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Development and validation of a vaccine hesitancy scale for COVID-19 to the Portuguese language

Desenvolvimento e validação de uma escala para hesitação vacinal para COVID-19 para a língua portuguesa

Desarrollo y validación de una escala de vacilación vacunal para COVID-19 para el idioma portugués

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Angelo Tunin Chica Pergo
ORCID: https://orcid.org/0000-0002-2270-8128
Faculty of Medicine of Itajubá, Brazil
E-mail: angelo.pergo@outlook.com
Alex Bacadini França
ORCID: https://orcid.org/0000-0001-9602-9294
Federal University of São Carlos, Brazil
E-mail: alex.tonante@gmail.com
Pedro Henrique Machado Teixeira
ORCID: https://orcid.org/0000-0001-7309-8764
Faculty of Medicine of Itajubá, Brazil
E-mail: pedrohtmx@hotmail.com
Lucas Brites Siqueira
ORCID: https://orcid.org/0000-0002-3751-617X
Faculty of Medicine of Itajubá, Brazil
E-mail: lucasbritessiq@outlook.com
Paulo José Oliveira Cortez
ORCID: https://orcid.org/0000-0001-8590-5172
Faculty of Medicine of Itajubá, Brazil
E-mail: drpaulocortez@gmail.com
Luciano Magalhães Vitorino
ORCID: https://orcid.org/0000-0003-1023-8488
Faculty of Medicine of Itajubá, Brazil
E-mail: lucianoenf@yahoo.com.br

Abstract
This is a psychometric study aimed at developing and validating a specific scale that assesses the vaccine hesitancy behavior of COVID-19 to the Portuguese language. The vaccine hesitancy scale for COVID-19 vaccines was developed in Brazil based on the Vaccine Hesitancy Scale developed by the Strategic Advisory Group of Experts on Immunization Working Group. Data were collected at the end of the first wave of the COVID-19 pandemic in Brazil (between March 1 and June 30 of 2021) by convenience sampling and snowballing using electronic surveys with 1345 participants. We carried out an exploratory factorial analysis (EFA) and confirmatory factorial analysis (CFA) of 10 items. Our findings for the EFA suggested only a single dimension and the unidimensional congruence of 0.95 and explained a common variance of 0.90; all items presented a significant factor loading (≥ 0.30) with excellent reliability (Cronbach's alpha of 0.88). The CFA showed the model fit indices were satisfactory (x2 = 66.0538, gl = 35, p = 0.001; RMSEA = 0.03 CI [0.02;0.04]); CFI = 0.98; TLI = 0.98) with the factor loadings cut-off ranging from 0.32 to 0.88. Our findings revealed that the vaccinal hesitancy assessment tool for COVID-19 vaccines in the Portuguese language has evidence of internal validity and reliability, and it is best represented as a unifactorial 10-item structure yielding a total score.
Keywords: COVID-19 vaccines; Vaccination refusa; Psychometrics; Validation study.

Resumo
Trata-se de um estudo psicométrico que visa desenvolver e validar uma escala específica que avalia o comportamento de hesitação vacinal da COVID-19 para a língua portuguesa. A escala de hesitação vacinal para vacinas COVID-19 foi desenvolvida no Brasil com base na *Vaccine Hesitancy Scal*e desenvolvida pelo S*trategic Advisory Group of Experts on Immunization Working Group*. Os dados foram coletados no final da primeira onda da pandemia de COVID-19 no Brasil (entre 1º de março e 30 de junho de 2021) por amostragem de conveniência e bola de neve

