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ORIGINAL PAPER

Community-Based Multi-Site Randomized Controlled Trial of Behavioral Activation for Patients with Depressive Disorders

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Abstract

Behavioral activation (BA) is a beneficial and relatively cost-effective treatment option for depression. This study utilized a pragmatic randomized controlled research design to investigate whether BA, as compared with treatment as usual (TAU), led to superior treatment effects, when delivered in community mental health settings by retrained community mental health professionals. Patients with depressive disorders (n = 64) were randomly assigned to a 10-session BA (n = 31) or TAU (n = 33) group. The depressive symptoms and behavioral engagement were assessed at the baseline, post-treatment, and a six-month follow-up. Results showed that, as compared to the TAU group, the BA group had: (1) a reduction in depression severity, as evidenced by large effect sizes and greater response rates, and (2) an increase in behavioral engagement. However, the post-treatment gains were not maintained at the six-month follow-up. The implications and limitations of the study are also discussed (KCT0004098, June 27, 2019, retrospectively registered).

Keywords Depression · Behavioral activation · Randomized controlled trial · Community mental health services

Introduction

Advancement in psychosocial interventions in the past decades has established treatment options that qualify as the gold standard for Major Depressive Disorder (MDD). Particularly, cognitive behavioral therapy (CBT), behavioral activation (BA) and interpersonal therapy (IPT) have been recommended as first-line psychological treatment options for the acute treatment of MDD (National Institute for Clinical Excellence & Britain, 2004; Parikh et al., 2016). However, despite the availability of evidence-based treatment options, less than 35% of adults with depression seek treatment (Lee, 2017; Wang et al., 2005). Given the MDD patients' poor access to appropriate treatments, disseminating effective and relatively parsimonious treatments that could be delivered by clinicians in a community mental health setting is of paramount importance.

Behavioral activation (BA) is a promising treatment option since it not only provides clinical effects comparable to CBT, but can also be delivered more cost-effectively than traditional CBT due to its relatively brief format (Cuijpers et al., 2007; Ekers et al., 2008; Richards et al., 2016; Simmonds-Buckley et al., 2019). Furthermore, it is proven to produce clinically significant effects even when delivered by a non-specialist with less intensive training in a routine care clinical setting (Dimidjian et al., 2017; Ekers et al., 2011; O'Mahen et al., 2014; Patel et al., 2017). BA might be delivered at a lower cost than CBT, which requires longer and more professional training of therapists. Indeed, a large randomized controlled non-inferiority study found that employing BA saved 21% of the cost when compared to CBT, resulting in similar clinical outcomes for patients with depression (Richards et al., 2016). Therefore, BA has the potential to be easily and cost-effectively disseminated in a community mental health setting, with comparable treatment effects.

Since mental health policies across the globe have emphasized the dissemination of evidence-based and cost-effective treatments (Australian Government Department of Health,

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2019; Committee on Quality of Health Care in America & Institute of Medicine Staff, 2001; Department of Health, 2008; Yim et al., 2013), it is important to investigate whether an effective and parsimonious psychosocial treatment such as BA would lead to superior treatment effects relative to treatment as usual (TAU) in community mental health settings. In addition, this line of research will also provide noteworthy and timely evidence for the promotion of pragmatic psychosocial treatments such as BA, not only in Korea, but also in other countries facing several obstacles related to mental health care, such as inadequate infrastructure for psychotherapy and greater expense for initiating services in community mental health settings.

The present study sought to examine the efficacy of BA on depressive symptoms in patients with depressive disorders, when delivered by retrained community mental health professionals with limited experience in psychotherapy or BA treatment. The primary aim of the current study was to investigate whether BA would be more effective than TAU in reducing symptom severity in patients with depressive disorders. As a secondary aim, we investigated whether BA would lead to superior treatment effects than TAU in increasing behavioral engagement.

Methods

Participants

The current study was approved by the Korea University Institutional Review Board. The sample size of the study was determined prior to the study, utilizing G*Power 3.1.9.4 (Faul et al., 2007) based on a mean effect size of Hedges's $g = -0.74$ reported in a previous meta-analysis of level of depressive symptoms at post treatment between BA and controls (Ekers et al., 2014). The recruitment was terminated based on the trial protocol (KCT0004098). There are no conflicts of interest for any author and all authors certify responsibility.

All participants provided written informed consent prior to pre-assessment. The participants, selected from 75 referrals, consisted of 64 individuals between the ages of 18 and 80 years who met the criteria for either MDD or dysthymic disorder. The diagnoses were confirmed based on either the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I; First et al., 1997) or the Mini-International Neuropsychiatric Interview (M.I.N.I.) (Sheehan et al., 1998). To examine the benefits of BA in a naturalistic community mental health setting, participants were recruited from six sites including community mental health centers ($n = 31$; 48%), local mental health clinics ($n = 30$; 47%), and other psychiatric rehabilitation centers ($n = 3$; 5%), regardless of their current use of pharmacological treatment.

Participants were excluded if they had: 1) a lifetime diagnosis of a stroke, brain injury or intellectual disability, 2) suicidal risk, 3) a history of neurological diseases or sensory deficits, 4) a diagnosis of alcohol or other substance-use disorders, or 5) a presence of other severe medical illnesses hindering research participation.

