TITLE: Transcendental Meditation for Post-traumatic Stress Disorder, Depression, and Anxiety: A Review of Clinical Effectiveness

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CONTEXT AND POLICY ISSUES

Transcendental Meditation (TM) is a type of mantra meditation that originated from the Vedic tradition of India and was popularized 50 years ago by the late Maharishi Mehesh Yogi.[1] Transcendental Meditation and TM are registered trademarks of Maharishi Vedic Education Development Corporation.[2] TM involves silently repeating a word or a phrase (mantra) until the mind is free of thought.[3] It is practised for 15-20 minutes twice daily, in a sitting position.[1] It requires no other lifestyle modification and is not religious in nature.[1]The elimination or reduction of mental activity leads to physical and mental calm, and a sense of peace and relaxation which triggers feelings of positive emotions.[4] Long-term effects of meditation include enhanced emotional stability, resilience to stress and negative life events, better concentration, and enhanced overall psycho-emotional balance.[4] Furthermore, there is evidence that practicing meditation is associated with physiological changes such as a decrease in catecholamines and cortisol levels.[3] There is also evidence that it increases levels of melatonin and serotonin.[4] Meditation may be used alone or as adjunct therapy to reduce symptoms associated with mental health disorders, stress-related diseases, and attention disorders.[4]

This report will review the evidence of the benefits of TM in adults with post-traumatic stress disorder (PTSD), anxiety or depression. Armed forces personnel or veterans will be considered as a special group. A recent study reported that more than 13% of Canadian military personnel suffered from a mental health disorder following deployment to Afghanistan.[5] PTSD was the most common diagnosis (8%), followed by depression (6%) of which 60% were co-morbid with PTSD.[5] The rate of any anxiety disorder was approximately 10%.[5]

RESEARCH QUESTION

What is the clinical effectiveness of transcendental meditation for adults with post-traumatic stress disorder, anxiety disorders, and depression?

KEY FINDINGS

Conclusions on the benefits of TM in the treatment of patients with PTSD, depression or anxiety cannot be drawn due to the poor quality of the two clinical trials retrieved.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, PsycINFO, The Cochrane Library (2013, Issue 7), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2003 and August 5, 2013.

Selection Criteria and Methods

One reviewer screened citations to identify publications that met the inclusion criteria. Potentially relevant articles were retrieved based on the review of titles and abstracts. One reviewer screened full-text articles which were considered for inclusion based on the selection criteria listed in Table 1.

Table 1: Selection Criteria

Population	Adults with post-traumatic stress disorder, depression or anxiety, with a focus on veteran/ military population
Intervention	Transcendental Meditation
Comparator	Any
Outcomes	Symptom reduction, quality of life
Study Designs	Health technology assessments/ systematic reviews/ meta-analysis, randomized controlled trials, non-randomized trials

Exclusion Criteria

Articles were excluded if they did not satisfy the selection criteria, were full text articles published prior to January 2003, or did not specify the type of meditation evaluated. In addition, health technology assessments, meta-analyses, and systematic reviews were excluded if there was incomplete reporting of methods or if they were superseded by a more recent or more rigorous review. Randomized controlled trials (RCTs) were excluded if they were described in a systematic review or meta-analysis included in this report. Non-randomized trials (non-RCTs) were excluded if they did not include a comparator group (case series).

Critical Appraisal of Individual Studies

Key methodological aspects relevant to each study design were appraised and summarized narratively. For RCTs and non-RCTs, the Downs and Black Checklist[6] was used.

SUMMARY OF EVIDENCE

Quantity of Research Available

The literature search yielded 365 citations. Upon screening titles and abstracts, 331 citations were excluded and 34 potentially relevant articles were retrieved for full-text review. An additional 3 potentially relevant reports came from other sources. The process of study selection is outlined in the PRISMA flowchart (Appendix 1).

