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**EVALUATING THE GAD-2 AS A SCREENING MEASURE FOR POST-STROKE
ANXIETY IN AN ACUTE STROKE UNIT**

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Abstract

The Hospital Anxiety and Depression Scale (HADS-A) is the only self-report screening test for anxiety validated in stroke patients. However, the HADS-A has limited clinical utility, due to its length of time to administer and cost to purchase. This study aimed to assess the validity of a freely available briefer alternative, the Generalized Anxiety Disorder 2-item (GAD-2) for use in the acute stroke setting. This study used retrospective analysis of a sequential sample in a clinical database of mood and cognitive scores. The GAD-2 demonstrated strong convergent validity with the HADS-A and good specificity and sensitivity. In conclusion, the GAD-2 may be a useful screen to consider for assessment of post-stroke anxiety in the acute setting. Methodological considerations and clinical applications are discussed.

Keywords: stroke, screening, anxiety, validation, GAD-2

Prevalence estimates suggest between 12.5 to 24.9% of stroke survivors experience clinical anxiety across the first two years following a stroke (Knapp et al., 2020). Clinical anxiety is associated with reduced social functioning and quality of life in stroke patients (Burton et al., 2013; D'alisa et al., 2005; Shimoda & Robinson, 1998) and reduced effectiveness of stroke rehabilitation (Donnellan et al., 2010; Swartzman et al., 1998). Studies also suggest patients with anxiety have a less encouraging prognosis than other mental health conditions such as depression (Aström et al., 1992; Morrison et al., 2005). Therefore, identifying patients with anxiety and providing them with appropriate intervention is clinically important.

Currently there are no self-report anxiety screens recommended in stroke guidance (ICSWP/Royal College of Physicians, 2016). This is not comparable with assessment of other psychological difficulties after stroke, such as depression, where several self-report screening measures are identified (ICSWP/Royal College of Physicians, 2016). More research into the relationship between anxiety and stroke has been called for by the Royal College of Physicians (2016), and a key step in achieving this is to develop self-report anxiety screening measures for stroke that combine good psychometric properties with clinical utility.

In a review of measures for post-stroke psychological difficulties, Bennett and Lincoln (2006) recommend that screening measures of anxiety should have a minimum sensitivity of .80 and specificity of over .60 to be useful for clinical practice. Furthermore, Burton and Tyson (2015) have provided guidance on determining the clinical utility of screening measures (see Table 1), arguing that screening measures should be freely available, quick to administer, and can be used without specialist training. Burton and Tyson (2015) found the Hospital Anxiety and Depression Anxiety Subscale (HADS-A; Zigmond & Snaith, 1983) was the only screening test for anxiety that achieved adequate psychometric properties and clinical utility. It is important to state that the Geriatric Anxiety Inventory (GAI) has since

been validated in a stroke setting, and possesses comparable clinical utility (Kneebone et al., 2016).

[Insert Table 1 here]

Hospital Anxiety and Depression Scale (HADS)

The HADS is a 14-item self-assessment scale designed to screen for anxiety and depression in non-psychiatric hospital settings. The HADS has been widely validated and used across a variety of setting (Bjelland et al., 2002). Unlike other measures of depression or anxiety, the HADS items focus comparably less on psychosomatic symptoms to avoid the confounding impact of physical health conditions. This is particularly advantageous in a stroke context given the high incidence rates of post-stroke fatigue, insomnia, changes in smell perception and dysphagia which may affect appetite, and impairments in sensory processing and body awareness (Acciarresi et al., 2014; Baylan et al., 2019; DiStefano et al., 2021; Heckmann et al., 2005; Wehling et al., 2015; Takizawa et al., 2016), all of which may confound the results on standard mood screens. However, the HADS has been critiqued for its lack of specificity, and factor analytic studies have found that the anxiety and depression subscales mostly measure general distress rather than being specific to anxiety and depression (Norton, Cosco, Doyle, Done & Sacker, 2013). While this is a well-documented issue across many self-report measures of depression and anxiety (Steer et al., 1999), the removal of psychosomatic symptoms of anxiety and distress may have exacerbated this problem in the HADS.

The psychometric properties of the HADS-A have been reported in stroke specific populations. Firstly, Furr and colleagues (2006) tested the factor structure of HADS in a stroke population and reported that the anxiety items all loaded strongly onto a single factor

(>0.5), unlike the depression items. Similarly, Kneebone et al (2015) reported that the HADS-A had adequate internal consistency in a stroke population also ($\alpha = 0.83$). The HADS-A also possesses good test-retest reliability ($r = 0.89$) in a sample of mixed stroke and myocardial infarct patients (Visser et al., 1995). It is noteworthy that Furr et al (2006) reported that on an acute stroke unit while 25% of patients were categorised as experiencing clinical anxiety on the HADS; only 8% of patients were categorised as experiencing both clinical anxiety and depression. This suggests some degree of specificity of the HADS-A scale in a stroke context.

