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Development and validation of Ayurveda based assessment scale for anxiety

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ABSTRACT

Background: Anxiety scale based on Ayurveda would help Ayurveda physicians to measure and initiate appropriate treatment strategies.
Objectives: The objective of the study was to develop a clinical assessment scale for anxiety based on Ayurveda science.
Materials and methods: Ayurveda assessment scale for anxiety (AAA) was developed and subjected to various psychometric evaluations. Patients of generalized anxiety disorder with social phobia (GAD with SP) (n = 31) meeting DSM-IV-TR criteria and age, sex-matched healthy subjects (n = 31) were enrolled from NIMHANS Psychiatry OPD. Two independent Ayurveda experts evaluated both patients and healthy subjects using AAA, Hamilton Anxiety Rating Scale (HARS), and Beck Anxiety Inventory (BAI). Reliability and validity assessments were carried out. The sensitivity to treatment-induced change was evaluated in a randomized controlled clinical trial. 72 patients of GAD with SP meeting DSM-IV-TR criteria, aged between 20 and 55 years, and either sex participated in the study. The duration of intervention was 30 days. The assessments were done through HARS, BAI, Beck Depression Inventory (BDI), AAA and Clinical Global Impression scales (Severity, Improvement, and Efficacy).
Results: The Interrater reliability was between - good to very good score. Validity of AAA with HARS and BAI was significant ($p < 0.001$). Scales recorded significant differences when compared between patients and healthy subjects ($p < 0.001$). AAA also recorded the sensitivity to treatment-induced changes in a randomized controlled study and noted a large effect size (>0.60).
Conclusions: The psychometric properties such as interrater reliability, validity (criteria, convergent, divergent, face) and sensitivity to change of AAA were promising.

1. Introduction

Anxiety, though is a normal emotion, is associated with a feeling of unease or unnecessary worry associated with various forms of stress being experienced across all species and age groups. Anxiety can be prevalent as a state or trait. Anxiety has physical, behavioural, emotional, and cognitive manifestations. However, anxiety disorders are a group of mental illness that is manifested as excessive or persistent fear and worry, that alters homeostasis. Anxiety is explained in Ayurveda under the disease *chittodwega*. *Chittodwega* is *udwigna chittata* [1]. *Udwega* means agitation, fear, distress, shaking, waving [2] and trembling, anxiety [3]. Pathophysiology of *Chittodwega* involves psychological components like *Tamas* with predominant *Rajas* and biological components like *Vatapradhan Tridosha*. The abnormalities in *raja* and *tama* can produce various psychological symptoms (*Mano dosha*) like worry, fear, sadness, anxiety, irritability, [4] and insomnia. Gastrointestinal manifestations like derangement in *Agni* (metabolic component) [5], diarrhoea [6], vomiting [7], thirst [8], abdominal pain and swelling [9], Respiratory systemic manifestations like *Rajayaksma*

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[10], *Pratishyaya* [11], Cardiovascular abnormalities like cardiac diseases [12], Urogenital systemic abnormalities like *Prameha* [13] and neurological dysfunctions like *Vatavyadhi* [14]. Finally, anxiety causes decrease in *Oja* (tissue essence) [15] and can lead to considerable comorbidities.

Ayurveda and psychiatry are the fields where subjectivity plays an important role. *Manasa* (mental state or a state of mind) is an important component of mental health in specific and overall health in general. In *manasa roga* (mental illness), functions of various subdomains like *manas* (mind), *buddhi* (intellect), *samjna* (orientation), *smruti* (memory), *bhakti* (desire), *shila* (temperament), *chest* (psychomotor activity) and *achara* (conduct) are affected. Assessment of *manasa* and *manasaroga* is a challenging field due to its high subjectivity and lack of biological markers in its assessments. However, in such a scenario, objective assessments are done through various clinical assessment scales. Assessment scales properly developed and used by competent individuals have various advantages as they aid in screening tests, assessment of diagnosis, comorbidity, symptoms, severity etc. and help in getting information pertaining to many psychological conditions. These clinical assessment scales play a pivotal role in subjective assessments in the field of psychiatry and psychology. However, changing diagnostic criteria of Diagnostic statistical manuals (DSM) and International classification of Diseases (ICD) makes the previous scales' validity questionable and their data needs to be used cautiously. New and untested scales yielding much larger effect sizes than well-established scales is an area of concern [16]. Most of the psychological studies conducted on the Indian population are executed on the basis of clinical tools developed elsewhere that reduce their relevance to Indian context.