Of the 37 potentially relevant reports, 30 were readily excluded. Seven systematic reviews[7-13] included studies with TM as an intervention. Upon further inspection of the clinical trials included within each SR, 3 SRs[8,9,11] were excluded because the patient populations of the clinical trials included in the SRs were not patients with PTSD, depression, or anxiety disorders. This left 4 eligible SRs.[7,10,12,13] The SRs authored by Kim et al.[7] and Strauss et al.[10] identified one pertinent clinical trial [Brooks and Scarano (1985)].[14] The SRs by Krisanaprakornkit et al.[12] and Arias et al.[13] identified one pertinent RCT [Raskin et al. (1980)].[15] Because each SR provided limited details on the included trials, a decision was made to review the two trials, even though they fell outside our search limit of 10 years.

One additional reference of potential interest is provided in Appendix 2.

Summary of Study Characteristics

A summary of the SRs are provided in Appendix 3, Table 1. The details of the study characteristics of the clinical trials are provided in Appendix 3, Tables 2 and 3, and below.

Raskin et al. (1980)[15] included adult patients with a diagnosis of anxiety neurosis with symptoms lasting one year or more and who scored at least 21 on the Taylor Manifest Anxiety Scale (TMAS). Patients who used anti-anxiety medications were allowed into the study. Those who abused alcohol or other substances, with medical problems that complicated the anxiety, or who had received previous training with one of the interventions were excluded from entering the study. A total of 55 patients underwent a 6-week baseline assessment during which psychological and social data were obtained. A total of 18 patients dropped out during the baseline period. Following the baseline period, patients were randomized to TM, relaxation training (RT), or electromyographic feedback (EMG-FB). Patients using anxiety drugs were evenly distributed among treatment groups. The treatment period lasted six weeks. An additional six patients dropped out during the early course of treatment. The treatment period was followed by a 6-week post treatment period and follow-up was conducted at three, six, 12, and 18 months. The mean follow-up was 9 months. A total of 31 patients were included in the analysis. Outcomes measured included trait anxiety (using TMAS), state anxiety [using the Current Mood Checklist (CMCL)], situational anxiety, anxiety symptoms, and sleep disturbance.

Brooks and Scarano (1985)[14] was a prospective non-RCT. The study is described as randomized; however an even/ odd numbering system was used to assign treatment which does not qualify as true randomization. A total of 25 Vietnam veterans with PTSD agreed to participate in the trial (enrollment started in November 1981). Patients were excluded if they were on major tranquilizers, antidepressants, or lithium carbonate; had a history of psychiatric hospitalizations; were suicidal or homicidal; were treated for alcoholism or substance abuse in the past year; or had previously practiced TM. Seven patients dropped out of the study during

treatment which left 10 patients assigned to TM and eight patients assigned to individual psychotherapy. Outcomes measured included Post-Vietnam Stress Disorder Scale (PVSDS) as a measure of degree of PTSD, emotional numbness (a subscale of PVSDS), TMAS, Beck Depression Inventory (BDI), and post-Vietnam adjustment (amount of alcohol consumption, degree of insomnia, employment status, and extent of family problems).

Summary of Critical Appraisal

Details of the critical appraisal of the clinical trials are presented in Appendix 4.

Because the clinical trials were conducted in the 1980s, the quality of the trials was not as rigorous as what is dictated by current standards. Raskin et al.,[15] clearly stated the objectives of the study and the inclusion/ exclusion criteria. The intervention and comparators were well described and a short description of the main outcomes was provided. A table of key patient characteristics, including the number of patients receiving medications and the number of patients who had received prior therapy for anxiety was included. The psychologist analyzing the data was blinded to the allocation of interventions. The trial is described as randomized, however there was no mention on how the randomization was carried out. Allocation to treatment was not concealed during randomization. The sample size calculation was not reported. The results did not show 95% confidence intervals. The analysis was not intention to treat and the patients who dropped out of the study or did not complete the follow-up were not described, and reasons for not completing the trial were not provided. The rate of adherence to treatment and whether or not patients did actually practice TM twice daily for the duration of the trial was not reported.

