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Computer-assisted cognitive behavior therapy to prevent relapse following electroconvulsive therapy

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Abstract

Objective—The goal of this study was to explore the feasibility and potential efficacy of providing computer-assisted cognitive behavior therapy (CCBT) following an index course of electroconvulsive therapy (ECT) to prevent relapse.

Method—In an open-label trial, subjects with major depressive episode who achieved response or remission following an acute treatment with ECT were recruited to enroll in a 9-module CCBT course. Subjects completed the CCBT modules in their own home at their own pace, but were asked to do at least one lesson per week, such that all 9 lessons would be completed in the first two months. Depression severity and relapse were monitored during the 6 months following ECT.

Results—Fifteen subjects (10 responders and 5 remitters) enrolled in the study and logged onto the CCBT course. The mean number of online lessons completed was 7.6 (SD 1.7) or 84% of the total lessons and the mean time spent working online was 8.4 hrs (SD 3.9 hrs). During the first two months (the prescribed time period), the mean number of lessons completed was 6.5 (SD 1.8) or 72% and the mean time spent working online was 6.8 hrs (SD 3.2 hrs). Of the entire sample of responders and remitters (n=15), 5 (33%) relapsed at 6 months. Of the 5 remitters, none relapsed during this time period.

Conclusion—Our results provide preliminary evidence that CCBT after ECT is feasible following ECT. Large, controlled trials are needed to definitively assess whether this strategy is efficacious in preventing relapse.

Keywords

electroconvulsive therapy; cognitive behavior therapy; computer-assisted cognitive behavior therapy; relapse; major depressive disorder

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Introduction

Major Depressive Disorder (MDD) is the most common mental illness and is associated with significant morbidity and mortality worldwide.¹ MDD affects many persons of all ages and backgrounds and has been shown to substantially impair work productivity,² costing the U.S. over \$210 billion per year in 2010. All FDA-approved oral antidepressants used as monotherapies generally only have modest benefits, with response rates (in relatively uncomplicated, non-chronic forms of MDD) of approximately 50% and remission rates of 30-35%.³⁻⁶ Treatment-resistant depression (TRD) is often defined as MDD that does not respond or remit to one or more adequate antidepressant trials⁷; TRD comprises one-third of all patients with MDD.⁸ In the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study, remission rates for patients who did not remit after the first treatment level were 31%, 14%, and 13% for the second, third, and fourth levels, respectively.⁸ TRD contributes substantially to the disease burden of MDD, with increased costs of health care and productivity loss of \$9,529 annually compared to treatment-responsive depression.⁹

Electroconvulsive therapy (ECT) is among the most effective treatment options for MDD and TRD, with response rates of 80-90% when used as 1st-line treatment and response rates of 50-60% in treatment-resistant depression.¹⁰ However, relapse (defined as return of depressive symptoms within 6 months) following ECT remains a major clinical problem. Relapse rates have been reported as high as 84% with no maintenance therapy¹¹ and typically range from 32-50% even with post-ECT pharmacotherapy or maintenance ECT.¹¹⁻¹⁴ In most clinical trials, relapse was most commonly seen within the first two months after treatment.^{10, 11, 13}

Cognitive behavioral therapy (CBT) is an effective adjunctive treatment to classic antidepressant medications¹⁵ and has been shown to be highly effective in relapse prevention following a course of psychotherapy or antidepressant medication.¹⁶⁻¹⁹ The goal of CBT is to learn new patterns of thinking and extinguish pathological and distorted thought patterns. Hence, CBT may be an effective relapse prevention strategy for patients who respond or remit following ECT. There are few studies investigating the effects of combining ECT and psychotherapy aimed at preventing relapse/recurrence,²⁰ in part because of the cognitive problems traditionally associated with ECT. However, recent advances in technique (i.e., ultra-brief pulse width, right unilateral)²¹ have reduced cognitive burden associated with ECT and may allow for psychotherapy shortly following a course of ECT. Indeed, at least two studies, including one by our group, have demonstrated the feasibility and potential efficacy of this approach, both of which utilized cognitive behavior therapy to prevent relapse following ECT.^{22, 23}

