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Screening for psychological distress using the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS): Initial validation of structural validity in dialysis patients

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ABSTRACT

Objective: To validate the factor structure of the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS)- which is a composite measure of depression and anxiety using the Patient Health Questionnaire-9 and Generalised Anxiety Disorder Scale (GAD-7), in a sample of haemodialysis patients.

Method: Screening data (n=182) used to select entry into a feasibility study of an online cognitive-behavioural therapy intervention for distress in dialysis patients were analysed here. Structural validity of the PHQ-ADS was evaluated using confirmatory factor analysis (CFA), assessing alternative models including a bi-factor model. In the bi-factor model all items from the PHQ-9 and GAD-7 (16-items in total) were loaded onto a general distress factor. Respective items of the PHQ-9 and GAD-7 were specified as subgroup factors. Omega-hierarchical was calculated to indicate the level of saturation of a multidimensional scale by a general factor. Construct validity was determined against the Brief Illness Perception Questionnaire.

Results: A bi-factor PHQ-ADS model had good fit to the data (chi-square=96.1, $p=0.26$, CFI=0.99; TLI=0.99; RMSEA=0.02). The general distress factor accounted for approximately 84% of the explained variance (omega-h= 0.90). Distress scores were significantly higher in females compare with males. There was a significant association between distress and negative illness perceptions ($r=0.58$, $p<0.01$).

Conclusions: The PHQ-ADS appears to have good structural validity in haemodialysis patients and is sufficiently unidimensional to warrant the use of a total distress score. A full psychometric analysis of the PHQ-ADS in a larger sample of dialysis patients is warranted.

INTRODUCTION

Psychological distress, including symptoms of depression and anxiety, is highly prevalent among individuals with End-Stage Kidney Failure (ESKF) treated with dialysis (1-3). Depression in particular has been well documented as a common extra renal comorbidity in approximately 30-40% of ESKF patients (2), and is associated with poor outcomes most notably increased mortality risk (4-7).

Within ESKF, depression symptoms have been evaluated using a variety of measures including the Beck Depression Inventory (BDI-II)(8, 9) and the Patient Health Questionnaire-9 (PHQ-9)(10, 11). These tools appear to hold good validity as severity measures of depression among individuals with kidney disease (12, 13). Although less studied in the context of ESKF, anxiety is thought to be common in dialysis patients (14) and has typically been evaluated using the Hospital Anxiety Depression Scale (HADS) (15-19).

Although many of these measures have been well validated in general and patient populations, it has been recently argued that a distress composite measure or score for depression and anxiety symptoms could be beneficial (20). The main premise for this argument is that depression and anxiety symptoms often coexist and interventional approaches (particularly psychologically based therapies) are effective at reducing both concurrently (20). Furthermore, given the high coexistence between depression and anxiety severity measures often produce moderate-high correlations between these constructs which implicates issues of multicollinearity in multivariate analysis (20). For example, the correlation between the depression and anxiety subscales of the HADS is often high, questioning the unique separation these symptoms. A meta-confirmatory factor analysis of the HADS has revealed the presence of a strong underlying general factor concluding that a total score is more appropriately applied to indicate general distress (21).

Kroenke et al (20) recently examined the validity of the Patient Health Questionnaire Anxiety and Depression Scale (PHQ-ADS), which is a composite score of depression and anxiety using the PHQ-9 (10, 11) and Generalised Anxiety Disorder Scale (GAD-7) (22). Data was utilised from three trials; two of which in patients with chronic musculoskeletal pain and the other in oncology patients. They found that a bi-factor measurement model was sufficiently unidimensional to warrant the use of a single composite score indicating distress. Moreover, the measure demonstrated adequate convergent and construct validity, in addition to preliminary evidence regarding sensitivity to change. Cut-off scores of 10, 20 and 30 are reported to correspond to mild, moderate and severe levels of distress (depression/anxiety).

The aim of the present study was to provide an initial evaluation of the PHQ-ADS structural validity in haemodialysis patients and to examine potential associations with clinical factors and illness perceptions. Screening data used to select entry into a feasibility study of an online cognitive-behavioural therapy intervention for distress in dialysis patients was utilised here (23, 24). We hypothesised that our findings would support those of Kroenke et al (20), revealing evidence for a bi-factor measurement model underlying the PHQ-ADS with sufficient unidimensionality to warrant use of a total distress score.