In Brooks and Scarano,[14] the objectives of the study were clear and the exclusion criteria well described. A description of the interventions was provided. The questionnaires were scored by an independent evaluator. The inclusion criteria were not well described and it is unclear if all participants had a diagnosis of PTSD. A detailed description of the patient characteristics was not provided. It was not specified whether or not patients could receive or did receive other treatments during the study. Furthermore, there was no mention as to whether or not the patients had received previous treatments for PTSD. The characteristics of the patients who dropped out of the study or did not complete the follow-up were not described and no reasons for dropping out were provided. The rate of adherence to treatment and whether or not patients did actually practice TM twice daily for the duration of the trial was not reported. The presence of potential confounders was not assessed. The Post-Vietnam Stress Disorder Scale is not a validated scale and no description was provided on the content of the scale and interpretation of its results. The post-Vietnam adjustments scale was not validated either. The duration of the study was 12 weeks which may be too short to assess the benefits of the interventions.

Summary of Findings

In Raskin et al.,[15] the mean age of patients in the TM group (n=10) and in the EMG-FB (n=11) was 32 years whereas patients in the RT group (n=10) had a mean age of 37 years (Appendix 5, Table 1). All patients had suffered from severe anxiety symptoms for more than 10 years. Most patients had received prior therapy, and two patients in each group were receiving medications for their anxiety. Most patients were female (74%).

At baseline, TMAS scores were statistically significantly different between groups; baseline differences were adjusted using a covariate analysis with repeated measures. Compared to baseline (within-group comparison), patients in all three groups improved in TMAS score (P<0.01), with scores decreasing by 5 to 13 points at end of treatment (Appendix 5, Table 2). Similarly, patients improved in CMCL score (by periods P<0.01 and by weeks P<0.05), situational anxiety (P<0.01), and symptomatic distress (P<0.01). Sleep was not statistically significantly improved. In social ratings, improvements in work, in social functioning, and in family relations were reported (P<0.05). There was no statistically significant difference between the three groups for all outcomes. A total of 13 patients were considered most improved overall (equally divided amongst treatments), 10 patients were deemed to have made moderate improvements, seven were unchanged, and three patients had worsening anxiety. At a mean follow-up of 9 months, of the most improved patients, three patients had improved further, seven had maintained their improvements, and three patients were worse.[15]

Patients had a mean age of 33.3 years in Brooks and Scarano,[14] and all patients were males. It is reported that had there were no statistically significant differences in demographics (age, marital status, annual income, time spent in the military and degree of combat, race, and location of service) between the two study groups.

Baseline scores were not statistically significantly different between groups, with the exception of insomnia as the psychotherapy group reported more difficulty sleeping than the TM group (P<0.01). Compared to psychotherapy, there were statistically significant improvements in the following variables with TM: degree of PTSD (P<0.05), emotional numbness (P<0.025), anxiety (P<0.005), depression (P<0.025), alcohol consumption (P<0.005), insomnia (P<0.001), and family problems (P<0.05) (Appendix 5, Table 3). No between-group difference in employment status was found. Within-group comparisons showed a statistically significant improvement in all variables for the TM group. At the end of the trial, 7 of 10 TM patients felt sufficiently improved to discontinue attendance at the Veteran Centre.[14]

Limitations

The literature search conducted for this report was limited to 10 years. However we found four comprehensive, good quality SRs which identified only two clinical trials in our population of interest. This underscores the lack of evidence of the use of TM as a treatment for PTSD and related disorders.

The clinical trials reviewed were conducted in the 1980s, had methodological issues, and included a small number of patients. No recent trials were retrieved. In both trials, attrition rate was high, with 24 of 55 (44%) patients and 7 of 25 (28%) patients dropping out of the trial at baseline or during treatment in Raskin et al.[15] and in Brooks and Scrarano,[14] respectively. Reasons for discontinuation were not provided which limits the interpretation of the trials. The two trials did not comment on whether or not patients experienced adverse events (for example depersonalization, affective flattening, or precipitation of psychosis or mania) due to TM. Both trials included a population of patients in their 30s, and findings may not be generalizable to older patients.

