or overestimation of nutrient intake estimates and obtain new intake parameters closer to the benchmark.<sup>2</sup>

However, the validated FFQs available for specific Brazilian population groups are mainly aimed at adults living in large urban centers.<sup>3,10,11</sup> Few instruments have been validated for pregnant women, particularly those in small- and medium-sized cities in different regions of the country.<sup>12</sup>

A precise and accurate assessment of food consumption is relevant, specifically during pregnancy, because inadequate nutrient intake during pregnancy is a risk factor in the development of morbimortality and occurrence of chronic diseases in mothers and children in the long term.<sup>13</sup>

## OBJECTIVE

This study aimed to validate and calibrate a semi-quantitative FFQ, for pregnant women receiving primary care in a municipality in Brazil's Northeast region.

## METHODS

### Study design and sample

This validation and calibration study of a food frequency method is nested in the research project “*Pregestational and gestational risk factors for postpartum maternal weight retention in a municipality in the Recôncavo Baiano*” undertaken by researchers from the Federal University of Recôncavo da Bahia.

This study adopted 24hR as the reference standard,<sup>3-5</sup> and the FFQ method was validated. A convenience sample of 53 pregnant women enrolled in prenatal care in 2012 in a Northeast municipality was selected. This sample size complies with the recommendation of 50–100 participants.<sup>6,14,15</sup> Three pregnant women were excluded because they had outlier values for total energy (above 6,000 kcal) in the 24hR, which could increase the possibility of a biased interpretation of other nutrients' intake values.<sup>16</sup>

Data were collected between February and December 2012 by researchers adequately trained in nutrition in the municipal health units during the first prenatal care visit. We gathered information on demographics (maternal age), socioeconomic status (schooling, income, marital status, and employment status), health (pathological history and clinical complications), reproductive history (gestational age, parity, and interpartum interval), and anthropometric characteristics, including lifestyle habits (alcohol consumption, smoking habits, and physical activity).

### Food-frequency questionnaire development and analysis

The customary food consumption pattern of these pregnant women was captured using the FFQ, including information on the time and place of meals, type of preparation, and amount

of food consumed. This instrument comprised a list of seventy-three foods, selected based on information from a pilot study's 24hR. Evidence indicates that the inclusion of 60–130 food items in an FFQ is sufficient to characterize an individual's usual diet.<sup>17</sup>

A minimum consumption frequency of 15% for each food item identified in the pilot study was adopted as an inclusion criterion for creating the FFQ.<sup>18</sup> Thus, 19 items were excluded from the frequency list: whole-grain rice, pasta, rye bread, polenta, chicory, zucchini, green beans, hamburgers, shrimp, pizza, mayonnaise, ice cream, chocolate bars, French fries, pears, grapes, canned fish, pudding, and wine. The following were included in the list: cassava, eggplant, oats, couscous, plantain, tangerine, guava, ready-made sauce, concentrated broth, ready-to-eat soup, jerked beef, sun-dried meat, and bologna.

Regardless of the criterion previously established, some regional foods representative of the culture and eating habits, whose consumption is related to seasonal variation, were also included in the list: *beiju* (tapioca pancake), *andu* (type of bean), and breadfruit. Sixteen items were thus included in the final list.

The qualitative-quantitative information on the frequency of food consumption, retrospective to the month before the interview,<sup>19</sup> was stratified into the following categories: more than three times a day, two to three times a day, once a day, five to six times a week, two to four times a week, once a week, and one to three times a month.

Images of the portions and utensils used were captured in a photographic record album and used to obtain the standard serving size for each food.<sup>20</sup> This strategy was used to reduce errors in estimating the actual amount of food consumed by the respondent.

All reported frequencies were converted into daily frequencies to analyze the consumption data. For this conversion, we considered the number of times the food was consumed per day and multiplied by the value “1” whenever the food was consumed daily. The mean reported interval was estimated and then divided by seven (weekly consumption) and 30 (monthly consumption) to calculate the daily frequency from weekly or monthly consumption. Thus, all consumption was expressed as mean daily consumption.

The food consumption measurement unit in grams per day was standardized based on the food composition table<sup>21</sup> and the list of replacement food groups in the food pyramid for the Brazilian population.<sup>7</sup> Excel 2010 (Microsoft, Washington, United States) and the Brazilian Food Composition Table<sup>21</sup> were used to estimate the daily values of energy and nutrients in the diet according to the FFQ record. We used Virtual Nutri Plus software (University of São Paulo-USP, São Paulo, Brazil) to evaluate the data obtained from the 24hR.

### Statistical analysis

Statistical analyses were performed considering the following steps:

- (i) Test of normality of dietary variables: Dietary variables (macronutrients and micronutrients) were tested for normality (Shapiro-Wilk test) to assess compliance with the method's assumptions. To improve their normality, the variables were log-converted when the normality assumption was not met.
- (ii) Comparison between the mean differences in caloric and nutrient availability measured by the two instruments (FFQ and 24hR): We employed the paired t-test for these analyses.
- (iii) Comparison between the correlation coefficients of the crude values of energy, macronutrients, and micronutrients estimated by the FFQ and 24hR: We used Pearson's correlation coefficient to observe the agreement between the values estimated by these methods.
- (iv) Adjustment for energy: The estimated values of the dietary variables were adjusted for energy, to minimize the effect of total caloric intake on the number of nutrients in the diet. For this, we employed residual analysis of linear regression.<sup>1,3</sup>
- (v) Validation analysis: Validation analysis was performed using Pearson's correlation test to compare the correlation coefficients of nutrients, estimated by the FFQ and 24hR and adjusted in the previous analysis stage.
- (vi) Calibration analysis: Finally, a calibration analysis was performed to minimize and remove errors in the instrument under test (FFQ) by applying a linear regression technique between the adjusted and validated nutrient values of the FFQ and the adjusted nutrients of the 24hR.
- (vii) Comparison between energy and nutrient estimates from the calibrated FFQ and energy-adjusted 24hR estimates, using Pearson's correlation coefficient: This analysis aimed to verify the agreement between the final estimates obtained by the test method and reference methods.

We employed SPSS version 17.0 (Chicago, United States) for statistical analyses. The statistical significance level of  $P \leq 0.05$  was chosen for the acceptance of the test's significance.

### Ethical approval

This study was approved by the Ethics Committee for Research Involving Human Beings of the Faculdade Adventista da Bahia (No. 4369.0.000.070-10) on September 14, 2010. All study procedures abided by the Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. Informed consent was obtained for experimentation with human participants and their privacy rights were respected.

## RESULTS

### Description of participants

The maternal sociodemographic, obstetric, and anthropometric characteristics are presented in **Table 1**. Most pregnant women

**Table 1.** Sociodemographic, obstetric, and anthropometric characterization of pregnant women. Santo Antônio Jesus (Bahia), Brazil, 2012

Variables	n (50)	%
<b>Maternal age</b>		
< 35 years	45	90
≥ 35 years	5	10
<b>Maternal schooling</b>		
< High School	48	96
≥ High School	2	4
<b>Income</b>		
≤ 1 minimum wage	16	32.0
> 1 minimum wage	34	68.0
<b>Religion</b>		
Catholic	26	51
Protestant	19	38.8
No religion	5	10.2
<b>Marital status</b>		
Single	9	18
Married/living with a partner	41	82
<b>Ethnicity/skin color</b>		
White	4	8
Brown	20	40
Black	24	48
Indigenous	2	4
<b>Tobacco use</b>		
Smoker/former smoker	30	60
Non-smoker	20	40
<b>Alcohol use</b>		
Yes	17	34
No	33	66
<b>Gestational trimester</b>		
First	29	58
Second	11	22
Third	10	20
<b>Prenatal care visits</b>		
< 7 visits	46	91.8
≥ 7 visits	4	8.2
<b>Number of pregnancies</b>		
Primiparous	32	64
Multiparous	18	36
<b>Gestational complications</b>		
Yes	30	60
No	20	40
<b>Maternal height</b>		
≤ 150 cm	4	8.3
> 150 cm	46	91.7
<b>Pregestational anthropometric status</b>		
Underweight	10	20
Eutrophy	25	50
Overweight	12	24
Obesity	3	6
<b>Gestational anthropometric status</b>		
Underweight	10	20
Eutrophy	19	38
Overweight	13	26
Obesity	8	16

(90%) were aged less than 35 years (mean = 26 years, standard deviation [SD] = 6.2 years). The level of schooling up to high school was 96.0%, and income  $\leq 1$  MW was reported by 32.0% of households. The Catholic religion was adopted by 50% of pregnant women; marriage or common-law marriage was reported by 82%; self-declared ethnicity/skin color was Black for 48%; smoking was reported by 60%; and alcohol use was reported by 34%.

Approximately 58% of the participants were included in the study in the first gestational trimester, and primiparity was 64%. We found that 91.8% of pregnant women made fewer than seven prenatal care visits, and 60% reported pregnancy complications.

The mean height was 160 cm (SD = 0.9 cm), and a height of  $> 150$  cm was observed in 91.7% of cases. The prevalence of pregestational eutrophy was 55.1% (24.3 kg/m<sup>2</sup>, SD = 14.2 kg/

m<sup>2</sup>) and overweight (overweight/obesity) was 40% (27.7 kg/m<sup>2</sup>, SD = 15.3 kg/m<sup>2</sup>). A mean weight gain of 5 kg was recorded (SD = 6.4 kg) during the gestational period, and 30% of the pregnant women were overweight/obese.

The descriptive analysis results indicated that carbohydrates, total fat, saturated fat, polyunsaturated fat, fiber, folate, vitamin B6, vitamin E, potassium, sodium, magnesium, and zinc from the 24hR did not show a normal distribution and were thus log-transformed. Regarding the FFQ, most nutrients were log-transformed, except for vitamin D and monounsaturated fat, which showed a normal distribution.

**Table 2** presents the mean values of calories and nutrients from the FFQ and 24hR. The mean difference between the 24hR and FFQ values for energy and most nutrients was statistically

**Table 2.** Mean, standard deviation, and difference in means of energy and nutrient intake adjusted for energy from the food frequency questionnaire and 24-hour recall. Santo Antônio de Jesus (Bahia), Brazil, 2012

Nutrient	FFQ		24hR		Difference of means	P value
	Mean	SD	Mean	SD		
Carbohydrate (g)	449.96	165.25	320.13	128.19	6.422	0.000**
Protein (g)	99.59	49.75	78.20	41.50	2.506	0.016*
Fat (g)	85.52	48.42	62.38	30.97	3.004	0.004**
Fibers (g)	34.08	16.23	16.31	9.30	7.328	0.000**
Polyunsaturated fat (g)	15.46	9.52	8.20	9.32	3.952	0.000**
Monounsaturated fat (g)	29.84	20.76	10.82	5.41	6.055	0.000**
Saturated fat (g)	27.89	16.30	18.45	9.92	3.628	0.001**
Cholesterol (mg)	360.70	236.84	289.70	595.55	0.799	0.428
Vitamin A (RE)	4017.09	3302.61	3653.33	13514.42	0.242	0.810
Vitamin D (mcg)	3.58	2.37	11.76	35.76	-1.601	0.116
Vitamin C (mg)	529.19	362.68	130.54	126.39	7.831	0.000**
Vitamin B3 (mg)	31.59	15.97	20.94	10.32	4.167	0.000**
Vitamin B1 (mg)	2.88	1.12	3.06	8.42	-0.151	0.880
Folate (mcg)	494.14	226.41	175.13	332.85	5.786	0.000**
Vitamin B2 (mg)	3.20	1.62	4.31	14.15	-0.559	0.579
Pantothenic acid (mg)	8.23	3.54	4.78	10.62	2.331	0.024*
Vitamin B6 (mg)	3.04	1.56	1.57	2.93	3.786	0.000**
Vitamin E (mg)	26.70	16.55	10.11	11.60	6.991	0.000**
Vitamin B12 (mcg)	28.96	31.18	14.59	38.15	2.246	0.029**
Potassium (mg)	5147.88	2100.00	2212.27	1030.63	10.562	0.000**
Sodium (mg)	2454.76	1348.55	2292.52	2499.57	0.373	0.711
Phosphorus (mg)	1414.30	595.70	1119.80	697.92	2.472	0.017**
Calcium (mg)	919.31	445.90	758.90	556.26	1.858	0.069
Iron (mg)	21.68	10.50	15.93	19.01	2.238	0.030*
Magnesium (mg)	389.35	146.95	191.23	82.86	10.013	0.000*
Copper (mg)	2.90	1.68	1.96	5.66	1.229	0.225
Zinc (mg)	12.85	7.70	8.49	7.41	2.950	0.005**
Selenium (mcg)	138.17	70.78	58.16	72.03	5.959	0.000**
Energy (kcal)	2959.41	1098.64	2154.79	840.78	5.286	0.000**

FFQ = food frequency questionnaire; 24hR = 24-hour recall; SD = standard deviation; RE = retinol equivalent.

\*Paired t-Test: Comparison of means between FFQ and R24h; P < 0.05; \*\*P < 0.01.

significant ( $P \leq 0.05$ ) (Table 2). Comparing the estimated values for the mean intake of energy and nutrients recorded by the 24hR and FFQ, we found that the FFQ overestimated the values of caloric availability; macronutrients; vitamins C, E, B3, B5, B6, B12, and folate; and minerals phosphorus, potassium, iron, magnesium, zinc, and selenium. The mean values of the consumption of other nutrients estimated using the two methods were similar ( $P > 0.05$ ).

In the validation analysis, we observed that Pearson's correlation coefficients, obtained by comparing the crude values estimated by the FFQ and 24hR methods, ranged from -0.15 (monounsaturated fat) to 0.50 (carbohydrate). Significant correlations were observed for calories ( $r = 0.41$ ), carbohydrates ( $r = 0.55$ ), vitamin E ( $r = 0.33$ ), potassium ( $r = 0.37$ ), copper ( $r = 0.29$ ), iron ( $r = 0.36$ ), and magnesium ( $r = 0.37$ ) (Table 3).

When adjusting nutrients for energy, correlation values for most nutrients changed, ranging from reductions (-0.33 for sodium) to increases (0.96 for folate). The correlations increased for vitamins D, B3, B12, C, and folate and were significant for the last two. A significant negative correlation was observed with sodium levels after adjusting for energy (Table 3). After calibration, we noted that the values of the nutrient correlation coefficients of the FFQ and the 24hR ranged from -0.95 (monounsaturated fat) to 0.99 (vitamin B12); were positive and significant for carbohydrate, protein, cholesterol, vitamin C, folate, vitamin B12 and iron; and significant, however, negative for total fat, monounsaturated fat, and energy (Table 3).

Table 4 displays the calibration results, regression coefficients, and respective confidence intervals for the dietary variables adjusted for energy. Variation was observed in the values of calibration factors from -0.23 (sodium) to 1.00 (folate). Calibration results for vitamin C, folate, sodium, phosphorus, and selenium were statistically significant. Table 5 presents the mean values of estimated, residual, constant, and adjusted macronutrients and micronutrients.

## DISCUSSION

This study's results indicate that the validation and calibration of the FFQ increased the accuracy of the instrument when compared to the reference standard (24hR); that is, they better estimated the population values of energy availability, macronutrients, monounsaturated fat, cholesterol, vitamin B12, vitamin C, folate, sodium, iron, and calcium, allowing the estimates produced by the instruments to better reflect the actual consumption.<sup>4</sup> Thus, this instrument can be used to associate feeding in the gestational period with maternal and fetal health.

Thus, the impact of applying statistical validation and calibration techniques adopted in this study was clearly observed by the change in the trend of agreement of the estimates of the values of crude, adjusted, and calibrated nutrients. Crude nutrients are values

**Table 3.** Pearson's correlation coefficient for crude energy and nutrients, adjusted for energy and calibrated, estimated using the food frequency questionnaire and 24-hour recall in a population of pregnant women. Santo Antônio de Jesus (Bahia), Brazil, 2012

Nutrient	Crude <i>r</i>	Adjusted <i>r</i>	Calibrated <i>r</i>
Carbohydrate (g)	0.50*	0.23	0.89**
Protein (g)	0.24	0.08	0.53**
Fat (g)	0.15	-0.05	-0.60**
Fibers (g)	0.17	0.02	0.02
Polyunsaturated fat (g)	0.13	0.03	0.03
Monounsaturated fat (g)	-0.15**	-0.23	-0.95**
Saturated fat (g)	0.09	-0.04	0.04
Cholesterol (mg)	0.18	0.01	0.81**
Vitamin A (RE)	0.09	0.18	0.17
Vitamin D (mcg)	-0.12**	0.21	-0.18
Vitamin C (mg)	0.31	0.75*	0.73**
Vitamin B3 (mg)	0.28*	0.16	0.15
Vitamin B1 (mg)	0.12	-0.04	0.11
Folate (mcg)	0.05	0.96*	0.92**
Vitamin B2 (mg)	0.14	0.06	0.03
Pantothenic acid (mg)	0.22	0.09	0.03
Vitamin B6 (mg)	0.23	0.08	0.08
Vitamin E (mg)	0.25	0.15	0.15
Vitamin B12 (mcg)	0.13	0.22	0.99**
Potassium (mg)	0.32*	0.24	0.23
Sodium (mg)	-0.14	-0.33*	0.31*
Phosphorus (mg)	0.24	0.10	0.06
Calcium (mg)	0.23	-0.05	-0.71**
Iron (mg)	0.21	0.11	0.75**
Magnesium (mg)	0.31*	0.18	0.17
Copper (mg)	0.31*	0.20	0.16
Zinc (mg)	0.09	-0.03	0.03
Selenium (mcg)	0.23	0.07	0.23
Energy (kcal)	0.39*	0.01	-0.38**

RE = retinol equivalent.

Nutrients with normal distribution; others were log-transformed; \* $P < 0.05$ ; \*\* $P < 0.01$ .

directly measured from the FFQ without any statistical treatment. Adjusted nutrients refer to those obtained after controlling for the effect of total energy available in the diet.<sup>1</sup> Specifically, this adjustment minimizes the confounding effect of total energy.

This study's calibration brought the estimates obtained from the FFQ closer to those provided by the adopted reference method (24hR). Essentially, it minimized or eliminated biases, thereby more precisely measuring the dietary intake of the investigated pregnant women.

**Table 4.** Calibration regression coefficients ( $\alpha$  and  $\lambda$ ) for energy-adjusted dietary variables, estimated using the food frequency questionnaire and 24-hour recall in a population of pregnant women. Santo Antônio de Jesus (Bahia), Brazil, 2012

Nutrients	$\alpha$	95% CI		$\lambda$	95% CI	
		Minimum	Maximum		Minimum	Maximum
Carbohydrate (g)	2.25	1.96	2.54	0.09	-0.02	0.20
Protein (g)	1.76	1.48	2.03	0.05	-0.09	0.19
Fat (g)	1.79	1.52	2.07	-0.02	-0.17	0.12
Fibers (g)	1.12	0.70	1.54	0.02	-0.26	0.30
Polyunsaturated fat (g)	0.66	0.19	1.13	0.04	-0.37	0.45
Monounsaturated fat (g)	12.51	9.98	15.04	-0.06	-0.12	0.01
Saturated fat (g)	1.24	0.87	1.62	-0.04	-0.31	0.23
Cholesterol (mg)	1.89	0.96	2.82	0.13	-0.24	0.51
Vitamin A (RE)	2.41	0.77	4.06	0.12	-0.36	0.59
Vitamin D (mcg)	3.61	2.81	4.41	0.05	-0.02	0.11
Vitamin C (mg)	1.73	1.64	1.83	0.01	0.01	0.01
Vitamin B3 (mg)	1.40	1.28	1.52	0.01	0.01	0.01
Vitamin B1 (mg)	0.44	0.39	0.49	0.01	-0.01	0.01
Folate (mcg)	0.00	-0.18	0.17	1.00	0.91	1.09
Vitamin B2 (mg)	0.45	0.39	0.52	0.01	0.01	0.01
Pantothenic acid (mg)	0.87	0.82	0.93	0.01	-0.01	0.01
Vitamin B6 (mg)	0.43	0.37	0.49	0.05	-0.11	0.20
Vitamin E (mg)	1.27	1.09	1.45	0.11	-0.09	0.31
Vitamin B12 (mcg)	1.15	0.99	1.29	0.01	0.01	0.01
Potassium (mg)	2.90	1.99	3.80	0.24	-0.04	0.51
Sodium (mg)	4.06	3.44	4.67	-0.23	-0.42	-0.04
Phosphorus (mg)	3.07	2.93	3.22	0.01	0.00	0.01
Calcium (mg)	1.31	1.19	1.43	0.01	0.01	0.01
Iron (mg)	1.27	1.19	1.35	0.01	0.01	0.01
Magnesium (mg)	2.17	1.54	2.79	0.18	-0.10	0.45
Copper (mg)	0.38	0.32	0.45	0.01	-0.04	0.02
Zinc (mg)	1.07	0.84	1.30	0.01	-0.29	0.23
Selenium (mcg)	2.08	1.99	2.16	0.01	0.01	0.01
Energy (kcal)	3.45	2.48	4.42	0.01	-0.29	0.29

CI = confidence interval; RE = retinol equivalent.

$\alpha$  is the regression constant,  $\lambda$  is the slope of the regression line.

The crude food consumption estimates, calculated using the FFQ, overestimated the mean availability of energy and most nutrients, compared with the 24hR standard. After adjusting for energy, we observed that many values of the assessed nutrients decreased, possibly because the diet's total energy value artificially raised the estimated values from the 24hR. Thus, total energy was a confounding factor in the evaluated relationship. When total energy was controlled for in the equation, we noted that the other nutrients' values decreased, possibly because the

external variations affecting the increase in these values were removed. We observed a decrease in the values of the estimated correlations and statistical significance. A study conducted in Brazil on pregnant women reported similar results, characterized by declining values of nutrient correlation coefficients after adjusting for energy, indicating that energy can change the individual values of dietary nutrients.<sup>8</sup>

The results of this study confirm existing findings regarding the under- or over-estimation of consumption<sup>1</sup> due to the assessment



**Table 5.** Mean values of estimated, residual, constant, and adjusted macronutrients and micronutrients. Santo Antônio de Jesus, Bahia, Brazil, 2012

Nutrients	Estimated nutrient		Residual nutrient		Constant nutrient		Adjusted nutrient	
	FFQ	24hR	FFQ	24hR	FFQ	24hR	FFQ	24hR
Carbohydrate*	2.62	2.47	0.01	0.009	2.62	2.48	2.62	2.48
Protein*	1.95	1.89	0.03	-0.27	1.9	1.99	1.96	1.89
Fat*	1.74	1.95	0.02	0.03	1.75	1.95	1.75	1.87
Fibers*	1.48	1.15	-2.20	-0.01	1.48	1.15	1.48	1.15
Polyunsaturated fat*	1.11	0.70	0.01	-0.01	1.10	0.71	1.11	0.70
Monounsaturated fat	1.48	0.99	-0.54	0.84	1.48	1.89	1.48	1.89
Saturated fat	1.37	1.18	-0.01	0.01	1.37	1.19	1.37	1.19
Cholesterol	2.46	2.47	0.55	0.01	2.46	2.47	289.7	2.47
Vitamin A	3.46	5.55	0.01	1.09	3.46	1.36	3.45	4.91
Vitamin D*	3.58	1.10	0.03	-0.96	3.58	1.10	3.77	3.56
Vitamin C*	2.62	2.11	-0.62	0.91	2.62	2.11	1.1	2.11
Vitamin B3	1.45	1.33	-0.03	-0.62	1.46	1.33	1.46	1.32
Vitamin B1*	0.42	4.04	0.00	-0.97	0.43	4.04	0.43	3.06
Folate*	2.65	1.98	-0.67	-0.01	2.65	1.98	1.98	1.98
Vitamin B2*	0.45	3.36	0.001	0.95	0.45	3.36	0.46	4.31
Pantothenic acid*	0.88	5.77	-0.001	-0.99	0.88	5.77	0.88	4.78
Vitamin B6*	0.43	-0.05	0.03	-0.01	0.43	-0.04	0.43	-0.04
Vitamin E*	1.35	0.80	-0.001	0.00	1.36	0.80	1.35	0.80
Vitamin B12	1.19	1.17	0.00	-0.42	1.20	1.17	1.19	1.16
Potassium*	3.68	3.30	-0.0010	0.0012	3.67	3.30	3.67	3.30
Sodium*	3.33	3.30	0.00010	0.0012	3.32	3.30	3.30	3.30
Phosphorus	3.11	3.04	0.001	-0.007	3.11	3.04	3.12	3.04
Calcium	2.90	2.87	-1.62	1.06	2.91	-2.87	1.29	2.88
Iron*	1.29	1.20	-0.001	0.02	1.29	1.20	1.29	1.21
Magnesium*	2.56	2.24	0.00	-0.001	2.56	2.25	2.5	2.25
Copper*	0.40	2.43	-0.001	-0.47	0.40	2.43	0.40	1.95
Zinc*	1.05	0.83	-0.002	-0.002	1.05	0.83	1.04	0.84
Selenium*	2.09	1.77	0.001	-0.90	2.09	1.77	2.09	1.76

FFQ = food frequency questionnaire; 24hR = 24-hour recall.

\*Values in logarithm.

methods, indicating the need to calibrate these instruments to correct such errors.

Thus, calibration can shift estimates of dietary intake closer to the actuals, making the estimates more accurate and less biased.<sup>22</sup> The adjustment or calibration factors ( $\lambda$ ) of the nutrients found in this study ranged from -0.23 (sodium) to 0.24 (potassium), except for folate, whose correction factor was 1.00. In studies on dietary data calibration, the ideal is to have the estimated parameters for the intercept ( $\alpha$ ) close to zero and the estimated values for  $\lambda$  close to the unit.<sup>23</sup>

The calibration factors can be considered attenuated as they were smaller than the unit for most of the nutrients investigated. This result can be explained by the flattened slope effect, which implies an attenuated slope of the line ( $\lambda$ ), generated by the control of several sources of bias (of information, in the reference instrument, in variations in the study period, and dietary calculations).<sup>23,24</sup> Results available in the literature indicate a similar trend of attenuation in the values of the calibration factors, with different variations between 0.10 and 0.48,<sup>10,25,26</sup> 0.50 and 0.70,<sup>27,28</sup> and between -0.05 and 0.28,<sup>23</sup> 0.4 and 0.9.<sup>29</sup>

The ideal method of diagnosing a population's food consumption should result in a nutrient distribution curve with zero mean and a standard deviation of 1. Obtaining these results would suggest that 95% of the assessed consumption would be similar to the population's consumption. This condition would indicate a lack of bias; that is, the mean intake captured by the instrument would be identical to the mean population's nutrient consumption as measured by the methodological instruments, if they were error-free. Reaching this level of perfection with a diagnostic instrument in any human health and nutritional situation could be unrealistic, considering the complex and multifaceted determination of people's living conditions.

However, no available method for evaluating food consumption meets these methodological conditions for qualifying it as the gold standard for evaluating food consumption; that is, all are subject to errors. These aspects also contribute to the low correlations found in this and other validation studies. This can be attributed to the limitations of the instruments (FFQ and 24hR) regarding intake estimates concerning the overestimated and underestimated portions consumed.<sup>1,30,31</sup>

Small correlations can also result from biased reporting, nutrient concentration differences among food lists and preparations in food composition tables used by food survey calculation software, and the use of the instruments' differential measurement scale.<sup>30,31</sup>

Additional considerations regarding this study's adopted methodology should be highlighted. The absence of normal distribution for some variables indicated the need for logarithmic transformation of those with non-parametric distribution.<sup>4</sup> Thus, some variables remained in their original form, while others were converted into logarithms, possibly limiting the reader's understanding.

Reapplying Pearson's correlation test, after the calibration phase, between the calibrated nutrients from the FFQ and the adjusted nutrients from the 24hR made the method more accurate in estimating the availability of energy and other nutrients from population values. Thus, the statistical analyses were consistent with the validation studies of FFQ in pregnant women, with *Pearson* or *Spearman's* correlation coefficient for validation purposes.<sup>32</sup>

Some food consumption studies finalized the validation of the questionnaire at this methodological stage,<sup>28,33,34</sup> while others did so after the calibration of nutrients was adjusted for energy.<sup>35-37</sup> However, in this study, besides validation and calibration, a new correlation test was performed between the calibrated nutrient values and those obtained by the reference method. This stage of verifying the final correlations, theoretically supported by the statistical assumptions of the test application, aimed to verify

the agreement between the calibrated estimates obtained by the method under test versus the reference method and is a differentiated step for consistency.

This step reinforces that this study's results did not occur by chance, given the methodological rigor adopted throughout, to allow for the attenuation of the limits inherent in the elaboration and application of the instruments, and the adoption of the analysis of food consumption information. Even so, the lack of standardization in the collection and analysis of food consumption data limits the impact and expectation of robust results that could be produced using validation analysis and instrument calibration.<sup>1,23</sup>

In assessing food consumption, the appropriateness of applying more than one instrument to record consumption or more than one recall compared with the FFQ should also be considered. This recommendation is based on the observation that studies that adopted four recalls registered low correlation coefficients for some nutrients.<sup>14</sup>

However, the calibration technique, as a statistical instrument, and the validation analysis this study used can minimize the adoption of only one 24hR compared with the instrument under test<sup>14</sup> and make the methodological model statistically more robust. Using only one 24hR instrument may not necessarily result in a significant difference in the variation of consumption reports, and this study's results were close to the population's consumption.

This study has several limitations. The assessment of food consumption depended on the participants' memory and ability to report the measurements and portions consumed. Food records, especially those using direct weighing, are better instruments for correctly estimating food consumption. Nevertheless, there could be better instruments for the sample, as study's participant have a low level of education.<sup>38</sup> In future studies, food intake for fewer days should be evaluated. In this study, the greater the number of days assessed by the standard diet instrument, the smaller the error inherent in the variability of interindividual consumption.<sup>38</sup> Generally, despite overestimating food intake, the FFQ showed good calibration and agreement with the 24hR and may be used in clinical practice to assess the food intake of pregnant women.

## CONCLUSION

This study contributes to nutritional epidemiology by expanding and improving knowledge regarding research techniques and instruments that minimize possible errors in measuring food consumption, a variable that is strongly influenced by numerous biological, social, cultural, and economic factors. The validated and calibrated FFQ can globally evaluate a pregnant woman's diet and can be used in a complementary way to specific nutrient instruments for this group.<sup>38</sup> We can

conclude that the FFQ used in this study can be employed in other epidemiological investigations to assess the food consumption of pregnant women with similar socioeconomic and demographic characteristics.

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# Exploring the effect of the structural model of active aging on the self-assessment of quality of life among older people: A cross-sectional and analytical study


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## ABSTRACT

**BACKGROUND:** Although studies have examined the relationship between variables associated with active aging and quality of life (QoL), no studies have been identified to have investigated the effect of a structural model of active aging on QoL in a representative sample of older people in the community.

**OBJECTIVE:** To measure the domains and facets of QoL in older people and identify the effect of the structural model of active aging on the self-assessment of QoL.

**DESIGN AND SETTING:** This cross-sectional analytical study included 957 older people living in urban areas. Data were collected from households using validated instruments between March and June 2018. Descriptive, confirmatory factor, and structural equation modeling analyses were performed.

**RESULTS:** Most older people self-rated their QoL as good (58.7%), and the highest mean scores were for the social relationships domain ( $70.12 \pm 15.4$ ) and the death and dying facet ( $75.43 \pm 26.7$ ). In contrast, the lowest mean scores were for the physical domains ( $64.41 \pm 17.1$ ) and social participation ( $67.20 \pm 16.2$ ) facets. It was found that active aging explained 50% of the variation in self-assessed QoL and directly and positively affected this outcome ( $\lambda = 0.70$ ;  $P < 0.001$ ).

**CONCLUSION:** Active aging had a direct and positive effect on the self-assessment of QoL, indicating that the more individuals actively aged, the better the self-assessment of QoL.

## INTRODUCTION

Active aging is defined as “the process of optimizing opportunities for health, participation, and safety, to improve the quality of life (QoL) as people age.”<sup>1</sup> In the theoretical model proposed by the World Health Organization (WHO), this paradigm contemplates the determinants of culture and gender, which are considered transversal factors that shape people and the environment in which they live throughout life; behavioral and personal, which are specific to each individual; and physical environment, social, economic, social services, and health, which constitute the contextual factors.<sup>1</sup>

In this scenario, the promotion of active aging has its primary objective to maintain or improve QoL.<sup>1</sup> It can be understood as the “individuals’ perception of their position in life concerning the context and value systems in which they fit in, including its objectives, expectations, standards, and concerns.”<sup>2</sup> Thus, its complexity is highlighted in the face of the interaction of components such as physical and psychological health, level of functional independence and social relationships, and the environment.<sup>3</sup>

Among older people, QoL can be assumed to be very good, or at least preserved, when they remain active, independent, and in good physical health and social relationships.<sup>4,5</sup> Although studies have investigated the relationship between variables associated with active aging and QoL,<sup>6-9</sup> no identified studies have verified the effect of a structural model of active aging according to the multidimensional design proposed by the WHO<sup>1</sup> on QoL in a representative sample of older adults in a community.

Notably, structural equation modeling (SEM) makes it possible to understand the interrelationship between multiple variables,<sup>10</sup> which enables the operationalization of the expanded concept of active aging adopted in this study,<sup>1</sup> and to analyze its effect on the QoL of older people. The findings of this study may raise reflections on advanced gerontological practices in line

with the current models of healthcare provision (which are not strictly focused on the physical aspects of senescence and senility), but, above all, on a multidimensional approach to active aging.

## OBJECTIVE

This study aimed to measure the domains and facets of the QoL of older people in the community and identify the effect of the structural model of active aging on the self-assessment of QoL.

## METHOD

### Design

The Strengthening the Reporting of Observational Studies in Epidemiology tool guided this cross-sectional and analytical study. Further, the study employed a quantitative approach and was a part of a larger project titled “Active Aging, Global Functionality and Quality of Life among Older People in the Uberaba Health Microregion (Minas Gerais),” developed in the urban area of a health microregion in the state of Minas Gerais. This microregion consists of eight municipalities and comprises 57% of the older population of the Southern Triangle Macroregion.

### Sample/Participants

The sample size calculation was based on the prevalence rate of 28.8% for lower participation in instrumental activities of daily living,<sup>11</sup> aiming for an accuracy of 3.0%, and a 95% confidence interval for a finite population of 43,166. Consequently, a minimum sample size of 858 older people was achieved. Considering a sample loss of 20%, the maximum number of attempts made was 980 older people.

Multistage cluster sampling was used for population selection. The first stage considered the arbitrary drawing using systematic sampling of 50% of the census tracts in each municipality in a health microregion. For each municipality, the number of households selected was calculated proportionately to the number of older adults residing in the eight cities in that region. The number of households was then divided by the number of census tracts to obtain a similar number of older people to be interviewed in each census tract. Finally, the first household was randomly selected in each census sector, and the others were selected in a standardized sense until the sector sample was saturated. Notably, one older person was recruited per household; if one more person aged 60 years or older was residing in that place, the person who had first contact with the interviewer was interviewed.

The inclusion criteria included individuals aged 60 years or older living in an urban area of a health microregion in Minas Gerais. Institutionalized older people were excluded if they had communication problems, such as deafness not corrected by devices,

severe speech disorders, cognitive decline according to the Mini-Mental State Examination (MMSE),<sup>12</sup> no informant to answer the Functional Activities Questionnaire (FAQ),<sup>13</sup> or a final score greater than or equal to six points in the FAQ.

Based on the eligibility criteria, 977 older people were interviewed; in this sample, 15 had severe cognitive decline, and five did not undergo a full interview. Therefore, 957 older adults were included in this study.

### Data collection

Interviews were conducted at the homes of older people from March to June 2018. Trained interviewers with previous experience in collecting data conducted these interviews. Five previously selected supervisors checked the interviews to verify the completion and consistency of the items and ensure quality control.

Cognitive decline was assessed using the MMSE, considering the following cutoff points:  $\leq 13$  for illiterate,  $\leq 18$  for low (1–4 incomplete years) and medium (4–8 incomplete years) education, and  $\leq 26$  for high ( $\geq 8$  full years) education.<sup>12</sup> If an older person presented a cognitive decline in the MMSE assessment, the informant was asked to participate, and the FAQ was applied, which verifies the presence and severity of cognitive decline based on the assessment of functionality and the need for assistance from other individuals.<sup>13</sup> The FAQ associated with the MMSE indicates the most severe presence of cognitive decline when the score is greater than or equal to 6 points.<sup>13</sup>

Sociodemographic and economic data were obtained through a structured questionnaire, which was elaborated upon and widely used by Collective Health Research Group members.

QoL was assessed based on the application of the World Health Organization Quality of Life-BREF (WHOQOL-BREF), which is composed of four domains: (1) physical, (2) psychological, (3) social relationships, and (4) environment,<sup>3</sup> and the World Health Organization Quality of Life-OLD (WHOQOL-OLD), which is a specific instrument for the older population, consisting of six facets: (1) functioning of the senses; (2) autonomy; (3) past, present, and future activities; (4) social participation; (5) death and dying; and (6) intimacy,<sup>14</sup> both validated in Brazil. Notably, the domains and facets of these instruments are composed of questions whose scores on a Likert scale vary according to the degree of satisfaction (1–5 points). The final scores (0–100 points) were calculated using Syntax, with the highest value corresponding to the best QoL.

The self-assessment of QoL was measured using the question, “How would you assess your quality of life?” This question had five response options: very poor, poor, not bad/not good, good, or very good. Notably, the questions regarding QoL were answered based on the last two weeks of life.

Furthermore, a structural model of active aging developed in a previous study, based on the theoretical framework of the WHO,<sup>1</sup> was used.<sup>15</sup> The instruments applied at a single moment to measure the determinants of the active aging model were defined considering the most used ones in gerontology and validated in Brazil (Chart 1).<sup>15-29</sup>

Chart 1 shows the instruments used for data collection and categorization of the observed variables in the SEM analysis.

### Data analysis

An electronic database was built using Excel (Microsoft, Redmond, Washington, United States) with double entries. After checking for inconsistencies between the two databases, the data were imported into the SPSS (IBM, Armonk, New York, United States) version 22.0 and Analysis of Moment Structures (AMOS – SPSS, IBM, Armonk, New York, United States).

**Chart 1.** Instruments used to measure the determinants of the active aging model and categorization of the observed variables

Behavioral determinant		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Anthropometric profile</b>	Body Mass Index; <sup>16</sup> Abdominal Circumference; <sup>17</sup> Calf Circumference; <sup>18</sup> and Brachial Circumference. <sup>19-20</sup>	Number of suitable items (0 to 4).
<b>Healthy life habits</b>		
Alcohol consumption	Do you usually consume alcoholic beverages?	Number of healthy life habits (0 to 4).
Sleep quality	Do you have any trouble sleeping?	
Physical activity	International Physical Activity Questionnaire. <sup>21</sup>	
Smoking	Do you smoke?	
<b>Self-care practices</b>		
Attitude towards taking medicines	Instrument for assessing attitude towards medication. <sup>22</sup>	Number of self-care practices (0 to 5).
Vaccination status	Assessment of the vaccination card of elderly individuals. <sup>23</sup>	
Preventive examinations	Have you undergone a preventive examination last year?	
Oral health	When was the last time you went to the dentist?	
Routine consultation	Did you undergo a routine check-up last year?	
Personal		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Cognitive ability</b>	Mini-Mental State Examination. <sup>12</sup>	No (1); Yes (0).
<b>Resilience</b>	Connor-Davidson Resilience Scale for Brazil-25. <sup>24-25</sup>	Resilience score.
<b>Depression, Emotional</b>	Geriatric Depression Scale. <sup>26</sup>	Number of depressive symptoms.
<b>Functioning of the senses</b>	How would you assess the functioning of hearing, vision, taste, smell, and touch?	Very bad (1); Bad (2); Neither bad nor good (3); Good (4), and Very good (5).
<b>Family history of Chronic Non-Communicable Diseases</b>	Brazilian Questionnaire of Functional and Multidimensional Assessment. <sup>27</sup>	No (1); Yes (0).
<b>Morbidities</b>	Brazilian Questionnaire of Functional and Multidimensional Assessment. <sup>27</sup>	Number of morbidities.
Physical Environment		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Physical security and protection</b>	Do you feel safe in your daily life?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).
<b>Physical environment</b>	Is your physical environment (climate, noise, pollution) healthy?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).
<b>Means of transport</b>	Are you satisfied with your means of transport?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).
<b>Environment in the home</b>	Are you satisfied with the conditions of your place of residence?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).

