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Original Article

COVID-19 contagion concern scale (PRE-COVID-19): Validation in Cuban patients with type 2 diabetes

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ABSTRACT

Aims: It is important to have valid and reliable measures to determine the psychological impact of COVID-19 in patients with diabetes; however, few instruments have been developed and validated for this population. Therefore, the aim of this study was to validate the Scale of Worry for Contagion of COVID-19 (PRE-COVID-19) in a sample of patients with diabetes mellitus (DM).
Materials and methods: A total of 219 patients (66.2% female, mean age 58.5 SD = 18.2) participated, selected through non-probabilistic sampling. The PRE-COVID-19 and the Generalized Anxiety Disorder Scale-2 were applied. Reliability analysis was performed for internal consistency, structural equation modeling and item response theory modeling.
Results: The results show that a unidimensional 5-item model presents satisfactory goodness-of-fit indices and excellent reliability values. Likewise, convergent validity between the PRE-COVID-19 and a measure of anxiety is evident. All items present adequate discrimination parameters, allowing for discerning between those patients with critical concern about COVID-19 contagion from those with severe concern.
Conclusion: It is concluded that the PRE-COVID-19 is an instrument with adequate psychometric properties to measure concern about COVID-19 infection and the emotional impact in patients with DM.

1. Introduction

In recent years, an increase in the prevalence of non-communicable diseases has been observed worldwide, especially in low-income countries [1]. Among noncommunicable diseases, diabetes mellitus (DM) has become a public health problem leading to high levels of morbidity and mortality [2]. It is estimated that by 2030 the number of patients with DM will increase to 380 million and by 2050 it will reach 439 million [3]. This problem becomes more relevant when taking into account that 50% of people with DM have not been diagnosed [4]. In Latin America, it was estimated that in 2019 the number of people with diabetes was 31.6 million, forecasting that by 2030, this figure will increase to 40.2 million and to 49.1 million by 2045 [5]. Similarly, a recent review indicated that, during 2005–2020, an increase in the prevalence of diabetes

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was observed in several Latin American countries [6]. Specifically, in Cuba an estimated 1,134,000 people between 20 and 79 years of age are currently living with DM, of whom 445,000 are undiagnosed [4], with a prevalence of 66.7 patients per 1000 people in the general population [7].

In the context of COVID-19, it has been estimated that 10.9% of patients with this virus have diabetes [8]. The prevalence of COVID-19 in patients with diabetes ranges from 24.9% in China [9] to 28% in Germany [10]; while, in Latin America rates of 16.6% [11] and 18.3% [12], are reported for Mexico and Brazil respectively. The presence of diabetes in patients with COVID-19 is associated with a twofold increase in mortality and severity of COVID-19 [13]; however, it is still not entirely clear whether it is diabetes per se or the various comorbidities or complications associated with the disease, which tend to lead to more severe COVID-19 cases [14].

While there is now a large body of knowledge on the relationship between diabetes and COVID-19, it is important to consider the impact of the pandemic on the mental health of people with diabetes [15]. Recent studies indicated that approximately 43% of diabetic patients showed significant levels of psychological distress, 75.8% have eating disorders, and 77.5% experience moderate to severe levels of sleep disturbances [16]. On the other hand, 36.3% of diabetic patients in India had anxiety about missing appointments with their physician, 27.3% felt anxiety about the spread of the COVID-19 pandemic, while, 20% were anxious about the unavailability of medications resulting from restrictions during the pandemic [17]. In addition, increased fear was observed related to COVID-19 [18]. Finally, 5% of adolescents with diabetes presented significant levels of anxiety and 12% showed signs of depression [19].

