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Measuring the ICD-11 adjustment disorder concept: Validity and sensitivity to change of the Adjustment Disorder – New Module questionnaire in a clinical intervention study

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Abstract

Adjustment disorder (AjD) is a frequent but under-researched diagnosis due in part to a lack of specific symptom criteria and adequate tools of measurement. The ICD-11 for the first time proposes a positive symptom catalogue to define AjD. This study presents a validation of the Adjustment Disorder – New Module (ADNM), the first symptom severity measure for AjD according to the ICD-11 concept. Validity and sensitivity to change were investigated in a sample of 190 individuals with a DSM-IV diagnosis of AjD. The ADNM scales demonstrated convergent and discriminant validity for anxiety symptoms (Hamilton Anxiety Scale; psychic anxiety r = 0.18–0.31), functional impairment (Sheehan Disability Scale; r = 0.18–0.47), and depression (Montgomery–Asberg Depression Scale; r = 0.13–0.30). At baseline 78% of the individuals with a DSM-IV diagnosis of AjD were also classified so by the ADNM. Repeated-measures ANOVA indicated significant ADNM-symptom decrease during treatment, replicating the patterns of the Hamilton Anxiety Scale, Sheehan Disability Scale, and Clinical Global Impression Scale. This article presents the first use of the ADNM as a measure for ICD-11 AjD in a randomized-controlled intervention study of AjD. It provides support for the construct validity and sensitivity to symptom change of this scale during pharmacological treatment.

KEYWORDS

methodology, randomized controlled trial, self-report measure, stress response disorders

1 | INTRODUCTION

Adjustment disorder (AjD) is one of the most frequent mental disorders in clinical practice, accounting for up to 30% of all cases in psychiatric and liaison samples (Casey, 2014; Evans et al., 2013; Stirman, DeRubeis, Crits-Christoph, & Rothman, 2005). The International Classification of Diseases, 11th revision (ICD-11) proposal is for AjD to be included, for the first time, in a separate grouping of disorders specifically associated with stress, along with post-traumatic stress disorder, complex post-traumatic stress disorder and prolonged grief disorder (Maercker et al., 2013a, 2013b). This article presents an evaluation of the Adjustment Disorder – New Module (ADNM) questionnaire (Einsle, Köllner, Dannemann, & Maercker, 2010), a self-report measure of AjD according to the ICD-11 concept (Maercker et al., 2013a, 2013b) in an intervention study.

AjD is defined as an emotional disturbance that develops as a consequence of a significant psychosocial stressor such as divorce, illness or disability, socio-economic problems or conflicts at home or work. The emotional and behavioral symptoms in AjD include otherwise normative reactions that manifest more intensely than usually expected when individuals are confronted with a specific stressor and are associated with significant social, occupational, and/or academic performance-related impairments (American Psychiatric Association, 2013; World Health Organization, 1992). The diagnostic concepts, as implemented in the current Diagnostic and Statistical Manual of Mental Disorders, 5th edition (DSM-5) and ICD-10, have been criticized for their lack of specific symptom descriptions and the difficulty of distinguishing between AjD and normal, adaptive stress reactions (Baumeister & Kufner, 2009; Casey & Bailey, 2011; Casey, 2014). Although DSM-5 now conceptualizes AjD as a stress-related syndrome in a separate chapter of "Trauma and Stress Related

Disorders", which perhaps was the most important change from DSM-IV (Strain & Friedman, 2011), the current diagnostic construct is crucially dependent on an exclusion criterion, so that a diagnosis of AjD is rarely applicable when another mental disorder is present.

The future ICD-11 diagnostic concept of AjD will implement fundamental changes and for the first time outlines a positive symptom catalogue for AjD rather than determining it with exclusion criteria (Maercker, Einsle, & Kollner, 2007). It describes a maladaptive reaction to an identifiable psychosocial stressor or multiple stressors (e.g. single stressful event, ongoing psychosocial difficulty or a combination of stressful life situations) with two explicitly defined core symptom groups, namely (1) preoccupation (previously termed intrusions; e.g. including excessive worry, recurrent and distressing thoughts about the stressor, or constant rumination about its implications) and (2) failure to adapt that significantly interferes with everyday functioning manifested for example by difficulties concentrating or sleep disturbances resulting in performance problems at work or at school. These symptoms are suggested to emerge within a month of the onset of the stressor(s) and tend to resolve in six months unless the stressor persists for a longer duration. Furthermore, it has been also proposed that an ICD-11 AjD diagnosis must be associated with significant distress or significant impairment in personal, family, social, educational, occupational, or other important areas of functioning.