The HADS-A has been evaluated in the context of post stroke anxiety to determine the optimal cut off score and associated sensitivity and specificity rates. A summary of this research is presented in Table 2. Typically, this research involves comparing the accuracy of the HADS-A with the criterion variable, i.e., a structured clinical interview using DSM-IV criterion for anxiety (O'Rourke et al., 1998; Sagan et al., 2009; Kneebone et al., 2015). It is important to note the significant variability in findings, with different cut off scores being proposed across almost all validation studies. This may reflect the variability between in-patient and out-patient contexts. Kneebone and colleagues (2015) collected their data in the UK using a rigorous methodology. They found that a cut off score on 5/6 on HADS-A achieved excellent sensitivity but poor specificity, whereas a cut off score of 8/9 achieved poor sensitivity but excellent specificity. The diagnostic accuracy of the upper cut off score was mirrored in the study by O'Rourke and colleagues (1998). One interpretation of this result is that the HADS-A is unable to accurately classify patients as experiencing clinical anxiety using a single score, and instead patients with a score of 0-5 are highly unlikely to be experiencing anxiety, 6-8 may be experiencing anxiety, and 9-21 are highly likely to be experiencing clinical anxiety.

[Insert Table 2 here]

Despite the HADS-A being reported as a psychometrically sound and useful screening measure of post-stroke anxiety, there are limitations for its use in some clinical settings. Neuropsychological measures need to be brief and simple (Bennett & Lincoln, 2006). Despite its brevity the HADS-A is substantially longer than equivalent screening tools for mood such as the Patient Health Questionnaire-2 (PHQ-2; Staples et al., 2019) which is commonly used post-stroke and can be completed in less than a minute (De Man-van Ginkel et al., 2012; Prisdie et al., 2016). This is a similar issue with the Geriatric Anxiety Inventory, which is 20 items long and has an even lengthier administration time. Secondly, the HADS-A has a cost associated with its use, which is a barrier to its utility in some NHS services. As such, despite the GADS and GAI being the only validated measures of post-stroke anxiety, both measures have issues with their clinical utility (see Burton & Tyson, 2015).

Generalised Anxiety Disorder 2-item (GAD-2)

The GAD-2 (Kroenke et al., 2007) is a validated screening measure for anxiety which addresses many of the time and cost barriers associated with the HADS. The GAD-2 meets all clinical utility criterion recommended by Burton & Tyson (2015; see Table 1). It is freely available, quick to administer (less than one minute), based on the well-validated Generalized Anxiety Disorder 7 scale (GAD-7; Kroenke et al., 2007; Spitzer et al., 2006) and none of its items focus on psychosomatic symptoms of anxiety. Both the GAD-7 and GAD-2 have been validated for screening anxiety in the general population, with a meta-analysis of diagnostic accuracy studies reporting pooled sensitivity and specificity values at a cut-off score of 3, of sensitivity .76 (95% CI .55–.89) and specificity .81 (95% CI .60–.92) (Plummer et al., 2016). Although neither the GAD-7 nor GAD-2 have been validated in a stroke patient population, the GAD-7 has been used in the stroke population (Eccles et al., 2017; Schmid et al., 2015; Bonner et al., 2016). Furthermore, the GAD-2 has close links to the PHQ-2, which has been

validated for use in the stroke population with high ratings of clinical utility (Burton & Tyson, 2015; Prisnie et al., 2016; De Man-van Ginkel et al., 2012).

In summary, the GAD-2 meets the criteria of clinical utility (Burton & Tyson, 2015) but it has yet to be validated for use in an acute stroke setting. The current study aims to address this by assessing the validity of the GAD-2 to distinguish between people with and without anxiety following a stroke in the acute setting.

METHOD

Sample

This study analysed information from an anonymised clinical database consisting of 193 stroke patients who were admitted onto an Acute Stroke Unit between October 2018 and November 2019. Mood and cognitive measures were administered to all patients deemed clinically appropriate for assessment by the lead Occupational Therapist on the ward. The assessments were delivered in the following order: PHQ-2, GAD-2, HADS, Oxford Cognitive Screen (Demeyere et al., 2015). The assessments were completed by Assistant Psychologists and Occupational Therapists. The database was populated for the purposes of information sharing between acute and community rehab trusts. On inspection, data from 48 patients had critical information missing, and this data were therefore removed from analysis. This resulted in data being available for 145 patients.

Measures

GAD-2

The GAD-2 is a brief screening measure for anxiety consisting of two items (Kroenke et al., 2007). Individuals are asked to rate how often they have experienced symptoms over the past 2 weeks on a 4-point scale (0 = not at all, 3 = every day). The total scores range from

0-6 with a maximum of 6. Given that the GAD-2 was administered in an acute setting, patients were instead asked to rate how often they have experienced symptoms ‘*since their stroke*’.

