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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Validation of the Montgomery–Åsberg Depression Rating Scale in depressed patients in Serbia

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SUMMARY

Introduction/Objective The aim of this study was the validation of the Montgomery–Åsberg Depression Rating Scale (MADRS) in patients in Serbia suffering from depression.

Methods Both test and retest situations have been conducted on 162 adult patients with major depressive disorder, and on 110 individuals that have not shown any type of mental disorder (control group). The sample included 58.8% male and 41.2% female participants, age between 20 and 79 years (M = 42.26, SD = 11.53) with no differences between groups in terms of participants' sex and age. The following instruments were used: MADRS, Hamilton Depression Rating Scale, and Brief Psychiatric Rating Scale.

Results MADRS has shown good psychometric characteristics: internal consistency, test-retest reliability, concurrent validity, and its discriminatory validity is adequate. Study also confirmed the one-dimensionality of the instrument. Statistically significant differences between the groups, in terms age and education, have been identified, but the effects of the differences were small.

Conclusion The MADRS scale has shown good psychometric characteristics in our study; thus, it may be used for the assessment of depressed states in Serbian patients.

Keywords: depression; Montgomery–Åsberg Depression Rating Scale; instrument validation

INTRODUCTION

According to the World Health Organization, in 2017, about 264 million people suffered from some form of depressive disorder, and depression is a leading cause of disability worldwide [1, 2]. Data from Serbia suggest that in 2014, 4.1% of the population had depressive disorder [3].

Apart from the clinical interview, measuring the degree of depression is mainly based on using the psychodiagnostic scales for assessing symptoms. Using these instruments is important because of objectivity in psychodiagnostics, quantitative expression of values (especially in clinical studies), and information relevant to the assessment of a clinical course and pharmacotherapy. However, there are several reasons why it is hard to evaluate depression. It might be because of the personality traits influence, physical disorders, comorbidities, and because depression symptoms can be a part of another diagnosis, like bipolar disorder or Parkinson disease [4, 5]. Finally, the results can also vary from one instrument to another, due to differences between self-assessment scales and clinician-administered scales, or some other methodological problem [6, 7, 8].

Depression assessment scales

Although various rating scales for depression are available (e.g., Hamilton Depression Rating Scale – HDRS, Montgomery–Åsberg Depression Rating Scale – MADRS, and Beck Depression Inventory – BDI), MADRS is one of the most frequently used scales for assessing severity of depression in research settings, clinical trials, and everyday primary care and clinical practice, and it has been translated into more than 24 languages [8, 9, 10]. The scale is applied and evaluated by psychiatrists in the form of a guided interview and it is suitable for monitoring change in the patient's state [9, 10]. Regardless if a structured interview is used or not, the scale has satisfactory reliability [11].

MADRS shows satisfactory psychometric characteristics, high agreement values between the examiners, and significant correlation with scores on HDRS, BDI, and the Mini-International Neuropsychiatric Interview [9, 10, 12]. A moderate to high association was shown between the patient's scores and the physician's scores [6, 7]; moreover, the patients perceived the scale as a useful tool that "added something" to the consultation with physicians [13]. Compared to HDRS, MADRS has shown greater sensitivity when distinguishing moderate and severe depression, and higher specificity than BDI-II in distinguishing individuals

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without depression in the primary care context [9, 14]. MADRS is also convenient when patients need to be tested efficiently and quickly, since the completion time is up to 10 minutes [9].

There are various opinions on factorial structure, because different studies have shown a different number of factors. A single-factor solution is the most frequent one [6, 15]. Other studies have shown that MADRS may have two or three factors, which represents different symptoms of depression, such as sadness and melancholy, or a general depression factor and motivational factor [16, 17]. The three-factor solution was proved useful in examining major depression disorder and in isolating subgroups of depressed patients with more pronounced symptoms [5]. There was even the four-factor model, in which the following factors were distinguished: covert sorrow, negative thoughts, alienation, as well as neurovegetative symptoms [18].

