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The effectiveness of mindful hypnotherapy on difficulties in emotion regulation, mindfulness, and mental health in patients with major depressive disorder

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Abstract:

BACKGROUND: More than 300 million people are affected by major depressive disorder, and despite advances in treatments over the past 50 years, this number is increasing worldwide. Due to the high prevalence and increasing numbers, along with problems in various aspects of the patient's life, new effective treatments are essential in this field.

MATERIALS AND METHODS: This study was a single-blinded randomized clinical trial. Thirty-four patients with major depressive disorder who were referred by clinical psychologists in the clinical psychology clinic of the Taleghani Hospital, Tehran, Iran, were selected by purposive sampling method and randomly assigned to the intervention and wait-list control groups. The Difficulties in Emotion Regulation Scale, the Five Facet Mindfulness Questionnaire, and the Mental Health Continuum Short Form were administered during the baseline and post treatment. Analyses of covariance and the repeated measures analysis of variance (ANOVA) procedure were performed to determine the difference between study groups.

RESULTS: The results of the analysis of covariance and repeated measures ANOVA showed a clinically significant decrease in difficulties in emotion regulation and a significant increase in mindfulness and mental health in the intervention group ($P < 0.001$). The mean score (standard deviation) of the difficulties in emotion regulation scores was 123.75 (21.10) in the experimental group at baseline and significantly decreased to 76.19 (26.45) and 68.00 (22.83) after the intervention and two-month follow-up, respectively ($P < 0.001$). Additionally, the mean scores (standard deviation) for mindfulness and mental health were 93.06 (8.23) and 19.63 (7.92), respectively, at baseline and significantly increased to 149.43 (16.99) and 51.62 (9.78), respectively, after the intervention and to 144.18 (20.55) and 48.50 (13.52) after a two-month follow-up ($P < 0.001$).

CONCLUSION: The results show that mindful hypnotherapy is an effective treatment for improving difficulties in emotion regulation, mindfulness, and mental health in patients with major depressive disorder.

Keywords:

Emotion regulation, major depressive disorder, mental-health, mindful hypnotherapy, mindfulness

Introduction

Major depressive disorder (MDD) is a major public health concern and one of the most prevalent psychiatric disorders that

is associated with psychosocial impairment, poor quality of life, significant disability, morbidity, and mortality.^[1-4] According to the World Health Organization (WHO), at a global level, more than 300 million

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people (about 4.4% of the world's population) are estimated to suffer from depression, and this number, globally and particularly in lower-income countries, is going up. Furthermore, depression is the major contributing factor to suicide deaths, which is ranked as one of the top 20 causes of death on a global scale with a number close to 800,000 per year.^[5]

One of the potential risk factors for depression is difficulties in emotion regulation.^[6,7] Previous studies show that emotion regulation difficulties are related to psychopathology, especially depression.^[8] Emotion regulation is the ability to modify the expression, experience, and physiology of emotion to meet situational demands^[9] and impairment in any of these components leads to difficulties in emotion regulation.^[10] In major depressive disorder, emotion regulation is impaired, along with persistent negative emotion and a reduction in positive emotion.^[11] Therefore, changing the processes that create and maintain emotion regulation problems is an important therapeutic task.

Another component that contributes to depression is a weakness in mindfulness.^[8,12] Mindfulness is defined as being aware of present-moment experiences (such as feelings, emotions, and thoughts) in a non-reactive and non-judgmental way with acceptance.^[13,14]

Although randomized control trials have proven that many therapeutic approaches, which include cognitive behavioral therapy (CBT), interpersonal psychotherapy (IPT), and antidepressant medications, can be effective for treating MDD, a significant number of individuals do not respond to either CBT or IPT or currently available medications.^[1,15] Moreover, antidepressants have shown no superior effect over placebo or affect depression and suicide rates.^[16] Also, 50% to 90% of these patients are profoundly vulnerable to relapse even after symptom reduction.^[17] Therefore, researchers and therapists should develop more effective treatments for MDD.

In recent years, new integrative psychotherapy approaches in clinical hypnotherapy, such as cognitive hypnotherapy (CH),^[18] have been developed by clinicians who consider hypnosis as a useful adjunct to mainstream psychotherapy for depression.^[15] Meta-analysis studies have shown that when CBT is combined with hypnosis (CBTH), therapeutic gains are statistically significantly superior to CBT alone.^[19] Another study showed that hypnosis also enhances the effectiveness of psychodynamic psychotherapy.^[20,21] Furthermore, new integrative therapies in mindfulness-based treatments such as mindfulness-based cognitive therapy (MBCT)^[22] have emerged in recent years. Finally, mindful hypnotherapy^[23] have emerged as a novel and effective

therapeutic approach from both mindfulness and hypnotherapy approaches. Psychotherapy integration focuses on the connection between theory, evidence, and techniques.^[24,25]

Mindful hypnotherapy (MH) by integrating hypnosis (hypnotic induction and suggestion) and mindfulness has critical clinical contemplation for improved intervention efficiency and effectiveness and attempts to produce a deeper level of change in patients.^[23,26,27] Hypnosis is a powerful delivery vehicle for mindfulness that enables mindfulness to be absorbed and integrated more easily, efficiently, and effectively.^[23] An important feature of mindfulness that is used in this treatment is a non-judgmental, accepting, and flexible relationship with one's internal (physical sensations, emotions, and thoughts) and external experience.^[23] Another principal used in both mindfulness and clinical hypnosis is guided imagery and alterations in attention for enriched mind-body connection.^[28] Other characteristics include non-judgmental attitudes and acceptance of what cannot be changed, resilience toward life's difficulties and focus on values, hypnotic imagery of compassion toward oneself and others, and post-hypnotic suggestions to elevate the willingness to practice mindfulness skills.^[23,29,30]

