Emotion Regulation Skills Training Enhances the Efficacy of Inpatient Cognitive Behavioral Therapy for Major Depressive Disorder: A Randomized Controlled Trial

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Abstract
Background: Deficits in emotion regulation skills are possible factors maintaining major depressive disorder (MDD). Therefore, the aim of the study was to test whether integrating a systematic emotion regulation training (ERT) enhances the efficacy of routine inpatient cognitive behavioral therapy (CBT) for MDD. *Methods:* In a prospective randomized controlled trial, 432 inpatients meeting criteria for MDD were assigned to receive either routine CBT or CBT enriched with an intense emotion regulation skills training (CBT-ERT). *Results:* Participants in the CBT-ERT condition demonstrated a significantly greater reduction in depression (response rates – CBT: 75.5%, CBT-ERT: 84.9%; remission rates – CBT: 51.1%, CBT-ERT: 65.1%). Moreover, CBT-ERT participants demonstrated a significantly greater reduction of negative affect, as well as a greater increase of well-being and emotion regulation skills particularly relevant for mental health. *Conclusions:* Integrating strategies that target emotion regulation skills improves the efficacy of CBT for MDD.

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Introduction

Major depressive disorder (MDD) is a prevalent [1], commonly recurrent [2] and often chronic [3] disorder that ranks fourth among all medical and psychiatric disorders when considering disease burden, and is considered the number one cause of disability [4]. Fortunately, in the past decades a number of psychotherapies for MDD have been developed with demonstrated efficacy in a large number of clinical trials [5–8]. However, these studies also indicate that up to 50% of patients fail to display clinically significant changes [9] and even those who do often suffer from residual subthreshold symptoms [10, 11]. Moreover, between 40 and 60% of patients with MDD relapse after an initial response to acute treatment [12, 13]. Based on such findings, it has been estimated that, at best, contemporary treatments can reduce only about one third of the disease burden associated with MDD [14].

In an attempt to further improve upon existing cognitive behavioral therapy (CBT) protocols, some authors have explored the role of emotion dysregulation for the maintenance of MDD [15–17]. Emotion regulation (ER) refers to 'processes responsible for monitoring, evaluating and modifying emotional reactions, especially their intensive and temporal features, to accomplish one's goals' [18].

Based on help- and hopelessness theories of depression, it has been suggested that adaptive ER skills may deactivate depressogenic schemata by providing control over undesired emotions in situations that are difficult to control [19]. Preliminary empirical support for the assumed relevance of ER skills comes from cross-sectional studies demonstrating that individuals suffering from MDD report difficulties with identifying their emotions [20, 21], accepting and tolerating negative emotions [22–25], compassionately supporting themselves when suffering from negative emotions [26, 27], and effectively modifying their own emotions [28–30]. Moreover, it has been shown that symptoms of depression are positively associated with ruminating/brooding, catastrophizing and expressional suppression [31, 32], which have been conceptualized as (ineffective) attempts to avoid negative emotions [33, 34].

Evidence from longitudinal studies suggests that these deficits may be important antecedents and not merely symptoms of MDD. For example, it has been shown that the expected ability to modify negative affect was negatively associated [30], whereas maladaptive ER strategies were positively associated with subsequent symptoms of depression [35–37] (for nonsignificant findings, see [38]). Similarly, studies using ecological momentary assessment have shown that responses of negative affect to aversive events persisted longer in depressed individuals than in nondepressed controls [39], and that the tendency to respond to aversive events with negative affect predicted depressive symptoms 2 months after the initial assessment in college students [40]. Moreover, tendencies to respond to aversive events with negative affect and negative mood regulation expectancies have been shown to predict less symptom reduction during CBT for MDD [41, 42].

Findings from experimental studies provide further support for the assumption that maladaptive responses to dysphoric mood states, such as rumination or suppression, impair the recovery from such states in individuals vulnerable to depression [23, 43–45], and that individuals with depression are more likely to utilize such strategies than healthy controls [43]. Finally, interventions that focus on enhancing ER, such as emotion-focused therapy [46], dialectical behavioral therapy [47] and exposure-based cognitive therapy [48] have been shown to be effective in MDD [48–54].

In sum, there is a considerable body of evidence supporting the notion that deficits in ER help maintain MDD and that modifying maladaptive ER strategies may lead to a reduction of depressive symptoms. Thus, systematically enhancing ER skills may improve the efficacy of CBT for MDD. Consistent with this hypothesis are the findings from a preliminary study investigating a heterogeneous clinical sample, which included a significant number of patients meeting criteria for MDD [55]. This study suggested that enriching routine CBT with a systematic emotion regulation skills training (ERT) may improve outcome during inpatient treatment. Although these results seem promising, they are preliminary because the study included a heterogeneous clinical sample with a primary diagnosis of MDD in only about 50% of participants and because participants were not completely randomized.

The present study is a randomized controlled trial with a sample of inpatients all meeting criteria for MDD. Our primary objective was to test the hypothesis that supplementing routine CBT with a systematic ERT (CBT-ERT) would enhance the reduction of depressive symptoms and increase response and remission rates among participants. As secondary objectives, we explored whether CBT-ERT would be superior to routine CBT for improving well-being, negative affect and ER skills, whether such a training would have specific effects on ER skills, and whether treatment would be moderated by pretreatment ER skills level, sex, age or type of MDD diagnosis (single episode vs. recurrent).