Given this scenario, it is important to have valid and reliable measures to determine the psychological impact of COVID-19 in patients with diabetes. However, few instruments have been developed and validated for this population, with only a few measures of fear currently available [20]. Thus, the Scale of Worry for Contagion of COVID-19 (PRE-COVID-19) was recently developed to assess concern about becoming infected with COVID-19 and the impact that this concern may have on people's daily functioning, specifically on their mood and their ability to perform their daily activities [21]. This concern, or worry, encompasses a set of emotional, cognitive, and behavioral reactions that are encompassed in a pattern of response to a threat and are a cue for the onset of anxiety and stress symptoms [22]. Having such a measure is important because people who are more worried about the pandemic tend to perceive greater risk of illness and adopt protective behaviors [23]. In addition, pandemic-related worry negatively affects their mental health, leading to, for example, increased levels of general anxiety and psychological distress, as well as lower levels of life satisfaction [24,25]. Finally, knowing and understanding the levels of worry about COVID-19 contagion would allow for generating evidence for interventions in health emergency situations [21].

The six items that make up the PRE-COVID-19 are grouped into a single dimension with excellent reliability; in addition, concern about becoming infected with COVID-19 showed significant correlations with anxiety, well-being, and overall health perception [21]. Originally, the PRE-COVID-19 was developed and validated for a general population; however, its psychometric properties have not been evaluated in patients with chronic conditions such as DM. Furthermore, the psychometric properties of this scale were evaluated based on classical test theory (CTT). CTT considers the assessment of a scale as an integrated whole, assuming that each individual possesses an inherent attribute, or true score, composed of an observed score and random error. Lower error variance better reflects the true scores, or inherent attributes, in the observed scores [26]. While CTT is still the most widely used method for psychometric assessment, the use of item response theory (IRT) is on the rise and assesses the relationship between latent traits and their observed variables. Specifically, this model analyzes the relationship between item properties, individuals' responses to those items, and the underlying trait being measured [27]. For some years now, the use of IRT models has been recommended to assess the psychometric quality of measurements in psychiatry [28]. Therefore, the aim of the present study was to evaluate the psychometric properties of the PRE-COVID-19 in a sample of Cuban patients with DM, combining both CTT and IRT. Specifically, evidence of validity based on internal structure, convergent validity, reliability and item characteristics (difficulty and discrimination) was evaluated.

2. Materials and Methods

2.1. Participants and procedure

The participants were patients with DM from nine primary health care areas corresponding to four Cuban provinces belonging to different regions of the country (Pinar del Río, Havana, Ciego de Ávila and Santiago de Cuba), selected by means of non-probabilistic sampling. The inclusion criteria included: 1) having type 2 diabetes mellitus according to the criteria of the World Health Organization 2) being $\geq$18 years of age 3) being attended in the previously mentioned health areas where their clinical histories were located and 4) being willing to participate in the research study and answer the survey after signing the informed consent form. Patients with severe mental illness or cognitive deficits (dementia, psychosis or mental disabilities) or any other apparent condition that compromised their ability to understand and complete the questionnaire were not included in the study. The sample size was calculated with the Soper software [29], which indicated a number of 200 participants. For this we considered the number of observed variables (6 items), latent variables of the model to be evaluated (concern for COVID-19 contagion), the anticipated effect size ($\lambda = 0.3$), the probability ($\alpha = 0.05$) and the statistical power ($1 - \beta = 0.95$).

Finally, 219 people with type 2 DM were surveyed. The application of the survey was carried out between the months of January and April 2021, while the patients attended consultation or in their own homes by the researchers trained for the task and complying with strict COVID-19 prevention protocols. The Cuban panorama in the fight against COVID-19 during the period of data collection was not favorable, as the country was in a phase of resurgence characterized by high numbers of people infected with the virus, much higher compared to the diagnoses at a similar point during the first stage of the disease, in 2020. Although government health measures were strengthened to contain the pandemic, the population's perception of risk was on the rise. During those dates, more than 64,414 positive diagnoses and 384 deaths were reported. Participation in the study was voluntary and no financial compensation was provided. All participants signed informed consent and were allowed to withdraw at any time from the study without having to justify their decision. In addition, the data were guaranteed to be confidential and anonymous. The study received approval from the ethics committee of the Universidad Privada del Norte in Peru (registration number: 20213002).