Despite previous studies on mindful hypnotherapy intervention having shown the feasibility, efficacy, and effectiveness of this novel intervention on mindfulness, psychological flexibility, and depression in college students,^[31] and another study having shown increased mindfulness skills and reduced stress reactivity,^[30] there have been no trials to date with MDD patients. The present study addresses these gaps in empirical literature by investigating the effectiveness of mindful hypnotherapy intervention on difficulties in emotion regulation, mindfulness, and mental health in patients with MDD.

Materials and Methods

Study design and setting

The current study is a single-blinded randomized control trial (RCT) that was conducted in 2022 in the Taleghani Hospital, Tehran, Iran. A random number sequence was generated with a random number generator function in SPSS software. For blinding, the data collector and analyst were not informed about the study objectives.

Study participants and sampling

Participants included adults with MDD who were referred by clinical psychologists in the clinical psychology clinic of Taleghani Hospital, Tehran, Iran. The sample size was calculated using G*Power software using analysis of covariance and considering effect size as

0.50, α as 0.05, power as 0.80, and considering two-group, which resulted in 34 participants.

Inclusion criteria: Diagnosis of MDD based on DSM-5; score above 28 on the Beck Depression Inventory-II; sign the informed consent form; aged between 18 and 50 years; and ability to attend sessions regularly.

Exclusion criteria: Serious suicidal ideation or any plan to attempt suicide; received a psychological treatment in the past 6 months; being under another psychological treatment simultaneously; recent substance abuse; diagnostic of borderline personality, bipolar, psychosis, or schizophrenia disorders.

Data collection tool and technique

The Difficulties in Emotion Regulation Scale (DERS), the Five-Facet Mindfulness Questionnaire (FFMQ), and the Mental Health Continuum Short Form (MHC-SF) were conducted at baseline, post intervention, and two-month follow-up.

Instruments

Difficulties in Emotion Regulation Scale (DERS): The DERS is a 36-item self-report with a five-point Likert scale, from scores 1 (almost never) to 5 (almost always). It includes six subscales that reflect the various dimensions of emotion regulation difficulties: non-acceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity. The overall score was calculated using the sum of all 36 items. The higher the total score, the more difficulties in emotion regulation. The DERS has good construct and predictive validity with other emotion regulation scales.^[32] Internal consistency for total DERS is relatively high (Cronbach's $\alpha = 0.94$). Also, each factor of the scale has a high level of internal consistency (Cronbach's $\alpha = 0.80$ to 0.93).^[33]

Five Facet Mindfulness Questionnaire (FFMQ): The FFMQ is a 39-item questionnaire that assesses five facets of a general tendency to be mindful of daily life.^[34] The five facets are (observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience) alongside overall mindfulness. Items ranging from 1 (never or very rarely true) to 5 (very often or always true) are rated on a five-point Likert-type scale. The overall score of mindfulness is calculated by summing up all 39 items, and higher scores reflect higher levels of mindfulness. The alpha coefficients of each subscale are reported from 0.82 to 0.93.^[35,36] The FFMQ have moderate-to-high internal consistency with Cronbach's α being 0.75 to 0.91.^[34] In another study, the internal consistency of the FFMQ total scale was 0.89.^[8]

Mental Health Continuum Short Form (MHC-SF): The mental health continuum was developed by Keyes^[37] and includes 14 items to assess positive mental health and health status in the past month. This questionnaire includes three subscales of emotional well-being, psychological well-being, and social well-being and is graded based on a six-point Likert scale from 0 (never) to 6 (every day). The minimum possible total score is 0 and the highest score is 70. The internal consistency of the overall MHC-SF was 0.74.^[37] In another study, the internal consistency for the total MHC-SF was ($\alpha =$) 0.89, along with the subscales of emotional well-being (0.83), psychological well-being (0.83), and social well-being (0.74).^[38]

Ethical consideration

This study was approved by the ethical review board of Shahid Beheshti University of Medical Sciences (ethical code No: IR.SBMU.RETECH.REC.1400.880) and Iranian registry of clinical trials (IRCT code No: IRCT20211210053342N1). All participants were informed about the conditions of the study and signed the informed consent form.

Intervention

Participants in the intervention group were treated for eight weeks, with one-hour individual sessions of mindful hypnotherapy, as illustrated in the mindful hypnotherapy manual [Table 1].^[23] The therapist was a clinical psychologist with four years of experience in clinical hypnotherapy and mindfulness-based interventions.

Statistical analysis

Collected data were analyzed using SPSS software, version 24. To evaluate the differences between groups in the sociodemographic and clinical characteristics in the baseline measures, the Chi-square [Table 2] and independent samples *t*-test [Table 3] were performed. Furthermore, to evaluate the equality of variances on groups of comparison analysis, Levene's test was performed [Table 3]. Table 4 provides the mean and standard deviation scores of clinical characteristics. Finally, analysis of covariance [Table 5] and repeated measures ANOVAs [Table 6] were conducted to compare study groups in clinical variables, including difficulties in emotion regulation, mindfulness, and mental health.

