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Research paper

Psychometric properties of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype questionnaire in Chinese patients with mood disorders

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ABSTRACT

Background: With the modification of DSM-5 mixed features specifier, a brief scale to screen mixed features in patients with mood disorders is needed in clinical practice. This study aimed to explore the psychometric properties of the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype (CUDOS-M-C) for the Chinese patients with mood disorders.

Methods: Overall, 300 patients with major depressive episode were recruited. All participants were assessed using CUDOS-M-C, Young Mania Rating Scale, Hamilton Anxiety Scale and Montgomery-Asberg Depression Rating Scale. The receiver operating characteristic (ROC) curve analysis was used to calculate the optimal cut-off values of CUDOS-M-C score. The reliability and validity of CUDOS-M-C were examined using Cronbach's alpha, intraclass correlation coefficient (ICC) and principal component analysis (PCA).

Results: The results of PCA indicated two-factor structure as the best solution for CUDOS-M-C, which explained 54.82% of cumulative variance. The Cronbach's alpha was 0.892 and the ICC was 0.853. The area under the ROC curve of the CUDOS-M-C for participants with mixed depression was 0.927 ($p < 0.001$) and the suitable cut-off value was 8, with a sensitivity of 91.6% and specificity of 79.9%.

Limitations: Most of the patients were recruited from eastern China and further research with larger sample is warranted. And this study did not perform confirmatory factor analysis to identify the generalization of factor structure of CUDOS-M-C. Besides, the study performed the test-retest reliability of CUDOS-M-C and further analysis is needed to ascertain the patient's post-treatment changes.

Conclusion: The CUDOS-M-C demonstrated to have satisfactory psychometric properties as a self-report scale, and could be applied to screen patients with mixed depression in clinical practice.

1. Introduction

The concept of mixed states of manic and depressive insanity was first introduced by Emil Kraepelin at the end of 19th century (Perugi et al., 2014), but its definition has been in controversy for a long time. In the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR)(American Psychiatric Association, 2000), the diagnosis of mixed states should meet all the criteria of manic and depressive episodes for at least one week, and this is not widely applied in clinical practice due to its narrow definition. So,

Abbreviations: CUDOS-M, the Clinically Useful Depression Outcome Scale supplemented with questions for the DSM-5 Mixed subtype; CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype; YMRS, Young Mania Rating Scale; HAMA, Hamilton Anxiety Scale; MADRS, Montgomery-Asberg Depression Rating Scale; ICC, intraclass correlation coefficient; PCA, principal component analysis; DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision; DSM-5, the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition; MFS, mixed features specifier; ROC, the Receiver Operating Characteristic; KMO, Kaiser–Meyer–Olkin; MDD, major depressive disorder; BD, bipolar disorder

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the concept of mixed states as a spectrum has been broadened by the Diagnostic and Statistical Manual of Mental Disorders Fifth Edition (DSM-5) (American Psychiatric Association, 2013), and proposed the term "mixed features specifier (MFS)". Patients with at least three symptoms of opposite polarity of [hypo]manic/depressive episode (except for some potentially overlap symptoms of both mania and depression) were defined as MFS. Previous studies have demonstrated that nearly one-third of manic episodes were diagnosed as MFS based on DSM-5 criteria (Vieta et al., 2014). A study conducted in 982 patients with major depressive episodes showed that the percentage of patients who met the criteria of MFS with bipolar I depression, bipolar II depression and unipolar major depression were 34%, 33.8% and 26%, respectively (McIntyre et al., 2015). Another study conducted in 907 patients with bipolar disorder also showed that 64.4% of patients have experienced mixed depression at least once (Miller et al., 2016). Compared to those with pure mania/depression, patients with MFS had more worsened clinical outcomes, higher suicidal risk and more comorbidities of substance abuse and other physical disorders (McIntyre et al., 2017; Perugi et al., 2014). Due to low recognition rate of MFS, it is necessary to improve the diagnostic accuracy of MFS to provide guidance for further treatment. However, no simple screening tool that is accurate to diagnose MFS is currently available in China.