The majority of the participants were women (66.2%) with a mean age of 58.5 years old (SD = 18.2). Thirty-two point nine percent had higher education. Of the total participants, 37.9% were retired and 32% were state workers; while 43.4 had more than 10 years with the disease. The majority (68.9%) had no associated chronic complications and were receiving treatment for diabetes (98.2%). More details of the sociodemographic variables can be seen in Table 1.

2.2. Instruments

Scale of Worry for Contagion of COVID-19 (PRE-COVID-19) [21]. The scale is comprised of 6 items that assess concern about becoming infected with COVID-19 and its impact on people's daily functioning, specifically on their mood and their ability to perform their daily activities. Each item presented 4 Likert-type response options (from 1 = never or rarely to 4 = almost all the time), with higher scores indicating greater concern about COVID-19 infection.

Generalized Anxiety Disorder Scale-2 (GAD-2) [30]. The GAD-2 consists of 2 items that measure an emotional (feeling nervous) and cognitive (worry) symptom of generalized anxiety in the past 2 weeks. The 2 items have 4 response options using a Likert-type scale (from 0 = not at all to 3 = almost every day), where a higher score indicates a higher level of generalized anxiety.

2.3. Data analysis

Confirmatory Factor Analysis (CFA) was performed using the *Diagonally Weighted Least Squares with Mean and Variance corrected* (WLSMV) estimator since the items are ordinal in nature [31]. The chi-square test (χ^2), the RMSEA index and the SRMR index were used to evaluate the model fit. In the case of the latter two indices, values less than 0.05 indicate good fit, and between 0.05 and 0.08 is considered acceptable [32]. In addition, the CFI and TLI indices were used, where values greater than 0.95 indicate good fit and greater than 0.90 an acceptable fit [33]. To assess validity based on the relationship with other constructs, structural equation modeling (SEM) was employed to assess the latent relationship between concern for being infected with COVID-19 and anxiety. The above fit indices, and their respective cutoff points, were used to assess the adequacy of the model. *Cronbach's alpha* coefficient and the omega coefficient were used to assess the internal consistency of the scale, where a value greater than 0.70 is adequate [34].

As for the use of Item Response Theory (IRT), a Graded Response Model (GRM) [35] was employed, specifically an extension of the 2-parameter logistic model (2-PLM) for ordered polytomous items [36]. For each item, two types of parameters were estimated: discrimination (a) and difficulty (b). The a parameter determines the slope at which item responses change as a function of the level in the latent trait and the b parameters determine how much of the latent trait the item requires to be answered in a given way. Since the scale has four response categories, there are three estimates of difficulty, one per threshold. The estimates for these three thresholds indicate the level of the latent variable at which an individual has a 50% chance of scoring at or above a particular response category. Item information curves (IIC) and the test information curve (TIC) were also calculated.

All statistical analyses were performed using the "lavaan" package [37] for the CFA and the "ltm" package for the GRM [38]. In all cases, the RStudio environment was used for R.

Table 1
Characteristics of the participants (n = 219).

Characteristic	n (%)
Age	58.5 (18.2)[a]
Sex	
Female	145 (66.2)
Male	74 (33.8)
Level of education	
University	72 (32.9)
Pre-university	63 (28.8)
Mid-level technical	39 (17.8)
Secondary	25 (11.4)
Primary	17 (7.8)
No schooling	3 (1.4)
Occupation	
Retired/pensioned	83 (37.9)
State employee	70 (32.0)
Self-employed	37 (17.0)
Housewife	17 (7.8)
Student	10 (4.6)
Unemployed	2 (0.9)
Time of evolution of diabetes (years)	
Less than 5	52 (23.7)
From 5 to 10	72 (32.9)
More than 10	95 (43.4)
Associated chronic complications [b]	
None	151 (68.9)
Diabetic foot	31 (14.2)
Polyneuropathy	20 (9.1)
Retinopathy	15 (6.8)
Nephropathy	7 (3.2)
Other	2 (0.9)
Treatment of diabetes	
Yes	215 (98.2)
No	4 (1.8)
Comorbidities	
Yes	141 (64.4)
No	78 (35.6)
Family member or friend infected by COVID-19	
Yes	110 (50.2)
No	109 (49.8)
Family member or friend deceased due to COVID-19	
No	210 (95.9)
Yes	9 (4.1)

a: mean and standard deviation; b: a patient may have more than one complication.