Methods

Design and Procedures
The efficacy of CBT-ERT was tested in a sample of 432 MDD inpatients from a routine mental health care hospital in Germany. In the second week of treatment, patients eligible for the study were introduced to the study aims and procedures. Participants meeting the study criteria were randomly allocated to receive either routine CBT or CBT-ERT. Randomization was performed by blindly drawing a random sample from shuffled consent forms that patients had completed after the group-based introductory sessions. This was done by blinded administrative staff not otherwise involved in the study. Results of the randomization process were first revealed to patients and therapists no earlier than 3 days before treatments started to differ between conditions. All procedures involved in the study were consistent with the generally accepted standards of ethical practice, approved by the clinic's review board and the German Federal Pension Fund, cost bearer of all participants. No adverse events were reported. The trial was registered under ISRCTN40594308.

Study Population
Participants were recruited from a routine clinical care sample treated between April 2008 and October 2009. To be eligible for the study, participants had to meet the following criteria: (1) current primary diagnosis of MDD according to DSM-IV criteria [56], (2) pretreatment BDI score >11, (3) 18 years of age or above, (4) anticipated treatment length of 4 weeks or more, (5) sufficient German language skills, (6) no severe current alcohol or drug addiction, suicidality, psychoses, brain damage or other mental or somatic disor-

der requiring other treatments, (7) no application for early retirement (as this has been shown to significantly diminish motivation to change) and (8) informed consent. In order to maximize the external validity of the findings and to ensure the representativeness of the sample, there were no further exclusion criteria (e.g. regarding comorbidity or antidepressive medication). Diagnostic assessments were conducted during the intake interview by experienced psychotherapists who were either psychologists or physicians with Master's degrees or above, and who had all been trained extensively in the Structured Clinical Interview for DSM-IV [57].

Treatments

Routine CBT

The hospital in which the current trial was conducted offers multicomponent inpatient CBT for various disorders. Depending on primary complaints, patients receive intervention modules specifically targeting these complaints. As MDD was the primary complaint of all participants in the present study, they all received CBT-based interventions focusing on symptoms of MDD. In addition, study participants received transdiagnostic interventions offered to all patients regardless of their particular diagnoses. The combination of disorder-specific and transdiagnostic interventions used in the hospital aims to take both the disorder-specific aspects and communalities across different disorders into account in order to provide the most effective and efficient treatment.

With regard to MDD-specific treatment, participants received at least one 45-min session of individual therapy and four 45-min sessions of group psychotherapy per week specifically targeting depression. Both individual and group therapy for depression were structured through modules typically used in CBT for depression [58]. These modules were addressed in a specific order with a typical amount of time allotted to each module. However, if therapists saw the need to focus in more detail on specific modules they were allowed to do so (for the rationale of such a module-based approach to treatment, see [59]). Modules included: (1) behavioral analyses [58], (2) behavioral activation [60], (3) cognitive restructuring [58] and (4) problem solving [61]. On the level of specific interventions, therapists were free to use CBT-based techniques such as response shaping, role playing, Socratic dialogue, guided self-talk, etc. to best attain the primary aim of the modules (i.e. establishing the CBT rationale for treatment of MDD, increasing the rate of positive reinforcers, reducing depressogenic thinking, and improving problem-solving skills, respectively) [62].

Study participants further received four 45-min sessions of transdiagnostic group therapy based on problem-solving therapy. In these groups, therapists first introduced the general problem-solving model and then practiced the application of the model to specific problems of the patients. When brainstorming potentially helpful problem-solving ideas, therapists ensured that cognitive restructuring techniques were considered a potentially useful means to solve problems. Other treatment components included an average of about six 45-min sessions of relaxation training, as well as four sessions of sports and two sessions of occupational therapy per week. Relaxation training was based on the rationale that an increased level of stress diminishes the positive valence of potentially reinforcing experiences [63]. Sports and occupational therapy followed a behavioral activation rationale; with enhancing motivation to participate in these activities being an important component in the behavioral activation module in group therapy for depression. Sports therapy uses various playful physical exercises to increase the rate of positive (social) activities and occupational therapy aimed to engage patients in reinforcing creative activities (such as sculpting, drawing, making pottery, weaving, taking pictures).

Depending on the specific needs of the individual patient, the treatment components described above were supplemented with disorder-specific group therapy focusing on comorbid disorders (if present), with physiotherapy and/or medical treatment. All treatments for comorbid disorders used disorder-specific CBT interventions (e.g. cognitive restructuring and exposure to cope with anxiety disorders) [62]. Physiotherapy typically utilizes certain physical exercises or manual therapy to reduce functional impairments caused by a medical condition. Medical treatment included various examinations, consultations and treatments of physical medical conditions. Although this treatment might also include antidepressive medication, the latter was only prescribed if nonpharmacological treatments appeared to be insufficient. Routine CBT psychotherapeutic treatment was delivered by 13 experienced therapists and 6 therapists in training (all of whom had a Master's degree in psychology or medicine); relaxation training was provided by licensed therapists and licensed and specifically trained nurses; sports and occupational therapy were administered by licensed sports and occupational cotherapists; medical treatment and physiotherapy were administered by medical doctors and licensed physiotherapists, respectively. Adherence to the CBT rationale in the routine CBT condition was ensured via weekly supervision and team meetings by licensed senior therapists and medical doctors.

CBT-ERT

In this condition, parts of the CBT program described above were replaced by a systematic ERT. For ERT, we used an abbreviated version of the Affect Regulation Training (ART) [19, 55, 64, 65]. ART is a transdiagnostic intervention which can be added to any form of empirically validated treatment whenever ER deficits are identified as a promising treatment target. The standard ART program consists of 12 modules, each lasting 1.5 h. Due to organizational constraints, the ERT program used in the current study was a modification of ART shortened to four 1.5-hour sessions and two 45-min sessions (by assigning some exercises and psychoeducational components as homework which are usually practiced or administered in the training sessions). The ERT (i.e. the shortened version of ART) took place in the third and fourth week of the inpatient treatment and replaced ten 45-min sessions of the routine CBT program. Which parts of the routine program were replaced by the ERT sessions differed across patients. On average, participants in the ERT condition received about two sessions less of group therapy for depression, two sessions less of group-based problem-solving therapy, three sessions less of sports therapy, one session less of relaxation training, two sessions less of occupational therapy and about one session less of group-based CBT for comorbid disorders. Individual therapy was never replaced with ERT sessions. The number of treatment sessions in both conditions is presented in table 1.