usando pesquisas eletrônicas com 1345 participantes. Foi realizada uma análise fatorial exploratória (AFE) e análise fatorial confirmatória (AFC) de 10 itens. Nossos achados para a AFE sugeriram apenas uma única dimensão e a congruência unidimensional de 0,95 e explicaram uma variância comum de 0,90; todos os itens apresentaram carga fatorial significativa (≥ 0,30) com excelente confiabilidade (Alfa de Cronbach de 0,88). A AFC mostrou que os índices de ajuste do modelo foram satisfatórios (x2 = 66.0538, gl = 35, p = 0.001; RMSEA = 0.03 IC [0.02;0.04]); CFI = 0.98; TLI = 0.98) com o corte das cargas fatoriais variando de 0,32 a 0,88. Nossos achados revelaram que a ferramenta de avaliação de hesitação vacinal para vacinas COVID-19 na língua portuguesa é uma escala válida e confiável, e é melhor representada como uma estrutura unifatorial de 10 itens que produz uma pontuação total.
Palavras-chave: Vacinas contra COVID-19; Recusa de vacinação; Psicometria; Estudos de validação.

Resumen
Este es un estudio psicométrico destinado a desarrollar y validar una escala específica que evalúa el comportamiento de reticencia a la vacuna de COVID-19 para el idioma portugués. La escala de vacilación de vacunas para las vacunas COVID-19 fue desarrollada en Brasil con base en la *Vaccine Hesitancy Scal*e desarrollada por el S*trategic Advisory Group of Experts on Immunization Working Group*. Los datos fueron recolectados al final de la primera ola de la pandemia de COVID-19 en Brasil (entre el 1 de marzo y el 30 de junio de 2021) por muestreo de conveniencia y bola de nieve utilizando encuestas electrónicas con 1345 participantes. Se realizó un análisis factorial exploratorio (AFE) y un análisis factorial confirmatorio (AFC) de 10 ítems. Nuestros hallazgos para el AFE sugirieron una sola dimensión y la congruencia unidimensional de 0,95 y explicaron una varianza común de 0,90; todos los ítems presentaron una carga factorial significativa (≥ 0,30) con excelente confiabilidad (alfa de Cronbach de 0,88). El AFC mostró que los índices de ajuste del modelo eran satisfactorios (x2 = 66,0538, gl = 35, p = 0,001; RMSEA = 0,03 IC [0,02; 0,04]); CFI = 0,98; TLI = 0,98) con un límite de carga factorial que oscila entre 0,32 y 0,88. Nuestros hallazgos revelaron que la herramienta de evaluación de la vacilación vacunal para las vacunas COVID-19 en lengua portuguesa es una escala válida y confiable, y se representa mejor como una estructura unifactorial de 10 ítems que arroja una puntuación total.
Palabras clave: Vacunas contra la COVID-19; Negativa a la vacunación; Psicometría; Estudio de validación.

1. Introduction

The vaccination programs implemented by multiple nations worldwide have provided huge advances in human health ("Why vaccination is safe and important ", 2019). Vaccination is still humanity's best defense against infectious diseases while being amazingly cost-effective — with estimated savings of 14 billion dollars in direct costs and 69 billion dollars in total societal costs in the United States alone ("Ten Great Public Health Achievements --- United States, 2001--2010 ", 2011). Nevertheless, we have a landscape where vaccine hesitancy (VH) has been on the rise, especially in the context of the COVID-19 pandemic (Machingaidze & Wiysonge, 2021). Vaccine hesitancy can be defined as the "delay in acceptance or refusal of vaccination despite the availability of vaccination services" (MacDonald, 2015).