3. Results

3.1. Descriptive analysis of the items

In Table 2, item 6 ("Is being worried about the possibility of getting coronavirus a major problem for you?") has the highest mean score in the sample ($M = 3.06$); whereas, item 3 ("During the last week, has thinking about the possibility of getting coronavirus affected your ability to carry out your day-to-day activities?") has the lowest mean score in the group of participants ($M = 1.38$). In addition, the pattern of responses for this item was markedly different from the other items. The majority of the participants in item 3 marked the option never (67%) in contrast to the answers given in the other items. It is also observed in the polychoric correlation matrix that all the items present a correlation coefficient between moderate and high. Regarding the skewness and kurtosis indices, it can be seen that all the items present adequate indices (As < ±2; Ku < ±7), according to the criteria set by Finney and DiStefano [39].

3.2. Validity based on the internal structure and reliability of the scale

Table 2 shows that the unidimensional model presents acceptable fit indices in the total sample of participants ($\chi^2 = 24.62$; df = 9; p = .003; RMSEA = 0.093 [CI90% 0.050−0.137]; SRMR = 0.048; CFI = 0.99; TLI = 0.99). However, it is observed that item 3 presents a moderate factorial weight ($\lambda = 0.50$) with a high level of associated error ($e_3 = 0.75$). Consequently, this item was eliminated and a second unidimensional model of five items was proposed, which presented acceptable fit indices ($\chi^2 = 20.89$; df = 5; p = .003; RMSEA = 0.125 [CI90% 0.073−0.183]; SRMR = 0.046; CFI = 0.99; TLI = 0.99). Factor weights in this model were high ($\lambda > 0.70$) with a low level of associated error ($e < 0.40$).

Likewise, it can be seen that the unidimensional six-item model presents adequate reliability indices ($\alpha = 0.90$; $\omega = 0.90$). These indices are slightly higher in the second five-item model ($\alpha = 0.92$; $\omega = 0.91$).

Table 2
Descriptive analysis of the items, polychoric correlation matrix, fit indices, factorial weights and reliability of the unidimensional model.

Items	*M*	*SD*	*g1*	*g2*	Response categories				Polychoric correlation matrix					
					A	B	C	D	1	2	3	4	5	6
Pre1	2.59	1.13	-.07	−1.38	22.2%	26.1%	22.7%	29.1%	1					
Pre2	2.28	.97	.12	−1.03	26.1%	30.5%	33%	10.3%	.72	1				
Pre3	1.38	.61	1.60	2.75	67%	28.6%	3.4%	1%	.47	.47	1			
Pre4	3.20	1.00	-.85	-.61	7.4%	19.7%	18.7%	54.2%	.69	.68	.40	1		
Pre5	2.85	.98	-.42	-.86	11.3%	22.7%	35.5%	30.5%	.81	.68	.42	.82	1	
Pre6	3.06	1.06	-.77	-.71	12.8%	14.8%	26.1%	46.3%	.52	.58	.31	.73	.74	1

Model	χ2	df	p	CFI	TLI	SRMR	RMSEA [90%CI]	Factor weight and error variance						Reliability	
								1	2	3	4	5	6	α	ω
Model 1	24.62	9	.003	.99	.99	.048	.093 [.050 −.137]	.86 (27)	.79 (.38)	.50 (.75)	.88 (.23)	.94 (.12)	.77 (.41)	.90	.90
Model 2	20.89	5	.001	.99	.99	.046	.125 [.073 −.183]	.85 (.27)	.78 (.39)	–	.88 (.23)	.94 (.12)	.77 (.40)	.92	.91

Note. *M* = Mean; *SD* = Standard Deviation; *g1* = Skewness; *g2* = Kurtosis; A = Never; B = Sometimes; C = Often; D = Almost all the time; Model 1 = Six items; Model 2 = Five items; χ2 = Chi square; df = degrees of freedom; SRMR: Standardized Root Mean Square Residual; TLI = Tucker-Lewis Index; CFI = Comparative Fit Index; RMSEA = Root Mean Square Error of Approximation; α = Cronbach's Alpha; ω = McDonald's Omega.