With regard to content and procedures, the highly structured and manualized ART (in both the original and the slightly shortened version used in this study) synthesizes techniques from CBT [63], dialectical behavioral therapy [47], mindfulness-based interventions [66], self-compassion trainings [26], emotion-focused therapy [46], and problem-solving therapies [67] in order to systematically enhance general ER skills. The training begins with a thorough outline of the biological and psychological origins, functions, mechanisms, and possible risks and benefits of emotional

Table 1. Sample characteristics

Demographics and comorbidity	Total (n = 432)	CBT (n = 237)	CBT-ERT (n = 195)	Test statistic	p
Gender, female[a]	356 (82.4)	200 (84.9)	156 (80.0)	1.42	0.25
Age, years[b]				1.62	0.11
Mean ± SD	46.44 ± 8.85	47.07 ± 9.00	45.67 ± 8.62		
High School[a]	138 (31.94)	68 (28.69)	70 (35.90)	2.56	0.12
Marital status[a]					
Single	111 (25.7)	61 (25.7)	50 (25.6)		
Married	186 (43.1)	98 (41.4)	88 (45.1)		
Separated/divorced	120 (27.8)	70 (29.5)	50 (25.6)	0.97	0.91
Widowed	15 (3.5)	8 (3.4)	7 (3.6)		
Comorbid axis I[a]	217 (50.2)	121 (51.1)	96 (49.2)	0.14	0.77
Anxiety disorders	33 (7.6)	22 (9.3)	11 (5.6)	2.01	0.20
Somatoform disorders	39 (9.0)	22 (9.3)	17 (8.7)	0.04	0.87
Eating disorders	41 (9.5)	27 (11.4)	14 (7.2)	2.21	0.19
SUD	39 (9.02)	22 (9.28)	17 (8.72)	0.04	0.87
Dysthymia	12 (2.8)	5 (2.1)	7 (3.6)	0.87	0.39
Comorbid axis II[a]	58 (13.5)	32 (13.5)	26 (13.3)	<0.01	0.99
Previous OPT[a]					
Previously ongoing	223 (51.62)	125 (52.74)	98 (50.26)		
Previously completed	88 (20.37)	48 (20.25)	40 (20.51)	0.32	0.85
Never before	121 (28.00)	64 (27.00)	57 (29.23)		
Previous IPT[a]					
Previously ongoing	9 (2.08)	5 (2.11)	4 (2.05)		
Previously completed	113 (26.16)	65 (27.43)	48 (24.62)	0.45	0.80
Never before	310 (71.76)	167 (70.46)	143 (73.33)		
Days in treatment[b]					
Mean ± SD	46.54 ± 7.94	46.67 ± 8.68	46.38 ± 6.96	0.37	0.71
Psychotherapy sessions[b]					
Mean ± SD	83.56 ± 16.05	83.44 ± 17.79	83.69 ± 13.68	0.17	0.87

Values are presented as numbers with percentages in parentheses, unless otherwise indicated. As all participants were Caucasians we do not report differences with regard to ethnicity. High School = German equivalent of High School Degree after 13 years of schooling. SUD = substance use/dependency disorders; OPT = outpatient psychotherapy; IPT = inpatient psychotherapy.

[a] The χ^2 test. [b] The t test.

reactions. Integrating findings and pictures from affective neurosciences, seven neural 'vicious cycles' are presented that are deemed important for long-term maintenance of negative emotions (e.g. activation of the amygdala can increase muscle tension and vice versa). For each vicious cycle, a technique is presented that is designed to interrupt the cycle. These skills include: (1) muscle relaxation, (2) breathing relaxation, (3) nonjudgmental perception of emotions, (4) acceptance and tolerance of emotions, (5) compassionate self-support (mood repair strategies to reduce the likelihood that impulsive-avoidance behaviors disrupt effortful attempts to regulate one's emotion), (6) identification of the causes of one's emotional response and (7) active modification of emotions (according to a five-step problem-solving model focusing exclusively on emotion modification).

It is of note that, although ART uses several of the techniques also included in routine CBT for depression (i.e. muscle relaxation, cognitive restructuring and problem solving), it differs from CBT for depression in that: (1) it explicitly works to enhance skills relevant for adaptively coping with various kinds of unwanted affective states (such as stress/tension, anxiety, anger, sadness, dysphoria, guilt, shame, etc.) as opposed to focusing on symptoms of depression (such as depressed mood, negative thinking and behavioral inactivity), (2) it strongly focuses on utilizing positive aspects of unwanted emotions (e.g. using one's anxiety to identify relevant threats and anxiety-related arousal to muster the energy to effectively cope with such threats) as opposed to exclusively working to reduce the intensity and/or duration of unwanted affective states, and (3) it systematically works to build a sequence of ER skills which is regularly practiced in highly structured exercises. Thus, although there is some overlap in techniques between CBT for depression and ART, the latter can clearly be distinguished from the former by the explicit and exclusive focus on enhancing general ER skills as opposed to targeting cognitive and behavioral antecedents of depression [19, 55, 64, 65] (see also online suppl. material; for all online suppl. material, see www.karger.com/doi/10.1159/000348448).

