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Functional Assessment in Greek Tension-Type Headache Sufferers: Validity, Reliability, Responsiveness and Psychometrics of the Migraine Disability Assessment Questionnaire (MIDAS)

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Authors' contributions

This work was carried out in collaboration between all authors. Author GG designed the study, wrote the protocol, and wrote the manuscript. Authors AP and PC managed the literature searches, the experimental process and the collection of the data. All authors read and approved the final manuscript.

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ABSTRACT

Introduction: Functional assessment in painful musculoskeletal disorders such as tension-type headache requires valid, reliable and sensitive instruments. MIDAS (Migraine Disability Assessment questionnaire) is an internationally well-known functional index which has not been validated in Greek headache sufferers.
Aims: The aim of the study was to assess headache related disability in Greek tension-type headache sufferers using MIDAS. The validity, reliability, responsiveness and psychometrics of the Greek MIDAS version were examined.
Study Design: A multicenter prospective design was followed.
Place and Duration of Study: The study took place in a medical rehabilitation unit and two physiotherapy private practices in Athens, from January - December 2010.
Methodology: A sample of 121 patients(101 women, age: 39.4±12.7; 20men, age: 35.5 ± 8.8,

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years) with tension-type headache was recruited. Internal consistency was computed and test-retest reliability was examined for a 7-day period. Responsiveness of the GR-MIDAS was tested before and after a behaviorally oriented physical therapy protocol. Convergent and divergent validity were also examined after comparing GR-MIDAS with SF-12, VAS, Pain Catastrophising Scale (PCS), Hospital Anxiety and Depression Scale (HAD) and Short-Form McGill Pain Questionnaire (SFMPQ).

Results: Cronbach's alpha (α) was satisfactory (0.80). Test-retest reliability was both excellent for the total score (ICC=0.95) and the individual items (0.87-0.98). Measures of responsiveness such as the Standardized Effect Size (SES=1.38) and the Standardized Response Mean (SRM=1.63) were shown to be acceptable, as well as the ROC curve statistic (AUC: 0.875 ±0.08). Convergent validity was evidenced (SF-12 vs MIDAS, r=-0.32, p<0.001), and also divergent validity [MIDAS vs $VAS_{average}$, r=0.31, p<0.01; MIDAS vs HAD: anxiety: r=0.17, NS, depression: r=016, NS; MIDAS vs PCS: r=0.13, NS; SFMPQ vs MIDAS: Affective: r=0.02, NS, Sensory: 0.11, NS].

Conclusion: The Greek version of MIDAS is a valid, reliable and sensitive functional measure for tension-type headache patients, comparable to the original version. The data of this study extend the psychometric properties of the instrument.

Keywords: MIDAS; Greek version; reliability; validity; responsiveness; sensitivity; psychometrics.

1. INTRODUCTION

Tension-type headache is the most often described active headache disorder with 42% prevalence in the general population [1]. In active headaches, the quality of life and function in the patients is a context where a number of instruments have been developped. One of the most used tools in the literature is the Migraine Disability Assessment questionnaire (MIDAS) [2,3].

MIDAS has been used in most types of headaches, including migraine [4], tension-type headache [5] and others [5,6]. It measures headache-related disability in all life domains over a 3-month period. It contains seven questions with a simple scoring method where only the first five questions are scored in order to produce the disability of headache score (range: 0-270). These first five questions investigate the influence of headache on three domains: paid work (questions 1 and 2), household work (questions 3 and 4) and impact of headache on recreational, social and family activities (question 5). The two additional questions concern headache frequency and headache intensity and aim to provide clinical information to the clinician. The total MIDAS score is the sum of the days affected regarding the first five questions. Four disability MIDAS grades are obtained: Grade I, little or no disability with the scores between 0-5, Grade II, mild disability with the scores between 6-10, MIDAS grade III (score 11 to 20; moderate disability), and MIDAS grade IV (score 21 or above; severe disability) [2,3].

The validity and reliability of MIDAS has been assessed in different linguistic variations, with satisfactory results. Generally, the internal consistency of the instrument, as assessed by the Cronbach's alpha (α) statistic, has been estimated from 0.69 – 0.87, and the test-retest reliability (r) from 0.44 – 0.98 (ICC and Pearson's or Spearman's correlation statistics). Specifically, the UK study showed an α=0.73 and r=0.83 [2,3], the Japanese version α=0.69 and r=0.83 [7], the Italian α=0.70 and r=0.77 [8], the French version r=0.84 [6], the Korean study α=0.75 and r=0.67-0.98 [9], the Taiwan α=0.79 and r=0.67 [10], the Turkish studies [11] α=0.87 and r=0.44-0.78 and [12] α=0.79 and r=0.83-0.90, the US study α=0.83 and r=0.84 [13], the Indian study α>0.90 and r=0.94 [4], the Malaysian version α=0.80-0.84 and r=0.73 [14], and the Iranian study α=0.80 and r=0.54-0.71 [5].

Unfortunately, it was not possible to locate in the literature a published valid and reliable version of the MIDAS appropriate for Greek speaking subjects. In order to be able to assess the functional status of headache sufferers, a cross-cultural adaptation of MIDAS is imperative. The aim of this study was to assess the validity, reliability and responsiveness of the Greek version of the MIDAS (MIDAS-GR) in a group of headache sufferers.