Table 3
Discrimination and difficulty parameters for scale items.

Model	Item	a	b_1	b_2	b_3
Model 1	Pre1	3.09	-.90	-.14	.54
	Pre2	2.37	-.82	.13	1.47
	Pre3	.95	.84	3.55	5.26
	Pre4	3.58	−1.65	-.67	-.15
	Pre5	4.42	−1.29	-.44	.46
	Pre6	1.93	−1.57	-.79	.12
Model 2	Pre1	3.02	-.88	-.13	.55
	Pre2	2.38	-.81	.14	1.48
	Pre4	3.63	−1.62	-.65	-.13
	Pre5	4.42	−1.28	-.43	.47
	Pre6	1.99	−1.54	-.77	.13

Note. Model 1 = Six items; Model 2 = Five items; a = discrimination parameters; b = difficulty parameters.

3.3. Item response theory model: Graded Response Model (GRM)

The results found in the Confirmatory Factor Analysis (CFA) show that the two main assumptions are met: the existence of unidimensionality and, consequently, local independence. Therefore, a Graded Response Model (GRM) was used, specifically an extension of the 2-parameter logistic model (2-PLM) for ordered polytomous items. Table 3 shows that almost all items (1, 2, 4, 5 and 6) of model 1 have discrimination parameters above the value of 1, generally considered as good discrimination [36]. However, item 3 does not show adequate discrimination indices (<1). Regarding model 2, all its items present adequate discrimination parameters (>1). Also, in its difficulty parameters, all threshold estimators increased monotonically.

Fig. 1 shows the IIC and TIC. In model 1 it is evident that item 3 fails to adequately measure the latent trait. With respect to model 2, the IIC shows that item 6 is the most accurate item of the scale for assessing the latent trait. In addition, the TIC shows that the test is more reliable (accurate) in the range of the scale between −1.5 and 1. For the above reasons, model 2 was chosen as the final structure of the scale and was used for the following statistical analyses.

3.4. Convergent validity

Taking into account the literature review, an SEM model was proposed to evaluate the latent relationship between concern about COVID-19 contagion and anxiety. For this sample, the model presents adequate fit indices (χ^2 = 37.31; df = 13; p = .000; RMSEA = 0.096; CFI = 0.99; TLI = 0.99) and the measurement models are adequately represented by their items. As shown in Fig. 2, concern about becoming infected with COVID-19 positively predicts the level of anxiety experienced by participants (0.64; p < .01). Taking these results into account, it can be concluded that the scale presents convergent validity based on that relation to another construct.

4. Discussion

Worry is one of the most common and important psychological response patterns during the COVID-19 pandemic [40], as it impacts protective behaviors, leading people to be more cautious [41]. This is even greater in patients with diabetes, where there is evidence of a higher incidence and severity of COVID-19 [42]. Therefore, there is a need to have an adequately validated measure of COVID-19 concern for this group. Thus, the present study evaluated the psychometric properties of the PRE-COVID-19 in a sample of Cuban patients with DM, combining both CTT and IRT.

Overall, the results based on CTT and IRT indicated that the five-item unidimensional model (eliminating item 3) has better psychometric properties than the original 6-item model. Item 3 ("During the last week, has thinking about the possibility of getting coronavirus affected your ability to carry out your day-to-day activities?") has the largest floor effect, with the majority of participants marking the "never" option (67%) as opposed to the responses they gave on the other items. This suggests the presence of a very restricted range of responses that would affect the variance of the items [43]. Item 3 also presents a moderate factor loading and a high level of associated error, making it the item that would least explain contagion concern compared to the others. Furthermore, from the IRT perspective, item 3 does not present adequate discrimination indices and fails to adequately measure the latent trait.

