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ORIGINAL RESEARCH

Comparison of the Efficacy Between Standard Measurement-Base Care (MBC) and Enhanced MBC for Major Depressive Disorder: A Pilot Study

Yuru He[1,2], Xing Wang[1,2], Zuowei Wang[3,4], Ping Zhang[5], Xiaojia Huang[3,4], Meihong Yu[5], Jill K Murphy[6], Erin E Michalak[6], Jing Liu[6], Tao Yang[1,2], Xiaorui Yang[7], Yiru Fang[1,8,9], Raymond W Lam[6], Jun Chen[1,2]

[1]Clinical Research Center, Shanghai Mental Health Center, Shanghai Jiao Tong University School of Medicine, Shanghai, People's Republic of China; [2]Shanghai Key Laboratory of Psychotic Disorders, Shanghai, People's Republic of China; [3]Division of Mood Disorders, Shanghai Hongkou Mental Health Center, Shanghai, People's Republic of China; [4]Clinical Research Center for Mental Health, School of Medicine, Shanghai University, Shanghai, People's Republic of China; [5]Fengxian District Mental Health Center, Shanghai, People's Republic of China; [6]Department of Psychiatry, University of British Columbia, Vancouver, Canada; [7]Department of Psychology, Shanghai Sixth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, People's Republic of China; [8]Department of Psychiatry & Affective Disorders Center, Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, People's Republic of China; [9]CAS Center for Excellence in Brain Science and Intelligence Technology, Shanghai, People's Republic of China

Correspondence: Jun Chen, Clinical Research Center, Shanghai Mental Health Center, Shanghai Jiao Tong University School of Medicine, Shanghai, 200030, People's Republic of China, Tel +86 21-34773367, Email doctorcj2010@gmail.com; Raymond W Lam, Department of Psychiatry, University of British Columbia, 2255 Wesbrook Mall, Vancouver, BC, V6T 2A1, Canada, Tel +1 604-822-7325, Email r.lam@ubc.ca

Purpose: To validate the efficacy of enhanced measurement-based care against standard measurement-based care in patients with major depressive disorder.

Patients and Methods: In this pilot study of an ongoing multicenter cluster randomized controlled trails, 160 patients diagnosed with major depressive disorder were enrolled from 2 mental health centers, with a plan to include 12 centers in total. One hundred patients engaged in a six-month evaluation using a technology-enhanced measurement-based care tool, including assessments of clinical symptoms, side effects, and functionality at baseline, two months, four months and six months. Simultaneously, the remaining 60 patients underwent standard paper-based measurement-based care, utilizing the same set of scales over the same six-month period, with assessments at the same time points.

Results: Patients utilizing the enhanced measurement-based care tool demonstrated a significantly higher reduction rate in PHQ-9 scores compared to those using standard paper-based measurement-based care during the two-month follow-up. Additionally, a notable positive correlation was observed between the frequency of enhanced measurement-based care tool usage and the quality of life during the two-month follow-up.

Conclusion: Enhanced measurement-based care has the effect of reducing depressive symptoms. Our study emphasized that using enhanced measurement-based care via smartphones is a feasible tool for patients with major depressive disorder. Our future study, including results from additional research centers, may further validate the effectiveness of enhanced measurement-based care.

Keywords: major depressive disorder, measurement-based care, enhanced measurement-based care, smartphone-based intervention

Introduction

Major depressive disorder (MDD) remains one of the most prevalent mental disorders and represents the highest disease burden among psychiatric illnesses,[1] which has become a major public health challenge for the whole world.[2] Despite the numerous therapeutic approaches for MDD,[3–5] such as antidepressants, psychotherapy, and non-invasive neuromodulation like Transcranial Magnetic Stimulation (TMS) and electroconvulsive therapy (ECT),[6–8] the treatment outcomes for

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MDD remain relatively poor.[9] One of the important contributing factors is that selective serotonin reuptake inhibitors (SSRIs), the recommended first-line treatment for MDD, prove beneficial to less than half of MDD patients.[10] Moreover, many patients also suffer from the side effects of antidepressants, making it harder for psychiatrists to adjust the prescription.[11] Patients' poor engagement may also lead to bad clinical outcomes, symptom relapse, and rehospitalization.[12] Therefore, a therapeutic approach that involves active patient participation in the diagnostic and treatment process, coupled with personalized treatment plans, holds the potential to enhance the effectiveness of depression treatment.