Procedure

Potential participants were referred to the study assessor located off-site via phone, primarily by a psychiatrist or other providers (e.g., social workers) working in community mental health settings in urban areas. For an initial diagnostic screening, participants with prior psychiatric diagnoses of MDD or dysthymic disorder were diagnostically confirmed based on chart review by a psychiatrist and a clinical psychologist of this research team (the corresponding authors of this study), and those without prior psychiatric diagnoses were screened through M.I.N.I. by independent assessors (i.e., doctoral-level clinical psychologists or trained clinical psychology graduates) under the supervision of the corresponding authors. Participants who passed the initial diagnostic screening were scheduled for an on-site clinical assessment to ascertain study eligibility by independent evaluators and were asked to provide written consent at each site of referrals. After determining eligibility, participants were randomly distributed into the two groups (BA or TAU) by an independent coordinator through a computer-generated randomization list. Participants then received their allocated intervention for 10 weeks. The same evaluations as the ones used at the baseline were administered immediately after the completion of the treatment as well as at the six-month follow-up post the intervention termination.

Therapists

The BA treatment was delivered by 10 mental health professionals (at least one or more therapists at each site) including psychiatric nurses, psychiatric social workers, psychiatric residents, and clinical psychology graduate research assistants. Most of the therapists, except for the psychiatry residents and clinical psychology research assistants, worked in community mental health settings for approximately 5 years or longer, with hardly any previous experience in evidence-based psychotherapy. Therapists received a full-day training via workshop sessions delivered by the corresponding authors. The training workshop focused on the theoretical backgrounds and intervention techniques essential to deliver a 10-session protocol of BA for depression. Therapists were prepared to deliver the BA through repeated role-playing,

practice, and feedback in developing BA formulations and possible problem-solving strategies, using fictitious cases. While delivering the BA treatment, therapists were provided with an on-site consultation meeting and an off-site telephonic supervision.

Treatments

Behavioral Activation

BA consisted of semi-structured sessions to re-engage participants with potentially antidepressant activities, which were expected to result in increased contact with positive consequences and subsequent reduction of depressive symptoms. The BA treatment protocol utilized in the study was based on the Brief Behavioral Activation Treatment for Depression (BATD; Lejuez et al., 2001), which was translated into Korean and modified in consideration of the Korean mental health setting and cultural differences (Table 1). In initial sessions, therapists established rapport with patients, introduced them to treatment rationales, and assessed the function of depressed behaviors via daily monitoring. Next, participants identified their values and goals within various life areas (e.g., relationships, education, recreation, health, spirituality, etc.), which would be used as a guide to select their activities for the following sessions. Subsequently, an activity hierarchy was constructed of 15 target activities rated from easiest to most difficult in terms of accomplishment. For the subsequent sessions, individuals planned for how they would include the target activities in their daily schedules and monitored the progress using a master activity log and behavioral checkout. Therapists led patients to adjust their activation level of an upcoming week as a function of the previous week's success or difficulty, while repeatedly monitoring whether the activation level would be associated with mood change. Participants could be less vulnerable to future depressive episodes by understanding the BA rationale and internalizing depression management strategies through a BA program. Participants in the BA condition received 10 one-hour face-to-face sessions in a small-group format (with each group including two to five patients) over a 10-week period, with sessions generally held once a week.

Treatment as Usual

Participants were offered appropriate interventions for their condition by their mental health worker as per normal practice. TAU involves case management including regular check-ups and psychosocial advice, recreational programs, and other non-BA or non-CBT services including topics such as medication management, stress management, basic social skills training, and vocational training.

Measurement of Adherence

Treatment adherence was assessed by a team of two psychiatrists, a licensed clinical psychologist, and two doctoral-level clinical psychology graduates sufficiently trained to deliver BA therapy. The evaluators observed and conducted on-site adherence assessments on 10% of all the treatment sessions (at least one session per treatment group), which were randomly selected. Since there was no established integrity assessment tool for the BA treatment, our research team designed a brief 7-item treatment fidelity checklist (Table 2). The checklist examines whether therapists complied with a BA treatment manual and consists of seven items (e.g., "Did the BA therapist check the patient's daily activities based on the *'Daily Activity Record'* form completed by the client?"). Raters assigned scores of 1 if BA therapists met a criterion proposed in each of the items and 0 if not. After the evaluation, adherence percentages were calculated for every assessment.

Measures

We collected demographic information at baseline on age, gender, years of education, age of onset, marital status, and antidepressant medication status. The participants completed both clinical interviews and self-report measures; at baseline, post-treatment and a six-month follow-up. The primary outcome measures for depressive symptoms included both the Hamilton Rating Scale for Depression (HRSD; Hamilton, 1960) and the Center for Epidemiologic Studies Depression Scale (CES-D; Radloff, 1977), since it is recommended to include both clinician-rated and self-report measures of depression for treatment outcome trials (Uher et al., 2012). The HRSD is a widely used 17-item semi-structured interview-based measure of depression severity, whereby higher scores represent higher levels of depression severity. The CES-D is a 20-item self-report measure to evaluate the presence and current level of depressive symptoms, with each item being scored on a scale of 0 to 3 according to the frequency of occurrence of the symptom during the past week. We used the Behavioral Activation for Depression Scale (BADS; Kanter et al., 2007) as the secondary outcome measure, to evaluate changes in behavioral engagement hypothesized to alleviate depressive symptoms during BA. It contains 25 items and comprises four subscales: Activation (seven items), Avoidance/Rumination (eight items), Work/School Impairment (five items), and Social Impairment (five items). To estimate

