

Validity and reliability of Hospital Anxiety and Depression Scale in cancer patients in Peru

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Abstract

The Hospital Anxiety and Depression Scale (HADS) despite being widely studied in various populations, there is still no consensus on its factor structure. Our study aims to evaluate the psychometric properties of HADS in people with cancer. It involved 467 patients-diagnosed with cancer, who could read and write and were treated in a public institution specialized in cancer. It was found that HADS is best suited to a bifactorial structure where there is one general factor (emotional distress) and two specific factors (anxiety and depression). HADS proves to be invariant according to sex and years of education. It is moderately related to Beck's anxiety and depression inventory. Also, it presents acceptable levels of reliability and relationship with instruments used in the diagnosis of anxiety and depression. Its brevity, versatility, hospital-focused design, and extensive study make HADS a very important instrument in the detection of anxiety and depression in cancer patients.

Introduction

Around the world, 792 million people suffer from a mental disorder (Ritchie & Roser, 2018). WHO estimates that one in ten people suffer from them, and one in four have suffered from them at some point in their lives (WHO, 2019).Of the emotional disorders, anxiety and depression are considered to be the main causes of disability and mortality (PAHO, 2017). Both represent 4.92% and 7.84% of life years lost due to disability (YLD), respectively. Also, it is estimated that globally 3.6% have anxiety, and 4.4% have depression (PAHO, 2017). In particular, in cancer patients, the prevalence of these disorders is higher, in case of anxiety it ranges from 9.8% to 10.3%; and in depression, it ranges from 16.3% to 16.5% (Mitchell et al., 2011).

The use of validated scales has been a widely used and cost-effective public health policy to assess affective disorders (Ehlers et al., 2018; Siu & Force, 2016). The literature reports that various instruments have been used to assess these disorders in cancer patients: Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Hospital Anxiety and Depression Scale (HADS), among others (Howell et al., 2015). However, it is HADS, which several systematic reviews refer to as one of the most widely used instruments for detecting affective disorders in cancer patients (Maters et al., 2013; Vodermaier & Millman, 2011). In particular, this instrument is aimed at the hospital population and its dimensions allow an assessment to be made from a psychosocial perspective (one-dimensional model of emotional distress) or a clinical perspective (two-dimensional model of anxiety and depression) (Norton et al., 2013; Zigmond & Snaith, 1983).

Since its inception, HADS has undergone extensive testing to verify both its validity and reliability in English and other languages (Al Aseri et al., 2015; Christensen et al., 2020; Lin et al., 2017; Reda, 2011; Yang et al., 2019), obtaining satisfactory results in different hospital populations; for example, in patients with heart disease, cancer, HIV, psychiatric disorders, among others (Christensen et al., 2020). However, studies on the factor structure of the scale have given heterogeneous results (Norton et al., 2013). These studies used methods such as exploratory factor analysis (EFAs), confirmatory factor analysis (CFAs)

and item response theory (IRT). These identified structural models based on one dimension (Waqas et al., 2019), two dimensions (Zigmond & Snaith, 1983) three dimensions (Caci et al., 2003; Dunbar et al., 2000; Friedman et al., 2001). Therefore, the factorial structure of the HADS is not conclusive, which could affect the validity of the instrument

In addition to the analysis of the HADS structure, it is important to analyse the measurement invariance, a property that gives the possibility of making comparisons between groups. If the invariance is met, for example, according to sex, it can be said that both men and women evaluated have a similar understanding of the same construct (Putnick & Bornstein, 2016). For HADS there are several evidences on measurement invariance. As for sex, the literature reports invariance (Annunziata et al., 2011; Hunt-Shanks et al., 2010; Iani et al., 2014; Stott, Orrell, et al., 2017; Stott, Spector, et al., 2017; Yang et al., 2019). In terms of age groups, the evidence is conflicting (Iani et al., 2014; Stott, Orrell, et al., 2017; Stott, Orrell, et al., 2017). On the other hand, preliminary evidence supporting invariance has been found among HIV patients with and without infection (Yang et al., 2019), and among stages of disease in people with cancer (Annunziata et al., 2011).