ERT groups participating in the shortened ART training in this study consisted of 8–10 participants and were led by clinical psychologists who had completed a 5-year university Master's degree in (clinical) psychology and were enrolled in advanced postgradu-

ate psychotherapy training. All ERT trainers had been intensively trained in the program and received weekly supervision by experienced clinicians and experienced ART trainers to ensure adherence to the abbreviated manual. ERT trainers were also involved in delivering routine CBT and received regular supervision for their CBT therapies in order to ensure adherence to the CBT rationale.

Measures
Depression
The primary outcome measure was the Beck Depression Inventory (BDI) [68]. The BDI is a 21-item self-report measure assessing somatic, behavioral, emotional and cognitive symptoms of depression on a 4-point Likert-type scale. High sum scores indicate severe depression (range: 0–63). The BDI is a commonly used measure with good reliability and validity [68]. In the present study, Cronbach's α was 0.82 (baseline).

As the BDI has been criticized for confounding symptoms of somatic/somatoform diseases (e.g. insomnia, weight loss) and for overemphasizing cognitive symptoms of depression [69, 70], we also administered the depression subscale of the Hamburg Modules for the Assessment of Psychosocial Health in Clinical Practice (HEALTH-49) [71]. The HEALTH-49 is an open-source instrument which is widely used in the German health care system. The depression subscale of the HEALTH-49 assesses different aspects of depression (feelings of sadness, worthlessness, hopelessness, guilt, anhedonia and suicidal ideation) with the help of 6 items that are rated on a 5-point Likert-type scale (0 = not at all to 4 = very much). Several validation studies have demonstrated high convergent validity and good reliability (α = 0.88) for the depression subscale [72]. In the present study, Cronbach's α for the depression scale of the HEALTH-49 was 0.84 (baseline).

ER Skills
Assessment of ER skills was based on the Adaptive Coping with Emotions Model proposed by Berking [19] as a synthesis and extension of previous ER theories [46, 73–76]. In this model, effective ER is conceptualized as the situation-adapted interplay of the abilities to: (1) be aware of emotions, (2) identify and label emotions, (3) correctly interpret emotion-related body sensations, (4) understand the prompts of emotions, (5) actively modify the quality, intensity and/or duration of an undesired emotion, (6) accept negative emotions when necessary, (7) tolerate negative emotions when they cannot be changed, (8) confront (vs. avoid) distressing situations when necessary to attain important goals and (9) compassionately support (encourage, self-soothe) oneself in emotionally distressing situations (in order to counterbalance potential short-term negative effects that engagement in the other skills may have on one's emotions). An important assumption of the ART model of adaptive ER is that only the abilities to modify emotions in a desired direction and/or accept and tolerate undesired emotions are ultimately relevant for mental health. In contrast, the other skills included in the model are only assumed to be relevant to the extent that they facilitate the application of the pivotal skills of modification and/or acceptance/tolerance (for further details, see [19] and online suppl. material). In cross-sectional and longitudinal studies, all skills included in the Adaptive Coping with Emotions Model have been shown to be negatively associated with various indicators of mental health problems in healthy, at-risk and clinical populations [55, 77–81]. Moreover, in several studies strong evidence was found for the hypothesis that the abilities of modification, acceptance and tolerance are particularly important for preventing or coping with mental health problems [55, 77, 78].

In order to assess the skills included in the ART model of adaptive ER, the Emotion Regulation Skills Questionnaire (ERSQ) was developed [80]. The ERSQ is a 27-item self-report instrument that utilizes a 5-point Likert-type scale (0 = not at all to 4 = almost always) to assess the respondent's adaptive ER skills in the previous week. Each skill is assessed with 3 items measuring (1) awareness (e.g. 'I paid attention to my feelings'), (2) clarity (e.g. 'I was clear about what emotions I was experiencing'), (3) understanding (e.g. 'I was aware of why I felt the way I felt'), (4) modification (e.g. 'I was able to influence my negative feelings'), (5) acceptance (e.g. 'I accepted my emotions') and (6) tolerance (e.g. 'I could endure my negative feelings') of emotions, as well as the use of sensations to identify emotions (e.g. 'my physical sensations were a good indication of how I was feeling'), readiness to confront distressing situations (e.g. 'I did what I had planned, even if it made me feel uncomfortable or anxious'), and compassionate self-support (e.g. 'I supported myself in emotionally distressing situations'). In addition to the subscales, the ERSQ consists of a total score, which is computed as the average of all items.

In previous studies, the ERSQ showed adequate-to-good internal consistencies (Cronbach's α = 0.90 for total score, and 0.68–0.81 for subscales) and adequate test-retest reliability (r_{tt} = 0.75 for total score, and 0.48–0.74 for subscales). Results from exploratory and confirmatory factor analyses provide support for the assumed dimensionality of the measure, and sensitivity to change has been demonstrated in multiple samples of clients undergoing psychotherapy. All scales have demonstrated positive associations with measures of well-being and mental health, and negative associations with measures of psychopathology and ER deficits [55, 77–81]. In the current study, the ERSQ showed acceptable internal consistencies for all subscales (α = 0.70–0.81) and good internal consistency for the total score (α = 0.94).

Negative Affect and Well-Being
To assess negative affect, we used the negative affect scale of the Positive and Negative Affect Scales (PANAS) [82]. The PANAS is a self-report instrument that consists of 20 items describing positive and negative affective states. Participants utilize a 5-point Likert-type scale (0 = not at all to 4 = almost always) to rate the frequency of these states in a given time period. For this study, we asked participants to report the frequency of negative affective states during the previous week in order to cover the same time period as assessed by the ERSQ. Internal consistency for the negative affect scale was good (Cronbach's α = 0.83, baseline). Well-being was assessed with the (reversed) impaired well-being subscale of the HEALTH-49. This scale consists of 5 items addressing affective well-being (at rest, relaxed, at ease, integrated, able to enjoy). Its validity and reliability have been demonstrated in several studies (r = 0.64 with a short version of the SF-36 Health Survey; α = 0.87–0.91) [72]. In the present study, Cronbach's α for the impaired well-being subscale of the HEALTH was 0.85 (baseline).