Table 1 Behavioral activation treatment protocol for depression

Session number	Key elements	Detailed contents
1	Discussion of depression Introduction to treatment rationale Introduction to daily monitoring	Give an overview of the program and set rules for the group Provide psychoeducation about depression Introduce treatment rationale Assess depressive symptom severity via self-report questionnaire (i.e., K-CES-D) and mark the score on a *'Depressive Symptom Severity Graph'* Introduce how to monitor activities each day using *'Daily Activity Record'* form Assignments: Complete *Daily Activity Record*
2	Daily monitoring: Review assignment Checking depressive/healthy behaviors	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record* Identify pattern of depressive / anti-depressant (healthy) behaviors Assignments: Complete *Daily Activity Record*
3	Daily monitoring: Review assignment Identifying values in each of 10 different life areas	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record* Identify values in the following life areas: Family relationships Social relationships Intimate relationships Education / Training Employment / Career Hobbies / Recreation Volunteer Work / Charity / Political Activities Physical / Health Issues Spirituality Psychological / Emotional Issues Assignments: Complete *Daily Activity Record*
4	Daily monitoring: Review assignment Identifying activities for each of the values Creating activity hierarchy	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record* Provide the following guidelines for activity selection: Observable, measurable, in its smallest pieces, and directly relevant to the values Identify activities for each of the values in life areas and select 15 activities to target during treatment sessions Rank 15 activities from 1 (least difficult) to 15 (most difficult) Introduce a new monitoring form with emotion record added Assignments: Complete *'Daily Activity Record (with Emotion Record)'*
5	Daily monitoring: Review assignment Activity planning	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record (with Emotion Record)* Set final goals (frequency and duration) for selected activities using the '*Master Activity Log'* Select the first few activities to start and include them in the coming week's schedule Introduce how to record progress on a daily basis, using the weekly *'Behavior Checkout'* (Optional) Schedule rewards for completing weekly goals Assignments: Complete *Daily Activity Record (with Emotion Record)* and *Behavior Checkout*

Table 1 (continued)

Session number	Key elements	Detailed contents
6–9	Daily monitoring: Review assignment Activity planning Activation	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record (with Emotion Record)* and *Behavior Checkout* Count the number of targeted activities done for a given week and create an *'Activity Graph'* Adjust activity goals for the upcoming week, considering the activities accomplished the previous week (Optional) Schedule rewards for completing weekly goals Assignments: Complete *Daily Activity Record (with Emotion Record)* and *Behavior Checkout*
10	Reviewing progress Preventing Relapse	Recall rules and goals of the program Assess depressive symptom severity via K-CES-D and mark the score and draw the progress line on the *Depressive Symptom Severity Graph* Monitor daily activities in the previous week based on the *Daily Activity Record (with Emotion Record)* and *Behavior Checkout* Count the number of targeted activities done for a given week and complete the *Activity Graph* Review the progress in the program by looking at both the *Depressive Symptom Severity Graph* and *Activity Graph* List strategies to prevent relapse of depression, considering lessons from the program Give certificates of completion

K-CES-D Korean version of Center for Epidemiologic Studies Depression Scale

Table 2 Behavioral activation treatment fidelity checklist

No	Items	Rating	
1	Did the BA therapist remind patient(s) of BA treatment goals before starting session?	Y	N
2	Did the BA therapist check patient's daily activities based on the *'Daily Activity Record'* form completed by client?	Y	N
3	Did the BA therapist monitor patient's performance on the planned activities in the previous week? (using *Master Activity Log* and *Behavior Checkout* forms)	Y	N
4	Did the BA therapist help patient(s) to identify activities that are relevant to their own life-goals? (repeatedly reminding patient(s) of their life-goals and giving a thought about goal-directed activities together)	Y	N
5	Did the BA therapist help patient(s) to schedule daily activities considering their usual activity-level and real-life conditions? (guiding patient(s) to gradually increase the frequency/duration or difficulty of their planned activities)	Y	N
6	Did the BA therapist help patient(s) to complete *Activity Graph* based on the number of activity-goals met for a given week?	Y	N
7	Did the BA therapist help patient(s) to schedule activities for the upcoming week and write down on the *Behavior Checkout* form?	Y	N

BA behavioral activation

premorbid intellectual functioning of depressive patients, the present study used the Korea Premorbid Intelligence Estimation–Information-only formula (KPIE-4IN; Kim et al., 2015) including raw scores for the Information subtest in the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV; Wechsler, 2008), age and years of education. All assessments were conducted by doctoral-level clinical psychologists or trained clinical psychology graduates who were blind to the treatment allocation.

Statistical Analyses

Independent t-tests and chi-square tests were conducted to find out baseline differences in the demographic and clinical characteristics between groups. All demographic information, except for education, was equivalent between the groups. The findings were re-analyzed with the inclusion of education as a covariate to determine whether treatment effects would remain after including this variable.

With an intent-to-treat (ITT) sample, a series of hierarchical linear mixed models were estimated for the outcome measures, utilizing the SAS PROC Mixed procedure. The compound symmetry model was used after entering the pre-treatment, post-treatment and six-month follow-up time-point data, with time centered during pre-treatment. Time was included as a within-subjects (Level 1) parameter while groups (BA or TAU) and individuals as between-subjects (Level 2) parameter. Post-hoc analyses were conducted with ANCOVAs at each time point (i.e., at post-treatment and a six-month follow-up) after considering baseline severity as a covariate. Effect sizes (i.e., partial eta squared and Cohen's *d*) were calculated for between-group changes at post-treatment. To evaluate the difference of clinical improvement by treatment, we compared the rates of response between the two groups on depressive outcomes (i.e., HRSD and CES-D) at post-treatment, using logistic regression, controlling for the years of education. Consistent with the analyses conducted in previous trials of BA (Dimidjian et al., 2017; Kanter et al., 2015), treatment differences in response rates were examined for the sample assessed at post-treatment and the ITT sample whereby all dropouts were assumed to be nonresponses and were included as the denominators of the calculations. Response was defined as a 50% or more reduction from baseline on the depressive symptom severity measures, as widely used in prior literature (e.g., Dimidjian et al., 2006).

