Published in final edited form as:

Sleep Biol Rhythms. 2019 July ; 17(3): 287–295. doi:10.1007/s41105-019-00211-6.

Brief behavioral treatment for insomnia in older adults with late-life treatment-resistant depression and insomnia: a pilot study

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Abstract

Objective: Brief Behavioral Treatment for Insomnia (BBTI) is an efficacious treatment of insomnia in older adults. Behavioral treatments for insomnia can also improve depression. However, it is unknown if BBTI is feasible or has an effect in patients with insomnia and late-life treatment resistant depression (LLTRD). The aims of this study were two-fold, to test: 1) the feasibility (defined by acceptability and retention rates) of BBTI and 2) the therapeutic potency of BBTI on symptoms of insomnia and depression.

Methods: Eleven older Veterans with LLTRD and insomnia were recruited in a randomized control trial to receive immediate (4-weeks of BBTI followed by 3-weeks of phone call check-ins and a final in-person 8-week assessment) or delayed (3-weeks of treatment as usual [wait-list control] followed by 4-weeks of BBTI and a final in-person 8-week assessment) BBTI. The primary outcome measures included the Patient Health Questionnaire (minus the sleep item) and the Insomnia Severity Index.

Results: BBTI was found to be feasible in older Veterans with insomnia and LLTRD; all participants recommended BBTI and retention rates were 90.9%. There was no difference in treatment effect between the immediate BBTI and delayed BBTI groups at week 4. After both groups (immediate and delayed) received BBTI, improvements were seen in both insomnia ($d = 1.06$) and depression ($d = 0.54$) scores.

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Conflict of Interest: On behalf of all authors, the corresponding author states that there is no conflict of interest.

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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

Conclusions: BBTI is a feasible treatment for insomnia in older adults with LLTRD. BBTI may be an effective adjunctive treatment for depression. Larger adequately-powered trials are required to confirm these preliminary findings.

Keywords

Behavioral treatment; insomnia; aging; treatment resistant depression

INTRODUCTION

Insomnia is defined as dissatisfaction with sleep quality or quantity, along with having difficulties falling asleep, staying asleep, or waking up too early for at least 3 nights per week for 3 or more months, leading to distress or daytime impairments [1]. Insomnia is a prevalent condition, affecting up to 35% of older adults, and is associated with increased health care utilization costs, disability, falls, and reduced quality of life [2–4].

Pharmacological treatments for insomnia are associated with increased risk of falls and cognitive impairment in older adults. The American College of Physicians [5], the American Academy of Sleep Medicine [6], and the National Institute of Health [7] recommend behavioral treatment options as the first-line treatment of insomnia. These include learning-based approaches like Cognitive Behavioral Therapy for Insomnia (CBTI) and briefer variants such as Brief Behavioral Treatment for Insomnia (BBTI) [8, 9]. BBTI focuses on the same behavioral elements as CBTI, but does not include cognitive techniques. CBT-I has the strongest evidence for treating insomnia [10], with minimal side effects and lack of medication interactions while offering the advantage of teaching patients self-management skills [11, 12]. Therefore, behavioral interventions are particularly recommended for older adults [13].

Insomnia frequently co-occurs with other mental health disorders, such as Major Depressive Disorder (MDD). More than half of older adults with MDD fail to remit with first line antidepressant treatment (e.g., selective serotonin reuptake inhibitors and serotonin-norepinephrine reuptake inhibitors), making late-life treatment resistant depression (LLTRD) the rule rather than the exception [14, 15]. Depression severity is associated with insomnia severity and the presence of one disorder is a risk factor for development of the other [16]. Depression may also be more difficult to treat in the presence of insomnia [17]. Partially or untreated depression in late-life increases the risk of cognitive impairment, caregiver burden, poor quality of life, medical comorbidities, and suicide [18–21]. Therefore, novel treatment approaches that address both symptoms of insomnia and depression in older adults are a priority.

Veterans are a unique patient population: more than one third of Veterans over age 60 who receive treatment for depression have also been diagnosed with other psychiatric conditions [22], and they are likely to have their depression undertreated, with up to one third prematurely discontinuing antidepressant medications [23]. Furthermore, around half of older Veterans suffer from insomnia [24]. Because of this, older Veterans with insomnia and LLTRD are at increased risk of having more severe illness and related disability.