In addition to the proposed ICD-11 AjD core symptoms, associated features reflecting ICD-10 and DSM-5 subtypes have been suggested: avoidance of stimuli, thoughts, and feelings connected to the stressor, depression, anxiety, or impulsive symptoms (Maercker et al., 2013b). An earlier proposal had included avoidance symptoms among the core symptom groups (e.g. Einsle et al., 2010; Maercker et al., 2007), though these were later reclassified as associated features (Maercker et al., 2013a, 2013b). The ICD-11 proposal is not to distinguish different subtypes of AjD.

The proposed diagnostic guidelines are based on empirical evidence from population based studies (e.g. Dobricki, Komproe, de Jong, & Maercker, 2010; Maercker et al., 2012) and were in essence approved as ICD-11 beta-version proposals by the World Health Organization (Maercker et al., 2013b). The revised ICD-11 concept of AjD already has been tested in a vignette-based clinical survey. Findings support the new concept (Keeley et al., 2016) and will be further tested in clinical trials in order to establish its clinical validity and utility more comprehensively.

There are no established questionnaires that specifically measure AjD-symptoms according to ICD-10 or DSM-5 and the category is not or only inadequately included in several diagnostic interviews such as the Structured Clinical Interview for DSM-IV (First, Spitzer, Gibbon, & Williams, 2002) or the Composite International Diagnostic Interview (CIDI; Kessler & Üstün, 2004). The ADNM questionnaire is the first instrument capable of capturing the ICD-11 concept of AjD. Its validity and psychometric properties have been evaluated in a series of studies (Bley, Einsle, Maercker, Weidner, & Joraschky, 2008; Dannemann et al., 2010; Einsle et al., 2010; Maercker et al., 2007), though its sensitivity to change has never been investigated in a clinical trial. The current investigation aims to examine the validity of the ADNM questionnaire in two ways which are of clinical relevance: (1) by establishing convergent and discriminant validity with regard to questionnaires that have not been included in prior validation studies and that are clinician-rated instead of self-report measures as used in the previous studies; (2) by investigating its sensitivity to change in an intervention study including four points of measurement. A specific focus is on investigating AjD core symptoms which are featured in the proposed ICD-11 diagnostic guidelines.

2 | METHOD

2.1 | Procedure and participants

Data of the present investigation were collected in a prospective multicenter study aiming at evaluating the efficacy of two psychotropic drugs (treatment 1: Etifoxine; treatment 2: Alprazolam) for treating AjD with symptoms of anxiety in a non-inferiority randomized-controlled design (see Stein, 2015). Recruitment took place among male and female outpatients aged 18–65 years at 17 primary care locations in Cape Town and Johannesburg, South Africa. The assessment of the multicenter study was conducted on four occasions, at baseline, day 7, day 28, and day 35 of the trial. Ethical approval was obtained from institutional and national review boards on human experimentation and participants gave written informed consent.

Inclusion criteria of the intervention study were a DSM-IV diagnosis of AjD with symptoms of anxiety (American Psychiatric Association, 2000) as well as baseline scores ≥20 on the Hamilton Anxiety Rating Scale (HAM-A; Hamilton, 1959), ≥ 5 on the Sheehan Disability Scale (SDS; Sheehan, Harnett-Sheehan, & Raj, 1996), and <20 on the Montgomery–Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979). Exclusion criteria included the presence of comorbid psychiatric or substance use disorders or suicidal thoughts as assessed by the Mini-International Neuropsychiatric Interview (Sheehan et al., 1998). A dropout analysis of this sample across the measurements has been presented by Stein (2015).