The Clinically Useful Depression Outcome Scale supplemented with questions for DSM-5 Mixed subtype (CUDOS-M) is a self-assessment scale that can be used as a screening tool for depressive patients with mixed features. This scale has been developed by Zimmerman et al. (2014), and includes 13 items based on the DSM-5 specific criteria for mixed depression with satisfactory reliability and validity. Each item of the scale is rated on a 5-point ordinal scale to indicate the frequency of symptoms during the past week (0 = not at all true [0 days]; 4 = almost always true [every day]) and the total score ranges from 0 to 52 (Zimmerman et al., 2014). Currently, the clinical scales for mania/hypomania symptoms are not optimal, including the Self-Report Inventory for Mania (SRMI) (Shugar et al., 1992) and the hypomania subscale of the symptom checklist 90-Revised (SCL-90R) (Hunter et al., 2000). The CUDOS-M scale has been developed to screen depressive patients with manic/hypomanic characteristics, and this could help in identifying patients with mixed depression. Due to the advantages of CUDOS-M such as its brevity and convenience, it is most widely used in clinical application. Moreover, it is relatively easy to complete and do not take more than two minutes to complete when compared to other self-report scales.

Hence, this study aimed to explore the psychometric properties of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype (CUDOS-M-C) in Chinese patients with mood disorders, and its screening utility in clinical practice.

2. Methods

2.1. Participants

In this observational, cross-sectional study, all outpatients or inpatients from the First Affiliated Hospital of Zhejiang University, School of Medicine from November 2017 to April 2019 were included. The inclusion criteria were as follows: patients 1) currently diagnosed with major depressive episode according to the Mini International Neuropsychiatric Interview for DSM-IV-TR (MINI Plus 5.0) (Sheehan et al., 1998; Si et al., 2009); 2) aged 16 to 65 years; 3) with at least 5 years of education; and 4) with mixed features as defined by DSM-5 to identify mixed depression. The flow chart of participants included in the study was shown in Fig. 1. Patients with neurological diseases or other major psychiatric disorders, such as schizophrenia and current substance abuse were excluded from the study. Furthermore, patients with severe depressive episodes that could not cooperate with the evaluation were also excluded. The study was approved by the Clinical Research Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine. All participants provided written informed consent.

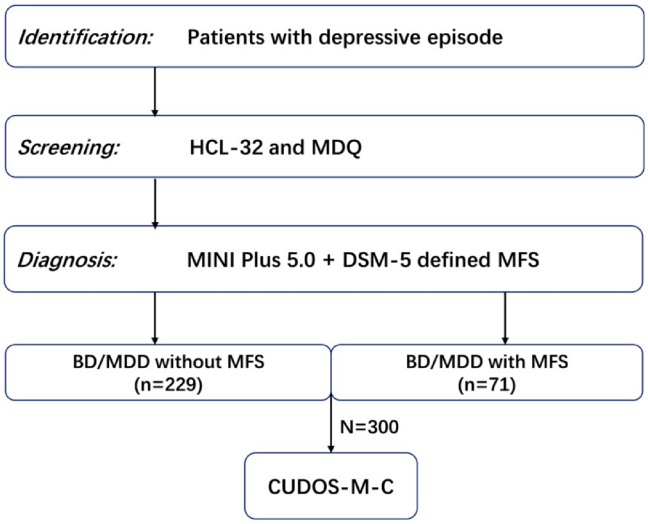

Fig. 1. *HCL-32, the Hypomania checklist-32; MDQ, Mood Disorder Questionnaire; BD, bipolar disorder; MDD, major depressive disorder; MFS, mixed features specifier; CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype

2.2. Procedure

The CUDOS-M includes 13 items, and are listed in Table 2. With the permission of the authors of CUDOS-M, the CUDOS-M-C (see appendix) was developed using the translation–back-translation method. Firstly, the original CUDOS-M scale was translated into Chinese by two skilled psychiatrists with clinical experience. Secondly, proofreading the scale should be conducted by a professional expert and then the scale should be back-translated by native English-speaking professionals with no previous knowledge of the scale. Finally, the back-translated CUDOS-M-C was compared with the original version and necessary revisions were made.

To examine the test–retest reliability of the CUDOS-M-C, retest was performed from day 2 to 5 after the first evaluation of the scale. For outpatients who did not live in Hangzhou and could not complete the retest in the clinic after several days, the CUDOS-M-C scale was sent as a message to them and they finished the retest based on their own or under the supervision of their guardians or family members. The inpatients have completed the retest directly in the ward 2-5 days after the first evaluation. A total of 180 patients completed the second assessment, and the interval time for retest was 3.02 ± 0.96 days.