Behavioral interventions for insomnia improve insomnia outcomes and prevent recurrence, including in those with depression [25, 26] and they may also lead to improvement in depression [27–31]. While BBTI is a feasible and effective treatment for insomnia in older adults with comorbid depression [9, 32], it is unknown if BBTI is feasible or is acceptable to patients with comorbid LLTRD. This is important because treatment resistant patients may be more challenging to treat, with up to 20% rate of non-compliance with treatments, which could be due to poor communication between patients and their providers, negative attitudes towards treatment, or cognitive impairment [33]. To address these questions, we conducted a pilot study of BBTI in older Veterans with co-occurring insomnia and LLTRD. The aims of this study were two-fold, to test: 1) the feasibility (defined by acceptability and retention rates) of BBTI and 2) the therapeutic potency of BBTI on symptoms of insomnia and depression. This data can be used to guide a larger adequately powered study detecting the effects of BBTI on depression in LLTRD.

MATERIALS AND METHODS

This paper presents findings from a randomized pilot clinical trial of immediate vs. delayed (wait-list control) BBTI. The study was approved by the VA Pittsburgh Healthcare System (VAPHS) Institutional Review Board and registered with [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT 02971150).

Participants

Participants were older Veterans who were receiving care through behavioral health clinics at the VAPHS and had a diagnosis of MDD and insomnia disorder based on the Diagnostic and Statistical Manual of Mental Disorders (DSM)-5 criteria [1]. Diagnoses of both conditions were established through electronic health record (EHR) review and a clinical interview, both completed by the first author during the screening process. Treatment resistance was defined as having failed at least one adequate trial of antidepressant treatment with an Antidepressant Treatment History Form (ATHF) [34] score ≥ 3 . Since this was a study of LLTRD, the minimum age for inclusion was 60 years. Participants were symptomatic for both conditions and all had a Montgomery-Asberg Depression Rating Scale (MADRS) [35] score ≥ 15 and an Insomnia Severity Index (ISI) [36] score ≥ 15 . Participants were excluded if they had cognitive impairment as indicated by a score of < 24 on the Montreal Cognitive Assessment (MoCA) [37]. Other exclusion criteria included any of the following diagnoses: lifetime or current diagnosis of bipolar I or II disorder, schizophrenia spectrum disorder, substance use disorder within the past 3 months, or high risk for suicide that could not be safely managed within the procedures of the clinical trial (as assessed by clinical interview). Other exclusion criteria that were determined by self-report and EHR review included disorders that would interfere with sleep treatments, such as untreated obstructive sleep apnea (OSA), symptomatic post-traumatic stress disorder (PTSD), restless legs syndrome, or rapid eye movement (REM) sleep behavior disorder. Participants with treated OSA were allowed.

Study procedure

Participants were recruited between June 2016 and March 2017 through patient chart reviews after receiving an IRB approved waiver of authorization as well as referrals from behavioral health providers. Around 1,587 charts were pre-screened and 118 patients were found to be eligible. A purposive sampling approach was followed. Twelve participants were consented, eleven of which were eligible and were enrolled in the study. Figure 1 summarizes participants' flow throughout the study. Participants were randomized in blocks of 4 to receive immediate or delayed (3-weeks wait-list control) BBTI. This design was implemented to encourage participant retention in the delayed BBTI treatment group. The total study duration of the trial was 8 weeks. The immediate treatment group received 4 weeks of BBTI following randomization, and then had weekly follow-up phone calls for an additional 3 weeks. A final face-to-face visit was held 8 weeks later. The delayed treatment group had phone follow-ups the first 3 weeks (wait-list control), then received the 4-week intervention followed by a final face-to-face visit at week 8. Assessments were completed pre- and post-BBTI.

Measures

Sociodemographic questionnaire.—Variables in the sociodemographic questionnaire included age, sex, race, marital status, education, occupation, and health ratings. The questionnaire also inquired about symptoms of sleep apnea, restless legs, as well as treatment history and use of antidepressant and sleep medications.

Screening Assessments—The MoCA [37] is a 30-point clinician administered test that assesses several cognitive domains. The MoCA is used as a cognitive screener and scores 26 are considered normal.

