



ABSTRACT

Objective: The contribution of components in cognitive behavior therapy (CBT) to the total reduction of depression symptoms has not been well elucidated, and previous studies couldn't exclude the human factors in the therapy. **Design:** This is a secondary analysis of a randomized, controlled trial comparing automated smartphone CBT without human factors plus antidepressant switch against antidepressant switch alone among patients with antidepressant-resistant depression. The present CBT consisted of self-monitoring, behavioral activation, and cognitive restructuring. We used linear regression to predict the overall pre- to post-symptom improvement based on improvement achieved by sessions teaching each cognitive or behavioral skill. The overall improvement was measured with the Beck Depression Inventory-II and the session-to-session improvement with K6. **Results:** Of the 164 participants originally enrolled in the study, 94 participants who completed all K6 evaluation were included in the primary analyses. The results indicated that K6 score reduction in the first half of behavioral activation significantly predicted BDI-II score reduction. The sensitivity analysis including 162 participants did not change the result. K6 score reductions after other CBT sessions did not significantly predict BDI-II score reduction. **Conclusion:** The behavioral activation seems to contribute to the total reduction of depressive symptoms even if human factors are excluded by using automated smartphone CBT. **KEYWORDS:** Cognitive behavioral therapy, depression, information technology, smartphone, component study

Behavioral Activation Contributed to the Total Reduction of Depression Symptoms in the Smartphone-based Cognitive Behavioral Therapy: A Secondary Analysis of a Randomized, Controlled Trial

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Innov Clin Neurosci. 2020;17(7–9):21–25

Cognitive behavioral therapy (CBT) is one of the most rigorously studied treatments for depression. One network meta-analysis showed its effect was large compared to wait-list controls and medium compared to usual care or placebo.¹ Studies indicate the efficacy of CBT in treating major depression is comparable to that of antidepressants.^{2,3}

Although CBT is an effective treatment package for depression, its constituent techniques are somewhat heterogeneous. The most common treatments include psychoeducation, self-monitoring, cognitive restructuring, behavioral activation, exposure, assertion training, problem-solving, and mindfulness.

The inevitable question then is which components contribute to the program's

effectiveness. Four meta-analyses focusing on components have been conducted, but the results were inconsistent.^{4–7} The first meta-analysis of 27 studies in CBT and other psychotherapies indicated that there was no significant difference between psychotherapies with or without the critical component.⁴ The second meta-analysis included 34 studies with bona fide CBT and non-bona fide treatments, which were not based on any recognized psychological principles, in children and adolescents. The results also showed that full CBT treatments had no significant additional benefit over their components.⁵ As a result, researchers emphasized the importance of the common factors in psychotherapies. However, these two meta-analyses did not distinguish between dismantling and additive designs. The

FUNDING: The study was funded by the Ministry of Health, Labor and Welfare, Japan (H-22-Seishin-Ippan-008) from April 2013 through March 2014, and thereafter by the Japan Foundation for Neuroscience and Mental Health (JFNMH). The JFNMH received donations from Asahi Kasei, Eli-Lilly, GSK, Janssen, MSD, Meiji Seika, Mochida, Otsuka, Pfizer, Shionogi, Taisho, and Mitsubishi-Tanabe. The funders had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

DISCLOSURES: Dr Mitsuhiro Yamada has received speaking fees from Meiji and has contracted research with Nippon Chemiphar. Dr Masatoshi Inagaki has received lecture fees from Pfizer, Mochida, Shionogi, Daiichi-Sankyo, Meiji, Takeda, and Sumitomo Dainippon Pharma. He has received royalties from Nippon-Hyoron-Sha, Nanzando, Seiwa-Shoten, Igaku-Shoin, and Technomics. Dr Norio Watanabe has received royalties from Akatsuki and Sogen-sha. Dr Chino has received lecture fees from Eli Lilly, Meiji and Mitsubishi-Tanabe. Dr Mantani has received lecture fees from Mochida, Eli Lilly and Meiji. Dr Kato has received lecture fees from Eli Lilly and Mitsubishi-Tanabe, and has contracted research with GlaxoSmithKline, MSD and Mitsubishi-Tanabe. He has received royalties from Kyowa Yakuin and Medical Tribune. Dr Furukawa reports personal fees from Meiji, Mitsubishi-Tanabe, MSD and Pfizer and a grant from Mitsubishi-Tanabe, outside the submitted work; he has a patent 2018-177688 pending. Dr Hissei Imai received the lecture fee from Tanabe-Mitsubishi pharma and Kyowa pharmaceutical industry outside the submitted work.