2.3. Assessment

When completing the self-report CUDOS-M-C assessment, patients were evaluated with the following scales: Montgomery-Asberg Depression Rating Scale (MADRS) (Montgomery and Asberg, 1979), Young Mania Rating Scale (YMRS) (Young et al., 1978) and Hamilton Anxiety Scale (HAMA) (Maier et al., 1988). The psychiatrists who used the DSM-5 mixed features criteria to diagnose patients with mixed depression were blinded to the scores of CUDOS-M-C. The severity of depression or hypomanic/manic episode was evaluated by using MADRS and YMRS, respectively. Moreover, HAMA was used to assess the severity of anxiety in all participants. To maintain consistency, all psychiatrists were provided with the same training for completing the assessment.

2.4. Data analyses

All data analyses were conducted using SPSS version 23.0, and the receiver operating characteristic (ROC) curve was performed using SigmaPlot version 13.0. Normality testing of all continuous variables was done with exploratory analysis. Variables with normal distribution were presented as means ± SD, otherwise, they were expressed as median (25% quantile, 75% quantile). The independent sample *t*-test, nonparametric test and chi-square (X^2) analyses were used if appropriate. Because the CUDOS-M-C scores were not normally distributed, the differences between the groups with mixed and without mixed features were analyzed using the Kruskal-Wallis test. Principal Components Analysis (PCA) was used to evaluate the factor structure of CUDOS-M-C. The common factors were extracted according to the Kaiser–Meyer–Olkin (KMO) and Bartlett's test, cumulative variance percentage and scree plot. Cronbach's alpha was used to assess the internal consistency reliability. The test-retest reliability of CUDOS-M-C was represented using the intraclass correlation coefficient (ICC) (Cicchetti, 1994). Spearman correlation coefficient was used to analyze the correlation between CUDOS-M-C and other scales. The validity of concurrent criterion was analyzed using the ROC curve. The diagnostic performance of CUDOS-M-C was shown by the area under the ROC curve. A p value of <0.05 was considered to be statistically significant.

3. Results

3.1. Demographic characteristics

Of the 300 participants included, 180 (60%) patients had bipolar depression without mixed features, 71 (23.7%) had depressive episodes with mixed features specifier (MDE-MFS), and 49 (16.3%) had major depressive disorder (MDD) without mixed features. The demographic data are presented in Table 1. The patients were divided into two groups (depressive episode with or without mixed features) for statistical analysis. The average age of participants was 25.1 years and their average education level was 12.0 years. The mean course of illness and age at the occurrence of first-episode age was 4.8 years and 20.0 years, respectively. The age, education level, total illness course and the first-episode age showed no significant differences between the groups. The proportion of females (58.7%) was higher than that of males (41.3%) but showed no significant differences in gender between the groups. Significant correlations were observed between the groups in the CUDOS-M-C and YMRS scores ($p<0.001$, $p<0.001$), while the MADRS and HAMA scores showed no significant difference ($p=1.360$, $p=1.380$).

3.2. Internal consistency reliability and test–retest reliability

The Cronbach's alpha of the CUDOS-M-C was 0.892, which showed an excellent internal consistency and reliability (Terwee et al., 2007). The Cronbach's alpha was not higher than 0.892 after deleting each item (ranged from 0.875 to 0.892), which indicated that no item was needed to be omitted. The corrected item-total correlations were between 0.420 and 0.766. Finally, 180 participants completed CUDOS-M-C twice, and the ICC $=0.853$ (95% CI: 0.802; 0.890, $p<0.001$) of the scale demonstrated acceptable test-retest reliability. The results of reliability analysis are shown in Table 2.

3.3. Validity of the CUDOS-M-C

The factor structure of the CUDOS-M-C was evaluated with PCA. The results of dimension reduction analysis revealed that the KMO was 0.890, and that of the Bartlett's test of sphericity was shown to be highly significant [$\chi2(78)=1820.021$, $p<0.001$]. Taken the eigen values for factor structure >1 as retention criteria, both the scree plot and eigen values indicated that the two-factor structure was the best solution after performing varimax rotation analysis, and this explained a cumulative variance of 54.82%. The items 1-10 of the scale indicated one factor, which showed the positive aspects of mixed depression (elation, increased energy and so on), explaining a variance of 36.06%. The items 11-13 indicated another factor, which are related to negative aspects such as risk behavior, explaining a variance of 18.76%. And the loading of each item on the common factors after varimax rotation is shown in Table 3.