It is challenging to isolate a responsible for the current landscape on VH and skepticism et al., 2011). Nonetheless, VH has negative effects on controlling preventable diseases such as pertussis (Gangarosa et al., 1998) and measles (Gardner, et al., 2020), among others, and has delayed efforts in controlling the global pandemic of Sars-Cov-2 (Harrison & Wu, 2020). Considering this troublesome scenario, collecting data on VH becomes more critical each day. Due to the global coronavirus pandemic, it is pivotal to develop tools for vaccines, especially those aimed at hesitancy attitudes (Sallam, 2021). A great contributor to this task is the Strategic Advisory Group of Experts on Immunization (SAGE), which was established in 1999 by the World Health Organization, resulting in, amongst other things, the Vaccination Hesitancy Scale (VHS) (Larson et al., 2015) (Shapiro et al., 2018). A modified version of the VHS has provided reliable data on measuring VH for the COVID-19 vaccines — primarily for China and the United States (Akel, et al., 2021). Nevertheless, social differences regarding COVID-19 vaccine acceptance have been significant (5.4% of Chinese participants have reported they would not accept a vaccine compared to 18.8% of US participants) (Akel et al., 2021). In the same context but with a different tool, 17 items were assessed in an Arabic population: 12.6% reported willingness to take the vaccine, while the remaining 87.4 % showed a hesitancy attitude toward COVID-19 vaccination (4.5% reported 'depends on the vaccine,' 20.9% stated that they 'will wait to see effects on others,' 21.7% were 'unsure,' and 40.4% reported 'no') (Qunaibi, et al., 2021). This is a highly contrasting scenario

to Brazil, where 91% of caretakers have shown acceptance of COVID-19 vaccines when asked if they would vaccinate their children (Bagateli et al., 2021). In one study, the VH for the COVID-19 vaccines in Portuguese-speaking countries reached 21.1% (overall prevalence) — showing a higher prevalence of VH among women, older adults, and people with higher levels of education. In fact, the authors reported perceived high stress, use of early treatments in the presence of symptoms, fear of future repercussions of the disease, participants that have tested positive for COVID-19, and people in close contact with someone who has had COVID-19 or died from the disease (de Sousa Á et al., 2021).

For Brazil, a scale for assessing general VH was applied during the COVID-19 pandemic for the Sars-Cov-2 vaccines. An average of 89.5% of vaccine acceptance and 10.5% for VH was reported (6.7% reported 'depends on the vaccine,' 2.5% stated that they 'do not intend to vaccinate,' and 1.3% were 'unsure') — revealing different rates in Brazilian regions, the highest VH being in central-western Brazil (12.5%) and the lowest in northern Brazil (10.1%) (Moore et al., 2021). Furthermore, the leading causes of high risk for VH were considered as 1) assessment of the vaccine's efficacy in the decision to vaccinate, 2) fear of adverse reactions, 3) the importance of the vaccine's country of origin, 4) the male sex and 5) having children (Moore et al., 2021).

Vaccines are a proven asset in healthcare and preventive medicine and help control infectious diseases worldwide, saving billions of dollars on spending. Nonetheless, vaccines have had a crisis in their public image (Black & Rappuoli, 2010). Assessing and understanding VH epidemiology is paramount to finding ways to deal with it — especially because of the coronavirus pandemic. To our knowledge, there is still no specific scale to assess the VH of COVID-19 vaccines to the Portuguese language. In order to bridge this gap, this study aimed to develop and validate to a Portuguese language a specific scale that assesses the VH behavior of COVID-19 vaccines based on the childhood vaccination hesitancy scale developed by the Strategic Advisory Group of Experts on Immunization (SAGE) of the United Nations.

2. Methodology

2.1 Study design

This psychometric study performed a secondary analysis to describe VH behaviors for COVID-19 vaccines during the Sars-Cov-2 pandemic in Brazil (Teixeira, 2021). This study was approved by the Research Ethics Committee of the Faculty of Medicine of Itajubá, Brazil (no. 4.558.835). All procedures were carried out according to Brazil's ethics regulations and the 1964 Helsinki Declaration.

2.2 Inclusion criteria and participant information

Eligibility criteria consisted of being 18 years old or older and living in Brazil. Participants with over 20% of missing data or who did not sign the free informed consent form were excluded. In total, 1407 participants were invited, including a total of 1345 volunteers from 25 of the 27 Brazilian states and 234 cities. Of the 62 volunteers that were excluded, 4 did not sign de free informed consent form, 56 were under 18, and 2 provided insufficient data.