Continue...



Chart 1. Continuation

Social		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Personal relationships</b>	How satisfied are you with your personal relationships?	Very dissatisfied (1); Dissatisfied (2); Neither dissatisfied nor satisfied (3); Satisfied (4); Very satisfied (5).
<b>Community activities</b>	Are you satisfied with the opportunities you have to participate in community activities?	Very dissatisfied (1); Dissatisfied (2); Neither dissatisfied nor satisfied (3); Satisfied (4); Very satisfied (5).
<b>Social network</b>	Network and social support scale. <sup>28</sup>	Number of relatives and friends.
<b>Social support</b>	Network and social support scale. <sup>28</sup>	Social support score.
<b>Education years</b>	How many full years of study do you have?	Full years of study.
<b>Out-of-school activities</b>	To what extent do you have opportunities for leisure activities?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).
<b>Advanced Activities of daily living</b>	Thirteen questions of a social nature. <sup>29</sup>	Number of activities performed.
Economic		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Paid work</b>	Do you have paid work?	Yes (1); No (0).
<b>Monthly individual income</b>	What is your individual monthly income?	<1 (1); 1+ 3 and ≥3.
<b>Money to meet basic needs</b>	Do you have enough money to meet your needs?	Nothing (1); Very little (2); So-so (3); Quite (4); Extremely (5).
<b>Assessment of economic condition</b>	How do you assess your economic condition?	Good (1); Bad (0).
<b>Retirement and pension</b>	Are you a retiree or pensioner?	Yes (1); No (0).
Social and health services		
Measured determinants	Instruments	Code in Structural Equation Modeling
<b>Self-assessment of the course of health status</b>	Comparing your health today with that of a year ago, would you say your health is worse, equal, or better? <sup>27</sup>	Worse (1); Equal (2); Best (3).
<b>Assessment of current health status</b>	How do you assess your health? <sup>27</sup>	Terrible (1); Bad (2); Regular (3); Good (4); Great (5).
<b>Access to health care services</b>	Are you satisfied with your access to health services?	Very dissatisfied (1); Dissatisfied (2); Neither dissatisfied nor satisfied (3); Satisfied (4); Very satisfied (5).
<b>Link with the health service</b>	Do you usually seek the same health service when you need care?	Yes (1); No (0).
<b>Access to continuous-use medicines</b>	Do you have access to continuous medicines?	Yes (1); No (0).

Fonte: Oliveira et al.<sup>15</sup>

The data were subjected to absolute and relative frequency analyses for categorical variables and mean and standard deviation for quantitative variables. A confirmatory factor analysis was performed using AMOS version 23.0 and SPSS version 22.0. This was to identify the effect of active aging on the QoL of older people and assess the quality of fit of the measurement model to the correlational structure among the observed variables.<sup>10</sup>

In the adjustment of the model, the identification strategy of the causal model with latent variables in two steps (two-step)

was used: (1) specifying and identifying the measurement sub-model and (2) identifying the structural sub-model, that is, establishing the trajectories for endogenous latent variables.<sup>10</sup> This method ensures that the measurement model is adequately validated and makes it possible to assess the plausibility of the structural model after ensuring the quality of the measurement model.<sup>10</sup>

In Step 1 of the two-step strategy, a structural model of active aging was used, as described in a previous study.<sup>15</sup>

In both stages, the parameters were estimated using the asymptotic distribution-free method, which is the most traditional method used in SEM analysis.<sup>10</sup> We also previously conducted an analysis of normality for the items observed through the asymmetry coefficients (sk) and kurtosis (ku), considering the deviation from normality sk indices > 3 and ku > 10.<sup>10</sup>

The quality of the global fit of the models was evaluated according to the following indices and their respective values: chi-square and degrees of freedom ( $\chi^2/gf$ )  $\leq 5.0$ , the goodness of fit index (GFI)  $\geq 0.90$ , comparative fit index (CFI)  $\geq 0.90$ , Tucker-Lewis index (TLI)  $\geq 0.90$ , Parsimony goodness of fit index (PGFI)  $\geq 0.60$ , Parsimony comparative fit index (PCFI)  $\geq 0.6$ , root mean square error of approximation (RMSEA)  $\leq 0.05$ , P - Root Mean Error of Approximation (PCLOSE)  $\geq 0.05$  and expected cross-validation index (MECVI); the lower the value, the better.<sup>10</sup> The relative normed fit index (RNFI) was calculated to assess the quality of the global structural model (Step 2). RNFI > 0.80 is an indicator of good fit and significant trajectories with  $P < 0.05$ .<sup>10</sup>

The quality of the local adjustment was identified based on the values of factor loadings ( $\lambda > 0.3$ )<sup>30</sup> and individual reliability ( $R^2 \geq 0.25$ ).<sup>10</sup> Modification indices greater than 11 ( $P < 0.001$ ) were used to refine the models, and the measurement errors that led to considerable improvement in the adjustment of the models were correlated.<sup>10</sup>

### Validity, reliability, and rigor

The instruments used in this study were validated in Brazil. The interviewers collected data from health professionals who underwent training and had qualifications in approaches to ethical research issues. Field supervisors reviewed the interviews to analyze the consistency and completeness of the questionnaire. This study was conducted using a representative sample of older people living in an urban area of a Brazilian municipality.

### Ethical considerations

The project was approved by the Human Research Ethics Committee by Universidade Federal do Triângulo Mineiro, on May 9, 2017 (CAAE:65885617.8.0000.5154). The interviews were conducted after obtaining consent from the participants and the participants signing the Free and Informed Consent Form.

### RESULTS

There was a predominance of female older people (66.9%), those aged 70–80 years (41.4%), those with 1–5 years of education (52.4%) and partners (42.8%), those who lived accompanied by other people (81.1%), and those with an individual monthly income of 1–3 minimum wages (85.8%) (Table 1).

Table 1 shows the sociodemographic and economic characteristics of older people living the health microregion.

**Table 1.** Frequency distribution of sociodemographic and economic characteristics of older people living in a health microregion, Minas Gerais, Brazil, 2020

Variables	Categories	n	%
Sex	Men	317	33.1
	Women	640	66.9
Age (years)	60–70	358	37.4
	70–80	396	41.4
	80 or older	203	21.2
Schooling (years)	None	171	17.9
	1–5 years	501	52.4
	5 years or more	285	29.7
Marital status	Single	63	6.6
	Living with spouse	410	42.8
	Widowed	377	39.4
	Divorced	107	11.2
Housing arrangement	Alone	181	18.9
	Accompanied	776	81.1
Monthly individual income (minimum wage)	< 1	80	8.4
	1–3	821	85.8
	$\geq 3$	56	5.8

In the QoL assessment, most older people classified it as good (58.7%), followed by not bad/not good (22.3%), very good (13.5%), poor (4.5%), and very poor (1.0%). In the QoL assessment using the WHOQOL-BREF, the highest mean score was for the social relationships (70.12  $\pm$  15.43) domain, and the smallest one was for the physical (64.41  $\pm$  17.15) domain (Table 2).

The facet of the WHOQOL-OLD that presented the highest mean score for QoL was death and dying (75.43  $\pm$  26.73), and the lowest score was in the social participation facet (67.29  $\pm$  16.29) (Table 2).

Table 2 shows the QoL scores measured using the WHOQOL-BREF and WHOQOL-OLD for older people living in a healthy microregion.

The structural model, which demonstrates the effect of active aging on the self-assessment of QoL of older people, showed a good quality of adjustment ( $\chi^2/gf = 3.63$ ,  $P < 0.001$ ; GFI = 0.93, CFI = 0.91, TLI = 0.90, PGFI = 0.72, PCFI = 0.76, RMSEA = 0.05, PCLOSE = 0.130, MECVI = 1.11, and RNFI = 0.94) (Figure 1).

**Table 2.** Distribution of Quality-of-Life scores of World Health Organization Quality of Life-BREF domains and World Health Organization Quality of Life-OLD facets of older people living in a health microregion, Minas Gerais, Brazil, 2020

Quality of life	Mean	Standard deviation
<b>WHOQOL-BREF domains</b>		
Physical	64.41	17.15
Psychological	70.07	14.28
Social relationship	70.12	15.43
Environment	65.88	13.02
<b>WHOQOL-OLD facets</b>		
Functioning of the senses	73.82	22.84
Autonomy	69.14	15.58
Past, present, and future activities	69.26	14.44
Social participation	67.20	16.29
Death and dying	75.43	26.73
Intimacy	72.72	19.96

WHOQOL-BREF = World Health Organization Quality of Life-BREF; WHOQOL-OLD = World Health Organization Quality of Life-OLD.

Most items had a standardized factor loading ( $\lambda > 0.3$ ) and adequate individual reliability ( $R^2 \geq 0.25$ ) (Table 3).

Table 3 shows the standardized factor loadings and individual reliability of the observed variables that comprise the structural model of the effect of active aging on the self-assessment of QoL in older people living in a health microregion.

It was found that acting aging, the second-order factor, explained 50% of the variation in self-assessment of QoL and had a direct and positive effect on this outcome ( $\lambda = 0.70$ ;  $P < 0.001$ ), showing that the more people actively aged, the better their self-assessment of QoL; that is, an increase in one active aging unit implies an increase of 0.70 in the self-assessment of QoL (Figure 1).

## DISCUSSION

In the current study, most older people self-assessed their QoL to be good. It was also found that the highest mean QoL scores were for the domain of social relationships and facet of death and dying, while the lowest was for physical relationships and social participation. Furthermore, a global structural model was proposed to measure the effect of active aging on the self-assessment of QoL in older people living in the urban area of a health microregion in Minas Gerais. Active aging was found to have a direct positive effect on these outcomes.

Data related to the QoL self-assessment, verified in the current study, were obtained from older people living in the city of Uberaba (MG), in which the majority (51.1%) rated their QoL as good.<sup>31</sup> However, different results were identified among older people from other cities in the same state as those in the research in

question, as a higher percentage classified QoL as regular (54%)<sup>32</sup> and poor (41.3%).<sup>6</sup> Such differences may be related to ethnic and cultural differences, as these can interfere with subjective measures self-reported by the older people, such as QoL.<sup>33</sup>

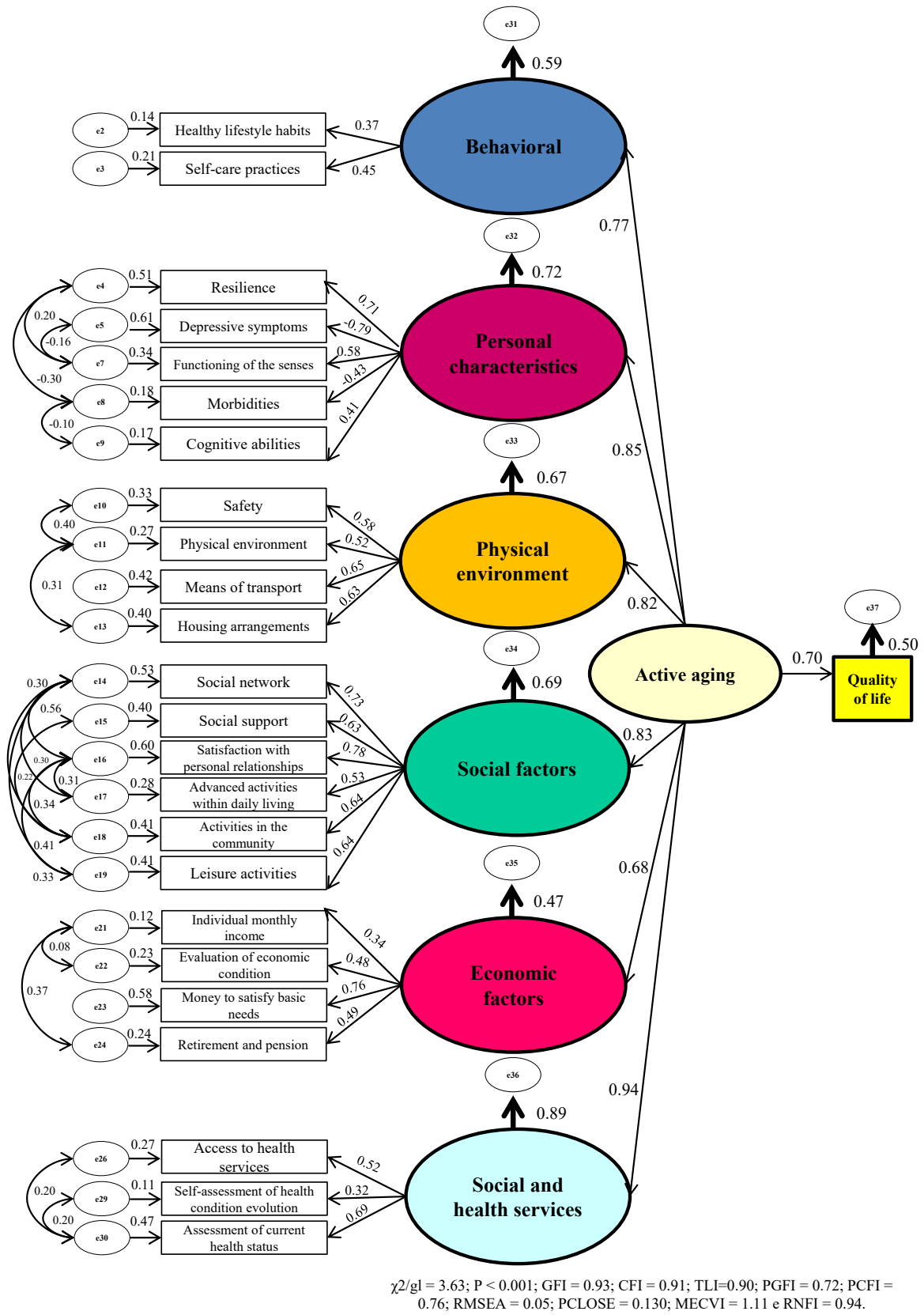
In the current study, higher mean scores were observed for the domain of social relationships, similar to studies conducted among older people in the community in Brazil<sup>31,34</sup> and Greece.<sup>35</sup> A varying result was shown in a survey in the Netherlands among people aged  $\geq 50$  years, in which this domain had the lowest QoL scores.<sup>36</sup> Positive personal relationships associated with an active social life contribute to the prevention of social isolation, reflecting the physical and mental health status of older people and, consequently, their QoL.<sup>37</sup> In this context, approaches that make it possible to integrate the family and components of the social network into care are resources that should be valued and used as they add to the QoL of older people.<sup>38</sup>

A lower score in the physical domain may indicate a more significant impact on daily activities; dependence on drugs or treatments and work capacity are aspects evaluated in this domain.<sup>3</sup> Similar data were found in other studies in Brazil,<sup>33,39</sup> Poland,<sup>8</sup> and Greece.<sup>35</sup> This finding highlights the importance of reevaluating the impact of physical health on the QoL of older people, with a view to establishing actions that favor self-care and maintenance of functionality and independence during aging.

The highest average scores in death and dying, verified in the research on screen, align with the findings among older people in Brazilians<sup>34,40</sup> and differ from studies conducted in the Netherlands, in which this facet was among those with the worst evaluations.<sup>37</sup> Such data suggest that these individuals are facing, in a good way, concerns and fears related to the end of life, which are items evaluated in this facet.<sup>3</sup>

The lowest scores obtained on the social participation facet corroborate the investigation among older people in the community in Brazil.<sup>40</sup> It is possible that the lowest scores on the social participation facet in the current study were due to the worse assessment of the physical domain because these QoL items may be associated, as shown in a previous study.<sup>41</sup> Reducing older people's social participation is a relevant aspect to consider. Generally, it is multifactorial and includes access to income and socialization difficulties, including physical aspects, which health services must monitor to improve decision-making capacity and life satisfaction.<sup>1,42</sup>

Although the promotion of active aging is considered the main action to face the challenges caused by the demographic aging process and to improve or maintain the QoL of older people,<sup>1,42</sup> there are critical gaps in the scientific literature regarding structural models that operationalize the concept of active aging in a broad and multidimensional approach. A survey developed with an older Spanish population stands out, in which an active aging model was developed based on the WHO proposal. However, the



QoL = quality of life; GFI = goodness of fit index; CFI = comparative fit index; TLI = Tucker-Lewis index; PCFI = Parsimony comparative fit index; RMSEA = root mean square error of approximation; PCLOSE = P-root mean error of Approximation; MECVI = expected cross-validation index; RNFI = relative normed fit index.

**Figure 1.** Structural model of the effect of active aging on the self-assessment of the quality of life of older people in the current study.

**Table 3.** Standardized factor loadings and individual reliability of the variables of the structural model of the effect of active aging on the self-assessment of the quality of life of older people living in a health microregion, Minas Gerais, Brazil, 2020

Variables	$\lambda^*$	$R^{2**}$	$P^{***}$
<b>Active aging and determinants</b>			
Behavioral	0.77	0.59	< 0.001
Personal	0.85	0.72	< 0.001
Physical environment	0.82	0.67	< 0.001
Social	0.83	0.69	< 0.001
Economic	0.68	0.47	< 0.001
Social and health services	0.94	0.89	< 0.001
<b>Behavioral determinants</b>			
Healthy lifestyle habits	0.37	0.14	< 0.001
Self-care practices	0.45	0.21	< 0.001
<b>Personal determinants</b>			
Resilience	0.71	0.51	< 0.001
Depressive symptoms	-0.79	0.61	< 0.001
Functioning of the senses	0.58	0.34	< 0.001
Morbidities	-0.43	0.18	< 0.001
Cognitive ability	0.41	0.17	0.002
<b>Physical environment</b>			
Safety	0.58	0.33	< 0.001
Physical environment	0.52	0.27	< 0.001
Means of transport	0.65	0.42	< 0.001
Housing arrangement	0.63	0.40	< 0.001
<b>Social determinants</b>			
Social network	0.73	0.53	< 0.001
Social support	0.63	0.40	< 0.001
Satisfaction with personal relationships	0.78	0.60	< 0.001
Advanced activities of daily living	0.53	0.28	< 0.001
Activities in the community	0.64	0.41	< 0.001
Leisure activities	0.64	0.41	< 0.001
<b>Economic determinants</b>			
Individual monthly income	0.34	0.12	< 0.001
Economic condition evaluation	0.48	0.23	< 0.001
Money to satisfy basic needs	0.76	0.58	< 0.001
Retirement and pension	0.49	0.24	0.009
<b>Health and social services</b>			
Health services access	0.53	0.28	< 0.001
Self-assessment of health condition evolution	0.32	0.11	< 0.001
Assessment of the current health status	0.77	0.59	< 0.001
<b>Self-assessment of quality of life</b>	0.70	0.50	< 0.001

\*Factor loading ( $\lambda$ ); \*\*Individual reliability ( $R^2$ ); \*\*\* $P < 0.05$ .

analyzed outcome variable was satisfaction with life, whose association was direct and positive.<sup>43</sup>

Studies on the association between active aging and QoL have evaluated the association between some variables that make up the determinants of active aging and QoL.<sup>6-9</sup> A study of community-dwelling older people in Spain using structural equation modeling found that the availability of social support was positively associated with QoL. It was also identified that perception of health and satisfaction with life were the two main variables for understanding QoL, regardless of the age variable, which did not affect the model.<sup>44</sup> However, the active aging model was tested from a psychosocial perspective, including four latent variables (depression, explicit memory, perceived QoL, and social resources). Furthermore, a selected sample of healthy older people was included, after excluding those with functional dependence, no education, visual and mental problems, cognitive alterations, or other criteria.<sup>44</sup>

Noteworthy, the active aging approach proposed by the WHO includes all people who are aging, including those who are frail, physically disabled, and require care; its main objective is to maintain or improve QoL.<sup>1</sup> The interest in studying the relationship between active aging and QoL assumes an increasingly essential role in society because of the aging population worldwide.<sup>45</sup> The way each elderly person faces and experiences the human aging process is also determined by the subjective assessment of their QoL, making it one of the main factors to be considered when analyzing the living conditions of the older population.<sup>4</sup>

Active aging and QoL are considered complementary concepts because QoL is believed to influence how individuals experience the aging process. The ability to remain active during this process is considered a determinant of QoL, whether in maintaining autonomy and independence, which contributes to performing daily tasks, or conducting social activities such as participating in groups and developing voluntary work.<sup>42</sup>

Therefore, given the current state of scientific knowledge, it appears that the findings of this study innovate by showing a direct and positive effect of the global structural model of active aging on the self-assessment of QoL in a representative sample of older people in the community, supporting discussions of a global public health policy to deal with the challenges of the aging population.<sup>1</sup> Furthermore, the results offer elements to study in the field of gerontology that can provide information that helps in developing and improving its practice, specifically in health care for the older population, to promote active aging and QoL.

This study has a limitation in that it excluded older people with severe cognitive impairment, which may have favored a healthier sample. However, the possibility of selection bias was minimized, as all eligible older individuals were interviewed. Moreover, as a limitation, the non-inclusion of variables related

to culture and sex can act as barriers or facilitators in the active aging process and interfere with subjective measures such as self-assessment of QoL. It is suggested that multicenter studies and national surveys should be conducted with representative samples of the older population in different Brazilian states, including the variables of culture and sex, to improve health care for the elderly and their QoL.

## CONCLUSION

In the self-assessment of QoL, most older adults classified their QoL as good. The highest mean scores were for the social relationships domain and the facets of death and dying, whereas the lowest scores were for physical relationships and social participation. Active aging had a direct and positive effect on the self-assessment of QoL, indicating that the more people actively aged, the better their self-assessment of QoL. Therefore, investigations into the determinants of active aging among older people in the community are relevant to establishing follow-up actions in health services. Additionally, primary care nurses had the most contact with older people. Therefore, identifying these aspects helps reflect actions to promote active aging, considering their effect on the QoL of this age group.

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# Enhancing understanding of SARS-CoV-2 infection among individuals with Down syndrome: An integrative review

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Integrative review.

## ABSTRACT

**BACKGROUND:** Down syndrome (DS) is a non-rare genetic condition that affects approximately 1 in every 800 live births worldwide. Further, it is associated with comorbidities, anatomical alterations of the respiratory tract, and immunological dysfunctions that make individuals more susceptible to respiratory infections.

**OBJECTIVE:** To systematize the current scientific knowledge about the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among individuals with DS.

**DESIGN AND SETTING:** This integrative review was conducted at the Universidade Federal de São Carlos, São Paulo, Brazil.

**METHODS:** This review was conducted in the following databases: the Virtual Health Library (Biblioteca Virtual em Saúde, BVS), PubMed, and Web of Science, using MeSH descriptors. The search included English or Portuguese studies published between January 1, 2020, and October 14, 2022.

**RESULTS:** A total of 55 articles from 24 countries were selected, comprising 21 case-control or cohort studies, 23 case reports or series, and 11 narrative reviews or opinion studies. The articles were grouped into five categories: previous comorbidities, coronavirus disease 2019 (COVID-19) clinical features and evolution, cytokine storm and interleukins, living in institutions as a risk factor, and behavioral actions as a protective factor against SARS-CoV-2 infection.

**CONCLUSION:** Individuals with DS are more susceptible to COVID-19 infection due to variables such as previous comorbidities, immunological factors, and their habitable environments. These aspects confer a higher risk of infection and an unfavorable clinical course. The precise pathways involved in the pathophysiology of COVID-19 in individuals with DS are not clear, thus requiring further studies.

**SYSTEMATIC REVIEW REGISTRATION:** The Open Science Framework registered the research protocol (<https://osf.io/jyb97/>).

## INTRODUCTION

Down syndrome (DS) is a non-rare genetic condition that affects approximately 1 in every 800 live births worldwide.<sup>1</sup> Phenotypically, DS is characterized by intellectual and developmental disabilities, facial dysmorphism, muscular hypotonia, and numerous birth defects, including cardiac and gastrointestinal anomalies.<sup>1,2</sup> Furthermore, individuals with DS have several immune defects, making them more susceptible to autoimmune diseases and infections, especially respiratory tract infections, which represent a relevant cause of mortality.<sup>3-5</sup>

The immune dysregulation in DS results from various factors spanning innate and adaptive systems.<sup>5</sup> There is a decrease in the number of natural killer cells, monocytes, and dendritic cells, in addition to decreased neutrophil chemotaxis. Moreover, thymus hypoplasia leads to significantly reduced T-lymphocyte numbers.<sup>5</sup> There is also a reduced number of all B-cell populations, especially switched memory B cells, which impair the adaptive immune response.<sup>5,6</sup> Additionally, structural alterations in the respiratory system, such as tracheomalacia and laryngomalacia, make it challenging to remove mucus and facilitate the colonization of the respiratory tract by pathogens.<sup>5</sup>

The life expectancy of individuals with DS has increased over the last few decades; nowadays, it exceeds 60 years.<sup>4</sup> In early childhood, congenital heart defects are the principal cause of death while in other stages of life, respiratory infections are the most common. Apart from respiratory diseases, neurological disorders such as dementia represent a risk for mortality in middle age.<sup>1,4</sup>

The SARS-CoV-2 infection has different courses in individuals with DS depending on comorbidities, changes in the immune response to the virus, time of infection, and therapeutic

approaches.<sup>7</sup> The lack of systematized information on how the disease affects this population is a barrier to discussing the specific risk of coronavirus disease 2019 (COVID-19).<sup>8</sup>

## OBJECTIVE

This integrative review aimed to systematize the current scientific knowledge about the behavior of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection among individuals with DS. In particular, to enhance understanding of the subject and identify gaps in the area.

## METHODS

### Research design

This integrative literature review was conducted per the literature<sup>9-11</sup> based on the Preferred Reporting Items for Systematic reviews and Meta-Analyses statement (PRISMA).<sup>12</sup> The research protocol was registered in the Open Science Framework (<https://osf.io/jyb97/>).<sup>13</sup>

Six steps were followed to ensure methodological rigor: (1) elaboration of the research question, selection of the databases, and identification of the descriptors; (2) definition of inclusion and exclusion criteria and search in databases; (3) data extraction from selected studies; (4) critical analysis of the included studies; (5) interpretation and discussion of the data; and (6) presentation of acquired knowledge.<sup>14</sup>

The guiding question of this review was: How is the infection behavior of the SARS-CoV-2 in individuals with DS? This question was designed by the population, intervention, comparison, outcome (PICO) strategy, as detailed in Table 1.<sup>15</sup>

### Search strategy

Literature searches were conducted in three databases: the Virtual Health Library (*Biblioteca Virtual em Saúde*, BVS), PubMed, and

Web of Science. In the BVS, Latin American and Caribbean Literature on Health Sciences (LILACS) databases were accessed, providing access to the Scientific Electronic Library Online (SciELO) database and the Pan American Health Organization Institutional Repository Information Sharing (PAHO-IRIS) database. In PubMed, the MEDLINE database was accessed and in the Web of Science database, the core collection was accessed.

For the search, we defined the following descriptors from the Medical Subject Headings (MeSH): ((47,XX,+21) OR (47,XY,+21) OR (Down Syndrome, Partial Trisomy 21) OR (Down's Syndrome) OR (Mongolism) OR (Partial Trisomy 21 Down Syndrome) OR (Trisomy 21) OR (Trisomy 21, Meiotic Nondisjunction) OR (Trisomy 21, Mitotic Nondisjunction) OR (Trisomy G)) AND ((SARS-CoV-2) OR (SARS-CoV-2 Virus) OR (SARS-CoV-2 Infection) OR (COVID-19) OR (COVID-19 Virus) OR (COVID19) OR (COVID-19 Pandemic) OR (COVID-19 Pandemics) OR (COVID-19 Virus Disease) OR (COVID-19 Virus Infection) OR (2019 Novel Coronavirus) OR (2019 Novel Coronavirus Disease) OR (2019 Novel Coronavirus Infection) OR (2019-nCoV) OR (2019-nCoV Disease) OR (2019-nCoV Infection) OR (Coronavirus Disease 2019) OR (Coronavirus Disease-19) OR (Coronavirus Disease 2019 Virus) OR (SARS Coronavirus 2 Infection) OR (SARS Coronavirus 2)) AND ((Cytokines) OR (Cytokine) OR (Pneumonia, Viral) OR (Risk Factors) OR (Health Correlates) OR (Population at Risk) OR (Populations at Risk) OR (Comorbidity)).

Two independent authors performed the searches on the databases. The compatibility of the material found was checked and then entered into the Rayyan software (Cambridge, United States, <https://www.rayyan.ai/>). Duplicate studies were identified and excluded using Rayyan. Title and abstract screening were applied to identify relevant studies in blind mode by two reviewers. When there was disagreement or doubt, a third reviewer was consulted. Finally, the articles were selected after a consensus discussion. The selected studies were read in their entirety. Further, with the help of the eligibility criteria, they were included or excluded from this review.

### Eligibility criteria

This review included papers published in English or Portuguese between January 1, 2020, and October 14, 2022. Manuscripts that discussed the infection of SARS-CoV-2 in individuals with DS, regardless of the methodology and type of study, were included. The exclusion criteria were: articles without adherence to the theme; not involving humans; in different languages; and duplicated texts in the databases.

### Data extraction and quality assessment

Data from the selected studies were extracted using a form (Supplemental file available at <https://doi.org/10.6084/m9.figshare.21277452.v4>),<sup>16</sup> which made it possible to summarize

**Table 1.** Research question following PICO parameters

<b>P</b>	Population	Who was studied?	Individuals with Down syndrome
<b>I</b>	Intervention	What happened?	Infection by SARS-CoV-2
<b>C</b>	Comparison	Comparison between populations	Individuals without Down syndrome
<b>O</b>	Outcome	What is the prognostic?	Down syndrome influences clinical infection caused by COVID-19, assessed by outcomes such as infection rates, morbidity, hospital admission, ICU stay, duration of hospital stay, mortality, complications, sequelae, etc.

COVID-19 = coronavirus disease 2019; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; ICU = intensive care unit.

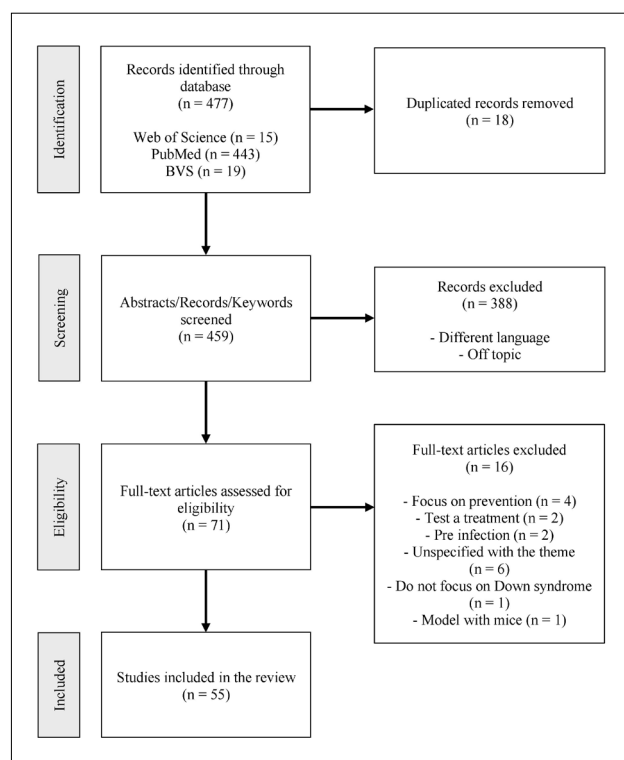
the information, verify the validity of the studies, and identify the relationships in the data. The following information was collected: authors, country of origin or year of publication, journal, study method, main results, and study conclusions.

The quality of the studies was evaluated and categorized by the level of evidence using the following criteria, modified from Melnyk and Fineout-Overholt:<sup>17</sup> I – a systematic review with meta-analysis of randomized controlled trials; II – randomized controlled trial; III – non-randomized controlled trial; IV – case-control or cohort study; V – a systematic review of descriptive or qualitative studies; VI – descriptive or qualitative study (including case reports and case series); VII – narrative review or expert opinion.

The authors reviewed the final studies independently and then worked collaboratively to establish the discussed categories. This inductive categorization allowed us to identify the main themes from the articles' results.<sup>18</sup>

## RESULTS

A total of 477 studies were identified in the databases in the initial search. After applying the eligibility criteria, 55 manuscripts were selected for this review. The selection process and exclusion reasons are described in Figure 1. The articles included were named A1 through A55.



**Figure 1.** The flow of the selection process of articles of this integrative review.

The selected articles are described in Table 2, which summarizes their location of origin, type of study, and level of evidence. The studies were conducted in 24 different countries. The United States of America (USA) comprises the highest number of studies (n = 16), followed by Brazil (n = 9), Spain (n = 8), and Italy (n = 6). We did not find studies with evidence levels I, II, III, or V. All 55 selected studies consisted of a case report or case series, cohort, case-control, review, or expert opinion with evidence levels IV, VI, and VII, respectively.

We organized these 55 manuscripts per the similarity of data and themes, grouping them into five categories as reported in Table 3. The categories represent elementary DS-related issues and changes resulting from the SARS-CoV-2 infection. Some studies were included in more than one category.

## DISCUSSION

Different features, such as previous biological features, interactions with the environment, and behavior patterns, have been described as modifiers of risk and outcome for SARS-CoV-2 infection in patients with DS.

### First category: Previous comorbidities in individuals with Down syndrome

Six main comorbidities directly or indirectly interfered with the clinical course of SARS-CoV-2 infection in individuals with DS: dementia, epilepsy, heart defects, sleep apnea, obesity, and thyroid pathologies.<sup>7,19-42</sup>

Higher dementia rates were observed in individuals with DS and COVID-19, when compared with individuals with COVID-19 without DS<sup>19,21,38</sup> and individuals with DS and respiratory infections caused by other etiologies.<sup>37</sup> Illouz et al.<sup>31</sup> described a change in the endocytosis process in individuals with DS related to some genes located on chromosome 21, including *Amyloid Beta Precursor Protein (APP)*, known to mediate dementia in these individuals. This gene is also involved in viral trafficking, changing endosomal fusion, which may be one factor that favors a higher risk of COVID-19 in individuals with DS and dementia.<sup>31</sup>

Epilepsy was a relevant comorbidity in individuals with intellectual disability and COVID-19,<sup>21</sup> and it was more common in individuals with DS.<sup>7,19,25,30,37</sup> It was indirectly associated with an unfavorable outcome related to other comorbidities and care challenges.

Heart defects were recurrent in DS individuals with COVID-19, mainly in the pediatric age group.<sup>20-24,26-29,35,36,40-45</sup> Children with DS seem more likely to be exposed to severe COVID-19 than those without DS.<sup>46</sup>

Simpson et al.<sup>24</sup> presented a case series of seven children, three of whom had DS, a heart defect, and COVID-19. In addition to the corrected tetralogy of Fallot, one of these infants had hypothyroidism and obstructive sleep apnea and died 2.5 months after a SARS-CoV-2

**Table 2.** Characterization and evidence level of studies included in this review

Article	Authors/Year	Location	Type of study	Evidence level	Number of individuals with DS and COVID-19
A1	Malle et al. (2021) <sup>19</sup>	USA	Case-control	IV	12
A2	El Kaouini et al. (2021) <sup>30</sup>	Morocco	Case report	VI	2
A3	De Cauwer and Spaepen (2021) <sup>65</sup>	Belgium	Case series	VI	4
A4	Dard, Janel and Vialard (2020) <sup>70</sup>	France	Expert opinion	VII	0
A5	Wadman (2020) <sup>71</sup>	USA	Expert opinion	VII	1
A6	Del Carmen et al. (2020) <sup>75</sup>	Spain	Expert opinion	VII	0
A7	Kantar et al. (2020) <sup>36</sup>	Italy	Case report	VI	2
A8	Real de Asua et al. (2021) <sup>37</sup>	Spain	Cohort	IV	86
A9	Russo et al. (2020) <sup>74</sup>	Brazil	Expert opinion	VII	0
A10	Babamahmoodi et al. (2020) <sup>66</sup>	Iran	Case report	VI	2
A11	Villani et al. (2020) <sup>38</sup>	Italy	Case series	VI	16
A12	Robayo et al. (2021) <sup>39</sup>	Colombia	Case report	VI	1
A13	Khoshnood et al. (2021) <sup>40</sup>	USA	Case report	VI	1
A14	Vita et al. (2021) <sup>7</sup>	Italy	Case report	VI	2
A15	Altable and de la Serna (2021) <sup>67</sup>	Spain	Narrative review	VII	0
A16	Kim-Hellmuth et al. (2021) <sup>41</sup>	Germany	Case report	VI	1
A17	Krishnan et al. (2020) <sup>42</sup>	USA	Case series	VI	3
A18	Emami et al. (2021) <sup>20</sup>	Iran	Case-control	IV	18
A19	Clift et al. (2021) <sup>21</sup>	UK	Cohort	IV	4,053
A20	Newman et al. (2021) <sup>22</sup>	USA	Case series	VI	4
A21	Stefanuto et al. (2021) <sup>23</sup>	Brazil	Case report	VI	1
A22	Simpson et al. (2020) <sup>24</sup>	Georgia	Case series	VI	3
A23	Perera et al. (2020) <sup>25</sup>	England and Ireland	Case series	VI	20
A24	Oyanagi et al. (2021) <sup>26</sup>	Japan	Case report	VI	1
A25	Malle et al. (2021) <sup>27</sup>	USA and Spain	Case report	VI	2
A26	Huls et al. (2021) <sup>28</sup>	USA, UK, Brazil, Italy, Spain, France, India	Case-control	IV	1,046
A27	Alsahabi et al. (2021) <sup>29</sup>	Saudi Arabia	Case report	VI	1
A28	Landes et al. (2021) <sup>72</sup>	USA	Cohort	IV	20
A29	De Toma and Dierssen (2021) <sup>53</sup>	Spain	Narrative review	VII	0
A30	Hippisley-Cox et al. (2021) <sup>63</sup>	England	Cohort	IV	3,963*
A31	Williamson et al. (2021) <sup>55</sup>	England	Cohort	IV	341
A32	Semenzato et al. (2021) <sup>56</sup>	France	Cohort	IV	256
A33	Santos et al. (2020) <sup>64</sup>	Brazil	Cohort	IV	73
A34	Bergman et al. (2021) <sup>57</sup>	Sweden	Case-control	IV	85
A35	Illouz et al. (2021) <sup>31</sup>	Israel	Cohort	IV and VI	20
A36	Illouz et al. (2021) <sup>68</sup>	Israel, USA, Spain, Canada, Switzerland.	Narrative review	VII	0
A37	Espinosa (2020) <sup>51</sup>	USA	Narrative review	VII	0
A38	Ma et al. (2021) <sup>49</sup>	USA	Case report	VI	1
A39	Amin et al. (2022) <sup>32</sup>	Bangladesh	Case report	VI	1
A40	Baksh et al. (2022) <sup>33</sup>	UK	Cohort	IV	651
A41	Boschiero (2022) <sup>58</sup>	Brazil	Cohort	IV	5,152
A42	Emes et al. (2021) <sup>46</sup>	USA, UK, Brazil, Italy, Spain, France, India, Germany	Cohort	IV	328
A43	Evangelho et al. (2022) <sup>54</sup>	Brazil	Expert opinion	VII	0
A44	Kobayashi et al. (2022) <sup>43</sup>	Japan	Case report	VI	1
A45	Koyama et al. (2022) <sup>62</sup>	USA	Cohort	IV	1,412
A46	Ku et al. (2022) <sup>59</sup>	USA	Cohort	IV	142
A47	Kuczborska, Buda and Ksiazek (2022) <sup>44</sup>	Poland	Case Report	VI	1
A48	Pinku et al. (2022) <sup>34</sup>	UK, India	Cohort	IV	1,272
A49	Shi et al. (2022) <sup>60</sup>	Scotland	Cohort	IV	79
A50	Silva et al. (2022) <sup>35</sup>	Brazil	Case series	VI	3
A51	Lunsky et al. (2022) <sup>61</sup>	Canada	Cohort	IV	121
A52	Majithia and Ribeiro (2022) <sup>50</sup>	USA	Expert opinion	VII	0
A53	Magalhães et al. (2022) <sup>45</sup>	Brazil	Case-control	IV	7
A54	Parasini et al. (2022) <sup>52</sup>	Italy	Case series	VI	6
A55	Atkinson et al. (2022) <sup>69</sup>	USA	Expert opinion	VII	0

DS = Down syndrome; COVID-19 = coronavirus disease 2019; UK = United Kingdom; USA = United States of America.