The final sample consisted of 190 individuals who received at least one dose of study treatment with at least one endpoint assessed. The age ranged between 18 and 65 years (mean [*M*] = 39.57, standard deviation [SD] = 12.29). More females (72.6%) than males (27.4%) participated in the study. The most common stressful life event responsible for the AjD symptomatology was related to family/love life (39.5%), followed by work/school (36.8%), financial problems (12.5%), and other (11.1%). Table 1 presents an overview of the symptom endorsement at baseline for anxiety (HAM-A), depression (MADRS), and functional impairment (SDS).

2.2 | Measures

2.2.1 | Adjustment Disorder – New Module (ADNM; Einsle et al., 2010)

The present study used the 29-item version of the ADNM questionnaire. In the first part, respondents report whether during the previous two years they had experienced any of six types of acute psychosocial stressors (e.g. divorce, death of a family member) and 10 types of persistent stressors (e.g. conflict at work, serious illness). In the second part, a 4-point Likert scale allows to rate the frequency of symptoms for the most distressing event (1 = never, 2 = rarely, 3 = sometimes,

TABLE 1 Sample characteristics at baseline

	N	Percentage
Gender		
Males	52	27.4
Females	138	72.6
Age group		
18–38	92	48.4
39–65	98	51.6
Type of main distress		
Family, love life	75	39.5
Work, school	70	36.8
Finance	24	12.6
Other	21	11.1
HAM-A total score		
20–24	48	25.3
25–30	69	36.3
>30	73	38.4
MADRS total score		
< 10	57	30.0
10–14	60	31.6
15–19	73	38.4
SDS total score		
0–10	4	2.1
11–20	116	61.1
21–30	38	20.0
missing	32	16.8

Note: HAM-A, Hamilton Anxiety Rating Scale; MADRS, Montgomery–Asberg Depression Rating Scale; SDS, Sheehan Disability Scale.

4 = often). The ADNM measures the two core symptom groups of preoccupations (5 items) and failure to adapt (5 items), as well as associated features of anxiety (3 items), depressive mood (6 items), avoidance (7 items), and impulse disturbance (3 items) which allow clinicians and researchers the possibility of a more precise identification of the syndrome presentation. The 29-item version of the ADNM (ADNM-29) does not include an impairment criterion ("The symptoms cause clinically significant impairment in social, occupational, or other important areas of functioning"). This item was added in the process of conceptualizing the 20-item version of the questionnaire (Maercker et al., 2012).

The ADNM-29 shows good internal consistency for core and associated features (α = 0.71 to α = 0.90) and satisfactory test–retest reliability rtt = 0.61 for preoccupations, rtt = 0.84 for failure to adapt, and rtt = 0.71–0.79 for the associated features subscales over a period of six weeks (Einsle et al., 2010). Previous findings of studies with the ADNM-29 had also shown that individuals with heightened scores indicated increased impairment on the Symptom Checklist-90 (SCL-90-R; Derogatis, 1977), the Impact of Event Scale (IES-R; Horowitz, Wilner, & Alvarez, 1979), and the Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), representing satisfactory convergent validity (Dannemann et al., 2010; Einsle et al., 2010). The ADNM-29 questionnaire was able to differentiate between emotional and non-emotional ICD-10 diagnoses (Bley et al., 2008). Finally, individuals with raised ADNM-29 scores report higher psychological strain and more motivation to start psychotherapy (Dannemann et al., 2010). Overall, these various measurements attest good psychometric properties to the ADNM and encourage further exploration.

Promising findings with the concept of the ADNM were also achieved with the ADNM-20 (Glaesmer, Romppel, Brähler, Hinz, & Maercker, 2015), a shorter version of the ADNM-29. For the ADNM-20, the 29-item version of the ADNM was shortened based on factor analytic studies that examined the structure of the questionnaire (Einsle et al., 2010; Maercker et al., 2007) and the criterion of impairment was added (the ADNM-20 is available at: http://www.psychology.uzh.ch/en/chairs/psypath/Research-Dissemination/self-report.html). In a more recent study using a sample of Swiss burglary victims, the internal consistency of the ADNM-20 sum score was α = 0.94, preoccupations showed α = 0.89, and failure to adapt α = 0.81. Satisfactory retest-reliability over a six-week period was demonstrated (r = 0.85–0.92 for the different subscales; Lorenz, 2016). Using latent class analysis on the ADNM-20, Glaesmer et al. (2015) examined whether the associated features subscales represent distinct factors in a representative sample of the German general population. The subscales were highly correlated and the findings suggest that AjD is a uni-facetted concept, as proposed for ICD-11.