2.3 Data collection

Data collection was carried out at the end of the first wave of the COVID-19 pandemic in Brazil (between March 1 and June 30 of 2021). The data were collected using strategies such as convenience sampling and snowballing using electronic surveys (prepared using Google Forms®). Due to the social distancing mandates and the risk of infection for participants and research assistants, face-to-face data collection was not possible. A link to the questionnaire was sent through social networks (Facebook, Instagram, WhatsApp, E-mail, and Twitter).

2.4 Measures

The Vaccine Hesitancy Scale for COVID-19 vaccines (VHS-COVID-19) was developed by using definitions of vaccine hesitancy attitudes, as well as by analyzing existing instruments such as the Vaccine Hesitancy Scale (VHS) developed by the SAGE (Shapiro et al., 2018).

The VHS-COVID-19 is measured using a five-point Likert-type scale, in which 1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, and 5 = strongly agree. It is composed of 10 items (5 items for general VH and 5 items on hesitation towards COVID-19 vaccines): 1) "Vaccines are important for my health," 2) "Vaccines work," 3) "Getting vaccinated is important for the health of the people around me," 4) "Regarding vaccination in general, I do not need vaccines for diseases that are no longer common these days," 5) "Regarding vaccination in general, I follow the guidelines of the health professionals that provide me care," 6) "Vaccines for COVID-19 approved by the Federal Government Health Agency are safe," 7) "COVID-19 vaccines are just as safe as other vaccines offered in the Health System," 8) "Vaccination is the best way to protect myself from COVID-19," 9) "I worry about severe adverse reactions from COVID-19 vaccines," and 10) "I am or I was afraid of being infected by COVID-19." The following items must be recorded (1=5, 2=4, 3=3, 4=2, and 5=1): 1, 2, 3, 5, 6, 7, 8, and 10. The authors do not recommend cut-off points. A high score means high VH for COVID-19 vaccine behaviors.

2.5 Analysis

To perform the analyses, we used the Solomon method to divide the sample into equivalent subsamples to perform the exploratory and confirmatory factor analysis (U. Lorenzo-Seva, 2021). This procedure was implemented directly in the FACTOR software (version 11.05.01).

2.6 Exploratory factorial analysis (EFA)

The dispersion matrix was generated through polychoric correlations. Sample adequacy and factorability were measured using the sample adequacy index: Kaiser-Meyer-Olkin (KMO) and the statistical significance of Bartlett's test (test of sphericity). The robust diagonally weighted least squares method was employed as the estimation method, which is more suitable for categorical data (nominal or ordinal) and robust for dealing with deviations from normality. Standardized factor loadings ≥0.30 were deemed relevant. Parallel analysis with a random permutation of the observed data was used to determine the number of factors (Timmerman & Lorenzo-Seva, 2011). Robust Promin rotation was also used (Urbano Lorenzo-Seva & Ferrando, 2019). Furthermore, the discrimination parameter and item thresholds were evaluated using Reckase's parameterization (Reckase, 1985). Internal consistency was accessed through Cronbach's alpha and McDonald's omega (≥0.60 to be considered satisfactory).

2.7 Confirmatory factorial analysis (CFA)

The utilized estimation method was robust diagonally weighted least squares (Asparouhov & Muthén, 2009) with standardized factor loadings. The adequacy of the model was assessed using the root mean square error of approximation (RMSEA), comparative fit index (CFI), and Tucker-Lewis Index (TLI) fit indices. According to the literature (Brown, 2006), RMSEA values must be below 0.08, and CFI and TLI values must be above 0.90, preferably 0.95.

EFA was performed using the FACTOR software (version 11.05.01) (P. J. Ferrando & Lorenzo-Seva, 2017). We performed the analysis using Solomon's method to split the sample into equivalent subsamples to execute the exploratory and confirmatory factorial analysis. This procedure was implemented directly on the FACTOR software. Internal consistency

analysis was performed via Cronbach's alpha and McDonald's omega, as well as confirmatory factor analysis using the JASP statistical software (version 0.15).

3. Results

The dataset was analyzed to detect inconsistent and/or missing values related to participant responses, and no inconsistencies or missing data were found. The sub-sample for EFA was 670 subjects, and 675 subjects for CFA (N = 1345).