\*The number refers to all individuals with DS in the study, not just those with COVID-19.

infection.<sup>24</sup> The other cardiopathies mentioned were primarily septal defects that were associated with severe infection and prolonged hospitalization.<sup>24,26,27,36,40–42,44</sup> Some studies stated whether the heart defect was surgically corrected, while others did not, making it difficult to conclude if surgical treatment of the heart disease changes the natural progression or outcome of the COVID-19 disease.

Sleep apnea was a comorbidity associated with obesity and heart disease and was also prevalent in the pediatric age group.<sup>22,24,36,40,42</sup> Apnea has been linked to a more severe course of COVID-19, ventilatory support, prolonged hospitalization, and death.<sup>24,36,42</sup>

Hypothyroidism was persistent,<sup>7,19,24,32,35,38,39</sup> Malle et al.<sup>19</sup> demonstrated a 50% prevalence among patients with DS hospitalized due to COVID-19. Despite this, thyroid disease did not appear to have played a direct role in the progression of COVID-19.<sup>19</sup>

Primary data revealed a worse prognosis in patients with more than one comorbidity. The cohort study by Pinku et al.<sup>34</sup> suggested that individuals with DS from low-income countries may have more comorbidities due to structural socioeconomic inequality.

Among the comorbidities, dementia plays an important role, due to its frequent association with other disorders. Interestingly, dementia and epilepsy had already been associated with complications of recurrent infections and premature death even before the COVID-19 pandemic.<sup>47</sup> In a cross-sectional study comprising 878 adults with DS over 45 years old, Bayen et al.<sup>48</sup> reported a 40% prevalence of dementia. It revealed that individuals with DS and dementia had more comorbidities than those without dementia and younger individuals. In particular, four treatable conditions – hypothyroidism, epilepsy, anemia, and weight loss – were more frequent in individuals with DS and dementia.<sup>48</sup>

**Second category: Clinical features and evolution of SARS-CoV-2 infection in individuals with Down syndrome**

Although the main clinical manifestations of COVID-19 infection in individuals with DS are similar to those in other individuals,

i.e., respiratory distress, fever, cough, and muscle pain,<sup>20</sup> the literature suggests that individuals with DS may have a distinct initial clinical presentation of COVID-19,<sup>22,26,38,39,43,49,50</sup> showing atypical symptoms such as hemoptysis, vomiting, diarrhea, abdominal pain, and autoimmune manifestations.<sup>22,26,38,43,49</sup> Additionally, unusual symptoms such as arrhythmia can be caused by underlying pathologies and mask the presence of respiratory symptoms.<sup>24,26</sup> These unusual symptoms were not directly related to a more severe course of COVID-19. Nonetheless, it can be associated with a delay in diagnosis and treatment, potentially resulting in worse outcomes.

Callea et al.<sup>8</sup> created a series of health education activities for individuals with DS and their families, emphasizing the importance of recognizing typical and atypical symptoms and notifying suspected cases to the health team. Furthermore, the same group developed protocols for healthcare professionals, with guidance on testing and managing COVID-19 in individuals with trisomy 21.<sup>8</sup>

One study described SARS-CoV-2 and tuberculosis coinfections,<sup>23</sup> in which the latter was diagnosed during hospitalization despite the individual having classic symptoms and having been in contact with a sibling already treated for tuberculosis. Furthermore, bacterial coinfections were prevalent complications in individuals with DS and COVID-19 and were described as the leading cause of death.<sup>21,28,35,38,51,52</sup> Through genetic bioinformatics analysis, De Toma and Dierssen<sup>53</sup> mapped the transcriptomic changes induced by trisomy 21 in pathways and proteins known to be affected by SARS-CoV-2, identifying risk factors for COVID-19 at different stages of infection.<sup>53</sup> The presence of the tripled *transmembrane protease serine 2* gene (*TMPRSS2*), located on chromosome 21, including an elevation of the bradykinin B1 receptor during the initial phase of the viral invasion, is related to angiotensin converting enzyme 2 (ACE-2). ACE-2 binds the viral protein S, facilitating viral entry into the host cell. This predisposes individuals with DS to severe acute respiratory syndrome.<sup>53,54</sup> Subsequently,

**Table 3.** Characterization of categories and studies included in each of them

Categories	Description of the category	Articles
1. Previous comorbidities in individuals with DS	It connects previous comorbidities in individuals with DS, such as seizures, dementia, heart defects, obesity, hypothyroidism, and apnea, with the SARS-CoV-2 infection.	A1, A2, A7, A8, A11, A12, A13, A14, A16, A17, A18, A19, A20, A21, A22, A23, A24, A25, A26, A27, A35, A39, A40, A42, A44, A47, A48, A50, A53.
2. Clinical features and evolution of SARS-CoV-2 infection in individuals with DS	It identifies symptoms related to COVID-19 in individuals with DS, the natural history of the disease, the occurrence of coinfections, and the outcomes in these individuals.	A1, A7, A11, A12, A13, A18, A19, A20, A21, A22, A24, A26, A29, A30, A31, A32, A33, A34, A37, A38, A39, A41, A43, A44, A45, A46, A49, A50, A51, A52, A54.
3. Cytokine storm, interleukins, and other laboratory changes	It identifies immunological dysfunctions in individuals with DS and COVID-19.	A2, A3, A10, A12, A15, A16, A25, A29, A36, A37, A39, A47, A50, A52, A55.
4. Living in institutions as a risk factor	It addresses the more severe course of SARS-CoV-2 infection in individuals with DS living in institutions.	A4, A5, A23, A28, A40.
5. Behavioral actions as a protective factor against SARS-CoV-2 infection	It shows that specific behavioral patterns in individuals with DS may be a protective factor against infection by SARS-CoV-2.	A6, A9.

SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; DS = Down syndrome; COVID-19 = coronavirus disease 2019.

in the immunopathogenesis of the disease, the authors detected negative regulation of the *NLR family pyrin domain containing 3* gene (*NLRP3*), which is involved in the immune system and is critical in maintaining homeostasis against infections. This would hypothetically contribute to the co-occurrence of viral and bacterial infections.<sup>53</sup>

Individuals with DS were four times more likely than the general population to acquire the SARS-CoV-2 infection.<sup>21</sup> They had a more severe clinical course and required more hospitalization<sup>52,55-61</sup> and intensive care unit (ICU) treatments.<sup>28,58,61,62</sup> Hüls et al.,<sup>28</sup> in a multicenter retrospective study involving 1,046 individuals with DS and COVID-19, showed a hospitalization rate of 56%, in which 50% were in the ICU. In a sample comprising 12 individuals with DS, Malle et al.<sup>19</sup> described sepsis in 10 patients (83%). Post-infectious conditions such as Kawasaki disease<sup>36</sup> and multisystem inflammation syndrome (MIS-C)<sup>40</sup> were observed in two pediatric patients. SARS-CoV-2 infection severity may be related to long COVID-19 or post-COVID conditions.<sup>32,50</sup>

The risk of mortality was also higher.<sup>21,56,59,61,63,64</sup> In the cohort study by Semenzato et al.,<sup>56</sup> involving 87,809 individuals hospitalized for COVID-19 and 256 individuals with DS, the chromosomal condition was the main factor associated with the risk of hospitalization and hospital mortality, ahead of five other comorbidities: intellectual disability, lung transplantation, kidney transplantation, end-stage renal disease, and lung cancer.<sup>56</sup> Similarly, in a cohort study carried out with the Brazilian population involving 73 individuals with DS and COVID-19 who died, Santos et al.<sup>64</sup> reported a 32% drop in the survival rate between five and 10 days of hospitalization, demonstrating that trisomy and length of hospital stay impacted the mortality. In a cohort study involving 4,053 patients with DS and COVID-19, Clift et al.<sup>21</sup> estimated a mortality rate 10 times greater than that of the general population. Hippisley-Cox et al.<sup>63</sup> showed a 12.7-fold more significant risk of death in those with trisomy in a sample of vaccinated individuals that included 3,963 individuals with DS.

It is essential to consider that most of the literature data come from hospital statistics. Individuals with a milder clinical course who remain at home during the infection are frequently overlooked. Consequently, the community's epidemiological picture of the illness is not fully covered.

### Third category: Cytokine storm, interleukins, and other laboratory changes

Elevated levels of inflammatory markers such as interleukin (IL)-6, IL-8, interferon (IFN), tumor necrosis factor (TNF), C-reactive protein, D-dimer, and lactate dehydrogenase were found in individuals with DS and COVID-19.<sup>27,30,35,39,41,44,51,65-67</sup> Individuals with DS tended to have a higher early initial response to infection, especially through the action of IFNs, which could theoretically

contain the viral spread. However, it is known that the coronavirus family, in general, has developed strategies to evade the effects of IFN, which probably also occurred with SARS-CoV-2.<sup>32,51,68</sup>

During the illness, individuals with DS often experience a cytokine storm influenced by viral action. De Toma and Dierssen<sup>53</sup> described the elevation of chemokines, specifically CXCL10, which, through stimulation of monocytes and IL-10, recruits fibrocytes and aids in the activation of macrophages, facilitating lung damage such as fibrosis and leads to a more severe manifestation of the disease. As chromosome 21 encodes four of the six types of interferon receptors, an extra copy of this chromosome can result in higher plasma levels of interferons.<sup>32,50</sup>

Altable and de la Serna<sup>67</sup> reported that changes in the levels of pro-inflammatory cytokines in individuals with DS could fluctuate with age, directly influencing the exacerbation of the immune response. There would be an immunodeficiency during childhood, resulting in a diminished pro-inflammatory response with lower levels of pro-inflammatory cytokines such as IL-2. Conversely, adults would experience the opposite scenario, with higher IL-2, IL-6, and TNF- $\alpha$  levels amplifying the inflammatory response. In both profiles, unfavorable factors seem to be associated with DS individuals: in childhood, they are more vulnerable to infection owing to immunodeficiency. However, in the adult stage, once infected, the increased immune response predisposes them to a worse prognosis.

Babamahmoodi et al.<sup>66</sup> reported two cases of adult individuals with DS and COVID-19: one patient had higher levels of IL-6 and died in three days due to respiratory failure, while another patient had lower IL-6 values and, despite developing severe COVID-19, had a favorable outcome.

High levels of inflammation seem to predispose to more severe disease and affect vaccine response in these individuals, proving to be a risk factor in the COVID-19 protection of individuals with DS and requiring greater attention to the doses and security measures.<sup>50,69</sup>

### Fourth category: Living in institutions as a risk factor

Considering that some individuals with DS live in communities or institutions, this population has been assigned as a COVID-19 risk group due to the ease of viral transmission.<sup>25,33,70,71</sup> More populated places seem to be associated with higher infection rates.<sup>70</sup> In a cohort of 543 individuals with intellectual disabilities, 56 of whom had DS, the trisomy of 21 represented a higher risk for COVID-19 infection.<sup>72</sup>

The demographic profile of institutionalized individuals with DS has been described as slightly different from that of individuals with intellectual disabilities due to other etiologies. Individuals with trisomy are usually younger and more likely to have dementia, hearing loss, or be overweight.<sup>73</sup> These variables might be linked to a higher vulnerability to COVID-19.

### Fifth category: Behavioral actions as a protective factor against SARS-CoV-2 infection

Since the COVID-19 pandemic started, behavioral actions have been a vital tool to prevent infection by SARS-CoV-2. In this context, Russo et al.<sup>74</sup> described positive results by using educational activities developed by organizations that support individuals with DS and conducted by multi-professional teams during the pandemic. Support strategies centered on the individual with DS and their caregivers, as well as healthy eating and physical activity habits, were shown to be fundamental approaches for COVID-19 prevention in the DS population.<sup>74</sup>

In the same direction, Del Carmen et al.<sup>75</sup> noted that individuals with DS have cognitive traits, such as constancy, tenacity, and a tendency to imitate and repeat behavior, that is interiorized and encourages them to commit to proposed tasks. Therefore, the fact that individuals with DS show easy adherence to behaviors, combined with good actions, may be an essential strategy to disseminate protective factors against SARS-CoV-2 infection. This could be linked to a significant decline in infections in individuals with DS following the first wave when numerous preventative measures had already been disseminated. These concepts cannot be applied to individuals with DS with a severe or profound intellectual deficit or dementia, which may explain why dementia appeared as an essential factor at risk.<sup>75</sup>

### Study limitations

This study has some limitations. Most selected articles have a low level of evidence, and no clinical trials or meta-analyses were found. Furthermore, the review includes publications published until October 14, 2022, and studies published after that were not included.

### CONCLUSIONS

This integrative review allowed us to identify studies that address the behavior of SARS-CoV-2 infection in individuals with DS. This population's susceptibility to COVID-19 illness is associated with predisposing factors such as previous comorbidities, particularly dementia, immunological dysfunctions, and environmental issues. This may confer a higher risk of infection and an unfavorable clinical course.

The precise pathways involved in the pathophysiology of COVID-19 in individuals with DS are still unclear. Future research developed with different methods—for instance, experimental and clinical studies—may lead to a better understanding of this issue.

Vaccination is currently the most effective strategy to prevent contamination by COVID-19 and its unfavorable outcomes among individuals with DS, as well as in the general population. Maintaining good hygiene by cleaning the hands regularly and thoroughly disinfecting surfaces frequently, especially those often

touched, such as door handles, faucets, and phone screens is important. Environmental measures such as avoiding spaces that are closed, crowded, or involve close contact should also be encouraged. To improve ventilation at home or school, it is recommended to bring in as much outdoor air as possible, for example, by opening windows; increasing air filtration in the heating, ventilation, and air conditioning systems by changing filters frequently and using filters that are properly fitted and provide higher filtration; using portable high-efficiency particulate air cleaners; and turning on exhaust fans or using other fans to improve airflow. Appropriate use of masks should still be considered in settings with multiple exposure risks.

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# Chronic pain among older adults and its impact on satisfaction with social participation: development and validation of the “Instrument to Assess Older Adults’ Social Participation”. A descriptive quantitative study

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## ABSTRACT

**BACKGROUND:** We aimed to develop and validate a practical instrument to assess older adults’ satisfaction with their social participation (SP).

**DESIGN AND SETTING:** This methodological validation study was conducted at a public higher education institution.

**METHODS:** A two-phase study was designed, developed, and validated to assess older adults’ satisfaction with their SP. In the first phase, we conceptualized SP and developed an “instrument to assess older adults’ satisfaction with their SP (IAPSI),” as approved by a committee of specialists, pre-tested, and partially validated. Second, we determined the IAPSI’s reproducibility using Cronbach’s alpha to measure internal consistency, Pearson’s and Spearman’s coefficients to measure correlations, the Bland-Altman plot and intraclass correlation coefficient (ICC) to measure reproducibility. We also generated a receiver operating characteristic (ROC) curve.

**RESULTS:** 102 older adults (mean age, 87.29) participated in the first phase. Moderate internal consistency (Cronbach’s alpha 0.7) and significant moderate correlations with quality of life by World Health Organization Quality of Life (WHOQOL)-bref and by WHOQOL-old social domains (Pearson’s coefficients 0.54 and 0.64, respectively;  $P < 0.001$ ) were found. The ROC curve indicated an IAPSI score of 17 as the threshold for the impact of pain on satisfaction with SP (83.3% sensitivity and 88.9% specificity,  $P < 0.001$ ). In the second phase, 56 older adults (between 81 and 90 years old) participated. We found adequate intra- and inter-observer reproducibility for the IAPSI (ICC 0.96 and 0.78, respectively).

**CONCLUSION:** We have developed a practical instrument with appropriate psychometric properties to assess older adults’ satisfaction with their SP.

## INTRODUCTION

Population aging is a worldwide reality, with several factors able to prevent this process from unfolding in an active and healthy way. The presence of pain can affect the physical, psychological, and social functions of older adults as well as their quality of life and must be recognized as a relevant problem for these individuals.<sup>1</sup>

Chronic pain is highly prevalent among older adults, affecting nearly 50% of those who live in the community and 80% of those who live in long-stay institutions.<sup>2</sup> Because this prevalence is so high, numerous severe and potentially debilitating consequences develop in the aging process in addition to greater health care expenses.<sup>3</sup>

Therefore, it is necessary to acquire knowledge about the impact of chronic pain among older adults. Consequently, it is important to consider the social aspects of these effects. A bidirectional relationship between chronic pain and social participation has been reported. The presence of chronic pain was found to have a negative impact on various social aspects, with these aspects also having a negative impact on pain, both resulting in unfavorable health consequences.<sup>4</sup>

Social participation during the aging process is a crucial topic and should be highly encouraged given that the current concept of health goes beyond questions regarding “diseases.”<sup>5</sup>

The scientific literature has not yet provided a well-defined consensus on older adults' social participation, which is a complex multidimensional process. Some authors argue that, from a social psychology perspective, individuals' social participation should conceptually include the time dedicated to social experiences and the time spent in the presence of others.<sup>6</sup>

If we consider the impact of chronic diseases and their treatments on quality of life, measuring older adults' degree of satisfaction with their social participation can provide relevant information.<sup>7</sup> Some instruments have already been proposed for such measures, but they derive mainly from a health perspective and address domains of self-care and mobility.<sup>6</sup> The Patient-Reported Outcomes Measurement Information System is one example, and there is already a Brazilian version with sets of items related to "Satisfaction with Participation in Social Roles" (14-items) and "Satisfaction with Participation in Discretionary Social Activities" (12-items). Although comprehensive, these methods do not offer clinical practicality.<sup>8</sup>

Thus far, we have not found an available measuring instrument throughout the extant body of literature that assesses social participation exclusively among the older adult population or any tools that assess these individuals' satisfaction with their social participation. We considered the possibility of assessing older adults' satisfaction with their social participation and applied this assessment to older adults with chronic pain.

## OBJECTIVE

We aimed to develop and validate a construct for this purpose by presenting a measuring instrument to assess older adults' satisfaction with social participation. This will allow us to understand the potential impact of chronic pain on their (that of older individuals) satisfaction with social participation.

## METHODS

This study has been methodologically validated. The methodology involved validating a prepared instrument and was conducted in two stages with approval from a Research Ethics Committee (**Figure 1**): **stage one** – the development and assessment of the reliability of a measuring instrument to assess older adults' satisfaction with their social participation (Certificate of Presentation of Ethical Appreciation:05444918.0.0000.5505, approval date December 4, 2021); **stage two** – an assessment of the reproducibility of the instrument to assess older adults' satisfaction with their social participation (IAPSI) among older adults with chronic pain (Certificate of Presentation of Ethical Appreciation:26467219.7.0000.5505, approval date January 16, 2020).

### Developing the instrument

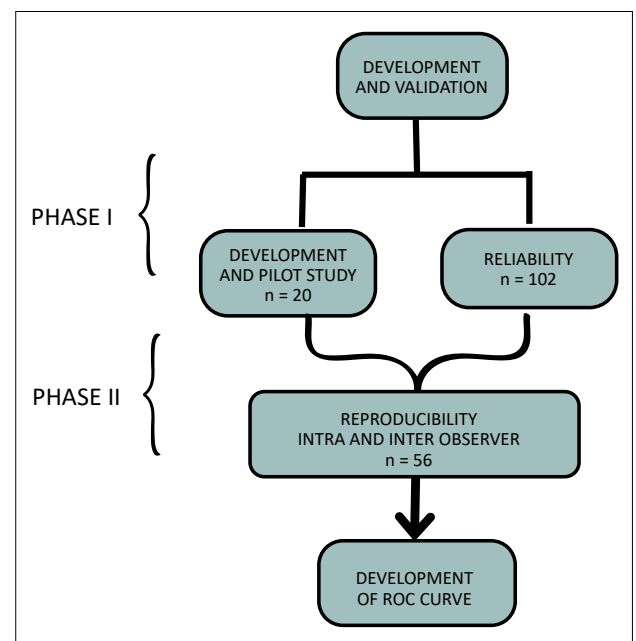
We developed a construct based on the handbook of procedures for "developing measuring instruments," suggested by Kline.<sup>9</sup>

This handbook refers to three phases: 1) Theoretical foundation – this instrument was based on a narrative bibliographic review of the topic "older adults' satisfaction with their social participation"; 2) Formulation of items for a simple construct – a process that involved preparing questions related to satisfaction with social participation in the aging process, which should include terms understood by older adults; 3) Preliminary analysis of the difficulties in understanding the formulated questions – a phase that required the participation of invited judges, i.e., a consensual judgment by a committee of experts on the subject matter was necessary, which was formed by six experienced specialists in different areas of health, namely social work, nursing, physical therapy, psychology, geriatrics, and algology.

For the theoretical foundation phase, we searched the LILACS and MEDLINE databases for publications in Portuguese and English using the index terms "social participation" and "older adult" over the preceding ten years. We also searched for references to chronic pain and its social aspects in older adults.

To formulate the items for the intended construct, we selected topics that had the best potential to translate "satisfaction with social participation among older adults" that could also have the potential to interact with the presence of pain. Thus, we developed a comprehensive questionnaire with short answers based on a 5-point Likert-type scale ("very dissatisfied", "dissatisfied", "neither satisfied nor dissatisfied", "satisfied", and "very satisfied").

The committee of invited specialists judged several aspects of the construct under development, covering aspects of: clarity, representativeness, and comprehensiveness of the questions; formatting



**Figure 1.** Diagram of the manufacturing process of development and validation.

of the established items; instructions regarding possible answers; and selection of the construct's main domains. After the judging committee pre-approved this construct, a pretest was conducted.

For the pre-test phase, we randomly selected 20 participants of both sexes who were 60 years or older and who were receiving care at a geriatrics and gerontology outpatient unit that provides public services in the city of São Paulo. All the participants provided written informed consent.

We assessed participants' potential difficulties in understanding the questions and their answers. After the pre-test phase, the judging committee issued another opinion for the final approval of the "Instrument to Assess Older Adults' Social Participation" (IAPSI) (**Appendix 1**).

We established that the items for the IAPSI should be arranged in four major domains of older adults' social participation: domestic life (household chores), community life (community events and means of transportation), interpersonal relationships (friends, family), and free time (spare time after satisfying all needs, leisure activities, and hobbies). We also determined that the construct would have only five items (one for domestic life, two for community life, one for interpersonal relationships, and one for free time) and that each would have five response options (a total of 25 responses).

With the judging committee's final approval, we have already obtained an important type of validity for a measuring instrument, "content validity," which is related to evaluating a measuring tool's representativeness with respect to the universe of content.<sup>10</sup>

### Reliability of the Measuring Instrument

The psychometric property of reliability refers to the consistency of a construct, which can be of three types: internal consistency (correlation between items), reproduction with a test-retest by the same observer (intraobserver reproducibility), and reproduction involving different observers (interobserver reproducibility).<sup>11</sup>

### Internal consistency assessment and validation

For these assessments, we randomly recruited adults of both sexes who were 60 years old or older and who were receiving care at a geriatrics and gerontology outpatient unit that provides public services in São Paulo. We adopted non-probability, casuistic, convenience sampling, involving individuals who wanted to participate in the study.

Those selected met the established criteria, and all signed an Informed Consent Form. The inclusion criterion required that participants receive regular follow-up care at the aforementioned outpatient unit. The exclusion criteria included older adults who presented with cognitive decline, as defined by a score in the Mini-Mental State Examination that is below the expected score for the individual's level of education, or with neoplasm-related pain, or who had been hospitalized in the last three months.

A semi-structured questionnaire with sociodemographic (age, sex, race/ethnicity, and marital status) and clinical data was administered individually. The latter data referred to older adults' personal perception of their health ("excellent", "good", "regular", and "bad"), presence of chronic pain (duration of six months or more), and pain intensity according to the verbal numerical rating scale (vNRS) (classification: 1–3 for mild pain; 4–6 for moderate pain; and 7 or more for severe pain).

At the same time, we applied two instruments to assess older adults' functionality in daily living, the Katz and Lawton scales, which relate to capabilities in basic and instrumental activities of daily living, respectively, and two instruments that are widely used to assess quality of life, the World Health Organization Quality of Life (WHOQOL)-bref and WHOQOL-old (only the social participation domain of the latter).<sup>12,13</sup> Finally, we applied the IAPSI and recorded its application time.

This process allowed us to evaluate the internal consistency of IAPSI and to obtain its "criterion validity," an "operationally defined" property, one of the most crucial steps in the validation of measuring instruments. This refers to the degree in which an instrument's operationalization is similar to others, stipulating that they should be similar.<sup>11</sup> This type of validity involves comparisons between the measuring instrument and a "gold standard" assessment. However, when such comparisons cannot be made, sometimes as a result of the absence of a gold standard, routine clinical parameters are used. Here, we obtained convergent criterion validity based on the correlations between the IAPSI and quality of life according to the WHOQOL-bref and the social domain of the WHOQOL-old.

### Reproducibility assessment

This assessment was performed in the second stage of the study, and the sample size was calculated by considering a maximum sampling error of 10% (ideally, it would be less than 5%; however, we considered the difficulties in data collection and the application of the instruments, especially the application of the IAPSI, which should be applied on two different days). With a 95% confidence level, we considered two aspects: the estimated number of older adults who regularly received care at the geriatrics and gerontology outpatient clinic at the Universidade Federal de São Paulo (approximately 1,600 patients) and the prevalence of chronic pain among these individuals, which would be approximately 20% according to the international literature and an observational study conducted in the aforementioned outpatient unit,<sup>14,15</sup> and determined a sample size of 55 participants.

In this phase, we initiated a new random recruitment of older adults of both sexes who were 60 years or older and who had received care at the same outpatient unit in the first phase of the study. The inclusion criteria were participants who experienced

chronic pain (duration of six months or more) of different etiologies with a minimum intensity of three, according to the vNRS, and were motivated to participate in this stage, which required their involvement in assessments on two different days. All the participants signed an Informed Consent Form. We excluded those who presented with cognitive decline, as defined by a score on the Mini-Mental State Examination that is below the expected score for the individual's level of education, or with neoplasm-related pain or those who had been hospitalized in the last three months.

We gathered demographic (age, sex, and race/ethnicity) and clinical data and referred to pain based on its intensity using the vNRS and its multidimensionality using the "Geriatric Pain Measure" (GPM). The latter instrument exclusively considers sensory-discriminative, affective-motivational, and cognitive-evaluative aspects of pain in older adults (classification: mild pain – 1–29; moderate – 30–69; severe – 70–100).<sup>16</sup>

To determine IAPSI's reproducibility of the IAPSI, we applied it three different times: on two different occasions in the initial assessment by two trained interviewers who made separate assessments (inter-observer reproducibility) and after 15 days, when the participants returned for another application of the IAPSI by only one of the interviewers involved (intra-observer reproducibility).

### Statistical analysis

IBM SPSS Statistics version 17 (Chicago, United States) and Microsoft Excel 2010 (Washington, United States) were used for the data analysis. Quantitative (mean and standard deviation) and qualitative variables were examined according to the Equality of Two Proportions tests. We determined IAPSI's internal consistency via Cronbach's alpha, and its associations with pain (vNRS and GPM), quality of life (WHOQOL-bref), and the social domain (WHOQOL-old) using Pearson's coefficient. We used Spearman's correlation for the correlations between the IAPSI and pain (ENV), WHOQOL-bref, and the social domain of the WHOQOL-old. We created a receiver operating characteristic (ROC) curve with the data from stage one of the study based on pain (intensity) and the cut-off point for overall quality of life of less than 60 by the WHOQOL-BREF, which demonstrated excellent sensitivity and a negative predictive value for the screening of older adults who probably had a worse quality of life.<sup>17</sup> We used the Bland-Altman plot and the intraclass correlation coefficient (ICC) to determine inter- and intra-observer agreement and established a 5% significance level.

### RESULTS

The development of the instrument culminated in a construct that was easily understood by older adults. Furthermore, the

researchers found that the tool was easy and quick to apply. The average completion time was four minutes.

A total of 102 older adults participated in the first stage of the study, most of whom were female (74%), white (60%), and widowed (63%). Moreover, the vast majority of participants were functionally independent for basic (98%) and instrumental (56%) activities of daily living (Table 1).

Chronic pain affected approximately 60% of the participants and its intensity was mostly moderate (mean vNRS, 6.1) (Table 1).

Regarding quality of life, according to the WHOQOL-bref, we found a higher mean in the psychological domain than in the other domains (score = 73.41), but the difference was not statistically significant. For the social domain of the WHOQOL-old, we observed a mean of 15.04 (Table 1).

Based on Cronbach's alpha, the IAPSI's internal consistency was moderate (approximately 0.7) (Table 2).

Overall, there was a significant correlation between IAPSI and quality of life by WHOQOL-bref and each of its domains, according to Pearson's coefficient (environment 50%, social 45%, psychological 40%, physical 31%, overall 54%;  $P < 0.001$ ). We also found a significant correlation between the IAPSI and the social domain of the WHOQOL-old (64%;  $P < 0.001$ ). We found adequate convergent criterion validity for the IAPSI.

An ROC curve was used to determine the cut-off score for the IAPSI, indicating the impact of chronic pain on older adults' satisfaction with their social participation. Scores less than or equal to 17.5, with 83.3% sensitivity and 88.9% specificity, indicated impact of chronic pain on older adults' satisfaction with their social participation ( $P < 0.001$ ).

In the second stage of the study, we obtained a sample of 56 older adults who were mostly female (89.3%) and white (62.5%). Additionally, most patients presented with moderate chronic pain according to the vNRS (mean intensity: 6) and GPM (mean score: 66.1). For the IAPSI, we observed a mean total score of 17.37 (ranging from 10 to 24) (Table 3).

There was an inverse correlation between IAPSI and pain, with greater pain corresponding to lower IAPSI scores. Thus, as pain worsens, older adults' satisfaction with their social participation lowers (Spearman's coefficient,  $-0.282$ ;  $P < 0.004$ ).

A comparison of the total scores between the application and reapplication of IAPSI by the same observer did not result in any significant difference ( $17.38 \pm 3.54$  versus  $17.55 \pm 3.53$ ;  $P = 0.79$ ), and the intra-observer ICC was 0.95. A comparison of the IAPSI scores by the two examiners of the study did not result in a significant difference either ( $17.38 \pm 3.54$  versus  $17.09 \pm 3.33$ ;  $P = 0.66$ ), and the inter-observer ICC was 0.78. The Bland-Altman plot indicated good agreement between the IAPSI scores obtained by the two examiners. The results were the same when comparing scores obtained by the same observer (Figure 2).

## DISCUSSION

Currently, there are no practical, standardized measuring instruments to clinically assess social participation in the aging process<sup>6</sup> or instruments for measuring older adults' satisfaction with their social participation, especially those with chronic pain.

The construct presented herein is the first to be developed for the purpose of approaching older adults' satisfaction with their social participation. The IAPSI is simple and quick to apply and older adults understand it well. It considers older adults' satisfaction with their social participation, and "social participation" has been considered one of the pillars of healthy aging.<sup>18</sup>

In preparing the intended construct, we tried to include important aspects of social participation by faithfully following the guide provided by Kline<sup>9</sup> for developing instruments. We also

**Table 2.** IAPSI's internal consistency based on Cronbach's alpha

IAPSI	Correlation between items
Item 1	0.452
Item 2	0.552
Item 3	0.688
Item 4	0.629
Item 5	0.494
<b>Total Cronbach's alpha</b>	<b>0.689</b>

IAPSI = Instrument to Assess Older Adults' Social Participation.

**Table 1.** Characteristics of the participants in stage one of the study

Characteristics	n	%	Mean	SD	Interval
<b>Age</b>	102		87.29	4.37	80–101
<b>Sex</b>					
Female	75	74			
Male	27	26			
<b>Race/Ethnicity</b>					
Black	1	1			
Asian	19	19			
White	61	60			
Other	21	20			
<b>Marital status</b>					
Married	29	28			
Divorced	5	5			
Single	4	4			
Widowed	64	63			
<b>BADL</b>					
Independent	100	98			
Partial dependence	1	1			
Total dependence	1	1			
<b>IADL</b>					
Independent	57	56			
Mild dependence	38	37			
Moderate dependence	6	6			
Severe dependence	1	1			
<b>Personal perception of health</b>					
Bad	2	2			
Regular	38	37			
Good	44	43			
Excellent	18	18			
<b>IAPSI</b>			18.59	2.69	12–25
<b>WHOQOL-bref</b>					
Physical domain			66.53	18.39	17.9–100
Psychological domain			73.41	14.21	29.2–100
Social domain			69.61	12.33	25–100
Environmental domain			65.95	12.47	18.8–96.9
Overall			68.89	10.74	33.4–91.4
<b>WHOQOL-old/Social</b>			15.04	2.69	8–24
<b>vNRS</b>			6.1	2.39	2–10

BADL = Basic activities of daily living; IADL = Instrumental activities of daily living; IAPSI = Instrument to Assess Older Adults' Social Participation; WHOQOL-bref/old = World Health Organization Quality of Life-brief/old; vNRS = Verbal Numerical Rating Scale; SD = standard deviation.

attempted to obtain adequate validation, which is important for measuring instruments.

Regarding the internal consistency of the IAPSI, a property related to the reliability of the measuring instruments, we found that it was moderate according to Cronbach's alpha (coefficient 0.7).

In the first stage of the study, there was a significant correlation between the IAPSI and the presence and intensity of chronic pain. We observed the same occurrence in the second stage of the study, when we found a correlation between the IAPSI and chronic pain based on its multidimensionality using the GPM. Decades since Tollison<sup>19</sup> described the complex phenomenon of pain and

emphasized an adequate assessment of its various dimensions in approaches to patients' pain conditions: physiological (semiological characteristics, among others), sensory (intensity, quality), affective (anxiety, depression), cognitive (meaning of pain, adaptive resources), behavioral (pain behavior, medication acceptance), psychosocial (interpersonal interaction, social and family life, interrelation with home/work, leisure), and sociocultural (ethnocultural, environmental factors). Pain was assessed in this manner. The social aspects of individuals with pain have long been considered important but have rarely been addressed.

There was a significant correlation between the IAPSI and quality of life, according to the WHOQOL-bref (all domains), and between the IAPSI and the social domain of the WHOQOL-old (all correlations;  $P < 0.001$ ). Recently, Ferreti et al.<sup>20</sup> noted that quality of life by WHOQOL-old changed in accordance with the presence or absence of pain, and that the social participation domain was one of the most affected in this evaluation. Celich and Galon (2009)<sup>21</sup> also observed that chronic pain among older adults was a limiting factor in their daily activities (going to church, dancing, and participating in community activities), restricting their social life and resulting in a negative perception of their quality of life. Therefore, approaches to aging are essential.

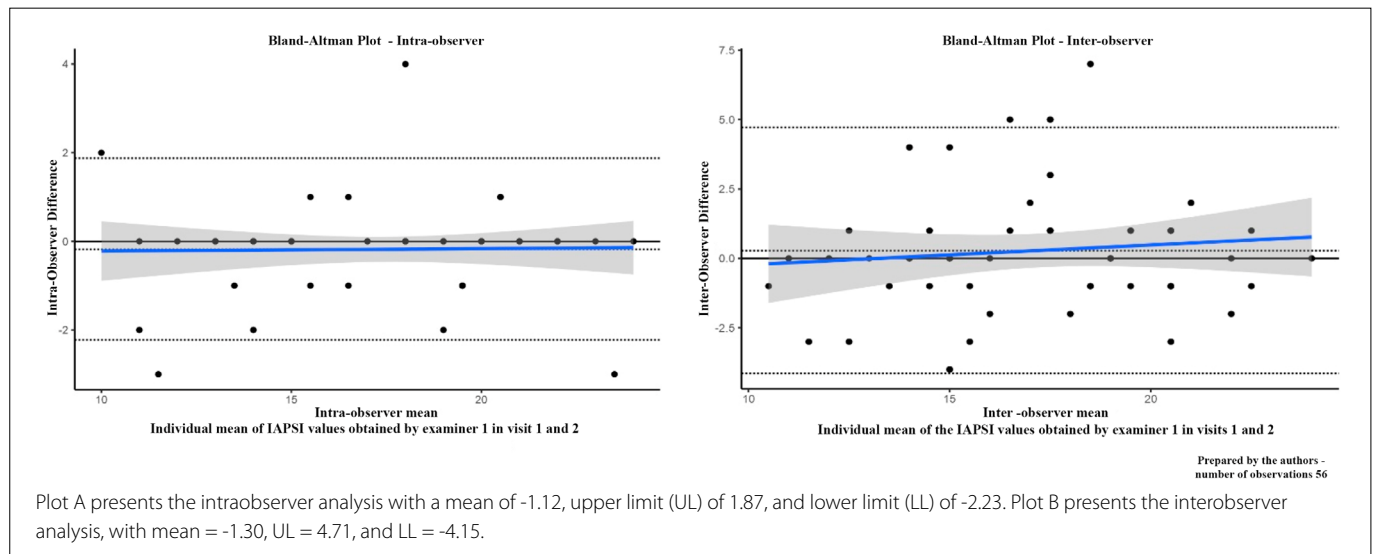
Regarding IAPSI reproducibility (inter- and intra-observer), we found strong inter- and intra-observer agreements according to the Bland-Altman plots (0.78 and 0.96 for inter- and intra-observer, respectively). Thus, an additional valid psychometric property was observed for the IAPSI.

Moreover, we evaluated the IAPSI's performance according to sensitivity and specificity indicators and constructed an ROC curve to determine the best cutoff point to assess the satisfaction of older adults with chronic pain with their social participation.

**Table 3.** Characteristics of the participants in stage two of the study

Characteristics	n	%	Mean	SD	Interval
<b>Age (years)</b>					
60–70	13	23.2			
71–80	14	25.0			
81–90	26	46.4			
91–100	2	3.6			
> 100	1	1.8			
<b>Sex</b>					
Female	50	74			
Male	6	26			
<b>Race/Ethnicity</b>					
Black	5	1			
Asian	1	19			
White	35	60			
Other	15	20			
<b>GPM</b>			66.10	20.24	8–99
<b>vNRS</b>			6	2	1–9
<b>IAPSI</b>			17.37	3.54	10–24

GPM = Geriatric Pain Measure; vNRS = verbal numerical rating scale; IAPSI = instrument to assess older adults' social participation; SD = standard deviation.



**Figure 2.** Bland-Altman plots.



With 83.3% sensitivity and 88.9% specificity, scores lower than or equal to 17.5 indicated the impact of chronic pain on older adults' satisfaction with their social participation ( $P < 0.001$ ).

This study presented limitations, such as the IAPSI's moderate internal consistency, which might even suggest that it contains items that can be excluded. However, the items evaluated were essential for social participation and were thus maintained in the construct. This weakness may be acceptable, as the instrument aims to measure different characteristics of social participation. Another limitation is that we assessed IAPSI in a population of considerably older and more functionally independent adults, which is interesting in a way, as it allowed for an early assessment of impacts that may impair functional capacity in the aging process.

Due to the importance and practicality of the IAPSI in assessing the impact of pain on older adults' satisfaction with their social participation, we suggest including this instrument in clinical protocols and research on approaches to pain during the aging process.

## CONCLUSION

In conclusion, the IAPSI is a proposed instrument for assessing older adults' satisfaction with their SP, especially for those with chronic pain. This construct was very simple and quick to apply, and demonstrated satisfactory measurement properties, such as internal consistency, reproducibility, content, and criterion validity.