2. MATERIALS AND METHODS

2.1 The original MIDAS and the Greek Version (MIDAS-GR)

The adaptation of MIDAS into Greek followed the guidelines published in the literature [15,16]. These included: the translation, the synthesis, the back-translation and the initial field testing

phases. A team of a psychologist, a physiotherapist, an occupational therapist, a medical doctor, a headache sufferer whose native language was English and a teacher of English as a foreign language, translated the questionnaire into Greek encouraged to strive for idiomatic rather than word-for-word translation, according to the published guidelines [16]. Cultural and vocabulary adaptations were agreed in a consensus meeting. Two bilingual professionals completed the back translation of the preliminary version, attempting conceptual equivalence, acceptability and adaptation of wording to the target population. No conceptual differences were noted between the two versions and the provisional-final questionnaire was tested. Field-testing of the provisional version included its completion by a small sub-selection of patients (n = 16) of the target group, by means of a one to- one interviews in order to examine the potential distribution of responses, comprehension and to ensure linguistic, face and content validity. The findings of this preliminary field-testing indicated that the adapted version appeared to retain its equivalence to the original.

2.2 Subjects

The first 121 tension-type headache patients who referred to physiotherapy/acupuncture in three private clinics were asked to participate in the study. All patients agreed and written consent was obtained to participate in the study. All authors declare that a copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal.

The patients' selection procedure was made by a neurology medical practice according to the criteria valid at the moment of the study (ICHD-II). Patients with tension-type headache who were found potentially appropriate by the neurologist to benefit from physiotherapy or acupuncture, were referred to the three private centers and were included in the study. The majority of patients were suffering from episodic tension type headache (74,5%, N=90) and the rest from chronic tension type headache (25,5%, N=31) according to the ICD-10 criteria (G44.2).

During the first visit (assessment) (t1), the MIDAS-GR and a battery of questionnaires were administered (see Instruments). A subgroup of patients (N = 39), randomly selected, was asked to complete the MIDAS-GR again after 7 days (t2) before initiating any treatment. A further randomly selected group of patients (N = 22) was asked to complete for a third time the MIDAS-GR (t3), together with their opinion if they were improved or not, after completion of a treatment protocol (see Testing the scale). Ethical approval was granted by the TEI of Athens in the context of conducting research towards the completion of undergraduate dissertations. All parts of the study were developed within the principles and standards of the 1964 Declaration of Helsinki and in accordance with the Guidelines on the Practice of Ethics Committees in Medical Research Involving Human Subjects.

2.3 Instruments

The patients completed the following questionnaires (at t1):

- A general socio-demographic questionnaire in order to extract epidemiology data, based on the Diamond Headache questionnaire [17]. [Appendix 2]
- The Greek version of the migraine disability assessment questionnaire (MIDAS-GR), as formulated by the adapting procedure. [Appendix 1]
- The Greek version of the short-form McGill Pain Questionnaire (SF-MPQ). The SF-MPQ consists of 15 descriptors (11 sensory; 4 affective) which are rated on an intensity scale from 0-3 (0 = none, 1 = mild, 2 = moderate, 3 = severe). Three pain scores are derived from the sum of the intensity rank values of the words chosen for sensory (SFMPQ-S), affective (SFMPQ-A) and total descriptors (SFMPQ-T) [18,19].
- The Visual Analogue Scale (VAS) in order to describe the average intensity of pain during the last week. This 10 cm line, anchored with the phrases ‘‘no pain’’ and ‘‘worst possible pain’’, is a well-validated measure in chronic pain [20].
- The Greek version of the hospital anxiety and depression scale (HADs) (HAD-GR). A 14-item questionnaire (scaled 0–3) of two subscales, the 7-item HAD-Anxiety and the 7-item HAD-Depression, used to assess the levels of anxiety and depression, with validity and reliability shown for the Greek version [21].
- The Greek version of short-form SF-12 (SF). The 12 items in the SF-12 are a subset of those in the SF-36; SF-12 includes one or two items from each of the eight health concepts. Thus, the SF-12 measures eight concepts commonly

represented in widely used surveys: physical functioning, role limitations due to physical health problems, bodily pain, general health, vitality (energy/fatigue), social functioning, role limitations due to emotional problems and mental health (psychological distress and psychological well being). The scale officially has been adapted into Greek by the institute [22]

- A Greek version of the Pain Catastrophizing Scale (PCS). Pain catastrophizing is an important cognitive construct that has been linked with many aspects of the pain experience, including pain intensity, emotional distress, pain-related disability, and pain behaviour. The Pain Catastrophizing Scale (PCS), an instrument often used to assess this construct, reflects three aspects of catastrophizing: Rumination, Magnification, and Helplessness. The answers "never, in small degree, in mediocre degree, to a large extent, always" are marked by 0 - 4 degrees respectively. The Greek version has been shown to retain the properties of the original [23].

2.4 Procedure

Participants completed the questionnaires set (at t1), in a random order so to avoid bias (e.g. favoring of the first questionnaire tested). The administrator used a standardized script to explain the requirements of the questionnaires, and any questions were answered.

2.5 Testing the Scale

Short-term test–retest reliability was estimated on a subgroup of 39 headache patients randomly selected from the initial sample. The questionnaire was administered to the patients for the first time (t1) during their initial visit to the clinic. A repeat administration (t2) after 7 days and before first treatment session (without any active treatment in-between) was chosen in order to minimise clinical or cognitive changes but also to reduce any chance recall of previous answers. Responsiveness was examined for the MIDAS-GR after the implementation of a behaviourally oriented physical therapy/acupuncture program, in a subgroup of 22 subjects (t3). The physiotherapy approach was not structured and included any approach selected by the therapists (e.g. electrotherapy, deep friction massage, acupuncture, myofascial release techniques, etc.). Construct validity was assessed in the form of convergent and divergent validity. Convergent (criterion related) validity was studied by correlating the SF-12 and MIDAS-GR, since both tools estimate functionality. The expected correlation however between measures is not expected high, since the two tools intend to assess different aspects of functionality; the MIDAS estimates functionality regarding headaches and the SF–12 evaluates the functional capacity of quality of life, in general. Divergent validity was studied by correlating the MIDAS total score with variables assessing different concepts than function, such as: average pain intensity during last week assessed by a visual analogue scale (VAS: 0–10 cm); anxiety and depression assessed by the Greek version of the HAD; degree of catastrophising assessed by the Greek version of the PCS scale; sensory and affective parameters of pain assessed by the Greek version of the short-form MPQ.

