Received: 18 May 2023 | Revised: 22 October 2023 | Accepted: 12 November 2023

DOI: 10.1002/smi.3349

WILEY

RESEARCH ARTICLE

Measuring pandemic-related anxiety and confidence in care in chronic patients using the Psychological Consequences of a Pandemic Event (PCPE) questionnaire

Loretta Moroni[1] | Gioia Bottesi[2] | Giorgio Bertolotti[3] | Azzurra Cangiano[1] | Claudia Rizza[1] | Anna Malerba[2] | Anna Picozzi[1] | Roberto Burro[4]

[1]IRCCS MultiMedica, Sesto San Giovanni, Italy

[2]Department of General Psychology, University of Padova, Padova, Italy

[3]Primary Care Psychology, Arona, Novara, Italy

[4]Department of Human Sciences, University of Verona, Verona, Italy

Correspondence
Roberto Burro, Department of Human Sciences, University of Verona, Lungadige Porta Vittoria, 17, Verona 37129, Italy.
Email: roberto.burro@univr.it

Abstract

The COVID-19 pandemic has determined a considerable increase in psychological distress worldwide. Compared with the general population, patients with chronic conditions experience higher stress levels due to the increased risk of worse health outcomes from COVID-19 infection. Worries and fear of contagion could cause them to avoid going to their health facilities for medical examinations, which results in higher risks of morbidity and mortality. The present study aimed to develop and validate the Psychological Consequences of a Pandemic Event (PCPE) self-report questionnaire, and to assess the psychological effects of exposure to a pandemic on mood and on treatment adherence appropriate for patients with chronic diseases. Data were analysed with Rasch analysis after an Exploratory Factor Analysis and a Confirmatory Factor Analysis. We identified a final set of 10 items, divided into two independent factors labelled "pandemic-related anxiety" and "confidence in care". Finally, we transformed the raw scores of both factors into two interval scales (two rulers) that met the requirements of the fundamental measurement. The PCPE questionnaire has demonstrated to be a short and easy-to-administer measure, with valid and reliable psychometric properties, capable of assessing pandemic-related anxiety and confidence in care in patients with chronic clinical conditions.

KEYWORDS
chronic patients, confidence in care, factor analysis, pandemic stress, pandemic-related anxiety, Rasch analysis

1 | INTRODUCTION

The COVID-19 pandemic and lockdown have resulted in a significant increase in psychological distress in the general population (Balsamo & Carlucci, 2020; Brooks et al., 2020) and among healthcare providers (Bongelli et al., 2021; Lai et al., 2020). A systematic review analysed the effect of COVID-19 infection on long-term mental health outcomes in terms of anxiety, depression, and sleep disturbances in the short period following COVID-19 (Bourmistrova et al., 2022). An Italian study reported that COVID-19 survivors remained clinically

depressed three months after hospital discharge due to prolonged systemic inflammation (Mazza et al., 2021). However, symptoms at longer term were consistent with those reported by the general population, suggesting that the deterioration could be due to the indirect effects of psychosocial factors (Mazza et al., 2021).

There are several pathogenic stressors associated with a pandemic that could lead to psychological distress (Brooks et al., 2020; Paleari et al., 2021; Palumbo, 2020; Wilson et al., 2020). The construct that seems best suited to describe the association between the analysed stressors and the psychological consequences of a pandemic might be uncertainty distress, defined as "the subjective negative emotions experienced in response to the as yet unknown aspects of a given situation" (Freeston et al., 2020) (p.1). When an individual deals with situations where the outcome is unknown, they may experience a wide range of negative emotions such as anxiety, worry, frustration, anger, helplessness, and sadness. Uncertainty distress is a *normal* reaction to novel and unfamiliar situations. However, people who sustain high levels of uncertainty intolerance – a trait-like disposition reflecting negative emotional, cognitive, and behavioral reactions to uncertain situations – may experience heightened uncertainty distress and use uncertainty-reducing behaviors (e.g., worrying, avoidance) to modulate perceived uncertainty. This may produce a vicious cycle that puts individuals at risk of developing psychological maladjustment (Freeston et al., 2020).

A meta-analysis has considered 32 studies conducted in different health-related contingencies, showing that disease-related uncertainty is strongly and positively associated with high anxiety and avoidance behaviours toward health information (Kuang & Wilson, 2017), which could potentially compromise patient adherence to treatment, often in cases where such treatment is necessary such as in chronic patients. In the context of the COVID-19 pandemic, one of the elements of uncertainty concerned which groups were more vulnerable, and more likely to develop into severe cases (Hu & Wang, 2021). Hu and Wang (2021) conducted a meta-analysis to identify which clinical characteristics could be a risk factor for patient's worsening conditions following COVID-19 infection. Results showed that, regardless of age, individuals with hypertension, diabetes, and cardiovascular diseases that is, chronic conditions were more likely to develop into severe cases. Moreover, with advancing age, the worsening of the clinical picture was more attributable to the age itself rather than to the disease. Consequently, in chronic patients - as well as in all subjects requiring ongoing care - a pandemic might heighten anxiety levels and compromise trust in the health care system as a whole and in treatment specifically, undermining the chances of adequate treatment adherence. Noteworthy, during the COVID-19 pandemic many countries implemented measures such as lockdowns, restrictions on people movement and mobilization of health personnel to the frontline of the COVID-19 infection. This may be a problem for patients with chronic diseases who need visits, follow-ups, check-ups, and prescription refills since access to health facilities and their attending physicians could be denied (Kretchy et al., 2021). As stated by the National Plan for Chronic Diseases (Ministero della Salute. Piano Nazionale della Cronicità (PNC), 2016), these constraints need solving, especially because the goal of treating chronic patients is to promote empowerment, improving the patient's ability to cope with their condition, and developing self-care skills. To this end, it is crucial to work with the chronic patient to promote long-term adherence to treatment (Carraro et al., 2021; De Rosa et al., 2019).

Despite these considerations, extant literature has devoted little attention to these issues and to the development of short questionnaires that evaluate the psychological effects of a pandemic and its effects on treatment adherence in patients such as chronic ones, who require continuous, long-term treatment. The present study aimed to develop, and preliminarily validate, an Italian self-report questionnaire assessing the psychological effects of exposure to a pandemic on mood and treatment adherence. We aimed to develop a brief, easy-to-administer tool, suited for administration to hospitalized patients or those in long-term treatment to identify, in the clinical setting, those who need psychological support to cope with the psychological consequences of the pandemic and to promote good treatment adherence.