The MADRS [35] is a 10-item clinician administered diagnostic questionnaire used to measure depression severity. Each item yields a score of 0 to 6 and the overall score ranges from 0 to 60 with higher scores indicating increasing depression severity. Score ranges 0–6 indicate normal or absent symptoms, 7–19 is mild, 20–34 is moderate, and > 34 is severe depression.

The ATHF [34] is a clinician administered assessment that rates the adequacy of individual antidepressant trials in the current depressive episode. The ATHF score is based on dose and duration criteria. A score of 3 or more indicated a probable adequate trial, which was required for inclusion in the study. Higher scores indicate higher levels of treatment resistance.

Sleep Outcomes.—The primary sleep outcome was the ISI [36], a 7-item self-report insomnia rating scale. Each item is rated on a severity scale of 0 to 4. A total score 0–7 indicates no clinically significant insomnia, 8–14 subclinical, 15–21 moderate, and 22–28 severe insomnia. The strong reliability and validity of the ISI has been established [38, 39]. The Cronbach's alpha of ISI for this study was 0.80.

The self-report Consensus Sleep Diary (CSD) [40] was used to gather secondary sleep data such as: bed time, time out of bed, sleep onset latency (SOL), number of awakenings, wake

up after sleep onset (WASO), final wake time, and a sleep quality rating on a scale of 1 (very poor) to 5 (very poor). The values recorded in the CSD allow for the calculation of sleep variables including total sleep time (TST) and sleep efficiency (SE) which is the total sleep time/time in bed x100 [41]. These variables were used to guide BBTI.

Depression Outcome.—The primary outcome of depression was assessed with the Patient Health Questionnaire-9 (PHQ-9) [42] a 9-item self-report instrument used for screening, diagnosing, monitoring, and measuring the severity of depression. Higher scores indicate increasing depression severity. Score ranges and their corresponding interpretations are as follows: 5–9 = mild, 10–14 = moderate, 15–19 = moderately severe depression, and ≥ 20 = severe depression. The sleep item was removed from the score to eliminate the effect of sleep from depression. The Cronbach's alpha of PHQ-9 for this study was 0.87.

Quality of life.—The 12-Item Short Form Survey (SF-12) [43] is a self-report tool that measures domains of general health and health-related quality of life. The questions assess mental and physical functioning as well as overall health-related quality of life. Physical and Mental Health Composite Scores (PCS & MCS) are computed using the scores of twelve questions and range from 0 to 100, where a zero score indicates the lowest level of health measured by the scales and 100 indicates the highest level of health.

Treatment feasibility.—Treatment feasibility was based on acceptability and retention rates. Acceptability was determined by assessing adherence to sleep diary completion and patient satisfaction after study completion with the following question: “Would you recommend this treatment to other individuals with depression and insomnia?” Retention rates of $> 85\%$ were determined to be appropriate as they are consistent to those found in LLTRD literature [44].

Working Alliance.—The Working Alliance Inventory- Short Revised (WAI-SR)[45] was used to assess therapeutic alliance, or the degree of collaboration between the patient and therapist. The WAI-SR is a 12-item measures that is scored on a 5-point Likert scale with higher scores indicating a stronger alliance.

Intervention

BBTI focuses on sleep restriction and stimulus control principles [9, 46]. During the treatment session, the therapist guides the patients through a workbook, which includes delivery of treatment rationale and information on sleep regulation practices. BBTI treatment is delivered over 4 weeks, and includes 2 face-to-face sessions and 2 brief telephone calls. During the 2 face-to-face sessions (sessions # 1 and 3) which last 45 and 20 minutes respectively, the therapist reviews the patients' sleep diaries, provides a sleep prescription with specified sleep and wake up times, and assists them with coping skills. Phone sessions at week 2 and 4 last approximately 15 minutes and further explore ways to help the patient cope with insomnia related stress and problem solve any adherence issues. BBTI focuses on teaching the patient 4 main rules to reduce insomnia: 1) reduce time (awake) in bed, 2) don't go to bed unless feeling sleepy, 3) don't stay in bed unless asleep, and 4) get up at the same time every day.