Convergent validity is another important property to be analyzed, which is based on the relationship between the instruments that evaluate the same construct. Where these instruments are expected to relate to each other directly and strongly. In that sense, several studies have found a relationship between HADS and other variables in different settings (palliative care, brain tumour, and specific clinical groups). In terms of the total HADS score, a strong and positive correlation is reported with emotional distress (Emotional Distress Detection Scale-DEDS) (Limonero et al., 2012), post-traumatic stress and demoralization (Belar et al., 2019; Kyriaki Mystakidou et al., 2007), and with Psychosocial and Spiritual Needs of the Sick at the End of Life (ENP-E, in palliative patients) (Kyriaki Mystakidou et al., 2007). As for the anxiety subscale, a strong and positive correlation is reported with the State-Trait Anxiety Inventory (STAI), with the Prostate Cancer Memorial Anxiety Scale (MAX-PC), and with the DEDS subscale (Limonero et al., 2012; Mystakidou et al., 2009; Touzani et al., 2019). While with fear of recurrence (FoR) it obtained a moderate correlation (Hinz et al., 2015; Humphris et al., 2018; Shin et al., 2017); and with non-psychological variables, such as cancer-related fatigue, it showed a strong correlation (Fillion et al., 2003). On the depression subscale of the HADS, a strong and moderate positive correlation was reported with the Beck Depression Inventory and the Patient Health Questionnaire (PHQ-9), respectively (K. Mystakidou et al., 2007; Rooney et al., 2012); while, with non-psychological variables, such as cancer-related fatigue, it also showed a strong correlation (Fillion et al., 2003).

It is due to the need of valid and reliable instruments to detect affective disorders in hospital population and being the HADS one of the most used for this purpose, is that this study was conducted, which aims to assess the evidence of validity and reliability of HADS in cancer patients.

Materials And Methods Study design

This cross-sectional and psychometric study was carried out on cancer patients from a Peruvian public institution specialized in cancer, located in the city of Lima.

Setting

The evaluation was carried over a two-month period (July and August 2018) out by psychologists and psychology practitioners from the Mental Health Unit of the "Instituto Nacional de Enfermedades Neoplásicas" (INEN) trained in the administration of psychometric tests. The scales were administered individually to cancer patients confirmed, in mental health areas, hospitalization and, outpatient clinic from oncology departments: Breast and mixed tumors, Gynecology, Oncological Medicine, Abdominal, Head and Neck, Urology, Thorax, Neuro-Oncology, and Orthopedics.

Participants

The sample included 500 participants, who fulfilled the following inclusion criteria: be cancer patients of the National Institute of Neoplastic Diseases, is over 18 years old and have the ability to read and write. Furthermore, participants should not present physical discomfort during the administration, nor cognitive disabilities that limit understanding and the ability to complete the instruments of the current study. The sampling was intentionally non-probabilistic.

Procedures and Ethics

The protocol was approved by the INEN Research Ethics Committee and the Research Review Committee (N°239-2018-CIE/INEN). Participants were invited to participate in the research according to conventional ethical requirements. Subsequently, signed the written informed consent, and were provided with the questionnaire, which consisted of socio-demographic questions, the Peruvian adaptation of HADS, the BDI-II and, the BAI.

Instruments

The Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item questionnaire created by Zigmond and Snaith in 1983 (Al Aseri et al., 2015) to measure symptoms of anxiety and depression in patients with somatic illnesses. It has questions to detect cognitive symptoms of anxiety and depression. Furthermore, both subscales would provide an overall score for emotional distress. The scale is Likert-type, where 0 is the lowest score and 3; the highest; in order to measure the symptoms experienced during the last week.

The HADS translation (Muñiz et al., 2013) from English to Spanish was evaluated by two independent consultants who relied on the translation of the original test by Zigmond and Snaith (1983) into Spanish.And after was evaluated a reverse translation (Spanish - English).

Finally, the analysis regarding its clarity, relevance and belonging was carried out with ten expert judges (8 psychologists and 2 psychometrists).