3.1 Exploratory factorial analysis

Analysis of the internal structure. Bartlett's sphericity tests (6574.9 (df = 45; $p < 0.001$) and KMO (0.90) suggested interpretability of the items' correlation matrix. The parallel analysis suggested only one dimension, and the unidimensional congruence (UniCo) = 0.95 and explained common variance (ECV) = 0.90. UniCo values above 0.95 and ECV above 0.85 suggested that the data can be treated as essentially one-dimensional. Table 1 lists the factor loadings for the exploratory model, Cronbach's alpha reliability coefficients, and McDonald's omega.

Table 1 - Factorial loads, communalities, reliability coefficients Cronbach's alpha, McDonald's omega.

Item	Factor loadings	Communalities
1. Vaccines are important for my health	0.914	0.835
1. Vacinas são importantes para minha saúde		
2. Vaccines work	0.913	0.834
2. Vacinas funcionam		
3. Getting vaccinated is important for the health of the people around me	0.924	0.854
3. Estar vacinado é importante para a saúde das pessoas ao meu redor		
4. Regarding vaccination in general, I do not need vaccines for diseases that are no longer common these days	0.600	0.360
4. Em relação à vacinação em geral, não preciso de vacinas para doenças que não são mais comuns hoje em dia		
5. Regarding vaccination in general, I follow the guidelines of the health professionals that provide me care	0.802	0.643
5. *Em relação à vacinação em geral, sigo as orientações dos profissionais de saúde que me atendem*		
6. Vaccines for COVID-19 approved by the Federal Government Health Agency are safe	0.907	0.823
6. *As vacinas para COVID-19 aprovadas pela Agência Nacional de Vigilância Sanitária são seguras*		
7. COVID-19 vaccines are just as safe as other vaccines offered in the Health System	0.888	0.789
7. As vacinas contra a COVID-19 são tão seguras quanto as outras vacinas oferecidas pelo Sistema de Saúde		
8. Vaccination is the best way to protect myself from COVID-19	0.794	0.630
8. A vacinação é a melhor forma de me proteger da COVID-19		
9. I worry about severe adverse reactions from COVID-19 vaccines	0.489	0.239
9. Preocupo-me com reações adversas graves das vacinas COVID-19		
10. I am or I was afraid of being infected by COVID-19 virus	0.385	0.148
10. Tenho ou tive medo de ser infectado pelo vírus da COVID-19		

Cronbach's alpha = 0.88; IC (internal consistency) 95% (0.87–0.90); ω (McDonald's omega) =0.86; IC (internal consistency) 95% (0.85–0.88). Source: Authors.

When analyzing the composition of the items, all of them presented a significant factor loading (≥ 0.30) reflecting the corresponding operational-theoretical concept initially idealized. The measure of replicability of the factorial structure suggested that all factors could be replicated in future studies (H-Latent = 0.96 and H-Observed = 0.80) (Pere J. Ferrando &

Lorenzo-Seva, 2018). The instrument showed excellent Cronbach's alpha [α = 0.88; 95% IC (0.87–0.90)] and McDonald's omega [ω = 0.86; 95% IC (0.85–0.88)] indices. Next, the discrimination parameters and thresholds of the items evaluated using the Item Response Theory are reported (Table 2).

Table 2 - Item discrimination parameters and thresholds.