2.6 Statistical Analysis

All data inserted in the statistical analyses were examined for approximation of normal distribution (Kolmogorov– Smirnov goodness of fit test), skewness and kurtosis. Descriptive statistics and frequencies were also computed. Significance was set at $p < 0.05$ and it was adjusted when needed (Bonferroni correction). SPSS 17.0© was employed in the analyses.

Internal consistency of the MIDAS-GR was assessed using the Cronbach's alpha statistic (alpha – α), independently for each item and the total score.

Test–retest reliability was mainly examined with the Intraclass Correlation Coefficient (ICC) for the scores taken within 7 days (t1 and t2), allowing for the level of chance agreement and distribution effects. Both individual items and total score were examined using the ICC.
The non-parametric Spearman rank correlation coefficient (rho – ρ) was used for the question "how intense is your headache today" (PPI), because a normal distribution could not be demonstrated. For all parameters studied, Spearman coefficient values were interpreted as being an excellent relationship $\rho > 0.91$, good $\rho = 0.90–0.71$, moderate $\rho=0.70–0.51$, fair $\rho= 0.50–0.31$, and little or no relationship $\rho < 0.30$. The parametric Pearson rank correlation coefficient (r) (Pearson product moment correlation with extensions) was used in all other correlation analyses.

Much discussion exists concerning the calculation of responsiveness [24]. According to Terwee et al [24], responsiveness can be classified into three categories: (A) responsiveness as the ability to detect change in general (sensitivity to change); (B) responsiveness as the ability to detect clinically important change, and (C) responsiveness as the ability to detect real change in the concept being measured. In this study, it was attempted to calculate measures from all three categories, using the measurements at t1 (baseline) and t3 (after-Rx). Specifically, it was computed:

- From category A. The effect size [ES = Mean (t1- t3) of the total group/SDt1 of the total group] and the paired t test in all patients who underwent treatment (p-value). An effect size of less than 0.20 can be considered trivial, between 0.20 and 0.50 small, between 0.50 and 0.80 moderate, and greater than 0.80 large. A higher ES indicates greater sensitivity to change [24,25].
- From category B. The standardised effect size [SES = Mean (t1–t3) for the improved /SD t1 for the improved] and the paired t tests in patients who did improve (good to very good improvement) and did not improve (slight to no improvement) with the determination of important change according to the patient (p-value).
- The standardised response mean (SRM) [SRM = of the total group/SDt3 of the total group] is considered a more effective summary of the signal to noise ratio than SES, because it avoids the standard error of the mean in the denominator and is therefore less influenced by sample size [25]
- From category C. The receiver operating curve (ROC) with determination of important change according to the patient [area under the curve–AUC]. The patients determined their improvement using a three-options variable [(1): No improvement, (2): Slight improvement, (3): Good to very good improvement].

3. RESULTS

The characteristics of the subjects of the study are depicted in Table 1A and 1B.

3.1 Internal Consistency

The Cronbach's a value was found to be 0.80 (N=121) for all patients when considering all 7 items, although separately for men was higher (a=0.93, N=20) than women (a=0.74, N=101), probably due to the significant larger sample size. The inter-item correlation did not show any irregularities or redundant items (Table 2).

Table 1A. Patients demographic characteristics (N=121)

	N (%)	Mean ± SD (years)	
Men	20 (16.5%)	35.5 ± 8.8	
Women	101 (83.5%)	39.4 ± 12.7	
	Office work	55	(45.5%)
Type of work	Light manual	42	(34.7%)
	Heavy manual	24	(19.8%)
	Employee	80	(66.1%)
	Free lancer	18	(14.9%)
Occupation	Retired	4	(3.3%)
	Unemployed	1	(0.8%)
	Housework	13	(10.7%)
	Missing	5	(4.2%)

Table 1B. Patients demographic characteristics (N=121) – general health status

General Health (self-report)	Excellent	4	(3.3%)
	Very Good	36	(29.8%)
	Good	50	(41.3%)
	Satisfactory	28	(23.1%)
	Bad	2	(1.7%)
	Missing	1	(0.8%)

3.2 Reliability

Test-retest reliability within a week was shown to be excellent for MIDAS total score (ICC=0.95) and for the individual items (0.87-0.98) (Table 3).

3.3 Responsiveness

Responsiveness was examined by means of three different categories (see Methods). In the same way the results are presented.

3.3.1 Responsiveness as sensitivity to change

The effect size as a measure of internal responsiveness showed large values for the total MIDAS score (0.84), and moderate to large values for each separate question (0.43-3.17) (Table 4).

3.3.2 Responsiveness as the ability to detect clinically important change

The Standardized Effect Size and the SRM as measures to detect clinically important difference showed great values for the total score (SES=1.38, SRM=1.63), and the separate questions (SES=0.43-3.05, SRM=1.20-2.21) (Table 4 & 5).

3.3.3 Responsiveness as the ability to detect real change in the concept measured

The responsiveness of MIDAS score (with the important change determined by the patient), as measured with the ROC statistic produced an Area Under the Curve (AUC) that is satisfactory with scores of AUC=0.875 ± 0.08 (range 0.71 – 1.04), $p<0.05$ (Fig. 1).

3.4 Convergent Construct Validity

In order to make inferences about the convergent construct (criterion related) validity of MIDAS, the correlation between MIDAS scores and SF-12 was estimated. The results were satisfactory with a fair to moderate relationship, in general (MIDAS total score compared to SF-12 total score: r= -0.32, $p<0.001$). Separate correlations between all MIDAS and SF-12 questions are depicted in Table 6.