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former design compared full treatment with treatment without a specific component, while the latter design compared existing treatment against an existing treatment with an additional component.

Investigators of the third meta-analysis considered these design differences in their analysis. They included 66 studies with CBT as well as other psychotherapies. The results indicated that the added specific component yielded a significant effect in the meta-analysis of additive design studies, whereas there were no significant differences between treatments in dismantling design studies.⁶ The fourth meta-analysis included 16 studies with various psychotherapies and concluded that studies lack the statistical power and quality to draw any meaningful conclusion.⁷ In summary, the contribution of each component to the total effect remains unsolved in any kind of psychotherapies including CBT.

The present study is the first to evaluate the contribution of the components to the total effect by using smartphone CBT. We used the data from a randomized, controlled trial (RCT) evaluating smartphone-based CBT as an adjunct to pharmacotherapy. It was a guided self-help, nine-week intervention against patients with antidepressant-refractory depression.^{8,9} The results indicated that our smartphone CBT was effective in reducing depression severity.

All of the previous studies that evaluated components of CBT were conducted by human therapists.^{10–12} However, such studies are confounded by therapist factors. The alliance, empathy, and therapist differences are important factors in psychotherapy and will influence the outcome.¹³ Researchers conduct training and supervision while monitoring them via audio or videotapes and administering some scales to control these factors. However, therapy will not be completely the same in CBT conducted by human therapists. By contrast, our smartphone CBT app can completely control therapist factors, so that the therapy provided in the present study is essentially identical across participants. Moreover, in our smartphone CBT we can closely monitor the patients' participation in the therapy. In our smartphone CBT app, patients could not proceed to the next session without reading all the current session and completing the homework, and all of their activities were uploaded and recorded on the remote server.

Objectives. The aim of the present study is to clarify the contribution of the components of smartphone CBT package to the total effect. Elucidation of the more effective components of a complex intervention such as CBT is not only theoretically important but also pragmatically meaningful, as such knowledge will enable the future therapies to be more effective and efficient.

METHODS

Study design. This is a secondary analysis of an RCT comparing smartphone CBT plus antidepressant switch against antidepressant switch alone among patients with antidepressant-resistant depression who had not responded to one or more antidepressants at adequate dosage for four or more weeks. A detailed information of the RCT was described elsewhere.⁹

Participants. Included participants were patients with major depressive disorder without psychotic features diagnosed by the *Diagnostic and Statistical Manual of Mental Disorders (Fifth Edition)* aged between 25 and 59 years and refractory to antidepressant-treatment.

Procedure. In total, 164 participants were enrolled in the study and randomized 1:1 to the two arms. Participants in the CBT arm received smartphone CBT for nine weeks, and the other participants received CBT smartphone intervention after waiting for nine weeks, both in addition to medication switch, which is a standard treatment for treatment-resistant depression. They completed the Beck Depression Inventory-II (BDI-II)^{14,15} at baseline, at nine weeks (post-treatment) and at 17 weeks (post-treatment follow-up); in addition, they filled in K-6^{16,17} during smartphone CBT intervention at the beginning of every session.

Treatment. The smartphone CBT consists of the following eight sessions: one welcome session briefly explaining CBT and confirming the participants' ability to use the smartphone, two sessions on self-monitoring, two on behavioral activation, two on cognitive restructuring, and one session for relapse prevention. Participants were expected to complete each session within approximately one week. They must complete at least one homework to proceed to the next session and fill in K6 score at the beginning of each session. The details of the program was described previously.¹⁸

Sessions 1 and 2 are about self-monitoring. Participants learn how thought, behavior,

emotion, and physical reaction influence each other under emotion-evoking situations. Homework is to fill in a so-called Mind map, where participants describe the situation, their automatic thoughts, physical reaction, and behavior and choose their emotion from among the following four; sad/depressed; anxious/worried; angry; and happy and monitor its intensity in five grades. Session 1 teaches the principles of self-monitoring according to the cognitive-behavioral model, and Session 2 provides more tips for filling in a Mind map.

Sessions 3 and 4 teach behavioral activation. Participants learn how their behavior can influence their emotional status. Homework is a behavioral activation task, where participants choose one of the many pleasurable activities listed in the app or make up their own. They rate their expected level of mastery and pleasure before the activity and their achieved levels after the activity. Listed activities are categorized by the time required to finish them, namely, less than five seconds, less than five minutes, less than 60 minutes, and 60 minutes or more. Participants are advised to progress in small steps. Session 3 focuses on psychoeducation and tips about behavioral activation, including dividing a difficult task into small pieces and starting with activities with pleasure rather than those with sense of mastery. Session 4 includes review of Session 3 and other tips about behavioral activation, such as starting from activities one can do by oneself, scheduling, and imagining themselves completing the chosen activity.