Results

Baseline Characteristics

The study flow is presented in Fig. 1. Of the 75 participants who were referred to the trial, 11 were excluded (one due to job conflict, seven due to randomization refusal, and three due to lost contact). Sixty-four depressive patients were randomly allocated to either the BA (n = 31) or TAU (n = 33) group. The two groups did not differ, with the exception of years of education [t (58) = -2.64, p = 0.01] (Table 3). However, no difference was observed in the estimated premorbid IQ between the two groups [$t(58) = 0.90$, p = 0.37] (Table 3). There were no significant differences between those who completed the intervention and the dropouts on baseline HRSD scores [$M_{dropouts} = 23.62$ ($SD_{dropouts} = 5.11$), $M_{completers} = 24.00$ ($SD_{completers} = 7.69$)].

Treatment Integrity

Treatment adherence percentage among assessors for all reviewed sessions was approximately 87% (6 out of 7 items) on average, indicating that the major treatment components of BA were delivered largely in accordance with the original BA protocol.

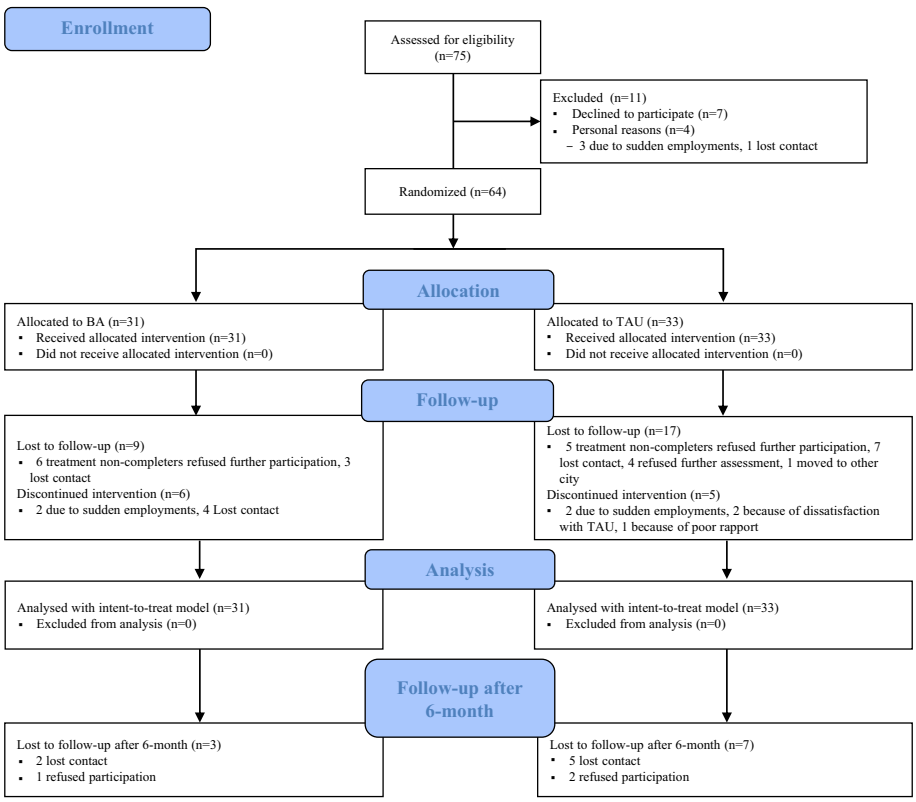

Fig. 1 CONSORT flow diagram. *BA* behavioral activation, *TAU* treatment as usual

Table 3 Baseline characteristics of participants

Baseline characteristics	BA condition ($n=31$)	TAU condition ($n=33$)	t or χ^2
Age, M (SD)	41.45 (19.22)	33.27 (15.83)	1.86
Age of onset, M (SD)	32.48 (13.25)	30.83 (14.55)	0.41
Years of education, M (SD)	10.54 (4.03)	12.88 (2.80)	− 2.64*
Premorbid IQ, M (SD)	102.54 (8.93)	100.31 (10.05)	0.90
Gender, n (%)			0.22
Men	14 (45.2)	13 (39.4)	
Women	17 (54.8)	20 (60.6)	
Marital status, n (%)			3.30
Married	5 (16.1)	6 (18.2)	
Single	15 (48.4)	21 (63.6)	
Divorced	8 (25.8)	3 (9.1)	
Bereaved	3 (9.7)	3 (9.1)	
Medication, n (%)	29 (93.5)	28 (84.8)	1.24
HRSD, M (SD)	24.23 (5.41)	23.48 (7.82)	0.44
CES-D, M (SD)	35.10 (12.08)	33.27 (13.88)	0.56
BADS, M (SD)	59.87 (23.52)	61.18 (24.72)	− 0.22

BA behavioral activation, *TAU* treatment as usual, *M* mean, *SD* standard deviation, *HRSD* Hamilton Rating Scale for Depression, *CES-D* Center for Epidemiologic Studies Depression Scale, *BADS* Behavioral Activation for Depression Scale