The main aim of this study was the validation of the MADRS psychometric properties in Serbian patients suffering from depression, and evaluation of its factorial structure, discriminative power, as well as external validity.

METHODS

Procedure

The study was conducted during a six-month period, between June and December of 2017, and the instruments were administered to the patients individually. The participation in the study was voluntary, anonymous, and informed consent was provided according to the provisions of the Declaration of Helsinki. The study protocol received ethical approval from the Ethical Committee, Dr. Laza Lazarević Clinic for Psychiatric Disorders in Belgrade, Serbia.

The first inclusion criterion for the clinical group was the diagnosis of unipolar depression without comorbidity (based on ICD-10 classification), diagnoses F32 and F33, except for the diagnosis with psychotic symptoms (F32.3 and F33.3). The other criteria were age of 18 years and above, a stable state in the previous two months, the treatment with antidepressants without modification of the therapeutic regimen in the previous two months, and Serbian as the native language.

The inclusion criteria for participants in control group were: absence of neurological and/or psychiatric disorders, age 18 years or above, Serbian as native language.

The clinical sample included patients from the Dr. Laza Lazarević Clinic for Psychiatric Disorders in Belgrade, Serbia. The diagnosis of mental disorder in this sample has been confirmed by the medical history records and anamnestic data. The absence of mental disorders in the control group has been established with the Brief Psychiatric Rating Scale (BPRS). Participants from both groups were included in the study only after they had read the information about the study and signed the consent to participate according to the Declaration of Helsinki. The control group sample was stratified and balanced based on sex and age data from the clinical sample. The sample was voluntary and consisted of the employees in public companies, such as the Belgrade Road Public Utility Company, Electric Power Distribution of Serbia, University Clinical Centre of Serbia. The remaining participants from this group were recruited via chain sampling.

Participants

The total number of participants was 272 – 162 from the clinical population (59.6%), and 110 in the control group (40.4%). There were 58.8% male and 41.2% female participants, their age being 20–79 years (M = 42.26, SD = 11.53). There were no differences between groups in terms of sex and age. Most of the participant had completed secondary school (59.1%), or had bachelor's degree (30% in the control, and 11.3% in the clinical group). The majority of participants with only elementary school was from the clinical group (10.6%), compared to the control group (2.7%); 16.4% of the non-clinical and 9.2% of the clinical sample had higher education.

Instruments

The study employed the following instruments.

MADRS [11] – contains 10 items in the seven-point Likert scoring format (from 0 – without difficulties, to 6 – significant difficulties). The level of depression is determined by the total sum, and it is classified as follows: 0–6 – without symptoms, 7–19 – mild depression, 20–34 – moderate depression, 34 and more – severe depression. MADRS has significant correlations with HDRS and BDI [9, 10, 12]. We used an original version of MADRS that was previously slightly modified after language and content validity test.

HDRS – serves to assess the degree of depression [19]. We used a 17-item version, determining depression according to the following scores: 0–7 – without depression, 8–15 – moderate depression, 16 and more – severe depression. The most recent validations of the instrument in Bangladesh and Poland showed satisfactory psychometric characteristics [16, 20]. Although it has long been considered a gold standard in the clinical assessment, over the years there have been several major problems with the scale [10]. The scale proved to be longitudinally unreliable and with a suboptimal number of responses offered. Also, the validity of the content is considered unsatisfactory due to somewhat outdated conception of depression. As a result, new versions have been made, with slightly different classification system of scores [21].

BPRS – a scale with 18 items, with a seven-point Likert scoring format (1–7). Studies have shown satisfactory reliability and validity, and it includes an assessment of the affects, thinking, anxiety, orientation, motor, and behavioral manifestations [22]. The main requirement for selecting subjects from the control group was a low score (< 30 points) on the BPRS as an indicator of the lack of psychopathology [22].

In addition to these instruments, we also used data obtained from medical history records. Other data (sex, age, and education) of participants from both groups were collected by an interview before the start of the test.