High-quality CBT, however, is not always readily available in the community. For instance, in our state of approximately 3.6 million people, there are only 9 CBT therapists with certification by the Beck Academy of Cognitive Therapy.²⁴ Owing to the dearth of well-trained CBT therapists and in an effort to more widely disseminate the powerful effects of this psychotherapy modality, computer-assisted versions of CBT have been developed, with clinical trials showing efficacy comparable to traditional CBT in select populations.²⁵⁻²⁷ As a follow-up to our previous study,²² the primary objectives of the present study were to

investigate the feasibility and potential efficacy of computer-assisted CBT (CCBT) following ECT to prevent relapse in an attempt to possibly identify a relapse prevention strategy that is easy to disseminate and can be tested in larger scale studies.

Methods

Subjects

The study was conducted at Yale Psychiatric Hospital and was approved by the local institutional review board prior to commencement and was registered on clinicaltrials.gov (NCT02176473). All subjects provided written informed consent. Patients ages 21 to 75 diagnosed with a major depressive episode (unipolar or bipolar depression) who had achieved response or remission following ECT delivered at the Yale-New Haven Hospital Interventional Psychiatry Service and were considered appropriate candidates for CBT were recruited to participate. Subjects were excluded if they had current or recent (within 6 months) substance use disorder; comorbid axis II pathology that was predominant to their depressive episode; psychotic disorder (not including major depressive episode with psychotic features); suicidal ideation with a plan; or did not possess basic computer skills or have regular access to a computer.

ECT Treatments

Similar to our previous study,²² ECT treatments were provided under general anesthesia in an ECT treatment suite of a university hospital with a MECTA Spectrum 5000Q device (MECTA Corporation, Tualatin, OR). For each treatment, quality of seizure morphology was confirmed by the attending psychiatrist reading the electroencephalographic strip. Stimulus threshold was titrated at the first treatment session, beginning at approximately 1J, and increasing the train duration by approximately 1 second with each subsequent stimulus until seizure was achieved. Subsequent treatments utilized energy levels 50% above seizure threshold for patients treated with bitemporal (BT) placement or 5 to 6 times seizure threshold for patients treated with right unilateral lead (RUL) placement. Based on previous research suggesting lower cognitive side effects with low pulse widths,²¹ the pulse-width of right unilateral treatments was maintained as low as possible (i.e., 0.30 ms); the pulse-width for bitemporal was held constant at 0.50 ms. The pulse amplitude was held constant at 800 mA. Subjects who showed little or no response after 6-7 RUL treatments were subsequently switched to bitemporal treatments. Initial electrode placement is almost always RUL in our community, except for cases of catatonia or clinically significant suicidal ideation.

CBT Program

As is the standard practice at our hospital, ECT patients gradually transition from receiving ECT treatments 3 times weekly to a continuation/maintenance schedule. Once the frequency of ECT was weekly or less frequent, subjects who consented to the study were enrolled in a well validated computer-assisted CBT program called Good Days Ahead (GDA, Empower Interactive, Inc.). This program consists of 9 computerized sessions, each 30-45 minutes in length, with homework assignments between sessions, similar to traditional CBT. Randomized trials using this software program have shown efficacy similar to traditional CBT when supported by brief (25 min) in-person psychotherapy sessions weekly or every

other week. Remission rates are approximately 39-40% following a full-course of either traditional or computer-assisted CBT in populations of MDD.²⁵⁻²⁸ The program focuses on the same principles of traditional CBT, namely, “identifying, labeling, and modifying automatic thoughts; the link between thought and action; identifying and modifying schemas; and identifying and correcting cognitive errors.”²⁶ The software provides modeling of CBT principles (in the form of short videos), enables an interactive forum by giving users feedback based on responses to questions, and encourages participants to apply the skills learned in CBT to their situations. Subjects completed the computer-assisted CBT in their own home at their own pace, but were asked to do at least one lesson per week, such that all 9 lessons would be completed in the first two months, the time period associated with the highest rates of relapse rates. During the first two months of the study, brief supportive telephone calls were made weekly to encourage compliance, answer questions, and reinforce CBT principles. All patients continued to receive pharmacotherapy, psychotherapy, or ECT maintenance therapy, as tolerated and recommended by their treating psychiatrist.