*$p<0.05$

Effects of BA on Depression Severity

BA treatment effects (i.e., treatment by time) were found for the measures of both HRSD (at significant level, p = 0.0339) and CES-D (at significant level, p = 0.0006) (Table 4). More specifically, while the participants of the two conditions did not differ at baseline, the BA group showed significantly greater reduction in the above-mentioned measures immediately after the treatment [on the HRSD, F (1, 36) = 4.26, p < 0.05; on the CES-D, F (1, 36) = 9.08, p < 0.01] (Fig. 2). Even after considering years of education as a covariate, all the significant findings reported above were maintained. However, the treatment effect was not maintained at the six-month follow-up. Effect sizes for the measures of both clinician-rated and self-reported depressive symptom severity were medium to large (Table 5).

Effects of BA on Behavioral Engagement

BA treatment effects were found for the measures of BADS total score (at trend level, p = 0.0779), the Activation subscale (at trend level, p = 0.0730), and the Work/School Impairment subscale (at significant level, p = 0.0429) (Table 4). In particular, while the groups did not differ at baseline, the BA group showed greater improvement on the above-mentioned measures immediately post-treatment [on the BADS total score, F (1, 36) = 5.03, p < 0.05; Activation subscale, F (1, 36) = 10.59, p < 0.005; Work/School Impairment subscale, F (1, 36) = 4.61, p < 0.05] (Fig. 3). Even after considering years of education as a covariate, all the above-mentioned significant findings were maintained. However, there were no treatment effects on the BADS Avoidance/Rumination and Social Impairment subscales. The treatment effect was not maintained at the six-month follow-up. Effect sizes for the BADS total score, Activation subscale and Work/School Impairment subscale ranged from medium to large, and those for the other two subscales were small to medium at post-treatment (Table 5).

Clinical Improvement in Depression Severity

With the sample that provided depressive symptom severity data at post-treatment, significantly more participants of the BA group met the response criteria than those of the TAU group immediately after treatment. On the HRSD, 45.5% of BA participants (10 of 22) achieved response criteria as compared to 18.8% of TAU participants (3 of 16), Wald χ^2 (1) = 4.55, $p = 0.03$, odds ratio (OR) = 6.61 (95% CI 1.17–37.47). For the CES-D, 40.9% of participants in BA (9 of 22) met criteria for response, compared to 12.5% of those allocated to TAU (2 of 16), Wald χ^2 (1) = 3.70, $p = 0.05$, OR = 5.98 (95% CI 0.97–36.99). Consistent with the post-test completers data, significant differences between treatments emerged favoring BA for the intent-to-treat sample (Fig. 4), both on the HRSD [BA = 32.3% (10 of 31), TAU = 9.1% (3 of 33), Wald χ^2 (1) = 6.72, $p = 0.01$, OR = 7.48 (95% CI 1.63–34.23)] and on the CES-D [BA = 29.0% (9 of 31), TAU = 6.1% (2 of 33), Wald χ^2 (1) = 5.46, $p = 0.02$, OR = 7.48 (95% CI 1.63–34.23)].

Discussion

The current study examined whether BA delivered in community mental health settings would be more effective than TAU in reducing the severity of depressive symptoms among community-dwelling individuals with depressive disorders. In addition, we also investigated whether BA would lead to superior treatment effects in increasing behavioral engagement, compared to TAU.

In the current study, the superior treatment gains in the depressive symptoms of participants exposed to BA as compared to participants exposed to TAU were associated with moderate to large effect sizes and higher rates of clinical improvement. The effect sizes found in this study (0.70 and 1.02 for HRSD and CES-D, respectively) compare

Table 4 Effects of study condition (BA vs. TAU) on depression severity and behavioral engagment

	Effect Estimate	SE	df	t	*p*
Depression severity					
HRSD					
Intercept	24.226	1.379	102.0	17.570	< .0001
Time	− 15.308	2.980	76.7	- 5.140	< .0001
Time^2	5.617	1.477	74.8	3.800	0.0003
Group	− 0.741	1.920	102.0	− 0.390	0.7003
Time × Group	9.613	4.602	80.7	2.090	0.0399
Time^2 × Group	− 4.365	2.366	79.8	− 1.840	0.0688
CES-D					
Intercept	35.097	2.359	85.6	14.880	< .0001
Time	− 25.558	4.225	69.8	− 6.050	< .0001
Time^2	10.210	2.088	68.3	4.890	< .0001
Group	− 1.824	3.285	85.6	− 0.560	0.5802
Time × Group	23.475	6.563	72.4	3.580	0.0006
Time^2 × Group	− 11.157	3.369	71.5	− 3.310	0.0015
Behavioral engagement					
BADS total					
Intercept	59.871	4.509	94.7	13.280	< .0001
Time	33.829	9.266	71.5	3.650	0.0005
Time^2	− 12.241	4.589	69.8	− 2.670	0.0095
Group	1.311	6.279	94.7	0.210	0.8351
Time × Group	− 25.627	14.335	75.2	− 1.790	0.0779
Time^2 × Group	9.810	7.369	74.2	1.330	0.1872
BADS Activation					
Intercept	12.387	1.271	105.0	9.740	< .0001
Time	14.759	2.907	73.8	5.080	< .0001
Time^2	− 6.576	1.443	71.8	− 4.560	< .0001
Group	− 1.720	1.771	105.0	− 0.970	0.3335
Time × Group	− 8.137	4.478	78.5	− 1.820	0.0730
Time^2 × Group	3.247	2.304	77.7	1.410	0.1627
BADS Avoidance/Rumination					
Intercept	27.258	1.832	94.7	14.880	< .0001
Time	− 5.461	3.744	72.0	− 1.460	0.1491
Time^2	1.313	1.854	70.2	0.710	0.4811
Group	0.469	2.552	94.7	0.180	0.8545
Time × Group	3.139	5.794	75.6	0.540	0.5896
Time^2 × Group	− 0.733	2.978	74.6	− 0.250	0.8062
BADS Work/School impairment					
Intercept	15.613	1.181	98.1	13.220	< .0001
Time	− 7.834	2.491	73.7	− 3.150	0.0024
Time^2	2.785	1.234	71.9	2.260	0.0271
Group	− 0.795	1.645	98.1	− 0.480	0.6300
Time × Group	7.924	3.850	77.5	2.060	0.0429
Time^2 × Group	− 3.367	1.980	76.6	− 1.700	0.0930
BADS Social impairment					
Intercept	17.645	1.476	94.8	11.960	< .0001
Time	− 6.125	3.044	71.3	− 2.010	0.0480
Time^2	1.747	1.508	69.5	1.160	0.2506
Group	− 2.706	2.055	94.8	− 1.320	0.1912
Time × Group	5.994	4.710	75.0	1.270	0.2071
Time^2 × Group	− 2.244	2.421	74.0	− 0.930	0.3570