Phone check-ins.—During the weeks that the participants were not receiving BBTI, they received a weekly phone call lasting around 10 mins during which the PHQ-9 and ISI were administered.

Data Analysis

We used measures of central tendency to describe the demographic and clinical characteristics of the sample. The baseline characteristics and pre-treatment outcomes of the immediate and delayed treatment conditions were compared with univariate analyses (chi-square tests, *t*-tests) to establish that randomization was successful. To examine the preliminary therapeutic potency of BBTI on participants' depression and sleep, the pre-treatment (Immediate vs Delayed) scores were compared against post-treatment (Immediate vs Delayed) scores using paired-sample *t*-tests; Cohen's *d* were calculated to determine effect size [47]. The reliable change index (RCI) was used to measure clinical significance of therapeutic change in the ISI and PHQ-9 minus sleep items ($RCI < -1.96$, $p < .05$); [48]. Repeated measures analysis of variance (ANOVA) was conducted to examine the interaction between time and group condition (immediate and delayed treatment) on ISI and PHQ-9 minus sleep item scores to examine the effect of time in the treatment vs waitlist groups.

RESULTS

The demographic and clinical characteristics of the participants are presented in Table 1. Univariate analyses (chi-square tests, *t*-tests) showed no significant differences among the demographic or pre-treatment symptom scores between the immediate and delayed treatment groups, suggesting that the randomization was successful.

Treatment Feasibility

In terms of acceptability, all but one participant completed sleep diaries and all participants indicated that they would recommend this treatment to others with LLTRD and insomnia. In terms of retention, all but one participant (90.9%) completed all sessions of BBTI. This participant dropped out after 2 sessions of BBTI due to family obligations.

Overall Therapeutic Potency of BBTI

To examine the overall therapeutic potency of BBTI on participants' depression and sleep, pre-treatment scores were compared against post-treatment scores for each group (see Table 2). In terms of sleep, BBTI showed a large effect ($d = 1.06$) for reducing ISI ratings from pre- to post-treatment ($M = 18.7$; $SD = 3.35$ vs. $M = 13.8$; $SD = 5.59$); much smaller effects were seen for sleep diary (i.e., SOL, WASO, and SE) improvements. Participants' PHQ-9 scores decreased from 16 (moderate depression) at pre-treatment to 12.0 (minor depression) at post-treatment ($d = 0.63$). PHQ-9 scores (minus the sleep item) decreased from 13.5 at pre-treatment to 10.3 at post-treatment ($d = 0.54$). Medium effect size changes occurred for the two depression measures from pre-treatment to post-treatment. After receiving BBTI, based on the RCI, 2/11 participants (18%) experienced clinically positive change on the ISI and PHQ-9 (minus sleep item) at post-treatment. Interestingly, the same two participants had significant change on both the ISI and PHQ-9 minus sleep. These two participants were both in the immediate treatment condition and were more likely to self-report worse health as

compared to those that did not have significant change in depression and sleep outcomes ($1.50 \pm .71$ vs. $3.78 \pm .97$; $t = 3.08$, $p = .01$).

Immediate vs. Delayed BBTI

On the ISI, the Time x Group Condition interaction was not significant, $F(1,8) = .54$, $p = .48$ (see Figure 2). There was, however, a significant main effect for time, $F(1,8) = 6.49$, $p = .03$, with both immediate (mean difference = 6.3, $SE = 8.1$) and delayed treatment (mean difference = 2.8, $SE = 5.9$) groups showing a decrease in mean ISI scores after 4 weeks in the trial. Similarly, the Time x Group Condition interaction for the PHQ-9 minus the sleep item was not significant, $F(1,7) = .51$, $p = .50$ (see Figure 3). Again, there was a significant main effect for time, $F(1,7) = 10.52$, $p = .01$, with both immediate (mean difference = 3.8, $SE = 3.5$) and delayed treatment (mean difference = 2.4, $SE = 2.2$) showing a decrease in mean PHQ-9 scores minus sleep item scores after 4 weeks in the trial. Compared to the delayed treatment that did not initially receive BBTI, the immediate treatment participants experienced greater rates of clinically significant positive change in the ISI (33% vs. 0%) and PHQ-9 minus the sleep item (33% vs. 20%) at post-treatment. However, the reliable change index for ISI ($\chi^2 = 2.04$, $p = .15$) and PHQ-9 minus the sleep item ($\chi^2 = .24$, $p = .62$) in the immediate treatment condition was not significantly different from the delayed treatment group.