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## Appendix 1. Instrument to assess older adults' social participation

### Instrument to Assess Older Adults' Social Participation - IAPSI

Please answer the following questions in reference to the last two weeks. If you are not sure about which answer to give, please choose the alternative that seems most appropriate to you.

<b>Domestic Life</b>	1 – How satisfied are you with your domestic activities?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
		1	2	3	4	5
<b>Community Life</b>	2– How satisfied are you with your participation in community events (mass, worship, fairs...)?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
		1	2	3	4	5
<b>Community Life</b>	3 – How satisfied are you with your means of transportation?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
		1	2	3	4	5
<b>Interpersonal Relations</b>	4 – How satisfied are you with your personal relationships (friends, family, acquaintances...)?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
		1	2	3	4	5
<b>Free Time</b>	5– How satisfied are you with the use of your free time (leisure, hobbies...)?	Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
		1	2	3	4	5

Domestic life: (1) \_\_\_\_\_

Community life: (2+3) \_\_\_\_\_

Interpersonal relations: (4) \_\_\_\_\_

Free time: (5) \_\_\_\_\_

Total score: \_\_\_\_\_ (sum of the points for each item based on the answers given)

**Note:** A higher score corresponds to a higher degree of satisfaction with social participation among older adults. Suggested cut-off score  $\leq 7$  for very dissatisfied.

# Assessing the effect of prophylactic ankle taping on ankle and knee biomechanics during landing tasks in healthy individuals: A cross-sectional observational study

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## ABSTRACT

**BACKGROUND:** Current research supports the fact that prophylactic ankle taping (AT) is effective in preventing ankle injuries in amateur and elite sports athletes.

**OBJECTIVE:** This study aimed to investigate the effect of AT on balance, knee valgus during drop jump and single-leg countermovement jump (SL-CMJ) landings, and ankle range of motion (ROM) restriction in healthy participants.

**DESIGN AND SETTING:** A cross-sectional observational study was conducted at the Universidad Europea de Madrid, Madrid, Spain.

**METHODS:** Participants: Thirty-nine healthy individuals participated in this study and performed the movements under two conditions (with and without tape). Outcome measurements: ankle ROM, balance, SL-CMJ height, flight time, ground time, and knee valgus. Before any intervention, a random process was developed with a 1:1 allocation ratio, and the participants were assigned to groups A (tape-no tape) and B (no tape-tape).

**RESULTS:** Significant differences between tape and no-tape moments were observed for drop jump knee valgus flexion ( $P = 0.007$ ), with an increase in knee valgus in participants with ankle taping. Similarly, the Y-balance test showed a significant decrease in all variables ( $P = 0.001$  and), ankle dorsiflexion ( $P = 0.001$ ) in participants with ankle taping.

**CONCLUSIONS:** AT is effective for immediate ankle ROM restriction. However, an increase in knee valgus during drop jump task and a decrease in lower limb balance were observed during drop jump task. Based on these results, it can be concluded that AT application in healthy individuals should not be recommended as it results in increase in injury risk factors.

## INTRODUCTION

Current research supports the fact that prophylactic ankle taping (AT) is useful in preventing ankle injuries in amateur and elite sports athletes. It provides extra stabilization of the ankle joint.<sup>1</sup> The primary strength of AT is limitation in the range of motion (ROM) of tibiotalar and subtalar joints, which results in an increase in the proprioceptive outputs.<sup>2</sup> Several studies have reported the efficacy of prophylactic approaches with rigid tapes and bracing in protecting the soft tissues and ligaments in maximal stress situations (e.g. jumps, landings, change-of-directions).<sup>3,4</sup> AT has been employed in sports and non-sports populations in rehabilitation and prevention to reduce the incidence of ankle sprain injuries that commonly occur during training, amateur or professional competition. The effects of rigid or semi-rigid tape approaches not only influences ankle joint restriction, but also has effect on other movements. For example, electromyography assessment reported a decrease in the peroneus contraction time and a decrease in the average eversion and inversion velocity times.<sup>5,6</sup> Other undesirable effects of ankle bandages have been reported, such as a decrease in jump performance in athletes or dermatologic manifestations.<sup>7,8</sup>

Extensive research has demonstrated the efficacy of AT in ROM restriction and injury prevention. Pederson et al. reported the prophylactic approach of AT in ankle joint fixation among Rugby players.<sup>9</sup> In the context of eversion-inversion limitation movements, Callaghan et al. showed the benefits of AT in non-weight bearing positions.<sup>10</sup> Several systematic reviews support the use

of rigid and elastic bandages in individuals with ankle sprain history for prevention and rehabilitation.<sup>11,12</sup>

Elite and amateur sports environments improve prevention and rehabilitation programs to decrease sports injuries. For example, the incidence rate of ankle sprain injury reported among basketball players is 3.85 per 1,000 individuals, and the primary cause of these injuries is the landing phase of jump movement.<sup>13</sup> Sport medicine doctors and medical staff focus on lower limb biomechanics to decrease the injury ratios.

Despite the evidence of reduction in the likelihood and severity of ankle sprain injury, restriction of normal foot and ankle biomechanics may increase the risk of injury to proximal joints, such as the knee. Previous studies on ski-boots have reported that these provide excellent ankle joint protection during sport performance; however, they have been associated with lower limb biomechanical disturbances, such as knee injuries.<sup>14</sup> Knee abduction motion, generally known as knee valgus, has been described as a factor associated with increased load on the knee joints and potential anterior cruciate ligament (ACL) injury during landing and change-of-direction biomechanics.<sup>15-18</sup> In this context, several authors have reported that knee abduction and medial movements during landing tasks were predisposing factors for development of ACL injury or patellofemoral pain in athletes, especially among females.<sup>17-19</sup>

Santos et al. delineated that AT was less rigid than a ski-boot. Thus, alterations in the ankle joint kinematics were observed with rigid tape and bracing during simple tasks.<sup>20</sup> Similarly, studies have reported that valgus movements and internal rotation of tibia play an important role in ACL injuries. For example, Stoffel et al. reported a reduction of 5 Nm in knee internal rotation during running/sidestepping tasks in individuals with AT compared to controls.<sup>1</sup>

## OBJECTIVE

This study aimed to investigate the effect of AT on balance, knee valgus during drop jump and single-leg countermovement jump (SL-CMJ) landings, and ankle ROM restriction in healthy participants. It was hypothesized that AT would be effective in restricting ankle ROM. However, it could result in a decrease in balance and an increase in knee-ankle valgus during landing in drop jumps and SL-CMJ tasks.

## METHODS

### Design and sample

This cross-sectional, descriptive, single-blinded, observational study was conducted in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines between February 2022 and May 2022 at the Research Lab of Universidad Europea, Madrid, Spain.

Thirty-nine healthy individuals were recruited for the study from the Universidad Europea Sport Facilities. Participants were excluded if they presented with any musculoskeletal condition requiring treatment during a period of three months prior to testing. Individuals with dermatologic disorders or tape allergy, and those who underwent lower-limb surgery or had foot orthoses were also excluded from the study.

### Ethical considerations

This study was approved by the Universidad Europea Research Ethics Committee (CIPI/213006.97; Dated: December 16, 2021). Written informed consent was obtained from all the participants before commencement of the study. All the procedures in this study were performed in accordance with the tenets of Declaration of Helsinki.

### Sample size

According to Williams et al.,<sup>21</sup> a convenience sample of 21 participants was considered sufficient to evaluate the effectiveness of AT on knee biomechanics during jumping and landing tasks. Finally, a total sample of 39 participants was recruited for the present study.

### Study Procedure

Before the assessment, basic anthropometric measures (height, weight, and body mass index) were recorded using a calibrated device, and the participants were instructed to complete a questionnaire to ensure that the study inclusion criteria were met.

### Randomization and blinding

Before any intervention, a random process was developed using the free software system (randomization.org) with a 1:1 allocation ratio, and the participants were assigned to groups A (assessments with tape assessments with no tape) and B (assessments with no tape- assessments with tape). All participants wore a pair of long socks that do not allow the rater to know whether they were taped.

### Ankle taping

The AT procedure was developed by an experimental physical therapist with more than five years of experience in taping in an elite sport environment. The ankles of the participants were covered with pre-wrap before the taping procedure in accordance with the Sports Medicine guidelines for taping methods.<sup>22</sup> AT was performed with a standard 38-mm self-adhesive tape starting with two anchor strips around the leg 10 cm above the malleoli. The next step consisted of two strips being placed from the medial side of the anchor tape to the lateral side with the foot in a neutral position.<sup>21</sup> The “figure sixes” focusing on the subtalar

joint were performed with an initial strip onto medial anchor thorough the plantar aspect of the foot attached onto the medial anchor. To complete the AT procedure, the therapist covered all free ends and spaces with tape.<sup>21</sup>

### Movement tasks

All jump trials were assessed by the same evaluator using standardized verbal commands. Before the measurements, each participant was instructed to perform a 10-minute warm-up session. Subsequently, for the drop-jump test, each participant jumped from a 30 cm box, with hands placed on the hips. Participants were instructed to: “jump up as fast as possible after contact and try to jump as high as possible with one leg”.<sup>23</sup> To initiate the drop, the participants were instructed to not jump out of the platform, rather just step out with one foot. Two jumps were performed, and the better result achieved for each jump were registered for the analyses. For SL-CMJ, participants were instructed to place one foot on the ground and the free leg behind at approximately 80-90° with their hand on the iliac crests, and then jump as high as possible.<sup>24</sup> In the same way, two trials were performed and recorded, and the highest jump was analyzed.

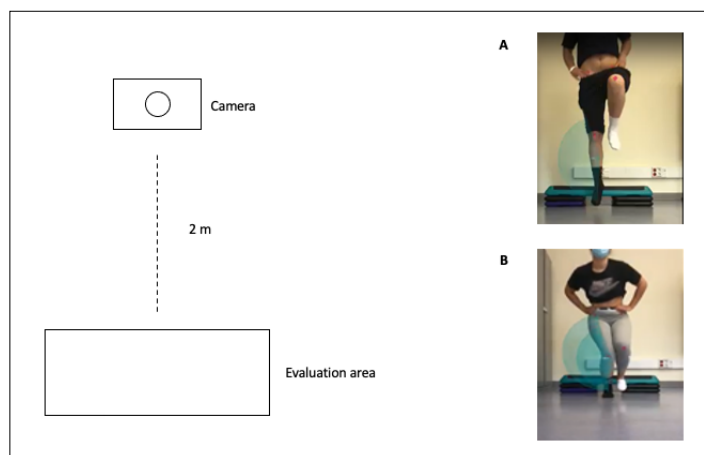
### Outcome measurements

Three-dimensional (3D) motion capture tools have been considered the “gold standard” for assessment and quantification of human movement.<sup>25</sup> Hanzlikova et al. reported that 3D systems were reliable in evaluating the multi-planar kinematics of the knee joint during functional tasks (e.g. landings, change-of-direction, cutting maneuvers).<sup>26</sup> However, due to the increased cost factor and difficulty in accessing the 3D systems, several two-dimensional (2D) methods have been developed and validated.<sup>27-30</sup> Irawan et al. reported that 2D tools for kinematics assessment was a reliable, unexpensive, and easy to use method that can be used in the clinical and research fields to evaluate knee valgus movement based on frontal plane projection angle during drop-jump and single leg landings.<sup>25</sup> The combination of smartphones-Kinovea has been proven to be a valid and reliable instrument for evaluation of joint kinematics and jump performances in different populations.<sup>31</sup> Therefore, in the present study, the iPhone 12 camera with 18 mm lens was used and it was positioned 2 m away from the evaluation zone. No zooming effect was applied at any time to standardize the procedure for all participants. All videos were imported into the freeware motion analysis Kinovea software (GPLv2 licence) [this software was created via non-profit collaboration of several researchers worldwide]. Kinovea is a free 2D motion analysis software that can be used to assess kinematic parameters. Several authors have used Kinovea to evaluate running and

vertical jump's or landings among athletes.<sup>32,33</sup> To assess knee valgus movement, the angle between the line from the anterior superior iliac spine (ASIS) to the middle of the patella and the line from the ASIS to the center of the ankle joints<sup>25</sup> on the frontal plane was measured. Although Kinovea allows analysis of kinematic parameters without any skin markers, these markers were placed on the ASIS and in the middle of the patella to improve the reliability of the evaluations.<sup>34</sup> One physical therapist with more than five years of experience in human motion analyses measured knee valgus angle in the frontal plane projection angle which resulted in the development of drop-jump test and SL-CMJ with Kinovea software (**Figure 1**).

Kinovea software was used to measure flight time, ground time contact, and jump height. Then, the first frame in which the foot left the floor completely (take-off phase) and the first frame in which the foot touched the floor again (landing phase) were employed to calculate the flight time and ground contact time. Flight times from the jump test by identifying takeoff and landing phases were used to calculate jump height using the equation described by Bosco et al.<sup>35</sup>

Y-balance test (YBT) was performed to assess balance. It consisted of three lines attached to the floor in the anterior, posteromedial, and posterolateral directions. Following the guidelines of Plisky et al., posterior lines were placed 135 from the anterior line, with 45 between the posterior lines.<sup>36</sup> Prior to the test, participants viewed a demonstration made by the rater to familiarize themselves with the process and practiced six trials on each leg in the three directions. Participants were instructed to stand barefoot at the center of the “Y” and each participant had to maintain a single-leg posture of the target limb and try to reach the maximum distance in every three direction. Hands were placed at the iliac crest, and the stance heel was in contact with the ground.<sup>36</sup> If the participants did not follow the instructions or any criteria were violated, the trial was repeated.



**Figure 1.** Drop-jump and countermovement jump assessments.

Maximal ankle dorsiflexion ROM was assessed using the valid and reliable *My Rom app* (Madrid, Spain, v.3.0.4) for the iPhone.<sup>37</sup> Participants were instructed to be in a weight-bearing lunge position and the device was placed under the tibial tuberosity. Each participant developed a maximal dorsiflexion of the ankle joint that was valued, and the application automatically reported the dorsiflexion angle and ankle asymmetry.

All the outcome measurements were carried out by the same investigator.

### Statistical analysis

SPSS software (version 23.0; IBM SPSS Statistics, Armonk, IBM Corp, United States) was used for statistical analyses. Shapiro-Wilk test was used to assess the normality of data distribution. Student's t-test and Mann-Whitney U test were used to check the differences between the groups (tape-no-tape and male-female comparisons) for parametric and non-parametric data, respectively. In addition, Levene's test was used to assess the equality of variances. The intra-class correlation coefficient (ICC) was calculated to evaluate the intra-rater reliability of all measurements. The level of significance was set at  $P < 0.02$  with an  $\alpha$  error of 0.05 (95% confidence interval) and a desired power of 80% ( $\beta$  error of 0.2).

### RESULTS

Sociodemographic data showed differences in height and weight between male and female participants, (Table 1). As shown in Table 2, significant differences were observed between tape and no tape movements in terms of drop jump knee valgus flexion ( $P = 0.007$ ), with an increase in knee valgus in participants with AT. Similarly, the YBT and ROM tests showed a significant decrease in medial ( $P = 0.001$ ), lateral ( $P = 0.001$ ), and anterior ( $P = 0.001$ ) ankle dorsiflexion ( $P = 0.001$ ) in participants with AT. Ankle dorsiflexion asymmetry also increased between ankles with and without taping ( $P = 0.001$ ). As shown in Table 3, significant differences were found between male and female participants in terms of drop jump and SL-CMJ height ( $P = 0.001$ ) and drop jump and SL-CMJ flight time ( $P = 0.001$ ). The remaining variables did not differ significantly between the male and female participants. In addition, intra-rater ICC values for movement task values were considered to be good. The values were: drop-jump height (ICC = 0.954), drop-jump flight (ICC = 0.971), drop-jump ground time (ICC = 0.991), drop-jump knee valgus

(ICC = 0.937), SL-CMJ height (ICC = 0.979), SL-CMJ flight time (ICC = 0.949), SL-CMJ ground time (ICC = 0.991) and SL-CMJ knee valgus (ICC = 0.994).

### DISCUSSION

The purpose of the present study was to assess lower-limb balance and knee biomechanics during landing tasks in participants with AT. There is no doubt that AT protects the ankle joint by

**Table 2.** Comparison of outcome measurements with and without ankle taping

Measures	No taping	Ankle taping	P value
Drop jump knee valgus F	12.92 ± 6.08	15.73 ± 8.15	0.007
Drop jump height	0.14 ± 0.05	0.13 ± 0.04	0.085
Drop jump flight time	0.33 ± 0.07	0.32 ± 0.05	0.208
Drop jump ground time	0.33 ± 0.05	0.50 ± 0.16	0.476
SL-CMJ knee valgus F	15.25 ± 7.84	13.95 ± 6.96	0.218
SL-CMJ height	0.13 ± 0.05	0.12 ± 0.04	0.228
SL-CMJ flight time	0.32 ± 0.06	0.31 ± 0.03	0.324
SL-CMJ ground time	0.91 ± 0.30	0.93 ± 0.28	0.762
Y-Balance anterior	86.0 ± 6.77	82.92 ± 7.96	0.001
Y-Balance medial	74.92 ± 9.95	70.56 ± 8.87	0.002
Y-Balance lateral	78.56 ± 7.59	74.82 ± 8.23	0.001
Ankle dorsiflexion DF	47.11 ± 7.90	39.22 ± 5.75	0.001
Ankle DF Asymmetry	7.69 ± 5.65	13.13 ± 7.79	0.001

F = flexion; DF = dominant foot; SL-CMJ = single-leg countermovement jump.

**Table 3.** Comparison of outcome measurements between female and male participants

Measures	Females	Males	P value
	No tape-tape	No tape-tape	No tape-tape
Drop jump knee valgus F	14.11–16.62	11.80–14.88	0.242–0.514
Drop jump height	0.10–0.10	0.17–0.15	0.001–0.001
Drop jump flight time	0.28–0.29	0.37–0.35	0.001–0.001
Drop jump ground time	0.65–0.52	0.47–0.48	0.299–0.501
SL-CMJ knee valgus F	16.09–14.78	14.46–13.17	0.524–0.477
SL-CMJ height	0.10–0.10	0.16–0.14	0.001–0.001
SL-CMJ flight time	0.28–0.29	0.14–0.36	0.001–0.008
SL-CMJ ground time	0.84–0.86	0.98–0.99	0.162–0.524
Y-Balance anterior	84.10–80.10	87.75–85.60	0.098–0.029
Y-Balance medial	71.68–66.68	78.00–4.20	0.046–0.006
Y-Balance lateral	76.42–73.31	80.60–76.25	0.086–0.272
Ankle dorsiflexion DF	48.37–40.34	44.22–38.27	0.108–0.270
Ankle DF Asymmetry	7.08–14.61	8.02–13.81	0.609–0.797

F = flexion; DF = dominant foot; SL-CMJ = single-leg countermovement jump.

**Table 1.** Sociodemographic data of the study population

Data	Total sample (n = 39)	Females (n = 19)	Males (n = 20)	P value females versus males
Age, years	21.20 ± 1.42	20.94 ± 1.89	21.45 ± 3.28	0.565
Height, m	1.71 ± 0.10	1.65 ± 0.06	1.77 ± 0.10	0.001
Weight, kg	64.84 ± 14.07	58.00 ± 8.32	71.00 ± 15.46	0.002
Body mass index, kg/m <sup>2</sup>	20.3 ± 5.9	19.20 ± 6.40	21.48 ± 5.46	0.236

preventing extreme movements in plantarflexion. In line with this, the results of the present study showed ROM restriction in both male and female participants in which AT was done, with a mobility decrease of almost 8°. In addition, the asymmetries between the taping ankle and the free ankle increased by more than 6°. In Romero et al. showed similar values in soccer and basketball players with a decrease in ankle ROM and increase in ankle asymmetry in players with prophylactic AT.<sup>38</sup> Despite poor evidence of asymmetrical ROM as a risk factor, foot and ankle biomechanics do not cause disturbances in ROM due to external stimuli, such as AT.<sup>39</sup>

Despite the fact that AT has been considered a good prophylactic method for ankle injury prevention, several authors have directly related ankle restriction with knee kinematic alterations.<sup>21</sup> Klem et al. postulated that an ankle inversion restriction could be related to an increase in the internal rotation of the knee as a compensation mechanism.<sup>40</sup> The present study showed a significant increase in knee valgus in the frontal plane in the drop-jump task in participants of either sex with a prophylactic AT. However, prior studies have shown that knee compensation movements in the frontal planes occur due to ankle restriction as a result of AT.<sup>1,41</sup> Previous evidence supports that restriction of ankle dorsiflexion is directly related to knee alterations or a valgus increase in the frontal plane, which is in accordance with the results of the present study.<sup>21,42</sup> The combination of tibial internal rotation with knee valgus has been described as a knee injury risk factor due to ACL strain.<sup>43</sup> Both hyperflexion and hyperextension added to internal tibial torque has also been related to the ACL injury mechanism. Therefore, the prevention methods to reduce the internal forces on ACL and internal meniscus during sports activities could help reduce the risk of knee injury.<sup>44</sup> Thus, based on the results of the present study and previous research, AT should be reconsidered as a prophylactic injury prevention method in healthy participants and among athletes involved in sports which frequently entails jumping and landings. Moreover, AT may also benefit the return-to-play and rehabilitation phases.<sup>38</sup>

In the context of height and flight time values, for both drop-jump and SL-CMJ tasks, we found a slight decrease among participants with AT. Moreover, the drop jump and SL-CMJ ground times were slightly increased in the bandage group. During landing tasks after a drop-jump or SL-CMJ, the joints and lower limbs must be prepared for energy dissipation.<sup>45</sup> Several authors have suggested that ankle joint restriction by AT may interfere with the ability of the lower limbs to attenuate ground reaction forces, which may result in decreasing the performance in jumping tasks, such as drop-jump or SL-CMJ.<sup>7,8,46</sup> The ability to jump, land and perform effective cutting maneuvers has been associated with better outcomes in sport events and a decrease in the risk of injury among athletes and players who have to be ready for high demands in all

the tasks, such as playing basketball or volleyball. Thus, a decrease in these abilities may be increasing the risk of injury.

In terms of lower limb balance, the present study showed a significant decrease in all three directions of YBT when classic AT was applied. However, several studies have reported the benefits of balance with the use of other ankle bandages, such as kinesiology tape in healthy individuals and athletes.<sup>47,48</sup> This disparity in results could be explained by the fact that different material properties affect the somatosensory outcomes or provide greater elasticity range.<sup>48</sup> In this context, disturbances in motor control, poor balance, or lack of neuromuscular aptitudes have been described as predictors of risk of injury in the lower limb. Consequently, all these aspects must be considered before implementation of bracing or AT approaches in healthy individuals.

For complete ankle and foot evaluation, other biomechanical parameters should also be fully assessed, such as leg length discrepancy or mobility of the first metatarsal head.<sup>49,50</sup>

This study had a few limitations. The cross-sectional design of the present study implies that the results should be taken into consideration because only a snapshot of time is considered difficult, making estimation of injury risk in a complete season or period of time an arduous task.<sup>21</sup> More studies should be performed to assess the effects of AT on foot plantar pressures or to assess the extrinsic and intrinsic foot muscles with electromyography.

### Clinical applications

The results of the present study demonstrate the effectiveness of AT in limiting extreme movements of the ankle joint immediately after its application. However, an increase in knee valgus during landing tasks was observed, which increased the risk of knee injury, such as ACL or meniscus damage. Moreover, a direct negative impact on jump performance was also seen. Therefore, the use of AT is not recommended in healthy individuals. In this regard, we suggest that strength or mobility exercises are the best choices for ankle sprain injury prevention in healthy individuals without involving the nearby joints.

### CONCLUSIONS

AT is effective for immediate ankle ROM restriction. However, an increase in knee valgus during drop jump task and a decrease in lower limb balance were observed. Based on these results, AT application in healthy individuals is not recommended due to the increase in injury risk factors.

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# Translation and cultural adaptation of the *Positive Aspects of Caregiving Scale* for caregivers of people living with dementia in Brazilian context: a methodological study

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## ABSTRACT

**BACKGROUND:** The Positive Aspects of Caregiving (PAC) scale is used to assess psychosocial benefits provided to caregivers by the task of caring. The PAC scale consists of nine items, assessed using a five-point Likert scale, with higher values indicating greater positive perceptions and gains from the caregiving experience.

**OBJECTIVE:** To translate and culturally adapt the PAC scale for informal Brazilian caregivers of people with dementia.

**DESIGN AND SETTING:** A methodological study was conducted at the Federal University of São Carlos.

**METHODS:** The following stages were carried out: Translation; Synthesis of the translations; Back-translation; Evaluation by an experts' committee; and Pre-test.

**RESULTS:** Two independent professionals translated the PAC scale. The consensus version was obtained by merging both translations, which were back-translated into English by a third translator. The expert committee comprised three specialists in the area and project researchers. All scale items presented a Content Validity Index of 1 (CVI = 1.0), and thus remained in the pre-final version of the instrument. The instrument was pre-tested with seven caregivers of people with dementia, the majority of whom were women (57.1%), with a degree of kinship corresponding to sons/daughters (57.1%) and an average age of 55.2 ( $\pm$  4.1) years. The caregivers considered it clear and understandable and made no suggestions for changes.

**CONCLUSION:** The PAC scale was translated and culturally adapted for use by informal caregivers of people with dementia in Brazil. However, a psychometric analysis of the instrument is necessary to provide normative data for this population group.

## INTRODUCTION

The Positive Aspects of Caregiving (PAC) can be defined as caregivers' gains or satisfaction resulting from the care experience and comprise different dimensions, such as perception of gain or reward, satisfaction, resilience, self-efficacy, self-esteem, sense of mastery, personal growth, and sense of life purpose.<sup>1-3</sup>

The PAC scale is widely used to assess the psychosocial benefits provided to caregivers by care tasks. The PAC scale was developed in 2004 by Tarlow et al. and consists of nine items that present assertions about a caregiver's mental or affective state associated with the care experience. It consists of a five-point Likert scale from (1) disagree a lot to (5) agree a lot, with total scores varying from 9 to 45 points and higher values indicating greater positive perceptions and gains from the caregiving experience.<sup>4</sup>

The PAC scale comprises two factors: Self-affirmation and Life perspective. The Self-affirmation factor, comprising six items, describes the confident and capable self-image of the caregiver. The Life perspective factor, which includes three items, describes improved interpersonal relationships and positive views of life. Internal consistency was  $\alpha = 0.89$  for the overall instrument.<sup>4</sup>

A systematic review of 53 studies aimed at exploring how the PAC affect the well-being of caregivers of people with dementia verified that they are associated with better mental health and quality of life, satisfaction with life, competence, and self-efficacy, as well as with lower levels of depressive symptoms and burden.<sup>2</sup> A longitudinal study which included 1,283 informal caregivers

of people with dementia identified associations between the PAC and caregivers' well-being and satisfaction with life.<sup>5</sup>

Informal caregivers frequently face stressful situations, including high task demands, physical wear out, financial problems, social isolation, and free time restrictions.<sup>6,7</sup> Previous studies have shown that caring for a person with dementia is associated with higher burden levels, more severe depressive symptoms, and psychological stress in caregivers.<sup>7-9</sup>

Studies on how the PAC scale is used have already been conducted with caregivers of people with dementia in Portugal,<sup>10</sup> the United States,<sup>11</sup> Greece,<sup>12</sup> Singapore,<sup>13</sup> and Japan.<sup>14</sup> In Brazil, the PAC are still less explored, and there is no translated and adapted version of the scale for the Brazilian context. Therefore, having a Brazilian version of the PAC scale is relevant, especially for informal caregivers of people with dementia.

## OBJECTIVE

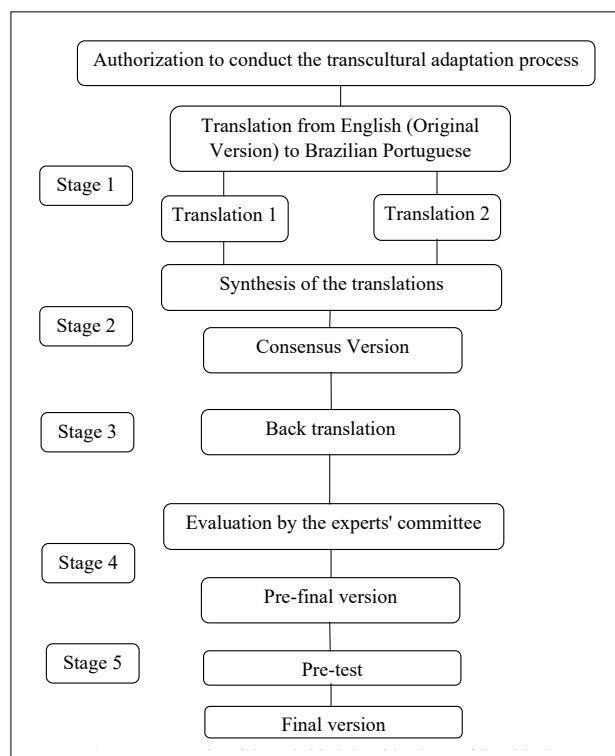
This study aimed to translate and culturally adapt the PAC scale for the informal caregivers of people with dementia in the Brazilian context.

## METHODS

This was a methodological study for the translation and transcultural adaptation of the PAC scale from English to Brazilian Portuguese. The adaptation process followed the stages recommended by Beaton et al.<sup>15</sup> to achieve semantic, idiomatic, cultural, and conceptual equivalence between the original instrument and the adapted version. Figure 1 illustrates the stages required to transculturally adapt an instrument.

Following the methodological modeling steps, authorization was requested from the author of the original scale to create a new Brazilian version. The researchers rigorously followed all scientific and ethical guidelines and the research was approved by the Committee of Ethics in Research with Human Beings of the Federal University of São Carlos (CAAE No. 88157118.0.1001.5504/ April 05, 2022).

In the first stage, the original version (written in American English) was translated by two qualified and independent translators, one from the health field and the other from psychology, and both proficient in English. The translation process undertaken by the two translators allowed for the detection of errors derived from divergent interpretations of ambiguous terms in the original language. The translations were produced by the researchers and translators working as teams in the second stage, thus creating a consensus version of the PAC scale. The subsequent back-translation stage involved a third translator who was fluent in both languages and native English speaker; however, this person was unaware of the objective of the current study. The instrument was sent to the authors for analysis and approval.



**Figure 1.** Representation of the methodological model and stages followed in the translation and transcultural adaptation process corresponding to the Positive Aspects of Caregiving Scale.

In the fourth stage, evaluation by the experts' committee, the specialists reviewed and compared all the translations produced with the objective of reaching a modified and adapted version for use in Brazil. The committee consisted of three judges fluent in the original language of the scale, with PhDs in academic training in Health and Psychology and experience with informal caregivers of people with dementia, and project researchers involved in the process. The Content Validity Index (CVI) was used for data analysis, employing a four-point Likert scale, where items scored as 1 and/or 2 were reviewed or excluded, and those scored as 3 and/or 4 were part of the calculation. An agreement value was calculated based on adding up each of the judges' answers to each item divided by the total number of answers, with a minimum recommended result of 0.78 to confirm equivalence of the instrument after the entire process.<sup>16</sup> After this evaluation, the pre-final version of the PAC scale was obtained.

In the fifth and last stages, the PAC scale was pre-tested in a convenience sample using the data saturation technique. In total, the sample comprised seven family caregivers of people with dementia with different profiles (sex, age, and degree of kinship), divided into two groups: four caregivers at the first moment and three caregivers later. In this study, we decided to use this test technique by administering the instrument in two groups. The objective of

dividing the participants was to gather notes from the first group and improve the writing of the items for better understanding by the second group. Before fully answering the questionnaire, the participants agreed to participate in the study by signing the Free and Informed Consent Form. The pre-test stage was conducted from July to September 2022 in an online format using *Google Forms*. The participants were asked about difficulties in filling the questionnaire or understanding the purpose or meaning of the questions. After the interviews, the experts' committee discussed the results and proposed the final version.

## RESULTS

Two versions were obtained, which were translated independently: T1 and T2. Once the translations were produced, the researchers met the translators to analyze and evaluate any and all discrepancies between both translated versions (T1 and T2), in addition to comparing them to the original instrument. Both translations were compared to reach consensus. The T1 and T2 versions were considerably similar. There were no significant translation difficulties; however, in the items that presented discrepancies, the translation that the study researchers considered to better express the original meaning of the terms and have the best meaning in Portuguese were retained. The reliability of the consensus version was evaluated by back-translation into English by another qualified translator and assessing similarities with the original instrument.

The materials were analyzed by an experts' committee that assessed the adequacy and clarity of the vocabulary and semantic, idiomatic, cultural, and conceptual equivalence. Changes to some items were suggested for the ease of understanding, as shown in **Table 1**.

After the experts' evaluation, all the items that made up the PAC scale were verified to have a CVI = 1.00, which was considered equivalent and maintained in the pre-final version of the instrument, as shown in **Table 2**.

Seven caregivers participated in the pre-test: four and three in the first and second groups, respectively. Of the sample, 57.1% were women and their degree of kinship to the person cared for corresponded to sons/daughters (57.1%), sisters (14.2%), nephews (14.2%), and daughters-in-law (14.2%), in the group from 40 to 70 years old, with a mean age of 55.2 ( $\pm$  4.1) years. The caregivers lived in the municipalities of São Carlos-SP (71.4%), Belo Horizonte-MG (14.2%), and Brasília-DF (14.2%). In the pre-test stage, the adapted version of the PAC scale was well accepted by family caregivers, who considered it easy to understand and fast to apply. They found no difficulty understanding the meaning and clarity of the scale items. Therefore, alterations to any questions were not necessary. The final version of the PAC scale is presented in **Table 3**.

## DISCUSSION

The current study satisfactorily implemented all the stages recommended in the literature to adapt and translate the PAC scale for caregivers of people with dementia in the Brazilian context.<sup>15</sup> This process significantly contributed to the quality of the result obtained, which resulted in a Portuguese version of the instrument that is linguistically faithful to the questionnaire in its original language (English) and had its adequacy unanimously confirmed by means of content validation.

Some changes can be suggested after the translation process for the questionnaire items to be better understood by the target population. Adaptation is essential in the process because it enables cultural equivalence, as cultures differ between populations. Consequently, this affects the reliability of the results obtained by applying the instrument.<sup>17</sup>

For the Brazilian version of the PAC scale, a pre-test was performed with family caregivers of people with dementia belonging to different age groups, with different degrees of kinship, and of both sexes. All the participants rated the scale as easy to understand and had no difficulty answering it. Consequently, it was not necessary to implement any changes in the final version of the scale after the translation and verification processes were performed by the experts' committee and study researchers. A systematic review of the literature on the PAC scale identified 52 studies that showed that the scale was used for multiple purposes and produced considerable evidence that it is valid and reliable, supporting the importance of understanding positive caregiving experiences.<sup>18</sup>

The study developed to transculturally adapt the PAC scale in Greece with caregivers of people with dementia found a result similar to the present study, as all 22 caregivers interviewed did not find any difficulties with translation of the instrument and did not have any point to note regarding the scale items.<sup>12</sup> Both the translation to the Brazilian context and Greek study adopted a methodological framework involving more than one translator from English to the native language of the countries, which ensured minimizing any misinterpretations.<sup>12</sup> In other countries, such as China,<sup>19</sup> Japan,<sup>14</sup> and Singapore,<sup>13</sup> only one translator took part in each stage: translation, back-translation, and consensus on the version to be evaluated.

Notably, the Brazilian study in question included more stages to certify the translation, namely, sending the subsequent version created by the third translator to the authors for content assessment and including a fourth stage for the scale to be evaluated by a committee comprised of three judges based on the CVI. These translation and transcultural adaptation processes are necessary because of the need to assess and discuss the positive aspects of the care task. This is because implementing meaningful and efficient support strategies for this population group is possible, as there are

**Table 1.** Evaluation of the translation and cultural adaptation of the Positive Aspects of Care scale by the experts' committee, São Carlos, 2022

Items from the original instrument in English	Consensus version prepared by the translators	Changes proposed by the experts' committee	Translated and adapted pre-final version
Title: Positive Aspects of Caregiving Scale	Escala de Aspectos Positivos do Cuidado		Escala de Aspectos Positivos do Cuidado
General Guidelines: Some caregivers say that, despite all the difficulties involved in giving care to a family member with memory or health problems, good things have come out of their caregiving experience too. I'm going to go over a few of the good things reported by some caregivers. I would like you to tell me how much you agree or disagree with these statements.	Alguns cuidadores dizem que, apesar de todas as dificuldades para cuidar de um familiar com problemas de memória ou de saúde, coisas boas também decorrem de sua experiência de cuidado. Vou comentar algumas dessas coisas boas relatadas por alguns cuidadores. Gostaria que você me dissesse o quanto você concorda ou discorda dessas afirmações. O cuidar...	Vou comentar algumas das coisas boas relatadas por alguns cuidadores. Gostaria que você me dissesse o quanto você concorda ou discorda dessas afirmações	Alguns cuidadores dizem que, apesar de todas as dificuldades para cuidar de um familiar com problemas de memória ou de saúde, coisas boas também decorrem de sua experiência de cuidado. Vou comentar algumas coisas boas relatadas por alguns cuidadores. Gostaria que você me dissesse o quanto você concorda ou discorda dessas afirmações. O cuidar...
<b>1. 1. Made me feel more useful.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>1. Fez com que eu me sinta mais útil.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito.	<b>1. Fez com que eu me sinta mais útil.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito.	
<b>2. Made me feel good about myself.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>2. Fez com que eu me sinta bem comigo mesmo.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito	Mesmo(a)	<b>2. Fez com que eu me sinta bem comigo mesmo(a).</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito
<b>3. Made me feel needed.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>3. Fez com que eu sinta que alguém precisa de mim.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito		<b>3. Fez com que eu sinta que alguém precisa de mim.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito
<b>4. Made me feel appreciated.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>4. Fez com que eu me sinta valorizado(a)</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito		<b>4. Fez com que eu me sinta valorizado(a).</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito
<b>5. Made me feel important.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>5. Fez com que eu me sinta importante.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito		<b>5. Fez com que eu me sinta importante.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito
<b>6. Made me feel strong and confident.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot	<b>6. Fez com que eu me sinta forte e confiante.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito		<b>6. Fez com que eu me sinta forte e confiante.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito

Continue...

**Table 1.** Continuation.

Items from the original instrument in English	Consensus version prepared by the translators	Changes proposed by the experts' committee	Translated and adapted pre-final version
<p><b>7. Enabled me to appreciate life more.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot</p>	<p><b>7. Fez com que eu valorize mais a vida.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>	Permitiu-me valorizar mais a vida	<p><b>7. Permitiu-me valorizar mais a vida.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>
<p><b>8. Enabled me to develop a more positive attitude toward life.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot</p>	<p><b>8. Permitiu-me desenvolver uma atitude mais positiva em relação à vida.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>		<p><b>8. Permitiu-me desenvolver uma atitude mais positiva em relação à vida.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>
<p><b>9. Strengthened my relationships with others.</b> 1: Disagree a lot; 2: Disagree a little; 3: Neither agree nor disagree; 4: Agree a little; 5: Agree a lot</p>	<p><b>9. Fortaleceu minhas relações com os outros.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>	Fortaleceu os meus relacionamentos com as outras pessoas.	<p><b>9. Fortaleceu os meus relacionamentos com as outras pessoas.</b> 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito</p>

**Table 2.** Percentage agreement rates among experts according to semantic and idiomatic assessments in the original and translated versions of the Positive Aspects of Care Scale. São Carlos, 2022

Items	CVI
1 Aspectos Positivos do Cuidado	1.00
2 Alguns cuidadores dizem que, apesar de todas as dificuldades para cuidar de um familiar com problemas de memória ou de saúde, coisas boas também decorrem de sua experiência de cuidado. Vou comentar algumas coisas boas relatadas por alguns cuidadores. Gostaria que você me dissesse o quanto você concorda ou discorda dessas afirmações	1.00
3 A escala de avaliação é a seguinte: 1: Discordo muito; 2: Discordo um pouco; 3: Nem concordo nem discordo; 4: Concordo um pouco; 5: Concordo muito.	1.00
4 O cuidar fez com que eu me sinta mais útil	1.00
5 O cuidar fez com que eu me sinta bem comigo mesmo(a)	1.00
6 O cuidar fez com que eu sinta que alguém precisa de mim	1.00
7 O cuidar fez com que eu me sinta valorizado(a)	1.00
8 O cuidar fez com que eu me sinta importante	1.00
9 O cuidar fez com que eu me sinta forte e confiante	1.00
10 O cuidar permitiu-me valorizar mais a vida	1.00
11 O cuidar permitiu-me desenvolver uma atitude mais positiva em relação à vida	1.00
12 O cuidar fortaleceu os meus relacionamentos com as outras pessoas	1.00

many studies on the harms to health experienced by informal caregivers of people with dementia.<sup>20</sup>

Liu et al.<sup>21</sup> state that it is important for health professionals and providers of community-based activities to help caregivers recognize sources of resilience that have developed across their life course and in the process of adapting to caregiving responsibility, grounded in one-on-one guidance sessions or support groups.