Data Analyses
We used the intent-to-treat (ITT) sample to test our hypotheses. We also explored how findings would differ if only completers were included in the analyses. With regard to: (1) the small variation in treatment, (2) the small-to-moderate effect sizes found in
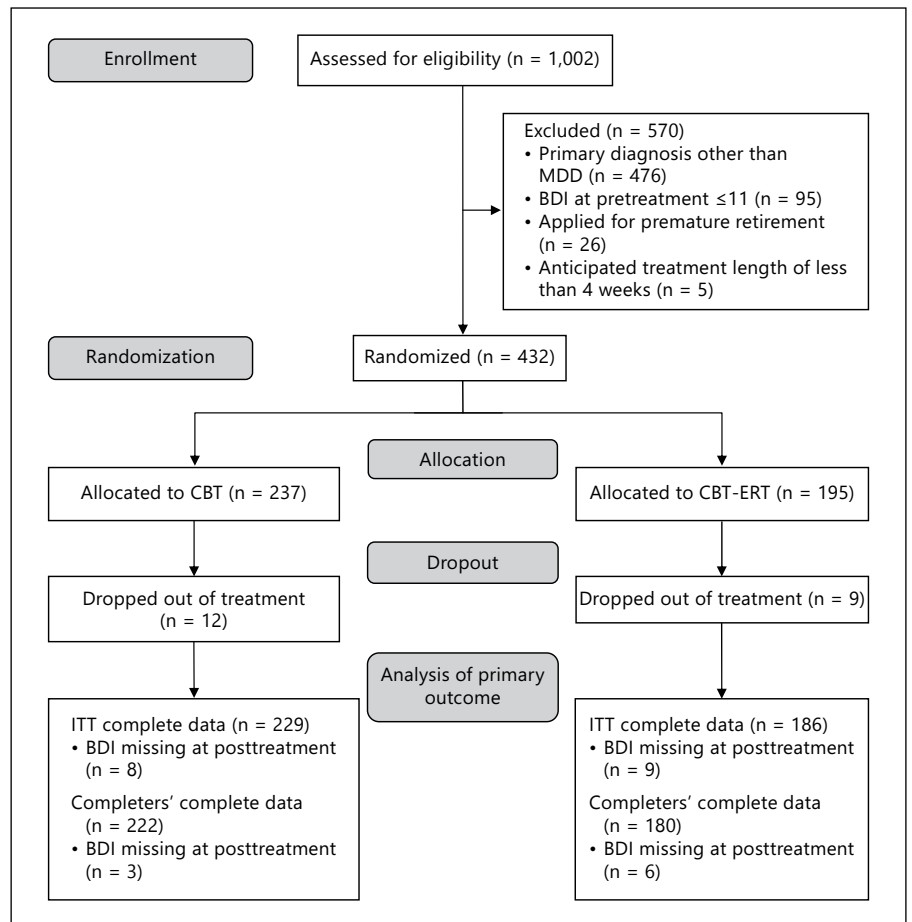
Fig. 1. CONSORT flow diagram.

our previous study ($\eta^2 = 0.04$ for the BDI, $\eta^2 = 0.002$–0.014 for ERSQ subscales) [55] and (3) our focus on a proof of principle, we powered the study to be able to detect small-to-moderate effects. In preliminary analyses, differences between treatment groups regarding gender, age, and baseline outcome scores were tested with simple t and χ^2 tests. To test between-subject intervention effects from pre- to posttreatment regarding decrease of BDI sum scores, we used hierarchical linear modeling (HLM) [83] with repeated measures (level 1) nested within participants (level 2).

Additionally, we compared response and remission rates across groups using contingency tables and χ^2 tests. For these analyses, we followed the guidelines proposed by Jacobson and Truax [84] and computed a reliable change index for each participant. Participants with a reliable change index of 1.96 or above were considered responders. Participants who additionally displayed a nonpathological posttreatment BDI score were considered remitters. Based on extensive sensitivity and specificity analyses of the German version of the BDI conducted by Riedel et al. [85], we set a posttreatment BDI sum score of 11 or below as a cutoff for remission. In order to explore the effects of including ERT into CBT on secondary outcome measures, we used the same HLM analyses as for the primary outcome. In order to compare the effects across outcomes we computed Cohen's d as effect sizes. In order to explore moderator effects, we included potential mod-

erators as factors into the HLM model and tested the 3-way interaction of time by group by moderator. For all comparisons, we set the critical α at 0.05 and used one-sided tests for unidirectional and two-sided tests for bidirectional hypotheses. SPSS 19.0 was used for all analyses.