Measurement-based care (MBC) refers to the routine use of simple, validated measurement scales, such as the Patient Health Questionnaire-9 (PHQ-9), to assess patients' symptoms on a regular basis.[13] Based on the measurement results, the doctor and patient can together make clinical decisions and select a more individualized treatment plan.[14,15] MBC could also help doctors determine whether patients responded to the treatment or not earlier than usual care alone.[16] There is numerous evidence indicating that MBC is an evidence-based practice. A recent meta-analysis indicated that using MBC to treat depression has higher remission rates and better medication adherence than usual care.[17] MBC has also been recommended by several guidelines, such as the American Psychological Association (APA) and the Canadian Network for Mood and Anxiety Treatments (CANMAT).[3,5] However, MBC is still underutilized in real clinical practice, with less than 20% of healthcare practitioners integrating MBC into their daily practice.[18] Barriers to implementing MBC in clinical practice primarily come from patients, doctors, and institutional levels. Patients may be concerned about the privacy and confidentiality,[19] while doctors may have low motivation to use MBC as well as negative attitudes towards MBC.[19,20] Institutional challenge may include higher personnel demands, and the cost to integrate MBC into the electronic medical record systems.[18]

Digital health platforms have emerged to meet the growing demand for accessible mental health care,[21,22] and conducting MBC on digital health platforms might help to tackle those barriers. There are several existing electronic MBC tools, such as using mobile phone webpages to represent the patient self-rated scales in figures (MoodFx, www.moodfx.ca), which could facilitate the participation of both health care professionals and patients in the MBC process.[23] In this way, the barriers to the follow-up process could be transformed into a catalyst, enabling collaborative decision-making for doctors and patients based on the scale results. One study showed that a smartphone-based daily evaluation monitoring tool could improve the quality of life and reduce perceived stress in bipolar patients.[24] Other studies focused on patients with ADHD also showed improvement in inattentive symptoms.[25] While there was numerous evidence supporting the augmentation of MBC with digital platform to improve the treatment outcomes of mental disorders, few studies have attempted to validate the role of technology enhanced MBC in depression.

To date, only a limited number of studies have explored the use of technology enhanced MBC for the treatment of depression,[26,27] with scant evidence regarding the efficacy of enhanced MBC. To address this gap, we initiated an international cooperation study, the Enhanced Measurement-Based Care Effectiveness for Depression (EMBED).[28] A cluster randomized clinical trial (RCT) was designed to validate the efficacy of enhanced measurement-based care (eMBC) for MDD. The present study represents the pilot results of this cluster RCT, investigating the efficacy of smartphone-based eMBC interventions for depression over a 6-month period, and aiming to provide preliminary evidence for the field of smartphone-based MBC.

Materials and Methods

Subjects

Our study was part of a large multicenter cluster RCT that will eventually include 12 mental health centers. Currently, it involved 2 mental health centers, with the remaining 10 centers to be included later. The study was conducted from September 3, 2022, to December 1, 2023, and approved by the Institutional Review Board of Shanghai Mental Health Center, Shanghai Hongkou Mental Health Center, and Fengxian District Mental Health Center. It was registered on ClinicalTrials.gov (NCT05527951). A total of 160 participants were enrolled in this study. Among them, 100 participants were recruited from Shanghai Hongkou Mental Health Center for the enhanced Measurement-Based Care(eMBC) group, and 60 participants were recruited from Fengxian District Mental Health Center for the MBC group. The difference in

sample size between the eMBC and MBC groups was due to the varying outpatient populations available at each center during the study period. All research personnel received standardized training to ensure consistency during patient enrollment and to guide participants in understanding how to use the WeChat mini-program. All patients completed and provided written informed consent. This study was carried out in accordance with the Declaration of Helsinki.

Inclusion criteria: Outpatients diagnosed with major depressive disorder by a trained psychiatrist, meeting the diagnostic criteria of ICD-10, aged between 18 and 65 years, possessing a smartphone that they can use proficiently, having at least a middle school level of education, possessing the legal capacity to sign the informed consent form.

Exclusion criteria: Presence of evident violent or aggressive behavior or tendencies during disease flare-ups or unstable conditions, inability to cooperate in completing the study content, manifestation of severe suicidal tendencies, absence of a smartphone, and other circumstances hindering cooperation or completion of the study.