The correlation between CUDOS-M-C and other three scales was evaluated using the Spearman correlation coefficient. The number of patients who completed the three scales (YMRS, HAMA and MADRS) ranged from 228 to 275 due to data unavailability. The CUDOS-M-C showed significant positive correlation with YMRS ($r = 0.614$, $p<0.001$) and HAMA ($r = 0.177$, $p = 0.007$). As expected, no significant correlation between CUDOS-M-C and MADRS was observed ($p > 0.05$). Besides, the ROC curve was used for predicting whether CUDOS-M-C score could primarily screen the depressive episode with mixed features (Fig. 2). Depression with MFS according to the DSM-5 criteria was considered as the diagnostic criteria. Of the 300 patients, 71 (23.7%) patients were diagnosed as having depression with mixed features. The area under the ROC curve of the CUDOS-M-C was 0.927 (95% CI: 0.895; 0.960, $p<0.0001$) (Fig. 2), which indicated an excellent differentiating ability. The results of sensitivity and specificity analysis for CUDOS-M-C are shown in Table 4, and the best cut-off value was calculated to be eight points. The sensitivity of this value was 0.916 (95% CI: 0.825; 0.968, $p<0.0001$) and the specificity was 0.799 (95% CI: 0.741; 0.849, $p<0.0001$).

Table 1
Demographic characteristics of all participants with depressive episode (BD/MDD).

	Total (n = 300)	With mixed features (n = 71)	Without mixed features (n = 229)	*p*-value
Age (years)	22(18,30)	20(18,31)	23(18,31)	0.009
Gender (M/F)	124/176	28/43	96/133	0.710
Education level (years)	12(10,15)	12(9,15)	12(10,15)	0.699
Illness course (years)	3(1,7)	3(1.5,6)	3(1,7)	0.821
First-episode age (years)	17(15,24)	16(13,23)	17(15,25)	0.092
CUDOS-M-C score	6(2,11)	16(11,24)	3(1,7)	<0.001
MADRS score	26.79 ± 9.62	28.11 ± 9.02	26.38 ± 9.78	1.360
YMRS score	4(0,1)	13(9,18)	2(0,5)	<0.001
HAMA score	22.74 ± 9.49	26.21 ± 9.28	21.45 ± 9.27	1.3801

BD, bipolar disorder; MDD, major depressive disorder; CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype; MADRS, Montgomery-Asberg Depression Rating Scale; YMRS, Young Mania Rating Scale; HAMA, Hamilton Anxiety Scale
Continuous variables with normal distribution were described as means ± SD and analyzed with independent sample t-test. Continuous variables with abnormal distribution were presented as median (25% quantile, 75% quantile) and analyzed with nonparametric test. And Chi-square test was used for categorical variables to analyze the association between groups.

Table 2
Corrected item-total correlation, internal consistency and test–retest reliability of CUDOS-M-C items.

CUDOS-M item	Corrected item-total correlation	Cronbach's alpha if item deleted	Test-retest reliability (n = 180)
I felt so happy and cheerful it was like a high	0.610	0.883	0.673
I had many brilliant, creative ideas	0.641	0.881	0.740
I felt extremely self-confident	0.584	0.884	0.769
I slept only a few hours but woke full of energy	0.560	0.886	0.702
My energy seemed endless	0.714	0.879	0.729
I was much more talkative than usual	0.716	0.877	0.783
I spoke faster than usual	0.766	0.875	0.799
My thoughts were racing through my mind	0.680	0.879	0.740
I took on many new projects because I felt I could do everything	0.594	0.884	0.591
I was much more social and outgoing than usual	0.532	0.886	0.561
I did wild, impulsive things	0.420	0.892	0.594
I spent money more freely than usual	0.473	0.891	0.735
I had many more thoughts and fantasies about sex	0.423	0.891	0.765
Total Scale			0.853

CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype
All correlations are significant at $p < 0.001$.

Table 3
The loading of each CUDOS-M-C item on common factors after varimax rotation.