2 | METHOD

2.1 | Questionnaire development

The Psychological Consequences of a Pandemic Event (PCPE) questionnaire was developed through the following steps: literature review and identification of clinical domains in line with our aim; selection of the psychological domains of anxiety, uncertainty distress, depression and adherence to treatment; review of existing, validated questionnaires developed in past pandemics for use in these domains as well as questionnaires under development specifically designed for the current COVID-19 pandemic (Fear of COVID-19 Scale, Ahorsu et al., 2022; Coronavirus Anxiety Scale, Lee, 2020a, 2020b; COVID-19 Anxiety Syndrome Scale; Nikčević & Spada, 2020; Carlucci et al., 2020; Balsamo & Carlucci, 2020); creation of an initial set of items. We first tested these items in a focus group of three clinical psychologists, one cardiologist and one nurse working in dialysis unit to integrate them with the clinical experience on patients with different ages, socio-economical statuses, and diagnoses. Subsequently, we gave the items to 10 patients in cardiac rehabilitation to evaluate if they could understand them and if they could give us a various range of responses. At the end of the process, we changed the wording or rephrased some of the items based on the outcome from these focus groups.

The 25 items (see Table 1) that emerged from this process were conceptually attributed to the three psychological domains of (1) anxiety and uncertainty intolerance; (2) negative feelings and social isolation; (3) treatment adherence and confidence in care. Items responses range on a 4-point Likert scale: "not at all", "a little", "moderately", "a lot". Within the set of items, 7 had a reverse score. Higher scores indicate increased psychological distress in relation to the pandemic. The approximate administration time of this pilot questionnaire was about 15 min.

TABLE 1 Initial set of 25 items in three ideal psychological domains.

Anxiety and intolerance of uncertainty	Negative feelings and social isolation	Treatment adherence and confidence in care
(1) I think that the world around me is not safe.	(5) I feel that this pandemic has interrupted my life	(3) I can take care of myself as I should do.
(2) The idea that my family members may be infected worries me.	(6) I avoid contact with anyone who is not wearing proper protective devices (e.g., a mask)	(4) I believe that the drugs I take make me more vulnerable to the virus
(7) I keep thinking about this virus.	(13) I think the future still holds something good for me.	(9) I forget to go to my scheduled medical appointments
(8) At this time I can't relax whenever I want	(18) If I were to contract the virus, my health would be seriously damaged	(11) I feel that I trust in the health system, in medicine, or in those who take care of me.
(10) Uncertainty about this virus makes my life unbearable	(20) I wish to go out of the house	(15) I struggle to put the doctor's advice into practice.
(12) If I come in contact with something I think is "contaminated", I have to disinfect myself immediately.	(24) I avoid going to places crowded with strangers.	(19) I'm afraid I won't be able to carry out my regular check-ups
(14) The quality of my sleep has deteriorated since the pandemic.		(21) I remember to take my medications
(16) I feel a sense of unease if I have to use an object knowing that it has been in contact with unknown people or specific individuals.		(23) I overlook some symptoms to avoid having to go to the emergency room
(17) I visit friends and relatives as I used to do before the pandemic		(25) I think safety devices are enough to protect me from the virus.
(22) Even when I'm careful, I often find myself thinking that I might get sick		

After collecting data and performing statistical analyses, we translated the draft questionnaire into English with the help of a native speaker. We then made a back translation of the items in order to spread and maybe validate the questionnaire in different countries.

2.2 | Inclusion criteria

We involved patients with chronic cardiac, oncological, or nephrological conditions who needed regular access to hospital for visits or treatment. Specifically, we recruited patients undergoing cardiac rehabilitation for chronic heart failure or after cardiac surgery, but with a previous history of cardiovascular disease; patients currently undergoing a chemotherapy; patients who had been on haemodialysis treatment for at least 1 month. We recruited both inpatients and outpatients aged between 18 and 100 years. We excluded patients with a history of a severe psychiatric disorder or with a severe neuropsychological impairment to avoid difficulties with items comprehension and ensure reliability of responses.

2.3 | Data collection and measures

We collected data from patients undergoing an in-hospital cardiac rehabilitation at the MultiMedica centre in Castellanza (VA) and at San Giuseppe Hospital in Milan Patients who were either recovering from oncological disease or under outpatient regime for chemotherapy at San Giuseppe Hospital were also included together with data from outpatient haemodialysis treatment at MultiMedica centre in Castellanza (VA) and Sesto San Giovanni (MI). A clinical psychologist explained the questionnaire to the patients motivating them to a self-compilation or helping them, if needed. The questionnaire was administered to the patients in Italian language. Data collection began in October 2020 and ended in June 2021, a time spanning between the first and third wave of COVID pandemic. The study was conducted according to the Declaration of Helsinki, and it was approved by the Research Ethics Committee of IRCCS MultiMedica (Sezione del Comitato Etico Centrale IRCCS Lombardia. MultiMedica). Protocol reference number: 450.2020. All participants provided consent to the protocol-specific informed consent form; data were collected and organized in a database where the patients' anonymity has been guaranteed. The authors ensure accuracy, completeness and timeliness of data collection and entry.

To test the criterion validity of the PCPE questionnaire, a psychologist administered it together with the AD-R questionnaire (Moroni et al., 2006) to a group of patients from the cardiac rehabilitation unit at MultiMedica centre in Castellanza. AD-R questionnaire assesses depression and anxiety using the short form of the Depression Questionnaire (QD-R - Vidotto et al., 2010) and the State-Trait Anxiety Inventory-X3 (STAI-X3 - Spielberger et al., 1970; Vidotto & Bertolotti, 1991). Another psychologist, blinded to the responses from the questionnaires, made an independent evaluation, discerning- yes or no- whether the patient was adherent to the rehabilitation program and, in general, to the care provided.

2.4 | Statistical analyses

To ensure the development of a robust tool complying with the requirements of "fundamental measurement" (Luce & Tukey, 1964), data were analysed with Rasch analysis (RA) (Andrich, 1988; Rasch, 1960) after computation of, in sequence, an Exploratory Factor Analysis (EFA) and a Confirmatory Factor Analysis (CFA). This

procedure has been increasingly supported in literature (Burro et al., 2021, 2022; Chiu et al., 2020; Panella et al., 2012; Raccanello et al., 2021; Vidotto et al., 2010) and lists among its main advantages the possibility to achieve "test free" and "sample-free" measures on an interval scale with logit as a unit of measurement (Burro, 2016).