Sessions 5 and 6 are about cognitive restructuring. Participants learn four perspectives that can lead them to alternative thoughts. The first one asks for the evidence for and against the automatic thoughts. The second asks for possible reasons to the contrary of the automatic thoughts through rating their subjective confidence in their thoughts. The third is to change the viewpoint by imagining a friend asking for help with the same automatic thoughts. The last one asks for some course of action to take in the case the automatic thought were true. Participants are asked to rate their intensity of emotion after looking at the alternative thoughts they have come up with. Session 5 deals with the first two perspectives, and Session 6 deals with the last two perspectives.

The final session is an epilogue that discusses relapse prevention. This session summarizes all the previous sessions, asks participants about

TABLE 1. Baseline characteristics.

MEASUREMENT	PARTICIPANTS INCLUDED IN THE PRIMARY ANALYSIS (N=94)	OTHER PARTICIPANTS (N=70)
Age, mean (SD)	41.6 (8.5)	38.9 (9.1)
Gender (female), %	50.0	56.9
Education (years), mean (SD)	14.8 (2.3)	15.0 (3.0)
Age at onset, mean (SD)	33.7 (10.0)	32.4 (11.0)
Episode number, mean (SD)	3.4 (5.0)	3.0 (4.1)
Episode duration (months), mean (SD)	25.2 (51.3)	23.3 (46.5)
Allocation (waiting list), %	36.2	70.8
Employment status, %	Full time	35.1
	Part time	10.6
	Leave of absence	27.7
	Homemaker	8.5
	Unemployed	18.1
Marital status, %	Single	36.2
	Divorced, separated	8.5
	Married	55.3
Baseline BDI score, mean (SD)	25.1 (13.0)	21.5 (12.6)

BDI: Beck Depression Inventory; SD: standard deviation

TABLE 2. Score reduction in BDI-II from pre- to post-intervention, and K6 score reduction after each session

SESSION/SCALE	SCORE REDUCTION, MEAN (SD)
BDI	6.68 (8.09)
K6 session	
Session 1 (self-monitoring: SM1)	1.53 (3.42)
Session 2 (self-monitoring: SM2)	0.76 (3.03)
Session 3 (behavioral activation: BA1)	1.04 (3.23)
Session 4 (behavioral activation: BA2)	0.20 (3.28)
Session 5 (cognitive restructuring: CR1)	0.23 (2.80)
Session 6 (cognitive restructuring: CR2)	0.84 (2.78)

BA: behavioral activation; BDI: Beck Depression Inventory; CR: cognitive restructuring; SM: self-monitoring

possible obstacles against using the CBT skills they have learned, and troubleshoots them.

MEASURES

The second edition of Beck Depression Inventory (BDI-II). The original Beck Depression Inventory (BDI) was published in 1961.¹⁹ It has been used widely for the self-evaluation of depression. The second edition of BDI (BDI-II) was developed in accordance with DSM-IV, and its reliability and validity have been established.²⁰ The reliability and validity of the Japanese version of BDI-II are also satisfactory.²¹ Cronbach's alpha of the present sample was 0.91.

K6. K6 is composed of six items based on the item response theory and used for the screening of common mental disorders and for the evaluation of psychological distress. The scale ranges from 0 to 24 and a higher score indicates

greater severity.¹⁶ Its reliability and validity are high, and the validity of the Japanese version has been established.^{17,22} Cronbach's alpha of the present sample was 0.87.

Data analysis. The aim of our analysis is to examine the contribution of each session to overall improvement. We defined the overall improvement as the score reduction in BDI-II from pre- to post-CBT intervention. The improvement after each session was calculated as the score reduction in K6 between sessions. For example, the score reduction between Sessions 2 and 3 is considered to indicate the improvement after Session 2.

First, univariate linear regression was conducted with the overall improvement represented by BDI-II score reduction as a dependent variable and the K6 score reduction between sessions as an independent variable.

Next, the multivariate linear regression adjusted for age, gender, and allocation was also conducted, using the same variables.

Our primary analysis was based on the completers' dataset, where the data was included only if participants completed all K6 evaluations. As all the K6 data after the dropout could not gain, it is appropriate to see the completer's dataset to compare the score reduction in each session. As a sensitivity analysis, we included all available K6 data to see the robustness of the primary results. We set the threshold for statistical significance at conventional $p < 0.05$.