2.2.2 | Diagnostic algorithm of the ADNM for this study

Individuals with a probable diagnosis of AjD according to the ICD-11 proposal endorsed at least three out of five core symptoms of preoccupations and failure to adapt (at least three items indicating a score of ≥3 on the 4-point rating scale). According to the inclusion and exclusion criteria of the study, this diagnostic algorithm is in line with the ICD-11 beta requirement on duration of symptoms and on the exclusion of other disorders. Subthreshold status was assigned if in each core symptom group at least two symptoms were endorsed. If no full diagnostic threshold or subthreshold status was determined, participants were assigned to the low symptom group.

2.2.3 | Anxiety rating scale (HAM-A; Hamilton, 1959)

The HAM-A is a widely used 14-item scale originally designed for patients diagnosed with anxiety neuroses. Two subscales of psychic anxiety and somatic anxiety were derived by factor analysis. The measure has been applied to individuals suffering from a variety of anxiety disorders such as panic, phobia, and generalized anxiety disorder (McDowell, 2006). Items are rated on a 5-point scale by a clinician, the HAM-A total score is calculated by the sum of the responses. A review on the validity of the HAM-A indicated good psychometric properties in clinical and non-clinical populations. Cronbach's α ranged from 0.68 to 0.93 (M = 0.83) and satisfactory sensitivity and specificity were estimated at approximately 0.80 (Bjelland, Dahl, Haug, & Neckelmann, 2002).

2.2.4 | Montgomery–Asberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979)

The MADRS measures depressive symptoms and was designed to be particularly sensitive to change when applied in clinical trials. It consists of 10 items rated on a 6-point Likert scale by a clinician. A symptom is considered to be present with a score of at least two. The scale shows appropriate inter-rater reliability (r = 0.76), satisfactory convergent validity with general measures of depression such as the Hamilton

Depression Rating Scale was (r = 0.45–0.47), as well as the capacity to differentiate between treatment responders and non-responders (Davidson, Turnbull, Strickland, Miller, & Graves, 1986). The MADRS was only assessed at baseline.

2.2.5 | Sheehan Disability Scale (SDS; Sheehan et al., 1996)

The SDS is a self-report questionnaire measuring functional impairment in the domains of work, social, and family life. It is rated on a 10-point metric scale. The sum of the three domains yields the SDS global score, ranging from 0 to 30. The internal consistency in a primary care sample was good (α = 0.83) and convergent validity was satisfactory in respect to general mental health as measured by the Short-Form Health Survey (r = −0.44; Luciano et al., 2010). The SDS has been shown to possess adequate sensitivity to impairment and changes as a result of treatment in different anxiety disorders (Olfson et al., 1997).

2.2.6 | Clinical Global Impression (CGI) scale (Guy, 1976)

The Clinical Global Impression (CGI) scale provides a brief assessment of a clinician's view of a patient's global clinical severity and is used as a standard primary outcome measure in pharmacological trials. Two one-item measures evaluate the severity of psychopathology and the change from the initiation of a treatment on a 7-point rating scale. The utility of the CGI scale as an index of global improvement was confirmed in different samples (e.g. Zaider, Heimberg, Fresco, Schneier, & Liebowitz, 2003).

2.3 | Statistical analysis

Data were analyzed using IBM SPSS Statistics version 23. Dropouts were excluded from the analyses at the measurement point concerned. Excluding dropouts, there were less than 2% missing values for each item of the ADNM questionnaire. Missing values were replaced using the subject-specific median on the subscale level, provided that no more than 30% of the answers were missing. Firstly, to test for convergent validity, Spearman rank correlations between ADNM scores and various measures of psychological health were computed at baseline. Secondly, a repeated-measures analysis of variance (ANOVA) was conducted with one factor time (four assessment points). The dependent variables were indicators of symptom burden (ADNM, HAM-A, CGI, SDS). Greenhouse–Geisser correction was applied for all outcome variables due to non-homogeneous variances and Bonferroni corrected comparisons of mean differences and comparisons of mean differences were Bonferroni corrected. Finally, sensitivity to change of the ADNM questionnaire in respect of the ICD-11 AjD diagnosis was investigated by evaluating the diagnostic status in respect of the frequency of falling into specific threshold and subthreshold categories during the four measurements of the treatment phase (probable diagnosis, subthreshold status, low symptoms).