HADS-A

The HADS-A functioned as the criterion variable for the current study. The HADS-A is a self-report measure which asks patients to rate their agreement with seven anxiety items over the previous week. Patients choose a response on a 4-point scale (0 = no symptoms, 3 = maximum impairment), to give a score out of a maximum of 21. HADS-A scores of 0-5 were classified as ‘No Clinical Anxiety’, 6-8 as ‘Possible Clinical Anxiety’, and 9-21 as ‘Clinical Anxiety’ based on research by Kneebone, 2015; Kneebone, personal communication).

Procedure

The anonymous database included the following information: age, time between stroke and assessment, age when assessed, when the stroke occurred, gender, location of stroke (as identified by a CT scan), and scores on cognitive and mood measures.

Ethical Approval

The study received full ethical approval from the University of Plymouth.

Data Analysis Plan

Statistical Package for the Social Sciences (SPSS), Version 25, was used for statistical analyses. Demographic data were assessed using chi-squared tests to assess for gender differences and age was considered using frequency count. To allow for deviations from normality, Pearson correlation with bootstrapping (1,000 replicates, bias-corrected and accelerated confidence intervals) was used to examine the correlation between anxiety and

HADS-A scores. A Shapiro-Wilk Test established if the data were normally distributed.

Patients in the 'No Clinical Anxiety' and 'Clinical Anxiety' groups, as defined by HADS-A, were compared on the GAD-2, and from this sensitivity, specificity, and area under the curve (AUC) figures were calculated.

Sample Size

A power analysis for a typical bivariate correlation of .29 could be detected at power = .90, alpha = .05 (one-tailed) with 120 participants. Receiver Operating Characteristic analysis would require a sample of 39 to distinguish a typical AUC of .8 from .5 (no prediction) at power = .80, alpha = .05.

RESULTS

Demographic data from the patients included in the sample are presented in Table 3.

[Insert Table 3 here]

Gender was found to be evenly represented in the sample ($X^2(145) = 3.36, p = .07$), with 42.1% female and 57.2% male patients. Age did not correlate with anxiety ($r(145) = .14, p = .09$). Despite the sample consisting of a wide age range (42 - 97 years) patients were primarily older ($\bar{x} = 71.95, SD = 12.75$).

HADS-A scores ranged from 0 to 21 (mean 5.52, SD 4.14). 58% of patients were classified as 'No Clinical Anxiety', 22% as 'Possible Clinical Anxiety', and 20% as 'Clinically Anxious'. This broadly matches meta-analytic prevalence statistics (Knapp et al., 2020). GAD-2 scores ranged from 0-6 (mean 1.30, SD 1.57). Test scores across the GAD-2 and HADS-A are presented in Table 4.

[Insert Table 4 here]

Psychometrics

Convergent Validity of the GAD-2 and HADS-A

The Shapiro-Wilk Test significance values indicated that the data were not normally distributed for the GAD-2 ($W(145) = .79, p > .00$), skewness 1.18, $p < .01$, kurtosis .45, $p > .05$) or the HADS-A ($W(145) = .92, p > .00$), skewness 1.11, $p < .01$, kurtosis 1.4, $p < .01$). Visual representation of these data as histograms and Q-plots is included in the appendices. A bootstrapped Pearson correlation between these measures ($r(145) = .65, p < .01$) demonstrated a statistically significant strong positive correlation (see Cohen, 1988).

Criterion Validity of the GAD-2

Patients scores on the GAD-2 were compared across the ‘No Clinical Anxiety’ group ($n=84$) and the ‘Clinical Anxiety’ group ($n=29$). The GAD-2 was effective at discriminating between patients with and without clinical anxiety (see Table 5 and Figure 1). Cut-off scores, along with sensitivity and specificity are presented in Table 6. Cut off scores of 0/1 and 1/2 both exceeded Bennett & Lincoln (2006) recommendations for minimum sensitivity and specificity levels. To determine the real-world impact of both cut off scores, positive predictive values (PPV) and negative predictive values (NPV) were calculated after adjusting for a base rate of clinical anxiety in stroke survivors at 19% (Knapp et al., 2020). The cut off 0/1 achieved a PPV of 0.37 and NPV of 0.98; whereas the cut off 1/2 achieved a PPV of 0.64 and NPV of 0.96.