RESULTS

Of the 164 participants originally enrolled in the study, 94 participants who completed all K6 evaluation were included in the primary analysis. Table 1 shows their baseline characteristics. The percentage of the participants allocated to the waiting list in the primary analysis was significantly higher than that in the secondary analysis ($\chi^2[1]=0.89$, $p < 0.001$). There was no significant difference in other baseline characteristics between the participants included in the primary analysis and those who were not.

The score reduction in BDI-II from pre- to post-intervention and in K6 between sessions. Table 2 shows the score reduction in BDI-II from pre- to post-intervention, and K6 score reduction between sessions. There is a significant difference in K6 score reductions between sessions (analysis of variance [ANOVA] $F[5, 558]=2.48$, $p=0.03$). Post-hoc comparison using the Tukey Honest Significant Difference (HSD) test indicated that the mean score reduction after Session 1 was significantly greater than that after Session 4 ($p=0.04$) or after Session 5 ($p=0.049$), but there was no significant difference among other comparisons.

The relationship between BDI-II and K6 score reduction. Tables 3A and 3B show the results of linear regression. The results of the univariate regression indicated that K6 score reduction in Session 3, that is, reduction after the first session of behavioral activation, explained 10 percent of the total variance ($R^2=0.10$, $F[1,92]=10.23$, $p=0.002$) and significantly predicted BDI-II score reduction ($\beta=0.32$, $p=0.002$). Other K6 score reductions did not significantly predict BDI-II score reduction. The multivariate linear regression adjusted for age, gender, and

allocation, and also indicated that K6 score reduction in Session 3 significantly predicted BDI-II score reduction (beta=0.31, p=0.004).

Sensitivity analysis. We conducted a sensitivity analysis including participants who did not complete all the K6 evaluation. The results were in accordance with the primary analysis in that K6 score reduction after Session 3 significantly predicted BDI-II score reduction in univariate regression (beta=0.26, p=0.002) and in multivariate regression adjusted for age, gender, and allocation (beta=0.26, p=0.001). However, K6 score reduction after Session 2 (second half of self-monitoring) also predicted BDI-II score reduction in univariate regression (beta=0.18, p=0.02) and in multivariate regression adjusted for age, gender, and allocation (beta=0.16, p=0.048). K6 score reduction in any other period did not significantly predict the total BDI-II score reduction.

DISCUSSION

The previous studies comparing the effect of components of CBT could not exclude the human factors in the CBT therapy. The present study is the first study to overcome the limitation by using the automated smartphone CBT. The results indicated that improvement seen during the behavioral activation was related to the total improvement, which was confirmed by an analysis adjusting for age, gender, and allocation, and in a sensitivity analysis.

Two component RCTs for depression have been published.^{10,11} These trials generally favored behavioral components. The first study compared behavioral activation only, behavioral activation plus cognitive restructuring, and behavioral activation plus cognitive restructuring plus schema work, but found no significant difference among the three.¹⁰ The study conducted by Dimidjian et al included a larger number of participants and compared expanded behavioral activation with cognitive therapy.¹¹ It showed that expanded behavioral activation was comparable to antidepressant medication and significantly superior to cognitive therapy in effect among patients with severe depression. A direct comparison RCT between behavioral activation only and full CBT has recently confirmed that the former was non-inferior to the latter.²³

One explanation of these advantages of behavioral activation compared with cognitive therapy is reducing avoidance. Patients with emotional disorders try to avoid unexpected

TABLE 3A. Univariate linear regression predicting score reduction in BDI-II based on between-session score reduction in K6 (completers' analysis, n=94)

SESSION	B	SE	p	R ²
Session 1 (SM1)	0.17	0.25	0.49	0.07
Session 2 (SM2)	0.15	0.28	0.59	0.06
Session 3 (BA1)	0.79	0.25	0.002	0.10
Session 4 (BA2)	0.22	0.26	0.39	0.01
Session 5 (CR1)	0.44	0.30	0.14	0.02
Session 6 (CR2)	0.29	0.30	0.35	0.01

BA: behavioral activation; BDI-II: Beck Depression Inventory-II; CR: cognitive restructuring; SM: self-monitoring "1" and "2" represents first-half and second-half of each component

TABLE 3B. Multivariate linear regression predicting score reduction in BDI-II based on between-session score reduction in K6 adjusted for age, gender and allocation group (completers' analysis, n=94)

SESSION	B	SE B	p
Session 1 (SM1)	0.20	0.25	0.42
Session 2 (SM2)	0.09	0.28	0.75
Session 3 (BA1)	0.77	0.25	0.004
Session 4 (BA2)	0.15	0.26	0.55
Session 5 (CR1)	0.42	0.30	0.16
Session 6 (CR2)	0.31	0.30	0.30

BA: behavioral activation; BDI-II: Beck Depression Inventory-II; CR: cognitive restructuring; SM: self-monitoring "1" and "2" represents first-half and second-half of each component

TABLE 4A. Univariate linear regression predicting score reduction in BDI-II based on between-session score reduction in K6 (secondary analysis).