The Beck Depression Inventory - Second Edition (BDI-II)

The BDI-II is a 21-item multiple-choice self-report inventory created by Beck and Steer in 1996 (Upton, 2013) to measure the severity of depressive symptoms in psychiatric patients and in normal adolescents and adults (13 to 80 year old individuals). The questions refer to the last week and the current moment and its administration can take approximately 15 minutes including cognitive and somatic symptoms. It has high internal consistency (α =0.91) (BrenIIa et al., 2013) and test-retest reliability (α =0.90). The evidence of convergent validity was robust, showed strong correlations with MMPI (r=0.58) and Depression Scale of SCL-90 (r=0.81). The factorial validity obtained two factors: somatic-affective and cognitive-affective respectively. The analysis of sex showed high significative differences while age was not observed (Beck et al., 1996; Quilty et al., 2010).

The Beck Anxiety Inventory (BAI)

The BAI is a 21 item self-applied scale created by Beck, Epstein, Brown and Steer in 1988, that measures the severity of anxiety symptoms in adults and adolescents (Beck et al., 1988) in psychiatric populations. The questions refer to the last week and the current moment; administration can take approximately 15 minutes. It shows a high internal consistency (α =0.92) and test-retest reliability over one week (*r*=75).

Statistical analysis

Five groups of analyses were carried out. First, characteristics of the participants were evaluated (sociodemographic characteristics) and item characteristics (standard deviation and mean). Second, a Confirmatory factor analysis (CFA) was used with the goal of evaluating ten models proposed about Hospital Anxiety and Depression Scale (Norton et al., 2013). Third, the measurement invariance was evaluated in order to know if the models are adequate according to groups (sex and education levels). Fourth, the relationship was evaluated with other variables: Beck Depression Inventory (BDI) and Beck Anxiety Inventory (BAI). Fifth, internal consistency was evaluated with alpha and omega coefficient.

Confirmatory factor analysis

CFA is a statistical procedure, which allows you to check the validity of the internal structure of an instrument (Batista-Foguet et al., 2004). In this study, the CFA was used to analyze ten models that have previously been shown to have adequate goodness-of-fit indices. Also, regarding ordinal data, the estimator weighted least squares with mean and variance adjusted (WLSMV) was chosen for CFA, and a polychoric matrix was used because they are designed for ordinal data (Dominguez-Lara, 2014; Li, 2016). The analysis was given in 3 stages. First, to evaluate the models adjustment index CFI, TLI, RMSEA, SRMR, and Confidence Interval (CI) with 90% was considered. Second, to evaluate overlapping factors the latent correlations between dimensions were to be considered. Third, to evaluate the relevance of a general factor in bifactor models (models 9 and 10) the following indices were used: Hierarchical Omega (ω H), Percentage of Uncontaminated Correlations (PUC) and Explained Common Variance (ECV).The data would be in favor of the general factor in case values of ω H \geq 0.70, PUC \geq 0.70 and ECV \geq 0.60 are found (Dominguez-Lara & Rodriguez, 2017).

Measurement invariance

A measurement invariance analysis was carried out, which allows demonstrating that the construct to be measured has the same meaning according to certain groups (Putnick & Bornstein, 2016). From the 10 initial models, the most parsimonious and best-fitting models (CFA) were taken. These models underwent measurement invariance analysis. The evaluation of levels of measurement invariance was carried out in 2 stages. In the first one, it was evaluated at the configuration and metric level, for the configuration level the factorial structures were evaluated to be equal, for the metric level the factorial loads were restricted to be equivalent. In the second stage, it was evaluated at the scalar level, where the intercepts were restricted to be equivalent. In both stages, the level of invariance was accepted if the variations in the CFI < 0.01. In addition, the values obtained through the DIF test were reported.

Relationship with other variables

This study reports the relationship between HADS and other instruments to measure depression and anxiety: BDI (Beck Depression Inventory) and BAI (Beck Anxiety Inventory). BDI has total, cognitive/affective, and somatic dimensions. BAI has a total, cognitive, and social dimension. The overall HADS factor is expected to be moderately related to the overall BAI and BDI factors and their dimensions. In addition, a moderate relationship is expected between the first HADS-specific factor (for depressive symptoms) with the general factor and BAI-specific factors. A moderate relationship is also expected between the second HADS-specific factor (for anxiety) with the general factor and BAI-specific factors. Finally, the values of the correlations are specified as very high (r > 0.9) high (r > 0.7), moderate (r > 0.5) and low (r > 0.3) correlations (Mukaka, 2012).