Intervention Conditions

eMBC group: The intervention of the eMBC group was enhanced by the technological method of the WeChat mini-program on mobile phones. WeChat is one of the most widely used social apps in China, with 1.336 billion monthly active users in 2023.[29] The WeChat mini-program is integrated within WeChat itself and developed by third-party companies to provide advanced functions without requiring a separate download,[30] making it convenient for people to use. To support eMBC, we have developed a WeChat mini-program that consists of mood tracking and self-management lessons.

Based on conventional treatment, the intervention involves patients independently completing the *"Mood Measure"* functions of the *"Easy to Recover"* WeChat mini-program (See Supplementary Figure 1), including four self-rated scales (The Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety Disorder scale (GAD-7), the Frequency, Intensity, Burden of Side Effects Rating (FIBSER) and Sheehan Disability Scale (SDS)).[31–34] Patients were asked to complete the *"Mood Measure"* regularly (recommendation: once every 2 weeks in the acute phase and once every 4/8 weeks in the maintenance phase). Patients were also asked to complete the *"Mood Measure"* before seeing a doctor. The *"Mood Measure"* also included graphical displays of the scores, interpretations of the scores, and recent changes in scores. Patients could unlock the *"Bounce Back"* section automatically if they meet the diagnosis criteria for mild and moderate depression (the total score of the patient's PHQ-9 is < 21, and the score of the 9th item in PHQ-9 $\neq 3$). The *"Bounce Back"* section, adapted from a program provided by the Canadian Mental Health Association (https://cmha.ca/bounce-back/), comprises six-week sessions, which is grounded in the principles of Cognitive Behavioral Therapy (CBT). Each session includes an introductory video, narrated slides, an exercise book, and worksheets designed for patient completion.

MBC group: Based on conventional treatment, the intervention was standard MBC. Patients were asked to complete a paper version of the 4 scales mentioned above (PHQ-9, GAD-7, FIBSER and SDS) at each outpatient visit and show the results to their doctors.

Data Collection and Measurement

All patients registered on the *esmile* WeChat mini-program to complete survey questions. The *esmile* WeChat mini-program is designed to collect research data, which is different from *Easy to Recover* WeChat mini-program.

At baseline, all patients independently filled out demographic information and scales on *esmile* WeChat mini-program. Self-rated scales include PHQ-9, GAD-7, SDS, FIBSER, and Quality of Life-6 (QOL-6).[35] Self-reported data from patients are collected at four time points: baseline, 2-month follow-up, 4-month follow-up, and 6-month follow-up.

This study primarily gathered demographic information, as well as PHQ-9, GAD-7, FIBSER, QOL6, and SDS scores via *esmile* WeChat mini-program and completion data obtained via *Easy to Recover* WeChat mini-program. Our primary outcome was the reduction rate of depression symptoms. The PHQ-9 assesses depressive symptoms, the GAD-7 evaluates anxiety symptoms, FIBSER is utilized for monitoring medication side effects, SDS is employed to measure functioning, and QOL-6 is for quality of life.[31–35]

Statistics Analysis

All statistical analyses were performed using SPSS 26.0 (IBM Corporation, Armonk New York, USA). We used Kolmogorov–Smirnov tests to assess the assumption of normality of all independent variables before the following analysis.

Age and education were compared between the eMBC and MBC groups using the Mann–Whitney test. We used the χ^2 test for between-group comparisons of gender. We used the Mann–Whitney test to compare the difference between baseline PHQ-9 scores, GAD-7 scores, FIBSER scores, and SDS scores. The independent samples *t*-test was used to compare the two groups' baseline QOL-6 scores.

The reduction rate is defined as baseline scores minus follow-up scores, then divided by baseline scores and multiplied by 100%. The two groups were compared using independent samples *t*-tests for PHQ-9 reduction rates at 6 months, FIBSER reduction rates at 2, 4 months, SDS reduction rates at 4, 6 months, and QOL reduction rates at three follow-up visits. The Mann–Whitney test was used to compare the two groups' PHQ-9 reduction rates at 2, 4 months, GAD-7 reduction rates at three follow-ups, FIBSER reduction rates at 2 months, and SDS reduction rates at 2 months.

We also analyzed the correlation between reduction rates of the 5 scales in *esmile* (PHQ-9, GAD-7, FIBSER, SDS, and QOL-6) and the corresponding frequency of scales completion on *Easy to Recover* using Spearman correlation for the 2, 4, and 6 months follow-ups. We used the Bonferroni method for the multiple comparison correction.