Statistical analyses and translation

We followed the recommendations for psychometric studies in which instruments are tested and validated [23]. For the translation of the scale into Serbian, a linguistic expert translated MADRS from English to Serbian, and this version was compared with the original in order to resolve potential discrepancies. Then, the instrument was translated back to English by another professional translator with a good command of both Serbian and English. The back-translation was compared with the original instrument and, after the necessary modifications, the scale was forwarded to further procedure.

The next step was that items' meaning and comprehensibility (*content validity*) were evaluated by two expert psychiatrists. All of the items were rated as appropriate and the final version of the scale was accepted.

Based on the recommendations for sample size [23, 24], we estimated that at least 100 respondents (minimum 10 subjects per item) were needed, since MADRS has 10 questions. When $\alpha = 0.05$, and the strength of the study $(1-\beta) = 0.80$, for testing the differences between two groups of t-tests (for example, subjects with or without depression), at least 51 subjects are needed per group, and testing the difference between three groups by the ANOVA test (e.g., respondents within the clinical group with mild, moderate, and severe depression) requires a total of 156 respondents. Based on all this and the calculations in the G*Power program (Heinrich-Heine-Universität Düsseldorf, Germany), the goal was to involve at least 160 subjects from the clinical population and at least 110 non-clinical respondents.

For the statistical analyses, we used exploratory factor analysis, t-test, Pearson correlation and intraclass correlation coefficient (ICC) for the reliability.

RESULTS

Factor structure

We used exploratory factor analysis with direct oblimin factor rotation. The analysis of the main components distinguishes one factor that explains 58.45% of the total variance (Table 1; Figure 1). All items have loadings above 0.50. Kaiser–Meyer–Olkin measure of representativeness was 0.90. Bartlett's sphericity test was statistically significant ($\chi^2(45) = 1698.03$, $p < 0.001$).

Analyzing individual items, item 6 (concentration difficulties) gives the largest share in the explanation of the variance with .072, item 2 with 0.71 (expressed sorrow), item 7 with 0.69 (difficulty in the commencement of activities), and item 1 with 0.69 (noticeable sorrow).

Table 1. Factor weights and explained variance in test and retest situation

Items	Test		Retest	
	Factor loadings	% of variance	Factor loadings	% of variance
MADRS1	0.830	0.689	0.836	0.698
MADRS2	0.844	0.712	0.822	0.676
MADRS3	0.692	0.479	0.584	0.341
MADRS4	0.695	0.483	0.722	0.521
MADRS5	0.652	0.425	0.647	0.418
MADRS6	0.846	0.716	0.804	0.646
MADRS7	0.832	0.693	0.852	0.726
MADRS8	0.772	0.596	0.787	0.619
MADRS9	0.727	0.528	0.732	0.536
MADRS10	0.723	0.523	0.717	0.514

MADRS – Montgomery–Åsberg Depression Rating Scale

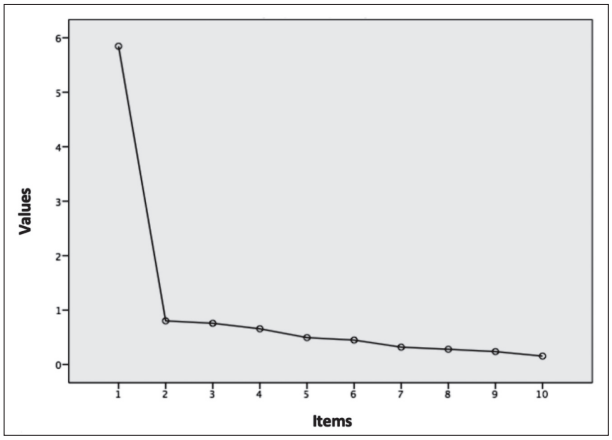

Figure 1. Diagram for the Montgomery–Åsberg Depression Rating Scale

Basic descriptive statistics are shown in Table 2.

Table 2. Descriptive data for Montgomery–Åsberg Depression Rating Scale (MADRS) in the clinical and the control group

MADRS	n	Mean	SD	Min.	Max.	skewness	kurtosis
Clinical group	162	13.28	11.8	0	51	1.01	0.2
Control group	110	1.7	1.96	0	8	1.31	0.46

Reliability analyses

The ICC is used in cases where there are more examiners or more repeated measurements in the research, and therefore it was suitable for this study. All of the measures that are given in Table 3 are referred to the combined measures of test and retest.