3 | RESULTS

3.1 | Correlations of outcome measures

Table 2 presents the correlations between the ADNM and the other measures. The ADNM total score correlated significantly with mostly strong effect sizes with all ADNM subscales (r = 0.62–0.83), whereas correlation coefficients of its subscales correlated with a medium to large extent (r = 0.39–0.63). With regard to discriminant validity, the ADNM total score and subscales significantly correlated to a small to medium extent with the HAM-A total score, which was mainly due to the HAM-A psychic anxiety subscale that correlated more highly (r = 0.18–0.31) than the somatic anxiety subscale (r = 0.05–0.24) with ADNM scores. HAM-A somatic anxiety was significantly related to the ADNM total score, the anxiety, avoidance, and the impulse control subscales but not to the core symptoms of preoccupations or failure to adapt, nor with depressive symptoms. All aspects of the ADNM were significantly associated to a small to medium extent with the SDS total score, measuring functional impairment (r = 0.22–0.45). Similarly, most ADNM subscales correlated significantly and with small or medium effect sizes with the SDS dimensions of work/school, social life, and family life/home responsibilities (r = 0.11–0.40). The ADNM anxiety, impulse control, and preoccupations, however, were unrelated with some dimensions of the SDS. Correlations with the MADRS total score were of small to medium effect size (r = 0.13–0.30) and significant for all ADNM scales except associated anxiety features.

3.2 | Symptom development

In order to evaluate sensitivity to change, the progression of AjD symptoms measured by the ADNM and other outcome measures was investigated. Means and standard deviations of the total sample are presented in Table 3. ANOVA revealed a significant main effect of time for all outcome measures.

Post hoc contrasts indicated a significant decrease of symptoms from baseline to day 7 and from day 7 to day 28 in the total sample (Table 4). There were no significant differences between day 28 and follow up (day 35) in respect of the ADNM subscale means, indicating that treatment effects were persistent.

3.3 | Diagnostic status

In a final step of evaluating the ADNM sensitivity to change, particularly in regard of the ICD-11 proposal (Maercker et al., 2013b), the diagnostic status was compared across the four measurement points (Table 5). At baseline, 77.9% of individuals were screened positively for ICD-11 AjD according to the new core symptoms, however without taking impairment into account. The proportion of individuals fulfilling the suggested ICD-11 diagnostic guidelines gradually declined during treatment and were similarly low at the last treatment assessment and the follow-up. Individuals categorized as subthreshold cases with two out of five ADNM ICD-11 AjD symptoms instead three out of five from the preoccupations and failure to adapt symptom groups counted 16.8% of the sample at baseline, increased to 44.2% by day 7 and thereafter decreased again in favor of a low symptoms group (not more than one ADNM ICD-11 AjD symptom in each of both symptom groups). The number of individuals showing the lowest ICD-11 AjD symptomatology increased from baseline to day 28 and remained similar at follow-up. Similarly, the HAM-A total scores were divided into four categories (Hamilton, 1959) in order to illustrate symptom progression over time. A striking decline of symptoms was observed during the first week,

TABLE 2 Intercorrelations of outcome measures in the total sample at baseline[a]