Results

Demographic and Clinical Characteristics

The eMBC group displayed a significantly higher average age (41.68 ± 13.54) compared to the MBC group (33.28 ± 12.21) (Z = 2.906, P < 0.001, see Table 1). No significant difference was observed in terms of educational level or the distribution of sex. Regarding clinical symptoms, we found no significant difference in baseline scores on the PHQ-9, GAD-7, FIBSER, SDS, and QOL-6 between the two groups. See Table 2 for detailed clinical symptoms at baseline and follow-up.

The Changes in Depressive Symptoms

The eMBC group showed a significantly higher PHQ-9 reduction rate than the MBC group at 2 months (Z = −2.262, p = 0.024, see Supplementary Figure 2). There was no significant difference in PHQ-9 reduction rate at 4 or 6 months. For GAD-7 addressing anxiety symptoms, FIBSER gauging medication side effects, SDS evaluating functional improvement, and QOL-6 assessing quality of life, there were no significant differences in the reduction rates at 2, 4, and 6 months of follow-up between the two groups (see Table 3 for details).

The Relationship Between the Frequency of Scale Completion and Quality of Life

In the eMBC group, a significant positive correlation was observed between the frequency of using *Easy to Recover* to complete scales and the reduction rate in quality of life scores during the two-month follow-up period (r = 0.687, p = 0.007, see

Table 1 Demographic and Clinical Characteristics of subjects at Baseline

	MBC Group	eMBC Group	Between-Group Comparisons
Participants (female/male)	60 (37/23)	100 (74/26)	χ^2 = 2.685, p = 0.101
Age (mean ± SD)	33.28 ± 12.21	41.68 ± 13.54	Z = 3.794, p < 0.001*
Education (years ± SD)	13.20 ± 3.47	13.98 ± 3.20	Z = 1.294, p = 0.196
PHQ-9 (mean ± SD)	11.92 ± 7.67	12.15 ± 6.27	Z = 0.381, p = 0.703
GAD-7 (mean ± SD)	9.85 ± 5.78	9.29 ± 5.70	Z = −0.605, p = 0.545
FIBSER (mean ± SD)	2.62 ± 3.53	2.73 ± 3.63	Z = 0.173, p = 0.863
SDS (mean ± SD)	12.60 ± 8.79	13.89 ± 8.71	Z = 0.923, p = 0.356
QOL-6 (mean ± SD)	18.02 ± 3.78	18.30 ± 3.42	T = −0.488, p = 0.626

Note: *P value < 0.05.

Abbreviations: PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder scale; FIBSER, the Frequency, Intensity, Burden of Side Effects Rating; SDS, Sheehan Disability Scale; QOL-6, Quality of Life-6.

Table 2 Clinical Symptoms at Baseline, 2 Month, 4 Month and 6 Month (Mean ± SD)

	MBC Group	eMBC Group
PHQ-9 scores		
Baseline	11.92 ± 7.67	12.15 ± 6.27
2 month	10.70 ± 6.51	5.86 ± 4.42
4 month	7.47 ± 5.70	4.83 ± 5.35
6 month	7.91 ± 6.28	7.52 ± 8.10
GAD-7 scores		
Baseline	9.85 ± 5.78	9.29 ± 5.70
2 month	7.98 ± 6.17	5.71 ± 4.87
4 month	5.92 ± 5.10	2.67 ± 2.58
6 month	6.48 ± 5.67	6.38 ± 6.87
FIBSER scores		
Baseline	2.62 ± 3.53	2.73 ± 3.63
2 month	2.47 ± 2.84	2.57 ± 3.84
4 month	1.61 ± 2.43	0.83 ± 1.32
6 month	1.55 ± 2.43	1.19 ± 2.73
SDS scores		
Baseline	12.60 ± 8.79	13.89 ± 8.71
2 month	10.04 ± 8.13	7.43 ± 6.17
4 month	7.00 ± 6.95	3.17 ± 3.97
6 month	7.06 ± 7.11	7.52 ± 8.42
QOL-6 scores		
Baseline	18.02 ± 3.78	18.30 ± 3.42
2 month	18.96 ± 3.45	19.86 ± 3.46
4 month	20.45 ± 4.27	22.17 ± 1.94
6 month	19.85 ± 3.83	19.76 ± 4.57