To correctly execute RA, some assumptions need to be tested beforehand: the presence of monotonicity (Kang et al., 2018), local independence (Debelak & Koller, 2020), unidimensionality (Christensen et al., 2002) and the absence of Differential Item Functioning (DIF) (Hagquist & Andrich, 2017). If one or more assumptions are not tested, this can be remedied (Linacre, 2002) with a number of recursive procedures such as rescoring of item scores (to address the violation of monotonicity), the re-allocation of items across domains (to account for local dependence), and item splitting (to counteract DIF). The analysis of standardized residuals allows for the evaluation of the degree of agreement between the participants' responses to items and the predictions made by the Rasch model (Wright & Masters, 1982). The next step is to evaluate the performance of each item through analysis of the infit and outfit Mean Squared (MSQ) indices (Wright & Linacre, 1984) and the use of the person-separation index (PSI) (Kreiner & Christensen, 2012) to assess the questionnaire's reliability in its complexity. If all assumptions are tested, the model-data fit can be assessed using Andersen's likelihood ratio test (Andersen, 1973). Finally, the raw scores can be transformed into an interval logit scale (Masters & Wright, 1997), a ruler that fulfils fundamental measurement requirements. In the event that the abovementioned procedures were not effective, or showed negative results, critical items can be removed, and the same procedure can be repeated iteratively.

2.4.1 | Exploratory factor analysis

In the current study, EFA operates on the covariance matrix of a set of items that were administered to the patients with the following aims: development of an explanatory theory on the consequences of exposure to a pandemic on anxiety ad treatment adherence; reduction of the number of items through the evaluation of each one's discriminative power within a specific factor; construction of a reliable and valid psychometric measure.

Normally, to execute an EFA, which is followed by a CFA, the total sample is split into two sub-samples, and EFA is computed on the first while CFA is performed on the second.

Since we had a sample of 214 individuals (see Table 2 for descriptive analysis), if we had run the analysis on the sub-samples of $n = 107$ subjects we would have run the risk of obtaining data

TABLE 2 Descriptive statistics of the sample.

		Frequency	% valid
Sex	Male	128	59.8%
	Female	86	40.2%
Unit	Cardiac Rehabilitation	91	50%
	Oncology	50	23.4%
	Dialysis	57	27.6%
Education level	Primary	39	18.2%
	Middle	66	30.8%
	High	81	37.9%
	Graduate	28	13.1%
Employment status	Employed	65	30.4%
	Unemployed	4	1.9%
	Stay at home parent	11	5.1%
	Retired	134	62.6%
Have you experienced a change in your occupation because of the current pandemic?	Yes	30	14%
	No	184	86%
Have you experienced financial difficulties because of the current pandemic?	Yes	30	14%
	No	184	86%
Did you get infected with COVID?	Yes	34	15.9%
	No	180	84.1%
Did you get a COVID vaccine (if available)?	Yes	109	50.9%
	No	105	49.1%

not sufficiently representative of the population and of the factorial structure resulting from the analyses being partially dependent upon the specificity of the two samples, thus lacking generalizability. To avert this risk, we employed a statistical procedure for resampling with replacement, which has already been adopted in other studies (Bongelli et al., 2022). A total of 1000 different sub-samples of 107 participants each were randomly extracted from the original sample of 214 individuals (it is possible to generate 1.43×10^{63} different samples of 107 subjects by extracting them from the larger sample of 214). An EFA was conducted on each one of these sub-samples. The result consists of the mean EFA of these 1000 analyses: in this way, the outcome can be evaluated as more stable and generalizable. The same logic is applied to the following analyses, which supplement EFA.

We employed the statistical software R, version 4.3.0 (R Core Team, 2023).

2.4.2 | Confirmatory factor analysis

CFA was conducted employing the Diagonally Weighted Least Squares estimation method, which was specifically designed for estimation of parameters for ordinal data. We tested the adequacy of confirmatory solutions by evaluating the following fit indices: the Root-Mean-Square Error of Approximation (RMSEA), the Comparative Fit Index (CFI), the Tucker-Lewis Index (TLI), the Standardized Root Mean Residual (SRMR), the Goodness of Fit Index (GFI), the Adjusted Goodness of Fit Index (AGFI) and the ratio of Chi-sq to degrees of freedom (*df*). The threshold values used to evaluate of goodness-of-fit were: 0.08 for RMSEA and SRMR, 0.95 for TLI and GFI, 0.90 for CFI and AGFI. In line with existing literature (Hu & Bentler, 1999; Schumacker et al., 2004), we only considered models that showed fit indices below the threshold values for RSMEA and SRMR and above the threshold values for CFI, TLI, GFI, and AGFI to be good. A Chi-sq/*df* ratio of 3 or less was considered adequate.

2.4.3 | Analysis of invariance

To establish whether the resulting model was invariant and generalizable across sex groups (that is, to evaluate if mean values of men and women were comparable) we compared the models of three factorial confirmatory multi-group analyses (structurally identical to the abovementioned one), computed on the completely original sample ($N = 214$), identifiable as follows:

- configural model: where the same latent constructs are examined without imposing equality constraints between the two sex groups;
- metric model: where the equality of factor loadings restriction is imposed between the group of males and females; and
- scalar model: in which the constraint of equality of factor loadings and intercepts between the group of males and females is imposed.

2.4.4 | Rasch analysis

RA is a unique approach of mathematical modelling to the considered single factors. In the case reported here, RA is implemented on psychometric measures developed through the combination of EFA and CFA to provide them with the properties of fundamental measurement, creating a proper measurement tool. RA was computed employing the Partial Credit Model (PCM; Masters & Wright, 1997). RA is a procedure used to statistically determine if data fit to the hypotheses and to the requirements of a mathematical model named after its creator, the Danish mathematician Georg Rasch (1960).

TABLE 3 Factor loadings (EFA) of PCPE items.

Original ID	Items text	F1 - pandemic-related anxiety	F2 - confidence in care
2	The idea that my family members may be infected worries me.	**0.711**	0.101
16	I feel a sense of unease if I have to use an object knowing that it has been in contact with unknown people or specific individuals (REVERSE)	**0.654**	0.124
7	I keep thinking about this virus.	**0.603**	−0.119
24	I avoid going to places crowded with strangers.	**0.591**	0.107
12	If I come in contact with something I think is "contaminated", I have to disinfect myself immediately.	**0.563**	0.149
25	I think safety devices are enough to protect me from the virus.	0.001	**0.457**
11	I feel that I trust in the health system, in medicine or in those who take care of me.	0.050	**0.448**
13	I think the future still holds something good for me.	−0.019	**0.405**
15	I struggle to put the doctor's advice into practice (REVERSE)	0.055	**0.394**
3	I can take care of myself as I should do.	−0.041	**0.392**

Note: Values in bold show in which domain the value of factor loadings is higher. Original ID indicates the item's position in the initial set of 25 items.

2.4.5 | Transformation of the raw score in an interval scale

Finally, raw scores of the factors were transformed into interval scales that meet the requirements of fundamental measurement. Fundamental Measurement refers to the process of directly measuring a property, without the need for derivation from other measurements. RA uses ordered qualitative observations to operationalize fundamental measurement.