3.5 Divergent Construct Validity

No correlation was noted between MIDAS score and a diversity of other pain-related constructs. Thus, no significant relationship emerged for MIDAS and pain catastrophising (PCS) (r=0.13, NS), anxiety (HAD anxiety scale) (r=0.17, NS), depression (HAD depression scale) (r=0.16, NS), and qualitative characteristics of pain such as the SFMPQ sensory (r=0.11, NS) and affective scores (r=0.02, NS).

It was interesting that although the multidimensional pain scales (SFMPQ sensory and affective scores) did not correlate with MIDAS score, the mono-dimensional intensity of

Table 2. Inter-item correlation matrix for all patients and all items (N=121)

Inter-item Correlation Matrix	MIDAS question 1	MIDAS question 2	MIDAS question 3	MIDAS question 4	MIDAS question 5	MIDAS question 6	MIDAS question 7
MIDAS Question 1	1.000	0.327	0.710	0.306	0.549	0.385	0.216
MIDAS Question 2	0.327	1.000	0.307	0.870	0.643	0.538	0.133
MIDAS Question 3	0.710	0.307	1.000	0.324	0.407	0.307	0.281
MIDAS Question 4	0.306	0.870	0.324	1.000	0.665	0.521	0.152
MIDAS Question 5	0.549	0.643	0.407	0.665	1.000	0.454	0.119
MIDAS Question 6	0.385	0.538	0.307	0.521	0.454	1.000	0.103
MIDAS Question 7	0.216	0.133	0.281	0.152	0.119	0.103	1.000

Table 3. ICC values for MIDAS total score and separate items (N=39)

(N=39)	ICC values (range)
MIDAS Total Score at t_1 vs t_2	0.953 (0.910-0.975)
MIDAS Question 1 at t_1 vs Q1 at t_2	0.976 (0.955-0.988)
MIDAS Question 2 at t_1 vs Q2 at t_2	0.960 (0.924-0.979)
MIDAS Question 3 at t_1 vs Q3 at t_2	0.965 (0.933-0.981)
MIDAS Question 4 at t_1 vs Q4 at t_2	0.935 (0.876-0.966)
MIDAS Question 5 at t_1 vs Q5 at t_2	0.923 (0.852-0.959)
MIDAS Question 6 at t_1 vs Q6 at t_2	0.938 (0.882-0.968)
MIDAS Question 7 at t_1 vs Q7 at t_2	0.874 (0.760-0.934)

Table 4. The Effect Size (ES) and Standardised Response Mean (SRM) statistics calculated for MIDAS

				Paired Differences						
	Mean	N	SD	Mean	SD	t	df	sig	ES	SRM
Midas score (baseline)	67.7	22	57.1	48.00	36.0	6.256	21	<0.001	0.84	1.63
Midas Score after-Rx	19.7	22	29.5							
Question 1 (baseline)	6.1	22	12.2	5.18	10.8	2.260	21	<0.05	0.43	2.21
Question 1 after-Rx	0.9	22	2.4							
Question 2 (baseline)	16.8	22	15.5	10.36	9.7	5.028	21	<0.001	0.66	1.12
Question 2 after-Rx	6.5	22	9.2							
Question 3 (baseline)	10.8	22	11.4	7.96	11.6	3.219	21	<0.005	0.70	1.59
Question 3 after-Rx	2.9	22	5.0							
Question 4 (baseline)	20.2	22	15.3	14.18	12.7	5.252	21	<0.001	0.93	1.61
Question 4 after-Rx	6.0	22	8.8							
Question 5 (baseline)	13.8	22	20.4	10.32	13.6	3.563	21	<0.005	0.51	1.22
Question 5 after-Rx	3.5	22	8.5							
Question 6 (baseline)	30.6	22	20.4	19.59	15.8	5.823	21	<0.001	0.96	2.10
Question 6 after-Rx	11.1	22	9.3							
Question 7 (baseline)	8.0	22	1.2	3.91	2.0	9.178	21	<0.001	3.17	2.20
Question 7 after-Rx	4.1	22	1.8							

Table 5. The Standardized effect size statistic for the improved patients

				Paired Differences					
	Mean	N	SD	Mean	SD	t	df	Sig. (2-tail)	SES
Slight to No Improvement									
Midas score (baseline)	128.0	4	107.41	53.75	78.74	2.511	3	0.087 *(NS)*	N/A
Midas Score after-Rx	54.3	4	57.59						
Good to Very good Improvement									
Midas score (baseline)	54.3	18	30.74	42.28	28.29	6.341	17	<0.001	1.38
Midas Score after-Rx	12.0	18	11.97						
Question 1 (baseline)	3.3	18	7.04	3.00	7.10	1.792	17	0.091	0.43
Question 1 after-Rx	0.3	18	0.67						
Question 2 (baseline)	14.9	18	13.35	10.39	9.94	4.436	17	<0.001	0.78
Question 2 after-Rx	4.6	18	5.72						
Question 3 (baseline)	8.5	18	7.52	6.17	9.43	2.774	17	0.013	0.82
Question 3 after-Rx	2.3	18	5.10						
Question 4 (baseline)	19.1	18	13.55	15.61	13.17	5.031	17	<0.001	1.15
Question 4 after-Rx	3.4	18	3.87						
Question 5 (baseline)	8.5	18	9.93	7.11	8.75	3.448	17	<0.005	0.72
Question 5 after-Rx	1.4	18	2.30						
Question 6 (baseline)	27.4	18	16.58	18.83	15.21	5.252	17	<0.001	1.14
Question 6 after-Rx	8.6	18	6.47						
Question 7 (baseline)	7.9	18	1.35	4.11	2.14	8.154	17	<0.001	3.05
Question 7 after-Rx	3.8	18	1.86						

pain as measured by VAS and a verbal rating scale (PPI) showed little to fair relationship (0.31-0.44) (Table 7).