Table 3 Reduction Rates of Clinical Symptoms at 2 Month, 4 Month and 6 Month

	MBC Group	eMBC Group	Between-Group Comparisons
PHQ-9 reduction rates			
2 month	−0.50 ± 2.47	0.38 ± 0.35	Z = −2.262, p = 0.024*
4 month	0.13 ± 0.87	−0.32 ± 1.54	Z = −0.408, p = 0.683
6 month	0.26 ± 0.35	0.08 ± 0.94	T = 0.977, p = 0.333
GAD-7 reduction rates			
2 month	0.09 ± 0.65	0.07 ± 0.63	Z = −0.112, p = 0.911
4 month	0.06 ± 1.33	0.43 ± 0.52	Z = −0.510, p = 0.610
6 month	0.17 ± 0.74	−0.24 ± 2.03	Z = −0.140, p = 0.888
FIBSER reduction rates			
2 month	0.37 ± 0.56	0.24 ± 1.01	T = 0.460, p = 0.649
4 month	0.56 ± 0.54	0.65 ± 0.41	T = −0.299, p = 0.768
6 month	0.49 ± 0.67	0.29 ± 1.07	Z = −0.222, p = 0.824
SDS reduction rates			
2 month	0.20 ± 0.47	0.07 ± 1.16	Z = −0.798, p = 0.425
4 month	0.37 ± 0.51	0.66 ± 0.49	T = 0.947, p = 0.350
6 month	0.33 ± 0.43	0.29 ± 0.66	T = 0.219, p = 0.827

(*Continued*)

Table 3 (Continued).

	MBC Group	eMBC Group	Between-Group Comparisons
QOL-6 reduction rates			
2 month	−0.09 ± 0.20	−0.07 ± 0.17	T = −0.253, p = 0.801
4 month	−0.13 ± 0.25	−0.09 ± 0.19	T = −0.379, p = 0.707
6 month	−0.08 ± 0.20	−0.05 ± 0.23	T = −0.556, p = 0.581

Note: *P value < 0.05.

Table 4 The Relationship Between the Frequency of Scale Completion and Quality of Life

	2 Month	4 Month	6 Month
PHQ-9 reduction rate rate rates	r = 0.150, p = 0.625	r = 0.921, p = 0.026	r = −0.275, p = 0.270
GAD-7 reduction rates	r = −0.111, p = 0.718	r = −0.105, p = 0.895	r = −0.215, p = 0.392
FIBSER reduction rate rates	r = 0.194, p = 0.646	r = −0.056, p = 0.944	r = −0.323, p = 0.333
SDS reduction rates	r = 0.033, p = 0.919	r = 0.500, p = 0.667	r = −0.263, p = 0.325
QOL-6 reduction rates	r = 0.687, p = 0.007*	r = −0.029, p = 0.956	r = 0.237, p = 0.314

Note: *P value < 0.01.

Supplementary Figure 3). While we found no correlations between the frequency of scale completion and the reduction rates of PHQ-9, GAD-7, SDS, and FIBSER during the whole follow-up period (see Table 4).

Discussion

In this study, 160 patients underwent a 6-month follow-up, utilizing enhanced measurement-based care via smartphone to evaluate their depressive symptoms, anxiety symptoms, medication side effects, and quality of life. We observed a significant improvement in the PHQ-9 scale within the eMBC group at the two-month follow-up compared to the MBC group. Additionally, within the eMBC group, a noteworthy positive correlation was identified between the frequency of scale completion in *Easy to Recover* and the reduction rate of QOL-6 at two months. These findings collectively suggest that smartphone-based eMBC may serve as a novel and effective way to treat individuals with depressive symptoms.

To our knowledge, this is the first study to compare a smartphone-based eMBC with a traditional paper-and-pencil MBC in the treatment of MDD. We found that the eMBC group had a significantly higher reduction rate of PHQ-9 than that in the MBC group at two months, whereas there was no significant difference in PHQ-9 reduction rate at four months and six months between the two groups. This aligns with our hypothesis that technology enhanced MBC offers patients a more flexible self-assessment platform for more convenient management of depression. This patient-centered data collection method allows patients to complete specified measurements beyond the clinical setting at their convenience by utilizing personal electronic devices (eg, smartphones, tablets, personal computers).[23] Therefore, it can offer more intensive monitoring of their symptoms, allowing both patients and clinicians to accurately identify changes in different aspects of their symptoms in a short term. This could enable timely adjustments to the treatment plan and ensure the prompt delivery of appropriate treatments.[16] By closely monitoring an individual's symptoms' change during the course of treatment, eMBC could inform both positive and adverse changes in treatment to both patients and physicians, making it possible to mitigate deterioration and enhance overall treatment outcomes.[36,37] During the follow-up, the reduction rates of PHQ-9 had no difference between the two groups at four months and six months. This suggested that the long-term efficacy of eMBC and MBC in the treatment and management of patients with depression is comparable. Given that MBC itself is an effective way to treat MDD, this might be caused by improvement in depressive symptoms in both groups, leading to a comparable efficacy between eMBC and MBC group.