Internal consistency analysis

To identify the consistency measure of the construct, this study performed an internal consistency analysis. Alpha and omega coefficients were used to evaluate internal consistency. In addition, they were considered to be acceptable values when the coefficients had values greater than 0.70 (Campo-Arias & Oviedo, 2008).

Software used

To realize analysis R and STATA were used. For analysis with R the following packages were used: 'lavaan', 'semTools', 'psych', and 'survey'.

Results

Characteristics of the participants

Initially, 500 participants were evaluated, but those who had missing data in the HADS (n=25, 5%) or were foreigners were eliminated (n=8, 1.6%). The study included 467 participants. The majority of participants were female (75.6%), their ages were in the range of 17-84 years (mean=45.9; SD=14.4), they were married or cohabiting (48.4%) and they were unemployed (78.4%), mostly housewives. The characteristics of the participants are presented in table 1.

Confirmatory factor analysis

The factor analysis identified that one-dimensional model presented low goodness-of-fit indices and that bifactor model of depression with three orthogonal factors, did not converge, so both models were discarded. The other models had adequate goodness-of-fit indices.

When analyzing one of the two correlated factorial models and four of the five three-factor models, it was found that the latent relationship between their dimensions was extremely high (>0.80), so these dimensions may be overlapping (see table 2). Therefore, these models were eliminated from the following analyses. In the case of the remaining correlated factor model, its latent relationship presented a high value ($\Phi = 0.794$).

In analyzing the remaining bifactor model (with two orthogonal factors), the explained common variance of the general factor was high (>0.70) and the variances of the specific dimensions were adequate (>0.20). Factorial loads were higher in the general factor than in the specific factors (see Table 3). In addition, the bifactor model presents better goodness-of-fit indices compared to all previous models. According to the values of the indices to evaluate the bifactor models (ω_H = 0.80, ECV = 0.72, PUC = 0.54; see table 3), the existence of unidimensionality is suggested (Dominguez-Lara & Rodriguez, 2017; Rodriguez et al., 2016). That is why the bifactor model with one general dimension and two specific dimensions of anxiety and depression was selected as the most appropriate (see figure 1). Thus, the rest of the analysis will be carried out with this model.

Measurement invariance

The invariance analysis identified that the bifactor model with one general factor and two specific factors of anxiety and depression, presented invariance according to sex and years of education. It was identified that Δ CFI was less than 0.01 in both cases (see table 4).

Although it was found that in the case of sex the ANOVA test pointed to a significant value (p = 0.01) when comparing metric invariance and strong invariance. It was not considered relevant since the p-value is very sensitive to sample size.

Relationship with other variables

It was found that the general factor and the specific factors of HADS, presented a moderate correlation with another scale of depression (BDI) that has a dimension of cognitive symptoms and another of somatic symptoms (r > 0.5).

However, by correlating the HADS factors with the factors of an anxiety scale (BAI) that has four factors. Only in the subjective symptom factor was a moderate correlation achieved with the general and specific anxiety factor of HADS (r >0.5, see figure 2). The rest of the factors of the BAI were weakly correlated with the HADS, with values between 0.47 and 0.18.

Internal consistency analysis

The general factor of HADS (ω =0.91; α =0.90) as its specific factors of anxiety (ω = 0.84; α =0.84) and depression (ω = 0.84; α =0.84) presented consistency coefficients.

Discussion Main funding

The HADS presents adequate psychometric properties with evidence of validity and reliability in the oncological population in Peru. Our results support that HADS presents a global factor of emotional discomfort and two specific factors (anxiety and depression). Therefore, HADS can have a global score and a score for each specific factor. Also, HADS can be used to make comparisons between men and women, and between people with different years of education. This suggests that the instrument is stable (invariant) among these groups.