Therefore, positive experiences related to the roles attributed to family caregivers of people with dementia include improvements in the relationship between the caregiver and the older adult, caregiver's confidence, learning to cope with difficult circumstances, and achieving satisfaction from the care responsibilities.<sup>22</sup>

A notable limitation of this study is the scarcity of Brazilian studies on PAC among informal caregivers of people with dementia,



**Table 3.** Final version of the Positive Aspects of Care scale translated and culturally adapted to Brazilian Portuguese. São Carlos, 2022

<b>Escala de Aspectos Positivos do Cuidado</b>					
<b>Alguns cuidadores dizem que, apesar de todas as dificuldades para cuidar de um familiar com problemas de memória ou de saúde, coisas boas também decorrem de sua experiência de cuidado. Vou comentar algumas coisas boas relatadas por alguns cuidadores. Gostaria que você me dissesse o quanto você concorda ou discorda dessas afirmações</b>					
	<b>Discordo muito</b>	<b>Discordo um pouco</b>	<b>Nem concordo nem discordo</b>	<b>Concordo um pouco</b>	<b>Concordo muito</b>
1. O cuidar fez com que eu me sinta mais útil.	1	2	3	4	5
2. O cuidar fez com que eu me sinta bem comigo mesmo(a).	1	2	3	4	5
3. O cuidar fez com que eu sinta que alguém precisa de mim.	1	2	3	4	5
4. O cuidar fez com que eu me sinta valorizado(a)	1	2	3	4	5
5. O cuidar fez com que eu me sinta importante	1	2	3	4	5
6. O cuidar fez com que eu me sinta forte e confiante	1	2	3	4	5
7. O cuidar permitiu-me valorizar mais a vida	1	2	3	4	5
8. O cuidar permitiu-me desenvolver uma atitude mais positiva em relação à vida.	1	2	3	4	5
9. O cuidar fortaleceu os meus relacionamentos com as outras pessoas	1	2	3	4	5

which makes it difficult to deepen the discussion. Another limitation of the current study is that the data were collected using a digital platform, which precluded the participation of people with no access to the digital environment or those who were unaware of the study. However, it is important to note that this study stands out for being innovative, and that its objective is to provide an instrument about the PAC. Consequently, future studies should perform psychometric analyses of the scale to provide a reliable instrument for use in clinical practice and intervention research.

## CONCLUSION

The PAC scale was translated and culturally adapted for use by informal caregivers of people with dementia in Brazil. The findings of this study showed strong agreement among the experts in the semantic and idiomatic assessments of the original and translated versions of the scale, thus confirming that the questionnaire could be used to evaluate the positive aspects associated with caregiving in the researched sample. This study has repercussions for enabling and comparing data to global findings, in addition to providing an easy- and fast-to-apply tool for health professionals that meets the demands of caregivers of people with dementia.

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# Comparison of nutritional status and growth curves of children and adolescents in the city of Goiânia, Goiás: cross-sectional study

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## KEY WORDS (MeSH terms):

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Nutritional status.  
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Public health.  
Obesity.

## AUTHORS' KEY WORDS:

Body weights and measures  
Body weight  
Unified health system.

## ABSTRACT

**BACKGROUND:** Nutritional status and growth curves can affect cognitive development, increase the risk of infection, and contribute to the development of chronic diseases. Its etiology is related to food, socio-economic, and maternal conditions. However, to date, no data on these parameters exist in the state of Goiás, Brazil.

**OBJECTIVE:** To compare the nutritional status and growth curves of children and adolescents in the city of Goiânia, Goiás, Brazil.

**DESIGN AND SETTING:** This was a cross-sectional study. A total of 529 individuals were recruited from a primary health center in the municipality.

**METHODS:** To assess nutritional status, the sample was divided into three categories: 3–4, 5–10, and 11–19 years, with z-score classification considering body mass index for age. The classification of growth curves was performed considering the median height values for age, assuming two references: (a) young Brazilian population and (b) one recommended for international use. The independent sample T-test was used to compare anthropometric variables.

**RESULTS:** The results showed that the classification of eutrophics represents a predominant percentage between both sexes (men: 03–04 = 55.4%; 05–10 = 57.6%; 11–19 = 53.5 % and women: 03–04 = 53.5%; 05–10 = 63.9%; 11–19 = 56.9%), and growth curves showed differences in specific periods in both sexes.

**CONCLUSIONS:** It can be concluded that children and adolescents from the city of Goiânia present as predominance the eutrophic nutritional status, followed by the risk of overweight, underweight, obesity, and malnutrition of both sexes.

## INTRODUCTION

The World Health Organization (WHO) considers children people aged between 0 and 10 years, and adolescents between 10 and 19 years of age.<sup>1</sup> The prevalence of children and adolescents in Brazil is around 60 million people.<sup>2</sup> In this age group, several important changes occur over the years, and for an adequate growth process, understanding the variables involved in this stage, such as the factors associated with malnutrition, overweight, and obesity, is essential.<sup>3</sup>

Malnutrition is a nutritional status directly related to infant morbidity and mortality, with a prevalence of up to 59% in certain regions such as Timor-Leste, Burundi, Niger, and Madagascar.<sup>4</sup> This nutritional status can affect cognitive development, increase the risk of infections, and contribute to the development of chronic diseases such as diabetes, hypertension and coronary diseases.<sup>5</sup> Its etiology is related to food, socioeconomic, maternal conditions, and health services<sup>6</sup> and may even interfere with the negativity in the country's economy.<sup>5</sup>

Although the risks associated with malnutrition are concerning, paradoxically, overweight and obesity have become increasingly frequent among children and young people.<sup>7,8</sup> This can contribute to the early development of chronic diseases, such as cardiovascular and metabolic,<sup>9</sup> and may reduce the life expectancy of this population.<sup>10</sup>

In a study conducted by Gordon-Larsen et al.,<sup>11</sup> evidence was found that the transition between adolescence and adulthood represents a period of risk for increased overweight and obesity regardless of sex. Therefore, monitoring nutritional status during the growth period can contribute to the prevention of these factors.

Growth curves enable the observation of the growth patterns of healthy individuals under environmental and social conditions favorable to their development. Thus, this instrument makes it possible to analyze and compare growth parameters in different regions of Brazil and other countries, observing the health condition of children and adolescents,<sup>12</sup> not only the risks of malnutrition but also the prevalence of overweight and obesity in this population.<sup>7</sup> These nutritional states may contribute to the early development of chronic diseases, such as cardiovascular and metabolic,<sup>9</sup> and may reduce the life expectancy of this population.<sup>10</sup>

Growth curves are internationally accepted standards for observing differences between populations or subgroups in a given region with regard to the health condition of children and adolescents.<sup>12</sup>

Therefore, the control of nutritional status and physical growth can contribute to the prevention of diseases and the creation of government actions to improve the quality of life of the general population.

## OBJECTIVE

This study aimed to compare the nutritional statuses and growth curves of children and adolescents in the cities of Goiânia and Goiás, Brazil.

## METHOD

To compare the nutritional status and growth curves, data were collected from a primary center of public health care in the city of Goiânia, Brazil. Health centers are managed by the Brazilian Unified Health System in Goiânia, Brazil. Data were collected between September and October 2011 from the medical records of individuals aged 3–19 years old.

A priori sample analysis revealed that to achieve a 0.5 effect size (ES) with a power of 0.95, a total of 210 participants would be necessary. Therefore, 529 participants were recruited to account for eventual attrition, which was approved by the Ethics Committee in Human Research, Universidade Federal de Goiás (CEP/CAAE:64091717.0.0000.5083), on March 9, 2017. All procedures were performed in accordance with the Declaration of Helsinki.

The sample was stratified into four categories for characterization: 3–5, 6–10, 11–15, and 16–19 years. Body mass and height were measured using a scale and stadiometer (Filizola PL200, São Paulo, Brazil) with accuracies of 100 g and 0.1 cm, respectively (Table 1).

The body mass index (BMI) was calculated by dividing the weight in kilograms by height square into meters. For nutritional status assessment, the sample was divided into three age categories (2007):<sup>13</sup> 3–4 (3 ≥ age ≤ 4 years), 5–10 (5 ≥ age ≤ 10 years), 11–19 (11 ≥ age ≤ 19 years); as a classification parameter, the score-z was adopted considering BMI for age (Table 2).

The classification of physical growth curves (Figures 1 and 2) was performed by graphical comparison of the median values of height for age, assuming two references: (a) the Brazilian young population

(Instituto Brasileiro de Geografia e Estatística [IBGE])<sup>14</sup> and (b) recommended for international use by the World Health organization.<sup>13</sup>

The normality of age, body mass, height, and body mass index data was analyzed using the Kolmogorov–Smirnov test. For comparison between variables, the t-test was used for independent samples for parametric data and the Mann–Whitney test for non-parametric data. Statistical significance was set at  $P < 0.05$ .

## RESULTS

A total of 253 females ( $9.55 \pm 5.36$  years,  $31.50 \pm 18.06$  kg,  $1.28 \pm 0.25$  m) and 276 males ( $8.42 \pm 4.96$  years,  $29.66 \pm 19.43$  kg,  $1.24 \pm 0.28$  m) were evaluated.

Groups aged between 16 and 19 years ( $16 \leq 19$  years) demonstrated significant difference in body mass ( $54.3 \pm 9.8$  and  $66.00 \pm 16.5$ ) ( $P = 0.003$ ), as well as in height ( $1.7 \pm 0.1$  and  $1.6 \pm 0.1$ ) ( $P = 0.000$ ), between men and women, respectively (Table 1). However, no significant differences were found in the other variables.

The classification of nutritional status using the Z-score (Tables 2 and 3) showed that eutrophication represents a higher percentage among groups of men (03–04 years = 55.4%; 05–10 years = 57.6%; 11–19 years = 53.8%) and women (03–04 years = 53.5%; 05–10 years = 63.9%; and 11–19 years = 56.9%). Despite the increased overweight in men (17.3%) compared with women (12.1%) in the age group between 11 and 19 years, overweight and obesity have higher percentages in women (13.8% and 5.2%, respectively), when compared with men (7.7% and 3.8%, respectively). In this context, a higher

**Table 1.** Characterization of the participants

Variable	n	Men	n	Women	P*
		Mean (DP)		Mean (DP)	
<b>Age (years)</b>					
03–05	109	$3.9 \pm 0.9$	86	$4.0 \pm 0.8$	0.376
06–10	69	$7.8 \pm 1.5$	60	$7.4 \pm 1.5$	0.207
11–15	52	$13.1 \pm 1.5$	43	$12.6 \pm 1.1$	0.430
16–19	35	$17.6 \pm 1.1$	48	$17.7 \pm 1.2$	0.585
<b>Body mass</b>					
03–05	109	$15.7 \pm 3.5$	86	$15.6 \pm 2.9$	0.848
06–10	69	$24.9 \pm 7.1$	60	$23.2 \pm 6.6$	0.221
11–15	52	$42.8 \pm 14.6$	43	$42.9 \pm 16.0$	0.975
16–19	35	$66.0 \pm 16.5$	48	$54.3 \pm 9.8$	0.003
<b>Stature</b>					
03–05	109	$1.0 \pm 0.1$	86	$1.0 \pm 0.1$	0.926
06–10	69	$1.2 \pm 0.1$	60	$1.2 \pm 0.1$	0.399
11–15	52	$1.5 \pm 0.2$	43	$1.5 \pm 0.2$	0.525
16–19	35	$1.7 \pm 0.1$	48	$1.6 \pm 0.1$	0.000
<b>Body mass index</b>					
03–05	109	$15.7 \pm 1.8$	86	$15.3 \pm 1.8$	0.241
06–10	69	$16.2 \pm 2.5$	60	$15.7 \pm 2.3$	0.502
11–15	52	$18.9 \pm 4.0$	43	$19.6 \pm 4.8$	0.432
16–19	35	$22.7 \pm 4.5$	48	$21.8 \pm 3.0$	0.900

percentage of overweight and obesity was demonstrated in men only between 3 and 4 years (12.2% and 5.4%, respectively) when compared with women (8.6% and 1.7%, respectively).

However, thinness had a higher prevalence percentage in women aged 3–4 years compared with men (12.1% and 5.4%, respectively); In addition, in groups 11 and 19 years, men had higher percentages of thinness than women (13.5% and 8.6%, respectively).

The growth curves between men and women (Figures 1 and 2) demonstrated differences between the sexes at 7 and 9 years, as well as between 15 and 17 years, with higher values for men. However, a decline in the curve for men aged 13 and 15 years was demonstrated when compared with the IBGE and WHO data.

## DISCUSSION

This study aimed to verify the nutritional status and growth curve of children and adolescents in the city of Goiânia, Goiás. The results

showed that male adolescents aged 16–19 years had greater heights and body masses than female adolescents. Regarding nutritional status, male and female children and adolescents had a higher prevalence of eutrophy; however, overweight and obesity were observed in all age groups. In addition, we found a significant difference between sexes in height and body mass in the age group of 16–19 years ( $P = 0.00$  and  $P = 0.00$ , respectively).

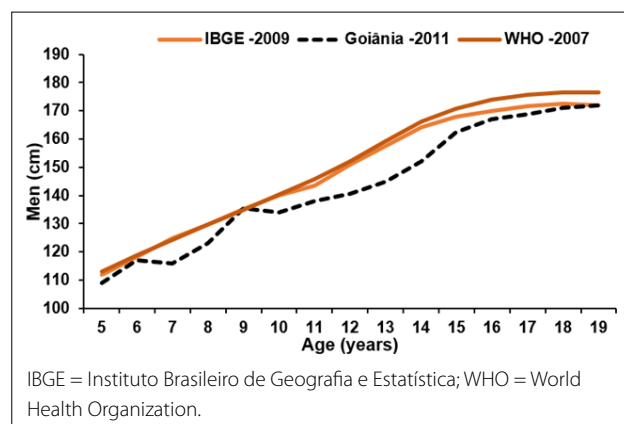
Additionally, body mass, height, and nutritional status are related. In a systematic review by Junior et al.<sup>15</sup> that analyzed the influence of these two factors on body fat in individuals aged 2–19 years, the results demonstrated a positive correlation between these factors and body fat in both sexes (men,  $r = 0.975$ ; women,  $r = 0.947$ ). This demonstrates the importance of monitoring growth curves during adolescence as a form of care for adults with obesity.

Regarding the growth curve, at the age of 19 years, a similar curve was verified among men in our study with IBGE data from

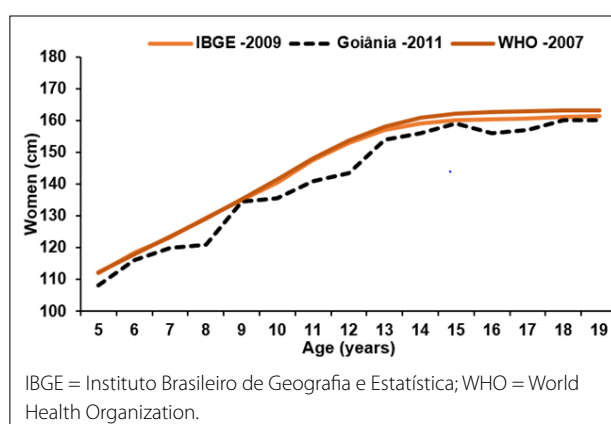
**Table 2.** Classification of nutritional status of males based on the World Health Organization (2007)

Age (year)	BMI-stature						
	n	ST	TH	ET	OW	OB	SB
03–04	74	1.4%	5.4%	55.4%	20.3%	12.2%	5.4%
05–10	60	5%	7.5%	57.6%	22.5%	6.3%	1.3%
11–19	52	3.8%	13.5%	53.8%	17.3%	7.7%	3.8%

BMI = body mass index; ST = severe thinness; TH = thinness; ET = eutrophy; OW = overweight; OB = obesity; SB = severe obesity.



**Figure 1.** Comparison of the growth curves of men in Goiânia with Instituto Brasileiro de Geografia e Estatística and World Health Organization data.



**Figure 2.** Comparison of women's growth curves in Goiânia with Instituto Brasileiro de Geografia e Estatística and World Health Organization data.

**Table 3.** Classification of nutritional status of females based on the World Health Organization (2007)

Age (year)	BMI-stature						
	n	ST	TH	ET	OW	OB	SB
03–04	58	1.7%	12.1%	53.5%	22.4%	8.6%	1.7%
05–10	60	1.6%	8.2%	63.9%	23.0%	3.3%	0%
11–19	58	3.4%	8.6%	56.9%	12.1%	13.8%	5.2%

BMI = body mass index; ST = severe thinness; TH = thinness; ET = eutrophy; OW = overweight; OB = obesity; SB = severe obesity.

2009 (1.70 cm); however, the curve was lower than the WHO in 2007 (1.80 cm). However, women presented a lower growth curve (1.55 cm) than that of the IBGE (1.58 cm) and WHO (1.60 cm) criteria. This demonstrates that Goiânia adolescents present a shorter stature compared with the two references adopted. This is justified by the average height of the population of Goiânia, which is 1.75 cm for men and 1.78 cm for women, below those of the IBGE and WHO.<sup>13,14</sup>

Regarding the findings on the classification of nutritional status, the results showed low percentages of obese adolescents with overweight in men (3.8% and 7.7%) as well as in women (5.2% and 13.8%), which do not corroborate with those of other regions in the country. Geremia et al.,<sup>16</sup> estimated the prevalence of overweight and obesity in adolescents with a mean age of  $12.45 \pm 1.49$  years in the city of Bento Gonçalves, in the interior of the state of Rio Grande do Sul, Brazil. Male adolescents have levels of overweight and obesity of 16.3% and 12.2%, respectively. However, female adolescents have levels of overweight and obesity of 16.2 and 5.5%, respectively. Possibly, the factors inherent in the higher percentage of obese and overweight individuals in the south of the country may be cultural influences, as some of the populations are Italian and German immigrants. Another factor contributing to the low rate of obesity and overweight among adolescents is the level of physical activity. In our study, adolescents in public education in Goiás, children, and adolescents who attend public schools have a higher level of physical activity than those who attend private education.<sup>8</sup>

However, when we compared our results with those of other Latin American countries, our results corroborate with the study of Atalah et al.<sup>17</sup> in Chile referring to the “eutrophic” nutritional status of adolescent men (55.4% and 62.18%, respectively) and overweight (20.3% and 15.83%, respectively). Additionally, the adolescent men in our study had a lower percentage of obesity (3.8%) compared with those in Chile (16.6%), which may be associated with the eating factors of the country; in addition, this divergence may have been influenced by the economic level and social differences, in which the higher the socioeconomic level and the lower the inequality, the higher the obesity,<sup>13</sup> which may justify the percentage results of obesity similar to the study (5.4%) reported by Capanzana et al.<sup>18</sup> on the Philippines, as this country has low social status, coupled with natural disasters, such as tsunamis, along with low investment in public policies.

In this context, despite similar results in other nutritional statuses, the study of Camarinha Graça e Nogueira,<sup>19</sup> conducted in Portugal, also reported percentage results of higher obesity (6.3%) than that in our study, demonstrating that countries with higher human development index (HDI) appear to favor the development of obesity, which is an important finding for future research.

Interestingly, we found results contrary to this hypothesis in the study by Ubesie et al.<sup>20</sup> in Africa, more specifically in southwestern Nigeria. Sixty-five percent of the children and adolescents were eutrophic, and 2% were underweight. These values resemble the nutritional status of young people in the city of Goiânia with the same age group: 63.9% eutrophic and 1.6% low weight. However, although Nigeria has a smaller HDI than Brazil, southeastern Nigeria has a better level of existence than the rest of the country, thus offering better living conditions for children and adolescents in this region.<sup>21</sup> Similar to the Nigerian study, children and adolescents also have low socioeconomic levels, which explains 1.6% of the population is underweight.<sup>21</sup>

However, HDI also appears to reflect the growth curve, and the study of Gomez-Campos et al.<sup>22</sup> analyzed the growth curve of children in Chile with a mean age of 11 years, noting a height greater than that of Brazilian children in both sexes (men 1.45 cm and women 1.35 cm). However, when we compared our findings with countries, such as East Timor, which has high levels of malnutrition and environmental disasters, as well as military conflicts, we found lower results than those found in our study in male adolescents (1.40 versus 1.60 cm) and females (1.30 versus 1.50 cm), as well as in that of the WHO (1.70 and 1.60 cm, respectively). This shows that the socioeconomic conditions in Brazil are better than those in some African and Asian countries.

In this sense, we find differences in the growth curve of our study compared with those of other countries in Europe. Riedlová et al.<sup>23</sup> analyzed 960 male children born in the Czech Republic aged 12 years. The mean height was 1.81 cm, which is higher than our findings (1.40 cm), as well as that of the WHO (1.79 cm). This difference may be related to the best living and feeding conditions of European children compared with those of Brazilian children.<sup>21</sup> In addition, genetic influences may also influence this variable.<sup>24</sup>

Cultural aspects can also influence the growth curve as shown in a study conducted by Bahchachi et al.<sup>25</sup> who analyzed the growth curve of 7,772 Algerian adolescents of both sexes. The results showed that female adolescents had an average of 1.57 cm of height, whereas male adolescents had an average of 1.75 cm. The Algerian study results are higher than that of the Goiânia male adolescents (1.70 cm); however, when compared with the females, the growth curve of Brazilian adolescents were higher (1.60 cm). In addition to Algeria, which had a high HDI (0.754), such differences between sexes may be related to cultural aspects. Algeria is a Muslim country where an explicit difference exists between the sexes, in which female children and adolescents are oriented to perform domestic services and take care of the family, while the opposite sex has more opportunities to develop their physical aspects, such as physical exercise and better feeding.<sup>21</sup> This demonstrates how much the physical and social environments influence nutritional status.<sup>3</sup>

Additionally, the comparison of growth curves between different regions of Brazil showed similar results between the cities of Campinas and Goiânia. Campos et al.<sup>26</sup> analyzed the growth curve of children and adolescents in the city of Campinas (SP). The results were similar in adolescents of both sexes aged 18 years: women presented an average height of 1.55 cm, whereas men, 1.70 cm. These values corroborate the results of our study, demonstrating that despite children and adolescents presenting a growth curve lower than that of the IBGE, it resembles other Brazilian cities.

Monego e Jardim<sup>27</sup> conducted a population-based study with 3,169 students in eastern Goiânia and identified overweight and obesity levels of 10.8% and 5.3% among male students and 11.3% and 4.5% among girls, with an average of 10.7 years (10.72 for boys and 10.76 for girls), presenting higher levels of overweight and obesity when compared with the results of this study for the age group of 5 to 10 years. The study by Monego e Jardim in 2006 was performed using data from students in 2001. Our study used data from 2011. In 10 years, the percentage of children and adolescents who were obese decreased, which is due to an increase in the practice of activity mainly in schools and an improvement in the population's socioeconomic levels.<sup>3</sup>

Therefore, the differences in nutritional status and growth curve are directly related to the culture of countries, socioeconomic conditions, and public policies that each region implement within its own state.<sup>28</sup> Particularly at the end of adolescence and early adulthood, a relationship exists between the response to adverse events and weight changes.<sup>29</sup> One manner to improve the growth curve related to body mass may be the practice of physical exercise. Adolescents who practice physical exercise have adequate control of body weight; however, inadequate lifestyles can impair this development.<sup>30</sup> Our research has a significant sample and is an original study. Not research has yet evaluated the growth curve of children and adolescents in both sexes in the city of Goiânia. As a limitation, we did not assess the socioeconomic levels and levels of physical activity. These results can contribute to the creation of public policies in the city of Goiânia and the region, which aim to reduce the risk of overweight and obesity, in addition to improving aspects related to growth curves and consequently economic, social and cultural development, through the investment of public policies in the sectors inherent to these aspects.

## CONCLUSION

Children and adolescents in the city of Goiânia present a predominantly eutrophic nutritional status, followed by the risk of overweight, underweight, obesity, and malnutrition in both sexes. A trend of increasing BMI over time exists. Additionally, the growth curve was lower than those of the WHO and IBGE levels. Despite the optimistic results regarding the percentage of eutrophication, the risk of being overweight is high among

men and women, which corroborates with some epidemiological studies that demonstrated a prevalence relationship of overweight in developed regions when compared with less developed regions, demonstrating that improving access to information inherent to body mass control and general health is required.

Additionally, further studies should be conducted in other regions of the state and country to verify the aspects inherent to the development of the population, which directly reflects national development.

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data curation (equal), formal analysis (equal), and writing—original draft (equal); Vieira CA: project administration (equal), supervision (equal), writing—original draft (supporting), writing—reviewing and editing (supporting). All authors contributed to the construction of the manuscript, including conceptualization and methodology, and read, agreed, and approved the final version for publication

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# Psychometric properties of the Providers Survey in the Brazilian context of mental health: a validation study

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## ABSTRACT

**BACKGROUND:** Precisely determining the aspects related to an instrument's validity and reliability measures allows for greater assurance of the quality of the results.

**OBJECTIVES:** To analyze the psychometric properties of The Providers Survey in the Brazilian context of mental health services.

**DESIGN AND SETTING:** The instrument validation study was conducted in Montes Claros, Minas Gerais, Brazil.

**METHODS:** The validation study was conducted using the Consensus-based Standards for the Selection of Health Measurement Instruments checklist to analyze its validity and reliability.

**RESULTS:** A committee of expert judges performed content validation after which the Content Validity Index was calculated. Construct validation took place through Exploratory Factor Analysis using the Kaiser-Meyer-Olkin Test criterion and Bartlett's Sphericity Test. Reliability was verified using test-retest reliability. The significance level adopted for the statistical tests was 5% ( $P < 0.05$ ). The final instrument comprised 54 questions. The Content Validity Index was 97%. Exploratory Factor Analysis identified a Kaiser-Meyer-Olkin index of 0.901 and Bartlett's Sphericity Test with  $P < 0.001$ . We obtained a Cronbach's alpha coefficient of 0.95 and an intraclass correlation coefficient of 0.849.

**CONCLUSIONS:** The Providers Survey, translated and adapted into Portuguese, was named the Work Assessment Instrument for the Recovery of Mental Health. It presented adequate psychometric properties for evaluating work-related practices for the recovery of psychosocial care network users.

## INTRODUCTION

The mental health policy in Brazil has shifted from a clinical model with an emphasis on reducing or removing mental health symptoms to a broader understanding based on an active, non-linear ongoing journey that involves rebuilding oneself and living a full and meaningful life. To this end, the concept of health is intimately disconnected from the absence of linked diseases, and harmonization exists between all conditioning factors and determinants of health, such as food, housing, leisure, safety, and work. The weight of these factors provides an individual with health from a biopsychosocial perspective.<sup>1,2</sup>

The inclusion of patients with mental disorders in daily and social activities began in Brazil in the 1970s and in the United States and in other European countries in the mid-1980s, and the use of the Recovery concept expanded. The expansion of this concept took place through the mobilization of users, family members, professionals, and managers in favor of actions that would provide an optimistic model of personal power to users of Mental Health services, thus consolidating a set of elements that empowered them to redirect their lives after being diagnosed with a mental disorder.<sup>3</sup>

One proposal for the implementation of Recovery for people with mental disorders is their insertion into the labor market, as work can act as a support component in the reinstatement of these individuals.<sup>4,5</sup>

Studies indicate that the inclusion of patients with mental disorders in the labor market has a positive economic, psychosocial, and clinical impact on their lives.<sup>6,7</sup> Another important point is that employment correlates with short-term reductions in mental health costs.<sup>8,9</sup>

In 2016, in the State of Connecticut in the United States, The Providers Survey instrument was developed to verify the perception of job providers regarding the relationship between work

and the recovery of people with mental disorders.<sup>10</sup> There is a lack of evaluative instruments regarding the proposals of Recovery applied in the Brazilian cultural context of Mental Health services, despite its strength in the international scenario.

Precisely determining the aspects related to the instrument's validity and reliability measures allows for greater assurance of the quality of results. It is worth noting, however, that validity and reliability are not fixed measures and may vary according to the population, type of study, and its purpose.<sup>11</sup>

For this study, this proposal was adopted to validate The Providers Survey instrument, based on an analysis of its psychometric properties, given that its cross-cultural adaptation was conducted in a previous study. This study contributes to clinical practice in the field of mental health by stimulating research on the perceptions of health professionals regarding the relationship between work and the recovery of people with mental disorders.<sup>12</sup>

## OBJECTIVES

This study aimed to analyze the psychometric properties of The Providers Survey instrument in the Brazilian context of mental health services through validation using the Consensus-Based Standards for the Selection of Health Measurement Instruments checklist for the analysis of content, construct validity, and reliability.

## METHODS

This instrument validation study aims to describe the psychometric properties of The Providers Survey in the Brazilian context of Mental Health services after cross-cultural adaptation.

For validation, we used the Consensus-Based Standards for the Selection of Health Measurement Instruments checklist to analyze the characteristics of validity and reliability.<sup>13</sup> The validity measure was verified by content validation through the evaluation of a committee of expert judges, followed by the calculation of the Content Validity Index, which was validated using Exploratory Factor Analysis. The reliability measure was verified from the analysis of Internal Consistency by Cronbach's alpha coefficient and the test-retest stability by the Intraclass Correlation Coefficient. Data were tabulated and analyzed using SPSS version 22.0 for Windows program (IBM, Armonk, New York, United States). Validity and reliability characteristics are relevant domains for validating measurement instruments.<sup>14,15</sup>

This project was approved by the Research Ethics Committee of the Universidade Estadual de Montes Claros (UNIMONTES) under Opinion No. 2,398,868 (Montes Claros, November 25, 2017). All participants agreed to participate in the study by signing the Free and Informed Consent Term form.

The Providers Survey instrument's original version was developed in Connecticut, the United States, and has 85 questions distributed in four domains. After cross-cultural adaptation for use

in Brazil, the instrument presented 65 questions distributed in three domains: Domain I, with 26 questions referring to important aspects of working with clients with mental disorders; Domain II, with 16 questions related to factors that allow people with mental disorders to obtain and maintain a job; and Domain III, with 23 questions related to factors that promote the recovery of people with mental disorders.<sup>12</sup>

After the cross-cultural adaptation, the psychometric properties of the instrument were verified. Subsequently, the instrument had 54 questions, with 24 questions in the first part of the instrument related to the work of health professionals with users in mental suffering, 14 questions referring to the components that allow users in mental suffering to obtain and maintain their jobs, and 16 questions referring to the importance of the components to promote the restoration/recovery of users in mental suffering.

Data collection for the assessment of the instrument's psychometric properties after cross-cultural adaptation was conducted between December 2019 and January 2020.

## RESULTS

For content validation, 10 Mental Health specialists, all with knowledge about Recovery, participated in this study and comprised a committee of expert judges/experts.

We performed an Exploratory Factor Analysis to validate this construct. At this stage, 496 questionnaires were sent, and 364 responses were returned. Of the total questionnaires answered, eight professionals refused to participate in the research and 38 questionnaires were not fully answered, leading to a loss rate of 26.6% (n = 132). Finally, 318 valid questionnaires were obtained. After validating the instrument, we verified its reliability through Internal Consistency analysis and its stability through test-retest.

### Content validation

The content validation stage of the Providers Survey instrument included the participation of a committee of 10 specialist professionals with different activities in the components of the Psychosocial Care Network in the city of Montes Claros, MG, Brazil, who had knowledge of mental health recovery. Of these professionals, two were doctors, one was a nurse, one was a dentist, and six were psychologists, as described in **Table 1**.

We sent a questionnaire containing The Providers Survey with 74 items to be evaluated by the expert committee. The content of this instrument refers to the Informed Consent Term form; participant identification data; type of service; position; working time; instrument title; and 26 questions related to Domain I, 16 questions related to Domain II, and 23 questions related to Domain III.

To verify the clarity, scope of the items, and the general structure and layout of the instrument, this questionnaire included a specific field related to each item so that each specialist could put

their considerations regarding the item evaluated for further adequacy. Throughout the evaluation process, the responsible team was able to clarify doubts and possible queries.

To conduct the aforementioned assessment of the instrument's items, we used a 4-point Likert scale, in which each item of the instrument received the following classification: 1) being a non-equivalent item; 2) a slightly equivalent item that needs many revisions; 3) an equivalent item that requires few revisions; and 4 a fully equivalent item. Instrument items with a score of 1 or 2 were excluded.

After this step, the instrument presented 69 items, as two questions from the first domain, two questions from the second domain, and one question from the third domain were excluded.

After the subjective assessment by the group of experts, the Content Validity Index was calculated. The 74 items were analyzed by 10 committee participants, totaling 740 responses, with 10 responses referring to each item of the instrument. From the sum of all responses classified as 3 or 4, followed by dividing by the total number of responses, we obtained a Content Validity Index of 97%.

### Construct validation

Construct validity, also known as factor validity, is considered one of the most important measures of instrument validity in research and aims to verify whether the items of the instrument have a reliable and adequate representation of the construct to be measured.

At this stage, 318 health professionals with higher education working in cities included in the Regional Health Management of Montes Claros, located in the north of the state of Minas Gerais, Brazil, participated as respondents, as described in Table 2.

The instrument version that also contained the ICF was sent via WhatsApp to 318 participants. The responses were consolidated in the Qualtrics Survey Software Platform, which is an online survey platform, from which the data were sent directly to Microsoft Excel 2016 (version 16.0) for Windows (Microsoft Corporation, Redmond, Washington, United States) and then exported to SPSS version 22.0, for Windows (National Opinion Research Center, Chicago, Illinois, United States).

The initial Exploratory Factor Analysis procedures indicated a Kaiser-Meyer-Olkin index of 0.901 and Bartlett's test, with a significance level of  $P < 0.001$ . The model was adjusted using principal component analysis. Varimax orthogonal rotation was used because it treats domains as independent. In the analysis of commonalities, all variables with factor loadings greater than 0.5 were maintained for matrix rotation. Six questions were eliminated because they had values lower than 0.5, as shown in Table 3. The factor loadings for each variable allowed for the identification of each variable with the respective factor. The three main factors/components of the instrument represent 49.1% of the total cumulative explained variance. After the construct validation stage, the instrument presented 54 questions distributed across three domains.

### Reliability

The reliability of the instrument was verified after content and construct validation. We verified the Internal Consistency using the  $\alpha$ -Cronbach's coefficient and the stability using the test-retest using the Intraclass Correlation Coefficient.

For the stability analysis, we used the test-retest with a sample of 51 respondents, with an average interval of 12 days after the test.

**Table 1.** Characterization of the members of the expert judges committee, Montes Claros, 2019

Specialist	Academic education	Experience in the field of Mental Health
1	Psychologist. Mental Health Specialist.	Preceptor of the Multiprofessional Residency in Family Health. Works in Primary Care. She served as a psychologist in Psychosocial Care Center.
2	Psychologist. Family Health Specialist.	Preceptor of the Multiprofessional Residency in Family Health. Works in Primary Care. Worked as a Psychosocial Care Center.
3	Psychologist. Family Health Specialist.	Preceptor of the Multiprofessional Residency in Family Health. Works in Primary Care.
4	Psychologist. Mental Health Specialist.	Preceptor of the Multiprofessional Residency in Family Health and Mental Health. Works in Primary Care. Worked as a Psychosocial Care Center.
5	Nurse. Family Health Specialist. Master in Primary Health Care.	Preceptor of the Multiprofessional Residency in Family Health. Works in Primary Care service.
6	Doctor. Specialist in Psychiatry and Psychotherapy.	Coordinator of the Residency in Psychiatry. Operates in the private network. Professor at the Department of Medicine at the State University of Montes Claros.
7	Psychologist. Doctor in Psychology. Master in Public Health.	Professor at the Department of Mental Health and Collective Health at the State University of Montes Claros.
8	Psychologist. Mental Health Specialist.	Works in Primary Care. Worked as an intern at Psychosocial Care Center.
9	Dentist surgeon. Family Health Specialist.	Preceptor of the Multiprofessional Residency in Family Health. Works in Primary Care service.
10	Doctor. Specialist in Family and Community Medicine.	Preceptor of the Residency in Family and Community Medicine. Works in Primary Care service.

Source: Prepared by the authors.

The Intraclass Correlation Coefficient to verify the stability of the instrument which presented a value of 0.849 using the Pearson correlation test ( $P < 0.001$ ), and the verification of the internal consistency returned an  $\alpha$ -Cronbach of 0.95.

**Table 2.** Characterization of professionals who participated in construct validation, Montes Claros, MG, Brazil, 2019 (n = 318)

Variables	n	%
<b>Age (years)</b>		
18–24	13	4.1
25–34	162	50.9
35–44	108	34.0
45–54	28	8.8
55–64	6	1.9
65–74	1	0.3
<b>Total</b>	<b>318</b>	<b>100.0</b>
<b>Gender</b>		
Man	71	22.3
Woman	247	77.7
<b>Total</b>	<b>318</b>	<b>100.0</b>
<b>County</b>		
Montes Claros	281	88.4
Bocaiuva	3	0.9
Janaúba	2	0.6
Salinas	5	1.6
Monte Azul	2	0.6
Rather not answer	25	7.9
<b>Total</b>	<b>318</b>	<b>100.0</b>
<b>Occupation area</b>		
Service professionals not specialized in Mental Health	269	84.6
Professionals of specialized services in Mental Health	46	14.5
Rather not answer	3	0.9
<b>Total</b>	<b>318</b>	<b>100.0</b>
<b>Office</b>		
Social worker	12	3.8
Dental surgeon	63	19.8
Coordinator/Manager	15	4.7
Nurse specialist in mental health	9	2.8
Nurse not specialist in mental health	119	37.4
Pharmaceutical	2	0.6
Physician (not psychiatrist)	62	19.5
Psychiatrist	2	0.6
Workshop monitor	1	0.3
Psychologist	29	9.1
Occupational therapist	3	0.9
Rather not answer	1	0.3
<b>Total</b>	<b>318</b>	<b>100.0</b>
<b>Working time (years)</b>		
Less than 1	26	8.2
1–2	69	21.7
3–5	84	26.4
6–9	64	20.1
10 or more	75	23.6
<b>Total</b>	<b>318</b>	<b>100.0</b>

Source: Prepared by the authors.

The significance level adopted for the statistical tests was 5% ( $P < 0.05$ ). All statistical analyses were performed using IBM SPSS statistical package software, version 22.0, for Windows (National Opinion Research Center, Chicago, Illinois, United States). The final version of this instrument is presented in **Table 4**.

After analyzing the psychometric properties of The Providers Survey instrument, it is clear that such measures may vary according to changes in the study population and context presented. It is desirable that new studies be conducted in several Brazilian regions to verify the attitudes and actions of professionals focused on incentive practices and approaches aimed at the recovery of the Psychosocial Care Network service users.

## DISCUSSION

We used a committee of expert judges to evaluate the constructs; of this committee, at least five were specialists in the area.<sup>16</sup> Based on the judgment of experts in the field, we verified the degree of equivalence of each item of the instrument under analysis to measure the degree of relevance of each item of the instrument in a given construct.