We found no significant differences between the eMBC and MBC groups concerning anxiety symptoms, functioning, and quality of life, which indicated that the efficacy of the eMBC and MBC was comparable for these dimensions during the follow-up period. In other words, it suggested that the eMBC was at least as useful as

MBC in these aspects. One plausible reason for this result might be that unlike the depressive symptom captured by PHQ-9, which could be ameliorated quickly by prompt and personalized medication adjustments, achieving full recovery in both functioning and quality of life requires an extended duration, as exemplified in existing literature.[38,39] Thus, the strength of smartphone-based eMBC might not be fully reflected when compared to standard MBC.

Regarding the eMBC group, there was a significant positive correlation between the frequency of patients completing the scale and the quality of life (QOL-6) at two months. A higher QOL-6 reduction rate was associated with an increased frequency of patients completing the scale. This implied that as the perceived quality of life worsened, patients tended to assess their conditions more often. Previous research focused on the utilization of a smartphone-based monitoring tool among bipolar patients revealed an association between quality of life and clinical symptoms, which indicated a close association between reduced quality of life and intensified symptoms.[24] It could be hypothesized that the flexible self-monitoring of symptoms may foster introspection and self-reflection, potentially resulting in positive therapeutic benefits for certain individuals.

This study has some limitations. The participants were recruited as part of a larger cluster RCT. Consequently, the sample size and follow-up duration were determined by the design of the RCT. Furthermore, the Shanghai Hongkou Mental Health Center is in an urban area, while the Fengxian District Mental Health Center is in the suburbs. The differing geographical locations of these centers are consistent with the observed age differences between the groups. Specifically, the Shanghai Hongkou Mental Health Center, located in an urban area, primarily serves a population with a higher proportion of middle-aged and elderly residents. In contrast, the Fengxian District Mental Health Center is situated near a university town in a suburban area, resulting in a younger patient demographic. This geographical context may explain the age differences between the eMBC and MBC groups and may have impacted the results. Therefore, in our future research, there will be more mental health centers from diverse geographical locations to balance the influence of geographical factors. Moreover, there will be an increase in the number of participants, which might be helpful in yielding more findings. An additional limitation is that this investigation only included eMBC and MBC, lacking a comparison with the treat-as-usual (TAU) group. However, as MBC has been proven to be an evidence-based practice, this lack of a TAU group should not be detrimental to the study. Additionally, we did not obtain specific information on pharmacological treatments due to privacy reasons. This limitation is acknowledged in this pilot study, and we plan to include detailed pharmacological information in our future research. Lastly, given that the study was conducted in Shanghai, a metropolitan city in China, the implementation of eMBC interventions in more remote areas may face more challenges. Hence, future multi-center studies are needed to further test the potential utility of eMBC in other cities in China.

Conclusion

This pilot study indicated that eMBC may have advantages in helping MDD patients to ameliorate their depressive symptoms in a short period, while in other aspects, it showed comparable efficacy compared to MBC. This supported the rationale for incorporating eMBC in the comprehensive management of depressed patients, particularly for achieving rapid remission of depressive symptoms. We also observed a connection between the frequency of completing scales and quality of life, suggesting that depressed patients were more likely to seek insights into their condition when perceiving a poor quality of life, which was exactly what eMBC could offer to patients promptly. Our findings suggest that while eMBC provides significant short-term benefits, its long-term efficacy is comparable to traditional MBC. Future studies should consider including a more diverse sample and collecting detailed pharmacological data to further understand the potential of eMBC. Taken together, our study demonstrated the potential clinical feasibility of using eMBC in managing the treatment of MDD.

Data Sharing Statement

The datasets generated or analyzed during the study are available from the corresponding author on reasonable request.

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