Results

Of the 34 patients with major depressive disorder who had been randomly assigned to MH and control groups (17 in each group), 31 patients (16 in MH group and 15 in the WLC group) completed the post-test and follow-up. Results from Chi-square test indicated that the two groups were similar in sociodemographic

Table 1: Overall content for treatment sessions

Session 1: Present-Moment Awareness

Introducing Hypnosis: Hypnosis was introduced and discussed in addition to the participants' previous experience, attitudes, and misconceptions regarding it. Personal information was also collected to personalize the hypnosis.

Introducing Mindfulness: Mindfulness, with an emphasis on present-moment awareness, was introduced. The awareness of experiences in the present moment is the essential basis of the practice of mindful hypnosis.

Hypnotic Induction for Present-Moment Awareness: The hypnotic induction for session one consisted of suggestions for "centering" oneself via present-moment awareness of raw sense data such as sounds and visual stimuli. Post-hypnotic suggestions were given to the participants for being able to do this easily in everyday life. At the end of the session, they were provided with a home practice hypnotic induction audio-record for session one.

Session 2: Non-judgmental Awareness and Acceptance of Bodily Sensations

Review Home Practice: Home practice was reviewed and any obstacles to the practice were discussed. It also discussed how well the previous week's content had been integrated into the client's life.

Mindfulness for Present-Moment Awareness and Acceptance of Bodily Sensations: mindfulness with an emphasis on present-moment awareness of bodily sensations was explained, and non-judgmental awareness and acceptance of these bodily sensations was practiced.

Hypnotic Induction for Non-judgmental Awareness and Acceptance of Bodily Sensations: Hypnotic suggestions included present-moment and non-judgmental awareness and acceptance of bodily sensations. Post-hypnotic suggestions for daily and regular practice and for the integration of mindful awareness of bodily sensations in daily life were given. At the end of the session, the participant was provided with a home practice hypnotic induction audio-record.

Session 3: Mindfulness of Thoughts and Emotions

Review Home Practice: Home practice and any questions that may have arisen when integrating the previous week's material were discussed.

Mindfulness for Non-Judgmental Awareness and Acceptance of Thoughts and Emotions: The concept of mindfulness of thoughts and emotions was elaborated upon by building on previous sessions. New material began with psychoeducation regarding thoughts and emotions and their relationship with symptoms. In these regards, habitual thoughts and emotions related to the patients' symptoms were explored; then, the participant was taught to become mindfully aware of thoughts and emotions. As with all sessions, these mindfulness skills were applied to the clients' situations and needs.

Hypnotic Induction with Content Non-Judgmental Awareness and Acceptance of Thoughts and Emotions: The hypnotic induction focused on a guided experience of the participant becoming mindfully aware of thoughts and emotions. In the session, participants were asked to become aware of a mild or moderately emotional recent event and were then guided through being mindfully aware of the emotion with acceptance. Post-hypnotic suggestions were given for daily mindfulness of thought and emotion. After the session, the participant was provided with a home practice hypnotic induction audio-record for session three.

Session 4: Integrating Self-Hypnosis into Mindful Hypnotherapy

Review Home Practice: As usual, home practice and any obstacles to the practice were discussed.

Self-Hypnosis Psychoeducation: The principles, steps, and the process of self-hypnosis were learned. Self-suggestions can be tailored to the client's particular needs or preferences, such as using sound or paying attention to the sensations of breathing to enter a trance.

Hypnotic Induction and Practice of Self-Hypnosis: This session included two hypnotic inductions. In the first induction, the participant was guided by detailed instruction through 10 steps of self-hypnosis and they named each step as it was performed. In the second part, each step was named and minimal guidance was provided, relying upon the subjects to guide themselves through the hypnosis experience in their own way. At the end of the session, the participant was provided with a self-hypnosis audio-record for home practice. Self-hypnosis without using audio recordings should also be practiced this week.

Session 5: Mindful Hypnotherapy for Compassion

Review Home Practice: Self-hypnosis practice and any obstacles and questions were discussed.

Mindful Self-Compassion and Compassion for Others: In this session, the client's self-attack, self-judgment, self-hatred, and lack of self-compassion were investigated. To fix these destructive ways of relating to the self, self-compassion was introduced with psychoeducation and was practiced as a useful attitude. Additionally, any reservations they may have had in cultivating greater self-compassion in addition to specific aspects of their life when self-compassion may be particularly difficult to practice were explored.

Hypnotic Induction with Content Self-Compassion and Compassion toward Others: The goal of hypnotic induction is to create a mental framework with compassion toward oneself and others. In the trance-like state, participants become more aware of feelings of compassion and loving-kindness. During the induction, a client begins by bringing to mind an individual who is easy to love (parent, mentor, god (s), etc.) and gradually expands the circle of this love to include oneself and others. Suggestions were then given for experiencing that same compassion toward a neutral party, those who are difficult to get along with, and for themselves. Post-hypnotic suggestions enable them to experience compassion frequently and recall it at will at difficult times. Finally, the participant was provided with a "hypnosis mindful self-compassion" home audio practice.

Session 6: Mindful Hypnotherapy for the Awareness of Values

Review Home Practice: As with previous sessions, home practice and any obstacles to the practice were reviewed.