Interactions based on multilevel modeling analysis with the intent-to-treat sample

BA behavioral activation, *TAU* treatment as usual, *HRSD* Hamilton Rating Scale for Depression, *CES-D* Center for Epidemiologic Studies Depression Scale, *BADS* Behavioral Activation for Depression Scale

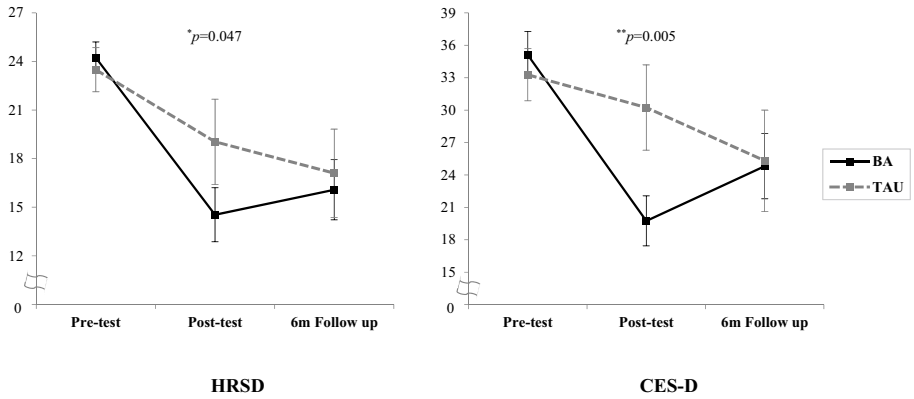

Fig. 2 Estimated means of depression severity. *HRSD* Hamilton Rating Scale for Depression, *CES-D* Center for Epidemiologic Studies Depression Scale, *BA* behavioral activation, *TAU* treatment as usual. *p*-values from ANCOVAs entering baseline symptom severity score as a covariate. $*p < 0.05$; $**p < 0.01$; $***p < 0.005$

Table 5 Descriptive statistics and effect sizes for depression severity and behavioral engagement

	BA condition			TAU condition			Effect size[a]	
	Pre M(SD) (n = 31)	Post M(SD) (n = 22)	FU M(SD) (n = 19)	Pre M(SD) (n = 33)	Post M(SD) (n = 16)	FU M(SD) (n = 9)	Partial eta squared (η_p^2)	Cohen's *d*
Depression severity								
HRSD Total	24.23 (5.41)	14.82 (7.83)	16.74 (8.10)	23.48 (7.82)	18.50 (10.54)	18.40 (8.63)	0.11*	0.70*
CES-D Total	35.10 (12.08)	18.95 (10.87)	25.84 (13.18)	33.27 (13.88)	25.94 (15.74)	27.80 (14.85)	0.21**	1.02**
Behavioral engagement								
BADS Total	59.87 (23.52)	83.14 (20.27)	75.47 (29.60)	61.18 (24.72)	73.50 (29.50)	67.10 (24.88)	0.13*	0.76*
Activation	12.39 (5.25)	21.09 (6.26)	15.42 (10.05)	10.67 (6.39)	15.31 (7.14)	10.30 (9.18)	0.23***	1.10***
Avoidance/ Rumination	27.26 (9.81)	22.77 (9.67)	22.26 (10.96)	27.73 (10.44)	24.13 (11.63)	26.50 (8.87)	0.03	0.35
Work/ School impairment	15.61 (7.05)	10.14 (5.22)	11.84 (7.14)	6.43 (8.58)	13.00 (9.10)	11.80 (6.96)	0.12*	0.72*
Social impairment	17.65 (7.95)	13.04 (8.64)	13.84 (7.72)	14.94 (8.58)	12.69 (9.08)	12.90 (6.15)	0.00	0.13

BA behavioral activation, *TAU* treatment as usual, *FU* follow-up, *M* mean, *SD* standard deviation, *HRSD* Hamilton Rating Scale for Depression, *CES-D* Center for Epidemiologic Studies Depression Scale, *BADS* Behavioral Activation for Depression Scale