2.4.6 | Criterion validity

Criterion validity is a type of validity that refers to the extent to which a measurement tool (such as a test or a questionnaire) accurately assesses a specific construct or trait that it is supposed to measure. It is determined by comparing the results of the measurement tool to a criterion or standard, such as a known measure of the construct, or an external criterion like an observer's rating, performance on a job task, or a gold standard measure. The degree of correlation between the results of the measurement tool and the criterion is used to assess criterion validity.

3 | RESULTS

We collected data from 214 patients from MultiMedica in Castellanza (VA), San Giuseppe Hospital in Milan and MultiMedica in Sesto San Giovanni (MI). Age ranged between 26 and 99 ($M = 64.99$, $SD = 12.06$) with a slight prevalence of males (59.8%) on females. Half of patients have a chronic cardiac disease while the other half are equally divided into patients with either a chronic renal failure or an oncological disease. This difference is due to heterogeneity in the access, across time, to the three different units: the turnover of patients with a chronic cardiac disease is markedly higher than the one of patients undergoing dialytic treatment, which are rather stable across time, and different to the turnover of patients at oncology unit, who undergo various type and length of chemotherapy. About half of patients are not adequately vaccinated for COVID disease due to lack of access at an early stage of the pandemic, and half of them have completed the vaccination cycle. Table 2 describes the sample.

3.1 | Exploratory factor analysis

Data were preliminarily analysed to check if they were suitable for factor analysis. The mean values of Bartlett's test of sphericity

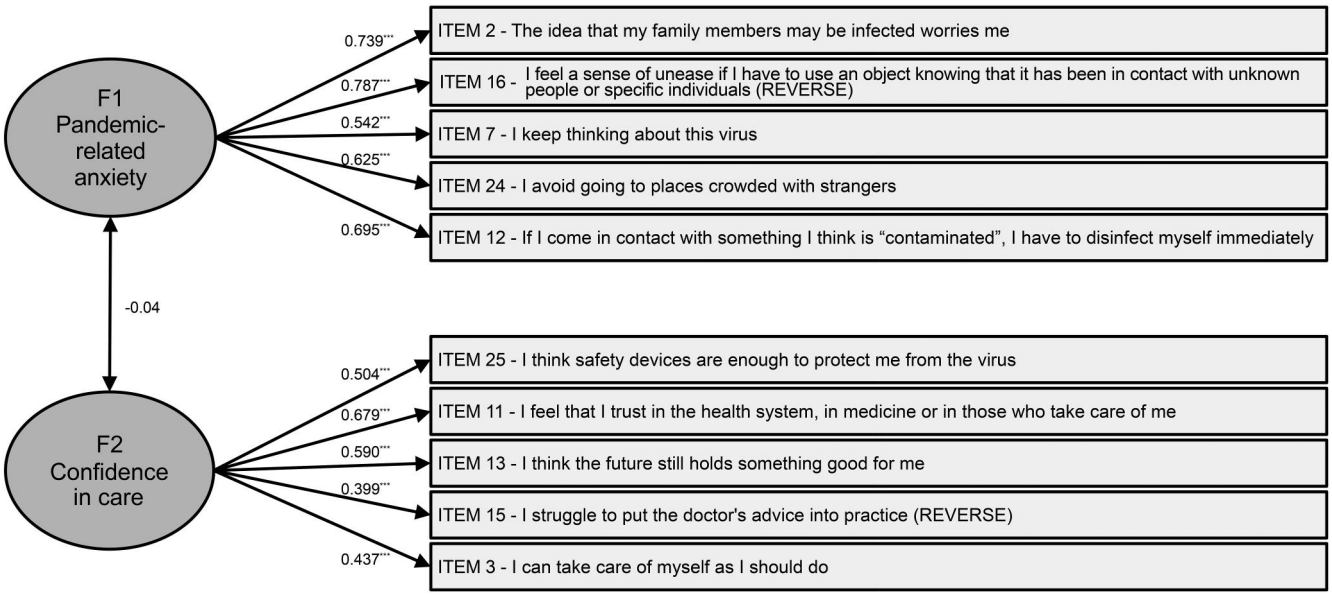

FIGURE 1 Confirmatory Factor Analysis model of PCPE items (figures represent standardized factor loadings, *** = $p < 0.001$).

Groups	Invariance model	CFI	RMSEA	SRMR	Invariance	ΔCFI	ΔRMSEA	ΔSRMR
Sex (M e F)	Configural	0.999	0.072	0.081		-	-	-
	Metric	0.999	0.077	0.082	Metric	–0.003	0.005	0.001
	Scalar	0.998	0.066	0.083	Scalar	–0.005	–0.011	0.001

Abbreviations: CFI, Comparative Fit Index; RMSEA, Root Mean Square Error of Approximation; SRMR, Standardized Root Mean Residual.

TABLE 4 Difference between fit indices for invariance purposes.

(χ^2 (300) = 1317.39; $p < 0.001$), and Kaiser-Meyer-Olkin's test (*KMO* = 0.78) suggested that data were adequate for all 1000 extractions. Three different methodologies were employed (Parallel analysis, Velicer's minimum average partial test 1976 original version and the 2000 revised version; O'connor, 2000; Velicer, 1976) to determine the most plausible number of factors to enter in the EFA. All methodologies indicated an average value of 2 out of the 1000 extractions. With this figure we then computed the mean EFA (promax oblique rotation). First, we discarded all items with low discriminative power, that is, items that had a difference in factor loadings between the two factors below 0.2. A rule of thumb (Stamper & Masterson, 2002) for figuring out cross-loading is to check the difference between the highest loading and the second highest loading for an item. If the absolute difference is ≤0.2, it means the item suffers from cross-loading. Second, we retained the best 5 items for each factor, in accordance with our objective to develop a short, easily administrable scale; these items were required to display a factor loading above 0.35. The outcome of this selection is reported in Table 3. Based on the relationship between the two factors and the items, we decided to label Factor 1 (F1) as "pandemic-related anxiety" and Factor 2 (F2) as "confidence in care".