CUDOS-M item	common factor 1	common factor 2
I felt so happy and cheerful it was like a high	.689	.186
I had many brilliant, creative ideas	.640	.321
I felt extremely self-confident	.769	.028
I slept only a few hours but woke full of energy	.700	.092
My energy seemed endless	.801	.186
I was much more talkative than usual	.710	.359
I spoke faster than usual	.709	.434
My thoughts were racing through my mind	.584	.470
I took on many new projects because I felt I could do everything	.661	.198
I was much more social and outgoing than usual	.470	.401
I did wild, impulsive things	.093	.759
I spent money more freely than usual	.160	.761
I had many more thoughts and fantasies about sex	.202	.602

CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype

3.4. Association with psychiatric diagnosis

The results of Kruskal-wallis test showed significant differences ($p < 0.001$) in the CUDOS-M-C scores among patients diagnosed with bipolar depression, mixed depression, and MDD.

4. Discussion

This study explored the psychometric properties of CUDOS-M-C for Chinese patients with mood disorders. The results suggested that CUDOS-M-C could be used to effectively screen depressive episode with mixed features due to its excellent internal consistency, and test-retest reliability and validity. The scale was validated for depressive episodes (BD, MDD and MFS) in 300 participants who completed the CUDOS-M-C, and this indicated good feasibility of the scale. Furthermore, most of the patients completed the CUDOS-M-C within one minute.

In our study, the scree plot and cumulative variance confirmed that two-factor structure as the best solution for the dimensionality of CUDOS-M-C. One factor was indicated by items 1-10, which were related to the positive aspects of mania episode (such as the inflated self-esteem and the elevated mood), while the other factor was indicated by items 11-13, which were related to the negative aspects of mania episode (such as impulsive behaviors). As expected, the CUDOS-M-C demonstrated good correlation with the YMRS but not with the MADRS. The CUDOS-M-C also demonstrated positive correlation with HAMA, suggesting that patients with mixed depression were more likely to coexist with anxiety disorders. The ROC curve demonstrated that CUDOS-M-C acts as a good screening tool for mixed depression at the

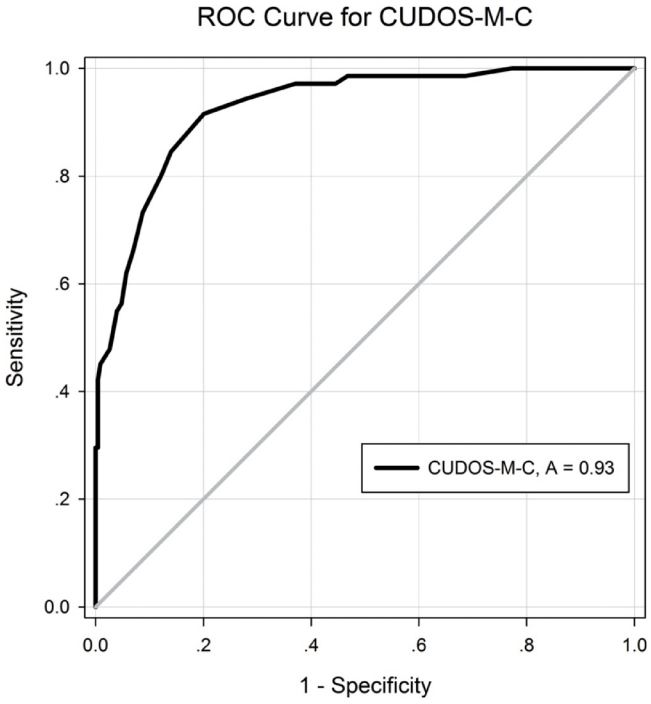

Fig. 2. ROC curve of the CUDOS-M-C in mixed depression ($p < 0.0001$)

Table 4
The sensitivity and specificity of CUDOS-M-C for predicting MDE-MFS.

CUDOS-M-C (cut-off)	Sensitivity	Specificity
7/8	0.930	0.760
8/9	0.916[a]	0.799[a]
9/10	0.845	0.860
10/11	0.803	0.878

MDE-MFS, major depressive episode with mixed features specifier; CUDOS-M-C, the Chinese version of the Clinically Useful Depression Outcome Scale supplemented with DSM-5 Mixed subtype
[a] The optimal cut-off score.

best cut-off value of 8.