In Brooks and Scarano,[14] the baseline scores for anxiety and depression (as measured with TMAS and BDI) were relatively low (<20) which may indicate that these patients were not severely anxious or depressed. This would limit the generalizability of findings. Patients who gave a perfect score of 4 (“no problem”) for post-Vietnam adjustment variables (alcohol

consumption, insomnia, employment and family problems) at baseline were excluded from the analysis unless the post score was lower than 4. Thus the analysis included a subset of patients with lower baseline scores (exact number of patients not provided), and not the full sample. Furthermore, these were not validated instruments and it could be that these scales lack construct validity because of ceiling effects. Finally, PTSD is a chronic disorder which requires long-term management, yet the duration of the trial was limited to 3 months with no long term follow-up.[14]

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

Four systematic reviews met our inclusion criteria. In two SRs, one RCT evaluated the use of TM in adults with anxiety and in another two SRs, one clinical trial evaluated the use of TM in Vietnam veterans with post-traumatic stress disorder. The two clinical trials were of interest to this report, but were published in the 1980s which was outside the scope of our 10-year search limit. However, the SRs were comprehensive and well conducted which expands the search criteria beyond 10 years and gives us confidence that all pertinent clinical trials were found. Hence, the articles were retrieved and the clinical trials were reviewed in more detail than what would have been feasible from the SRs alone.

The use of TM to treat anxiety disorders was compared to relaxation training or electromyographic feedback in an RCT of 55 patients of which only 31 were included in the analysis. All three treatment modalities were of comparable benefits in reducing signs and symptoms of anxiety; patients who improved maintained the benefits for at least 9 months. However, attrition rate was high; almost 50% of patients dropped out of the trial with no explanation provided.

Compared to individual psychotherapy, TM statistically significantly decreased symptoms of PTSD in one non-RCT. Of the 25 post-Vietnam veterans who agreed to participate in the trial, seven patients did not complete the trial for reasons unknown. The use of unvalidated instruments, the unclear diagnostic criteria required to enter the study, and the lack of information on concomitant and past treatments further complicate the interpretation of the findings.

The use of TM as a treatment for mental illness needs to be evaluated in larger scale RCTs with better designs and appropriate comparators. Until then, conclusions on its use as treatment modality for PTSD or related disorders cannot be made.