Clinometric is an area of instrument development that considers multiple constructs through a single index (like TNM Scores for cancer). Psychometrics assess a single construct like anxiety through a comprehensive multiple-item assessment. A wide variety of clinometrics have been tried in the field of anxiety disorders. Few of the gold standard scales used in the assessment of anxiety are Hamilton Anxiety Rating scale (HARS) and Beck Anxiety Inventory (BAI). HARS is a clinician-administered scale having 14 items that assess and quantify the severity of anxiety. Each item is scored on a five-point Likert-type scale ranging from 0 to 4. Higher scores indicate increased severity of anxiety. It evaluates the broad range of symptoms common to different types of DSM -IV anxiety disorders [17]. The main limitations of HARS include the inadequate measurement of worry which is the core manifestation of GAD [18] and the poor discrimination of anxiety and depression [19]. The BAI is a 21-item self-report questionnaire that assesses the manifestations of anxiety. Each item is rated on a four-point scale, ranging from 0 to 3. BAI has excellent internal consistency ($a = 0.92$) and high test–retest reliability ($r = 0.75$) [20]. One limitations of BAI is that it is a better tool for assessing panic disorder than other spectra of anxiety disorders [21].

Information on the concepts of clinometric and psychometrics is available in ancient Ayurveda texts. Documentation of information in *Samhitas* was done following systematic and stringent guidelines. These can be applied in the context of psychometric components of clinical assessment scales. The reliability and validity component is explained in the context of *siddhanta* [22]. The scale needs to be established after rigorous testing by many methods and scholars (परीक्षकैर्बहुविधं परीक्ष्य हेतुभिश्च साधयित्वा स्थाप्यते निर्णयः, *Parikshakai bahu vidham pareeksha hetubhisha sadhayitwa sthapyate nirnaya*). The scales should have construct and content validity which could be through condensing the less important (*Uddhesh tantra Yukti*) and elaborating the primary components (*Nirdesha tantra yukti*) [23]. Congruent and divergent validity (असङ्कुलप्रकरणमिति अमिश्रीभूतप्रकरणम्, *Asankula prakaranmiti Amishribhuta prakaranam*) needs to be followed [24]. Items must be clear, unambiguous, contextual terms (पुष्कलाभिधानमिति सम्यगर्थ समर्पक वाक्यम्, *Pushkaladhanmiti samyagartha samarpaka vakyam*), in a systematic order (*Kramagatartha*) and easy to administer (*Trividha shishya buddhi hitam*) [24]. All these attributes make it a gold standard scale (*sarva tantra siddhanta*) [22]. Scales on clinometric and psychometrics in Ayurveda are yet to be developed and few works have been reported in assessments of personality. *Charaka* child personality inventory (CCPI) is a self-rating scale to measure *tridoshas* in *children* [25]. Mysore *tridosha* scale is a personality scale, that assess the *dosha prakurti* through psychological aspects of *dosha* [26]. Scale differentiating *Unmada* (psychosis) symptoms based on *tridosha* (homeostatic principles) by using the concepts of ayurvedic medicine is reported. These scales measure *tridosha* disturbance in psychotic disorders; paranoid schizophrenia, schizophrenia (unspecified), and unspecified non-organic psychosis to have high scores on *vata, pitta,* and *kapha* dosha respectively [27]. Ayurveda clinical assessment scales in assessing psychiatric diseases like anxiety disorders, depressive disorders, psychotic disorders, or any of the psychological manifestations like anxiety, depression, sleep disturbances, etc remain to be studied. To date there are no effective indigenous clinical measurement tools, especially to measure anxiety. Assessment on the basis of Ayurveda perspective of psychiatric disorders is highly warranted as this will help in validating the Ayurveda medications through the lens of Ayurveda. Hence, the present study was planned to develop and validate the Ayurveda assessment scale for Anxiety (AAA).