METHODS

Patients and study design:

Established haemodialysis patients (HD) from the renal service of Guy's & St Thomas' NHS foundation trust were screened for depression and anxiety symptoms using the PHQ-9 and GAD-7 respectively (n=182). As part of routine care, screening was delivered on-dialysis using IMPARTS (Integrating Mental and Physical healthcare: Research Training and Services) web-based screening interface (25). IMPARTS has research ethics approval from the National Research Ethics Service Research Database Committee, which permits the use of de-identified

data collected through IMPARTS for research purposes (ethics application reference number: 12/SC/0422). Patients were eligible to be screened providing they were ≥ 18 years old, received in-centre HD and could speak English. The screening process asked potential patients for permission to contact them about participation in the feasibility study. Patients who: had mild-moderately severe psychological distress symptoms, [scores of 5-19 on the Patient Health Questionnaire (PHQ-9) and/or a score ranging from 5-14 on the Generalised Anxiety Disorder questionnaire (GAD-7)] and who gave permission for research contact were then approached to seek consent for the participation in the trial (23). The study received NHS ethics approval.

Screening Measures:

PHQ-9 and GAD-7: Depression symptoms were assessed using the PHQ-9 (10, 11). The PHQ-9 assesses nine symptoms, with each item rated on whether the symptom has bothered the respondent “not at all”, “several days”, “more than half of the days” or “nearly every day” in the last two weeks. A sum score ranging between 0-27 indicates severity, with higher scores representing more severe depression. PHQ-9 scores of 5, 10, 15, and 20 represent mild, moderate, moderately severe and severe depression, respectively. The GAD-7 (22) has seven items with response options identical to the PHQ-9. A sum score ranging between 0-21 indicates severity, with higher scores representing more severe anxiety. Cut points of 5, 10, and 15 can be interpreted as representing mild, moderate, and severe levels of anxiety.

PHQ-ADS: Is a composite measure of depression and anxiety, taken from summing the PHQ-9 and GAD-7 items (20). Bi-factor CFA from three trial data sets provided evidence for a bi-factor structure underlying the PHQ-ADS, with sufficient unidimensionality to warrant a total score for distress. Score can range from 0 – 48, with higher scores indicating more distress)

The PHQ-ADS demonstrated good convergent and construct validity. Cut-points of 10, 20 and 30 can be used to indicate mild, moderate and severe levels of distress.

Illness Perceptions: The Brief Illness Perception Questionnaire (B-IPQ) (26) was used to assess illness perceptions. Seven items measured beliefs about ESKF on different dimensions scored on a Likert scale from 0 (not at all) to 10 (extremely) including, *Consequences*, *Timeline*, *Personal Control*, *Treatment Control*, *Illness Coherence*, *Concern* and *Emotion*. As used in previous studies (27, 28), a sum score was calculated for the B-IPQ. In the present study, higher scores indicate more unhelpful negative perceptions of ESKF.

Demographic and clinical data

As part of the IMPARTS screen the following data were collected automatically via electronic records; Age, gender, serum haemoglobin (g/L), serum albumin (g/L), and C-reactive protein (CRP, mg/L). CRP was categorised as above or below 5 mg/L to indicate the presence of inflammation (CRP > 5mg/L). Comorbidities (presence of cancer, liver disease, lung disease, cardiovascular disease, ischemic heart disease, diabetes, peripheral vascular disease smoking status and history of depression) were recorded from medical notes (identified conditions listed), but only in patients who provided consent for their notes to be manually accessed *independently* from the routine IMPARTS screen (n=116/182; 63.7%). Depression (PHQ-9), anxiety (GAD-7) and distress scores (PHQ-ADS) did not differ significantly between those with available comorbidity data and those without. A summary of patient demographic and clinical characteristics are shown in table 1.

STATISTICAL METHODS

Confirmatory factor analysis (CFA) was used to evaluate the factor structures of the PHQ-9, GAD-7 and PHQ-ADS, using Weighted Least-Squares with Mean and Variance adjustment (WLSMV) estimation. For the GAD-7, a unidimensional (1-factor) model was evaluated. Bi-factor models were tested for the PHQ-9 and PHQ-ADS.

In the bi-factor PHQ-9 model, all 9 items were loaded onto a general depression factor. Items were also loaded onto two smaller group factors – somatic (3-items) and affective/cognitive (6-items). Correlations between all latent factors were fixed to zero and variances of the latent factors fixed (@1). For the PHQ-ADS bi-factor model, all items from the PHQ-9 and GAD-7 (16-items in total) were loaded onto a general distress factor. Group factors for the PHQ-9 (depression) and GAD-7 (anxiety) were also specified within this model and with fixed variances and correlations between factors. In addition, one and two factor PHQ-ADS models were tested. MPlus version 7.3 was used for the analysis.

Assessment of goodness-of-fit was based on standard structural equation modelling criteria including, confirmatory fit index (CFI) $>.95$, root mean squared error of approximation (RMSEA) $<.08$, and the Tucker-Lewis index (TLI) $>.95$ (29). Reliability of the total and subscale scores was assessed using the omega index, along with an indicator of the saturation of a multidimensional scale by a general factor, omega-hierarchical, for the bi-factor models (30, 31). Construct validity between the distress and illness perceptions was examined using correlation. In addition, illness perception scores across PHQ-ADS ordinal categories (cut-off scores) were assessed using ANOVA. Correlations between demographic and clinical factors with distress were also explored.