Patients with bipolar disorder more likely exhibited mixed features than those with unipolar disorder (Vazquez et al., 2018). It was noted that patients with bipolar depressive episodes had higher CUDO-M-C scores than those with MDD in our study ($p < 0.001$), which was consistent with that of the previous research (Zimmerman et al., 2014). Meanwhile, bipolar depression patients with mixed features had higher CUDO-M-C scores than those without mixed features ($p < 0.001$). Regardless of whether a patient had bipolar disorder or MDD, the diagnostic criteria for mixed features in depressive episode remain the same (American Psychiatric Association, 2013). As most of the participants included in our study were diagnosed with bipolar depression, the use of CUDOS-M-C as a screening tool might be more specific and further verification in a larger sample size of patients with depression is warranted.

Although there are many self-assessments or clinician-rated scales to screen depressive patients in clinical practice, such as the Patient Health Questionnaire-9 (PHQ-9)(Kroenke et al., 2001) and the Self-rating depression scale (SDS) (Zung, 1965), there are only very few brief and effective screening tools for depression with mixed features. The HCL-32 and the MDQ could evaluate the mania/hypomania episodes, but they do not differentiate whether the manic/hypomanic state is a lifetime or current event (Angst et al., 2005; Hirschfeld et al., 2000). In the present study, HCL-32 and MDQ were applied to screen bipolar depression or MDD. A modified version of the hypomania checklist-32 (mHCL-32) has been developed to screen mixed depression (Prieto et al., 2015). However, mHCL-32 takes too long by patients in clinical practice and so briefer tools to evaluate their condition are preferable (Zimmerman and McGlinchey, 2008). Recently, another clinician-rated scale named The Koukopoulos Mixed Depression Rating Scale (KMDRS) was developed to screen depression with mixed features (Sani et al., 2018). However, the Koukopoulos criteria was used as the “gold standard” for mixed depression, which included symptoms like irritability and psychic agitation, and are excluded from the criteria of MFS in DSM-5 as they are common both in depression and mania episodes and might lead to over-diagnosis (Perugi et al., 2014). The CUDOS-M-C is hence regarded as a brief scale with only 13 items based on the DSM-5 criteria.

However, there are several limitations in this study. Firstly, most of the patients were recruited from a general hospital in the eastern coastal area of China. To apply CUDOS-M-C scale in China, further research using a larger sample size from multiple centers is needed. Secondly, at the time of study implementation, there was no diagnostic interview scale or widely used scales for DSM-5 MFS. Therefore, patients could be assessed only by experienced psychiatrists based on the diagnostic criteria of DSM-5. Thirdly, this study did not perform confirmatory factor analysis to identify the generalization of factor structure of CUDOS-M-C, which will be the focus of our further research. Finally, the study performed the test-retest reliability of CUDOS-M-C and further analysis is needed to ascertain the post-treatment changes of the patients.

The CUDOS-M-C presented a two components structure through PCA with extremely good reliability and validity. Also the scale is time-saving and easy to apply in clinical practice, with an appropriate cut-off value, facilitating screening for depression with mixed features.

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Author contribution statement

Y.L. and S.H. designed the research; Y.L., T.T., W.H., J.B., J.B., L.C. Z.Y. and H.T. performed the research; Y.L. analyzed the data and wrote the paper. S.H., L.M., X.Y. and C.H. edited the manuscript. All authors have approved the final article.

Declarations of Competing Interest

None.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jad.2020.09.117.

Appendix

临床实用DSM-5抑郁混合特征量表(CUDOS-M)
以下每个条目都描述了一种状态, 请圈出在过去一周内 (包括今天) , 最符合自己的分数.

评定日期	没有 (0天)	很少 (1~2天)	有时 (3~4天)	经常 (5~6天)	每天 (7天)
1. 我感觉很开心和愉悦, 甚至有点过头	0	1	2	3	4
2. 我有很多奇妙的,有创意的想法	0	1	2	3	4
3. 我感到极度自信	0	1	2	3	4
4. 我只需睡几个小时, 醒后仍然精力充沛	0	1	2	3	4
5. 我觉得浑身有使不完的劲儿	0	1	2	3	4
6. 我比平时要更健谈	0	1	2	3	4
7. 我比平时语速加快了	0	1	2	3	4
8. 我感觉自己比平时脑子转得飞快	0	1	2	3	4
9. 我承担了许多新任务, 因为我觉得我什么都能干	0	1	2	3	4
10. 我比平时更喜欢出门,跟人打交道	0	1	2	3	4
11. 我干了一些疯狂,冲动的事情	0	1	2	3	4
12. 我比平时更随意花钱	0	1	2	3	4
13. 我对性有更多的想法和幻想	0	1	2	3	4
总分:					

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