Results

As shown in figure 1, out of 1,002 patients screened, 432 met the study criteria and were randomly allocated to a treatment condition. Due to administrative reasons, only 45.14% of participants could be allocated to the CBT-ERT condition. In periods with limited ERT treatment capacities, allocation probabilities (initially set to $p_i = 0.5$) were adapted according to the availability of resources (drawing only as many consent forms of patients as could participate in CBT-ERT). Out of the 432 participants in the ITT sample, 411 completed treatment as scheduled. Preliminary analyses indicated that, for all

measures, the rate of missing data was below 1% and skewness was acceptable for the intended analytic strategies (e.g. $BDI_{pre/post}$: v = 0.73/1.33). Baseline characteristics of participants are presented in table 1. There were no significant differences between treatment conditions regarding sociodemographics, pretreatment psychopathology, length of inpatient treatment, number of treatment sessions or prior psychotherapeutic treatments (for relevance of the latter, see [86]). The highest BDI sum was 48 in the CBT and 51 in the CBT-ERT condition. The BDI sum scores were strongly correlated with the HEALTH-D depression scale (r = 0.67) and with the negative affect scale of the PANAS (r = 0.51), and weakly to moderately correlated with the ERSQ scales (r = 0.26–0.46; for all correlations, see online suppl. material). These findings provide evidence for the independence of the outcome measures. Moreover, they indicate that ER skills differ with regard to how strongly they are associated with symptoms of depression.

In order to test our primary hypothesis that treatment groups would differ with regard to the decrease of BDI sum scores from time 1 to time 2, we conducted an HLM analysis with time (0 = time 1; 1 = time 2), group (0 = CBT-ERT; 1 = CBT) and the interaction between time and group as predictor variables and the BDI sum scores as the outcome variable. There were almost no differences in model fit between a model assuming compound symmetry and a model assuming a heterogeneous autoregressive covariance structure (BCI = 6,039.71 vs. 6,039.84). We therefore implemented the more parsimonious (compound symmetry) model in all further analyses. The main effect of time was significant (π = –13.54; SE = 0.65; d.f. = 419.12; t = –20.72; p < 0.001; CI = –14.61 to –12.46), indicating an overall decrease in BDI scores during treatment (d = 1.4). The main effect of group was nonsignificant (β = –1.35; SE = 1.51; d.f. = 667.10; t = –0.90; p = 0.37; CI = –3.84 to 1.13), providing evidence that the randomization was successful with regard to balancing pretreatment depressive symptom severity across treatment conditions. For the effect that was most relevant to our primary hypothesis, the interaction between time and group was significant (β = 1.74; SE = 0.88; d.f. = 418.21; t = 1.98; p = 0.03; CI = 0.29–3.19), indicating that the reduction in BDI scores was significantly larger for patients in the CBT-ERT condition than for patients in the CBT condition. However, with d = 0.16, these differences between groups were small according to conventions proposed by Cohen [87].

Of the 432 participants in the ITT sample, 415 completed the BDI at pre- and posttreatment assessment and were included in the response and remission analyses. With regard to response to treatment, 158 out of 186 patients were identified as responders (84.9%) in the CBT-ERT condition and 173 out of 229 (75.5%) in the CBT condition ($χ^2$ = 5.62; d.f. = 1; p > 0.01). Thus, with OR = 1.83, the likelihood of response was notably larger in the CBT-ERT condition than in the CBT condition. Similar effects were found with regard to remission (reliable change and BDI posttreatment ≤11), with 121 out of 186 patients (65.1%) attaining remission in the CBT-ERT condition as compared to 117 out of 229 (51.1%; $χ^2$ = 8.18; d.f. = 1; p > 0.01) in the CBT condition. Consistently, with OR = 1.78, the likelihood of remission was notably larger in the CBT-ERT condition than in the routine CBT condition.

The HLM analyses revealed significant time effects for all outcomes including ERSQ subscales (all p < 0.001), with symptoms of depression and negative affect decreasing and well-being and ER skills increasing during treatment. With regard to differences between treatment conditions, results presented in table 2 indicate that the slight superiority of the CBT-ERT condition was also found in the alternative measure of depressive symptom severity. Moreover, participants in the CBT-ERT group demonstrated a significantly greater increase in well-being and a significantly greater decrease in negative affect. With regard to ER, differences between treatment conditions regarding gains on the $ERSQ_{total}$ score unexpectedly failed to reach the level of statistical significance by a small margin (p = 0.062; d = –0.12). However, the groups differed significantly with regard to various ERSQ subscales. With regard to specific ER skills, the strongest effects were found for the ability to compassionately support oneself when working to cope with challenging emotions, for the abilities to accept and tolerate negative emotions, and for the ability to purposefully modify undesired emotions. Thus, gains seem to be particularly strong in skills which are considered particularly important in the ART model of adaptive ER and which are more explicitly focused upon in ART than in routine CBT [19].

In order to explore potential moderators of treatment effects, we tested whether sex, age, type of MDD diagnosis (single episode vs. recurrent), and pretreatment ER skills would predict the effect of treatment on change in the BDI score. For this purpose, we included the respective variables in the HLM models and tested the significance of the three-way interaction between time, group and the potential moderator. In these analyses, none of the three-way interactions were significant (all p > 0.57), indicating that neither pretreatment ER skills, sex, age, nor type of MDD diagnosis moderated the effect of including ERT in

Table 2. Descriptive statistics, time × treatment effects, and effect sizes for group comparisons on all outcomes (including ERSQ subscales)