It is considered that each value of the ICC 0.75–0.90 is good, and values over 0.90 represent excellent test-retest reliability [25]. Cronbach's alpha values obtained at the first test ($\alpha = 0.84$) suggests high internal reliability of the scale considering the small number of items. The total test and retest scores also showed significant correlation ($r = 0.89$, $p < 0.01$). Therefore, all items, as well as the overall result, give good indication of reliability in repeated measurements, which suggests that longitudinal measurements can be considered reliable.

Table 3. Intraclass correlation coefficient (ICC) by items on the Montgomery–Åsberg Depression Rating Scale (all the items of the ICC are significant at the level of 0.01)

Items	M	SD	ICC	95% CI	
				Lower bound	Upper bound
1	2.06	2.93	0.87	0.83	0.9
2	2.01	2.83	0.84	0.8	0.88
3	2.18	2.48	0.88	0.85	0.91
4	1.75	2.78	0.9	0.87	0.92
5	0.78	2.01	0.86	0.82	0.89
6	1.45	2.52	0.87	0.84	0.9
7	1.55	2.54	0.86	0.82	0.89
8	1.41	2.65	0.88	0.84	0.9
9	1.39	2.19	0.84	0.80	0.88
10	0.56	1.72	0.87	0.83	0.9
Total	15.13	19.37	0.93	0.91	0.95

Discriminative sensitivity

The t-test results support the fact that there are statistically significant differences with large effect size between the clinical and non-clinical populations in both test and retest situation (Table 4).

Table 4. Differences between the clinical and the control group test and retest scores

Group	Clinical		Control		t	95% CI		Cohen's d
	M	SD	M	SD		Lower bound	Upper bound	
MADRS test	13.28	11.8	1.7	1.96	12.25*	9.72	13.45	1.37
MADRS retest	10.23	10.27	1.08	1.42	11.18*	7.53	10.76	1.25

MADRS – Montgomery–Åsberg Depression Rating Scale
* < 0.01

Discriminating power of the total score was shown to be satisfactory (canonical correlation 0.53; Wilk's lambda 0.52, $p < 0.001$; 77.2% of the participants correctly classified). The obtained results indicate that the area under the receiver operating characteristic curve is 0.878 (ranging 0.837–0.919). Cut-off score of 7 and above suggests the presence of depressive symptoms (mild depression category in original classification), since it showed the best sensitivity (0.636) and specificity (0.955).

External validation

In order to test external or concurrent validity of the scale, the scores on the MADRS were correlated with the scores on the HDRS scale. There was a statistically significant and very high positive correlation between these scores ($r = 0.96$, $p < 0.01$).

Demographic variables and MADRS scores

MADRS scores have shown no statistically significant differences between males and females (test: $t(272) = 1.80$, $p > 0.05$, retest: $t(272) = 1.78$, $p > 0.05$). A statistically significant difference in age groups was found ($F(3, 268) = 6.36$, $p < 0.01$), with medium effect size ($\eta^2 = 0.07$). The group of the oldest participants (above 52 years old) shows the highest scores ($M = 12.64$, $SD = 12.6$). Similar results are shown for the differences in education ($F(3, 248) = 9.68$, $p < 0.01$, $\eta^2 = 0.1$), where participants with the lowest education level (elementary school) show the highest scores ($M = 16.39$, $SD = 13.91$).

DISCUSSION

The research was conducted in order to validate the MADRS scale for Serbian patients, because it has wide application in assessing depressive disorders.

According to our findings, it can be concluded that MADRS has satisfactory internal reliability and psychometric characteristics in the test-retest situation. Other researchers have found that the MADRS scale has good psychometric characteristics, with the ICC varying from 0.89 to as much as 0.98, depending on the person who conducts an interview with the patient [12, 26]. The reliability of the entire instrument in our study was excellent (ICC = 0.93, r = 0.000), indicating that MADRS gives the same results on repeated measurements, and is good for monitoring, i.e., for use in longitudinal studies. The results show that all item intercorrelations in test and retest situations are also positive and strong (more than 0.60).