[Insert Tables 5 and 6 here]

[Insert Figure 1 here]

Relationship Between GAD-2 and PHQ-2

A Pearson’s correlation coefficient was calculated to determine the strength of the relationship between scores on the GAD-2 and PHQ-2. A moderate positive correlation was found between the two variables, $r(143) = 0.62, p < 0.001$, which accounted for 38% of the

variance. Scores on the GAD-2 and PHQ-2 for the whole sample were recoded using the cut off score of 1/2, to categorise patients who screened positive or negative for anxiety and depression. Table 7 includes a frequency count of patient categorisation. Standard residuals suggest that the proportion of patients who screened positive for both anxiety and depression (20%) was significantly higher than expected. Similarly, the proportion of patients who screened positive with just clinical anxiety (12%) or clinical depression (9%) was statistically lower than expected.

[insert Table 7 here]

DISCUSSION

The current study sought to assess the psychometric properties of the GAD-2 in an acute stroke unit. Overall, scores on the GAD-2 correlated strongly with scores on the HADS-A, which suggests they are measuring the same construct – clinical anxiety. Furthermore, the GAD-2 was very effective at discriminating between patients with and without clinical anxiety (as defined by the HADS-A). Taken together, this suggests that the GAD-2 may be clinically useful for screening patients with anxiety in an acute stroke setting.

On the GAD-2, the cut off scores of 0/1 and 1/2 both exceeded the minimum psychometric requirements set by Bennett and Lincoln (2006). The authors of this study propose that the cut off score of 1/2 is preferable for use in clinical practice. It is well known that the lower the base rate of the condition, the more important the specificity statistic is for accurate classification of patients on screening instruments. When calculating PPV and NPA using a 19% base rate for anxiety, as identified by Knapp et al (2020), the cut off score of 0/1 produced an unacceptably low accuracy for positively identifying anxiety, i.e., only 1 in 3 patients who scored above the cut off would be experiencing the condition. In contrast, while

the cut off score of 1/2 reduced the NPV marginally, it was associated with a significantly higher PPV, which is preferable for clinical practice.

It is important to note that scores on the GAD-2 and PHQ-2 were strongly related. One of the criticisms of the HADS is its poor specificity for anxiety and depression, and instead it measures general distress (Norton et al., 2013). Patients in our sample who scored high on the GAD-2 also tended to score similarly on PHQ-2. Furthermore, when comparing the classification of patients on GAD-2 and PHQ-2, a disproportionate number of patients were identified as experiencing both anxiety and depression. However, it is well documented that anxiety and depression are comorbid conditions, with approximately 50% of people experiencing one condition also meeting criterion for the other (Hirschfeld, 2001). The rate of comorbidity between GAD-2 and PHQ-2 was 49% (see Table 7) which closely aligns to the comorbidity rate. Therefore, while the GAD-2 and PHQ-2 are related and may both be sensitive to general distress, the rate of comorbidity was in the expected range, which suggests that the measure is not just sampling general distress, and 51% of patients who were identified as having a psychological difficulty, only exceeded the cut off on one of the measures. This suggests at least some discriminant ability between anxiety and depression within this battery.

Methodological Critique

The sample used met all power calculation requirements and fell within comparable range of other validation studies of stroke-specific anxiety screening measures (Johnson et al., 1995; O'Rourke et al., 1998 & Sagen et al., 2009). Internal validity of the GAD-2 was not considered due to the questionnaire being a 2-item measure only. A limitation of this study is that a psychiatric interview, the gold standard criterion measure for diagnostic accuracy studies (Burton & Tyson, 2015), was not employed. Instead, the HADS-A was used as a

criterion variable. The HADS has been criticised for limited ability to accurately classify patients as having anxiety or depression (Norton et al., 2013). However, given the extremely high incidence of stroke related physical symptoms, which overlap with psychosomatic symptoms (Acciarresi et al., 2014; Baylan et al., 2019; DiStefano et al., 2021; Heckmann et al., 2005; Wehling et al., 2015; Takizawa et al., 2016), and the stroke specific research which found that the HADS-A achieved acceptable factor structure, internal consistency, and re-test reliability (Furr et al., 2006; Kneebone et al., 2015; Visser et al., 1995), it was still considered the most appropriate screening measure of anxiety for this study. This study used an upper and low cut off score to categorise patients with anxiety on the HADS, which was selected for based on an up-to-date interpretation of the stroke literature. However, this approach still introduced a 12-13% error rate in both identifying patients with and without clinical anxiety (Kneebone et al., 2015, personal communication). This is an important consideration, and a potential source of bias.

Future Research

The primary limitations of this study are the use of a clinical database and the use of HADS-A as a criterion variable for anxiety. Repeating this study with a systematic sampling method and a structured clinical interview against DSM-5 criterion for anxiety, would significantly improve the internal validity of this study.