Subscales	CBT		CBT-ERT		HLM: time × treatment					
	before (mean ± SD)	after (mean ± SD)	before (mean ± SD)	after (mean ± SD)	β	SE	d.f.	t	95% CI	d
BDI	24.45±8.35	12.72±9.86	24.06±8.65	10.30±8.90	1.74	0.88	418.21	1.98*	0.29 to 3.19	0.16
HEALTH-D	2.24±0.88	1.27±0.86	2.21±0.89	1.06±0.81	0.17	0.09	423.65	1.86*	0.02 to 0.32	0.16
HEALTH-IWB	2.97±0.61	1.85±0.79	2.94±0.66	1.65±0.76	0.16	0.08	424.94	1.95*	0.02 to 0.30	0.17
PANAS-N	2.06±0.83	1.28±0.86	2.06±0.78	1.06±0.74	0.20	0.09	423.72	2.31*	0.06 to 0.34	0.20
ERSQ$_{total}$	2.52±0.68	3.29±0.77	2.56±0.68	3.46±0.70	−0.12	0.08	417.63	−1.54[a]	−0.25 to 0.01	−0.12
ERSQ-AW	2.75±0.90	3.72±0.93	2.80±1.00	3.84±0.78	−0.06	0.10	417.92	−0.64	−0.23 to 0.10	−0.06
ERSQ-SE	2.94±0.93	3.59±0.82	3.06±0.90	3.70±0.77	<0.01	0.09	418.30	0.04	−0.15 to 0.16	0.02
ERSQ-CL	2.77±0.98	3.46±0.90	2.81±0.92	3.60±0.79	−0.09	0.10	424.12	−0.90	−0.26 to 0.08	−0.07
ERSQ-UN	2.60±0.95	3.44±0.93	2.68±0.99	3.59±0.79	−0.07	0.10	425.22	−0.65	−0.24 to 0.10	−0.05
ERSQ-AC	2.42±0.84	3.20±0.94	2.46±0.86	3.46±0.82	−0.20	0.10	414.88	−1.98*	−0.36 to −0.03	−0.16
ERSQ-RES	2.06±0.86	2.90±1.00	2.10±0.83	3.16±0.87	−0.20	0.10	416.55	1.96*	−0.37 to −0.03	−0.16
ERSQ-SESU	2.52±0.88	3.15±0.90	2.46±0.82	3.34±0.82	−0.22	0.09	412.71	−2.36**	−0.38 to −0.07	−0.19
ERSQ-R to C	2.63±0.88	3.18±0.85	2.64±0.94	3.30±0.86	−0.09	0.10	416.10	−0.90	−0.25 to 0.08	−0.04
ERSQ-MOD	2.02±0.76	2.99±0.95	2.03±0.75	3.18±0.83	−0.17	0.09	417.66	−1.76*	−0.32 to −0.01	−0.14

CBT = Routine CBT; CBT-ERT = CBT enriched with systematic ERT; HEALTH-D = depression subscale of the HEALTH-49; ERSQ$_{total}$ = ERSQ total score; PANAS-N = Negative Affect Scale of the PANAS; HEALTH-IWB= impaired well-being subscale of the HEALTH; ERSQ subscales: AW = awareness; SE = sensation; CL = clarity; UN = understanding; AC = acceptance; RES = resilience; SESU = compassionate self-support; R to C = readiness to confront (situations that cue aversive emotions); MOD = modification of negative emotions. * p < 0.05; ** p < 0.01.
[a] Trend of significance, i.e. p < 0.10.

CBT. Further analyses indicated that for all findings (HLM, response and remission rates and moderator analyses), results did not differ significantly if we used the sample of completers instead of the ITT sample.

Discussion

Deficits in ER skills are considered a putative maintaining factor in MDD. However, it has yet to be clarified whether such skills are also a promising target in the treatment of MDD. Therefore, the goal of this study was to evaluate whether strengthening the focus on ER can enhance the efficacy of inpatient CBT for MDD. Results show that patients participating in CBT enriched with ERT reported about a 10% higher response rate and a 14% higher remission rate than did participants in the routine CBT condition. Additionally, the enriched version of CBT appears to be significantly more effective with regard to enhancing patients' well-being and reducing negative affect. Moreover, we found evidence for the superiority of CBT-ERT with regard to strengthening ER skills considered particularly important for mental health, such as compassionate self-support, resilience, and abilities to accept and modify negative emotions [26,

27, 55, 77, 78, 88–90]. Further, exploratory analyses indicated that neither pretreatment ER skills, sex, age, nor type of MDD diagnosis (single-episode vs. recurrent) moderated the effects of CBT-ERT. The findings are consistent with our previous study, showing that integrating systematic ERT into routine CBT was associated with a stronger reduction of depressive symptoms in a heterogeneous sample of inpatients [55]. Thus, including treatment components focusing on enhancing ER skills appears to be a promising way of further improving the efficacy of CBT for depression.

It should be noted that the effect sizes for the between-group comparisons were relatively small. This might indicate that the clinical benefit of explicitly focusing on ER skills is limited. On the other hand, the small effects might also be explained by the fact that the differences in treatment between the two conditions were limited to only ten 45-min sessions during an average length of treatment of about 46 days. Since most of the time both groups received the same CBT-based interventions and were exposed to the same putative common factors (e.g. peer-support, protective environment), small effects were to be expected even if patients benefitted more during the ERT part than during the same number of sessions of routine CBT (as both represent only a small section of the whole time in treatment).

The unexpected finding that integrating ERT did not lead to a greater increase in the total score of the ERSQ appears to contradict the assumption that enhancing ER skills is the mechanism responsible for the effects of including the training on depression. However, according to the ART model of adaptive coping with emotions, only the abilities to modify painful emotions and to accept and tolerate them (if modification is difficult or impossible) are considered to be ultimately important for mental health [19]. The other skills included in the model are important only to the extent that they facilitate these skills. For example, being able to be aware of one's emotions and correctly identify them does not necessarily foster mental health. Many patients do hardly anything else than monitor their emotions and many have eventually acquired impressive skills to distinguish between different kinds of emotional anguish without benefitting from these skills. On the contrary, such a focus on negative emotions often appears to contribute to the maintenance of the disorder. Empirical evidence that modification and acceptance/tolerance are more important for mental health comes from several correlational, longitudinal and mediational studies [55, 77, 78, 80, 81]. Therefore, the ERSQ$_{total}$ score is not the most informative criteria when exploring the mechanisms relevant for the effects of including the ERT. Instead, such explorations should focus on the subscales of the ERSQ and clarify whether including the ERT leads to gains with regard to particularly relevant subscales (such as acceptance, tolerance and modification). It is of note that, consistent with the assumed relevance of ER skills for coping with depression, participants in the CBT-ERT condition displayed significantly greater gains on all these scales than did participants in the routine CBT condition. This finding provides preliminary support for the notion that enhancing relevant ER skills through specific interventions can reduce symptoms of depression. Moreover, the findings point to modification, acceptance and tolerance (and potentially compassionate self-support) as skills deserving a specific focus in treatment. However, since the use of measures against type I error accumulation was not feasible due to power issues, these findings are preliminary. Thus, future (dismantling) studies should test explicit hypotheses on relevant skills as mechanisms of change responsible for the trainings effect on depression.