RESULTS

Factor structures of the GAD-7 and PHQ-9

A one factor GAD-7 model had good model fit (chi-square=17.0, df=13, $p=0.20$; CFI=0.99; TLI=0.99; RMSEA=0.04) and high internal reliability ($\alpha=0.85$). The bi-factor PHQ-9 model also demonstrated good model fit (chi-square=8.0, df=18, $p=0.97$; CFI=1.0; TLI=1.0; RMSEA<0.01). The general factor accounted for approximately 73.3% of the explained variance. Omega-hierarchical (Omega-h) was 0.75 suggesting that the PHQ-9 is sufficiently unidimensional to warrant the use of a total score. The correlation between the general PHQ-9 factor and the GAD-7 latent factor was high ($r=0.671$, S.E =0.10, $p<0.01$).

Factor structure of the PHQ-ADS

A summary of the alternative CFA models for the PHQ-ADS is presented in table 2. Both one and two factor models had good fit to the data as evidenced by their respective model fit indices, however in both models the chi-square statistics were significant. In the two factor model, the correlation between the depression and anxiety factors was high ($r=0.94$, s.e= 0.024, $p<0.01$). The bi-factor model had the best fit to the data due to desirable fit indices and a non-significant chi-square (table 2). The general distress factor accounted for approximately 84% of the explained common variance between items. Omega-h was 0.90 suggesting that the PHQ-ADS is sufficiently unidimensional to warrant the use of a total distress score.

Correlates of distress (PHQ-ADS total score)

Distress scores were unrelated to haemoglobin, serum albumin, potassium, CRP and the number of co-morbidities. Distress scores for females were on average 3.3 (s.e= 1.25) points higher than males ($p=0.008$). There was a small negative correlation between age and distress

($r=-0.15$, $p=0.04$). There was a significant association between distress and negative illness perceptions ($r=0.58$, $p<0.01$), an effect size suggesting suitable construct validity.

Severity of distress according to PHQ-ADS cut-offs

109 (59.9%, [95% CI 52.7, 67.0]) patients scored between 0-9 and therefore did not meet thresholds for the presence of distress. The prevalence of mild, moderate and severe levels of distress according to the PHQ-ADS cut-offs was, 25.3% (95% CI 19.2, 31.3), 12.1% (95% CI 7.7, 17.0) and 2.7% (95% CI 0.5, 5.5) respectively. Illness perception scores across the PHQ-ADS ordinal categories are shown in table 3, demonstrating a “dose-response” association between distress severity and negative (unhelpful) illness perceptions. As expected PHQ-9 and GAD-7 scores had a significant incremental increase across PHQ-ADS ordinal categories.

When using the PHQ-9 ordinal categories, 78 (42.9%, [95% CI 35.7, 50.0]) of patients scored between 0-4, indicating minimal depressive symptoms. The presence of mild, moderate, moderately severe and severe depression symptoms, as indicated by the PHQ-9 was 35.7% (95% CI 28.6, 42.9), 14.3% (95% CI 9.3, 19.8), 4.9% (95% CI 2.2, 8.8) and 2.2 % (95% CI 0.5, 4.4) respectively. Employing the GAD-7 cut-offs revealed that 126 (69.2%, [95% CI 62.6, 75.8]) had minimal anxiety symptoms (scores between 0-4). The presence of mild, moderate, and severe anxiety symptoms was 20.3% (95% CI 14.8, 26.4), 7.7% (95% CI 3.8, 11.5) and 2.7% (95% CI 0.5, 5.5) respectively. As expected there was a strong association between the proportion of patients in the respective PHQ-ADS severity categories with both GAD-7 and PHQ-9 severity^a categories ($p<0.01$)

^a PHQ-9 moderate and moderately severe categories were collapsed so each measure had four ordinal categories (none/minimal, mild, moderate and severe).

DISCUSSION

The aim of this study was to provide the first examination of the structural validity of the PHQ-ADS among ESKF patients treated with haemodialysis. We found that a bi-factor measurement model for the PHQ-ADS had very good fit to the data and was sufficiently unidimensional to warrant the use of single composite score indicating distress. Our findings therefore support those of Kroenke et al (20) and provides supportive evidence for this composite distress measure in dialysis patients.

Since this study utilised screening data via IMPARTS in order to identify potential patients for an interventional feasibility study, we were unable to provide a full psychometric evaluation including retest reliability and convergent validity. However, we were able to demonstrate construct validity against illness perceptions, which have consistently been shown to be related to depression and mental health amongst individuals with kidney disease (32-35). Distress scores also correlated with age and were higher in females, results which support past findings in relation to depression symptoms among dialysis patients [for reviews see (3, 36)]. Distress was also unrelated to comorbidity which is in line with other research showing that illness perception, rather than disease severity, is associated with distress in long-term conditions (37).