In the five-item model made by removing item 3, item 5 ("How often do you worry about getting coronavirus?") would seem to best explain concern about contagion; whereas, from IRT, it is suggested that item 6 ("Is worrying about getting coronavirus an important problem for you?") is the most accurate of the scale for assessing the latent trait. These findings are expected since both items refer to the belief about the probability of becoming infected with COVID-19, which is an important construct within theoretical models of health behavior, such as the health belief model [44] or

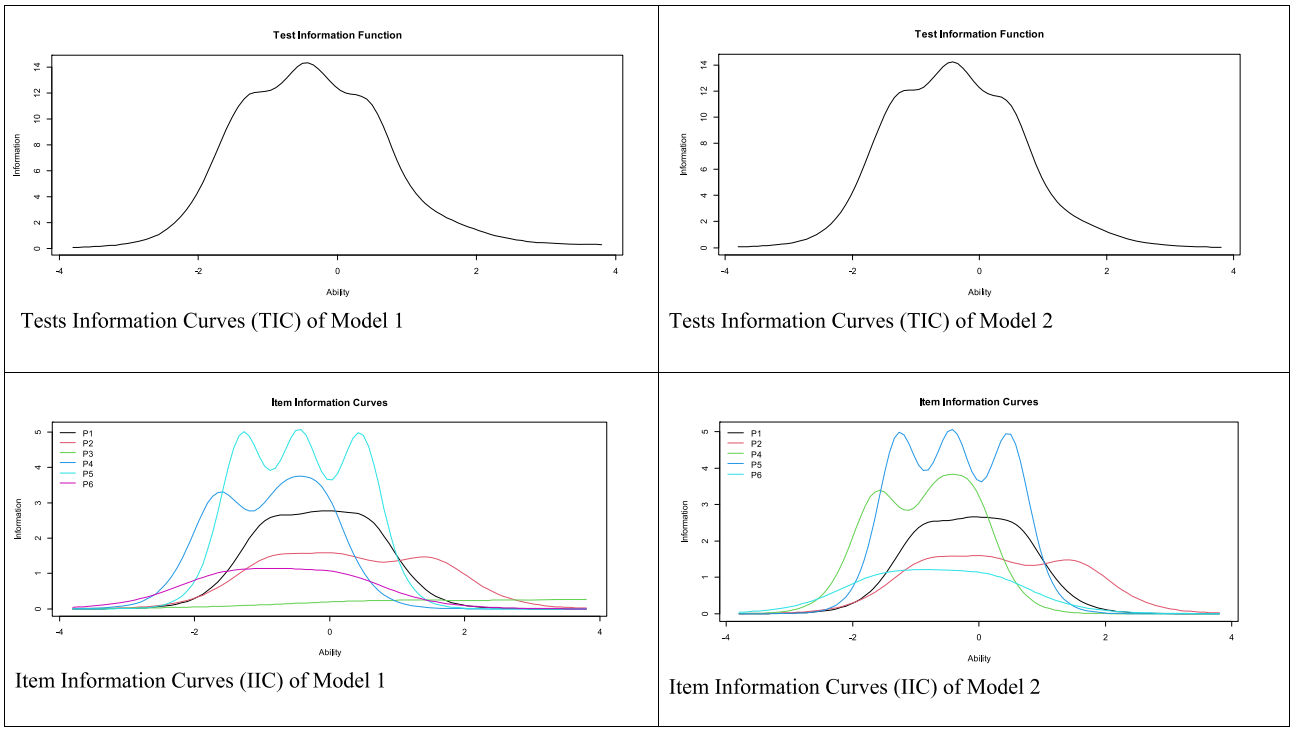

Fig. 1. Item and test information curves for the scale.