Clinical Applications

In 2016, the ICSWP and Royal College of Physicians guidelines stated that there was a lack of adequate measures to screen for post-stroke anxiety, and subsequently provided limited guidance on this area of practice. However, there have been significant developments in this area of practice. Firstly, the HADS-A has been evaluated in subacute and community

settings in the UK (Kneebone et al., 2015; O'Rourke et al., 1998), and from this research, the authors of this study recommend the use of upper and lower cut off scores to facilitate meaningful interpretation. Furthermore, Kneebone and colleagues (2015) also found that the GAI is very accurate at identifying anxiety using a single cut off score. Additionally, for patients with aphasia, the Behavioural Observations of Anxiety scale has been developed and is an effective observational measure for identifying anxiety (Eccles, Morris & Kneebone, 2017). Finally, this study has found that the GAD-2, a quick and freely available measure, may also be a valid screening measure of anxiety in an acute stroke setting. Therefore, there are now a suite of available measures for post-stroke anxiety which have been validated in different contexts (acute, subacute and community), for different populations (aphasia friendly), and offer different advantages (accuracy (GAI) and brevity (GAD-2)).

Within acute settings, the combination of the GAD-2 and PHQ-2 offers the potential for a brief but clinically useful screening combination for anxiety and depression.

Conclusions

While different measures of post-stroke anxiety have been validated, there is a need for measures which are freely available, quick to administer, and do not require specialist training, so that anxiety screening can be facilitated in acute settings (Bennett & Lincoln, 2006). The GAD-2 has high clinical utility but has not been validated in a stroke context. The current study compared patient data on the HADS-A and GAD-2. Overall, the GAD-2 achieved excellent classification accuracy relative to the HADS-A, and the current study recommends that a cut off score of 1/2 provides the optimal balance between sensitivity and specificity for use in clinical practice. However, unlike in other post-stroke anxiety validation studies, this study did not use a structured clinical interview as a criterion variable, and therefore there is increased risk that bias may have affected the results. As such, while the

results of this study demonstrate that the GAD-2 has clinical utility, it is important to approach the use of the GAD-2 in practice with appropriate caution and recognise both the limits of this study but also the limitations of screening more generally, and not over-interpret the significance of GAD-2 cut off scores in influencing stroke care.