2. Material and methods

2.1. Development of Ayurveda assessment scale for anxiety (AAA)

Literature search on key words like *Udwega, Mana, Chitta, Satwa, Raja, Tama, Vata, Manasa dosha* [4] [*Kama* (Passion), *Krodha* (Anger), *Lobha* (Greed), *Irsha* (Envy), *Maana* (Pride), *Mada* (Arrogance), *Soka* (Grief), *Chittodwega* (Anxiety), *Chinta* (Worry), *Bhaya* (Fear), *Harsha* (Exhilaration), *Vishada* (Anguish, Depression), *Abhyasuya* (Jealousy) and *Dainya* (Meanness/Inferiority complex)] in 9 classical texts of *Charaka Samhita, Sushruta Samhita, Astanga Hrudaya, Astanga Sangraha, Madhava Nidana, Bhavaprakash, Bhaisajya Ratnavali, Yogaratnakar, Kashyapa Samhita* were carried out.

Keywords were also searched in *Hetu* (etiological factor) and *Linga* (manifestations) and their association was assessed. Repetitive, non-contextual, and descriptions not meeting above criteria were omitted. Content validity was assessed through ten experts serving as judges of which nine were Ayurveda physicians with more than ten years of clinical experience and the tenth expert was a psychiatrist. Close-ended questions using ordinal scales were developed. The order of choices were from lower to higher or from negative to positive on a four-point scale. The response options were as direct and specific as possible.

2.2. Assessment of reliability and validity

62 subjects were recruited in the study; with 31 patients of GAD with co-morbid generalized social phobia (GAD with SP) meeting the DSM-IV-TR criteria, between the age group of 20–55 years, either sex from the Psychiatry OPD, National Institute of Mental Health and Neurosciences (NIMHANS) Bangalore. The other 31 subjects were age and sex-matched healthy controls. Two independent Ayurveda experts evaluated the anxiety levels of both patients and healthy subjects using AAA and other conventional and gold standard anxiety rating scales like HARS [28] and BAI [29].

Beck Depression Inventory (BDI) [30] was used to rule out significant depression (BDI<17).

2.3. Assessment of sensitivity to treatment induced change

72 patients of GAD with SP meeting DSM IV TR criteria, aged between 20 and 55 years from either sex, were enrolled in a randomized controlled clinical trial. They were randomly placed in three groups: Group I (n = 24) received *Manasamitra Vataka* tablets (100 mg twice daily for 30 days). In Group II along with the *Manasamitra Vataka*, additional *Shirodhara* (therapy involving dripping of medicated oil [*Brahmi tail*] over the forehead) treatment for the first 7 days was administered. Group III (n = 24) was administered with clonazepam 0.75 mg daily in a divided dose for 30 days. The assessment of anxiety was done using the HARS, BAI, AAA, and other assessments were BDI, Clinical Global Impression scales (CGI) (Severity, Improvement and Efficacy) [31]. The nature and design of the study were explained to patients, and informed consent was obtained. The study was approved by the Institute ethics committee (NIMH:ES:Ph.D (NP):2007−10:BRT. Dated 30.9.2009). Convenient sampling method was employed for sampling.

2.4. Statistical analysis

Statistical analysis was carried out using SPSS Version 20.0. Socio-demographic characteristics of patients (GAD with SP) and healthy controls were analysed by Chi square and independent sample t- test. The interrater reliability or agreement was assessed by Cohen's Kappa statistic for the 18 items of AAA Assessment Scale. Validity was accomplished through correlation between the AAA, HARS, and BAI and was calculated using Pearson's correlation coefficient 'r', set at 5% ($p < 0.05$). Split half reliability of AAA was through Pearson's correlation coefficient 'r', set at 5% ($p < 0.05$). Factor analytic co-efficient was obtained for each item. Kaiser-Meyer-Olkin measure of sampling adequacy for subscale item analysis was done. Effect size calculated by Partial Eta Square method. It assessed the effect of treatment through the outcome from baseline to the 15th and 30th day of treatment. The criteria used for interpreting effect size measures were as follows: 0−0.2 as minimal, 0.2−0.5 as small, 0.5−0.8 as medium, and above 0.8 as large effect size [32].