3.2 | Confirmatory factor analysis

CFA was computed on the entire sample (*N* = 214). Regarding F1 (pandemic-related anxiety): Cronbach's alpha = 0.755; McDonald's omega = 0.759; Regarding F2 (confidence in care): Cronbach's alpha = 0.698; McDonald's omega = 0.728. Figure 1 reports the fit indices and the diagram-plot resulting from the CFA. All considered indices were deemed adequate: CFI = 0.962; TLI = 0.950;

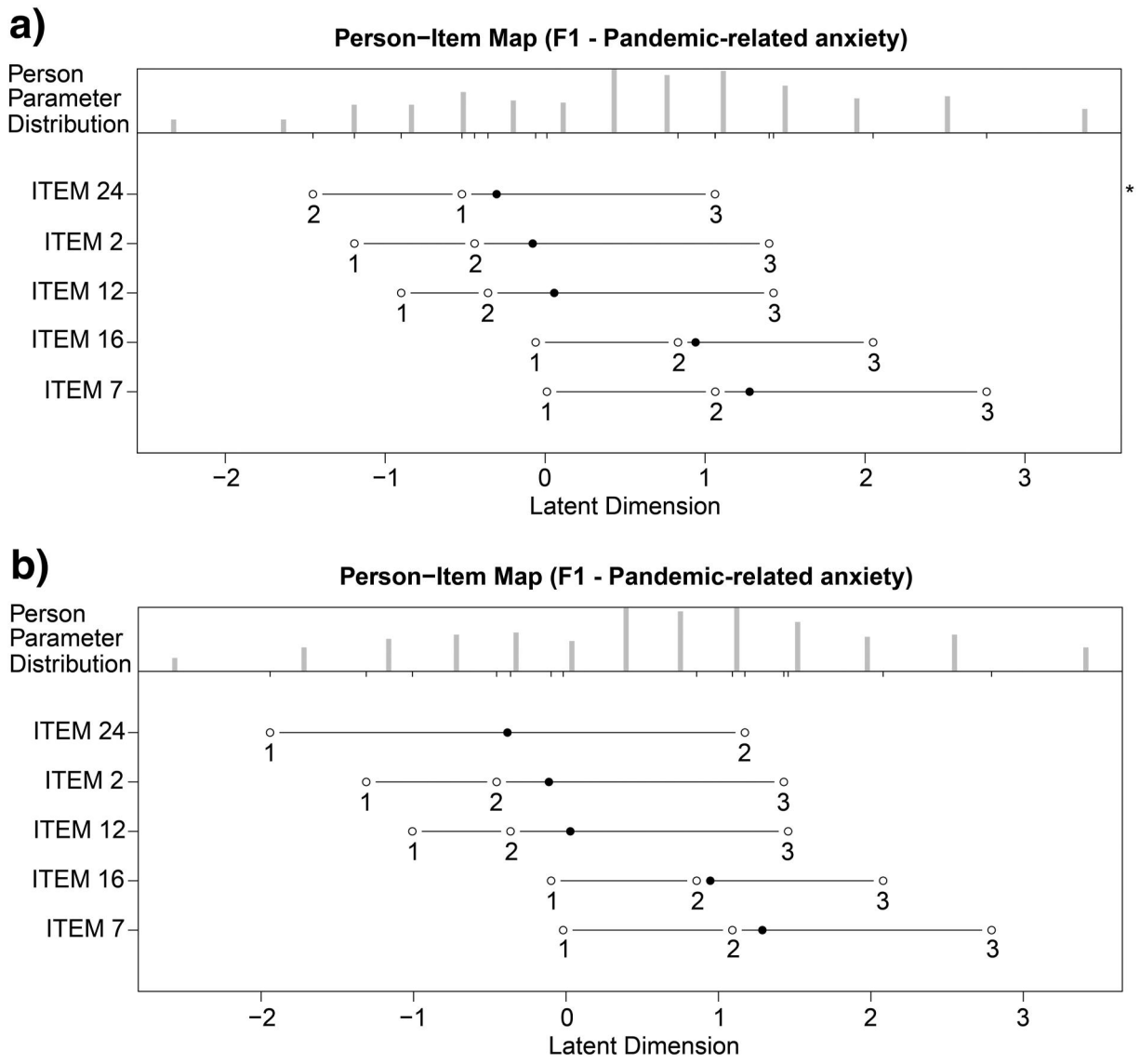

FIGURE 2 (a) Person-Item Map (b) Person-Item Map after rescoring of item 24. The filled circles represent the locations of the discriminant abilities of the items. Open circles represent thresholds. The asterisk indicates a problematic item with unordered thresholds.

RMSEA = 0.064; SRMR = 0.079; GFI = 0.979; AGFI = 0.953; $\chi^2 = 63.920$; $df = 34$; $\chi^2/df = 1.88$.

Using the calculated RMSEA index as an effect-size and with an alpha of 0.05, the post-hoc power analysis says that a sample of 214 subjects is associated with a power of 87%. The a-priori power analysis indicated that the number of subjects required to have 80% power was 187. Moreover, our sample size was sufficient as it met the recommended ratio of 5:1 or more between observations and parameters, with 41 estimated parameters and 214 participants, providing a ratio of 5.22:1 (Kline, 2016). The model is, therefore, adequate.

3.3 | Analysis of invariance

To compare the three models, we considered the differences of the three indices, CFI, SRMR and RMSEA between the three multi-group models (configural vs. metric and metric vs. scalar). Invariance is verified if there is a difference of CFI less than or equal to 0.010, a difference of RMSEA less than or equal to 0.015 and a difference of SRMR less than or equal to 0.030 in the configural versus metric comparison, and less than or equal to 0.010 in the metric versus scalar comparison (Chen, 2007). As can be seen in Table 4, Δ values are good: invariance is verified, and the means of males and females can be compared.

3.4 | Rasch analysis

3.4.1 | Testing of requirements

The first step is to verify the monotonicity requirement, to check whether the thresholds (i.e., the transition points between two