Factor analysis

Our study identified that the bifactor model is the most appropriate factorial structure of ADH in cancer patients in Peru. This is in line with what was found in a systematic review performing a meta-confirmation analysis of HADS, where it found that the bifactor model is the most suitable (Norton et al., 2013). Other studies have identified an alternative one, two, or three-dimensional models (Annunziata et al., 2011; Emons et al., 2010; Gale et al., 2010; Ó. Galindo Vázquez et al., 2015; Matsudaira et al., 2009; Norton et al., 2013; Terol-Cantero et al., 2015). Our study and the meta-confirmation study mentioned above tested these alternative models and agree that the bifactor model is the most adequate.

This could be due to the fact that some HADS studies have used methods of analysis that are not suitable or have proved inefficient for psychometric studies (e.g. main components, scree plots, eigenvalues, varimax) (Christensen et al., 2020; Cosco et al., 2012; Gale et al., 2010; Nezlek et al., 2019). So, this could have introduced bias in their measurements, which could have led them to identify heterogeneity of models. On the other hand, it is worth mentioning that not all studies evaluated the ten factorial models assessed in our study, so it is possible that other models would have been more appropriate.

The bifactor model consists of a general factor and specific orthogonal factors (where the correlation between factors is zero). In the bifactor model, it is the general factor that strongly explains the variance of the HADS items and the specific factors explain the variance of a group of items each (depression explains even items; anxiety explains odd items), although these specific factors explain the items less than the general factor. In the HADS, the specific factors identified would be anxiety and depression. As for the general factor, this would be called emotional distress, which is defined as a state of negative affect suggesting the presence of affective disorders (Vodermaier et al., 2009). We chose to keep this term of emotional distress because it is widely used in the literature when referring to the assessment of both anxiety and depression (Lee et al., 2018; Milligan et al., 2018; Yan et al., 2019).

The existence of a general factor that can explain all the items is in line with the proposal of the transdiagnostic models. These models focus on the underlying common symptoms or processes between diagnostic categories (Mansell et al., 2009; Norton & Paulus, 2017). In this study, emotional distress will be the transdiagnostic factor between anxiety and depression present in HADS. The evidence is not yet conclusive about the single term or transdiagnostic factors present between anxiety and depression. Therefore, we can find in the literature constructs such as dysregulation of negative affect, repetitive negative thinking, and rumination, which point to be transdiagnostic factors for emotional disorders (Akbari et al., 2015; Hofmann et al., 2012; Hsu et al., 2015). On the other hand, the bifactor structure of HADS seems to solve the problem of overlapping symptoms between anxiety and depression and the high correlation between factors (anxiety and depression) (Aarstad et al., 2005; Kirkova et al., 2011; Schellekens et al., 2020), stating that both constructs are present in an orthogonal way and it is a general factor that explains most of the variance of the items.

When the HADS was built, the physical symptoms of anxiety and depression were omitted, so that they would not be confused with the natural physical symptoms of patients' illnesses in hospitals (Zigmond & Snaith, 1983). That's why the HADS was originally intended to assess the emotional and cognitive aspects of anxiety and depression. Transdiagnostic models do not contradict the presence of specific factors such as anxiety and depression, since they do not pretend to oppose specific diagnoses. Instead, they suggest using specific models or transdiagnostic depending on whether it is clinically significant or whether the presence of specific diagnoses is necessary, which may well complement the information provided by the transdiagnostic factors (Mansell et al., 2009). Finally, although specific anxiety and depression sa sufficient to make a diagnosis of anxiety and depression. This would require further evaluation.

In terms of usefulness, 3 strengths were identified in the HADS bifactor structure. First, the HADS would be a versatile instrument, which would work very well as a filter to identify emotional distress (transdiagnostic factor) and would allow specifying the specific symptomatology (i.e. presence of depression or anxiety symptoms). This would be very useful in terms of further evaluation, giving more information about whether the patient has any emotional disorder and whether it is more specifically anxiety and/or depression. Second, it is important to note the brevity of the HADS, with the 14 items it has proven to be of great value in detecting emotional distress and symptoms of anxiety and depression. Thirdly, HADS is a tool that stands out for its configuration, in which physical symptoms are not taken into account. This is noteworthy because it decreases the likelihood of false positives due to the physical symptoms of anxiety and depression.