Item	*a*	*b*1	*b*2	*b*3	*b*4
1. Vaccines are important for my health *1. Vacinas são importantes para minha saúde*	2.248	0.921	2.061	2.472	3.009
2. Vaccines work *2. Vacinas funcionam*	2.239	0.736	1.877	3.011	3.252
3. Getting vaccinated is important for the health of the people around me *3. Estar vacinado é importante para a saúde das pessoas ao meu redor*	2.415	0.827	1.788	2.310	2.562
4. Regarding vaccination in general, I do not need vaccines for diseases that are no longer common these days *4. Em relação à vacinação em geral, não preciso de vacinas para doenças que não são mais comuns hoje em dia*	0.750	0.552	2.001	2.495	3.619
5. Regarding vaccination in general, I follow the guidelines of the health professionals that provide me care 5. *Em relação à vacinação em geral, sigo as orientações dos profissionais de saúde que me atendem*	1.342	0.423	2.043	2.761	3.429
6. Vaccines for COVID-19 approved by the Federal Government Health Agency are safe 6. *As vacinas para COVID-19 aprovadas pela Agência Nacional de Vigilância Sanitária são seguras*	2.156	-0.041	1.111	1.871	2.440
7. COVID-19 vaccines are just as safe as other vaccines offered in the Health System *7. As vacinas contra a COVID-19 são tão seguras quanto as outras vacinas oferecidas pelo Sistema de Saúde*	1.932	-0.208	0.844	1.472	2.172
8. Vaccination is the best way to protect myself from COVID-19 *8. A vacinação é a melhor forma de me proteger da COVID-19*	1.306	-0.194	1.179	1.816	2.400
9. I worry about severe adverse reactions from COVID-19 vaccines 9. *Preocupo-me com reações adversas graves das vacinas COVID-19*	0.560	-2.208	0.424	0.876	2.442
10. I am or I was afraid of being infected by COVID-19 virus, *10. Tenho ou tive medo de ser infectado pelo vírus da COVID-19*	0.417	-0.588	2.050	3.138	4.727

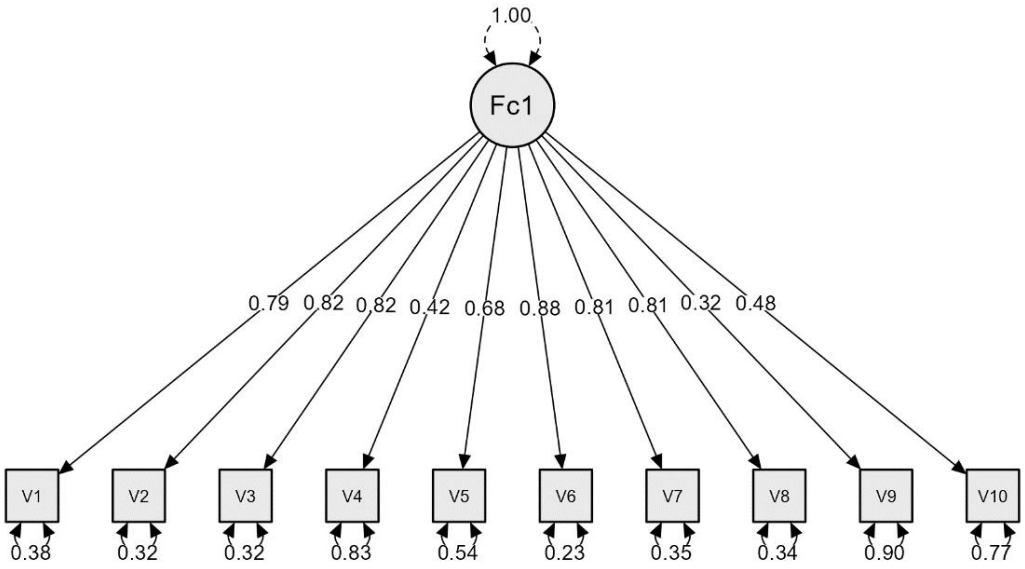
a: items discrimination in each parameter; *b*: thresholds. Source: Authors.

As shown in Table 2, the most discriminating item was item 3, 'Getting vaccinated is important for the health of people around me' (a = 2.415). Regarding the items' thresholds, no unexpected response pattern was found, so the higher the response category of the scale, the higher the level of latent trait needed to endorse it.