Measures total/subscale scores baseline	Correlation coefficients between total/subscale scores at baseline (Spearman)													
	1	2	3	4	5	6	7	8	9	10	11	12	13	14
ANDM total score (1)														
ADNM subscales:														
Preoccupations (2)	.769**													
Failure to adapt (3)	.823**	.524**												
Depressive mood (4)	.789**	.468**	.634**											
Anxiety (5)	.672**	.574**	.500**	.423**										
Avoidance (6)	.833**	.613**	.591**	.558**	.487**									
Impulse control (7)	.622**	.432**	.518**	.389**	.432**	.423**								
HAM-A total score (8)	.255**	.165*	.217**	.217**	.244**	.181*	.251**							
Psychic anxiety (9)	.310**	.246**	.275**	.283**	.304**	.202**	.183*	.782**						
Somatic anxiety (10)	.132	.047	.084	.111	.124	.114	.243**	.852**	.378**					
Sheehan disability scale total score (11)	.452**	.279**	.379**	.471**	.245**	.361**	.215**	.209**	.214**	.150				
Work/school (12)	.303**	.208**	.305**	.312**	.248**	.167**	.154	.217**	.296**	.076	.592**			
Social life (13)	.389**	.274**	.308**	.372**	.161*	.400**	.111	.243**	.176*	.229**	.771**	.232**		
Family life/Home responsibilities (14)	.243**	.115	.211**	.288**	.125	.178*	.124	.107	.070	.135	.739**	.173*	.475**	
MADRS total score (15)	.297**	.207**	.294**	.299**	.125	.231*	.151*	.142	.295**	-.031	.132	.131	.054	.049

Measures total/subscale scores baseline

Correlation coefficients between total/subscale scores at baseline (Spearman)

Note. *$p < .05$; **$p < .01$; [a]Coefficients are drawn from non-prametric correlations (Spearman) of baseline data from the total sample; ADNM, Adjustment Disorder – New Module, HAM-A, Hamilton Anxiety Rating Scale, MADRS, Montgomery Asberg Depression Rating Scale; SDS, Sheehan Disability Scale.

TABLE 3 Significance of change of the various outcome measures from baseline to day 35

Measures	Baseline		Day 7		Day 28		Day 35		Main effect time	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	F(*df*)	p
ANDM total score[a]	89.62	13.04	71.90	17.39	57.59	18.66	57.79	21.90	243.94(2.39)	.00
ADNM subscales[b]										
Preoccupations	16.59	2.82	13.3	3.75	10.39	3.87	10.54	4.26	207.17(2.57	.00
Failure to adapt	14.94	2.91	12.07	3.26	9.72	3.38	9.85	3.91	181.82(2.53)	.00
Depressive mood	16.39	3.32	13.05	3.39	10.73	3.53	10.66	4.16	183.16(2.50)	.00
Anxiety	9.65	1.97	7.52	2.38	5.79	2.39	6.06	2.72	182.17(2.65)	.00
Avoidance	21.56	3.8	18.03	4.48	14.7	5.11	14.32	5.66	158.26(2.46)	.00
Impulse control	10.48	1.78	7.94	2.35	6.26	2.35	6.36	2.83	205.14(2.51)	.00
HAM-A total score[c]	29.87	6.73	13.39	6.83	7.06	6.40	7.71	8.26	669.37(2.34)	.00
CGI-C score[d]			1.97	.88	1.44	.71	1.61	1.03	25.56(1.75)	.00
Sheehan disability scale (total score)[e]	17.75	4.8	11.10	6.03	5.99	5.62	7.54	5.62	255.46(2.35)	.00

[a]N = 176–190;

[b]N = 176–190;

[c]N = 177–190;

[d]N = 176–187;

[e]N = 144–15; ADNM, Adjustment Disorder – New Module; HAM-A, Hamilton Anxiety Rating Scale; CGI, Clinical Global Impression Scale; SDS, Sheehan Disability Scale.

Day 7 Day 28 Day 35.

TABLE 4 Mean differences between assessments of selected Adjustment Disorder – New Module (ADNM) scores and Hamilton Anxiety Rating Scale (HAM-A)

		Mean differences of selected ADNM scores				
Assessment	Number	ADNM total	Pre-occupations	Failure to adapt	Anxiety	HAM-A
1 to	2	18.35***	3.36***	3.03***	2.17***	16.42***
	3	32.38***	6.23***	5.36***	3.85***	22.88***
	4	32.00***	6.08***	5.17***	3.55***	22.08***
2 to	3	14.03***	2.87***	2.33***	1.67***	6.47***
	4	13.65***	2.73***	2.15***	1.38***	5.66***
3 to	4	0.38	0.14	0.19	0.29	0.80

Note: *$p < 0.05$; **$p < 0.01$; ***$p < 0.001$ (Bonferroni corrected for multiple comparisons).