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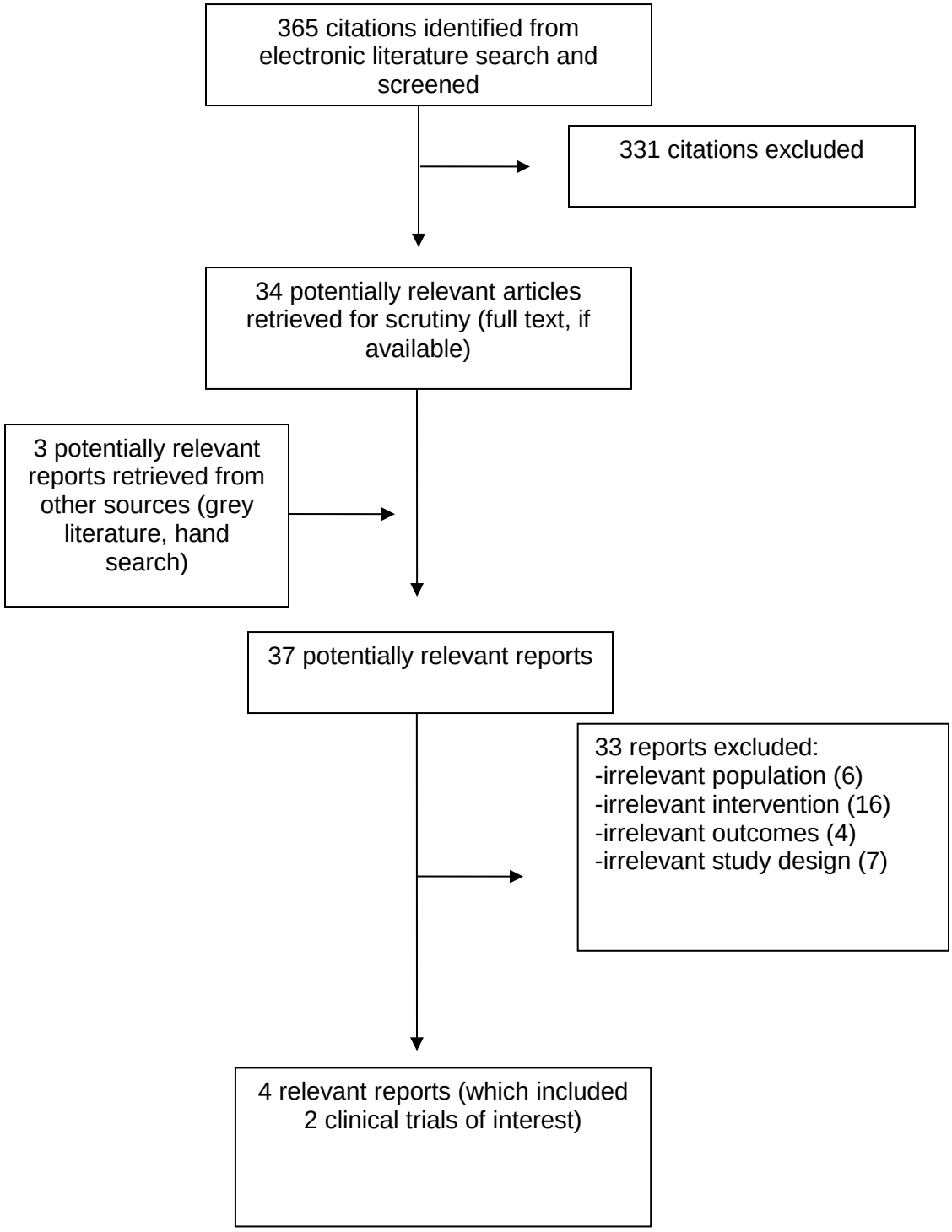
APPENDIX 1: Selection of Included Studies



APPENDIX 2: Additional Reference of Potential Interest

Rosenthal JZ, Grosswald S, Ross R, Rosenthal N. Effects of transcendental meditation in veterans of Operation Enduring Freedom and Operation Iraqi Freedom with posttraumatic stress disorder: a pilot study. Mil Med. 2011 Jun;176(6):626-30.
PubMed: PM21702378

APPENDIX 3: Characteristics of Included Publications

Table 1: Summary of Systematic Reviews

Author, Year, Funding Source	Key Inclusion Criteria, N Studies	Interventions	Outcomes
Kim et al., 2013[7] Not stated	Patients with PTSD Studies up to June 2012 N=16 studies of which 1 study was on TM	Mind-body practices (a comparator was not required for the study to be included)	PTSD symptom severity
Strauss et al., 2011[10] US Department of Veterans Affairs	Adult patients with PTSD Studies up to April 2011 N=7 studies of which 1 study was on TM	Complementary and alternative medicine interventions vs. Control group or standard care	Change in PTSD symptoms and quality of life
Krisanaprakornkit et al., 2009[12] Cochrane Collaboration Review	Adult patients with a diagnosis of anxiety disorders with or without another comorbid psychiatric condition RCTs up to June 2005 N=2 studies of which 1 study was on TM	Concentrative meditation or mindfulness meditation vs. One or combination of pharmacologic therapy, other psychological therapy, other methods of meditation, or no intervention/ waiting list	Improvement in clinical anxiety scale, improvement in anxiety level, or global improvement
Arias et al., 2006[13] Not stated	Patient with a disease for which meditation is intended as a treatment RCTs up to November 2005 N=20 studies of which 1 study was on TM	Meditation techniques vs. Wait-list, active treatment, placebo, or sham	Outcomes to reflect relevant disease parameters
PTSD=Post-traumatic stress disorder, **RCTs**=randomized controlled trials, **TM**=transcendental meditation			