Assessments and Outcomes

At the conclusion of the index course of ECT and prior to starting CBT, baseline ratings of depression were completed using the Montgomery-Åsberg Depression Rating Scale (MADRS),²⁹ the Beck Depressive Inventory II (BDI),³⁰ the Quick Inventory of Depressive Symptomatology-Self Report (QIDS),³¹ and the Clinical Global Impression (CGI) scale.³² The BDI and QIDS were administered at the completion of every other lesson (approximately weekly) for the first four weeks and monthly thereafter. The MADRS was administered on a monthly basis. Similar to other research,³³ relapse was defined as having a MADRS score ≥ 20 at final visit, hospitalization for depression or suicidality, or needing another index course of ECT treatments (3 times weekly). As this was a pilot, feasibility study, the principal question we aimed to answer was whether subjects would actually complete the CBT lessons online in their own homes on their own time. This was assessed via completion rates of CBT sessions as well as total hours logged on to the program. To draw preliminary inferences regarding potential efficacy, our data was qualitatively compared to a previous study by our group examining the feasibility of traditional CBT in an open-label pilot study²² as well as historical rates of relapse from the literature.

Results

Demographic and Clinical Information

Thirty-six potential subjects were screened for participation in the study, with 15 (80% female) subjects who eventually enrolled and participated in at least one online CBT session (see Figure 1). Subjects were well educated and mostly married (Table 1). The mean age was 48.1 years (SD 10.9, range 27-70). All were taking some form of concomitant psychotropic medication. While all subjects had prior psychotherapy treatment, only two (13%) had prior experience with CBT. Thirteen (87%) subjects continued psychotherapy following the acute course of ECT, while one (6.7%) initiated a new group psychotherapy course following acute treatment and one (6.7%) did not continue psychotherapy. Three subjects (20%) withdrew from the study prematurely, all due to relapse (2 subjects relapsed one month following completion of their index ECT course and one subject relapsed at two months).

Progress of those subjects who withdrew was not monitored once participation was discontinued. All subjects who withdrew relapsed prior to withdrawal. Hence, using last observation carried forward (LOCF) method is a conservative approach to the analysis of their missing data.

ECT Treatments

As is the practice standard in our community, all patients who demonstrated clinical response received recommendations to undergo continuation ECT for the 6 months following index course. Six of the original 15 patients underwent continuation ECT throughout the entire 6 month study follow up period, with 5 additional participants discontinuing ECT prematurely during the continuation phase. The mean number of treatments during the index course and 6-month follow up are given in Table 1. Most patients (14/15) began ECT as right unilateral (RUL), ultra-brief pulse width, with three patients switching to the bitemporal electrode placement technique part-way through their index course to increase efficacy. One patient (who subsequently withdrew due to relapse) reported that cognitive problems impaired her ability to engage in the computer-assisted CBT course.

CCBT Treatment Compliance

Subjects were asked to complete at least one online lesson every week, such that all 9 lessons would be complete during the initial 2 months of the study period (when relapse rates are highest). The mean number of online CBT lessons completed throughout the study was 7.6 (SD 1.7) or 84%. The mean number completed during the first two months was 6.5 (SD 1.8) or 72%. The mean time spent working on the online program was 8.4 hrs (SD 3.9 hrs). The mean time spent online during the first 2 months was 6.8 hrs (SD 3.2 hrs). Given that participants were asked to complete at least one lesson per week, an episode of non-compliance was declared when a participant did not login to the program for a period of at least 2 weeks. Most (13/15) participants had at least one episode of non-compliance. The mean number of episodes of non-compliance was 1.5 (SD 1.1). There were no correlations between age and CCBT completion rate or age and time spent working on the online program.