3. Results

3.1. Design and development of AAA

The literature survey disclosed 61 descriptions meeting the set criteria. Their descriptions and English translations were presented to 10 judges comprising of nine Ayurveda experts and a psychiatrist. After a thorough review and multiple discussions, the panel of experts zeroed down the 61 descriptions to 18 descriptions based on the content specificity to anxiety disorders. Additionally, these 18 items are recorded by the author *Vagbhat* [33]. Each of these items was defined, refined, semi-structured, and anchor points were developed through literary search and discussions. We used an interval scale/Likert scale of 0−3 with 4 degrees of measurement in the order of severity. Items could also measure different subcomponents of anxiety disorders. Psychological components such as worry, disturbed mind, fear, sadness, speech disturbances (*Moha*, *Dainya*, *Bhaya*, *Shoka*, *Pralapa*); neuro-endocrinal components such as giddiness, sensory and motor deficits, sleep disturbance, involuntary movements, desire for warmth/cold intolerance, fainting and conscious disturbances (*majja shosha, indriya upaghata, nidra nasha, kampa, ushna kamita, samjna nasha*); gastro intestinal components such as flatulence, bloating, constipation (*Admana, atopa, malasangha*); musculoskeletal - pains and aches (*Asthi shoola*); general somatic manifestations like weight loss, debility (*Karshya*, *Bala upaghata*), complexion disturbance (*Karshnya*). Dosha assessments of AAA Scale items revealed that 9 items were of *Raja dosha*, 6 were of *Vata dosha* and 3 were of *Tama dosha*.

3.2. Content validity

Out of the ten experts who served as judges, seven judges agreed on all 18 items, two judges agreed on 16 items (88%), and one Judge on 15 items (83.3%).

3.3. Reliability

Profiles of patients with GAD with SP (n = 31) and Healthy subjects (n = 31) were comparable in terms of age, gender, height, weight, and BMI (Table 1). Anxiety assessment through AAA, HARS, BAI, BDI showed significant difference ($p < 0.001$) between anxiety patients and the healthy group (Table 2). Reliability assessment through interrater agreement of 18 items of AAA showed moderate agreement on two items (Kappa, 0.41−0.60), good agreement (Kappa, 0.61−0.80) in 7 items and 9 items showed very good agreement (Kappa, 0.81−1.00). Hence, interrater agreement was from good to very good scale for AAA.

Two interrater assessment of patients with GAD with SP for anxiety using the scales like AAA, HARS and BAI revealed that the total scores of rater 1 were significantly correlated with total scores of rater 2 on all these scales, AAA total scores of rater 1 with rater 2 ($r = 0.962$, $p < 0.001$), HARS total scores of rater 1 ($r = 0.687$, $p < 0.001$), HARS total scores of rater 2 ($r = 0.658$, $p < 0.001$), BAI total scores of rater 1 ($r = 0.679$, $p < 0.001$), BAI total scores of rater 2 ($r = 0.659$, $p < 0.001$).

The assessment of anxiety on healthy subjects using AAA scale, HARS and BAI also showed a significant correlation between rater 1 and rater 2 on all scales; AAA total scores of rater 1 with rater 2 ($r = 0.841$, $p < 0.001$), HARS total scores of rater 1 ($r = 0.789$, $p < 0.001$), HARS total scores of rater 2 ($r = 0.512$, $p = 0.003$), BAI total scores of rater 1 ($r = 0.838$, $p < 0.001$), BAI total scores of rater 2 ($r = 0.510$, $p = 0.003$).

Internal consistency of AAA-on Patients of GAD with SP (n = 31) showed Cronbach's alpha = 0.749. The Split-Half reliability (odd and even) of AAA scale was $r = 0.58$, $p = 0.001$. Split half reliability was 0.733 highlighting that AAA scale has acceptable internal consistency.

Factor analytic co-efficient obtained for each item in the *AAA* was more than 0.32. The number of items are highly correlated (Table 3).