SESSION	B	SE B	p	R ²
Session 1 (SM1) (n=162)	0.08	0.16	0.60	0.002
Session 2 (SM2) (n=162)	0.42	0.19	0.02	0.03
Session 3 (BA1) (n=142)	0.64	0.20	0.001	0.07
Session 4 (BA2) (n=130)	0.23	0.22	0.28	0.01
Session 5 (CR1) (n=116)	0.17	0.25	0.51	0.004
Session 6 (CR2) (n=94)	0.29	0.30	0.35	0.01

BA: behavioral activation; BDI-II: Beck Depression Inventory-II; CR: cognitive restructuring; SM: self-monitoring "1" and "2" represents first-half and second-half of each component

TABLE 4B. Multivariate linear regression predicting score reduction in BDI-II based on between-session score reduction in K6 adjusted for age, gender and allocation group (full analysis set)

SESSION	B	SE B	p
Session 1 (SM1) (n=162)	0.13	0.15	0.40
Session 2 (SM2) (n=162)	0.37	0.19	0.048
Session 3 (BA1) (n=142)	0.64	0.20	0.001
Session 4 (BA2) (n=130)	0.19	0.22	0.38
Session 5 (CR1) (n=116)	0.14	0.25	0.59
Session 6 (CR2) (n=94)	0.30	0.31	0.30

BA: behavioral activation; BDI-II: Beck Depression Inventory-II; CR: cognitive restructuring; SM: self-monitoring "1" and "2" represents first-half and second-half of each component

emotional experience, which might prevent recovery from subjective distress.^{24,25} Another explanation is change in reality. A study analyzing cognitive therapy showed that interpersonal cognitive change was negatively related to global functioning, but actual interpersonal change was positively related to it.²⁶

The present trial controlled the human therapist factors, as it was conducted through an automated smartphone CBT app. Our results were also supportive of the importance of the behavioral component in smartphone CBT. The improvement in depressive symptoms during behavioral sessions was significantly associated with the total improvement of depressive symptoms, whereas there were no significant relations between the improvement during self-monitoring or cognitive restructuring sessions and the total improvement.

One question is if the present result just reflects the order of the components. In fact, Rabin et al²⁷ reported that the depressive symptoms diminish in curvilinear manner, and the improvement occurred most in the first 3 to 4 weeks. In our study, the behavior session, which was related to the total effect in the present study, was conducted in around 3 to 5 weeks. However, the improvement in the present study was not curvilinear—the relatively big improvement occurred after Sessions 1, 3, and 6, with the biggest improvement after Session 1, which was not significantly related to the total effect. This means that the biggest improvement seen after the initial session does not necessarily contribute to the total improvement. The results suggest that improvement might be accelerated if one gets a positive effect from behavioral activation.

Interestingly, only the first of the two behavioral activation sessions was significantly related to the total effect. The first session focused on psychoeducation and tips about behavioral activation, such as breaking down difficult tasks into small pieces and starting from activities with pleasure, rather than those with mastery. The second session focused on other tips about behavioral activation, including starting from activities one can do by oneself, scheduling, and imagining the goals. It might be that the former tips are enough to produce the effect, but such a hypothesis should be tested in a future trial.

Limitations. The present study has some limitations. First, we did not analyze the long-term effects of the behavior component. Gortner et al²⁸ showed CBT was no more effective than

its components in preventing relapse by the two-year follow up. Whether the improvement seen in the behavioral activation session of our smartphone app is related to long-term improvement should be examined. Second, the present study is only observational in nature, and we should confirm the importance of behavioral components in other study designs, such as additive or dismantling, and various sequential designs. Another weakness in our study, as well as other studies, is that the findings might be confounded by the order of components, but such ordering effect has never been properly researched.

By contrast, the strengths of the present study are that we were able to completely control for therapist factors and to closely monitor patients' participation and progress. No study using face-to-face CBT by live therapists has examined such details.

CONCLUSION

In conclusion, this longitudinal observational study suggests that the behavioral component makes a significant contribution to the total reduction of depressive symptoms, even if human factors are excluded by automated smartphone CBT. Future CBT therapists, as well as CBT apps, might wish to put more emphasis on behavioral activation during the course of conducting the total CBT package.

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