4. DISCUSSION

The aim of this study was to examine the reliability, validity and responsiveness of the Greek version of the MIDAS (MIDAS-GR) questionnaire, one of the most useful tools for assessing function in headaches [2,8]. The MIDAS-GR was shown to have satisfactory internal consistency, excellent test-retest reliability and acceptable responsiveness in order to be used as an outcome measure. Its construct validity was evidenced both as convergent and divergent validity.

The comprehension of MIDAS-GR was mostly excellent during our study since patients did not ask for particular clarifications and gave consistent answers, double checked by the examiners.

4.1 Internal Consistency

The Cronbach's alpha statistic was found to be 0.8 (N=121) for MIDAS-GR. This is considered a

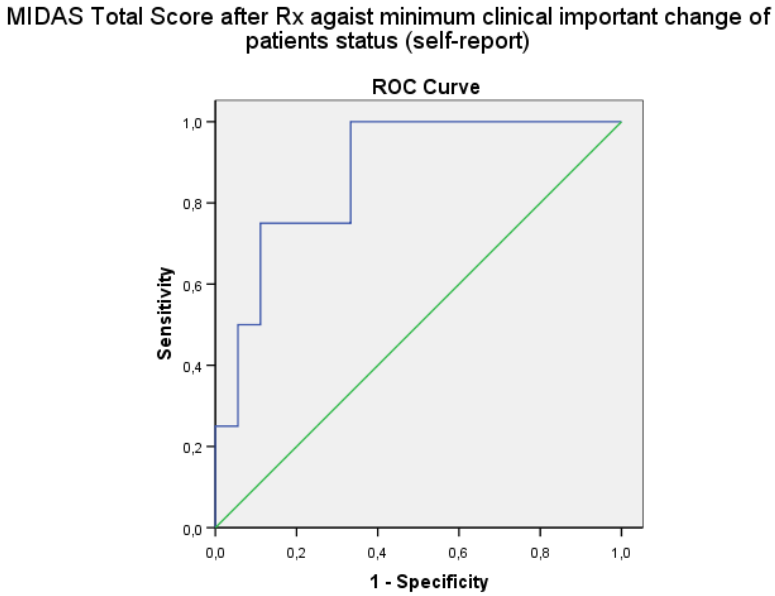

Fig. 1. ROC statistic for MIDAS total score against the important change when determined by the patient

Table 6. Bivariate correlation between MIDAS and SF-12 questions

	MIDAS Q 1	MIDAS Q 2	MIDAS Q 3	MIDAS Q 4	MIDAS Q 5	MIDAS Q 6	MIDAS Q 7
SF12 Question 1	0.344(**)	0.049(NS)	0.330(**)	0.155(NS)	0.253(**)	0.195(*)	-0.059
SF12 Question 2A	-0.278(**)	0.014(NS)	-0.343(**)	-0.090(NS)	-0.026(NS)	-0.262(**)	-0.262(**)
SF12 Question 2B	-0.289(**)	-0.173(NS)	-0.329(**)	-0.258(**)	-0.243(**)	-0.330(**)	-0.329(**)
SF12 Question 3A	-0.259(**)	-0.277(**)	-0.319(**)	-0.339(**)	-0.180(*)	-0.350(**)	-0.258(**)
SF12 Question 3B	-0.254(**)	-0.252(**)	-0.379(**)	-0.270(**)	-0.174(NS)	-0.345(**)	-0.310(**)
SF12 Question 4A	-0.235(**)	-0.222(*)	-0.340(**)	-0.303(**)	-0.242(**)	-0.301(**)	-0.175(NS)
SF12 Question 4B	-0.278(**)	-0.255(**)	-0.310(**)	-0.349(**)	-0.296(**)	-0.270(**)	-0.268(**)
SF12 Question 5	0.267(**)	0.444(**)	0.416(**)	0.515(**)	0.354(**)	0.372(**)	0.477(**)
SF12 Question 6A	0.124(NS)	0.202(*)	0.132(NS)	0.216(*)	0.183(*)	0.189(*)	0.220(*)
SF12 Question 6B	0.194(*)	0.148(NS)	0.167(NS)	0.163(NS)	0.224(*)	0.140(NS)	0.255(**)
SF12 Question 6C	-0.198(*)	-0.228(*)	-0.241(**)	-0.314(**)	-0.313(**)	-0.163(NS)	-0.258(**)
SF12 Question 7	-0.242(**)	-0.287(**)	-0.332(**)	-0.385(**)	-0.444(**)	-0.295(**)	-0.109

**: p<.05, **: p<.001, NS: non-significant*

Table 7. Bivariate correlation between MIDAS Total Score and other pain constructs.

Pearson's Correlation (r) (N=121)	**MIDAS Total score (Q1-Q5)**
Short Form McGill - Sensory score (Q1-11)	0.109 (NS)
Short Form McGill - Affective score (Q12-15)	0.024 (NS)
VAS average for last week	0.305(**)
VAS max for last week	0.320(**)
VAS today	0.439(**)
How intense is your pain today?	*(Spearman's ρ)* 0.395(**)
HAD Anxiety score	0.174 (NS)
HAD Depression score	0.156 (NS)
PCS Total Score	0.127 (NS)

***: p<.001, *: p<.05, NS: non-significant*

satisfactory value capable to evidence the sound internal consistency of the instrument. On top of that, a separate inter-item correlation matrix was computed in order to confirm the finding. Indeed, Table 2 demonstrates the correlation coefficient among all questions. With correlation values that do not exceed 0.9, it is realized the different nature of each construct measured by MIDAS,

showing no redundant items. Our results are in perfect accordance with most studies in the literature [5,6,10,12-14], very close to others [2,3,9] and in some distance from a few (lower values [7,8], higher values [4,11]). The homogeneity of our sample (patients referred to physiotherapy after initial medical examination) may be an important factor contributing to the relatively high value of internal consistency. It cannot though be justified why two studies in the literature have presented such high Cronbach's values [4,11].