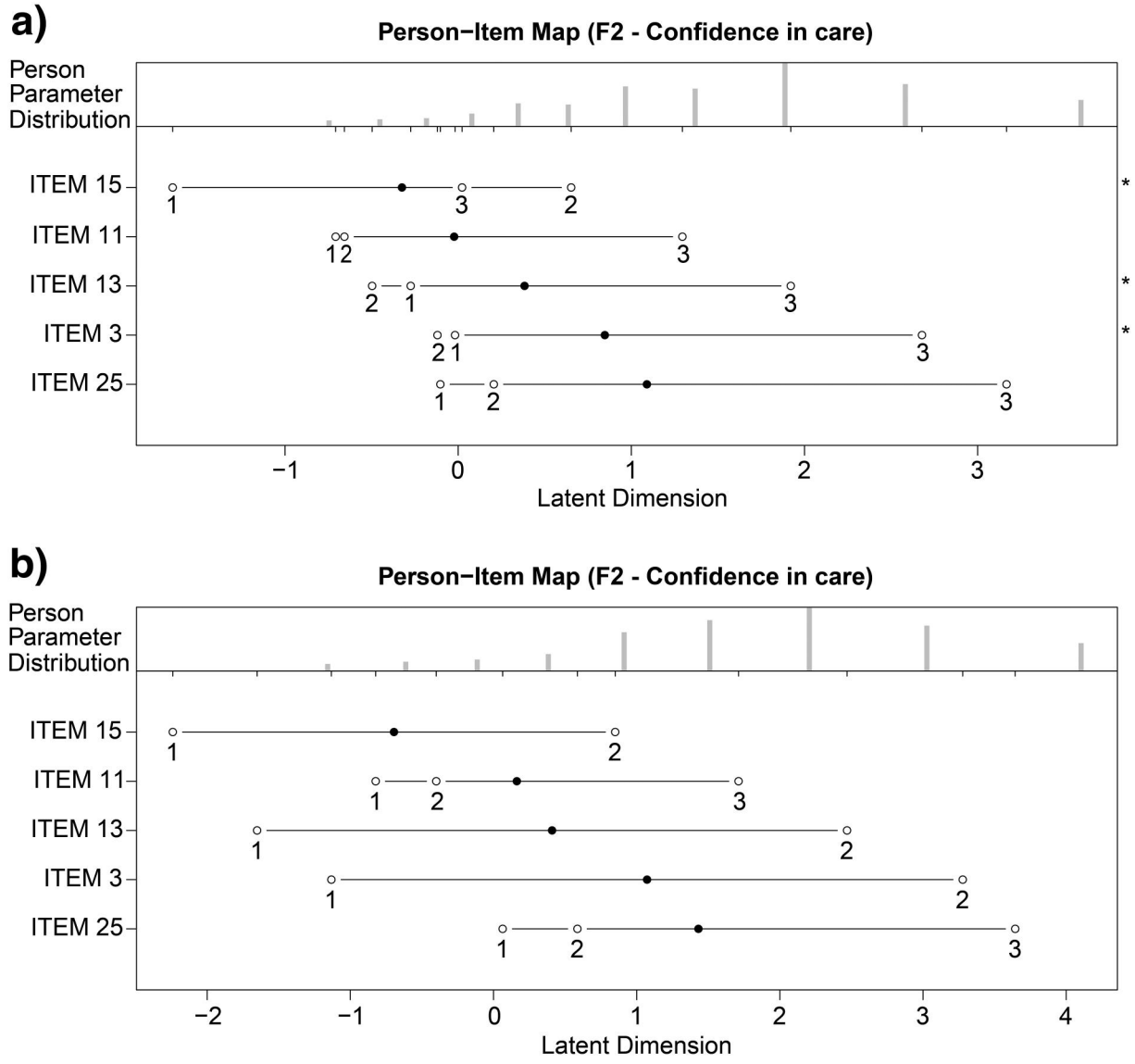

FIGURE 3 (a) Person-Item Map (b) Person-Item Map after rescoring items 3, 13, 15. The filled circles represent the locations of the discriminant abilities of the items. Open circles represent thresholds. The asterisk indicates a problematic item with unordered thresholds.

different scores), were correctly ordered. With respect to Factor F1 (pandemic-related anxiety), the person-item map (Figure 2) indicates lack of monotonicity of item 24. By rescoring the responses of item 24 from "1 2 3 4" to "1 2 2 3" the monotonicity is confirmed (Kang et al., 2018).

Regarding Factor F2 (confidence in care), the person-item map indicates a lack of monotonicity of items 3, 13, 11, 15 and 21 (Figure 3). Rescoring, again, the answers given to the above-mentioned items from "1 2 3 4" to "1 2 2 3" the monotonicity is confirmed.

The second step consists in verifying the requirement of local independence, which entails that the items within each factor should not be correlated with each other. With reference to both Factor F1 (pandemic-related anxiety) and Factor F2 (confidence in care), since there are no positive correlations greater than 0.3 between item residuals (Debelak & Koller, 2020), the presence of local independence is confirmed. Specifically, the values ranged from −0.071 to −0.428 for factor F1 and from −0.004 to −0.453 for factor F2.

In the third step, we used a principal components analysis (PCA) to check for unidimensionality after rescoring. This method evaluates the correlation among standardized residuals from Rasch model analyses to determine if additional dimensions have influenced item responses. In the context of RA, PCA of residuals are referred to as contrasts since they reflect different patterns of responses to the principal latent variable (Chou & Wang, 2010; Raîche, 2005; Smith, 1996). Unidimensionality is confirmed when all contrasts have a value less than 2 (Linacre, 2016). Our results showed the largest contrast was 1.637 for F1 (pandemic-related anxiety) and 1.701 for F2 (confidence in care), indicating unidimensionality.

The fourth step checks for the absence of DIF, meaning that we checked whether the instrument measures the subgroups of males and females in the same way. The Standardised P-DIF index says that there is no DIF, with respect to gender, for both Factor F1 (pandemic-related anxiety) and F2 (confidence in care). Precisely, the value of the statistic is always within ±0.1 (Magis et al., 2010): for F1: −0.095 < Standardized P-DIF <0.084 and for F2: −0.039 < Standardized P-DIF <0.022. The fifth step checks for the percentage of subjects whose answers are not in line with the predictions made by the Rasch model. The percentage of Misfitting Persons is small: for F1 (pandemic-related anxiety): 3.333% and for F2 (confidence in care): 1.923%. The sixth step checks for the performance of the individual items. To check whether the individual items perform well in measuring the latent dimension, the infit-MSQ and outfit-MSQ indices are assessed (Table 5).

All infit-MSQ and outfit-MSQ values for both F1 (pandemic-related anxiety) and F2 (confidence in care) fall in the range 0.40–1.60 (Wright & Linacre, 1994). Thus, all items perform well within their own factor. The seventh step assesses the reliability of the instrument by calculating the PSI for each of the factors: for F1 (pandemic-related anxiety): PSI = 0.720, and for F2 (confidence in care): PSI = 0.674. These values are acceptable. The eighth and final step assesses the overall fit of the data to the Rasch model. This is done by performing Andersen's LR-test (Andersen, 1973) for each of the two factors. The results are as follows: for F1 (pandemic-related anxiety): χ^2: 15.438, *df*: 13, *p*-value: 0.281, and for F2 (confidence in care): χ^2: 5.213, *df*: 11, *p*-value: 0.920. Since both results are not significant, we can support that the fit is good. To conclude, Table 6 shows the final test with its item-by-item response scale (also in the original language).

TABLE 5 Fit indices of the individual items within the respective factors.