Similarly, the finding that pretreatment deficits in ER skills did not moderate the difference between treatment conditions may seem to contradict the idea that alleviating such deficits with specific interventions reduces symptoms of depression. It could be argued that diminishing deficits in skills relevant for mental health is the mechanism of change of psychotherapeutic interventions and that, consequently, the more skills deficits a patient displays the more he/she should benefit from an intervention effectively targeting these deficits. Although this is a reasonable argument, the empirical evidence indicates that this might not necessarily be the process relevant for change. For example, in a predictor study using the data from the NIMH study of Elkin and colleagues [91], it was found that – inconsistent with the aforementioned argument – patients displaying less interpersonal problems benefitted more from interpersonal therapy and patients displaying less dysfunctional attitudes benefitted more from CBT [91]. This has led some authors [92] to propose that enhancing individual resources of patients with the help of specific interventions which focus on these resources is an important process driving change during treatment. Thus, the nonsignificant findings on potential moderators may result from deficit reduction effects and strength utilization effects annulling each other. Since these interpretations are merely speculative at this point, future research on the issue is needed.

There are several limitations to this study. First, treatment outcome was exclusively assessed with the help of self-report instruments and only at pre- and posttreatment. Thus, future research will need to replicate these findings while complementing self-reports with observer-based measures, preferably assessed at multiple time points including follow-ups. Second, the study was conducted in a routine treatment center which provides patients with a multicomponent CBT-based treatment tailored to their individual needs. In this setting, we replaced various parts of the CBT-based treatment with an intensive ERT. The replaced parts included to some extent interventions which aimed to increase the rate of positive reinforcements in accordance with the behavioral activation module but used sports and occupational therapy in order to attain this aim. Therefore, it can be argued that the CBT-ERT condition is not compared with a pure CBT condition but with a condition partly tarnished by the use of sports and occupational therapy. However, a significant part of the purely psychotherapeutic interventions in the routine CBT condition did focus on behavioral activation and at this point there is no evidence suggesting that, once the concept is introduced, treatment would be more effective if the training part of behavioral activation was done by psychotherapists instead of cotherapists [93]. Neither is there evidence that the use of a completely open approach to reinforcing activities is superior to an ap-

proach in which the training component involves specific themes such as the ones used in sports therapy and occupational therapy. At least in a pragmatic sense [94], it can be concluded that replacing various parts of a routine multicomponent and multiprofessional CBT-based treatment program with an intense ERT increases the efficacy of the treatment. Nevertheless, future studies should compare the efficacy of CBT-ERT with a CBT condition not involving the means of sports and occupational therapy.

Third, due to the use of a routine treatment setting we were unable to tape treatment sessions and assess quantitative data on treatment integrity and adherence to treatment protocols. However, therapists in the routine CBT condition were all licensed health care professionals who had received intensive training in CBT, followed a clear protocol, and had weekly supervision by experienced supervisors. Additionally, ERT trainers followed a clear and highly standardized protocol which includes a standardized set of power point slides and word-for-word suggestions on how to comment on them for the psychoeducation on emotions, as well as a standardized set of audio files which guide participants through a set of skill-building exercises. Moreover, ERT trainers received an intense training in ERT prior to participating in the study, as well as weekly supervision aiming to foster adherence to the ERT manual. Finally, significant group differences on ERSQ subscales representing skills which are focused upon in ERT but not so much in routine CBT (such as acceptance and tolerance of emotions, self-support and modification of emotions) suggest specific effects of ERT on outcome. In sum, there is sufficient reason to assume that integrity and adherence were sufficient and that treatment conditions did significantly differ with regard to focus of treatment, therapeutic strategies and specific interventions.

Strengths of the study include the use of a randomized controlled design in a routine treatment setting [95], very good retention of participants, and a comparatively large sample size. The latter provided a rare opportunity to investigate small effects of great theoretical significance. In research on psychological treatments of depression, very few dismantling studies with sufficient statistical power to detect small differences have been conducted. As this type of research is very important for clarifying how psychological treatments work and for further improving their efficacy, the study significantly contributes to the literature.

In sum, consistent with previous research, the study provides a proof of principle that supplementing routine CBT with a systematic ERT may help improve the efficacy of currently available treatments for MDD. This should encourage future research on the potential benefits of enhancing adaptive ER skills in individuals suffering from depression. More specifically, future studies should first focus on identifying ER skills particularly effective for preventing and/or coping with depression, then develop and evaluate interventions most effectively enhancing such skills and, finally, clarify how such interventions can best be integrated into empirically validated treatments for depression. In this context, it is particularly important to test whether including ERT as an adjunctive component integrated into the acute treatment is less, as, or more effective than including ERT as a (second-step) component in a sequential treatment plan targeting acute symptoms with CBT (or other empirically validated interventions) and subsequently focusing on enhancing well-being and/or general ER skills in order to improve stability of outcome [96].

Acknowledgments

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