4.2 Test–retest reliability

Test-retest reliability after a week was shown to be excellent in our study (ICC=0.89). This finding is in accordance with the rest of the literature [2,3,6,7,9,12,13], despite the fact that lower values have been presented [5,8,10,11,14]. The standardised procedure that was followed and the relatively homogenous sample may be the reasons of the high degree of reproducibility in our study. In general, our data together with the literature can safely claim the reproducibility of the MIDAS instrument from 2 to 21 days.

4.3 Responsiveness

Responsiveness of MIDAS was shown in three different ways. Using SES, SRM and ROC analysis, it was shown that MIDAS is a quite sensitive measure in depicting the change after treating headache patients. Actually, it is the first time in the literature that it is evidenced the treatment result of a structured physiotherapy/ acupuncture behaviorally oriented program. With an impressive reduction in MIDAS total score mean values (from 106 to 35), MIDAS managed to illustrate the subjective experience of improvement that patients reported. The Area under the curve in our study reached an impressive 0.875, $p < .001$, when in another MIDAS responsiveness study was computed at AUC=0.7, $p < .001$[26]. However, in the latter, a general approach of primary care treatment of migraine was described, without any further explanations about the type or details of what treatment was followed (possibly pharmaceutical?). This great difference in ROC values between the two studies, apart from the difference in the type of selected treatment, it could possibly be attributed to the different type of headache complaints that were treated. In our study tension type headaches were treated, where a physiotherapy (including acupuncture) treatment protocol has possibly more to offer than for migraine type of headaches. On top of that, our patient group was homogenous because it was initially screened by a medical doctor for its appropriateness to refer to physiotherapy. This detail differentiates the quality of the sample and may be responsible for the higher values in the ROC analysis.

4.4 Psychometrics – Construct Validity

MIDAS-GR was examined for its construct validity in two ways: through convergent and divergent construct validity. By comparing MIDAS with other completely different constructs such as the sensory and affective pain score (SFMPQ), level of depression, anxiety (HAD) and catastrophising (PCS) we would expect no correlation, since MIDAS is a measure of disability and it should be clearly distinguished from other known constructs. This was actually evidenced by our findings with non significant correlation between MIDAS and the above constructs, confirming that headache related disability as measured by MIDAS is a separate distinctive measure and cannot be explained or predicted by them.

On the contrary, one would expect that a specific-condition functional index such as MIDAS would show some degree of correlation when compared to more general quality of life health-related measures that include estimation of function (convergent/criterion related validity). It was our purpose to investigate the relationship between MIDAS and SF-12. The reason that SF-12 was selected in favor of the more classic SF-36, it was purely on practical grounds in order to minimize the examination time of the patients. Besides, it has been shown the very close relationship of SF-36 and SF-12 [27]. MIDAS and SF-12 were found to be inversely moderate correlated ($r = -0.32$, $p<0.001$). Moderate correlations can be justified if we consider that SF-12 is a general tool, while MIDAS is specially designed for evaluation of headache disability. The literature supports our findings since two studies have examined the relationship of SF-36 and MIDAS with very close results [5, 27]. Fuh and Wang [27] presented a range of $r=-0.30$ to $r=-0.53$. $p<0.01$ across all SF-36 subscales, whereas Alireza et al. [5] in a very recent paper described values above $r > -0.2$, $p<0.001$. These higher MIDAS scores that are accompanied by lower SF-12 scores in our study, they can be perceived as a proof to convergent validity.

Interestingly, MIDAS was shown to correlate significantly with the measure of pain intensity (VAS). All VAS measurements for the last seven days (VASmax, VASaverage, VAStoday) were moderate correlated (0.38, 0.36, 0.47 respectively) with MIDAS, explaining the 13%-22% of the variance of MIDAS, indicating that the two constructs are related. This is not uncommon in the literature [5, 28] where similar values have been described (MIDAS vs VAS/NRS: 0.36, $p<0.001$ [5]). An explanation for this finding is plausibly given by Stewart and colleagues [28]: "..by definition, since the MIDAS score is implicitly based on headache frequency, the number of disability days from headache are central to the score. Moreover, since there is a pain threshold for disability, the MIDAS score is also indirectly related to the level of pain experienced from headache..". Despite the moderate association between them, function and pain intensity or headache frequency are still separate constructs irrespective the fact that they may be related.

4.5 Limitations of the Study

One of the primary concerns for this study was the homogenous sample that was employed. Participants were referred to physiotherapy/acupuncture services after consulting a neurologist and were selected on the basis of their appropriateness for physiotherapy/acupuncture treatment. This resulted for the majority of the patients, to mostly include in the study physiotherapy/acupuncture sensitive tension-type headache cases. In this sense, the generalizability of the sensitivity results may be somewhat compromised when concerning to other types of headaches. Additionally, since this study's aim was to assess the validity, reliability, responsiveness, and psychometrics of MIDAS tool and not to provide epidemiology or other data regarding headaches, it is considered of secondary importance what was the type of headache treatment selected, especially when taking into account that the golden standard of improved or not status was defined by the patient himself.

Another limitation of this study was that the samples for reliability and sensitivity testing were not completely independent. The respondents filled the questionnaires twice in the reliability testing and twice for the sensitivity study. Unfortunately there were cases that patients participated in both studies (reliability and sensitivity), whereas the ideal would be to have completely independent samples. Although, we feel that this may not affect in a serious way the final results, we properly mention this drawback in the limitations section.

5. CONCLUSION

The Greek version of MIDAS was shown to be a valid, reliable and responsive instrument that attains the properties of the original questionnaire and follows the standards of the rest cross-culturally adapted versions of MIDAS. It is suitable for use with Greek speaking headache populations and can be used for estimating headache-related disability.