After the subjective assessment performed by the group of experts, we calculated the Content Validity Index, which measures the percentage of judges who agreed on the aspects of each item of the instrument.<sup>14,15</sup> Instrument items that received a score of 1 or 2 were excluded.<sup>13</sup> An acceptable Content Validity Index must be at least 0.80, and preferably greater than 0.90.<sup>12,14,15,17,18</sup>

For construct validation, we used the Factor Analysis strategy, considered one of the most important measures of instrument validity in research that aim to verify if the items of a given instrument are a reliable and adequate representation of the construct to be measured.<sup>14,15</sup>

Following the recommendations regarding the constitution of the sample to conduct a Factor Analysis, we aimed for the participation of at least 100 respondents, with 5–10 respondents being ideal for each item of the questionnaire.<sup>11,19–21</sup>

To assess the factorial structure of the instrument, we used the Kaiser-Meyer-Olkin index and Bartlett's Sphericity Test with a significance level of  $P < 0.001$ , which indicates the suitability of factor analysis in the process.<sup>22</sup>

After verifying the suitability of the factor analysis, we rotated the matrix to separate the variables between factors. The varimax rotation method is the most commonly used method in research of this nature, as it treats domains as independent allowing us to exclude questions with a factor loading  $< 0.5$ . Studies recommend that the Principal Components should have eigenvalues  $> 1$ .<sup>23–25</sup>

To assess the reliability of an instrument, we used the internal consistency based on Cronbach's alpha coefficient and the stability based on the test-retest using the Intraclass Correlation Coefficient via the Pearson correlation test.<sup>14,15</sup> The test-retest, which allows the reproduction of a result in time and space, provides homogeneity

**Table 3.** Rotating component matrix elaborated in the construct validation stage, Montes Claros, Minas Gerais, Brazil, 2019

Variables	Components		
	1	2	3
Hosting the user, their family, and/or companions	0.5	0.1	0.0
Recording a complete personal and family anamnesis/history	0.7	0.1	0.1
Conducting case follow-up	0.6	0.3	0.0
Providing a reference technician for case management	0.5	0.1	0.1
Offering counseling and/or guidance and/or psychotherapy or other psychological interventions	0.6	0.1	-0.1
Participating in the formulation of the diagnosis	0.6	0.1	-0.1
Prescribing and/or administering medication	0.5	0.0	0.1
Monitoring medication adherence	0.6	0.1	0.1
Providing guidance on the use of medications and the effect on the user's psychological condition for the user, their family members and/or companions	0.7	0.1	0.1
Identifying and addressing stigma and discrimination/prejudice	0.6	0.0	0.2
Referring users to medical care and assistance	0.6	0.2	0.0
Referring users to social support services to search for work/employment (legal associations and public services)	0.7	0.1	0.2
Providing job search support	0.6	0.0	0.3
Referring users to the treatment of alcoholism and/or the use of psychoactive substances	0.7	0.3	0.0
Providing treatment for alcoholism and/or the use of other psychoactive substances	0.6	0.2	0.0
Referring users to the housing support service	0.6	0.0	0.2
Providing housing search support	0.5	0.0	0.2
Referring users to socialization activities and recreational/leisure support	0.7	0.0	0.1
Providing socialization activities and recreational/leisure support	0.6	0.0	0.2
Referring users to legal support	0.5	-0.1	0.2
Involving family members in supporting users in mental distress	0.7	0.1	0.0
Providing peer support and guidance and/or therapeutic companion	0.7	0.1	0.1
Providing guidance on the self-care and well-being of users	0.7	0.3	0.0
Addressing issues related to the various forms of violence and/or other forms rights violations	0.7	0.1	0.2
Setting a goal for getting a job	0.2	0.1	0.6
Including users in work/employment support programs, regardless of the severity of their symptoms or other underlying difficulties	0.1	0.2	0.6
Conducting a job search as soon as the person shows interest in working	0.2	0.1	0.7
Integrating vocational support with clinical care for the user in an individualized way	0.2	0.1	0.8
Being aware of users' preferences regarding a job/occupation	0.2	0.1	0.7
Identifying and addressing cases of discrimination at work/employment	0.2	0.1	0.7
Encouraging the person to seek employment	0.2	0.3	0.5
Identifying and addressing negative internalized views of themselves that make people believe they are incapable of working	0.2	0.3	0.6
Involving family members in supporting the user's efforts to seek or maintain employment	0.3	0.4	0.5
Engaging peers to support the user's efforts to seek or maintain work/job	0.3	0.3	0.6
Recognizing work/employment as an important need in the restoration of the user	0.2	0.4	0.6
Recognizing the job as a source of stress that should be avoided	-0.1	0.0	0.6
Recognizing employment as offering a valuable social role or as an important source of identity reinforcement	0.2	0.3	0.5
Recognizing employment as a factor that can increase the risk of relapse/crisis of users in mental suffering	-0.1	0.0	0.6
Being connected to something that goes beyond oneself (e.g., spirituality/religiosity)	0.0	0.3	0.3
Being hopeful	0.0	0.7	0.1
Having a life project	0.2	0.7	0.0
Having stable housing/place	0.1	0.7	0.2
Being abstinent from drugs and alcohol	0.1	0.5	0.2
Being employed in formal or informal work	0.1	0.4	0.4
Eliminating all psychiatric symptoms	0.0	0.2	0.4
Having family support	0.1	0.7	0.0
Having friends or people to trust and/or partner or spouse	0.2	0.7	0.0
Adhering to prescribed treatments	0.1	0.7	0.0
Adapting to psychiatric symptoms	0.0	0.2	0.4
Having a sense of belonging in the community and valuing their cultural and social identity	0.2	0.7	0.2
Taking control of one's own life/autonomy	0.1	0.6	0.3
Having something that gives meaning/meaning to life	0.1	0.6	0.2

Continue...

**Table 3.** Continuation

Variables	Components		
	1	2	3
Having quality medical care and/or multi-professional assistance	0.1	0.7	0.1
Believing in oneself as a capable person	0.1	0.8	0.0
Being financially independent	0.0	0.4	0.3
Participating in recreational/leisure social activities	0.1	0.6	0.2
Having a long period of stability (i.e., no crises)	0.0	0.5	0.1
Eating healthy and practicing physical activity	0.1	0.6	0.2
Questioning and rejecting social stereotypes of users in mental distress (e.g., "patient with mental illness" or addict)	0.0	0.3	0.3
Being valued for their activities in the community	0.1	0.7	0.2

Extraction method: Principal component analysis.

Rotation method: Varimax with Kaiser normalization.

**Table 4.** Final Version of the Work Assessment Instrument for Recovery in Mental Health – (IATRE-SM), Montes Claros, Minas Gearis, Brazil, 2019 (Brazilian version of The Providers Survey instrument)

PART 1						
Please indicate how important the following activities are in your work with mentally ill users. Where: 1-Not important, 2-Somewhat important, 3-Not at all and not very important, 4-Important, 5-Very important, 6-Not part of my job).						
DOMAIN	1	2	3	4	5	6
Hosting the user, their family, and/or companions						
Recording a complete personal and family anamnesis/history						
Conducting case follow-up						
Providing a reference technician for case management						
Offering counseling and/or guidance or psychotherapy/other psychological interventions						
Participating in the formulation of the diagnosis						
Prescribing and/or administering medication						
Monitoring medication adherence						
Guiding the use of medications and the effect on the user's psychic condition for the user, their family members, and/or companions						
Identifying and addressing stigma and discrimination/prejudice						
Referring users for medical attention and care						
Referring users to social support services to search for work/employment (legal associations and public services)						
Providing job search support						
Referring users for treatment of alcoholism and/or the use of psychoactive substances						
Providing treatment for alcoholism and/or the use of other psychoactive substances						
Referring users to the housing support service						
Providing housing search support						
Referring users to socialization activities and recreational/leisure support						
Providing socialization activities and recreational/leisure support						
Referring users to legal support						
Involving family members in supporting users in mental distress						
Providing peer support and guidance and/or a therapeutic companion						
Providing guidance on the self-care and well-being of users						
Addressing issues related to forms of violence or forms rights violations.						
PART 2						
Please indicate how important the following components are to enabling users in mental distress to obtain and keep their jobs. Where: 1-Not important, 2-Somewhat important, 3-Not at all and not very important, 4-Important, 5-Very important, 6-I prefer not to answer.						
DOMAIN	1	2	3	4	5	6
Setting a goal for getting a job						
Including users in work/employment support programs, regardless of the severity of their symptoms or other underlying difficulties						
Conducting a job search as soon as the person shows interest in working						
Integrating vocational support with clinical care in an individualized way						
Being aware of users' preferences regarding a job/occupation						
Identifying and addressing cases of discrimination at work/employment						

Continue...

**Table 4.** Continuation

Encouraging the person to seek employment						
Identifying and addressing negative internalized views of themselves that make people believe they are incapable of working						
Involving the family in supporting the user's efforts to seek or maintain employment						
Engaging peers in supporting the user's efforts to seek or maintain work/job						
Recognizing the work/job as important in the recovery of the user						
Recognizing the job as a source of stress that should be avoided						
Recognizing employment as offering a valuable social role or as an important source of identity reinforcement						
Recognizing employment as a risk factor for relapse/crisis of users in mental suffering						
<b>PART 3</b>						
<b>Indicate the degree of importance of the following components to promote the restoration/recovery of users in mental suffering. Where: 1-Not important, 2-Somewhat important, 3-Not at all and not very important, 4-Important, 5-Very important, 6-I prefer not to answer.</b>						
<b>DOMAIN</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>
Being hopeful						
Having a life project						
Having stable housing/place						
Being abstinent from drugs and alcohol						
Having family support						
Having friends or people to trust and/or partner or spouse						
Adhering to prescribed treatments						
Having a sense of belonging in the community and value their cultural and social identity						
Taking control of their own life/autonomy						
Having something that gives meaning to life						
Having quality medical care and/or multi-professional assistance						
Believing in oneself as a capable person						
Participating in recreational/leisure social activities						
Having a long period of stability (i.e., no crises)						
Eating healthy and practice physical activity						
Being valued for their activities in the community						

and equivalence between different respondents.<sup>13,16</sup> Test-retest reliability tends to decrease when the time interval is prolonged, and for this reason, we conducted a verification within an interval of 10 to 14 days between the test and retest on a sample of at least 15% of the participants or a minimum of 50 respondents.<sup>26,27</sup>

For the verification of internal consistency, values above 0.70 for the  $\alpha$ -Cronbach are accepted as adequate. As for the Intraclass Correlation Coefficient, values between 0.6 and 0.79 indicate a substantial correlation and values greater than or equal to 0.80 indicate an almost complete correlation.<sup>14,15,26,27</sup>

It is noteworthy that the present study followed all the recommendations proposed to verify the psychometric properties of measurement instruments considering the context of mental health in Brazil through an approach to health professionals regarding the importance of work as an important component in individuals' mental health recovery.

This study is limited by the variability in the context and organization of The Political Action Network for Sustainability in each region of Brazil, resulting in different results in different contexts. Precisely determining the aspects related to the instrument's validity and reliability measures allows for greater assurance of the

quality of results. However, it is worth clarifying that validity and reliability are not fixed measures and may vary according to the population, type of study, and purpose.

## CONCLUSION

Through the values obtained in the validation process of The Providers Survey instrument using the Consensus-Based Standards for the Selection of Health Measurement Instruments checklist, we found that the Brazilian version of the instrument had content validity, construct validity, and reliability, which was verified by internal consistency and stability. Therefore, it is an instrument capable of exploring the phenomenon to be studied, and its items reliably and adequately represent the measured construct. All the instrument's parts measure the same characteristic, which guarantees its reliability, and confers homogeneity among the different respondents.

The instrument developed instrument was named the Work Assessment Instrument for Recovery in Mental Health (IATRE-SM). From its use, it is expected that mental health services in Brazil will be guided by the Recovery concept to prepare users so that they can face society and engage in the recovery process. It is also



expected that users will be perceived as individuals capable of integrating into society and exercising their autonomy, assuming an active role in the community. Based on the results of this study, we encourage research on the perceptions of health professionals regarding the relationship between work and recovery for people with mental disorders.

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# The Brazilian army and the low prevalence of sexually transmitted infections in women of the military garrison of Campinas between 2017 to 2020: a prospective, cross-sectional epidemiological study

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## ABSTRACT

**BACKGROUND:** Given the characteristics of military missions, intense interpersonal contact, and wide variation in casual relationships, the military has long been recognized as a high-risk population for sexually transmitted infections (STIs).

**OBJECTIVE:** To assess the prevalence of STIs and socioepidemiological profile of women in the military garrison of Campinas.

**DESIGN AND SETTING:** This prospective, cross-sectional epidemiological study, assisted by the Health Fund in the military garrison of Campinas, assessed the prevalence of human immunodeficiency virus (HIV), hepatitis B and C, syphilis, human papillomavirus (HPV), *chlamydia*, and *gonococcus* in military women or companions of soldiers with active or previously active sexual life.

**METHODS:** This study included 647 women based on the non-inclusion criteria. They underwent clinical and laboratory tests for diagnosis of STIs. For statistical analysis, patients were divided into groups according to the presence or absence of STIs and into age groups.

**RESULTS:** Most women were military dependents, and the majority were asymptomatic. The prevalence of STIs, in ascending order, was 0.3% for hepatitis B and C, 0.62% for syphilis, 0.62% for gonorrhea, 1.08% for chlamydia, and 2.63% for HPV. There were no cases of HIV infection.

**CONCLUSIONS:** The Brazilian Army has the most women-like dependents in the military, belonging to the hierarchical circle of the squares. Early onset of sexual activity favored STIs approximately twice, and younger women had approximately seven times more chlamydia infections. In the general population studied, the prevalence of STIs was lower than expected than in the armed forces of other nations.

## INTRODUCTION

In the armed forces, the characteristics of the missions, intense interpersonal interactions, wide variations in casual relationships, and long periods of abstinence and transit favor sexually transmitted infections (STIs). Historically, STI rates among military personnel in the United States have been higher than those among civilians.<sup>1</sup>

Young male soldiers are likely to be the main vectors of STIs, which can increase transmission to young military women and dependents, since close coexistence can stimulate affective and sexual bonds. Irregular use of condoms can also have a significant impact. Chao et al. demonstrated that 25% of the Brazilian population had sexarche before 15 years of age, and another 35% between 15–19 years of age. In the same survey, the regular use of condoms was unsatisfactory, with only a 39% use among people aged 15–64 years.<sup>2–4</sup>

A large survey of women in the United States military identified a 9.2% prevalence of chlamydia infection among female recruits, with a peak of 12.2% at 17 years of age. Prevalence declined markedly with increasing age, dropping to 5% for women over 25 years of age.<sup>5</sup>

In Brazil, there are few studies relating military behavior to STIs or any other diseases. Since 1996, the Brazilian Department of Sexually Transmitted Infections, STI-AIDS and Viral Hepatitis, has conducted probability sampling surveys to determine the prevalence of human immunodeficiency virus (HIV), hepatitis B and C, and syphilis by assessing sexual and risk behaviors among recruits aged 17–22 years old from the Brazilian Army using questionnaires.<sup>6–8</sup>

Currently, one of the major concerns in the Brazilian Army is the sexual health of women who begin their military career very early (between 17 and 20 years of age in the military line).<sup>9</sup>

According to the Pan American Health Organization, half of the new HIV infections arise in children under 24 years of age, with the majority being sexually transmitted.<sup>10,11</sup>

According to a recent study in the United States, STIs are on the rise in the United States military, and women are more affected than men by all infections except syphilis. Younger soldiers, aged  $\leq 24$  years, are affected by most of the diseases at higher rates than of any other age group.<sup>12</sup>

Women are a growing number within the Armed Forces; however, militarism is still a male-dominated space in which the woman has a marked place as the wife and partner of the military husband.<sup>13-16</sup>

In the Brazilian Army, female soldiers make up 3.2% of the Force's personnel and possess 5.35% of the assets in the military garrison of Campinas. Compared to the British Armed Forces, in which 10% of the personnel are women, Brazil is still far behind the female contingent of other nations.<sup>17</sup>

## OBJECTIVE

To assess the prevalence of STIs and the socioepidemiological profile of women in the military garrison of Campinas.

## METHODS

This was a prospective, cross-sectional epidemiological study involving women who attended the Medical Center of the Military Garrison of Campinas from 2017 to 2020 by free and spontaneous demand. The study was approved by the Universidade Federal de São Paulo Ethics Committee (number 2.580.983) on April 4, 2018.

Initially, 1,019 women who consulted at the Medical Center of the Military Garrison of Campinas were selected. They were military personnel or wives and/or companions of military users of the Brazilian Army Health Fund, who had an active or previously active sexual life, of which 647 were allocated to the study. Civil servants, women with no past or present sexual life, and those who had acquired any of the infections, as evaluated through non-sexual means, were excluded. For comparison purposes, two groups were established: 1) the GENERAL Group, which corresponded to the 647 women allocated to the study, and 2) the WITH-STI group, which corresponded only to those who were diagnosed with STIs during the study.

The participants underwent directed anamnesis, complete physical examination, cervico-vaginal material collection, and blood collection for serological tests.

Due to the financial and logistical characteristics of the gynecology service in the military garrison of Campinas, the collection

of material for the examination of cervico-vaginal oncotic colposcopy was performed in a conventional environment. For statistical analysis of the cytological findings, three results were established: negative, minor cytological alterations that corresponded to the results of squamous cell atypia of undetermined significance (ASCUS), and low-grade intraepithelial lesion (LIEBG); cytological alterations greater than these corresponding to the results of squamous cell atypia that did not exclude high-grade (ASC-H), glandular cell atypia (AGC), and high-grade intraepithelial lesion (LIEAG). There were no cases of cancer; therefore, we did not compute this finding.

Colposcopy was performed only in women with altered cytology results or visual alterations of the cervix on gynecological examination. The terminology used followed the norms of the International Federation of Cervical Pathology and Colposcopy.<sup>18</sup> In the presence of abnormal findings, a biopsy was performed with punch-hole forceps, and the collected material was deposited in a vial containing a formaldehyde solution and sent for pathological study.

All the molecular tests were automated. To perform human papillomavirus (HPV) hybrid capture and real-time polymerase chain reaction tests for the diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*, the liquid seeding medium Cellpreserv from KOLPLAST (Itupeva, Brazil) was used. Two samples were collected from each woman and placed in separate Cellpreserv vials, because the analysis methodology for HPV was different from that for *Chlamydia trachomatis*/*Neisseria gonorrhoeae*.

Serological blood samples were collected by peripheral vein puncture in the internal laboratory at the Medical Center of the Military Garrison of Campinas and sent to the central laboratory of the São Paulo Military Hospital for automated analysis.

In the statistical analysis, frequency comparisons were performed using the chi-square test or Fisher's exact test, where necessary. The significance level was set to 0.05, and statistical analysis was performed using Minitab-19 software. Among the analyses and data crossing between the variables, the cutoff age of 25 years was chosen in view of the recommendations for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* screening in women aged 14–25 years and > 25 years for cervical cancer.

## RESULTS

The 647 women included in this study were military personnel, sexual partners of military personnel, and dependents. The mean age was 38 years  $\pm$  standard deviation (SD) 16.13. Their minimum and maximum ages were 14 and 93 years, respectively. The analysis was conducted from 2017 to 2020. In the last year, there was a significant decrease in visits, with a consequent decrease in the number of women who could be evaluated due to the beginning of the coronavirus disease-2019 pandemic.

In the general population studied, the prevalence of STIs, in increasing order of incidence, was 0% for HIV, 0.3% for hepatitis B and C (2 cases), 0.62% for syphilis (4 cases), 0.62% for gonorrhea (4 cases), 1.08% for chlamydia (7 cases), and 2.63% for HPV (17 cases). As there were no cases of HIV infection, this information has been removed from the tables and graphs. The frequency of infection found in the group of 30 women with 34 diagnosed STIs was 5.89% for hepatitis B and C, 11.77% for syphilis, 11.77% for gonorrhea, 20.58% for chlamydia, and 50% for HPV (Table 1).

In the general epidemiological assessment, the largest number corresponded to the dependents of the military, with 479 women (74.03%), followed by 117 (18.08%) full-time military women, and finally, 51 (7.88%) pensioners.

The group aged 25 years or older had the highest absolute number of women (n = 480) and the most frequent relationship presented in this same group was “dependents” of military personnel (73.95%), with a statistically significant result (P = 0.00001).

About rank or graduation, in the lowest age group, there was a preponderance of “soldiers” (63.47%) and in the highest, there

was an almost equal division between “enlisted” and “officers,” with 52.7% and 47.29%, respectively (P = 0.0159). Thus, according to the hierarchical circle to which the woman belonged, we had a general preponderance of the “enlisted” circle, with about 11% more than the circle of officers. Regarding age groups, the largest proportion of the enlisted circle was more evident in the group of people under 25 years old, with almost 30% more than the circle of officers. In the older age group, the proportions were similar between the two groups. The results were statistically significant for these data (Table 2).

Of the 30 women diagnosed with STIs, 18 were younger than 25 years and 12 were 25 years or older. The largest number also corresponded to military dependents, with 23 women (76.67%), followed by seven (23.33%) full-time military personnel and, finally, no pensioners, but without statistical significance between the types of attachment, hierarchical circles, and age groups (Table 2). The mean age in this group was 36.9 years (± SD 10.46), with a minimum and a maximum age of 17 and 59 years, respectively.

By subtracting the infected women from the 647 women studied, we created a WITHOUT-STI group with 617 women. We then

**Table 1.** Sexually transmitted infection prevalence in the general population

	Disease	Prevalence n = 647 (%)	Frequency n = 34 (%)	Number of cases n = 647
General population (n = 647)	HBsAg	0.15	2.94	1
	HCV	0.15	2.94	1
	Syphilis (VDRL)	0.62	11.77	4
	Hybrid Capture HPV	2.63	50	17
	Chlamydia (PCR-RT)	1.08	20.58	7
	Gonorrhea (PCR-RT)	0.62	11.77	4

HBsAg = hepatitis B antigen; HCV = hepatitis C virus; VDRL = Venereal Disease Research Laboratory; HPV = human papillomavirus; PCR-RT = reverse transcription followed by polymerase chain reaction.

**Table 2.** Distribution of women in groups, according to the post and link to the Brazilian Army, according to age group

	Variable	< 25 (n = 167)		≥ 25 (n = 480)		P*
General group	<b>Hierarchical circle</b>					
	Officers	61	(36.52%)	227	(47.29%)	0.0159*
	Squares	106	(63.47%)	253	(52.7%)	
	<b>Link with Army</b>					
	Dependent on military	124	(72.25%)	355	(73.95%)	< 0.0001*
	Holder	41	(24.55%)	76	(15.83%)	
Pensioner	2	(1.19%)	49	(10.2%)		
	Variable	< 25 (n = 18)		≥ 25 (n = 12)		P*
Group with sexually transmitted infections	<b>Hierarchical circle</b>					
	Officers	5	(27.78%)	3	(25%)	0.8661
	Squares	13	(72.22%)	9	(75%)	
	<b>Link with Army</b>					
	Dependent on military	12	(66.67%)	11	(91.67%)	0.2751
	Holder	6	(33.33%)	1	(8.33%)	
Pensioner	0	(0%)	0	(0%)		

\*Pearson's Chi-square test.

compared the WITHOUT-STI group (n = 617) with the WITH-STI group (n = 30).

In the WITH-STI group, more than half of the population studied was nulliparous, the rest had between one and three children, and no woman had more than three children. The number of abortions was almost five times higher in the WITHOUT-STI group, which was a statistically significant finding (P = 0.00007) (Table 3).

The number of partners was restricted to 10 for approximately 80% of women in both groups. However, the percentage of women in the WITH-STI group was approximately seven times higher (P = 0.00343) when they had 11 or more partners (Table 3).

Most women in the WITHOUT-STI group had established relationships, while most women in the WITH-STI group did not have a steady partnership, though this data was not statistically significant (Table 3).

An earlier age of sexual initiation (17 years or less) favored the presence of STIs about 1.5 times more and almost 2 times more when sexarche occurred at 14 years or less. (Table 3)

Most women (75%) were asymptomatic and went to consult for routine exams. Oncotic colpocytology was performed in 483 women, who were 25 years of age or older and others who showed a desire to undergo the examination. When cervico-vaginal cytological evaluation was performed, the results showed 410 (84.89%) normal examinations, 68 (14.08%) with minor alterations, and 5 (1.03%) with major alterations. There were only cases of ASCUS, LIEBG, and LIEAG, and no cases of AGC or ASC-H. Of the 73 colposcopies resulting from altered cytology, 60 (82.2%) were normal, 12 (16.44%) had minor findings, and 1 (1.37%) had major

findings. Of the 13 biopsies generated, 7 (53.84%) had a report of chronic cervicitis, 5 (38.46%) had low-grade lesions, and 1 (7.69%) had a high-grade lesion. Thus, after colpohistological confirmation, approximately 1% of the 483 women were diagnosed with a low-grade lesion in the uterine cervix and 0.21% with a high-grade lesion as the final diagnosis.

There were three cases of concomitant STIs, totaling 34 infections in 30 women: one woman with HPV associated with Chlamydia and Gonococcus and, the other two with Chlamydia and Gonococcus.

In the GENERAL population, the ratio of Chlamydia to gonorrhea infection in both age groups tended toward 2:1. The group of patients younger than 25 years showed a tendency toward a higher proportion of Chlamydia and Neisseria, as well as syphilis and HPV, and a lower proportion for hepatitis. Chlamydia was more frequent in women under 25 years of age (P = 0.0144), while gonorrhea showed a similar trend (P = 0.0549). (Table 4, Graph 1)

When the same age comparison in women in the WITH-STI group was made, the group of younger women under 25 years of age also tended to have a higher proportion of Chlamydia and Neisseria but lower proportions of syphilis and hepatitis. HPV was significantly more prevalent in older women than in younger women (P = 0.00158).

## DISCUSSION

This study is unprecedented in the Brazilian Armed Forces. Previous studies have only involved young, conscripted men entering mandatory military service.

**Table 3.** Distribution of the epidemiological profile of the 647 women treated at the Medical Post of the Military Garrison of Campinas gynecology outpatient clinic, according to the presence of Sexually Transmitted Infections

Variable	Without STI (n = 617)		With STI (n = 30)		P*
<b>Parity</b>					
0	239	(38.73%)	18	(60%)	0.08601
1-3	325	(52.67%)	12	(40%)	
4-7	53	(8.59%)	0	(0%)	
<b>Number of abortions</b>					
0	327	(53%)	27	(90%)	0.00007*
≥ 1	290	(47%)	3	(10%)	
<b>Number of partners</b>					
1-5	443	(71.80%)	21	(70%)	0.00343*
6-10	37	(6%)	3	(10%)	
≥ 11	9	(1.46%)	3	(10%)	
Unknown/unanswered	128	(20.74%)	3	(10%)	
<b>Marital status</b>					
Married / Stable union	374	(60.62%)	14	(46.67%)	0.12781
Single / Widow	243	(39.38%)	16	(53.33%)	
<b>Sexual onset</b>					
≤ 14	43	(6.97%)	4	(13.33%)	0.20125
15-17	198	(32.09%)	13	(43.33%)	
≥ 18	342	(55.43%)	13	(43.33%)	

\*Pearson's Chi-square test; STI = sexually transmitted infection.

**Table 4.** General distribution of test results according to age group in the general population (n = total of 647) and with sexually transmitted infections (n = 30)

Variable		< 25 (n = 167)		≥ 25 (n = 480)		P*
<b>General (n = 647)</b>	<b>HBsAg</b>					
	Positive	0	(0%)	1	(0.21%)	
	Negative	167	(100%)	479	(99.79%)	1.0000
	<b>HCV</b>					
	Positive	0	(0%)	1	(0.21%)	
	Negative	167	(100%)	479	(99.79%)	1.0000
	<b>Syphilis (VDRL)</b>					
	Positive	2	(1.20%)	2	(0.42%)	
	Negative	165	(98.8%)	478	(99.58%)	0.2752
	<b>Hybrid capture HPV</b>					
	Positive	6	(3.59%)	11	(2.29%)	
	Negative	161	(96.4%)	469	(97.71%)	0.4005
	<b>Chlamydia (PCR-RT)</b>					
	Positive	5	(2.99%)	2	(0.42%)	
	Negative	162	(97%)	478	(99.58%)	0.0144*
	<b>Gonorrhea (PCR-RT)</b>					
	Positive	3	(1.79%)	1	(0.21%)	
	Negative	164	(98.2%)	479	(99.79%)	0.0549
<b>With sexually transmitted infections (n = 30)</b>	<b>Variable</b>	<b>&lt; 25 (n = 18)</b>		<b>≥ 25 (n = 12)</b>		<b>P*</b>
	<b>HBsAg</b>					
	Positive	0	(0%)	1	(8.33%)	
	Negative	18	(100%)	11	(91.67%)	
	<b>HCV</b>					0.76508
	Positive	0	(0%)	1	(8.33%)	
	Negative	18	(100%)	11	(91.67%)	
	<b>Syphilis (VDRL)</b>					
	Positive	2	(11.11%)	2	(16.67%)	0.66100
	Negative	16	(88.89%)	10	(83.33%)	
	<b>Hybrid capture HPV</b>					
	Positive	6	(33.33%)	11	(91.67%)	0.00158*
	Negative	12	(66.67%)	1	(8.33%)	
	<b>Chlamydia (PCR-RT)</b>					
	Positive	5	(27.78%)	2	(16.67%)	0.48086
	Negative	13	(72.22%)	10	(83.33%)	
	<b>Gonorrhea (PCR-RT)</b>					
	Positive	3	(16.67%)	1	(8.33%)	0.51067
Negative	15	(83.33%)	11	(91.67%)		

\*Pearson's Chi-square test.

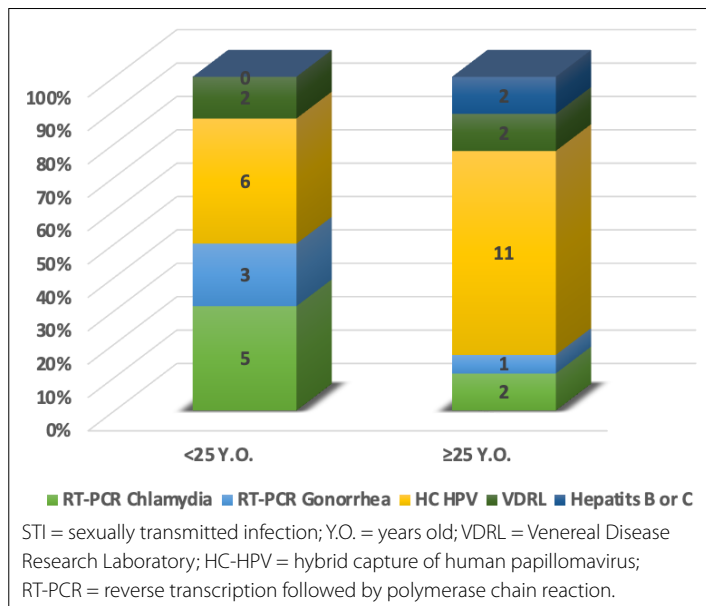
HBsAg = hepatitis B antigen; HCV = hepatitis C virus; VDRL = Venereal Disease Research Laboratory; HPV = human papillomavirus; PCR-RT = reverse transcription followed by polymerase chain reaction.

The military garrison of Campinas consists of more than 7,000 beneficiaries of the Brazilian Army Health Fund, including approximately 2,600 active-duty military men and women.

Most of the women treated as outpatients sought preventive gynecological consultations, and 75% of them were asymptomatic. These data are consistent with the profile of the Brazilian female population, which is more concerned about health than the male population. Genital discharge was the most frequent complaint, particularly in younger patients.

Due to the type of activity developed, some military women and companions of military men are more likely to be involved in high-risk sexual practices and contract STIs for the following reasons: less use of barrier contraception, little knowledge about gynecological health, and lower education level.<sup>18-21</sup>

However, a bias that we can point out for the population studied is the fact that the military garrison is located in a region of greater purchasing and educational power with a high human development index (the Campinas region), which may explain



**Graph 1.** Numeric comparison among women with STIs in relation to age group.

the low number of diagnosed STIs, regardless of age. It is also a population that has adequate guidance on preventive measures, in addition to being a peace army.

In this study, majority of the women (almost 56%) made up the hierarchical circle of the squares. This is because to be recruited in this class, only a technical high school or elementary educational level is required. For the rank of officers, a higher educational level is required.

The highest prevalence of stable relationships was directly proportional to the absence of STIs, with 60.62% in the WITHOUT-STI group. However, in the WITH-STI group, there was an inversion of this proportion, with 53.33% of women without a steady partnership, thus consistent with the greater presence of STIs in the groups where there was greater turnover in the partnership.

In the evaluation of the 647 women, most of them (54.87%) started sexual activity later, when they were 18 years old or older. This is probably because they have more stable habits infringed upon by military customs, which may have been a protective factor against STIs.

Early sexual intercourse favored the presence of STIs, given that 56.67% of women with STI had sexual intercourse before 17 years of age. Thus, corroborating what is known about early sexual initiation and the inconsistent use of condoms during the first sexual intercourse could leave adolescents in a situation of greater vulnerability.

In this line, if we consider women up to 17 years of age as adolescents, we have approximately 40% of all women starting their sexual activity in adolescence and less than 7% of girls

starting their sexual activity as early as 14 years of age. This number is lower than the 10% reported in a recent study carried out in Italy.<sup>22</sup>

A more constant behavior was observed with regard to the partnership, since more than 70% of the women had between one and five partners. In general, this picture reflects an expected “family model,” operated by the Army, which reflects the case of families in which only the husband is in the military. This is different from the US military, where nearly 60% of women report having more than one sexual partner per year. A separate study revealed that 27% of female service members interviewed had more than one partner in the previous 90 days. In this study, only 17% reported regular condom use. It is noteworthy that there is an important difference in the behavior of the military in periods of war compared to periods of peace, since war is still considered a harbinger of STIs today.<sup>23-26</sup>

According to the World Health Organization, adolescence is a fundamentally biological process that occurs in individuals aged between 10 and 19 years. A survey found that 49.25% of the investigated adolescents had already started their sexual lives. The occurrence of the first intercourse before 15 years of age was observed in approximately 30% of these individuals. These data are similar to those of other studies that revealed that most adolescents experience their first sexual intercourse at this age. Early sexual initiation is considered a risk factor, as is the number of sexual partners exposed to STIs.<sup>23</sup>

Like the GENERAL population, the STI group in its entirety (100%) had between 0 and 3 children, 60% of whom were nulliparous. Therefore, the presence of STIs did not increase the number of abortions, since women without STIs had approximately five times more abortions than women with STIs. Again, military habits that involve military families seem to favor family planning as well as the prevention of STIs. Additionally, of the 483 women, approximately 1% were diagnosed with a low-grade lesion in the uterine cervix and 0.21% with a high-grade lesion as the final diagnosis.

There were three cases of concomitant STIs, totaling 34 infections in 30 women: one woman with HPV associated with Chlamydia and Gonococcus and the other two with Chlamydia and Gonococcus.

The ratio of Chlamydia to gonorrhoea infection in both age groups tended toward 2:1. The group of patients younger than 25 years showed a tendency toward a higher proportion of every sexual disease studied except for hepatitis. Chlamydia was more frequent in women under 25 years of age ( $P = 0.0144$ ), while gonorrhoea showed a similar trend ( $P = 0.0549$ ). (Table 4, Graph 1)

When the same age comparison in women with STIs was made, HPV was significantly more prevalent in older women than in younger women ( $P = 0.00158$ ).



## CONCLUSION

The present study with women who consulted at the Medical Center of the Military Garrison of Campinas between 2017 and 2020 showed a low prevalence of STIs, with 4.64% of the studied population infected by at least one agent surveyed. The combined prevalence rates were 0.30% for hepatitis B and C, 0.62% for syphilis, 1.08% and 0.62% for Chlamydia and Gonococcus, respectively, and 2.62% for HPV. There were no cases of HIV and no statistically significant differences in the prevalence rates of Hepatitis B and C, syphilis, or HPV infections. Regarding Chlamydia infection, there was a statistically significant difference in the prevalence in women under 25 years of age, and Neisseria infection followed the same trend. Early sexual intercourse prevailed in the younger age group and favored the presence of STIs in both age groups.

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# Drug use among medical students in São Paulo, Brazil: a cross-sectional study during the coronavirus disease 2019 pandemic

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University student drinking.

## ABSTRACT

**BACKGROUND:** Medical students demonstrate higher rates of substance use than other university students and the general population. The challenges imposed by the coronavirus disease 2019 (COVID-19) pandemic raised significant concerns about mental health and substance use.

**OBJECTIVES:** Assess the current prevalence of substance use among medical students at the University of São Paulo and evaluate the impact of the COVID-19 pandemic on drug consumption.

**DESIGN AND SETTING:** A cross-sectional study was conducted on 275 medical students from the University of São Paulo Medical School (São Paulo, Brazil) in August 2020.

**METHODS:** Substance use (lifetime, previous 12 months, and frequency of use before and during the COVID-19 pandemic) and socioeconomic data were assessed using an online self-administered questionnaire. Symptoms of depression were assessed using the Patient Health Questionnaire-9.

**RESULTS:** Alcohol was the most consumed substance in their lifetime (95.6%), followed by illicit drugs (61.1%), marijuana (60%), and tobacco (57.5%). The most commonly consumed substances in the previous year were alcohol (82.9%), illicit drugs (44.7%), marijuana (42.5%), and tobacco (36%). Students in the first two academic years consumed fewer substances than those from higher years. There was a decreasing trend in the prevalence of most substances used after the COVID-19 pandemic among sporadic users. However, frequent users maintained their drug use patterns.

**CONCLUSION:** The prevalence of substance use was high in this population and increased from the basic to the clinical cycle. The COVID-19 pandemic may have affected the frequency of drug use and prevalence estimates.

## INTRODUCTION

Substance use is a complex phenomenon including health, socioeconomic, and criminal dimensions that occur globally and affect all age ranges. According to the United Nations Office on Drugs and Crime, global substance use is rising, increasing from 4.8% of the global population aged 15–64 in 2009 to 5.5% in 2019.<sup>1</sup> Young adults, especially university students, are among the most vulnerable groups associated with risky behaviors, including substance use.<sup>2</sup> University student of alcohol and illicit drug use are reportedly higher than those from the general population.<sup>3</sup>

Among the university population, medical students use more alcohol and other drugs than non-medical ones.<sup>4</sup> Additionally, stress, competitiveness, high pressure to perform, lack of sleep, changes in social support (parental and companionship) during university, a tendency towards unhealthy diets, and little exercise are some of the issues related to psychological pain and drug use among this population.<sup>5</sup>

Constant drug-related medical and social changes can alter the prevalence of drug use among medical students, highlighting the need to monitor this behavior. The liberalization of cannabis in many countries,<sup>6</sup> using psychoactive substances (especially psychedelics) to treat psychiatric disorders,<sup>7–10</sup> and using psychostimulants (especially methylphenidate) to improve academic performance,<sup>11</sup> are some issues potentially associated with increasing substance use in this population. Moreover, drug consumption can begin in medical school and continue throughout professional life,<sup>12</sup> impacting physicians quality of life and exposing patients to potential risk.<sup>13</sup> Substance use disorders are likely to affect 8–15% of all physicians.<sup>14</sup> Since this behavior seems to begin in the university setting, assessment and management of medical students' substance use may be of great importance.

Additionally, in 2020, the challenges imposed by the coronavirus disease 2019 (COVID-19) pandemic, especially self-quarantine and social distancing, led to significant concerns about mental health<sup>15</sup> and substance use. Quarantine was shown to affect the consumption of alcohol among students<sup>16</sup> as well as tobacco and other illicit drugs among the general population.<sup>17-19</sup>

All the issues mentioned above indicate the need for conducting studies on substance use among medical students. Therefore, this study aimed to evaluate the current prevalence of alcohol, tobacco, and illicit drug use among medical students and assess how the COVID-19 pandemic may have affected this behavior.