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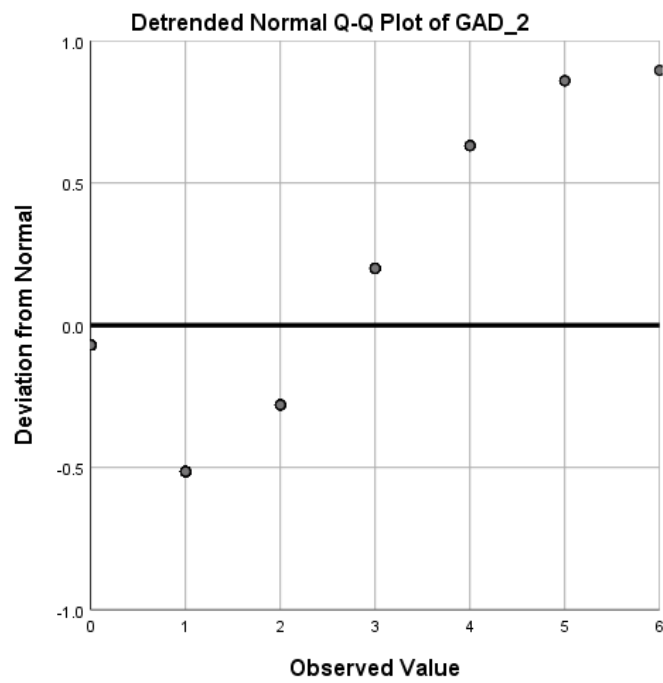
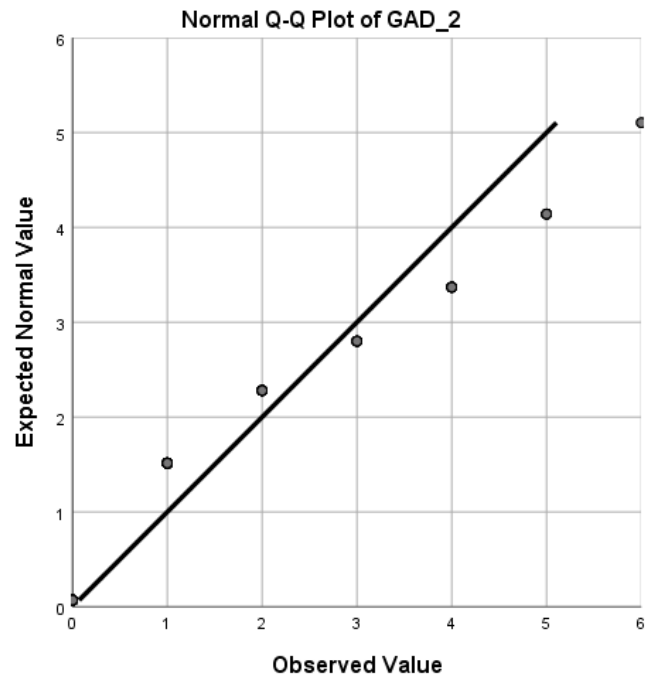
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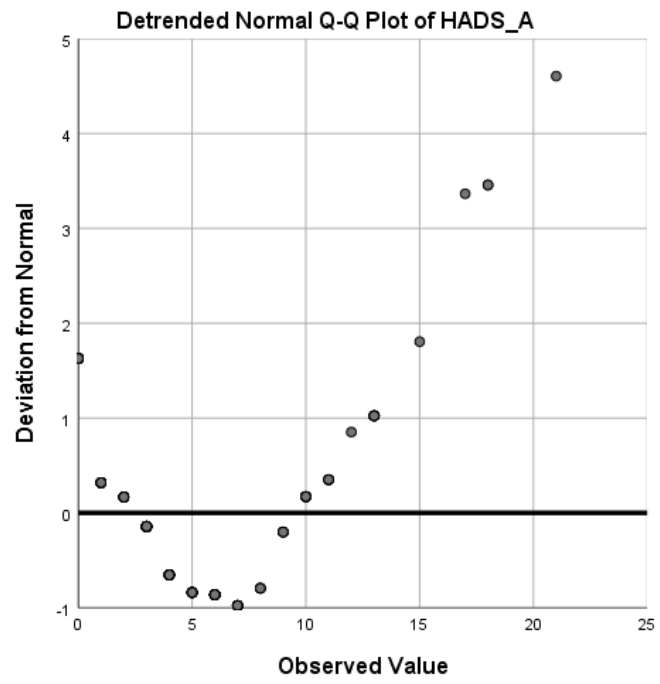
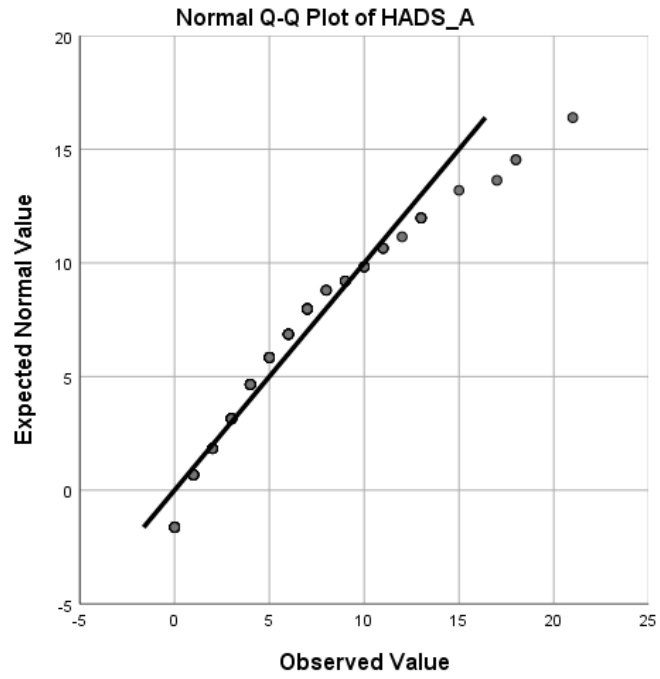
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Appendices