3.2 Confirmatory factorial analysis

The model fit indices were satisfactory (x^2 = 66.0538, *gl* = 35, *p* = 0.001; RMSEA = 0.03 IC [0.02;0.04]); CFI = 0.98; TLI = 0.98). According to the literature (Brown, 2006), RMSEA values must be below 0.08, and CFI and TLI values above 0.90, preferably 0.95. Figure 1 illustrates the confirmatory factor model with the respective standardized factor loadings.

Figure 1 - Unifactorial structure and the respective standardized factor loadings. (x2 = 66.0538, *gl* = 35, p = 0.001; RMSEA = 0.03 IC [0.02;0.04]; CFI = 0.98; TLI = 0.98).



Source: Authors.

The factor loadings presented factor loadings above the established cut-off point of 0.30, ranging from 0.32 to 0.88.

4. Discussion

This study aimed to develop and validate a VH assessment tool for COVID-19 vaccines to the Portuguese language during the pandemic in Brazil. Our findings show that the VH scale for COVID-19 (VHS-COVID-19) vaccines in a Portuguese language is a valid and reliable scale and, best represented as a unifactorial 10-item structure yielding a total score. We found a satisfactory model and factor loadings in the CFA. For better decision-making among healthcare professionals and researchers, it is essential to have a specific, valid, and reliable scale to assess HV behavior of COVID-19 vaccines, making this a valuable tool to be replicated in other countries.

From 2021 to 2022, numerous studies were developed to assess specific scales for VH for COVID-19 vaccines. A study validated the adult Vaccine Hesitancy Scale (aVHS) for the COVID-19 vaccines in China and the United States. This scale showed reliable evidence, with good internal consistency in the Chinese study (10-items; α = 0.729) and the American study (10-items; α = 0.893) (Akel et al., 2021). Another validated scale was the COVID-19 Vaccine Hesitancy Scale (CoVaH), which contains 15 items divided into three dimensions (vaccine risk, skepticism, and fear of vaccine). The internal validity of the total scale was also higher (α = 0.937) (Kotta, et al., 2022). The Vaccine Concerns in COVID-19 Scale (VaCCS) was developed with Americans and Australians, and this scale contains 35 items with 8 subscales. The internal consistency Omega (ω) was 0.800, which is considered good internal consistency (Hamilton & Hagger, 2022). We observed that there are several options for scales with good reliability.

The analyses suggest that the best way to use the scale presented in this paper is with a unifactorial 10-item structure yielding a total score. A higher score represents greater hesitation toward the COVID-19 vaccine. The CFA has shown the model to be adequate and considered satisfactory for reapplying in future studies.

Vaccine hesitation is an important issue for public health, and it has become even more relevant during the COVID-19 pandemic. This subject has been and will continue to be relevant for healthcare professionals, public health administrators, and researchers. A specific, reliable, and replicable scale is crucial for planning and preventing vaccine hesitancy for COVID-19 to make better-informed decisions towards it. To our knowledge, no scale has been developed in Portuguese language, and the scale may be validated in other cultures and languages. Thus, this study provides a reliable and contextualized cultural tool, thereby closing the literature gap.

Despite our promising findings, this study has some limitations that must be identified. Although, we provide item discrimination in each dimension and item discrimination analysis based on Item Response Theory, content validation of created items was not performed. Our study lacks test-retest and criterion (concurrent) validity analysis. It is particularly challenging for HV rating scales to achieve concurrent validity given the wide variation in conceptualization, measurement method, and psychometric characteristics. Another concern was the selection bias related to internet access, considering our database came from an online survey. This means of data collection could impact the geographic areas, economic status, or even age from which the data was collected. Nevertheless, this study went further to secure an excellent scientific tool that can facilitate cultural adaptation for countries within the Portuguese-speaking community. Moreover, we used and performed the confirmatory factorial analysis, which provided more and more solid data than tools that did not perform any validation.

5. Conclusion

Our findings indicated that the VHS-COVID-19 scale has evidence of internal validity and reliability. The assessments of VH for COVID-19 vaccines in Primary Health Care must be part-and-parcel of routine care planning. The use of a short tool with 10-items can increase adherence to its use in clinical practice.

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