COMPETING INTERESTS

Authors declare that no competing interests exist.

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APPENDIX

1. The Greek version of MIDAS questionnaire (1 page)

ΕΡΩΤΗΜΑΤΟΛΟΓΙΟ MIDAS

1. Πόσες μέρες τους τελευταίους 3 μήνες απουσιάζατε από την εργασία σας ή από το σχολείο εξαιτίας του πονοκέφαλου σας;.....
2. Πόσες μέρες τους τελευταίους 3 μήνες η παραγωγικότητα σας στη δουλειά ή στο σχολείο μειώθηκε στο μισό ή και περισσότερο εξαιτίας του πονοκέφαλου σας; (μην συμπεριλάβετε τις μέρες που υπολογίσατε στην ερώτηση 1, δηλαδή τις μέρες που απουσιάζατε από τη δουλειά ή το σχολείο).....
3. Πόσες μέρες τους τελευταίους 3 μήνες δεν ήσασταν σε θέση να κάνετε τις δουλειές του σπιτιού εξαιτίας του πονοκέφαλου σας;.....
4. Πόσες μέρες, τους τελευταίους 3 μήνες, η παραγωγικότητα σας στις δουλειές του σπιτιού μειώθηκε στο μισό ή και περισσότερο εξαιτίας του πονοκέφαλου; (μην συμπεριλάβετε τις μέρες που υπολογίσατε στην ερώτηση 3, δηλαδή τις ημέρες που δεν ήσαστε σε θέση να κάνετε τις δουλειές του σπιτιού).....
5. Πόσες μέρες, τους τελευταίους 3 μήνες, δεν ήσαστε σε θέση να συμμετάσχετε σε οικογενειακές, κοινωνικές ή ψυχαγωγικές εκδηλώσεις εξαιτίας του πονοκέφαλού σας;.....

    A. Πόσες μέρες τους τελευταίους 3 μήνες είχατε πονοκέφαλο; (αν ο τελευταίος πονοκέφαλος κράτησε πάνω από 1 μέρα, μετρήστε όλες τις μέρες).....
    B. Σε μια κλίμακα 0 – 10, κατά μέσο όρο πόσο επώδυνοι ήταν οι πονοκέφαλοι; (0 = καθόλου πόνος, 10 = ο χειρότερος δυνατός πόνος).....

2. The questionnaire used to collect the sample's sociodemographic data (4 pages)

Ερωτηματολόγιο Αξιολόγησης Πονοκεφάλων

Ονοματεπώνυμο_____

Υπογραφή_____

Ημερομηνία _____ / _____ / _____

Παρατηρήσεις/Σχόλια:

_____

_____

_____

Το ερωτηματολόγιο αυτό θα μας βοηθήσει να κατανοήσουμε καλύτερα τα γενικότερ προβλήματα της υγείας σας.

Η συμπλήρωση του ερωτηματολογίου είναι εθελοντική. Παρακαλούμε, απαντήσετε σε όλες τις ερωτήσεις. Εάν το επιθυμείτε, μπορείτε να κάνε παρατηρήσεις στο τέλος του ερωτηματολογίου.

Όλα τα στοιχεία σας θα παραμείνουν εμπιστευτικά και η επεξεργασία τους γίνει από γιατρούς/φυσικοθεραπευτές που δεσμεύονται από το Ιατρικό απόρρητ

Α. Προσωπικά στοιχεία

1. Φύλο : α) Άνδρας ☐ β)Γυναίκα ☐

2. Έτος Γέννησης_____**3.Ύψος**_____**4.Βάρος**_____

5.Επαγγελματική Κατάσταση (σημειώστε √ στο κουτάκι που σας αφορά)

Μισθωτός	Αυτο-εργοδοτούμενος	Συνταξιούχος	Άνεργος	Οικιακά

6.Εργασία (σημειώστε √ στο κουτάκι που σας αφορά)

Γραφείο	Ελαφριά Χειρωνακτική	Βαριά Χειρωνακτική

Β. Γενική κατάσταση Υγείας

1. **Πώς θα χαρακτηρίζατε την κατάσταση της υγείας σας;**

Άριστη	Πολύ καλή	Καλή	Μέτρια	Κακή
1	2	3	4	5

2. Έχετε κάποιο από τα παρακάτω ιατρικά προβλήματα; (μπορείτε να σημειώσετε √ σε ένα ή περισσότερα κουτάκια που σας αφορούν)

Ναι	
☐	Καρδιοπάθεια
☐	Υπέρταση
☐	Οστεοπόρωση
☐	Καρκίνο
☐	Κατάθλιψη
☐	Οστεοαρθρίτιδα
☐	Ρευματοειδή αρθρίτιδα

Άλλο ιατρικό πρόβλημα :

_____

_____

_____

_____

_____

Γ. Σχετικά με τους πονοκεφάλους σας

1. Είναι η πρώτη φορά που έχετε πονοκεφάλους; α) Ναι β) Όχι

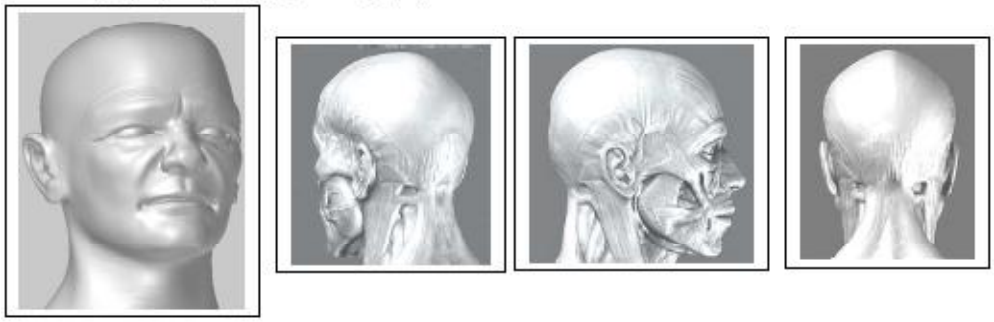
1α. Πριν από πόσο καιρό είχατε πονοκεφάλους για πρώτη φορά; .....