Q-Q Plots





Histograms

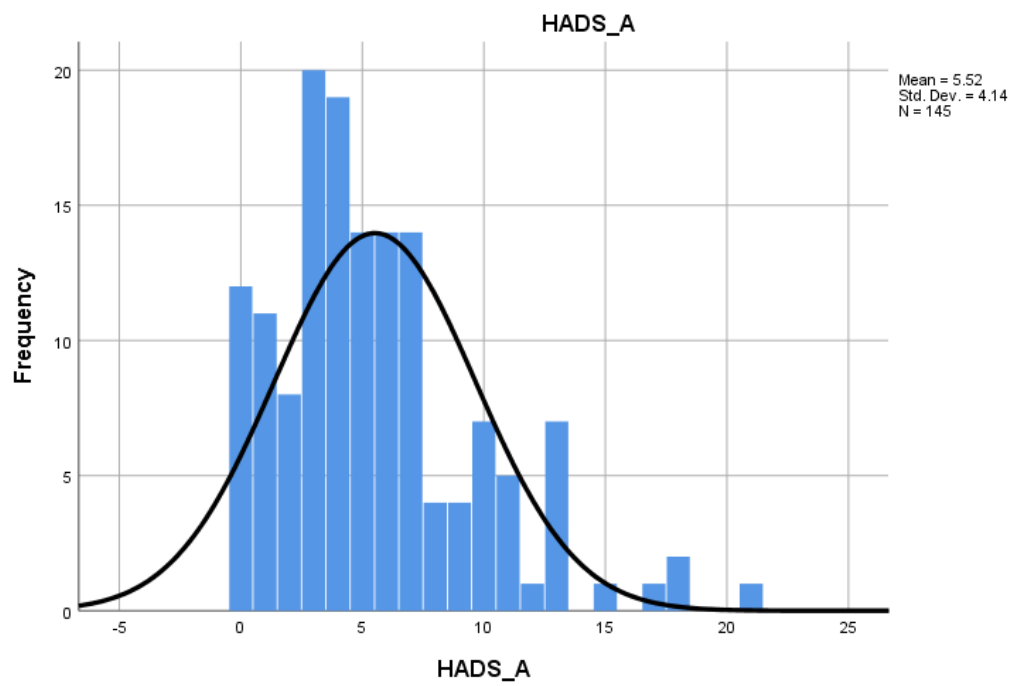
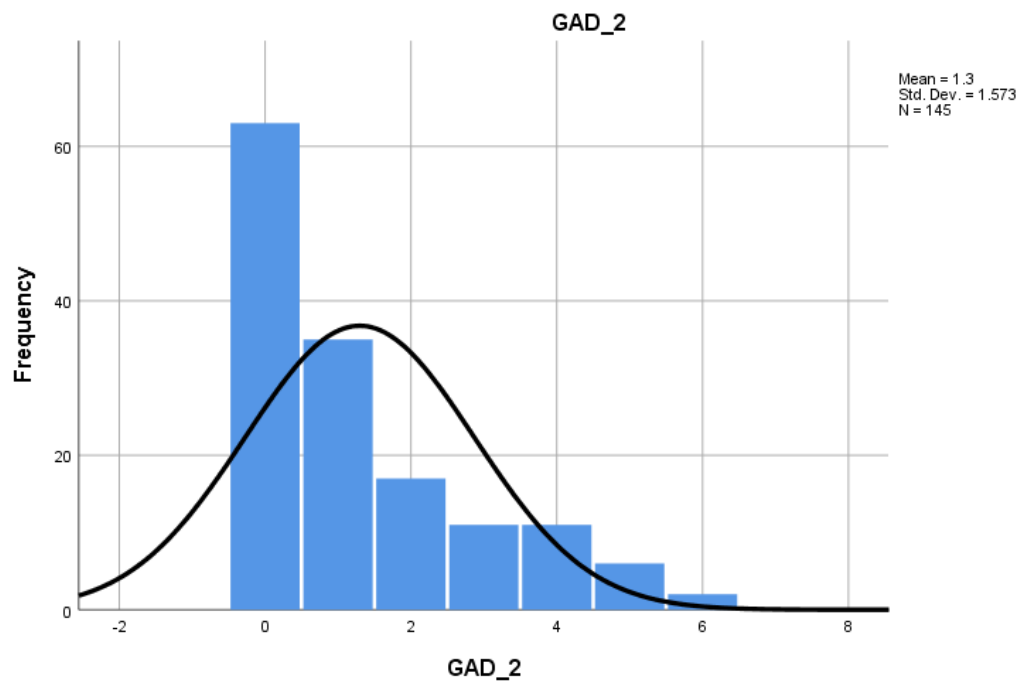


Table 1

Burton & Tyson (2015) Criteria for rating the clinical utility of post-stroke 'mood' screening measures

	Time to administer and score	Initial costs for purchase	Additional cost per record form	Need for specialist training	Total score/6
0	≥11 minutes	≥ £100	Additional cost or unavailable	Specialist training required	
1	6-10 minutes	<£100	No additional costs	No specialist training required	
2	≤ 5 minutes	Freely available			
HADS-A	2	0	0	1	3
GAD-2	2	2	1	1	6

Notes. Higher scores indicate greater clinical utility

Table 2**Diagnostic Accuracy of HADS-A Post-Stroke**

First author	Sample	Time since Stroke	Criterion	Cut off	Sensitivity	Specificity
Johnson (1995)	Not available	4 months post stroke	DSM-III diagnosis for anxiety	5/6	0.95	0.46
O'Rourke (1998)	105 patients from UK	6 months post-stroke	Structured Clinical Interview using DSM-IV criterion for anxiety	6/7	0.83	0.68
				8/9	0.50	0.87
				10/11	0.42	0.92
Sagan (2009)	104 patients from Norway	4 months post stroke	Structured Clinical Interview using DSM-IV criterion for anxiety	4/5	0.83	0.65
Kneebone (2015)	81 patients from UK	Inpatient post-acute rehabilitation (sub-acute)	Structured Clinical Interview using DSM-IV criterion for anxiety	5/6	0.88	0.54
				8/9*	0.50	0.87

Please note that the diagnostic accuracy of the cut off of 8-9 from Kneebone (2015) was obtained through personal communication