## METHODS

### Study design

A cross-sectional study was conducted among medical students at the Faculdade de Medicina da Universidade de São Paulo (FMUSP) in São Paulo, Brazil, in August 2020. Online questionnaires were sent to students institutional e-mail addresses. Data were collected through online questionnaires administered at the Research Electronic Data Capture platform.<sup>20</sup>

The study protocol was approved by the Ethical Committee of the Hospital das Clínicas of the FMUSP (approval number: 33080920.4.0000.0068-A-05-06-20; approval date: July 24, 2020). Informed consent was obtained from all participants.

### Participants

All medical students enrolled in the FMUSP from the first to the sixth year were contacted via institutional email (medical school in Brazil is a 6-year degree program). Contact was conducted through eight emails sent twice a week. Messages inviting students to participate were also sent to messaging app groups. The FMUSP accepts 175 new students annually, resulting to a final population of 1,050 contacted participants.

### Data collection: Instruments

Socioeconomic data collected included variables such as age, gender, current school year, marital status, religion, family income, self-evaluated academic performance (i.e., good/average/lacking), household status (i.e., living alone/with parents or grandparents/with friends), and student academic results (i.e., passed, failed, leave of absence, or dismissal).

The use of alcohol and other drugs was assessed using a questionnaire used in previous studies conducted by our group,<sup>21,22</sup> which evaluated substance use during lifetime and in the previous 12 months. Consumption was assessed by the question “Have you used—at any time in your life or in the last 12 months—[name of the drug] without medical guidance?”

The following substances were surveyed: alcohol; tobacco; marijuana (and hashish); hallucinogens (LSD, mushroom tea, and mescaline); cocaine; crack cocaine; amphetamines; anticholinergics; benzodiazepines; opiates; sedatives and barbiturates; anabolic steroids; and inhalants.

The impact of the pandemic on drug use was assessed among students who reported using any substance within the last 12 months. Missing values of the remaining students were filled with “Didn’t use.” Frequency of use was assessed before and during the pandemic with the following question: “How frequently did you use [name of the drug] before the pandemic started?” and “How frequently do you use [name of drug] now?” Consumption patterns before and after the COVID-19 outbreak were categorized as (1) less than once a week or (2) once a week or more.

Symptoms of depression were assessed using the Patient Health Questionnaire-9 (PHQ-9),<sup>23</sup> a 9-item depression module from the full PHQ, with an extra final question asking, “How difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?” This self-administered scale ranges from 0 to 27, as each of the 9 items can be scored from 0 (not at all) to 3 (nearly every day).

### Analysis

The minimum sample size for a 95% confidence level and a 5% level of precision was obtained using Cochran’s formula for sample size calculation, adjusted by finite population correction. The degree of variability was obtained from a previous study conducted by our group, which evaluated the use of alcohol and other drugs by medical students from the University of São Paulo Medical School in 2001.<sup>22</sup> Using 24.3% as the previous rate of lifetime marijuana use among students, the minimum sample size was estimated at 225 students.

Collected variables were compared between genders and according to the academic year (grouped into the basic cycle, composed of first and second years; clinical cycle, composed of third and fourth years; and internship, composed of fifth and sixth years) using t-tests or  $\chi^2$  tests, according to variable type. Frequency of substance use was compared using  $\chi^2$  tests. The association between substance use and socioeconomic factors was evaluated using linear models, with substance use as the dependent variable and family income, household status, self-evaluated academic performance, and academic results as independent variables, controlling for gender and age. The association between tobacco use and mental health symptoms was also investigated using linear models, with tobacco use as the dependent variable and mental health scores as independent variables, while controlling for gender, age, household income, and current school year. All analyses were performed in Python 3.7.6 (Python Software Foundation, Wilmington, United States)<sup>24</sup> using the statsmodels package.<sup>25</sup> Statistical significance was set at an alpha of 0.05.

## RESULTS

### Participants

From 1,050 contacted students, data were collected from 275 participants who completed the questionnaires. The sample comprised 159 (57.8%) males, 113 (41.1%) females, and 3 (1.1%) non-binary gender students. The mean age was 23 years old, and most students were single, with no religious affiliations, and from affluent classes. Seventy-eight (28.4%) students were in the basic cycle, 111 (40.4%) in the clinical cycle, and 86 (31.3%) in internship (Table 1). Non-binary gender students were excluded from some comparisons because of the small sample size.

### Substance use among medical students

Regarding lifetime use, alcohol was the most consumed substance in our sample (95.6%,  $n = 263$ ), followed by marijuana (60%,  $n = 165$ ), and tobacco (57.5%,  $n = 158$ ). Additionally, 168 (61.1%) students reported consuming illicit drugs. Substances that were most consumed in the last year were alcohol (82.9%,  $n = 228$ ), marijuana (42.5%,  $n = 117$ ), and tobacco (36%,  $n = 99$ ). Moreover, 123 (44.7%) students reported using illicit drugs. The general prevalence of all drugs is shown in Table 2.

### Factors associated with substance use

Considering the previous 12-month period, students with a higher family income (more than 20 minimum wages) had higher prevalence rates of substance use than students with a

lower family income (less than two minimum wages) ( $P < 0.01$ ). During assessment, the Brazilian minimum wage was approximately USD 236. The same association was observed in the last year of alcohol use group ( $P < 0.01$ ). Regarding the last year of tobacco use, we found that living with family members was a protective factor compared to living with friends ( $P = 0.04$ ). Tobacco use was associated with worse self-evaluated academic performance, with a higher prevalence rate of tobacco use among students who evaluated their academic performance as 'average/lacking' compared to students who rated their academic performance as 'good' ( $P = 0.04$ ). Analyzing mental health data with tobacco consumption, we found that students who used tobacco in the previous year had more severe depression symptoms, as measured by the PHQ-9 scale ( $P = 0.01$ ). Last year, using any illegal substance, living with family members ( $P < 0.01$ ), or alone ( $P = 0.02$ ) was a protective factor compared to living with friends, and was also associated with worse self-evaluated academic performance ( $P = 0.04$ ).

Analysis of academic results of the students (passed, failed, leave of absence, and dismissal) did not show any association with substance use.

### COVID-19 pandemic impact on drug use

Significant differences were observed in the frequency of substance use before and after the COVID-19 outbreak for alcohol, tobacco, marijuana, cocaine, inhalants, hallucinogens, and ecstasy (Table 3). In general, there was a decrease in the frequency of use when the pandemic started, with a reduction in the number of students who reported using less than once a week (alcohol: pre-pandemic 135 versus 107 during pandemic,  $P < 0.01$ ; tobacco: 52 versus 17,  $P < 0.01$ ; cannabis: 83 versus 36,  $P < 0.01$ ; cocaine: 20 versus 2,  $P < 0.01$ ; inhalants: 29 versus 4,  $P < 0.01$ ; hallucinogens: 50 versus 24,  $P < 0.01$ ; ecstasy: 64 versus 9,  $P < 0.01$ ).

**Table 1.** Demographics characteristics of enrolled participants

n = 275	
<b>Academic cycle, n (%)</b>	
Basic	78 (28.4)
Clinical	111 (40.4)
Internship	86 (31.3)
<b>Gender, n (%)</b>	
Male	159 (57.8)
Female	113 (41.1)
Non-binary	3 (1.1)
Age, mean (SD)	23.3 (3.6)
<b>Marital status, n (%)</b>	
Married	7 (2.5)
Single	268 (97.5)
<b>Religion, n (%)</b>	
No	174 (63.3)
Yes	101 (36.7)
<b>Family income, n (%)</b>	
More than 20 MW	73 (26.5)
10-20x MW	66 (24.0)
4-10x MW	78 (28.4)
2-4x MW	47 (17.1)
0-2 MW	11 (4.0)

SD = standard deviation; MW = minimum wage.

**Table 2.** Last year and lifetime prevalence of substance use among medical students

Substance	Lifetime	Last year
Alcohol	263 (95.6)	228 (82.9)
Marijuana	165 (60.0)	117 (42.5)
Tobacco	158 (57.5)	99 (36.0)
Ecstasy	87 (31.6)	66 (24.0)
Hallucinogens	76 (27.6)	53 (19.3)
Inhalants	60 (21.8)	30 (10.9)
Amphetamines	55 (20.0)	32 (11.6)
Tranquillizers	35 (12.7)	23 (8.4)
Cocaine	34 (12.4)	21 (7.6)
Opiates	18 (6.5)	8 (2.9)
Steroids	5 (1.8)	2 (0.7)
Sedatives	3 (1.1)	1 (0.4)
Crack cocaine	2 (0.7)	0 (0.0)
Anticholinergics	1 (0.4)	0 (0.0)

and an increase in the number of students who reported not using at all (alcohol: pre-pandemic 48 versus 98 during the pandemic,  $P < 0.01$ ; tobacco: 186 versus 225,  $P < 0.01$ ; cannabis: 163 versus 209,  $P < 0.01$ ; cocaine: 255 versus 270,  $P < 0.01$ ; inhalants: 246 versus 271,  $P < 0.01$ ; hallucinogens: 225 versus 251,  $P < 0.01$ ; ecstasy: 210 versus 265,  $P < 0.01$ ). However, the number of students who reported using these substances more than once a week remained stable during this period.

### Drug use according to gender and academic year

In lifetime assessments, male students consumed more ecstasy (males 37.1% versus females 23.9%,  $P = 0.029$ ) and hallucinogens (males 32.7% versus females 20.4%,  $P = 0.035$ ). In the last 12 months, males also consumed more tobacco (males 40.9% versus females 28.3%,  $P = 0.045$ ) and ecstasy (males 28.9% versus females 16.8%,  $P = 0.03$ ) (Table 4). For all other surveyed substances, there were no significant differences between genders.

**Table 3.** Frequencies of substance use among medical students before and after the coronavirus disease 2019 pandemic outbreak

		Frequencies		P value
		Before	After	
Alcohol	Didn't use	48	98	<b>&lt; 0.01</b>
	< once/week	135	107	
	≥ once/week	92	70	
Tobacco	Didn't use	186	225	<b>&lt; 0.01</b>
	< once/week	52	17	
	≥ once/week	37	33	
Marijuana	Didn't use	163	209	<b>&lt; 0.01</b>
	< once/week	83	36	
	≥ once/week	29	30	
Cocaine	Didn't use	255	270	<b>&lt; 0.01</b>
	< once/week	20	2	
	≥ once/week	0	3	
Crack	Didn't use	275	275	-
	< once/week	0	0	
	≥ once/week	0	0	
Amphetamines	Didn't use	245	257	0.18
	< once/week	20	13	
	≥ once/week	10	5	
Anticholinergics	Didn't use	275	275	-
	< once/week	0	0	
	≥ once/week	0	0	
Tranquilizers	Didn't use	255	262	0.13
	< once/week	16	7	
	≥ once/week	4	6	
Opiates	Didn't use	267	273	0.11
	< once/week	7	2	
	≥ once/week	1	0	
Sedatives	Didn't use	274	274	1
	< once/week	0	1	
	≥ once/week	1	0	
Steroids	Didn't use	273	275	0.5
	< once/week	2	0	
	≥ once/week	0	0	
Inhalants	Didn't use	246	271	<b>&lt; 0.01</b>
	< once/week	29	4	
	≥ once/week	0	0	
Hallucinogens	Didn't use	225	251	<b>&lt; 0.01</b>
	< once/week	50	24	
	≥ once/week	0	0	
Ecstasy	Didn't use	210	265	<b>&lt; 0.01</b>
	< once/week	64	9	
	≥ once/week	1	1	

Significant comparisons are indicated in bold.

When assessing differences between medical school years, there was a significant difference between the basic cycle and the latter years. Significant difference between groups was observed for lifetime use of marijuana (basic 41% versus clinical 64.9% versus internship 70.9%,  $P < 0.001$ ), cocaine (basic 5.1% versus clinical 12.6% versus internship 18.6%,  $P = 0.028$ ), amphetamines (basic 10.3% versus clinical 21.6% versus internship 26.7%,  $P = 0.027$ ), inhalants (basic 10.3% versus clinical 23.4% versus internship 30.2%,  $P = 0.007$ ), hallucinogens (basic 11.5% versus clinical 33.3% versus internship 34.9%,  $P = 0.001$ ) and ecstasy (basic 19.2% versus clinical 35.1% versus internship 38.4%,  $P = 0.018$ ). Additionally, significant differences between the groups were observed for last year use of marijuana (basic 26.9% versus clinical 53.2% versus internship 43%,  $P = 0.002$ ), cocaine (basic 2.6% versus clinical 7.2% versus internship 12.8%,  $P = 0.045$ ), hallucinogens (basic 7.7% versus clinical 25.2% versus internship 22.1%,  $P = 0.008$ ), and ecstasy (basic 12.8% versus clinical 27.9% versus internship 29.1%,  $P = 0.024$ ) (Table 5).

**Table 4.** Last year and lifetime prevalence of substance use among medical students, by gender

	Grouped by gender			P value
	Male	Female		
Lifetime	Alcohol	151 (95.0)	109 (96.5)	0.766
	Tobacco	94 (59.1)	62 (54.9)	0.566
	Marijuana	93 (58.5)	70 (61.9)	0.654
	Cocaine	23 (14.5)	9 (8.0)	0.147
	Crack	2 (1.3)	0 (0.0)	0.513
	Amphetamines	37 (23.3)	17 (15.0)	0.128
	Anticholinergics	0 (0.0)	0 (0.0)	-
	Tranquilizers	18 (11.3)	16 (14.2)	0.609
	Opiates	9 (5.7)	7 (6.2)	1
	Sedatives	1 (0.6)	2 (1.8)	0.572
	Steroids	2 (1.3)	2 (1.8)	1
	Inhalants	40 (25.2)	19 (16.8)	0.135
	Hallucinogens	52 (32.7)	23 (20.4)	<b>0.035</b>
	Ecstasy	59 (37.1)	27 (23.9)	<b>0.029</b>
	Last year	Alcohol	130 (81.8)	95 (84.1)
Tobacco		65 (40.9)	32 (28.3)	<b>0.045</b>
Marijuana		74 (46.5)	41 (36.3)	0.118
Cocaine		13 (8.2)	7 (6.2)	0.703
Crack		0 (0.0)	0 (0.0)	-
Amphetamines		22 (13.8)	9 (8.0)	0.191
Anticholinergics		0 (0.0)	0 (0.0)	-
Tranquilizers		10 (6.3)	12 (10.6)	0.287
Opiates		2 (1.3)	5 (4.4)	0.131
Sedatives		0 (0.0)	1 (0.9)	0.415
Steroids		1 (0.6)	1 (0.9)	1
Inhalants		22 (13.8)	7 (6.2)	0.07
Hallucinogens		37 (23.3)	15 (13.3)	0.056
Ecstasy		46 (28.9)	19 (16.8)	<b>0.03</b>

Significant comparisons are indicated in bold.

Post-hoc analyses comparing individual groups revealed that drug use prevalence mainly differed between basic and clinical cycles. Significant differences, after Bonferroni correction for multiple comparisons between these two groups, were observed for lifetime use of hallucinogens ( $p_{adj} < 0.001$ ), amphetamines ( $p_{adj} = 0.017$ ), inhalants ( $p_{adj} = 0.006$ ), marijuana ( $p_{adj} < 0.001$ ), and ecstasy ( $p_{adj} = 0.003$ ), and for use in the last year of hallucinogens ( $p_{adj} < 0.001$ ), marijuana ( $p_{adj} < 0.001$ ), and ecstasy ( $p_{adj} = 0.003$ ). The use of cocaine differed only in terms of lifetime use between basic and internship cycles ( $p_{adj} = 0.031$ ). In contrast, using for the last year did not differ between groups after correction (Table 5).

## DISCUSSION

This study evaluated the prevalence of substance use among students from a medical school in São Paulo, Brazil, during the COVID-19 pandemic. After the COVID-19 outbreak, we observed decreased use among students who reported less than once weekly use of substances and maintained use among students who reported weekly drug use. Finally, we compared the consumption rates between genders and academic years to identify which students were more prone to substance use.

The rate of substance use in our sample was higher than that among the general population of the same age<sup>26</sup> and general university students in Brazil.<sup>27</sup> Notably, cannabis is now the second most used drug among medical students, consistent with the more general trend observed among high school students in the United States<sup>28</sup> and elsewhere. Additionally, the way cannabis is seen or used among medical students may influence the detection of substance use problems among patients in their future medical practice, as physician experience with drugs may affect how they perceive these problems.<sup>29</sup> Physicians may also participate in developing future drug policies, and their attitudes as well as experiences with substances may influence their roles.

Tobacco use has almost doubled in the last 19 years when current data were compared to those obtained in the same sample in 2001.<sup>22</sup> This was unexpected as Brazil has a very efficient program to control smoking,<sup>30</sup> with national rates continuously decreasing. Still, although other studies did not observe a similar increase,<sup>31</sup> consumption rate was similar to that observed among general university students in Brazil.<sup>32</sup> Alternative tobacco products (i.e., little cigars and cigarillos, e-cigarettes, and hookah), with potential appeal to the youth, may be associated with increased tobacco consumption among our population.<sup>33</sup> Moreover, data showed that tobacco users in the last year had worse self-evaluated academic performance, and more severe depression symptoms measured by the PHQ-9 scale. The literature demonstrates a significant association between smoking and depression risk<sup>34</sup> as well as symptoms.<sup>35</sup> Additionally, a study conducted among Canadian medical students showed an association between current tobacco use and

higher psychological distress. This study suggests that substance use may be a coping mechanism to deal with stress and the risk of burnout.<sup>36</sup> This may also be the case of students from our sample, and tobacco may serve as a proxy to detect psychologically vulnerable students.

Ecstasy and hallucinogen use in this study was much higher than that among the general population and other medical students;<sup>26,37</sup> although there is a general trend observed in other countries of increasing use of those substances.<sup>38-41</sup> In our sample, during last year, cocaine was used by 7.6% of the students, a higher rate than that from previous studies investigating Brazilian medical students.<sup>37,42</sup> Finally, amphetamine use was more frequent in our sample than in other studies, whereas alcohol and inhalant consumption rates were similar.<sup>32,37,43,44</sup>

Regarding the impact of the COVID-19 outbreak on the frequency of substance use, our findings suggest an overall reduction in consumption. There was a decrease in the number of students who reported “less than once a week” use of alcohol, tobacco,

cannabis, cocaine, inhalants, hallucinogens, and ecstasy. On the other hand, the frequency of students who used drugs “once or more than once a week” remained constant during the COVID-19 pandemic. Social situations, such as parties where exposure to these substances occur, stopped happening after the pandemic started, which may have led to a decrease in substance use among infrequent users. In contrast, for higher-frequency users, our findings did not show a significant difference after the advent of the pandemic. This might be due to these students making use of these substances irrespective of social gatherings. Other studies evaluating the effects of the pandemic on substance use have reported similar findings, with a decrease in the overall consumption prevalence but an increase in the frequency of marijuana, alcohol, and tobacco use among users.<sup>19,45</sup>

We also analyzed the influence of gender and academic year on drug consumption. In our sample, men consumed more tobacco, ecstasy, and hallucinogens than women did. These findings are in line with other studies analyzing Brazilian and American

**Table 5.** Last year and lifetime prevalence of substance use among medical students, by academic cycle

	Grouped by Academic cycle				Post-hoc comparisons			
	Basic	Clinical	Internship	P value	Basic - Clinical	Basic - Internship	Clinical - Internship	
					P value*	P value*	P value*	
Lifetime	Alcohol	72 (92.3)	108 (97.3)	83 (96.5)	0.291	-	-	-
	Tobacco	38 (48.7)	66 (59.5)	54 (62.8)	0.164	-	-	-
	Marijuana	32 (41.0)	72 (64.9)	61 (70.9)	< 0.001	< 0.001	<b>0.004</b>	0.957
	Cocaine	4 (5.1)	14 (12.6)	16 (18.6)	0.028	0.085	<b>0.031</b>	1.000
	Crack	1 (1.3)	0 (0.0)	1 (1.2)	0.517	-	-	-
	Amphetamines	8 (10.3)	24 (21.6)	23 (26.7)	0.027	<b>0.017</b>	<b>0.026</b>	1.000
	Anticholinergics	0 (0.0)	0 (0.0)	1 (1.2)	0.596	-	-	-
	Tranquilizers	7 (9.0)	16 (14.4)	12 (14.0)	0.499	-	-	-
	Opiates	2 (2.6)	7 (6.3)	9 (10.5)	0.121	-	-	-
	Sedatives	2 (2.6)	1 (0.9)	0 (0.0)	0.372	-	-	-
	Steroids	1 (1.3)	1 (0.9)	3 (3.5)	0.523	-	-	-
	Inhalants	8 (10.3)	26 (23.4)	26 (30.2)	0.007	<b>0.006</b>	<b>0.006</b>	1.000
	Hallucinogens	9 (11.5)	37 (33.3)	30 (34.9)	0.001	< 0.001	<b>0.002</b>	1.000
	Ecstasy	15 (19.2)	39 (35.1)	33 (38.4)	0.018	<b>0.003</b>	<b>0.029</b>	1.000
	Previous year	Alcohol	59 (75.6)	95 (85.6)	74 (86.0)	0.131	-	-
Tobacco		22 (28.2)	48 (43.2)	29 (33.7)	0.092	-	-	-
Marijuana		21 (26.9)	59 (53.2)	37 (43.0)	0.002	< 0.001	0.110	0.054
Cocaine		2 (2.6)	8 (7.2)	11 (12.8)	0.045	0.318	0.063	1.000
Crack		78 (100.0)	111 (100.0)	86 (100.0)	NA	-	-	-
Amphetamines		4 (5.1)	15 (13.5)	13 (15.1)	0.086	-	-	-
Anticholinergics		78 (100.0)	111 (100.0)	86 (100.0)	NA	-	-	-
Tranquilizers		4 (5.1)	11 (9.9)	8 (9.3)	0.495	-	-	-
Opiates		0 (0.0)	3 (2.7)	5 (5.8)	0.066	-	-	-
Sedatives		0 (0.0)	1 (0.9)	0 (0.0)	1	-	-	-
Steroids		0 (0.0)	0 (0.0)	2 (2.3)	0.177	-	-	-
Inhalants		5 (6.4)	12 (10.8)	13 (15.1)	0.203	-	-	-
Hallucinogens		6 (7.7)	28 (25.2)	19 (22.1)	<b>0.008</b>	< 0.001	<b>0.038</b>	0.666
Ecstasy		10 (12.8)	31 (27.9)	25 (29.1)	<b>0.024</b>	<b>0.003</b>	<b>0.040</b>	1.000

NA = not applicable.

\*P value: Bonferroni-adjusted P value. Basic: first and second year; Clinical: third and fourth year; Internship: fifth and sixth year. Significant comparisons are indicated in bold.



populations.<sup>26,46</sup> Regarding alcohol consumption among medical students, we found convergent use between genders, which was also observed in other non-medical student samples.<sup>22,47-49</sup>

A study conducted in 2001 in our setting reported greater use of amphetamines by women,<sup>22</sup> but this difference seems to be diminishing. At that time, amphetamines were mainly anorectic drugs (amfepramone, mazindol, and phenylethylamine) used by young women to reduce weight. These drugs were proscribed in Brazil in 2011. The currently available amphetamines in Brazil are mainly used for treating attention deficit hyperactivity disorder. Currently, non-medical use of amphetamines is primarily for academic performance improvement (“academic doping”), an increasingly common behavior among both genders, contributing to reducing the differences seen in previous studies.<sup>50-52</sup>

This study also showed a significant increase in the use of hallucinogens, amphetamines, cocaine, inhalants, marijuana, and ecstasy from the basic to clinical cycle. This is not surprising, given the age differences between cycles, and may reflect the natural progression of growing older and being exposed to novel experiences.<sup>22,44</sup> However, besides aging, this finding could also be attributed to the increasing academic, professional, and financial stressors as medical students progress to their final clinical years.<sup>53,54</sup> Therefore, medical school managers must be aware of this trend and implement preventive actions to avoid or mitigate it.

As medical schools are frequently linked to hospital settings, students should have ready access to mental healthcare. Unfortunately, the literature does not confirm this assumption.<sup>55,56</sup> Moreover, in the medical student milieu, substance use policies are often punitive and stigmatized.<sup>57</sup> Asking for emotional help can be seen as a weakness and career-threatening.<sup>58</sup> Therefore, mental health care should be actively offered to this population.

This study had some limitations. First, our estimates were assessed in the context of the COVID-19 pandemic, following the implementation of social distancing measures. The effects of this confounder could not be discriminated within our sample, potentially influencing the drug use profile for the last year. However, the overall data shown in this study are compatible with those of other studies that evaluated substance use among medical students and studies conducted in the COVID-19 pandemic context. Second, participant responses may be subject to memory bias, which is a prevalent concern in retrospective studies. To minimize this effect, we used a standardized questionnaire to assess substance use during specific and objective periods. Additionally, despite being higher than the sample size estimates, our response rate (26.2 %) can be considered low and may reduce external validity. However, the distribution of respondents according to gender and academic cycle is consistent with the general proportion of students in our institution. Therefore, it was difficult to determine how the relatively low response rate affected the results. Moreover, our study

is based on a convenience sample that may impair the representativeness of our results. This limitation is common in surveys for this type of population and has been observed in most studies on this subject.<sup>2,31,40,50,51</sup>

## CONCLUSION

This study showed a high prevalence of substance use among medical school students. There was a trend toward convergent substance consumption between genders, and drug use increased from the basic to the clinical cycle. The COVID-19 pandemic may have influenced prevalence estimates, decreased the frequency of substance use among sporadic users, but it did not significantly affect frequent users. Drug use among this population may have important impacts on student mental health at present, and on patient care as well as health policies in the future.

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# Post-partum weight retention in Northeastern Brazilian women: a prospective NISAMI cohort study

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## ABSTRACT

**BACKGROUND:** Weight retention during the post-partum period is associated with excessive weight gain.

**OBJECTIVES:** To investigate factors associated with maternal weight retention at six months post-partum (PPWR).

**DESIGN AND SETTING:** A prospective cohort study was conducted with 127 women monitored using prenatal services.

**METHODS:** The outcome variable was represented by post-partum maternal weight retention and calculated as the difference between the mother's weight at sixth month post-partum and her pregestational weight.

**RESULTS:** The mean age of the pregnant women was  $26.7 \pm 5.25$  years old, and the post-partum maternal weight retention was 46.5%. The proximal determinants showed a direct association with PPWR after adjusting for the distal and intermediate variables: excessive gestational weight gain (odds ratio [OR]:3.34; confidence interval [CI]:1.16–9.59), greater adherence to dietary intake pattern 2 (composed of red meats and derivatives, eggs, industrialized foods, and coffee) (OR:2.70; CI:1.16–6.32), and the absence of exclusive maternal breastfeeding in the first month (OR:3.40; CI:1.27–9.12), as well as primiparity (OR:2.36; CI:1.00–5.55), an intermediate determinant. Insufficient weight gain in pregnancy was inversely associated with the outcome (OR:0.35; CI:0.31–0.93).

**CONCLUSIONS:** Among the hierarchical determinants, proximal factors were interrelated with maternal weight retention, indicating that excessive total weight gain, an inadequate dietary intake pattern, and the absence of exclusive maternal breastfeeding in the first month of life work as dampeners of the return to pre-gestational weight. Prepartum and post-partum care interventions can contribute to reducing excess weight in women.

## INTRODUCTION

Nutritional alterations in the pregnancy-puerperal cycle, expressed as weight accumulation during pregnancy and the post-partum period, represent a risk factor for maternal weight retention. In a relatively short period, the modifications that occur in this stage of life are characterized by an expressive increase in nutrient demands, a high dietary intake, excessive weight gain, and lifestyle changes, which can represent etiological factors of weight retention in women.<sup>1</sup> Research regarding post-partum maternal weight retention is in its infancy, both in Brazil and globally. A systematic review including post-partum studies from various countries indicates that 14 to 20% of women present > 5 kg of mean body weight retention from the sixth to the eighteenth month post-partum, varying from 0.5 to 4.0 kg.<sup>2</sup> In Brazil, a review which included studies between 1997 and 2008 recorded a 14 to 65% variation in PPWR that was above expectations and a significant association with excessive gestational weight gain, indicating population differences.<sup>3</sup> However, the risk and impact of weight accumulation on the body fat composition of women in the long run still need investigation.

Studies have shown relationship between post-partum weight gain and factors represented by an inadequate maternal diet in the pre- and peri-conceptional periods through pre-gestational excess weight or obesity, physical inactivity during pregnancy, unfavorable socioeconomic and demographic factors, multiparity, insufficient maternal breastfeeding time, or an inadequate type of dietary regime for the breastfed child in the first six months of life.<sup>4-7</sup>

These factors often interact with the different determinants of the hierarchy (distal, intermediate, and proximal) situated in other spheres of society and the environment in which

the woman and her child live, configuring the health-disease phenomenon in this life stage. We identified a multifaceted relationship between post-partum maternal weight retention and various factors associated with this outcome. Thus, a hierarchical approach is indicated as a methodology for covering the complexity of this association, considering the different life contexts of the mother and child. However, not much information is generated based on the hierarchical approach to health-disease phenomena using selected observations in the pregnancy-puerperal cycle.

Further studies with different methodologies and results are required to draw consistent evidence for population groups living in diverse geographical regions and under different living conditions. Thus, this study aimed to provide insights into the factors associated with weight retention at the end of the sixth post-partum month.

## OBJECTIVE

This study aimed to analyze the factors associated with maternal weight gain in the sixth-month post-partum period.

## METHODS

### Study design and sample

In this prospective cohort, pregnant women were monitored in a municipality in the northeastern region of Brazil from April 2012 to August 2014 as part of the prenatal service provided by the Health Units.

A total of 233 pregnant women suitable for participation in prenatal services were identified. After applying the inclusion criteria, 185 healthy pregnant women residing in an urban area of the municipality, aged 18 years or older, had a single pregnancy of up to 14 weeks at the time of eligibility, proved by ultrasound, were free of previous diseases or pregnancy-related complications, and had completed gestational follow-up were included. Of these, 58 either migrated to other municipalities or dropped out of participation in the post-partum stage. Thus, the participation of 127 women was recorded, for whom almost all the necessary information for the second stage of the study was available (**Figure 1**).

The duration of follow-up for the pregnant women was 12 months, with six months at each stage, the first corresponding to the pregnancy phase and the second to the post-partum phase.

Considering that the sample was not estimated to analyze maternal weight gain and associated factors, the power to detect and identify excessive maternal weight gain was calculated a posteriori. Under these circumstances, the calculated power was 99%, with a 5% margin of error and a 95% confidence interval (CI).

## Data collection and measurements

At the beginning of the study, pregnant women were enrolled in the study at Family Health Units. The following data were collected.

**Sociodemographic and lifestyle data:** During the prenatal visit, the women provided information on the socioeconomic and demographic conditions of their family, lifestyle habits, and prenatal care, which were recorded in a structured questionnaire.

**Reproductive and obstetric conditions:** Gestational age was calculated either based on the last menstrual cycle date, available on the pregnant woman's chart, or the gestational age as recorded from the first ultrasound performed at the end of the first trimester.

**Anthropometric data:** The pre-gestational body mass index (pgBMI) was used to evaluate the pre-gestational maternal anthropometric status. This index was obtained as the ratio between pre-gestational weight (kg) and height squared (m<sup>2</sup>), classified based on the parameters of the Institute of Medicine (IOM).<sup>8</sup> Pre-gestational weight (PGW) was collected from the Pregnant Woman's card.

**Food and dietary data:** Dietary intake during pregnancy was investigated at the first visit (8–14 weeks of gestation) using a semi-quantitative food frequency questionnaire adapted and prevalidated for the study population, composed of 73 food items. Details of the food consumption assessment have been recorded in a previous study.<sup>9</sup>

The woman's dietary intake was assessed using the factor analysis technique with the extraction of principal components, considering a factor loading  $\geq 0.4$  for the composition of each pattern.<sup>9</sup> The dietary groups were aggregated into four patterns: pattern 1 (cereals, roots, and tubers group; vegetables and legumes group; white meats); pattern 2 (red meat and egg group; meat products [in Portuguese: carne do sol, carne de sertão] and sausages group; industrialized foods group; coffee); pattern 3 (legumes group; fruits group; milk and dairy products group); and pattern 4 (sugars and sweet group; fats and fried snacks group).

### Pregnancy follow-up

Weight gain during pregnancy was used to assess and monitor the adequacy of weight gain during the gestational period. Anthropometric measurements were collected in the first, second, and third trimesters and were calculated in duplicate by a nutritionist and duly trained students from the health sector following standardized procedures.<sup>10</sup> A maximum variation of 0.5 cm and 100 g was accepted for the height and weight measurements, respectively. A portable digital balance was used to measure weight (Marte, São Paulo, SP, Brazil) with a 150 kg capacity and 100 g sensitivity was previously calibrated and reassessed periodically. The mother's height was calculated using a portable stadiometer with a capacity of 2000 mm and 0.5 cm sensitivity (Welmy S.A. São Paulo, SP, Brazil).

Variation in weight gain was used to evaluate weight increase during pregnancy. It was calculated based on the difference between the mother's weight at the end of pregnancy and her pre-gestational weight.

The classification of the increase in weight gain followed the IOM recommendations,<sup>8</sup> in which an increase of 12.5 to 18.0 kg was considered adequate for women who began their pregnancy with a low weight (pgBMI < 18.5 kg/m<sup>2</sup>), 11.5 to 16.0 kg for eutrophic women (pgBMI = 18.5 to 24.9 kg/m<sup>2</sup>), 7.0 to 11.5 kg for overweight women (pgBMI = 25.0 to 29.9 kg/m<sup>2</sup>), and 5.0 to 9.0 kg for obese women at the start of the pregnancy (pgBMI > 30.0 kg/m<sup>2</sup>). We considered the gestational weight increase excessive when it exceeded the limits recommended by the IOM for each pg BMI range and insufficient when it fell below the recommended level.<sup>8</sup>

In the post-partum phase, the women's homes were visited twice. The mothers provided information about the delivery and health conditions of both themselves and their newborns, recorded using a standardized questionnaire.

**Breastfeeding:** The dietary intake of breastfed children was investigated, focusing on their dietary regime and the age at which each food or dietary group was first introduced.

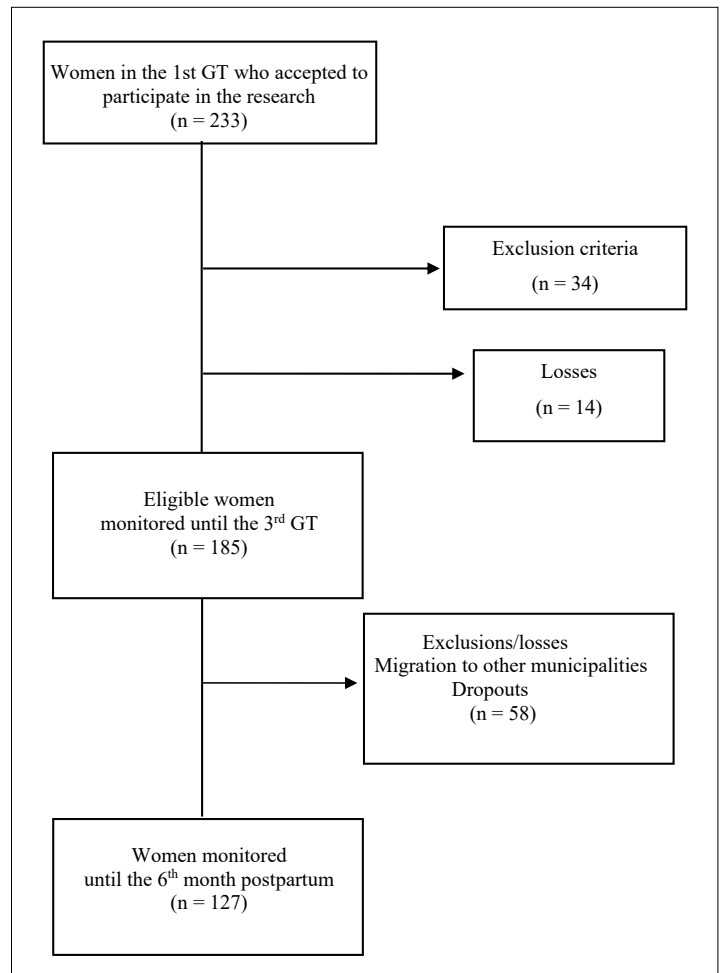
**Post-partum maternal weight retention** During the post-partum period, anthropometric measurements at birth were collected by a trained technician from the maternity unit using calibrated equipment provided by the research team and recorded in a health booklet for children. Additional information regarding birth weight was obtained from the Live Birth Information System.

The cut-off point proposed by Ruesten et al. was considered to classify the intensity of PPWR.<sup>1</sup> Thus, ≥ 5% pre-gestational weight retention was classified in the risk category<sup>1</sup> as reference category (0), and < 5% pre-gestational weight retention was considered.

### Hierarchical approach

The outcome variable of this study was represented by post-partum maternal weight retention, which was calculated as the difference between the mother's weight in the sixth month post-partum and her pregestational weight.

The exposure variables were included in the statistical analysis model of this study according to hierarchical levels (**Figure 2**). Thus, the following socioeconomic factors were considered at the distal level of determination: family income per capita (0 = 1/2 MW; 1 = ≤ 1/2 MW), participation in an income-based transfer program (0 = no; 1 = yes), and the number of residents in the household (0 = up to 4; 1 = more than 4). At the intermediate level of determination, the following sociodemographic, reproductive, and lifestyle factors were included: the mother's age (0 = ≤ 21 years old; 1 = > 21 years old), the mother's schooling (0 = > 8 years of study; 1 = ≤ 8 years of study), self-reported race/colour (0 = others; 1 =



**Figure 1.** Cohort flowchart for capturing the sample, Santo Antônio de Jesus, Bahia, 2012-2014. GT = gestational trimester.

black), marital status (0 = with a partner; 1 = no partner), parity (0 = 1 child or more; 1 = primiparous), type of delivery (0 = natural; 1 = cesarean), alcohol consumption (0 = no; 1 = yes), and smoking (0 = no; 1 = yes).

At the proximal level of determination, the following maternal nutritional and lifestyle conditions were included: pre-gestational anthropometric nutritional status (0 = adequate; 1 = inadequate), weight gain during pregnancy (0 = low or adequate; 1 = excessive), dietary intake in pregnancy assessed according to the dietary patterns (0 = above the median; 1 = below the median), exclusive provision of maternal milk in the first month (0 = yes; 1 = no), exclusive provision of maternal milk in the sixth month (0 = yes; 1 = no), and weight of the newborn (0 = adequate ≥ 3000 g; 1 = insufficient < 3000 g).

### Statistical analysis

We used a logistic regression technique with a hierarchical approach to analyze the association between exposure and response

variables. PPWR was used as the dependent variable. The exposure variables were allocated at the levels of determination (level I or distal, involves socioeconomic factors, level II or intermediate, is represented by maternal sociodemographic, reproductive, and lifestyle factors, and level III or proximal, covers the nutritional conditions of the woman and child) (Figure 2).

Initially, the consistency of the data was evaluated. Descriptive statistics were used to estimate the occurrence measures of all independent variables using the chi-square test or Fischer's exact test at a 5% significance level.

We used the backward technique to select the variables that should compose the model, adopting the criterion of  $P < 0.20$  with statistical significance in the bivariate analysis. Thus, all the exposure variables whose relationship with the response variable was  $< 0.20$  formed part of the multivariate model.

In the first stage of the multivariate analysis, we included all level I or distal (socioeconomic) factors, progressively eliminating

them until only those whose association with post-partum weight retention (PPWR) generated a  $P$  value  $< 0.05$  remained. In the second phase of the analysis, we included level II variables of the intermediate determinants (sociodemographic, reproductive, and lifestyle factors) adjusted by level I variables. Level II variables were then chosen, and those that had a significant statistical association were maintained in the model. The same procedure was employed to test the association between the third hierarchical level (proximal) variables (nutritional conditions of the mother and child) and the event, adjusted for Level I and II variables. All statistically significant ( $P < 0.05$ ) associations formed part of the final model.