Review Previous Sessions: Materials from the previous sessions were reviewed to provide a context for the new material. Over the previous week, clients explored what they needed in the present moment to be well and to care for themselves. This principle of compassion can be expanded to encompass their greater life goals and embrace a greater sense of congruence with their values.

Mindful Awareness of Values and Living Based on Values: The client's values and sense of meaning in life were explored, as well as the extent to which the participant has been acting congruently with these values and pursuing a meaningful life. Naturally, some clients were already aware of many of their values that were discussed in this

Contd...

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Table 1: Contd...

session. For clients who had a clear understanding of their values and sense of purpose in life, session 6 could be an opportunity to reflect on these themes and re-dedicate themselves to those activities and perspectives that feed their sense of meaning. If daily life was congruent with the participant's values, the session focused on deepening and expanding it, in addition to the participant becoming mindful of their values daily. If incongruence was discovered, obstacles to congruence were identified, and MH skills that participants had newly learned were used to overcome these obstacles.

Hypnotic Induction for Awareness of Values and Living Based on Values: Hypnotic induction is meant to evoke a greater sense of meaning in life. In the hypnotic trance, suggestions were given for dedication to the participant's values, integrating principles of mindfulness to support the congruence between these values and the pursuit of personally meaningful life goals, and behavior. At the end of the session, the participant was provided with a hypnotic induction audio recording for home practice.

Session 7: Deepening and Integrating Mindful Hypnosis

Review Home Practice: Before the session began, home practice and any obstacles to it were reviewed.

Integrating all Aspects of Mindfulness into Daily Life: The client's progress in integrating mindfulness into their daily life was discussed. Also, the client's understanding of mindfulness concepts was reinforced by further discussion and education. This session was an opportunity to ensure that MH was helping the client address their presenting concern. Some clients may still be struggling with some obstacles in their lives, and they may feel unsure of how to apply what they know to overcome them. In addressing specific problems, the therapist can bring in myriad components of MH practice and provide a model for how a client can bring MH to bear on future problems once treatment ends.

Hypnotic Induction for Deepening and Integrating Mindfulness: In hypnotic induction, all aspects of mindfulness were integrated into the client's individual goals and needs. The provided script was integrated with the individual goals, needs, and current problems, and every part of the mindfulness practice that needs to be practiced more, according to the mentioned issues, was reinforced. Finally, the participant was provided with the "Integrated Mindful Hypnotherapy" audio recording for home practice.

Session 8: Termination and Transition to Long-Term Practice

Review Home Practice: Before the session began, home practice and any obstacles to it were reviewed.

Transition to Long-Term Practice of Mindful Hypnosis: The strategic themes of session 8 included reviewing and reinforcing what clients had learned throughout the intervention, as well as helping them maintain their therapeutic gains and transition to long-term practice. Any type of treatment gain, such as the reduction of depression or other positive effects and changes in perception, attitude, emotions, and other therapeutic mechanisms based on mindfulness experience that led to the maintenance of positive changes later in life was highlighted and discussed. Then, the therapist and client collaborated to outline what actions could be taken to remove barriers to maintenance and make constructive changes in the future.

Hypnotic Induction: Hypnotic suggestions included relaxation and present-moment and nonjudgmental awareness of internal and external experiences, such as thoughts, sensations, and emotions, without trying to avoid or get caught up in them. Also, the client was guided toward becoming aware of this moment with equanimity and compassion/self-compassion. Post-hypnotic suggestions were given for the long-term continuation of daily mindful hypnotherapy practice, as well as for integrating mindfulness as a trait and an easily accessible state of mind.

Table 2: Demographic characteristics of the participants

Variable	MH Mean (SD)	WLC Mean (SD)	Chi-squared test
Age (years)	32.75 (9.42)	31.33 (6.42)	0.630
Education Level			
Diploma	4	3	0.526
Associate	2	1	
Bachelor	6	7	
Master	2	4	
PhD	2	0	
Marital Status			
Single	10	9	0.567
Married	5	5	
Divorced	0	1	
Widow	1	0	
Occupation			
Employed	9	8	0.387
Housewife	4	4	
Student	3	1	
Unemployed	0	2	

MH=Mindful hypnotherapy; WLC=Wait-list control group; SD=Standard deviation

variables ($P > .05$). Additionally, the independent sample *t*-test indicated that the two groups were similar in clinical variables, including difficulties in emotion regulation, mindfulness, and mental health

at pre-intervention evaluation ($P > .05$). Furthermore, Levene's test indicated that variances of difficulties in emotion regulation, mindfulness, and mental health were equal in the study groups ($P > .05$).

According to the presented data in Table 5, there was a significant reduction in all aspects of difficulties in emotion regulation, including non-acceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, lack of emotional clarity and total scores in the intervention group compared with the control group ($P < 0.001$).