TABLE 5 Adjustment Disorder – New Module (ADNM) diagnostic status and Hamilton Anxiety Rating Scale (HAM-A) scores during treatment

	Diagnostic status according to ADNM core symptoms			HAM-A total score categories			
Assessment time	Probable diagnosis[a,d] *N* (%)	Subthreshold status[b,d] *N* (%)	Low symptoms[c,d] *N* (%)	>30 *N* (%)	25–30 *N* (%)	18–24 *N* (%)	<18 *N* (%)
Baseline (*N* = 190)	148 (77.9)	32 (16.8)	10 (5.3)	73 (38.4)	69 (36.3)	48 (25.3)	—
Day 7 (*N* = 189)	77 (40.5)	84 (44.2)	29 (15.3)	3 (1.6)	7 (3.7)	40 (21.1)	140 (73.7)
Day 28 (*N* = 178)	32 (16.8)	71 (37.4)	76 (45.8)	2 (1.1)	1 (0.5)	9 (4.7)	169 (88.9)
Day 35 (*N* = 176)	35 (18.4)	67 (35.3)	74 (46.3)	5 (2.6)	3 (1.6)	16 (8.4)	153 (80.5)

[a]Fully applies to the diagnostic algorithm: for core symptom groups (preoccupations, failure to adapt) at least three out of five symptoms.

[b]In each of the core symptom groups (preoccupation, failure to adapt) at least two symptoms but no full diagnostic threshold status.

[c]No full diagnostic threshold or subthreshold status.

[d]A symptom is counted as present if the individual item score is equal or more than three (≤ 3 on the 4-point Likert scale).

reflected in a decrease of individuals in the highest category (score > 30) from 38.4% to 1.6% of the sample. Moreover, by day 7, most individuals had transited to the lowest group with a score less than 18 points.

4 | DISCUSSION

The ADNM questionnaire is a theory-driven instrument that measures AjD as a stress response disorder, according to the new diagnostic concept of the ICD-11 (Maercker et al., 2007, 2013a, 2013b). The future AjD definition has reacted to critiques of the AjD conceptualizations and now presents more approachable diagnostic criteria which help to sharpen the definition of the disease and should render the diagnostic process more clear. The present article presents the results on the first use of the ADNM in a randomized-controlled intervention study. It provides support for the convergent and discriminant validity of the ADNM questionnaire as well as for its sensitivity to symptom change during pharmacological treatment.

In a first step, the correlations of the ADNM subscales were investigated, which were slightly higher in the present sample than in a sample of psychosomatic outpatients or a sample of individuals with clinically relevant cardiac arrhythmias (Einsle et al., 2010). This may be explained by higher homogeneity of the present sample, which fully consisted of individuals suffering from AjD with anxious symptomatology. The correlations of the ADNM scores and anxiety as measured by the HAM-A (Hamilton, 1959), however, are relatively low (r = 0.18–0.34). This finding is consistent with the possibility that the ADNM mainly addresses the ICD-11 AjD construct, while the HAM-A mostly assesses generalized anxiety disorder symptoms. However, the relatively low correlations of HAM-A and ADNM scores could be also due to variances in the assessment method as the HAM-A is a clinician-rated measure while the ADNM is based on self-report information. Similar discordances between self-report and clinician-rated measures were found for depressive symptoms (e.g. Bailey & Coppen, 1976; Enns, Larsen, & Cox, 2000) and may be due to differences in item content or due to specific subgroups of patients whose introspective perception differs from observer ratings (Enns et al., 2000). Correlations with total functional impairment measured by the SDS (Sheehan et al., 1996) were of a medium extent. Patients with a higher ADNM symptom load showed more functional impairment in their everyday life with regard to work, social, and family life. This is in line with previous findings that individuals suffering from many AjD symptoms as measured by the ADNM tend to rate their ability to cope with a stressor as insufficient (Einsle et al., 2010). Overall, the present results further establish the convergent validity of the ADNM questionnaire.