Original ID	Infit-MSQ	Outfit-MSQ
F1-Pandemic-related anxiety		
2	0.741	0.752
16	0.693	0.653
7	1.067	1.029
24	0.883	0.852
12	0.850	0.883
F2-Confidence in care		
25	0.779	0.809
11	0.646	0.677
13	0.811	0.790
15	0.964	1.022
3	0.830	0.809

3.5 | Transformation of the raw score into an interval scale

Since all requirements of the RA have been verified and fulfilled, it is finally possible to transform the raw scores of both factors into two interval scales (two rulers) that meet the requirements of the fundamental measurement. Table 7 is reported for conversion from the raw total score to the logit interval total score (logit unit of measurement). For convenience and readability, the logit score is varied from a minimum of 1 to a maximum of 10. After the rescoring made at step 1 of the RA, Factor 1 (pandemic-related anxiety) has a total score between 5 and 19, while for Factor 2 (confidence in care) the total score is between 5 and 17.

3.6 | Analysis of criterion validity

The criterion validity analysis was carried out on a sub-sample of 50 patients coming entirely from the cardiac rehabilitation unit. Table 8 shows the values of Pearson's *r* coefficient for testing the correlation between the scores obtained on the two factors of the PCPE

TABLE 6 Showing the PCPE test with its item-by-item response scale.

Factor	Original ID	ID	Items text	Please indicate your level of agreement or disagreement with the following statements by selecting a number next to each
F1 pandemic-related anxiety	2	1	The idea that my family members may be infected worries me.	1 = not at all; 2 = a little; 3 = moderately; 4 = a lot
			L'idea che i miei familiari possano essere contagiati mi preoccupa.	1 = per nulla; 2 = poco; 3 = abbastanza; 4 = molto
	16 (REVERSE)	2	I feel a sense of unease if I have to use an object knowing that it has been in contact with unknown people or specific individuals.	4 = not at all; 3 = a little; 2 = moderately; 1 = a lot
			Utilizzo un oggetto anche quando so che è stato in contatto con estranei o determinate persone.	4 = per nulla; 3 = poco; 2 = abbastanza; 1 = molto
	7	3	I keep thinking about this virus.	1 = not at all; 2 = a little; 3 = moderately; 4 = a lot
			Continuo a pensare a questo virus.	1 = per nulla; 2 = poco; 3 = abbastanza; 4 = molto
	24	4	I avoid going to places crowded with strangers.	1 = not at all; 2 = a little; 2 = moderately; 3 = a lot (rescored)
			Evito di recarmi in luoghi affollati da gente sconosciuta.	1 = per nulla; 2 = poco; 2 = abbastanza; 3 = molto (rescored)
	12	5	If I come in contact with something I think is "contaminated", I have to disinfect myself immediately.	1 = not at all; 2 = a little; 3 = moderately; 4 = a lot
			Se entro in contatto con qualcosa che io penso "contaminato" devo correre subito a disinfettarmi.	1 = per nulla; 2 = poco; 3 = abbastanza; 4 = molto
F2 confidence in care	25	6	I think safety devices are enough to protect me from the virus.	1 = not at all; 2 = a little; 3 = moderately; 4 = a lot
			Penso che i dispositivi di sicurezza siano sufficienti a proteggermi dal virus.	1 = per nulla; 2 = poco; 3 = abbastanza; 4 = molto
	11	7	I feel that I trust in the health system, in medicine, or in those who take care for me.	1 = not at all; 2 = a little; 3 = moderately; 4 = a lot
			Sento di aver fiducia nel Sistema Sanitario, nella medicina o in chi mi cura.	1 = per nulla; 2 = poco; 3 = abbastanza; 4 = molto
	13	8	I think the future still holds something good for me.	1 = not at all; 2 = a little; 2 = moderately; 3 = a lot (rescored)
			Penso che il futuro mi riservi ancora qualcosa di buono.	1 = per nulla; 2 = poco; 2 = abbastanza; 3 = molto (rescored)
	15 (REVERSE)	9	I struggle to put the doctor's advice into practice.	3 = not at all; 2 = a little; 2 = moderately; 1 = a lot (rescored)
			Fatico a mettere in pratica i consigli forniti dal medico.	3 = per nulla; 2 = poco; 2 = abbastanza; 1 = molto (rescored)
	3	10	I can take care of myself as I should do.	1 = not at all; 2 = a little; 2 = moderately; 3 = a lot (rescored)
			Sono in grado di curarmi come dovrei.	1 = per nulla; 2 = poco; 2 = abbastanza; 3 = molto (rescored)

Note: ID indicates the item's position in the PCPE questionnaire.

questionnaire, as they emerged from the previously reported analyses, the scores obtained on the AD-R questionnaire to assess anxiety and mood, and an independent clinical judgement concerning the patient's adherence to treatment (yes/no).

We observe a significant positive correlation between pandemic-related anxiety, as measured by Factor 1 of the PCPE questionnaire, the state anxiety and the mood, as measured by the AD-R form, supporting a good criterion validity. Factor 1 appears to be independent of confidence in care, as measured by Factor 2 of the PCPE questionnaire, which is instead negatively correlated with mood, confirming the fact that a person who manifests pandemic-related discomfort may be distrustful of the treatment they are receiving.

TABLE 7 For converting raw scores into logit interval scores.

PCPE factor	Total score	Logit total score
F1 (pandemic-related anxiety)	5	1.000
	6	2.057
	7	3.032
	8	3.670
	9	4.181
	10	4.631
	11	5.052
	12	5.461
	13	5.871
	14	6.295
	15	6.755
	16	7.280
	17	7.938
	18	8.929
	19	10.000
F2 (confidence in care)	5	1.000
	6	1.891
	7	2.640
	8	3.258
	9	3.832
	10	4.358
	11	4.881
	12	5.439
	13	6.068
	14	6.801
	15	7.665
	16	8.800
	17	10.000

Note: Example: If for F1 (pandemic-related anxiety) we get a total score of 15 (i.e., the sum of items 2, 16, 7, 24, 12 gives a value of 15 using the scores from the Table 6), its logit score will be 6.755. If for F2 (confidence in care) we get, for example, a total score of 10 (i.e., the sum of items 25, 11, 13, 15, 3 gives value 10 using the scores from the Table 6), its logit score will be 4.358.

4 | DISCUSSION

The present study sought to develop a short and easy-to-administer tool, with valid and reliable psychometric properties, to evaluate pandemic-related anxiety and confidence in care in patients with chronic medical conditions. It seems particularly relevant to explore these factors in this population since uncertainty is inherent to illness and health which always carry, to a certain degree, ambiguity and unpredictability (Bottesi et al., 2019; Carraro et al., 2021).