Table 3*Demographics of Sample*

	Mean	SD
Age (years) at assessment	71.95	12.75
Gender		
% male	57.2	
% female	42.1	
Time since stroke (days)	4.39	3.29
Brain side of stroke		
% right	25.5	
% left	23.4	
% bilateral	31.0	

Table 4*Test scores*

Test	N	Mean	SD
GAD-2	145	1.30	1.57
HADS-A	145	5.52	4.14

Table 5

GAD-2 Area Under the Curve (AUC)

<i>AUC</i>	<i>Standard Error</i>	<i>Significance</i>	<i>Lower CI (95%)</i>	<i>Upper CI (95%)</i>
.903	.37	.000	.83	.975

CI = Confidence Interval

Table 6*GAD-2 cut off scores*

Cut-off	Sensitivity	Specificity
0/1	.93	.63
1/2	.83	.89
2/3	.59	.95
3/4	.48	.99
4/5	.24	.90
5/6	.07	1

Table 7

Patient Categorisation using GAD-2 and PHQ-2 (N=140)

	No Anxiety		Anxiety	
	Freq	Std Res	Freq	Std Res
No Depression	83	1.9	17	-2.9
Depression	12	2.7	28	4.2

* Freq = Frequency; Std Res = standardised residual

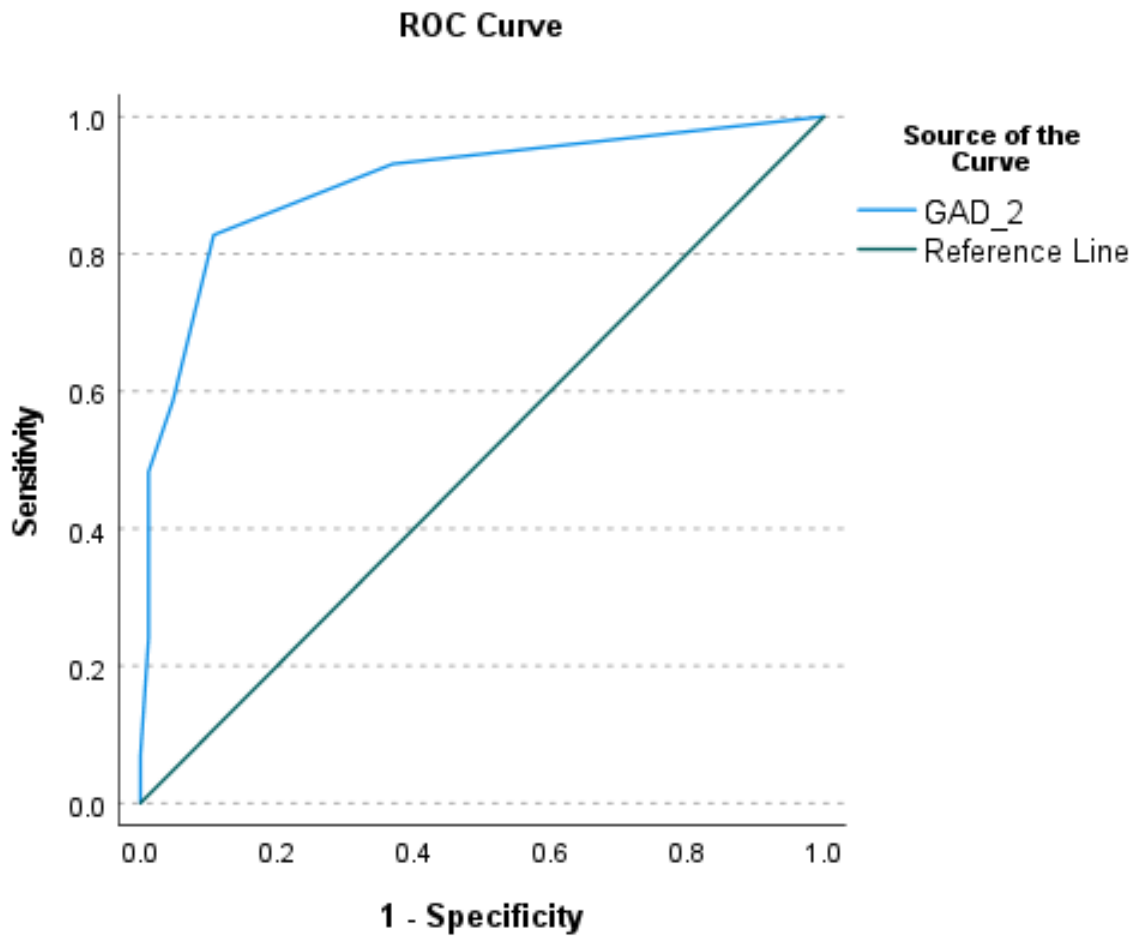


Figure 1

GAD-2 Receiver Operating Characteristics Curve