[a]Between-group effect sizes at posttreatment; magnitude of partial eta squared: small = .01, medium = .06, large = .14; magnitude of Cohen's *d*: small = 0.2, medium = 0.5, large = 0.8 (Cohen, 1988)

$*p < 0.05$; $**p < 0.01$; $***p < 0.005$

favorably with an overall aggregated effect size of 0.72 on post-treatment depression outcomes from 13 studies (461 participants) comparing group BA to controls (Simmonds-Buckley et al., 2019). Data for categorical response rates in the present study indicate that, relative to TAU, BA brought more participants to response status by the end of treatment, in line with the results of prior trials comparing BA with TAU (Ekers et al., 2011; Kanter et al., 2015). Moreover, findings on treatment effects favoring the BA group extended the findings of the previous studies (Dimidjian et al., 2017;

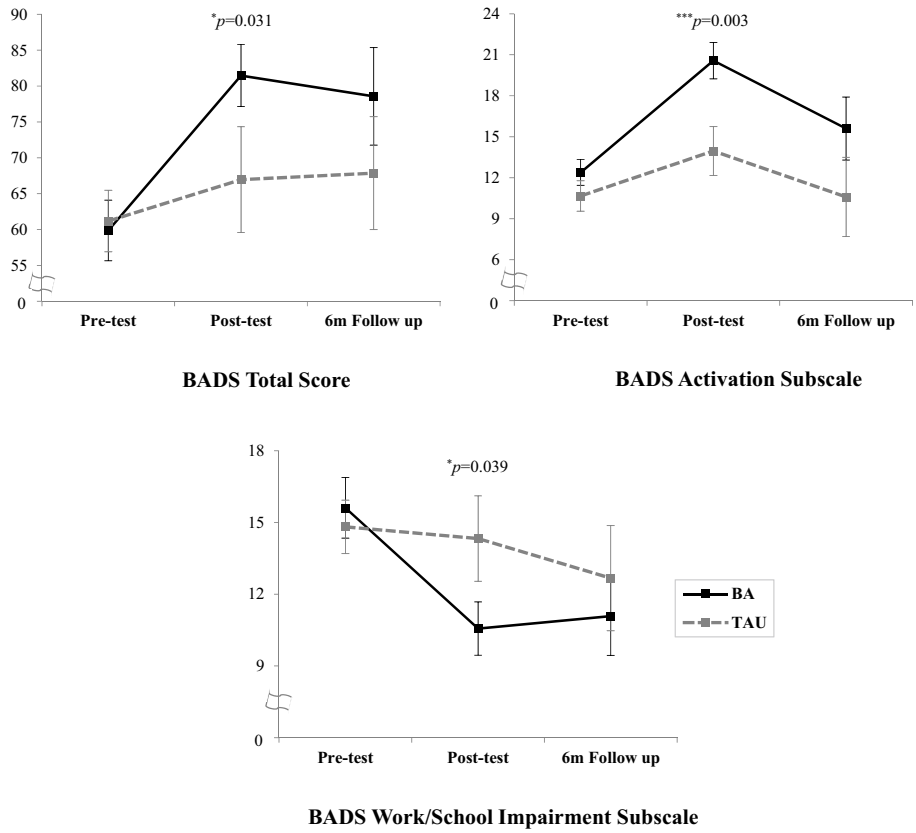

Fig. 3 Estimated means of behavioral engagement. *BADS* Behavioral Activation for Depression Scale, *BA* behavioral activation, *TAU* treatment as usual. *p*-values from ANCOVAs entering baseline symptom severity score as a covariate. *$p < 0.05$; **$p < 0.01$; ***$p < 0.005$

Ekers et al., 2011; O'Mahen et al., 2014) by providing evidence for improvement using clinical interview measures rated by the clinicians.

We also observed greater activation and less impairments in work and school functioning for the BA group than for the TAU group. These results suggest that the BA conducted in the study adequately yielded purported changes in patient behavior expected to occur over the course of the BA intervention for depression. However, avoidant behavior and social impairment did not show significant differences across the two groups in this study. With regard to avoidant behvaiors, they may have been difficult to reduce due to the BA program in this study being delivered for a relatively short duration, and avoidance being only indirectly addressed through graded activity hierarchies (Trew, 2011), usually in the latter half of the 10 sessions. These results were consistent with the previous BA study which had more explicit focus on positively reinforced behaviors for a shorter duration (Takagaki et al., 2016). Regarding social impairment, interpersonal activities were less likely to be planned into the daily schedule of the participants until the end of the 10-session treatment since most participants in the current study categorized social activities as being more difficult and less urgent in the activity hierarchy. Thus, it is speculated that more avoidance-targeted and longer BA programs would elicit favorable treatment effects of BA on avoidance behaviors and social impairment.