3.4. Validity

Content validity was based on agreements of all ten judges. Convergent validity of AAA with HARS and BAI in anxiety patients showed a strong positive relationship; HARS ($r = 0.69$, $p < 0.001$), BAI ($r = 0.68$, $p < 0.001$). Similarly, healthy subjects also showed a positive relationship; HARS ($r = 0.63$), BAI ($r = 0.62$). Divergent validity of AAA, HARS, and BAI with regard to anxiety patients and healthy subjects showed minimal correlation AAA ($r = -0.056$), HARS ($r = -0.112$), BAI ($r = -0.02$). Total Scores of AAA, HARS and BAI showed significant ($p < 0.001$) differences on comparing healthy with anxiety patients (Table 2). Concurrent validity is established as AAA scales could effectively distinguish healthy subjects from anxiety patients. Face validity assessment showed that satisfaction with the scale related to measurement of their disease was very good in 8 (25.8%), good in 17 patients (54.8%),

Table 1
Profiles of patients of GAD with SP and Healthy subjects. Expressed in Mean, standard deviations (S.D.).

Sl No	Variable	GAD + SP	Normal Controls	T/chi-sq value	p value
1	Age (Yrs)	32.12 ± 7.85	29.29 ± 3.49	0.123	0.071
2	Gender (M:F)	24:7	21:10	0.393	0.401
3	Weight (Kgs)	62.59 ± 9.07	63.46 ± 12.46	0.952	0.444
4	Height (cms)	164.58 ± 8.36	163.03 ± 7.42	0.940	0.859
5	Body Mass Index	23.40 ± 3.96	23.64 ± 2.63	0.888	0.773

GAD-Generalized Anxiety Disorder, SP-Social Phobia.

Table 2
Assessment through different clinical assessment scales in patients of anxiety and healthy individuals. Expressed in Mean, standard deviations (S.D.).

Sl No	Variable	GAD and SP (n = 31)	Healthy Controls (n = 31)	p value (independent T test)
1	AAA	18.09 ± 4.62	3.80 ± 2.12	<0.001
2	HARS	31.70 ± 4.44	4.51 ± 1.63	<0.001
3	BAI	27.38 ± 7.74	4.87 ± 1.83	<0.001
4	BDI	13.0 ± 3.59	5.9 ± 2.13	<0.001

AAA-Ayurveda Assessment scale for Anxiety, HARS-Hamilton Anxiety Rating Scale, BAI-Beck Anxiety Inventory, BDT-Beck Depression Inventory.

moderate in 4 patients (12.9%), and poor satisfaction was observed in 2 patients (0.6%). Factor analysis showed that all items scored were above 0.32 (Table No. 3). Kaiser-Meyer-Olkin Measure of sampling adequacy for subscale item analysis showed good sampling adequacy and was above 0.5. Factor loadings in each item ranged from 0.32 to 0.90.

3.5. Sensitivity to treatment-induced changes

AAA sensitivity to treatment-induced change was assessed in a randomized controlled clinical trial. Baseline scores of HARS, BAI, AAA, and CGI-Severity in all three groups were comparable (Table 4). Effects of interventions showed that AAA was sensitive enough to record the change on 15th and 30th day of treatment ($F(2,124) = 372.03$, $p < 0.001$). There was no significant effect of group $F(2, 62) = 0.358$, $p = 0.70$ or group × time interaction ($F(4,124) = 1.189$, $p = 0.319$). Groups were comparable. The effect size of Groups II and I showed a small effect compared to Group III. Effect size in all groups on 15th and 30th day were large (Table 5). The effect of interventions on other scales like HARS, BAI, WHO quality of life -BREF, CGI Improvement and Efficacy is already reported [34] and were similar to assessments through AAA scale.

4. Discussion

The present study detailed the development and validation of a comprehensive anxiety assessment scale based on Ayurveda science, the Ayurveda Anxiety Assessment scale (AAA) for the first time. We were able to evaluate comprehensively an Ayurveda Assessment tool for anxiety disorders. We have studied the reliability, validity and sensitivity to change of AAA and are promising. AAA covers all important features of anxiety like worry, anxiety, fear, and somatic symptoms as well as all major manifestations of anxiety spectrum disorders. Reliability and content validity were assessed through interrater agreement and all such measures showed encouraging results as all items scored between the range of 0.32–0.90 in Factor Analysis.