Clinical Outcomes

Generally, subjects maintained gains achieved during the acute phase of ECT, analyzing both completers only and intention-to-treat (Figure 1). Including the three subjects who withdrew prematurely, most subjects (10/15) had lower or equivalent MADRS scores at their final visit compared to their baseline (immediately post-ECT) visit. Including only those who completed the study, 10 of 12 had MADRS scores at 6-month follow up less than or equal to the baseline visit. Similar results were seen using self-report measures. Among all who began the study and completed at least one CBT lesson (intention-to-treat), most (12/15) had lower or equivalent QIDS scores at final compared to baseline visit; 13 of 15 reported a lower or equivalent BDI score at the final compared to baseline visit. Five subjects had achieved remission (MADRS ≤ 10) by conclusion of the index course of ECT; all 5 of these subjects retained remission by study end at 6 months, with one additional subject achieving remission by study end. Five participants relapsed during the course of the study, with 3

doing so within 2 months and 2 at the last visit (Figure 2). Compared to those who did not relapse, participants who eventually relapsed completed significantly fewer CCBT lessons in total (6.4 v. 8.3, $t=-2.37$, $p=0.034$) and during the first two months (5.2 v. 7.2, $t=-2.33$, $p=0.037$). There was no difference in clinical outcomes or CBT completion rates between those who received bitemporal ECT compared to those who received right unilateral ECT.

Discussion

This preliminary study demonstrates that it is feasible to institute adjunctive computer-assisted CBT in a population of patients who have recently finished an index course of ECT. In addressing our primary question of feasibility, the compliance rates of 84% total lesson completion and 72% lesson completion within the first 2 months suggest that the majority of the subjects were able to complete the CBT lessons in their own homes, on their own times with minimal support structure. Our data also suggest that CCBT may be beneficial in treating residual symptoms as well as maintaining remission. Traditionally, it has been thought that psychotherapeutic interventions were not appropriate for ECT patients because cognitive side effects would limit the ability to engage in such interventions. However, the data presented here suggest otherwise. While one patient reported cognitive side effects that limited her ability to engage in CCBT, the majority (93%) of participants in this study were able to engage in CCBT. Additionally, experience from our prior study utilizing traditional CBT also suggests that patients can engage meaningfully in traditional CBT immediately following a course of ECT.²² Furthermore, all subjects from the current study had prior psychotherapy experience and almost all continued or initiated new psychotherapy treatment shortly following the acute course of ECT. That only two subjects had previous exposure to CBT in a patient population of severe depression underscores the lack of availability of this effective psychotherapy modality.

A major limitation of this study was the lack of rigorous neurocognitive assessments that could have more definitively showed that cognitive impairment from ECT did not interfere with CCBT. This data would also have been useful to assess any correlation between executive function and relapse following ECT, as executive function is correlated with response to CBT.³⁴

It is important to note that the CCBT program utilized in this study was not designed as a stand-alone, online psychotherapy program but was intended to be used in conjunction with in-person CBT, reducing the total time required for therapist-patient interaction. However, due to funding constraints and the goal of examining conditions in which this could be more easily disseminated in most communities, it was used in this study with minimal support (brief phone calls on a weekly basis). Considering this limitation, compliance was generally high, especially in a population recently receiving ECT. On average, over 80% of lessons were completed over the study period, with 72% of these being completed in the prescribed time period (the initial two months).

While this was an open-label trial, our results compare favorably to historical data. In sum, most subjects had lower depression scores at their final visit compared to baseline (10/15 for MADRS, 12/15 for QIDS, and 13/15 for BDI). While 33% of our total sample eventually

relapsed (counting both remitters and responders), all (n=5) subjects who achieved remission remained well at 6 months, with one additional subject achieving remission by study end. In large trials, historical rates of relapse of post-ECT *remitted* patients range from 31-50% at approximately 6 months with both continuation pharmacotherapy^{11, 12, 35} or continuation ECT¹² as maintenance strategies. At least one smaller study has reported favorable relapse rates (32% at 1 year) among both remitters *and* responders utilizing continuation ECT as a maintenance strategy.³³ Hence, it is possible that the CCBT intervention utilized in this study did not have a direct effect on the low rate of relapse among remitters. On the other hand, a prior randomized trial utilizing group CBT as a maintenance strategy was superior to both continuation pharmacotherapy and continuation ECT;²³ hence, it is also possible CCBT could be an effective strategy or adjunctive treatment to maintain remission or response in ECT patients. Our results also are similar qualitatively to our previous study evaluating the feasibility and potential efficacy of traditional CBT following ECT,²² though a direct comparison utilizing a randomized design is needed to draw more meaningful conclusions regarding comparative efficacies of traditional and computer-assisted CBT modalities in this clinical context. In our previous study, participants underwent a 12-week, in-person CBT course that began following the index course of ECT. The CBT was concurrent with a continuation ECT course and was performed by therapists who had undergone training and certification from the Beck Academy of Cognitive Therapy. Among those who completed the CBT course, all had lower or equivalent BDI scores 9 months following the index course of ECT compared to their scores immediately following the ECT course,²² which is similar to the current study.