Measurement invariance

A crucial aspect in clinical assessment is to determine whether the instrument is invariant between different groups, i.e., whether the two or more groups can understand the construct equivalently assessed by the scale and thus make comparisons between those groups (Putnick & Bornstein, 2016). Since if an instrument is not invariant among different groups, different sensitivity and specificity analyses will be required, which would limit its clinical use, to name one example.

Our study found that there are no differences in the factor structure of HADS in the Peruvian oncological population according to sex, as previously evidenced in other studies conducted in a sample of the Italian community and HIV patients in China (Iani et al., 2014; Yang et al., 2019). This suggests that HADS is useful for detecting symptoms of emotional distress, anxiety, and depression among men and women, although the clinical manifestations of depression and anxiety may be different according to sex (Zarragoitía Alonso, 2013). It is important to note that other HADS studies proposing alternative two-or three-dimensional factor structures have also found evidence of invariance between men and women (Annunziata et al., 2011; Czerwiński et al., 2020; Fong & Ho, 2014; Hunt-Shanks et al., 2010; Stott, Orrell, et al., 2017; Stott, Spector, et al., 2017). Unlike other instruments used to measure depression and

anxiety such as PHQ-9 and DASS (Villarreal-Zegarra et al., 2019). This is an encouraging finding since the instrument seems to allow an assessment of anxiety, depression, and emotional distress without distinction of sex in different populations, even despite using other less adequate factorial models.

On the other hand, it was shown that HADS can measure the symptoms of emotional distress, anxiety, and depression in the Peruvian cancer population with different years of study (less than 6 years, between 7 to 11 years and 12 or more years), one point relevant and that had not been previously evidenced. Although it had previously been pointed out that the uneven distribution of the elements of inverse writing could influence vulnerable populations such as people with low levels of education due to the difficulty that it would generate in reading activity (Lin et al., 2017). However, these results support that the instrument has an equal factorial structure, the items contribute similarly and that the intersections are equivalent in the groups. Despite the heterogeneous characteristics of the evidence in the sample of an institute specialized in cancer that houses populations from different geographical areas of Peru and different levels of education. This makes it possible to affirm that the variables are evaluated in the same way in all groups, which is a valuable feature for public health decisions.

Relationship with other variables

Regarding the relationship of HADS with other variables, this study found moderate correlations with the general factor of emotional distress and the specific factors with the dimensions of the BDI, which indicates a strength regarding the feasibility of HADS. To detect symptoms of depression, as previously evidenced in previous studies in cancer populations (O. Galindo Vázquez et al., 2015), other clinical populations such as patients with lung diseases (Phan et al., 2016), fibromyalgia (Cabrera et al., 2015), congenital heart disease (Westhoff-Bleck et al., 2019) and non-clinical population (Ó. Galindo Vázquez et al., 2015). Furthermore, in the case of BAI, only a moderate relationship was found between the general and anxiety factor of HADS and the subjective symptoms factor of BAI, which is understandable given that HADS does not consider physical symptoms for the evaluation of these constructs, similar to previous studies (Aarstad et al., 2005).

Internal consistency analysis

In the bifactorial model of the HADS were found acceptable levels of reliability (ω > 0.70 and α > 0.70) for both the general factor and the specific factors, which coincide with the results of other studies (Cabrera et al., 2015; O. Galindo Vázquez et al., 2015; Li et al., 2016; Martínez López et al., 2012; Terol-Cantero et al., 2015). Having an acceptable level of reliability is something that strengthens and makes the use of HADS more relevant, since it is shown that this instrument has a good degree of stability in its measurements.

Public health Implications

This study provides different evidence of validity and reliability of HADS in the Peruvian oncological population, which supports its use within the context of oncological patient care. HADS can be used as a tool to evaluate the clinical progress of people receiving psychological care in an oncological context. Also, it can be used as a research tool in clinical trials or longitudinal studies in cancer patients, since it is an instrument with solid evidence of validity and reliability.