Sensitivity to change was assessed through a randomized clinical trial. Intervention with Clonazepam, *Manasamitravataka*, *Manasamitravataka* and *Shirodhara* was evaluated in patients of GAD with social phobia. Outcomes assessed through the clinical assessment scales other than AAA have already been reported. AAA assessment was comparable to other clinical anxiety scales (HARS, BAI) both before and after treatments. AAA was also comparable to other scales like WHO Quality of Life-Bref (WHOQOL Bref), Clinical Global Impression Scales (CGI-severity, improvement, and efficacy). Suggesting it to effectively note the comprehensive improvement of Anxiety patients. It effectively picked the clinical change on the 15th and 30th day of interventions. This study also demonstrated that *Manasamitravataka* and *Shirodhara* preserve slow-wave sleep and promote sleep continuity in anxiety patients [35].

Reliability, validity and sensitivity to change are widely used tools to assess psychometric properties of new scales. Beliefs about Emotions Scale (BES) [36] assessment showed good

Table 3
Factor analysis of AAA items.

Factor	Number of Items	Items and Factor value
1	8	*Majjashosha* (giddiness) (0.90), *Pralapa* (speech disturbance) (0.73), *Karshnya* (derangement in body complexion) (0.65), *Atopa* (abdominal gurgling sounds) (0.54), *Karsha* (loss of weight) (0.32), *Admana* (abdominal distention with flatus) (0.42), *Balaupaghata* (debility) (0.35), *Malasanga* (constipation) (0.35)
2	4	*Bhaya* (anxiety) (0.86), *Shoka* (sadness) (0.66), *Karsha* (loss of weight) (0.62), *Admana* (abdominal distention with flatus) (0.35)
3	6	*Asthishoola* (pain) (0.86), *Atopa* (abdominal gurgling sounds) (0.52), *Admana* (abdominal distention with flatus) (0.61), *Samjna* nasha (disturbance in orientation and consciousness) (0.41), *Malasanga* (constipation) (0.43), *Nidranasha* (sleep disturbance) (0.56)
4	3	*Dainya* (disturbed mind) (0.83), *Moha* (worry) (0.79), *Indriya upaghata* (sensory and motor deficits) (0.78)
5	2	*Moha* (worry) (0.41), *Ushna kamita* (desire for warm environment/cold intolerance) (0.90)
6	4	*Karshnya* (derangement in body complexion) (0.44), *Atopa* (abdominal gurgling sounds) (0.40), *Balaupaghata* (debility) (0.76), *Malasanga* (constipation) (0.51)
7	2	*Kampa* (involuntary movements) (0.81), *Nidranasha* (sleep disturbance) (0.59)

Table 4
Comparison of Clinical variables in all the three groups at baseline- HARS, AAA, BAI, BDI, CGI-Severity. Values are expressed as Mean, standard deviations (S.D).

Sl. No	Clinical Variables	Time of Assessment	GP-I (n = 22)	GP −II (n = 22)	GP-III (n = 21)	p value
1	HARS	Pre treatment	31.58 ± 3.23	32.63 ± 3.31	31.85 ± 4.28	0.732
2	BAI	Pre treatment	26.50 ± 5.13	30.63 ± 5.32	26.57 ± 7.92	0.055
3	BDI	Pre treatment	13.66 ± 4.70	14.41 ± 2.31	12.52 ± 3.74	0.498
4	AAA	Pre treatment	18.27 ± 3.81	19.27 ± 2.84	16.95 ± 3.80	0.104
5	CGI-Severity	Pre treatment	4.50 ± 0.51	4.82 ± 0.52	4.38 ± 0.49	0.441

AAA-Ayurveda Assessment scale for Anxiety, HARS-Hamilton Anxiety Rating Scale, BAI-Beck Anxiety Inventory, BDI-Beck Depression Inventory, CGI-Clinical Global Impression.

Table 5
Effect of Interventions on AAA scale. Expressed in Mean ± Standard Deviation. *p < 0.05, **p < 0.01, ***p < 0.001.