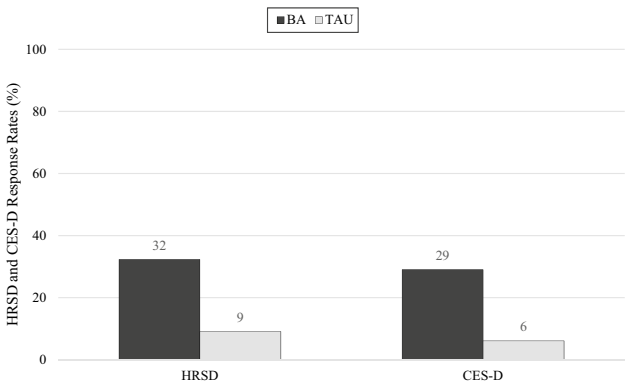

Fig. 4 Response rates at post-treatment based on depression severity measures with the intent-to-treat sample. *HRSD* Hamilton Rating Scale for Depression, *CES-D* Center for Epidemiologic Studies Depression Scale, *BA* behavioral activation, *TAU* treatment as usual

Finally, inconsistent with our hypothesis, the treatment effects of BA were not maintained at the six-month follow-up. Two potential explanations should be noted. First, unlike previous research demonstrating a sustained effect of BA, most participants in this study received psychiatric medication, and the TAU group received non-BA treatment services, which may have reduced expected group differences

at the six-month follow-up. Despite the rebound effect in the follow-up period, it is worth noting that depression severity was still lower and the level of behavioral engagement was still greater at 6 months in the intervention group compared to the control group. Additionally, this result seems to have greater ecological validity than previous research in which participants were not excluded owing to their current use of antidepressants and the BA intervention was delivered by mental health workers in community mental health clinics. Second, as opposed to earlier trials (Dobson et al., 2008; Moradveisi et al., 2013), less treatment focus on functional avoidance and the relatively shorter duration of the BA program in this study might have led to non-significant long-term effects. Moreover, since the baseline depression severity of the participants in our study was higher than that in previous studies, the current population may have required booster sessions and/or a relatively longer version of BA for sustained treatment effects. Thus, a subsequent trial is needed to investigate whether a revision of the BA protocol to include more sessions dealing with avoidant behaviors, and the provision of more intensive training and frequent supervision would result in more effective relapse prevention relative to usual care.

The current study had some limitations worth noting. First, despite consistent efforts to sustain contact with the community-dwelling study participants, a relatively large number of participants dropped out of this study. The attrition rates of our research (i.e. 29.03% for BA and 51.52% for TAU at post-treatment) were slightly higher than that (i.e. 23.80% for BA and 45.45% for TAU at post-treatment) of one earlier trial that compared BA with TAU in a community mental health clinic setting (Kanter et al., 2015). However, given that the current study performed a randomized controlled trial across different community centers and clinics, the dropout rate of this study was not seen as unpromising, but rather reflective of the differences in access to evidence-based treatment in Korea's multiple community mental health centers. We also found that more patients dropped out in the TAU group than in the BA group. This differential rate of attrition between the two arms is similar to the pattern in previous research (Dimidjian et al., 2006; Kanter et al., 2015; Moradveisi et al., 2013), wherein the drop-out rate in the BA group was relatively lower than that in the control group. One possible explanation for the discrepancy in drop-out rate is that patients in BA condition incrementally engaged in positively reinforced activities following the course of BA, which might have led to consistent participation in more treatment sessions. Another potential explanation is that participants receiving BA could have been more motivated to complete treatment sessions than those in the usual care group since the BA therapists were trained to utilize motivational interviewing techniques when giving assignments, if necessary. Future research should investigate whether these hypothesized BA techniques would more successfully motivate clients to complete sessions than the control intervention. Second, we assessed treatment fidelity by sampling one session from each BA program delivered in multiple community clinics. Although we believe that 87% treatment integrity can be interpreted as adequate, future trials should examine whether enhancing and ensuring therapist competency through additional training, thorough supervision, and frequent fidelity checks improves and retains treatment outcomes. Third, this study indicates that BA could be effectively delivered in real-world community mental health centers. It is worth noting that, although the present study speaks to the generalizability of the results to community mental health settings in Korea, future trials are needed to examine the effectiveness of BA in other treatment settings (e.g., a psychiatric in-patient, individual therapy implemented by an experienced clinician) in Korea. Fourth, the interpretation of treatment differences in response rates at post-treatment needs caution given that the rates of attrition in this study are higher than those in previous trials using similar methods (e.g., Kanter et al., 2015). Although the clinical significance analyses conducted with the ITT sample assume nonresponse for all dropouts, we cannot rule out the possibility that some non-completers actually did experience clinical improvement or that the pattern of attrition was different between the two groups. These possibilities should not be overlooked when interpreting the differential response rates between the intervention group and the controls with the full ITT sample.

The findings of our study suggest that BA can be disseminated to wider community mental health settings by less specialized mental health workers with minimal training, consistent with earlier trials proving dissemination feasibility (Dimidjian et al., 2017; Ekers et al., 2011; O'Mahen et al., 2014). Now that dissemination feasibility has been examined, future trials with a larger sample and with longer therapy sessions (or boost-up sessions) should investigate whether treatment effects can be sustained after the termination of acute treatment. Furthermore, the mechanisms of change in treatment should also be examined with hypothesized behavioral mediators (e.g., changes in thoughts or actions) during intervention.

Author Contributions EL—Formal analysis, Investigation, Data Curation, Writing- Original Draft, Visualization. YH—Investigation, Visualization, Writing- Review & Editing. YJC—Investigation, Data Curation. JHO—Investigation, Project administration. NRH—Investigation. HJS—Conceptualization, Methodology, Writing- Review & Editing, Supervision, Project administration, Funding acquisition.

KHC—Conceptualization, Methodology, Formal analysis, Writing- Review & Editing, Supervision, Project administration. Funding acquisition.

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Declarations

Conflict of interest The authors have no conflicts of interest to declare.

Ethical Approval Approval was obtained from the ethics committee of the Korea University. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

Consent to Participate Informed consent was obtained from all individual participants included in the study.

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