The Peruvian health system is overburdened and mental health professionals are insufficient and have very little time to treat patients (Toyama et al., 2017). Thus, HADS, because of its brevity (only 14 items) and empirical support, could be a good option for assessing depressive and anxiety symptoms within the hospital setting. Mainly in rural areas of Peru, where the percentage of mental health care is much lower (Villarreal-Zegarra et al., 2020) This would be attractive in public health, which will already facilitate and speed up the identification and referral processes of patients with any of these symptoms; therefore, policy-makers can be used as an input to clinical practice guidelines (Howell et al., 2015).

Strengths and limitations

One of the strengths of our study is the certainty that the participants had cancer since they all had previous medical exams to confirm the disease. However, our study has four major limitations. First, it does not provide a cohort point for identifying whether or not participants have symptoms of depression, anxiety, or emotional distress. Therefore, future studies on sensitivity and specificity are needed. Second, our data were selected in a non-probabilistic way, so our results cannot be generalized to the entire cancer population in Peru. Third, because we had a small sample size, we could not perform analyses of variance among other interest groups such as age, income, living in rural and urban areas, or stages of cancer. Fourth, the relationship of HADS with other clinically relevant variables such as quality of life, well-being, or other instruments of emotional distress could not be assessed (Mansell et al., 2009; Milligan et al., 2018; Norton & Paulus, 2017).

Conclusions

Our results support the use of HADS in the oncological population in Peru since it is an instrument with evidence of validity and reliability. Our data support a bifactor model of HADS, with one general factor of emotional distress and two specific factors (anxiety and depression). Besides, it is invariant, presents convergent validity, and adequate internal consistency coefficients.

Declarations

Ethics approval and consent to participate

Ethical approval was granted by the Ethical Review Committee of the National Institute of Neoplastic Diseases (INEN), who ensured the participants' voluntary and confidential participation, understanding of informed consent, and protocols for the care of the data obtained.

Patient consent statement

All participants included in the study have given written informed consent. Participants were aware that their participation was voluntary, confidential and understood the informed consent.

Consent for publication

Not applicable

Availability of data and materials

The data used in the analysis is attached as https://doi.org/10.6084/m9.figshare.13626773.

Competing interests

The authors report no conflict of interest when conducting the study, analyzing the data, or writing the manuscript.

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Authors' contributions

ALVE: Conceptualization, Data Curation, Investigation, Methodology, Project Administration, Validation, Writing – Original Draft Preparation, Approval of the final version.

JAM: Methodology, Validation, Writing – Original Draft Preparation, Approval of the final version.

DVZ: Formal Analysis, Methodology, Supervision, Validation, Writing – Review & Editing, Approval of the final version.

LEV: Conceptualization, Writing - Review & Editing, Approval of the final version.

JCSR: Conceptualization, Writing – Review & Editing, Approval of the final version.

FLD: Conceptualization, Writing – Review & Editing, Approval of the final version.

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Tables

Table 1. Characteristics of the participants.

		n	%
Sex	Men	114	24.4%
	Women	353	75.6%
Age	17 to 19	13	2.8%
	20 to 29	59	12.6%
	30 to 39	84	18.0%
	40 to 49	109	23.3%
	50 to 59	113	24.2%
	60 to more	89	19.1%
Type of care	Outpatient clinic	185	39.6%
	Outpatient	154	33.0%
	Hospitalization	128	27.4%
Civil status	Married or Cohabiting	226	48.4%
	Divorced or Separated	52	11.1%
	Single	167	35.8%
	Widower	22	4.7%
Educational years	At least 6 years old	79	17.0%
	7 to 11 years	215	46.0%
	12 to more	173	37.0%
Laboral status	Unemployed	366	78.4%
	Employee	33	7.1%
	Independent	68	14.6%
Previous psychological assistance No			61.5%
	Yes	180	38.5%

Table 2. Goodness-of-fit indices and latent correlations of each of the models evaluated for HADS.