Consistent with our hypotheses, the analyses revealed that the PCPE questionnaire consists of two main factors: pandemic-related anxiety and confidence in care. From a conceptual perspective, both dimensions appear highly intertwined with the constructs of intolerance of uncertainty and uncertainty distress, since (1) anxiety represents a response to the perceived threat and uncertainty that typically are associated with a pandemic (Freeston et al., 2020), and (2) people with high uncertainty intolerance of may avoid or distrust medical settings as a way to reduce their anxiety. Indeed, intolerance to uncertainty in the context of a pandemic has been shown to be predictive of higher levels of anxiety in a study by Taha et al. (2014) in the context of the H1N1 virus pandemic. Thus, it is not surprising that several tools where developed to measure, in the first phase of the COVID-19 pandemic, this construct (e.g., Fear of COVID-19 Scale, Ahorsu et al., 2022; Coronavirus Anxiety Scale, Lee, 2020a, 2020b; COVID-19 Anxiety Syndrome Scale; Nikčević & Spada, 2020); however, these studies did not include patients with chronic conditions in their validation sample. As previously argued, the joint assessment of pandemic-related anxiety and confidence in care has significant implications in terms of treatment adherence. According to the Uncertainty in Illness Theory (Mishel, 1990), novel disease-related stimuli generate uncertainty when patients are unfamiliar with the events they are experiencing (e.g., symptoms, healthcare environment, treatment activities) or when their expectations do not align with their experiences. The assessment of these stimuli is mediated by the individual's cognitive abilities and by the characteristics of the environment, which influence how the patient interprets illness-related stimuli (Zhang, 2017). Thus, the evaluation and the appraisal of uncertainty contribute to the feeling of uncertainty itself (Zhang, 2017). Uncertainty in illness can be evaluated in different ways, depending on the positive or negative meaning attributed to it, and this results in different outcomes and coping strategies implemented to face it (Kuang & Wilson, 2017). When the situation of uncertainty is evaluated as a threat and produces intense anxiety, patients might implement active strategies to eliminate the source of uncertainty (e.g., seeking information), but also strategies to control emotions, such as emotional disengagement and avoidance of all illness-related aspects, to minimize uncertainty distress (Kuang & Wilson, 2017; Zhang, 2017). Available evidence shows that the greater the levels of illness-driven anxiety (in the case at hand, exacerbated by fear of contagion) the more avoidance of physicians and reminders of illness can extend to the point of jeopardizing health (Doherty-Torstrick et al., 2016), thus increasing morbidity and mortality risks in chronic patients (Zakaria et al., 2020).

This study has some limitations. First, the sample size and characteristics do not allow conclusions to be drawn as to whether the questionnaire can be used reliably in a national or international context. Indeed, patients who participated in this study were recruited exclusively from three clinics settled in Northern Italy. Furthermore, the gender distribution within the sample did not allow to test gender invariance of the PCPE questionnaire. Finally, the

TABLE 8 Pearson's *r* correlation coefficients between the scores obtained on the PCPE factors, as they emerged from the statistical analyses carried out and expressed in logit, and the scores obtained on the AD-R form (STAI X3 and QD-R) and the independent clinical judgement regarding adherence to treatment.

Dimension	PCPE-F1 Pandemic-related anxiety (logit)	PCPE-F2 Confidence in care (logit)
PCPE-F1 Pandemic-related anxiety (logit)	-	-
PCPE-F2 Confidence in care (logit)	−0.237 (*ns*)	-
STAI-X3	0.525***	−0.438***
QD-R	0.357*	−0.509***
Clinical judgement on patient's adherence to treatment (yes/no)	0.298*	−0.100 (*ns*)

Abbreviations: QD-R, Depression Questionnaire- Revised; STAI-X3, State Trait Anxiety Inventory- X3.
*$p < 0.05$; ***$p < 0.001$; *ns* = non-significant *p*-value.

cross-sectional nature of this study did not allow to collect data on psychological and/or medical outcome variables to test the predictive validity of this measure.

Despite these shortcomings, a key strength of this study was that it involved patients who were accessing the hospital facility during the pandemic period, with all the difficulties that are associated with collecting data in such circumstances. These were chronic, dialysed, oncological or cardiac patients, who often witnessed isolation or contagion of both other patients and hospital staff, and who were subject to security measures to gain access to the hospital and receive treatment. Another strength lays within the structural features of the PCPE questionnaire: ease and simplicity of items allows for administration to old or frail people. Moreover, the broadness of items, which address contagion and isolation, makes this questionnaire suitable for use in different pandemic situations, whenever viruses are spread through contact or by air. The PCPE questionnaire, with its concerted and rapid assessment of both pandemic-related anxiety and confidence in care, would help to identify potentially problematic aspects accurately and promptly in chronic patients. Such an evaluation can help devise support interventions focusing on the management of uncertainty distress, anxiety, and that promote a sense of trust in health personnel to establish adequate adherence to treatment.

AUTHOR CONTRIBUTION

Loretta Moroni: Conceptualization; formal analysis and investigation; writing - original draft preparation; writing - review and editing; supervision. **Gioia Bottesi**: Conceptualization; writing - original draft preparation; writing - review and editing; supervision. **Giorgio Bertolotti**: Conceptualization; writing - original draft preparation; writing - review and editing; supervision. **Azzurra Cangiano**: Formal analysis and investigation. **Claudia Rizza**: Conceptualization; formal analysis and investigation. **Anna Malerba**: Writing - review and editing. **Anna Picozzi**: Writing - review and editing; supervision. **Roberto Burro**: Conceptualization; methodology; formal analysis and investigation; writing - original draft preparation; writing - review and editing; Supervision. All authors read and approved the final manuscript.

ACKNOWLEDGEMENTS

This work has been supported by Ministry of Health - Ricerca Corrente - IRCCS MultiMedica. No funding was received for conducting this study.

CONFLICT OF INTEREST STATEMENT

The authors have no competing interests to declare that are relevant to the content of this article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available here: https://dx.doi.org/10.21227/qkgg-kt47.

ETHICS STATEMENT

The study was approved by the Research Ethics Committee of IRCCS MultiMedica (Sezione del Comitato Etico Centrale IRCCS Lombardia. MultiMedica). Protocol reference number: 450.2020. View pag. 4 in the manuscript.

CONSENT TO PARTICIPATE

All participants provided written informed consent.

ORCID

Gioia Bottesi https://orcid.org/0000-0002-8411-8887
Giorgio Bertolotti https://orcid.org/0000-0002-3079-1945
Anna Malerba https://orcid.org/0000-0001-6245-1104
Roberto Burro https://orcid.org/0000-0002-4491-2015

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How to cite this article: Moroni, L., Bottesi, G., Bertolotti, G., Cangiano, A., Rizza, C., Malerba, A., Picozzi, A., & Burro, R. (2023). Measuring pandemic-related anxiety and confidence in care in chronic patients using the Psychological Consequences of a Pandemic Event (PCPE) questionnaire. *Stress and Health*, 1–14. https://doi.org/10.1002/smi.3349