While admittedly speculative at this point, it is possible that ECT may create a period of enhanced neuroplasticity³⁶ and hence afford an opportune window of time to institute a course of CBT with the aims of retraining negative thoughts patterns and core beliefs. The results of this study suggest that adjunctive CCBT was beneficial continuing to lower depression severity and reducing relapse rates. Further evidence supporting this hypothesis was presented by our previous open-label study with standard in-person CBT,²² and a larger randomized controlled trial showing that group CBT was superior to both medication and continuation ECT in preventing relapse.²³

There were several limitations to this phase treatment development study. A number of other factors may have contributed to the generally positive outcomes in this study, including concomitant medications or psychotherapy (which were not controlled), the natural course of the depressive illness, increased attention from research staff or other concomitant psychosocial interventions. However, despite these limitations the data suggest the treatment was adopted and utilized by the large majority of the study participants, and may have provided some clinical benefit in further reducing depression severity and reducing the rate of relapse. Considering the relative ease with which CCBT could be disseminated and the continuing problem of relapse post-ECT, larger controlled studies examining CCBT in reducing relapse after ECT are warranted.

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Figure 1.
CONSORT diagram. CCBT indicates computer-assisted cognitive behavioral therapy.

Figure 2.

Depression severity for 6 months following index course of ECT as measured by the Montgomery Asberg Depression Rating Scale (MADRS), Beck Depressive Inventory (BDI), and Quick Inventory of Depressive Symptomatology (QIDS). 'Baseline' refers to severity score immediately following completing index course of ECT. Figures on the left represent completers only (n=12); on the right are intention-to-treat (n=15), last observation carried forward (LOCF). Error bars are standard error of the mean.

Figure 3.

Kaplan-Meier survival curve showing the probability of continuing without relapse throughout the study period (6 months following completion of index course of ECT). Relapse is defined as MADRS score ≥ 20 at last study visit, hospitalization due to depression or suicidal ideation, or requirement of another index course of ECT. CCBT – computer-assisted cognitive behavior therapy. TAU – treatment as usual.

Table 1
Demographic and Clinical Characteristics

Variable	Mean/No. (SD/%)
Age	48.1 (10.9)
Male	3 (20%)
Married	10 (66.7%)
Education, years	15.9 (0.5)
Began ECT as inpatients	4 (26.7%)
Bipolar diagnosis	3 (20%)
History of psychotherapy	15 (100%)
History of CBT	2 (13.3%)
Concomitant antidepressant	12 (80%)
Concomitant antipsychotic	5 (33.3%)
Concomitant mood stabilizer	6 (40%)
Concomitant psychotherapy (not CBT)	14 (93.3%)
Mean no. ECT treatments (acute phase)	12.5 (4.9)
Mean no. ECT treatments (continuation)	7.5 (4.6)
Mean MADRS at baseline, following acute phase of ECT (n=15)	14.7 (5.8)
Mean MADRS, 6-month follow up (n=15, LOCF)	14.5 (12.6)
Mean MADRS, 6-month follow up, completers only (n=12)	11.2 (11.6)
Mean no. online sessions completed (maximum of 9)	7.6 (1.7)
Mean no. online sessions completed in the first 2 months	6.5 (1.8)
Mean time (hrs) spent logged in to CCBT program during study (6 months)	8.4 (3.9)
Mean time (hrs) spent logged in to CCBT program during the first 2 months	6.8 (3.2)

CCBT – computer-assisted cognitive behavior therapy; LOCF – last observation carried forward