1β. Εάν είχατε και παλαιότερα, ποιες από τις παρακάτω θεραπείες ακολουθήσατε; (μπορείτε να σημειώσετε √ σε ένα ή περισσότερα κουτάκια που σας αφορούν)

Ναι			Ναι
☐	Καμία θεραπεία	Χειροπρακτική	☐
☐	Φαρμακευτική	Ανάπαυση στο κρεβάτι	☐
☐	Φυσιοθεραπεία	Εγχύσεις, διηθήσεις ουσιών	☐
☐	Γυμναστική/Περπάτημα/Κολύμβηση	Άλλο.....	☐
☐	Βελονισμο		☐

1γ. Ποιο ήταν το αποτέλεσμα των παραπάνω θεραπειών που ακολουθήσατε;

2. Οι ενοχλήσεις που αισθάνεστε είναι: (μπορείτε να σημειώσετε μία ή περισσότερες διαγραμμισμένες περιοχές που σας αφορούν)



3. Πόσο συχνοί είναι οι πονοκέφαλοι σος;

- ☐ Περισσότερες από μια φορά την ημέρα
- ☐ Μια φορά την ημέρα
- ☐ Περισσότερες από μια φορά την εβδομάδα
- ☐ Μια φορά την εβδομάδα
- ☐ Περισσότερες από μια φορά το μήνα
- ☐ Μια φορά το μήνα
- ☐ Μια φορά στους …… μήνες

4. Τελευταίος πονοκέφαλος πότε ήταν; …

5. Πώς θα αισθανόσασταν εάν έπρεπε να περάσετε την υπόλοιπη ζωή σας με τα συμπτώματα που έχετε σήμερα;

Πολύ δυσαρεστημένος	Ελαφρά δυσαρεστημένος	Αδιάφορα	Ελαφρά ευχαριστημένος	Πολύ ευχαριστημένος
1	2	3	4	5

6. (*για γυναίκες μόνο*) Θα συσχετίζατε τους πονοκεφάλους σας με την έμμηνο ρύση σας;

.....

7. Παρακάτω περιγράφονται κάποιες επιπλέον ερωτήσεις σε σχέση με τους πονοκεφάλους σας. Παρακαλούμε πολύ απαντήστε σε όλες τις ερωτήσεις ανάλογα με τα δικά σας συμπτώματα.

		Παντα	Πολύ συχνά	Δεν είμαι σίγουρος/η	Σπάνια	Ποτέ
1	Ο πονοκέφαλος ξεκινά από τη μια πλευρά του κεφαλιού;					
2	Ο πόνος είναι πιο δυνατός στη μια πλευρά του κεφαλιού;					
3	Ο θόρυβος ή το φως επιδεινόνει τον πόνο;					
4	Ο πόνος μετατίθεται από τη μία μεριά του κεφαλιού στην άλλη;					
5	Ο πονοκέφαλος σας προκαλεί έντονα συναισθήματα μελαγχολίας;					
6	Κατά τη διάρκεια του πονοκέφαλου τα κάτω και τα άνω άκρα παγώνουν;					
7	Κατά τη διάρκεια του πονοκέφαλου υγραίνονται/δακρύζουν τα μάτια σας, έχετε φαγούρα, νιώθετε κάψιμο;					
8	Κατά τη διάρκεια του πονοκέφαλου έχετε ενοχλήσεις στο στομάχι (π.χ "γουργουρίσματα");					
9	Κατά τη διάρκεια του πονοκέφαλου χάνετε την όρεξή σας;					
10	Ο πόνος εντοπίζεται και στις δύο πλευρές του κεφαλιού;					
11	Ο πόνος μοιάζει σαν «χτυπήματα με σφυρί»;					
12	Ο πόνος συζάνεται με τη κίνηση του κεφαλιού;					
13	Ξυπνάτε με πονοκέφαλο;					
14	Ο πονοκέφαλος σας ξυπνά κατά τη διάρκεια της νύχτας;					
15	Ο πονοκέφαλος υποχωρεί, όταν ξαπλώνετε;					
16	Ο πονοκέφαλος ξεκινά το πρωί και χειροτερεύει το απόγευμα;					
17	Οι αλλαγές του καιρού σας προκαλούν πονοκέφαλο;					
18	Ο πονοκέφαλος εμφανίζεται κατόπιν έντασης ή στρες;					

In Summary, the sociodemographic questionnaire includes questions regarding demographic data, such as name, gender, age, height, weight, type of work, the self-estimation of health status (excellent to bad) and the self-report of major medical problems. The questionnaire continues with questions regarding the status of the patients' headache with questions regarding the time since headache started, if there were previous treatments followed and what was the result of the treatments, where the pain exactly is located on a pain-drawing, what is the frequency of the headaches, when it was the last headache, what the patient would feel if he/she had to suffer this type of headache for the rest of his/her life, if this headache can be related to the menstrual cycle for the women. The last section of the questionnaire is a modification of the Diamond questionnaire for Headaches. Specifically this last part contains questions regarding the unilateral or bilateral presence of symptoms, the intensity of the headache, the presence or not of photophobia or noise related symptoms, the radiation of pain bilateral, the presence of depressive symptoms, the feeling of "cold" hands, symptoms from the eyes (crying), from the stomach, loss of appetite, throbbing pain, morning headache, headache during the night, diurnal variation of headache, improvement of symptoms when lying, weather change related headache and stress-related headache. The full version of the English version can be found in reference [17].

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The peer review history for this paper can be accessed here:
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