An analysis of the main components identified one factor explaining 58.45% of the variance, and it was confirmed that the MADRS measures a unique construct – depression. The one-dimensionality of the MADRS scale was previously confirmed in a large, multinational study involving depressed patients [6], as well as in other similar studies [12]. The items that proved to be most significant in factor analysis in both test situations in our study are difficulty with concentration, expressed sorrow, difficulty in starting the activity, and noticeable sadness.

MADRS shows significant differences between the clinical and the non-clinical population, which supports the discriminatory validity of the scale, in both test and retest situation. A recent study confirms, with rather high values of sensitivity and specificity, that the cut-off point for moderate depression is 20 (sensitivity 98%; specificity 96%), and the cut-off point for severe depression is 34 (sensitivity 98%; specificity 92%) [12]. In our study, a cut-off score of 7+ suggests the presence of depressive symptoms (mild depression category in the original classification).

What is particularly significant is the strong positive correlation between the MADRS and the HDRS-17, as it was also suggested by previous studies [8]. A number of studies comparing the MADRS and HDRS-17 have shown that the MADRS has a higher sensitivity to changes that occur under the effect of therapy [8, 27, 28].

It is important to note that there are certain differences in the scores in terms of demographic categories. No differences were found according to the sex criterion; however, the oldest participants and those with primary school education reported the highest scores. Medical conditions, cognitive deficits, loss of significant others,

and changes in social life associated with old age might decrease the applicability of some psychological treatments and influence the treatment outcome in elderly depressed people, but they can also influence the comprehension of the items, and an increased tendency towards depressive reactions upon testing [29]. The prevalence of depression is greater in individuals with lower socio-economic status and lower qualifications, which may be the reason why our results show that the participants with only primary school education report higher scores in comparison to other qualification levels [30].

A possible confounding variable of the present study is the effect of pharmacotherapy, as the change in the scores may depend on the type of the drug, the dosage of the drug, and the reactivity to the therapy. Other confounding variables relate to changes in the environment of respondents (improvement in relationships with fellowmen, the effects of psychotherapy, etc.).

CONCLUSION

The MADRS scale has shown good psychometric characteristics in our study; thus, it may be used for the assessment of depressive disorders in Serbian patients.

Conflict of interest: None declared.

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Валидација српске верзије скале Монтгомери–Осберг за процену депресије код депресивних болесника

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САЖЕТАК

Увод/Циљ Циљ ове студије била је валидација скале Монтгомери–Осберг за процену депресије код болесника у Србији који болују од депресије.

Методе И тест и ретест ситуације су спроведене на 162 одрасла болесника која имају дијагностикован депресивни поремећај, и на контролној групи од 110 особа које немају ниједан облик менталних поремећаја. Узорак је чинило 58,8% испитаника мушког и 41,2% женског пола, узраста између 20 и 79 година (M = 42,26, *SD* = 11,53), при чему није било разлике између испитиваних група по полу и годинама. Примењени су следећи инструменти: скала Монтгомери–Осберг за процену депресије, Хамилтонова скала за процену депресије, као и Кратка скала за психијатријску процену.

Резултати Психометријске карактеристике скале Монтгомери–Осберг за процену депресије, као што су интерна конзистенција, тест-ретест поузданост, екстерна валидност са Хамилтоновом скалом и дискриминаторна валидност, показале су се као адекватне. Студија је такође потврдила једнофакторску структуру инструмента. Добијене су статистички значајне разлике у скоровима између група по узрасту и образовању, али су ови ефекти разлика мали.

Закључак Скала Монтгомери–Осберг за процену депресије показала је добре психометријске карактеристике у нашој студији и као таква се може користити за процену депресивних стања код болесника у Србији.

Кључне речи: депресија; скала Монтгомери–Осберг; валидација инструмента