The results of repeated measure ANOVAs [Table 6] revealed the significant effect of time (the baseline, post-intervention, and follow-up), with the main effect of time, $F = 9.98$ to 19.54 , $P < 0.001$, and effect size of .25 to .40 for subscales, and total score $F = 22.38$, $P < 0.001$, effect size = 0.43. The within-subject test of repeated measure analysis indicates a significant time \times group, with the main effect, $F = 12.93$ to 29.06 , $P < 0.001$, and effect size = 0.30 to 0.50, and total score $F = 27.20$, $P < 0.001$, effect size = 0.48. The between-subject test indicates a significant difference between groups across

Table 3: Levene’s test of equality of variances and Independent t-test for equality of means

Variable	Subscales	Independent t-test for Equality of Means at Baseline		Levene’s Test of Equality of Variances			
		Sig. (2-tailed)	F	Post Intervention		Follow-Up	
				Sig.	F	Sig.	
Difficulties in Emotion Regulation	Non-acceptance	0.937	2.801	0.105	0.258	0.615	
	Goals	0.625	2.592	0.118	1.290	0.265	
	Impulsiveness	0.767	1.622	0.213	1.173	0.288	
	Awareness	0.155	0.700	0.410	0.057	0.814	
	Strategies	0.811	3.579	0.069	1.842	0.185	
	Clarity	0.853	0.265	0.611	0.215	0.646	
	Total	0.843	2.913	0.099	2.057	0.162	
Mindfulness	Observing	0.594	0.826	0.371	0.095	0.760	
	Describing	0.094	0.041	0.841	0.825	0.371	
	Acting with awareness	0.715	0.279	0.601	0.001	0.981	
	Non-judgment of inner experience	0.516	2.848	0.102	2.431	0.130	
	Non-reactivity to inner experience	0.992	0.055	0.816	2.661	0.114	
	Total	0.237	2.499	0.125	2.966	0.096	
	Total	0.069	1.844	0.185	2.686	0.112	
Mental Health	Emotional well-being	0.134	2.306	0.140	0.115	0.737	
	Psychological well-being	0.067	1.677	0.206	3.355	0.077	
	Social well-being	0.065	2.834	0.103	3.243	0.082	
	Total	0.065	2.834	0.103	3.243	0.082	

time, with the main effect, $F = 13.12$ to 60.54 , $P < 0.001$, and effect size = 0.31 to 0.67, and for the total score, $F = 35.55$, $P < 0.001$, effect size = 0.55. In other words, the intervention group resulted in significant changes in difficulties in emotion regulation over time.

Results of Analysis of covariance also indicate that observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience aspects of mindfulness has significant improvement in the intervention group compared with the control group in the baseline to post-intervention, and follow-up; in fact, a reduction was not observed in the control group ($P < 0.001$).

The results of repeated measure ANOVAs revealed the significant effect of time, $F = 21.35$ to 59.75 , $P < 0.001$, and effect size of 0.42 to 0.67 for subscales, and total score $F = 74.85$, $P < 0.001$, effect size = 0.72. The within-subject test of repeated measure analysis indicates a significant time \times group, with the main effect for subscales except describing subscale, $F = 12.06$ to 36.36 , $P < 0.001$, and effect size = 0.29 to 0.55, and for total score $F = 35.31$, $P < 0.001$, size = 0.54. For describing subscale results was $F = 3.94$ and $P < 0.032$ and effect size = 0.12. The between-subject test indicates a significant difference between groups across time, with the main effect, $F = 24.59$ to 63.29 , $P < 0.001$, and effect size = 0.47 to 0.68, and for the total score, $F = 74.79$, $P < 0.001$, effect size = 0.72. The intervention group resulted in significant changes in the mindfulness scores over time.

Finally, results of emotional, psychological, and social well-being and total score of mental health showed a significant increase in the mindful hypnotherapy group

compared with the control group ($P < 0.001$). The results of repeated measure ANOVAs revealed the significant effect of time, $F = 27.17$ to 56.00 , $P < 0.001$, and effect size of 0.48 to 0.65 for subscales, and total score $F = 52.14$, $P < 0.001$, effect size = 0.64. The within-subject test of repeated measure analysis indicates a significant time \times group, with the main effect for subscales, $F = 22.53$ to 51.24 , $P < .001$, and effect size = 0.43 to 0.63, and for total score $F = 44.82$, $P < 0.001$, and effect size = 0.60. The between-subject test indicates a significant difference between groups across time, with the main effect, $F = 49.07$ to 115.48 , $P < 0.001$, and effect size = 0.62 to 0.79, and for the total score, $F = 84.38$, $P < 0.001$, and effect size = 0.74. the intervention group resulted in significant changes in mental health scores over time.

Discussion

Current study evaluated the effectiveness of mindful hypnotherapy in the reduction of difficulties in emotion regulation and improving mindfulness and mental health in patients with MDD. Results showed statistically significant changes in outcome variables after intervention, including improvements in mindfulness and mental health compared to control groups. Also, the intervention group had a statistically significant decrease in difficulties in emotion regulation after treatment compared with the control group. These findings were similar to those of a previous study on mindful hypnotherapy in overall mindfulness^[30,31].