Excel software was used to input the dietary intake data, SSPSS (version 17.0; SPSS, Chicago, United States) for data entry and factor analysis, and STATA 10.0 (Stata Corporation, College Station, Texas, United States) for multivariate modeling.

### Ethical approval

The Faculdade Adventista da Bahia's Ethics Committee for Research Involving Human Beings granted approval (No. 4369.0.000.070-10) for this study on September 14, 2010. All study procedures were performed in accordance with the Declaration of Helsinki, code of ethics established by the World Medical Association for human experiments. Informed consent was obtained for the experimentation with human subjects, and the privacy rights of human subjects were observed.

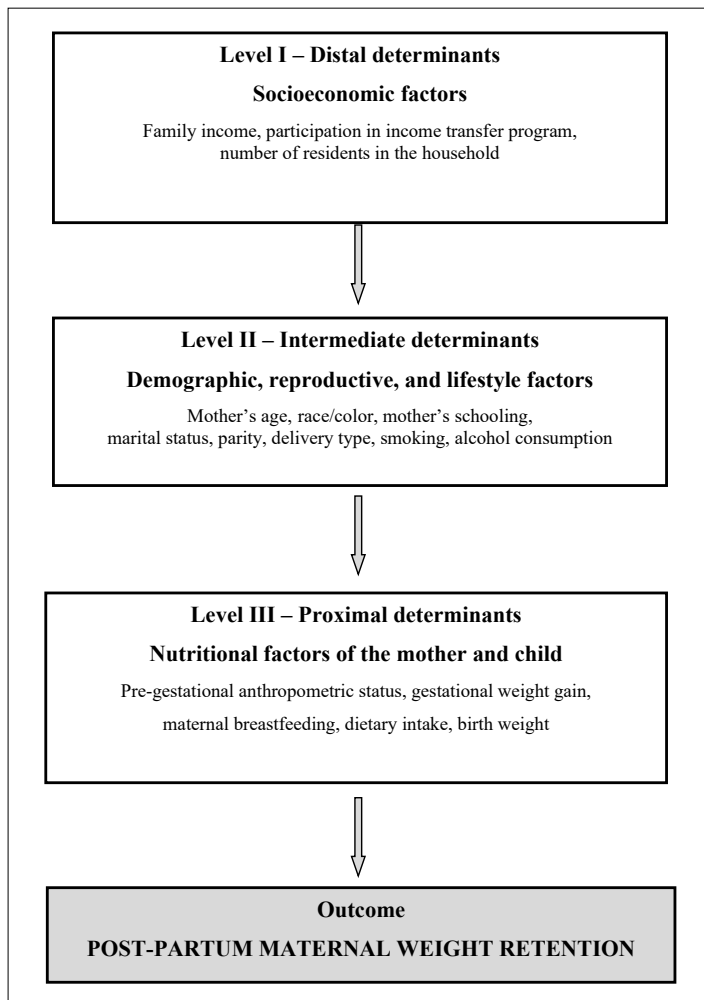
### RESULTS

#### Description of participants

There were 127 women in this study, with a mean age of  $26.7 \pm 5.25$  years old. The frequency of post-partum maternal weight retention was 46.5%, and the mean was  $6.58 \pm 5.98$  kg. At the start of pregnancy, the mean pgBMI was  $24.46 \pm 4.92$  kg/m<sup>2</sup> and  $28.57 \pm 4.34$  kg/m<sup>2</sup> at the end. The mean gestational weight gain was  $11.4 \pm 9.20$  kg, which was adequate in 22.8% of the cases. Their mean height was  $1.59 \pm 0.06$  m. The total prevalence of maternal breastfeeding was 59.1% in the sixth month post-partum and was exclusive in 15% of cases. The mean age at which complementary foods were introduced into the breastfed children's diet was  $3.47 \pm 2.37$  months (data not presented).

#### Main analysis

The results of the bivariate analysis are shown in Table 1. The family income per capita variable ( $P = 0.48$ ) (level I), although it did not have a  $P$  value  $\leq 0.20$ , was included in the multivariate analysis model due to the association of this variable with health and nutrition events, showing the pertinence of its inclusion in the statistical model because of its epidemiological relevance.



**Figure 2.** Hierarchical structure of the analysis of the factors associated with post-partum maternal weight retention, Santo Antônio de Jesus, Bahia, 2012-2014.



**Table 1.** Socioeconomic characteristics (distal determinants), sociodemographic, reproductive, and lifestyle characteristics (intermediate determinants), and nutritional characteristics of the woman and child (proximal determinants), according to post-partum weight retention, in Santo Antônio de Jesus, BA, 2012–14

Distal determinants	n	Weight retention*		P value
		Yes n (%)	No n (%)	
<b>Income per capita**</b>				
≥ 1/2 MW	90	40 (44.44)	50 (55.56)	0.48
< 1/2 MW	37	19 (51.35)	18 (48.65)	
<b>Number of residents in the household</b>				
Up to 4 people	109	52 (47.71)	57 (52.29)	0.49
> 4 people	18	7 (38.39)	11 (61.11)	
<b>Participation in an income transfer program</b>				
No	103	49 (47.57)	54 (52.43)	0.60
Bolsa Família program	24	10 (41.67)	14 (58.33)	
<b>Intermediate Determinants</b>				
<b>Mother's age</b>				
> 21 years old	103	44 (42.72)	59 (57.28)	0.08
≤ 21 years old	24	15 (62.50)	9 (37.50)	
<b>Race/color</b>				
Others***	74	38 (51.35)	36 (48.65)	0.19
Black	53	21 (39.62)	32 (60.38)	
<b>Mother's schooling</b>				
> 8 years	87	42 (48.28)	45 (51.72)	0.54
≤ 8 years	40	17 (42.50)	23 (57.50)	
<b>Marital status</b>				
With a partner	116	55 (47.41)	61 (52.59)	0.48
No partner	11	4 (36.36)	7 (63.64)	
<b>Parity</b>				
Primiparous	67	36 (53.73)	31 (46.27)	0.08
≥ 1 child	60	23 (38.33)	37 (61.67)	
<b>Delivery type</b>				
Normal	29	18 (62.07)	11 (37.93)	0.06
Cesarean	98	41 (41.84)	57 (58.16)	
<b>Alcohol consumption</b>				
Yes	84	43 (51.19)	41 (48.81)	0.14
No	43	16 (37.21)	27 (62.79)	
<b>Smoking</b>				
Yes	22	12 (54.55)	10 (45.45)	0.40
No	105	47 (44.76)	58 (55.24)	
<b>Proximal determinants</b>				
<b>Pre-gestational body mass index</b>				
Adequate	70	34 (48.57)	36 (51.43)	0.60
Inadequate	57	25 (43.86)	32 (56.14)	
<b>Weight gain during pregnancy</b>				
Insufficient	49	12 (24.49)	37 (75.51)	0.00
Adequate	43	22 (51.16)	21 (48.84)	
Excessive	35	25 (71.43)	10 (28.57)	
<b>Exclusive breastfeeding up to sixth month</b>				
Yes	19	5 (26.32)	14 (73.68)	0.06
No	108	54 (50.00)	54 (50.00)	
<b>Exclusive breastfeeding in the first month</b>				
Yes	96	40 (41.67)	56 (58.33)	0.06
No	31	19 (61.29)	12 (38.71)	
<b>Dietary intake (Pattern 1)****</b>				
Adequate	68	31 (45.59)	37 (54.41)	0.83
Inadequate	59	28 (47.46)	31 (52.54)	
<b>Dietary intake (Pattern 2)****</b>				
Adequate	64	28 (43.75)	36 (56.25)	0.04
Inadequate	63	39 (61.90)	24 (38.10)	
<b>Dietary intake (Pattern 3)****</b>				
Adequate	72	33 (45.83)	39 (54.17)	0.87
Inadequate	55	26 (47.27)	29 (52.73)	
<b>Dietary intake (Pattern 4)****</b>				
Adequate	64	30 (46.88)	34 (53.13)	0.92
Inadequate	63	29 (46.03)	34 (53.97)	
<b>Weight (newborn)</b>				
Adequate (≥ 3000 g)	100	47 (47.00)	53 (53.00)	0.81
Insufficient (< 3000 g)	27	12 (44.44)	15 (55.56)	

\*Refers to the sixth month of the post-partum period; \*\*Baseline minimum wage = 622.00 BRL; \*\*\*Race/color variable, the "others" category included white, brown, indigenous, and yellow; \*\*\*\*Pattern 1 (cereals, roots, and tubers; vegetables and legumes; white meats); Pattern 2 (red meats and eggs; meat products and sausages; industrialized foods; coffee); Pattern 3 (legumes; fruits; milk and dairy products); and Pattern 4 (sugars and sweets; fats and fried snack).

Among the sociodemographic, reproductive, and lifestyle factors (level II – intermediate), the parity variable (odds ratio [OR]:2.36; CI:1.00–5.55) was identified after adjusting for the family income variable. The results of the multivariate analysis for the level III (proximal) variables, adjusted by the level I and II variables, indicated that excessive gestational weight gain (OR:3.34; CI:1.16–9.59), insufficient gestational weight gain (OR:0.35; CI:0.13–0.93), dietary intake pattern 2, composed of red meat and derivatives, eggs, sausages, industrialized foods, and coffee (OR:2.70; CI:1.16–6.32), and the absence of exclusive maternal breastfeeding in the first month (OR:3.40; CI:1.27–9.12) were associated with post-partum maternal weight retention in the final model (Table 2).

## DISCUSSION

The findings of this study indicate that women from a municipality in the northeastern region of Brazil had a high prevalence (46.5%) of maternal weight retention in the sixth post-partum month. We also observed factors associated with events at proximal and intermediate hierarchical levels. Thus, these results reaffirm the close relationship between hierarchical determinants and health conditions. The absence of exclusive maternal breastfeeding in the first month post-partum, greater adhesion to a dietary intake pattern based on red meat, eggs, industrialized products, processed foods, sausages, and coffee (proximal determinants), and primiparity (intermediate determinant) were associated with maternal weight retention. In addition, excessive

gestational weight gain promoted PPWR, whereas insufficient gain dampened it (proximal determinant).

These results highlight that at six months post-partum, maternal weight retention > 5 kg is an important risk factor for long-term maintenance of excess weight,<sup>1,8</sup> reinforcing the hypothesis that this stage of life, is a period of risk for the occurrence of excess weight in the female population. In this study, women who gained excessive weight presented a 3.3 times higher risk (CI) for PPWR than those who showed weight gain within established limits.<sup>8</sup>

However, it was also observed that insufficient weight gain during pregnancy prevents weight retention, which would manifest itself in a reduction in the woman's weight. Both situations are undesirable and may have a negative impact on women's health because they can contribute to the accumulation or depletion of essential nutrients. Thus, in the first six months post-partum, the fat reserves accumulated during pregnancy should have already been mobilized for lactation, with energy and nutrient supplementation needed for breastfeeding continuity. In this sense, inadequate dietary intake and lifestyle habits lead to excess and insufficient weight gain in the pregnancy-puerperal cycle, resulting in risks to the health and nutrition of mother and child.

The recommendations<sup>8</sup> are outlined considering the pre-gestational maternal anthropometric status and the results of monitoring weight gain during pregnancy. When dietary intake is above the level recommended for the body mass index range, reserves are also converted into body fat. However, in this situation, the

**Table 2.** Adjusted odds ratio of the determinant factors (distal, intermediate, and proximal) of weight retention in the sixth month post-partum period obtained through the hierarchized model of the logistic regression analysis, in Santo Antônio de Jesus, BA, 2012–14

Distal determinants: socioeconomic factors	OR	CI 95%	P value
<b>Income per capita</b>			
≥ 1/2 MW	1.00		
< 1/2 MW	2.05	0.79–5.29	0.138
<b>Intermediate determinants: sociodemographic, reproductive, and lifestyle factors<sup>*</sup></b>			
<b>Race/color</b>			
Others	1.00	–	–
Black	0.59	0.25–1.37	0.220
<b>Parity</b>			
≥ 1 child	1.00	–	–
Primiparous	2.36	1.01–5.55	0.049
<b>Proximal determinants: Nutritional characteristics of the mother and child<sup>**</sup></b>			
<b>Gestational weight gain</b>			
Adequate	1.00	–	–
Excessive	3.34	1.16–9.59	0.025
Insufficient	0.35	0.13–0.93	0.034
<b>Dietary intake (Pattern 2)</b>			
Adequate	1.00	–	–
Inadequate	2.70	1.16–6.32	0.022
<b>Exclusive breastfeeding in the first month</b>			
Yes	1.00	–	–
No	3.40	1.27–9.12	0.015

<sup>\*</sup>The Level 2 association measures were adjusted by Level 1 variables; <sup>\*\*</sup>The Level 3 association measures were adjusted by Level 1 and 2 variables.

OR = odds ratio; CI = confidence interval.

diet exceeds the need for lactation expenditure and thus contributes to maternal weight accumulation. The results of this study are consistent with those of other studies conducted using different methodologies and populations, including those done in Brazil.<sup>9,11</sup>

The excessive consumption of red meats, meat products, sausages, industrialized foods, and coffee raises the risk of PPWR by 2.70 times (CI:1.16–6.32). It should be considered that although this pattern includes some foods that are sources of proteins with high biological value (meats and eggs) and iron (red meats), recommended for the gestational period, cultural factors also encourage these foods to be fried, adding unhealthy fats and increasing the calorie content and supply of sodium derived from salty meat and sausages, increasing the risk associated with them<sup>9</sup> and corroborating other epidemiological studies on dietary intake during pregnancy.<sup>11,12</sup>

However, greater adherence to healthy dietary patterns did not prevent PPWR in this study. The negative effect of the high total energy value of the diet may have a more significant dampening impact on the outcome, given the low maternal preference for healthier foods. Adherence to healthy food patterns and their relationship with PPWR have been controversial in other investigations.<sup>13</sup>

Maternal breastfeeding, another proximal factor studied, generated results that support already existing evidences that it is a strong deterrent to adequate post-partum maternal weight.<sup>7,14</sup> In this study, a greater risk of weight retention was observed in women who did not exclusively breastfeed during the first post-partum month. This period can be the most critical for mothers, as it implies lower energy expenditure for breastfeeding, consequently exacerbating weight accumulation, and also for the child because maternal milk may already be substituted for other foods not recommended during this stage of development.

Lactation implies a high mobilization of energy and nutrients derived from the diet and maternal reserves to meet nutritional demands. This is associated with greater energy expenditure and a greater decline in body weight accumulated during pregnancy. This finding is corroborated by studies that associate a longer exclusive breastfeeding time with a greater frequency of a return to pre-gestational weight.<sup>14-18</sup> However, discrepancies can be observed in some studies, resulting from the variations in aspects related to the regime, intensity, and duration of maternal breastfeeding. This may explain the controversial results regarding this subject.<sup>19,20</sup>

Primiparity was another reproductive factors at the intermediate determination level associated with weight retention in women.<sup>7</sup> A study cohort of 12,875 women from Nova Scotia, Canada, showed that multiparous women who gained more weight than recommended by the GWG guidelines ended up retaining more post-partum weight (5.3 kg, 95% CI 5.1–5.5) than primiparous

women (4.3 kg, 95% CI 4.0–4.7).<sup>21</sup> However, the evidence for the role of parity in PPWR is inconclusive.<sup>22</sup>

This study found no significant association between socioeconomic and demographic variables and PPWR. We chose to maintain family income per capita (a distal level variable) to adjust the other model levels because of the known influence of unfavorable socioeconomic conditions and a precarious state of health and nutrition. Family income per capita may impact this stage of life by resulting in decrease access to prenatal care, less social and family support to care for the child, and greater barriers to weight control, which could favor weight accumulation in this phase.<sup>23,24</sup>

In this study, the factors influencing maternal weight retention were interrelated in determining the weight adequacy pattern in Brazilian women during the reproductive period. These results reinforce the epidemiological relevance of basic prenatal monitoring actions, including nutritional assessments focused on controlling weight gain, adequate dietary intake, and a healthy lifestyle, to contribute to the health care and nutrition of the infant-maternal group.

As limitations of the study, we identified a loss in the follow-up, a characteristic that represents an implicit challenge for longitudinal studies.<sup>25</sup> The present investigation was conducted with a population in low socioeconomic conditions. Migration due to temporary (rented) residences, resulted in a 31.3% loss in the 12-month follow-up period. However, these losses were random for the studied variables, especially those associated with events.

The methodological care taken in this study and the appropriate statistical analyses used ensured reliable results compatible with those of the other studies mentioned here.

## CONCLUSION

The results of this study contribute to scientific knowledge on the determinant factors of PPWR in the context of the northeast region of Brazil, for which data on the occurrence and magnitude of the problem are scarce. Pre- and post-partum care interventions represent positive actions that could contribute to reducing excess weight in women. In light of these considerations, it is pertinent to recommend an increase in the number of studies on gestational weight gain and dietary intake during pregnancy and their relationship with PPWR, with larger samples and a population from different living conditions, to understand the complexity of the phenomena that determine this event.

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Papers with a commercial objective will not be accepted: please review the Journal's conflicts of interest policy below.

*São Paulo Medical Journal* accepts manuscripts previously deposited in a trusted preprint server.

*São Paulo Medical Journal* supports Open Science practices. It invites reviewers to join Open Peer Review practices through acceptance that their identities can be revealed to the authors of articles. However, this is purely an invitation: reviewers may also continue to provide their input anonymously.

*São Paulo Medical Journal* is an open-access publication. This means that it publishes full texts online with free access for readers.

*São Paulo Medical Journal* applies a publication fee in the form of an article processing charge (APC) for all studies conducted outside of Brazil. This rate will be charged to the corresponding author when the study has been accepted on the grounds of its scientific merit. This fee is US\$ 500.00 and is independent of the length of the text. The corresponding author should wait to receive the journal's invoice before making the payment. The article will only be published after presentation of the proof of payment. Submission is free for all. Associação Paulista de Medicina provides financial support for the Journal.

Articles accepted for publication become the Journal's property for copyright purposes, in accordance with Creative Commons attribution type BY.

### Transparency and integrity: guidelines for writing

The Journal recommends that all articles submitted should comply with the editorial quality standards established in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals,<sup>1</sup> as updated in the Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals. These standards were created and published by the International Committee of Medical

Journal Editors (ICMJE) as a step towards integrity and transparency in science reporting and they were updated in December 2018.<sup>1</sup>

All studies published in *São Paulo Medical Journal* must be described in accordance with the specific guidelines for papers reporting on clinical trials (CONSORT),<sup>2</sup> systematic reviews and meta-analyses (PRISMA),<sup>3,4</sup> observational studies (STROBE),<sup>5,6</sup> case reports (CARE)<sup>7</sup> and accuracy studies on diagnostic tests (STARD).<sup>8,9</sup> These guidelines ensure that all methodological procedures have been described, and that no result has been omitted. If none of the above reporting guidelines are adequate for the study design, authors are encouraged to visit the EQUATOR Network website (<http://www.equator-network.org/>) to search for appropriate tools.

### Conflicts of interest

Authors are required to describe any conflicts of interest that may exist regarding the research or the publication of the article. Failure to disclose any conflicts of interest is a form of misconduct.

Conflicts of interest may be financial or non-financial. The Journal recommends that the item "Conflicts of interest" at <http://www.icmje.org> should be read to obtain clarifications regarding what may or may not be considered to be a conflict of interest. The existence and declaration of conflicts of interest is not an impediment to publication at all.

### Acknowledgements and funding

Grants, bursaries and any other financial support for studies must be mentioned separately, after the references, in a section named "Acknowledgements." Any financial support should be acknowledged, always with the funding agency name, and with the protocol number whenever possible. Donation of materials used in the research can and should be acknowledged too.

This section should also be used to acknowledge any other contributions from individuals or professionals who have helped in producing or reviewing the study, and whose contributions to the publication do not constitute authorship.

### Authorship

The Journal supports the position taken by the ICMJE (<http://www.icmje.org>) regarding authorship. All authors should read ICMJE's recommendations to obtain clarifications regarding the criteria for authorship and to verify whether all of them have made enough contributions to be considered authors.<sup>10</sup>

All authors of articles published in *São Paulo Medical Journal* need to have contributed actively to the discussion of the study results and should review and approve the final version that is to be released. If one author has not contributed enough or has not approved the final version of the manuscript, he/she must be transferred to the Acknowledgement section.

The corresponding author is the primary guarantor of all ethical issues relating to the manuscript, before, during and after its

publication. However, *São Paulo Medical Journal* and ICMJE consider that all authors are held fully responsible for the study, regarding the accuracy or integrity of data and data interpretation in the text. Contributions such as data collection only do not constitute authorship.

The addition or deletion of authors' names in the manuscript byline is possible only if the corresponding author provides the reason for the rearrangement and a written signed agreement from all authors. Modifications to the order of the authors are possible, but also need to be justified. Authors whose names are removed or inserted must agree with this in writing. Publication of the article cannot proceed without a declaration of authorship contributions signed by all authors.

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*São Paulo Medical Journal* supports Open Science practices. Authors must therefore complete an open science compliance form, which is available from: [https://wp.scielo.org/wp-content/uploads/Open-Science-Compliance-Form\\_en.docx](https://wp.scielo.org/wp-content/uploads/Open-Science-Compliance-Form_en.docx).

### Redundant or duplicate publication

*São Paulo Medical Journal* will avoid publishing redundant or duplicate articles. The Journal agrees with the ICMJE definition of redundant publication,<sup>11</sup> i.e. an attempt to report or publish the same results from a study twice. This includes but is not limited to publication of patient cohort data that has already been published, without clear reference to the previous publication. In situations in which authors are making a secondary analysis on data that has already published elsewhere, they must state this clearly. Moreover, the outcomes assessed in each analysis should be clearly differentiated.

### The Journal's peer review policy and procedures

After receipt of the article through the electronic submission system, it will be read by the editorial team, who will check whether the text complies with the Journal's Instructions for Authors regarding format. The Journal has adopted the *CrossRef Similarity Check* system for identifying plagiarism and any text that has been plagiarized, in whole or in part, will be promptly rejected. Self-plagiarism will also be monitored.

When the general format of the manuscript is deemed acceptable and fully compliant with these Instructions for Authors, and only then, the editorial team will submit the article to the Editor-in-Chief, who will firstly evaluate its scope. If the editor finds that the topic is of interest for publication, he will assign at least two reviewers/referees with expertise in the theme, to evaluate the quality of the study. After a period varying from one to several weeks, the authors will then

receive the reviewers' evaluations and will be required to provide all further information requested and the corrections that may be necessary for publication. These reviewers, as well as the Editorial Team and the Editor-in-Chief, may also deem the article to be unsuitable for publication by *São Paulo Medical Journal* at this point.

At the time of manuscript submission, the authors will be asked to indicate the names of three to five referees. All of them should be from outside the institution where the authors work and at least two should preferably be from outside Brazil. The Editor-in-Chief is free to choose them to review the paper or to rely on the *São Paulo Medical Journal's* Editorial Board alone.

Articles will be rejected without peer review if:

- they do not present Ethics Committee approval (or a justification for the absence of this);
- they fail to adhere to the format for text and figures described here.

### After peer review

Peer reviewers, associated editors and the Editor-in-Chief may ask for clarifications or changes to be made to the manuscript. The authors should then send their article back to the Journal, with the modifications made as requested. Changes to the text should be highlighted (in a different color or using a text editor tool to track changes). Failure to show the changes clearly might result in the paper being returned to the authors.

The modified article must be accompanied by a letter answering the referees' comments, point by point. The modified article and the response letter are presented to the editorial team and reviewers, who will verify whether the problems have been resolved adequately. The text and the reviewers' final evaluations, along with the response letter, will then be sent to the Editor-in-Chief for a decision.

Manuscripts that are found to be suitable for publication through their scientific merit will be considered "provisionally accepted". However, all articles will subsequently be scrutinized to check for any problems regarding the reporting, i.e. sentence construction, spelling, grammar, numerical/statistical problems, bibliographical references and other matters that may arise, especially in the Methods section. The adherence to reporting guidelines will be checked at this point, and the staff will point out any information regarding methodology or results that the authors should provide. This is done in order to ensure transparency and integrity of publication, and to allow reproducibility.

The editorial team will then provide page proofs for the authors to review and approve. No article is published without this final author approval. All authors should review the proof, although the Journal asks the corresponding author to give final approval.

### Submission

Articles should be submitted only after they have been formatted as described below. Texts must be submitted exclusively through the Internet, using the Journal's electronic submission system, which is available at <http://mc04.manuscriptcentral.com/spmj-scielo>. Submissions sent by e-mail or through the post will not be accepted.

The manuscript should be divided into two files. The first of these, the main document (“blinded”), should contain the article title, article type, keywords and abstract, article text, references and tables, but must omit all information about the authors. The second of these, the “title page”, should contain all the information about the authors.

To format these documents, use Times New Roman font, font size 12, line spacing 1.5, justified text and numbered pages.

The corresponding author is responsible for the submission. However, all authors should approve the final version of the manuscript that is to be submitted and should be aware of and approve any changes that might be made after peer review.

### Covering letter

All manuscripts must be submitted with a covering letter signed at least by the corresponding author. The letter must contain the following five essential items relating to the manuscript:

1. a declaration that the manuscript is original and that the text is not under consideration by any other journal;
2. a statement that the manuscript has been approved by all authors, who agree to cede the copyrights to the Journal, disclose all sources of funding and declare all potential conflicts of interest;
3. a statement that the study protocol was endorsed by an Internal Review Board (Ethics Committee), including the date and number of the approval (in the case of original articles). This is required for absolutely all studies involving human subjects or patient data (such as medical records), in accordance with the Committee on Publication Ethics (COPE) guidelines, and even for case reports. A copy of the approval document must be submitted to the Journal;
4. each author should indicate a valid, up-to-date email address for contact;
5. a list of a minimum of five potential referees outside of the authors’ institutions, who could be invited, at the Editor-in-Chief’s discretion, to evaluate the manuscript.

### General guidelines for original articles

The following are considered to be full-text original articles: clinical trials; cohort, case-control, prevalence, incidence, accuracy and cost-effectiveness studies; case series (i.e. case reports on more than three patients analyzed together); and systematic reviews with or without meta-analysis. These types of article should be written with a maximum of 3,500 words (from the introduction to the end of the conclusion).

Typical main headings in the text include Introduction, Methods, Results, Discussion and Conclusion. The authors can and should use short subheadings too, especially those concerning the reporting guideline items.

### Trial and systematic review registration policy

*São Paulo Medical Journal* supports the clinical trial registration policies of the World Health Organization (WHO) and the

International Committee of Medical Journal Editors (ICMJE) and recognizes the importance of these initiatives for registration and international dissemination of information on randomized clinical trials, with open access. Thus, since 2008, manuscripts on clinical trials are accepted for publication if they have received an identification number from one of the public clinical trial registration database (such as ClinicalTrials.gov and/or REBEC and/or the World Health Organization; the options are stated at <http://www.icmje.org>). The identification number should be declared at the end of the abstract. Articles describing systematic reviews must provide the protocol registration number from a reliable database, such as PROSPERO, Open Science Framework, Cochrane, Joanna Briggs and others. Articles presenting clinical trials or systematic reviews without registration protocols will be promptly rejected without peer review.

Results from cases with DNA sequences must be deposited in appropriate public databases. The protocol number or URL can be requested at any time during the editorial review. Publication of other research data in public repositories is also recommended, since it contributes towards replicability of research, increases article visibility and possibly improves access to health information.

### Sample size

All studies published in SPMJ must present a description of how the sample size was arrived at. If it was a convenience or purposive sample, the authors must declare so and explain the characteristics of this sample and recruitment method. For clinical trials, for instance, it is mandatory to inform each of the three main values used to calculate sample size:

- power (usually 80% or more);
- level of significance (usually 0.05 or lower);
- clinically meaningful difference (effect size targeted), according to the main outcome measurement.

Regardless of study results (if “positive” or “negative”), the journal will probably reject articles of trials using underpowered samples, when sample size has not been properly calculated or the calculation has not been fully described as indicated above.

### Abbreviations, acronyms and products

Abbreviations and acronyms must not be used, even those in everyday use, unless they are defined when first used in the text. However, authors should avoid them for clarity whenever possible. Drugs or medications must be referred to using their generic names (without capital letters), with avoidance of casual mention of commercial or brand names.

### Interventions

All drugs, including anesthetics, should be followed by the dosage and posology used.



Any product cited in the Methods section, such as diagnostic or therapeutic equipment, tests, reagents, instruments, utensils, prostheses, orthoses and intraoperative devices, must be described together with the manufacturer's name and place (city and country) of manufacture in parentheses. The version of the software used should be mentioned.

Any other interventions, such as exercises, psychological assessments or educational sessions, should be described in enough details to allow reproducibility. The Journal recommends that the TIDieR reporting guidelines should be used to describe interventions, both in clinical trials and in observational studies.<sup>13</sup>

### Supplementary material

Because supplementary material comprises documents that do not form part of the text of the manuscript, São Paulo Medical Journal will not publish it. The authors should cite an access link that allows readers to view the supplementary material.

### Short communications

Short communications are reports on the results from ongoing studies or studies that have recently been concluded for which urgent publication is important. They should be structured in the same way as original articles. The authors of this kind of communication should explain, in the covering letter, why they believe that publication is urgent. Short communications and case reports must be limited to 1,000 words (from the introduction to the end of the conclusion).

### Case reports, case series, narrative reviews and letters to the editor

Starting in June 2018, only individual case reports dealing with situations of public health emergencies will be accepted by *São Paulo Medical Journal*. Case reports that had already been accepted for publication up to May 2018 will still be published in a timely manner.

After initial evaluation of scope by the editor-in-chief, case reports, case series and narrative reviews will be considered for peer-review evaluation only when accompanied by a systematic search of the literature, in which relevant studies found (based on their level of evidence) are presented and discussed.<sup>12</sup> The search strategy for each database and the number of articles obtained from each database should be shown in a table. This is mandatory for all case reports, case series and narrative reviews submitted for publication. Failure to provide the search description will lead to rejection before peer review.

The access route to the electronic databases used should be stated (for example, PubMed, OVID, Elsevier or Bireme). For the search strategies, MeSH terms must be used for Medline, LILACS, and Cochrane Library. DeCS terms must be used for LILACS. Emtree terms must be used for Embase. Also, for LILACS, the search strategy must be conducted using English (MeSH), Spanish (DeCS) and Portuguese (DeCS) terms concomitantly. The search

strategies must be presented exactly as they were used during the search, including parentheses, quotation marks and Boolean operators (AND, OR, and NOT). The search dates should be indicated in the text or in the table.

Patients have the right to privacy. Submission of case reports and case series must contain a declaration that all patients gave their consent to have their cases reported (even for patients cared for in public institutions), in text and images (photographs or imaging examination reproductions). The Journal will take care to cover any anatomical part or examination section that might allow patient identification. For deceased patients whose relatives cannot be contacted, the authors should consult the Editor-in-Chief. All case reports and case series must be evaluated and approved by an ethics committee.

Case reports should be reported in accordance with the CARE Statement,<sup>7</sup> including a timeline of interventions. They should be structured in the same way as original articles.

Case reports must not be submitted as letters. Letters to the editor address articles that have been published in the *São Paulo Medical Journal* or may deal with health issues of interest. In the category of letters to the editor, the text has a free format, but must not exceed 500 words and five references.

### FORMAT: FOR ALL TYPES OF ARTICLES

#### Title page

The title page must contain the following items:

1. Type of paper (original article, review or updating article, short communication or letter to the editor);
2. Title of the paper in English, which should be brief but informative, and should mention the study design.<sup>14</sup> Clinical trial, cohort, cross-sectional or case-control study, and systematic review are the most common study designs. Note: the study design declared in the title should be the same in the methods and in the abstract;
3. Full name of each author. The editorial policy of the *São Paulo Medical Journal* is that abbreviations of authors' names must not be used; therefore, we ask that names be stated in full, without using abbreviations;
4. Place or institution where the work was developed, city and country;
5. Each author should indicate the way his/her name should be used in indexing. For example: for "João Costa Andrade", the indexed name could be "Costa-Andrade J." or "Andrade JC", as preferred;
6. The author's professional background (Physician, Pharmacist, Nurse, Dietitian or another professional description, or Undergraduate Student); and his/her position currently held (for example, Master's or Doctoral Student, Assistant Professor, Associate Professor or Professor), in the department and institution where he/she works, and the city and country (affiliations);

7. Each author should present his/her ORCID identification number (as obtained from HYPERLINK "<http://www.orcid.org/>" [www.orcid.org](http://www.orcid.org/));
8. Each author must inform his contribution, preferably following the CRediT system (see above in Authorship);
9. Date and venue of the event at which the paper was presented, if applicable, such as congresses, seminars or dissertation or thesis presentations.
10. Sources of financial support for the study, bursaries or funding for purchasing or donation of equipment or drugs. The protocol number for the funding must be presented with the name of the issuing institution. For Brazilian authors, all grants that can be considered to be related to production of the study must be declared, such as fellowships for undergraduate, master's and doctoral students; along with possible support for postgraduate programs (such as CAPES) and for the authors individually, such as awards for established investigators (productivity; CNPq), accompanied by the respective grant numbers.
11. Description of any conflicts of interest held by the authors (see above).
12. Complete postal address, e-mail address and telephone number of the author to be contacted about the publication process in the Journal (the "corresponding author"). This author should also indicate a postal address, e-mail address and telephone number that can be published together with the article. *São Paulo Medical Journal* recommends that an office address (rather than a residential address) should be informed for publication.

*Second page: abstract and keywords*

The second page must include the title and a structured abstract in English with a maximum of 250 words. References must not be cited in the abstract.

The following headings must be used in the structured abstract:

- Background – Describe the context and rationale for the study;
- Objectives - Describe the study aims. These aims need to be concordant with the study objectives in the main text of the article, and with the conclusions;
- Design and setting – Declare the study design correctly, and the setting (type of institution or center and geographical location);
- Methods – Describe the methods briefly. It is not necessary to give all the details on statistics in the abstract;
- Results – Report the primary results;
- Conclusions – Make a succinct statement about data interpretation, answering the research question presented previously. Check that this is concordant with the conclusions in the main text of the article;
- Clinical Trial or Systematic Review Registration – Mandatory for clinical trials and systematic reviews; optional for observational studies. List the URL, as well as the Unique Identifier, on the publicly accessible website on which the trial is registered.

- MeSH Terms - Three to five keywords in English must be chosen from the Medical Subject Headings (MeSH) list of Index Medicus, which is available at <http://www.ncbi.nlm.nih.gov/sites/entrez?db=mesh>. These terms will help librarians to quickly index the article.
- Author keywords - The authors should also add three to six "author keywords" that they think express the main article themes. These keywords should be different from the MeSH terms and preferably different from words already used in the title and abstract, so as to improve the discoverability of the article by readers doing a search in PubMed. They provide an additional chance for the article to be retrieved, read and cited. Combinations of words and variations (different wording or plurals, for example) are encouraged.

*References*

For any manuscript, all statements in the text that do not result from the study presented for publication in the *São Paulo Medical Journal* but from other studies must be accompanied by a quotation of the source of the data. All statements regarding health statistics and epidemiological data should generally be followed by references to the sources that generated this information, even if the data are only available electronically.

*São Paulo Medical Journal* uses the reference style known as the "Vancouver style," as recommended by the International Committee of Medical Journal Editors (ICMJE). Follow the instructions and examples at [www.icmje.org](http://www.icmje.org), item "References," for the format.

In the text, the references must be numbered in the order of citation. The citation numbers must be inserted after periods/full stops or commas in sentences, and in superscript (without parentheses or square brackets). References cited in the legends of tables and figures must maintain sequence with the references mentioned in the text.

In the list of references, all the authors must be listed if there are up to and including five authors; if there are six or more, the first three should be cited, followed by the expression "et al." For books, the city of publication and the name of the publishing house are mandatory. For texts published on the internet, the complete uniform resource locator (URL) or address is necessary (not only the main home page of a website or link), so that by copying the complete address into a computer internet browser, the Journal's readers will be taken to the exact document cited, and not to a general website.

At the end of each reference, please insert the "PMID" number (for papers indexed in PubMed) and the link to the "DOI" number if available.

Authors are responsible for providing a complete and accurate list of references. All references cited in the text must appear in the reference list, and every item in the reference list must be cited in the text. Also, citations must be in the correct sequence.

Manuscripts that do not follow these guidelines for references will be returned to the authors for adjustments.

The reference list should be inserted after the conclusions and before the tables and figures.

### Figures and tables

Images must be submitted at a minimum size that is reproducible in the printed edition. Figures should be sent at a resolution of 300 DPI and minimum size of 2,500 pixels (width) and be recorded in “.jpg” or “.tif” format. Images submitted in inadequate formats will not be accepted.

Images must not be embedded inside Microsoft PowerPoint or Microsoft Word documents, because this reduces the image size. Authors must send the images separately, outside of .doc or .ppt documents. Failure to send the original images at appropriate sizes leads to paper rejection before peer review.

Flowcharts are an exception: these must be drawn in an editable document (such as Microsoft Word or PowerPoint), and should not be sent as an image that can't be changed.

Figures such as bars or line graphs should be accompanied by the tables of data from which they have been generated (for example, sending them in the Microsoft Excel spreadsheets, and not as image files). This allows the Journal to correct legends and titles if necessary, and to format the graphs according to the Journal's style. Graphs generated from software such as SPSS or RevMan must be generated at the appropriate size, so that they can be printed (see above). Authors must provide internal legends/captions in correct English.

All the figures and tables should be cited in the text. All figures and tables must contain legends or titles that precisely describe their content and the context or sample from which the information was obtained (i.e. what the results presented are and what the kind of sample or setting was). The reader should be able to understand the content of the figures and tables simply by reading the titles (without the need to consult the text), i.e. titles should be complete. Acronyms or abbreviations in figure and table titles are not acceptable. If it is necessary to use acronyms or abbreviations inside a table or figure (for better formatting), they must be spelled out in a legend below the table or figure.

For figures relating to microscopic findings (i.e. histopathological results), a scale must be embedded in the image to indicate the magnification used (just like in a map scale). The staining agents (in histology or immunohistochemistry evaluations) should be specified in the figure legend.

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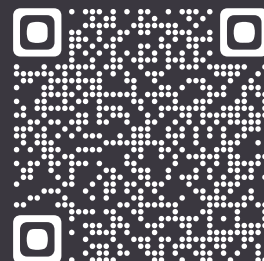
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<sup>1</sup> A disponibilidade e as características da rede hospitalar e/ou do benefício especial podem variar conforme as condições contratuais do plano adquirido. Planos de saúde coletivos por adesão, conforme as regras da ANS. Informações resumidas. A comercialização dos planos respeita a área de abrangência das respectivas operadoras de saúde. Os preços e as redes estão sujeitos a alterações, por parte das respectivas operadoras de saúde, respeitadas as condições contratuais e legais (Lei nº 9.656/98). Condições contratuais disponíveis para análise. Janeiro/2024.

<sup>2</sup> O desconto é aplicado automaticamente na contratação do plano de saúde da operadora SulAmérica para mais de uma vida por grupo familiar. Caso haja exclusão de dependentes, o preço será ajustado automaticamente para o praticado na contratação de uma vida.

<sup>3</sup> Na contratação de qualquer plano de saúde do portfólio da seguradora SulAmérica Companhia de Seguro Saúde, CNPJ/MF nº 01.685.053/0013-90 e SulAmérica Serviços de Saúde S.A., CNPJ/MF nº 02.866.602/0001-51, os beneficiários (titulares e dependentes) receberão, sem custo adicional, o produto odontológico: Odonto Mais / Adesão Odonto - Rol Ampliado, registro ANS 476.270/16-3 que também será implantado, sem custo adicional, às novas inclusões (ex.: recém-nascido, recém-casado, filho, etc) durante a vigência do contrato. A condição aqui mencionada poderá ser descontinuada a critério da SulAmérica.



SulAmérica:  
ANS nº 005622  
Qualicorp  
Adm. de Benefícios:  
ANS nº 417173