Therapeutic Alliance

The total alliance score was 46.2 ($SD = 8.87$) with the following subscale scores: Goals ($M = 16.3$; $SD = 3.3$), Tasks ($M = 14.3$; $SD = 3.95$), and Bond ($M = 15.6$; $SD = 3.31$). Compared to the immediate treatment group, the delayed treatment group had significantly higher scores on the Goals ($M = 18.6$; $SD = 1.67$ vs. $M = 14.0$; $SD = 3.0$; $t = -2.99$, $p = .02$) and Bond ($M = 17.8$; $SD = 1.30$ vs. $M = 13.4$; $SD = 3.29$; $t = -2.78$, $p = .02$) subscales, as well as the Total score ($M = 52.2$; $SD = 5.31$ vs. $M = 40.2$; $SD = 7.66$; $t = -2.88$, $p = .02$).

DISCUSSION

This pilot study tested the feasibility and preliminary therapeutic potency of BBTI in older adults with LLTRD and insomnia. We had three major findings. First, based on measures of acceptability and retention, BBTI was feasible. Second, while there was no differential effect between BBTI and the control condition, there was a main effect for time on both insomnia and depression outcomes, such that both the immediate and delayed treatment groups had improvements after 4 weeks. Third, significant improvements were seen in both insomnia and depression scores after BBTI. Interestingly, the two participants who had clinically significant improvement in insomnia were the same participants who also had clinically significant improvements in depression and both were in the immediate treatment group. BBTI may be well suited for those with insomnia, depression, and poor perceived health. Our findings are consistent with the literature showing that treatment of insomnia is associated with improvement in depression [25].

BBTI offer several advantages as compared to CBTI. BBTI requires fewer sessions that are briefer, and may be delivered by a wide range of healthcare providers (e.g., social workers,

nurses) in non-specialized medical settings. As such, BBTI may be more easily implemented in general medical settings such as primary care. CBTI in comparison typically requires more sessions, usually all in person, and are delivered by a doctoral level psychologist. In the VA, CBTI can be delivered by licensed mental health clinicians in psychology, psychiatry, social work, and marriage and family therapy; however, the majority of trained providers are psychologists. Furthermore, BBTI includes 2 phone sessions to further decrease patient burden and facilitate access to care [49].

If BBTI is feasible and effective in LLTRD, this would offer a much needed safe alternative treatment option for this population. The rate at which the world's population of older adults is growing is unprecedented. Currently, 8.5% (617 million) of people are aged 65 and over. By 2050, this is expected to increase to almost 17% (1.6 billion) [50]. Up to 15% of older adults experience depressive symptoms [51]. Late-life depression has significant direct and indirect costs and can raise health care costs for older adults by around 50% [52–54]. Furthermore, partially or untreated late-life depression increases the risk for dementia, medical comorbidities, poor quality of life, caregiver burnout, and suicidality [55–59]. Given the high rates of treatment resistance and its consequences, there is a crucial need to develop and implement safe treatments for the aging population.

This study had several limitations, the first of which is the small sample size. The study was designed to assess acceptability and feasibility, and to estimate the magnitude of changes in symptoms; therefore, it was not adequately powered to detect group differences. Given the vulnerability of this population, conducting a pilot study was the logical first step before engaging participants in larger randomized controlled trial. While pilot studies are not well situated to engage in traditional hypothesis testing analyses [60], small pilot studies can be informative for guiding future research design and have been previously published [61]. Having collected the data, we felt obligated to analyze outcomes in this study, but for the same reasons that effect sizes in pilot studies are unreliable [62], statistical outcomes of pilot studies are also unreliable. Therefore, these results need to be interpreted with caution and should be replicated with other larger adequately powered randomized clinical trials.

Other limitations of this study include only used self-report measures for sleep. Measures such as actigraphy may provide important objective data to complement self-report measures. Also, OSA is frequently comorbid with late-life depression, and use of subjective reports of OSA symptoms to rule out participants may not be reliable [63]. Lastly, the findings may not be generalizable to younger adults, civilians, and Veterans who receive care outside the VA healthcare system.