4.1 | Symptom development

A second aim of this study was to explore sensitivity to change of the ADNM questionnaire. It was found that the ADNM total score and subscales decreased across treatment, thereby replicating the pattern of the well-established HAM-A questionnaire. The validity of this finding is further supported by a similar reduction in functional impairment, measured by the SDS. Finally, the CGI scale (Guy, 1976), representing a clinician's view of the patient's mental health status, also demonstrates improvement during treatment. The findings with regard to the ADNM questionnaire are in line with the results presented in the original publication on this sample, which demonstrated that the medical treatments administered to participants in this study were effective in reducing anxiety (Stein, 2015). These analyses indicate that ADNM is a suitable measurement to assess symptom strength of ADNM and score changes over time and agrees with change patterns of other established symptom severity measures.

Seventy-eight per cent of the individuals in this sample who had received a DSM-IV diagnosis of AjD at baseline were screened positively for AjD by the ADNM questionnaire, taking into account the core symptom groups of preoccupations and failure to adapt. The algorithm represents the proposed diagnostic concept of the ICD-11 which differs significantly from DSM-IV criteria of AjD on which the inclusion into the study was based. As the ICD-11 concept is more specific (Maercker et al., 2013a), the lower percentage of clinically significant AjD in this sample is an expectable result while our results on the change in diagnostic status further confirm that the ADNM is a suitable instrument to assess changes in ICD-11 AjD diagnostic status over time.

While a rapid decrease in anxiety symptoms from baseline to day 7 was observed on the HAM-A, the ADNM showed a steadier decline across treatment. This discrepancy may be due to the fact that the ICD-11 construct measured by the ADNM views anxiety as an accessory rather than a core symptom of AjD. This speculation would favor the ADNM for the assessment of ICD-11 AjD in this type of investigation, and should be confirmed in future studies. It is also plausible that cognitive symptoms of preoccupations such as excessive worries or recurrent and distressing thoughts about the stressor, as well as failure to adjust to the event such as difficulties concentrating and sleeping, or the neglect of pleasant activities are not fully addressed by the medication provided in the trial. By the end of the treatment, only 46% of the individuals reported low symptoms of AjD while 89% of the sample had migrated into the lowest anxiety symptoms group defined by the HAM-A questionnaire. In order to treat the full range of AjD symptoms, additional intervention may be needed. Several studies show successful treatment of AjD symptoms by cognitive behavioral interventions (e.g. Van der Klink, Blonk, Schene, & Van Dijk, 2003), brief dynamic psychotherapy (Ben-Itzhak et al., 2012; Maina, Forner, & Bogetto, 2005), or client centered psychotherapy (Altenhöfer, Schulz, Schwab, & Eckert, 2007). However, caution is required in the interpretation of these findings as the studies used ICD-10 and DSM-IV conceptualizations of AjD.

There are some limitations to the current study that deserve emphasis. The sample consisted of individuals who experienced AjD characterized by anxious symptoms which limits generalization of the results to manifestations of AjD with different symptom profiles. Furthermore, the ADNM is the only questionnaire measuring AjD in general and capturing the ICD-11 AjD concept in particular. Since no gold standard measure exists, sensitivity to change was established by comparison to HAM-A scores. The fact that HAM-A is designed for capturing anxious symptomatology but not the full spectrum of AjD is another limitation of the present study. Finally, the ADNM-29 questionnaire applied in this study did not include the criterion of clinically significant impairment which is proposed to be part of the future ICD-11 definition of AjD.

In conclusion, the results of the current study contribute to the empirical body of literature on the validity of the ADNM questionnaire (Bley et al., 2008; Dannemann et al., 2010; Einsle et al., 2010) and expand them now to the ICD-11 diagnostic proposal of AjD. The results of the current study support the use of the ADNM in clinical trials due to its sound convergent and discriminant validity as well as good sensitivity to change. Due to the lack of specific diagnostic criteria and adequate measurement instruments, scientific interest in AjD has been limited in the past. A reliable and valid questionnaire for AjD such as the ADNM will significantly facilitate future research.

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