One of the potential and transdiagnostic risk factors of depression is difficulties in emotion regulation.^[6,7] Over recent years, emotion regulation has been considered a central process in the etiology and treatment of

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Table 4: Mean and standard deviation pre intervention, post intervention, and at follow-up

Variable	Subscale	Group	Mean (SD)		
			Pre Intervention	Post Intervention	Follow-Up
Difficulties in Emotion Regulation	Non-acceptance of emotional responses (NONACCEPT)	MH	19.50 (5.21)	12.25 (6.88)	9.63 (3.79)
		WLC	19.67 (6.33)	19.53 (4.65)	20.53 (5.09)
	Difficulty engaging in goal-directed behavior (GOALS)	MH	20.06 (4.82)	12.06 (5.63)	11.56 (3.75)
		WLC	19.20 (4.88)	19.67 (4.30)	19.87 (3.54)
	Impulse control difficulties (IMPULSE)	MH	20.69 (5.25)	12.69 (5.63)	12.00 (4.23)
		WLC	21.27 (5.53)	21.60 (4.51)	21.67 (4.10)
	Lack of emotional awareness (AWARENESS)	MH	18.37 (4.14)	11.19 (3.48)	11.31 (3.62)
		WLC	20.53 (4.06)	22.20 (5.25)	21.13 (4.61)
	Limited access to emotion regulation strategies (STRATEGIES)	MH	29.69 (6.52)	14.81 (5.41)	14.94 (7.15)
		WLC	29.07 (7.78)	30.40 (4.61)	30.67 (6.04)
Lack of emotional clarity (CLARITY)	MH	15.44 (3.77)	8.56 (2.22)	8.56 (2.33)	
	WLC	15.67 (2.99)	15.93 (3.01)	14.73 (2.60)	
Total score	MH	123.75 (21.10)	76.19 (26.45)	68.00 (22.83)	
	WLC	125.40 (24.86)	126.93 (18.06)	128.60 (19.11)	
Mindfulness	Observing	MH	21.50 (4.27)	33.06 (3.51)	31.87 (4.58)
		WLC	20.73 (3.59)	22.53 (5.59)	23.00 (5.59)
	Describing	MH	20.81 (3.69)	28.44 (3.22)	27.81 (3.35)
		WLC	18.53 (3.62)	22.20 (2.54)	23.73 (2.68)
	Acting with awareness	MH	17.63 (3.42)	29.31 (6.42)	29.63 (6.21)
		WLC	17.13 (3.99)	20.07 (5.52)	18.40 (6.12)
	Non-judgment of inner experience	MH	16.88 (3.03)	32.63 (5.12)	31.31 (5.79)
		WLC	16.00 (4.30)	17.93 (3.63)	17.80 (4.17)
	Non-reactivity to inner experience	MH	16.25 (3.58)	26.00 (3.09)	24.06 (4.23)
		WLC	16.27 (5.12)	16.47 (2.92)	15.87 (3.24)
Total	MH	93.06 (8.23)	149.43 (16.99)	144.18 (20.55)	
	WLC	88.66 (11.84)	99.20 (11.83)	98.06 (13.95)	
Mental Health	Emotional well-being	MH	5.00 (2.47)	11.44 (2.03)	9.94 (3.25)
		WLC	3.20 (2.83)	3.40 (2.38)	3.67 (2.05)
	Psychological well-being	MH	8.81 (4.59)	22.50 (5.15)	21.31 (6.35)
		WLC	6.20 (4.84)	5.93 (3.78)	8.67 (6.35)
	Social well-being	MH	5.81 (1.97)	17.69 (3.64)	17.25 (4.55)
		WLC	4.20 (2.70)	4.33 (2.87)	4.60 (2.50)
	Total MHC	MH	19.63 (7.92)	51.62 (9.78)	48.50 (13.52)
		WLC	13.60 (9.50)	13.67 (7.47)	16.27 (7.96)

MH=Mindful hypnotherapy; WLC=Wait-list control group; SD=Standard deviation

psychopathology (39, 40), and many mental disorders are characterized by problems with emotion regulation (41, 42). Emotion regulation is the ability to modify the expression, experience, and physiology of emotion to meet situational demands.^[9] Impairment in any of these components leads to difficulties in emotion regulation.^[10] In MDD, emotion regulation is impaired, alongside persistent negative emotions and a reduction in positive emotions.^[11] Furthermore, emotion regulation, which has obtained growing support in the field of transdiagnostic process,^[8,39,40] identify as a pathway through which mindfulness improves mental health.^[8]

Besides the difficulties in emotion regulation, another key component that contributes to depression is a deficiency in mindfulness features.^[8,12] Mindfulness refers to a process that leads one to a mental state characterized by non-judgmental awareness of the present moment's internal (body sensations,

emotions, thoughts) and external experience, while encouraging openness, curiosity, and acceptance.^[41,42] Mindfulness is a common factor across all schools of psychotherapy^[43] and is consistently associated with lower rates of depression,^[8,12] fewer emotion regulation difficulties,^[44,45] and greater mental health.^[46] Therefore, in mindful hypnotherapy, learning aspects of mindfulness including present-moment awareness, non-judgmental awareness of bodily sensation, non-judgmental awareness of thoughts and emotions, and awareness of personal values and meaning in life, in addition to self-hypnosis and self-compassion, leads to improvement in mindfulness, emotion regulation, and mental health.