Clinical variables	Groups I (n = 22) II (n = 22) III (n = 21)	Baseline	15th day	30th day	p value			Effect size		Effect Size	
					BL-15th day	BL-30th day	15th −30th day	BL-15th day	BL-30th day	Gp I-Gp III	Gp II-Gp III
AAA	I	18.27 ± 3.81	11.50 ± 3.06	7.90 ± 3.37	<0.001***	<0.001***	<0.001***	0.69	0.82	0.04	0.12
	II	19.27 ± 2.84	12.00 ± 2.89	8.27 ± 3.93	<0.001***	<0.001***	<0.001***	0.78	0.84		
	III	16.95 ± 3.80	11.61 ± 3.21	6.90 ± 4.22	<0.001***	<0.001***	<0.001***	0.60	0.78		

AAA-Ayurveda Assessment scale for Anxiety.

internal reliability, validity (good correlation with a measure of negative perfectionism, dysfunctional attitudes, self-sacrifice, depression, anxiety, and fatigue) and sensitivity to change when compared before and after Cognitive behaviour therapy. Personal and Social Performance scale (PSP) [37]was assessed through reliability (test-retest and interrater reliability), validity (good correlation with CGI-Severity and Positive and Negative Syndrome Scale) and sensitivity to change. Sensitivity to change was explored through correlations of change in PSP with change in Clinical Global Index-Severity and Positive and Negative Syndrome Scale (PANSS) in acute symptoms of schizophrenia. Lower Extremity Functional Scale (LEFS) [38] assessment in patients with lower extremity impairments secondary to stroke showed good reliability, validity, and sensitivity to change. Reliability through test-retest, validity through six other measures of function and correlation was moderate to high, sensitivity to change were noted in single-item linear analog scale (LAS) of function before and after intervention.

Applying conventional research models on complementary and alternative medicines (CAM) needs to be done with caution. CAM research needs to address the model validity as CAM has unique diagnostic taxonomy, treatment process, and therapeutic context [39]. Hence, clinical assessment scales developed through Ayurveda meeting the model validity along with the rigor of conventional research model is the current need. The current study validates the AAA scale as per the guidelines documented in the ancient Ayurveda texts. Items are clear, unambiguous, and contextual meeting the criteria of *Pushkaladhan.* Items are adequately condensed and elaborated meeting the *uddesh* and *nirdesh tantayukti* respectively and are in a systematic order (*Kramagatartha*). AAA is easy to administer and can be used by any trained clinician (*T. shishya buddhi hitam*) and meets *A. prakaranmiti* and *AMishribhuta prakaranam* (congruent and divergent validity), AAA meets the criteria of *siddhanta* as it is tested by many methods and different scholars. It has all the attributes of a gold standard scale *(sarva tantra siddhanta)*. AAA assesses the predominant *Raja* and *Vata* along with *Tama* dosha, that form the important pathological substrates of anxiety in Ayurveda. Items are the observations of the *Vagbhata*, author of one of the main ancient Ayurveda textbooks. Hence, AAA meets the model validity of the Ayurveda science.

The present study has many strengths. The study evaluated AAA scale through various parameters of reliability (interrater agreement, internal consistency), validity (content, criteria validity of convergent and divergent, concurrent, face) and sensitivity to change. Various components of AAA have been picked by exploring the Ayurveda ancient textbooks, with inputs from Ayurveda physicians and a psychiatrist in the context of anxiety disorders. Limitations of the study are the small sample size. Further studies with a large sample, which are multi-centric may give better information on the AAA scale. Reliability can be further assessed through a one-week test−retest method as such approaches study whether the scale is overly sensitive to daily variations in mood. Evaluation of other types of anxiety disorders like panic disorder, agoraphobia etc. will also be helpful.

5. Conclusion

AAA is a clinician rated assessment scale with a minimum score of 0 and maximum score of 54, administered by a trained health professional, time frame covered in the assessment is the past 2 weeks and the time required to complete the rating is 15−20 min. The study showed that AAA mean scores for mild anxiety were 6.7−11.23, moderate anxiety was 11.23−18.3 and severe was above 18.3. AAA is not a diagnostic tool. Outcomes may point to significant pathological anxiety but not the presence of an anxiety disorder. AAA scale meets the model validity and psychometric parameters like reliability, validity, and sensitivity to change.

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Author contributions

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Conflict of interest

There is no conflict of interest.

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