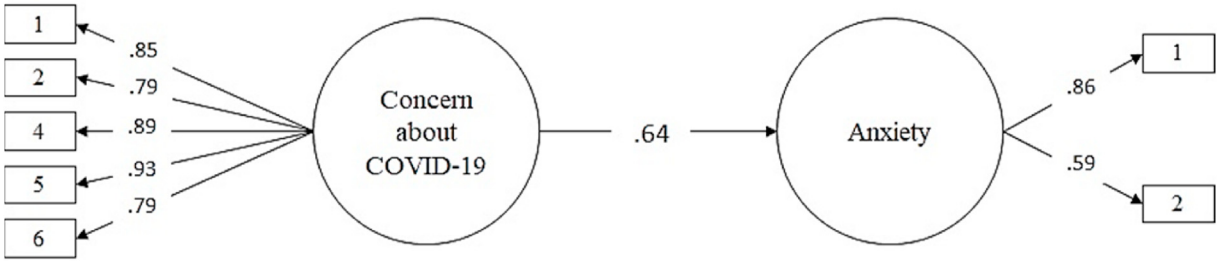

Fig. 2. Predictive model of COVID-19 contagion concern on the level of anxiety experienced.

the protective motivation theory [45], and which has demonstrated relationships with the presence of protective behaviors [46]. A higher perception of risk of contagion tends to lead to better preventive actions and better disease control [47]. Moreover, the belief about the likelihood of contracting COVID-19 is even more important if we consider that just over 50% of diabetic patients are afraid of COVID-19 [20]. In general, all items of the five-item model present adequate discrimination parameters. In this sense, responses to these items would provide the PRE-COVID-19 with the ability to discern between those who have a critical concern about COVID-19 contagion versus those who have a severe concern. Also, IRT findings would indicate that higher levels of contagion concern are required to respond to the higher response categories.

Furthermore, regarding convergent validity evidence, worry about getting COVID-19 positively predicts the level of anxiety. In this sense, worry appears to be a maladaptive coping strategy to manage the distress associated with COVID-19 [48]. While both constructs are related, they are also conceptually different, as anxiety presents feelings of tension and arousal [49]. Likewise, other studies suggest that the relationship between concern for becoming infected with COVID-19 and anxiety could be mediated by cognitive emotion regulation strategies [50]. The findings regarding the relationship between worry about contagion and anxiety should be interpreted with caution, since anxiety was measured with only 2 items referring to the frequency of anxious symptoms. Thus, future studies could add measures with indicators on the severity and duration of anxiety [21].

Although this is the first study to evaluate the psychometric properties of the PRE-COVID-19 in a clinical sample (patients with DM) using CTT and IRT procedures, it is not free of limitations. First, non-probabilistic convenience sampling was used, so the findings could not be generalized to the entire population of people with DM in Cuba. In this sense, multicenter studies are needed in patients with diabetes and in the general population. Second, the study was cross-sectional which does not provide information on the impact of time on contagion concern. As the pandemic unfolds, information about the disease, its causes, consequences and possible cure changes. Therefore, longitudinal studies with the PRE-COVID-19 are needed that can provide important information on how concern about COVID-19 contagion changes based on changing rates of diagnosed cases and deaths, as well as medical responses to cope with the pandemic. Third, using self-report measures can lead to participants' responses being influenced by social desirability biases. Thus, future studies should use other

types of measures for further analysis.

Despite these limitations, the findings have important implications. Thus, studies on the impact of the COVID-19 pandemic on mental health in diabetic patients would benefit from including an assessment of concern about COVID-19 contagion, both as an outcome measure and as an explanatory variable associated with other mental health indicators. In addition, identifying levels of contagion concern and their relationships to specific demographic variables (e.g., gender, socioeconomic status, etc.) would allow for potential risk groups to be located. This would help decision-makers and health professionals to identify those patients with DM who are more likely to be concerned about COVID-19 infection and to develop preventive and intervention actions.

Declaration of competing interest

Tomás Caycho-Rodríguez, Lindsey W. Vilca, Ibraín Enrique Corrales-Reyes, Frank Hernández-García, Antonio Pupo Pérez, Patricia González Quintana, Enrique Rolando Pérez García, Luis Alberto Lazo Herrera declare that they have no conflict of interest.

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