In conclusion, while we did not detect a treatment effect between immediate and delayed BBTI after 4 weeks, this study provides preliminary feasibility findings that support the use of BBTI in older adults with LLTRD and insomnia. Since we are unable to definitely determine the effects of BBTI on insomnia and depression in LLTRD, a large adequately powered randomized trial is needed to test the effects of adjunctive BBTI to improve both insomnia and depression outcomes in this difficult to treat population.

Acknowledgment:

The contents of this article do not represent the views of the U.S. Department of Veterans Affairs or the United States Government.

Financial Support: This work was supported by the Veterans Integrated Service Network (VISN) 4 Mental Illness Research, Education, and Clinical Center Pilot Project Funds (PI: Gebara) at the Veterans Affairs Pittsburgh Healthcare System and T32 MH019986.

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Figure 1.
Consort flow diagram

Figure 2. ISI mean scores in the immediate (BBTI) and delayed (wait list control) treatment conditions.

Figure 3. PHQ-9 minus sleep item mean scores in the immediate (BBTI) and delayed (wait list control) treatment conditions.

Table 1.

Baseline Demographic and Clinical Characteristics Stratified by Condition (N = 11)

	Immediate BBTI	Delayed BBTI
	<i>M ± SD or N</i>	<i>M ± SD or N</i>
Total	6	5
Age	64.00 ± 2.53	66.20 ± 5.40
Sex		
Female	2	1
Male	4	4
Race/Ethnicity		
White	5	4
Black	1	1
Marital Status		
Not Married	3	2
Married	3	3
Education		
Less than high school (HS)	2	0
HS Graduate/ GED	1	2
Post HS/ Some College	2	3
College Degree	1	0
Employment Status		
Retired	3	2
Part-time	1	1
Disability	1	2
Other	1	0
Overall Health Rating	2.83 ± 1.47	4.00 ± .71
Health Condition Present:		
Cardiovascular	2	1
Endocrine	1	2
Integumentary	1	1
Lymphatic	1	0
Musculoskeletal	4	2
Nervous	3	1
Renal/Urinary	0	1
Respiratory	0	2
MOCA	26.67 ± 1.97	27.60 ± 1.52
ATHF	14.50 ± 5.68	11.40 ± 4.56
Current Medications:		
Mood	6	4
Sleep	4	3
SF-12		
PCS-12	31.98 ± 10.13	34.81 ± 6.19

	Immediate BBTI	Delayed BBTI
	<i>M ± SD or N</i>	<i>M ± SD or N</i>
MCS-12	32.55 ± 3.33	31.08 ± 4.09

Note. Overall Health Rating was assessed on a 6 point Likert scale in the demographics questionnaire; Montreal Cognitive Assessment (MoCA), Antidepressant History Form (ATHF), Insomnia Severity Index (ISI), Montgomery-Asberg Depression Rating Scale (MADRS), 12-Item Short Form Survey (SF-12); Physical Composite Score (PCS); Mental Composite Score (MCS). Medications for sleep include lorazepam, clonazepam, and zolpidem, and trazodone; medications for mood include selective serotonin reuptake inhibitors, selective norepinephrine reuptake inhibitors, mirtazapine, and bupropion.

Table 2.

Sleep and Depression Scores at Pre- and Post-BBTI Treatment

	Pre-Treatment		Post-Treatment		Post-ES
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>	<i>d</i>
Sleep Variables					
ISI	18.7	3.35	13.8	5.59	1.06
SOL	53.3	51.66	45.4	52.05	.15
WASO	45.5	60.31	35.6	30.68	.21
SE	70.3	22.44	77.3	22.70	-.31
Depression Variables					
PHQ-9 with sleep	16.0	5.29	12.0	7.29	.63
PHQ-9 without sleep	13.5	5.26	10.3	6.48	.54

Note. M = Mean; SD = standard deviation; SOL = sleep onset latency; WASO = wake after sleep onset; SE = sleep efficiency; ISI = Insomnia Severity Index; PHQ-9 = Patient Health Questionnaire; ES = effect size.