Additionally, depressed patients generally have diminished sensory capacity, leading to a dull sensory experience, loss of libido, and generalized anhedonia.^[47] In MH, sensory capacity can be improved by acceptance

Table 5: Comparison of outcome measures pre intervention to post intervention and follow-up based on analysis of covariance (ANCOVA)

Variable	Subscale	Source	F	Sig.	Effect Size	Observed Power
Difficulties in Emotion Regulation	Non-acceptance of emotional responses (NONACCEPT)	Post intervention	12.50	0.001 ^{a,b}	0.309	0.927
		Follow-up	48.42	0.000 ^{a,b}	0.634	1.000
		Multivariate tests	23.43	0.000 ^{a,b}	0.635	1.000
	Difficulty engaging in goal-directed behavior (GOALS)	Post intervention	26.12	0.000 ^{a,b}	0.483	0.999
		Follow-up	49.60	0.000 ^{a,b}	0.639	1.000
		Multivariate tests	24.22	0.000 ^{a,b}	0.642	1.000
	Impulse control difficulties (IMPULSE)	Post intervention	25.40	0.000 ^{a,b}	0.476	0.998
		Follow-up	49.22	0.000 ^{a,b}	0.637	1.000
		Multivariate tests	23.76	0.000 ^{a,b}	0.638	1.000
	Lack of emotional awareness (AWARENESS)	Post intervention	48.41	0.000 ^{a,b}	0.634	1.000
		Follow-up	38.94	0.000 ^{a,b}	0.582	1.000
		Multivariate tests	24.52	0.000 ^{a,b}	0.645	1.000
	Limited access to emotion regulation strategies (STRATEGIES)	Post intervention	97.08	0.000 ^{a,b}	0.776	1.000
		Follow-up	45.42	0.000 ^{a,b}	0.619	1.000
		Multivariate tests	47.53	0.000 ^{a,b}	0.779	1.000
	Lack of emotional clarity (CLARITY)	Post intervention	58.64	0.000 ^{a,b}	0.677	1.000
		Follow-up	49.01	0.000 ^{a,b}	0.636	1.000
		Multivariate tests	41.62	0.000 ^{a,b}	0.755	1.000
Total score	Post intervention	40.16	0.000 ^{a,b}	0.589	1.000	
	Follow-up	63.70	0.000 ^{a,b}	0.695	1.000	
	Multivariate tests	30.76	0.000 ^{a,b}	0.695	1.000	
Mindfulness	Observing	Post intervention	38.22	0.000 ^{a,b}	0.577	1.000
		Follow-up	22.19	0.000 ^{a,b}	0.442	0.995
		Multivariate tests	18.42	0.000 ^{a,b}	0.577	1.000
	Describing	Post intervention	28.48	0.000 ^{a,b}	0.504	0.999
		Follow-up	11.13	0.002a	0.285	0.896
		Multivariate tests	14.10	0.000 ^{a,b}	0.511	0.997
	Acting with awareness	Post intervention	17.68	0.000 ^{a,b}	0.387	0.982
		Follow-up	24.98	0.000 ^{a,b}	0.472	0.998
		Multivariate tests	12.89	0.000 ^{a,b}	0.489	0.994
	Non-judgment of inner experience	Post intervention	84.30	0.000 ^{a,b}	0.751	1.000
		Follow-up	51.73	0.000 ^{a,b}	0.649	1.000
		Multivariate tests	41.50	0.000 ^{a,b}	0.755	1.000
	Non-reactivity to inner experience	Post intervention	80.55	0.000 ^{a,b}	0.742	1.000
		Follow-up	35.72	0.000 ^{a,b}	0.561	1.000
		Multivariate tests	38.83	0.000 ^{a,b}	0.742	1.000
	Total	Post intervention	81.47	0.000 ^{a,b}	0.744	1.000
		Follow-up	48.50	0.000 ^{a,b}	0.634	1.000
		Multivariate tests	39.37	0.000 ^{a,b}	0.745	1.000
Mental Health	Emotional well-being	Post intervention	99.32	0.000 ^{a,b}	0.780	1.000
		Follow-up	32.07	0.000 ^{a,b}	0.534	1.000
		Multivariate tests	50.09	0.000 ^{a,b}	0.788	1.000
	Psychological well-being	Post intervention	101.41	0.000 ^{a,b}	0.784	1.000
		Follow-up	25.28	0.000 ^{a,b}	0.474	0.998
		Multivariate tests	49.77	0.000 ^{a,b}	0.787	1.000
	Social well-being	Post intervention	107.08	0.000 ^{a,b}	0.793	1.000
		Follow-up	74.76	0.000 ^{a,b}	0.728	1.000
		Multivariate tests	52.90	0.000 ^{a,b}	0.797	1.000
	Total MHC	Post intervention	128.84	0.000 ^{a,b}	0.821	1.000
		Follow-up	51.89	0.000 ^{a,b}	0.650	1.000
		Multivariate tests	66.07	0.000 ^{a,b}	0.830	1.000

^aP<0.05, ^bP<0.001

and non-judgmental awareness of physical sensations. Furthermore, when people constantly evaluate and judge themselves negatively, parts of the self dissociate.^[46] Thus,

in MH by creating a new relationship with themselves and with compassion, there is less self-judgment and more self-kindness.

Table 6: Comparison of outcome measures pre treatment to post treatment and follow-up based on repeated measures ANOVA