Employing the PHQ-ADS ordinal severity categories revealed that the proportion of patients meeting criteria for mild and moderate levels of distress was 25.3% and 12.1% respectively. These data support a large literature highlighting that symptoms of distress are common among individuals with kidney disease (1). In addition, mixed symptoms of depression and anxiety commonly co-occur in patients with long-term conditions; yet many patients do not meet criteria for a formal diagnosis of either condition, and as such do not receive psychological input (38). In this regard, the PHQ-ADS might have an important clinical

utility in order to better detect patients with elevated symptoms of distress who might benefit from appropriate psychological interventions.

Severe levels of distress, as indicated by a score of 30-48, were low in the present study (2.7%). This might be the result of sample bias, since it possible that those with higher levels of distress were more likely to refuse screening. However, PHQ-9 and GAD-7 scores had a significant incremental increase across PHQ-ADS ordinal categories. Taken together the utility and reliability of the PHQ-ADS cut-offs as applied to dialysis patients needs further investigation.

As argued by Kroenke et al (20), the PHQ-ADS does not undermine the utility or value of using either the PHQ-9 or GAD-7. Both a one-factor GAD-7 model and a bi-factor PHQ-9 model had good fit and reliability in the current analysis. Rather the PHQ-ADS appears a reliable alternative if a composite distress measurement is desired or deemed more appropriate for clinical or research purposes.

Our study has several limitations which are worthy to note when interpreting the results. Our sample size was relatively small and a full psychometric evaluation was not possible. Only a small number of eligible patients consented to participate in the associated feasibility intervention study (23). Consequently, it was not possible to examine the PHQ-ADS with regards to sensitivity to change in this context. Due to the nature of the screening procedure, we did not have access to dialysis related information including adequacy and length of time receiving treatment. Furthermore, comorbidity data was only available in a subset of the sample, although distress scores did not differ between those with and without comorbidity information.

In conclusion, our findings provide support for the structural validity of the PHQ-ADS and suggests that a total sum score appropriately captures distress severity in haemodialysis

patients. A full psychometric evaluation is now warranted in this setting in order to provide further evidence regarding the utility of the PHQ-ADS in long-term physical conditions.

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Table 1: Patient characteristics

Variable	Statistic
Age (mean, s.d)	54.9 (16.9)
Gender (male, %)	102 (56)
Haemoglobin g/L (mean, s.d)	10.5 (1.5)
Serum Albumin g/L (mean, s.d)	41.2 (4.5)
CRP ^a (>5 mg/L, %)	79 (43.6)
Co-morbidities ^a	
Diabetes	38 (32.8)
Ischemic Heart Disease	29 (25.0)
Peripheral Vascular Disease	19 (16.4)
Cardiovascular Disease	17 (14.7)
Liver Disease	8 (6.9)
Lung Disease	4 (3.4)
Current smoker	2 (1.7)
History of depression	2 (1.7)

^a noted from medical records-only available in a subsample (n=116)

Table 2: CFA models for the PHQ-ADS

Model	Chi-Square (df), p-value	Number of free parameters	CFI	TLI	RMSEA
1-factor	1700.8 (104), p<0.01	67	0.967	0.962	0.060
2-factor	165.4 (103), p<0.01	68	0.969	0.964	0.058
Bi-factor	96.1 (88), p=0.26	83	0.99	0.99	0.022

Root mean squared error of approximation (RMSEA); Confirmatory Fit Index (CFI); Tucker-Lewis index (TLI); Degrees of freedom (df)

Table 3: Mean Illness Perception, PHQ-9 and GAD-7 scores across PHQ-ADS ordinal categories (95% confidence intervals).

Measure	PHQ-ADS ordinal categories				p-value
	<i>Minimal (0-9)</i> <i>n=109</i>	<i>Mild (10-19)</i> <i>n=46</i>	<i>Moderate (20-29)</i> <i>n=22</i>	<i>Severe (30-48)</i> <i>n=5</i>	
B-IPQ	34.7 (32.4, 37.0)	45.8 (43.0, 48.4)	52.5 (49.6, 55.2)	53.4 (46.6, 63.3)	<0.01
PHQ-9	3.1 (2.7, 3.5)	8.4 (7.7, 9.1)	13.6 (12.4, 14.6)	20.8 (19.5, 22.0)	<0.01
GAD-7	1.1 (0.9, 1.4)	4.8 (4.2, 5.5)	10.0 (8.5, 11.4)	15.6 (11.0, 20.5)	<0.01

p-value corresponds to one-way ANOVA