	\mathbf{X}^2	df	CFI	TLI	RMS	SEA [CI	90%]	SRMR	ΦAnx-Dep	ο ΦRAN-An	x ΦRAN-Dep
1. Razavi	306.3	3770	0.933	0.921	0.080	[0.071	-0.089] 0.064	-	-	-
2. Zigmond & Snaith	204.2	276	0.963	0.955	0.060	[0.050	-0.070] 0.052	0.807	-	-
3. Moorey	191.8	376	0.966	0.960	0.057	[0.047	-0.067] 0.051	0.794	-	-
4. Friedman	177.2	173	0.970	0.962	0.055	[0.045	-0.066] 0.049	0.748 ^a	0.997 ^a	0.812 ^a
5. Caci	212.6	674	0.960	0.950	0.063	[0.054	-0.073] 0.054	0.776 ^r	0.920 ^r	0.965 ^r
6. Brandberg	225.6	674	0.956	0.946	0.066	[0.057	-0.076] 0.056	0.762 ^r	0.940 ^r	0.926 ^r
7. Dunbar	189.0)74(0.966	0.959	0.058	[0.048	-0.068] 0.050	0.714^{n}	0.916 ⁿ	0.841 ⁿ
8. Dunbar, higher-order	190.3	875	0.966	0.956	0.057	[0.047	-0.068] 0.050	-	0.888 ⁿ	0.820 ⁿ
9. Bifactor, 2 group-factors	141.0) 63	0.977	0.967	0.052	[0.040	-0.063] 0.042	-	_	-
10. Bifactor, 3 group factor	S				Not	conver	ging	-	-	-	-

Anx = Anxiety. Dep = Depression. RAN = Restlessness / Agitation / Negative Affection. r = Restlessness. a = Agitation. $n = Negative Affection. \Phi = latent correlation between dimensions. X² = Chi squared. df = Degrees of freedom. CFI = Comparative fit index. TLI = Tucker-Lewis index. RMSEA = Root mean square error of approximation. SRMR = Standardized root mean square residual.$

Table 3. Factorial loads and indices of the bifactor model (with two orthogonal factors) of HADS.

	General Fac	ctor Anxiety	Depression	n R ²
HADS1	0.628	0.340		0.510
HADS3	0.575	0.503		0.584
HADS5	0.597	0.365		0.490
HADS7	0.651	0.108		0.435
HADS9	0.425	0.252		0.244
HADS11	0.468	0.319		0.321
HADS13	0.531	0.547		0.581
HADS2	0.432		0.878	0.958
HADS4	0.749		0.191	0.597
HADS6	0.738		0.046	0.547
HADS8	0.424		0.165	0.207
HADS10	0.501		0.050	0.254
HADS12	0.714		0.103	0.520
HADS14	0.552		0.182	0.338
Explained common variance (ECV)) 0.717	0.309	0.258	-
PUC	0.538	-	-	-
Hierarchical Omega	0.800	0.239	0.113	
Average factorial load $(\lambda_{average})$	0.570	0.348	0.231	-

Table 4. Analysis of factor invariance of the HADS bifactor model (with two orthogonal factors) according to sex and educational years.

	Invariance	Robust X ² goodr					DIF	FTE	ST	
		Value	df	CFI 1	RMSEA	SRMR	$\Delta \mathrm{CFI}$	Value	df	р
Sex	Basal	217.9	126	0.974	0.056	0.051	-	-	-	-
	Metric invariance	238.0	140	0.972	0.055	0.051	-0.002	18.951	14().167
	Strong invariance	289.8	165	0.964	0.057	0.058	-0.008	42.908	25(0.014
	Unique Factor Invariance	310.2	179	0.963	0.056	0.058	-0.002	22.39	14().071
Educational ye	ars Basal	299.6	189	0.970	0.062	0.060	-	-	-	-
	Metric invariance	341.8	217	0.966	0.061	0.060	-0.004	39.059	28(0.080
	Strong invariance	403.2	267	0.963	0.057	0.071	-0.003	65.961	500).065
	Unique Factor Invariance	448.5	295	0.958	0.058	0.072	-0.005	40.626	28().085

df = Degrees of freedom. CFI = Comparative-Fit-Index. RMSEA = Root Mean Square Error of Approximation. SRMR = Standardized root mean square residual. ΔCFI = Variation of the Comparative-Fit-Index. DIFFTEST = ANOVA difference test.