Variable	Subscale	Test	Source	F	Sig.	Effect size	Observed power
Difficulties in Emotion Regulation	Non-acceptance of emotional responses	Within-subjects effects	Time	9.98	0.000 ^{a,b}	0.256	0.968
			Time × Group	12.93	0.000 ^{a,b}	0.308	0.992
		Between-subjects effects	Group	16.51	0.000 ^{a,b}	0.363	0.975
		Within-subjects effects	Time	17.12	0.000 ^{a,b}	0.371	0.998
	Difficulty engaging in goal-directed behavior		Time × Group	22.63	0.000 ^{a,b}	0.438	1.000
		Between-subjects effects	Group	13.12	0.001 ^{a,b}	0.312	0.938
	Impulse control difficulties	Within-subjects effects	Time	14.39	0.000 ^{a,b}	0.332	0.990
			Time × Group	17.17	0.000 ^{a,b}	0.372	0.997
		Between-subjects effects	Group	19.02	0.000 ^{a,b}	0.396	0.988
		Within-subjects effects	Time	12.77	0.000 ^{a,b}	0.306	0.986
	Lack of emotional awareness		Time × Group	24.20	0.000 ^{a,b}	0.455	1.000
		Between-subjects effects	Group	35.16	0.000 ^{a,b}	0.548	1.000
	Limited access to emotion regulation strategies	Within-subjects effects	Time	19.54	0.000 ^{a,b}	0.403	0.999
			Time × Group	29.06	0.000 ^{a,b}	0.501	1.000
		Between-subjects effects	Group	32.95	0.000 ^{a,b}	0.532	1.000
		Within-subjects effects	Time	16.45	0.000 ^{a,b}	0.362	0.998
	Lack of emotional clarity		Time × Group	13.60	0.000 ^{a,b}	0.319	0.993
		Between-subjects effects	Group	60.54	0.000 ^{a,b}	0.676	1.000
Total score	Within-subjects effects	Time	22.38	0.000 ^{a,b}	0.436	1.000	
		Time × Group	27.20	0.000 ^{a,b}	0.484	1.000	
	Between-subjects effects	Group	35.55	0.000 ^{a,b}	0.551	1.000	
	Within-subjects effects	Time	32.25	0.000 ^{a,b}	0.527	1.000	
Mindfulness	Observing		Time × Group	15.58	0.000 ^{a,b}	0.350	0.994
		Between-subjects effects	Group	29.13	0.000 ^{a,b}	0.501	0.999
	Describing	Within-subjects effects	Time	46.33	0.000 ^{a,b}	0.615	1.000
			Time × Group	3.94	0.032a	0.120	0.632
		Between-subjects effects	Group	26.02	0.000 ^{a,b}	0.473	0.998
		Within-subjects effects	Time	24.14	0.000 ^{a,b}	0.454	1.000
	Acting with awareness		Time × Group	12.06	0.000 ^{a,b}	0.294	0.988
		Between-subjects effects	Group	24.59	0.000 ^{a,b}	0.459	0.998
	Non-judgment of inner experience	Within-subjects effects	Time	59.75	0.000 ^{a,b}	0.673	1.000
			Time × Group	36.36	0.000 ^{a,b}	0.556	1.000
		Between-subjects effects	Group	63.29	0.000 ^{a,b}	0.686	1.000
		Within-subjects effects	Time	21.35	0.000 ^{a,b}	0.424	0.999
	Non-reactivity to inner experience		Time × Group	21.36	0.000 ^{a,b}	0.424	0.999
		Between-subjects effects	Group	34.61	0.000 ^{a,b}	0.544	1.000
	Total	Within-subjects effects	Time	74.85	0.000 ^{a,b}	0.721	1.000
			Time × Group	35.31	0.000 ^{a,b}	0.549	1.000
		Between-subjects effects	Group	74.79	0.000 ^{a,b}	0.721	1.000
		Within-subjects effects	Time	27.17	0.000 ^{a,b}	0.484	1.000
Mental Health	Emotional well-being		Time × Group	22.53	0.000 ^{a,b}	0.437	1.000
		Between-subjects effects	Group	54.20	0.000 ^{a,b}	0.651	1.000
	Psychological well-being	Within-subjects effects	Time	34.97	0.000 ^{a,b}	0.547	1.000
			Time × Group	26.73	0.000 ^{a,b}	0.480	1.000
		Between-subjects effects	Group	49.07	0.000 ^{a,b}	0.629	1.000
		Within-subjects effects	Time	56.00	0.000 ^{a,b}	0.659	1.000
	Social well-being		Time × Group	51.24	0.000 ^{a,b}	0.639	1.000
		Between-subjects effects	Group	115.48	0.000 ^{a,b}	0.799	1.000
	Total MHC	Within-subjects effects	Time	52.14	0.000 ^{a,b}	0.643	1.000
			Time × Group	44.82	0.000 ^{a,b}	0.607	1.000
		Between-subjects effects	Group	84.38	0.000 ^{a,b}	0.744	1.000

^aP<0.05, ^bP<0.001

The strength of this study was its investigation of the effects of a new psychological intervention and technique for patients with MDD. Mindful hypnotherapy is a

unique empirically based psychological intervention that uses hypnosis in combination with mindfulness strategies.

Limitation and recommendation

This study has a several limitations, including gender of the study sample that were females and lack of an active control condition. Future investigations should attempt to extend these results to another gender and comparison it with another active intervention. The effectiveness of mindful hypnotherapy should be examined for other mental disorders, as well as emotional problems in chronic diseases such as chronic pain.

Conclusion

In conclusion, strong evidence has been shown that emotion regulation and mindfulness are two mechanisms that underlie depression. In this regard, the current study showed that mindful hypnotherapy is an effective intervention for improving emotion regulation and mindfulness and, as a result, mental health in patients with major depressive disorder. Given that these results were obtained in both mindfulness and hypnosis contexts, this intervention showed its potential to improve emotion regulation problems and it's could be known as a background for further research and interventions for treating disorders and issues related to emotion regulation.

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Conflicts of interest

There are no conflicts of interest.

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