Table 2: Summary of Randomized Controlled Trial included the SRs

Author, Year, Country, Funding Source	Inclusion and Exclusion Criteria, Sample size, Patient Characteristics	Study Design, Interventions	Outcomes
Raskin et al., 1980[15] USA National Institute of Mental Health; National Institute of Health	Inclusion: Diagnosis of anxiety neurosis; TMAS score at least 21 Exclusion: Medical problem which complicated anxiety; alcohol or other substance abuse; formal training in one of the interventions Sample size: Enrolled: n=55 Drop-out: n=18 at baseline Drop-out: n=6 during treatment period Lost to follow-up: n=3 Analyzed: n=31 Patients characteristics: 26% males, mean age=33.6 years	Study design: 6-week baseline period then patients randomly assigned to one of 3 treatments. Treatment period of 6 weeks followed by 6 weeks of observation. Follow-up at 3, 6, 12, and 18 months after post treatment period (mean follow-up=9 months). No blinding although an independent psychologist collected psychological and social data. Interventions: TM vs. RT vs. EMG-FB	TMAS CMCL Situational anxiety Anxiety symptoms Sleep disturbance Social ratings (SSIAM)

CMCL=Current Mood Checklist, **EMG-FB**= Electromyographic feedback, **RT**= relaxation training, **SSIAM**=Structured and Scaled Interview to Assess Maladjustment, **TM**=transcendental meditation, **TMAS**=Taylor Manifest Anxiety Scale

Anxiety symptoms: patients chose 3 physical symptoms that they attributed to anxiety; each symptom rated daily on a four-point scale (absent, mild, moderate or severe)
CMCL: 65-item true-false inventory administered weekly
Situation anxiety: patients named 3 situations that made them anxious; anxiety level in these situations were rated on a four-point scale (absent, mild, moderate or severe) administered daily
Sleep disturbance: sleep latency, time awake during the night and the use of sedatives recorded daily
Social ratings: The Structured and Scaled Interview to Assess Maladjustment (SSIAM) is a 60-item, multi-dimensional questionnaire that assesses the objective and subjective facets of maladjustment, indicating levels of distress, deviant behavior and friction – administered at baseline and at the end of the post-treatment period
TMAS: 50-item, true-false responses to measure anxiety – score from 0 to 50 with the higher the score representing a higher level of anxiety; administered on entry, prior to treatment, at the end of treatment and at the end of the post-treatment period

Table 3: Summary of Non-randomized Controlled Trial included in the SRs

Author, year, country, funding source	Inclusion and Exclusion Criteria, Sample size, Patient Characteristics	Study Design, Interventions	Outcomes
Brooks and Scarano, 1985[14] USA Private donations from the community	Inclusion: Vietnam veterans seeking treatment for PTSD Exclusion: Patients on antidepressants, major tranquilizers, or lithium carbonate; history of previous psychiatric hospitalizations; patients who are suicidal or homicidal; patients who have been treated for alcoholism or drug abuse in past year; patients who practice TM Sample size: Enrolled: n=25 Treated: n=18 Drop-outs: n=7 Analyzed: n=18 Patients characteristics: 100% males, mean age=33.3 years	Study design: Patients assigned numbers; odd-numbered patients assigned to TM and even-numbered patients assigned to psychotherapy; 12 weeks treatment duration. Questionnaire scored by an independent evaluator. Interventions: TM vs. psychotherapy	Degree of PTSD (PVSDS) Emotional numbness (subscale of PVSDS) TMAS BDI Post-Vietnam adjustment (amount of alcohol consumption, degree of insomnia, employment status, extent of family problems)

BDI=Beck Depression Inventory, **PTSD**=Post-traumatic stress disorder, **PVSDS**=Post-Vietnam Stress Disorder Scale, **TM**=transcendental meditation, **TMAS**=Taylor Manifest Anxiety Scale

BDI: 21-question multiple-choice self-report inventory used for measuring the severity of depression; items rated on a four-point scale (0 being lowest intensity and 3 being highest) – score from 0 to 63, with a higher score indicating severe depression

Post-Vietnam adjustment: maximum score is 4, with 4=no problem (no other information provided)

PVSDS: not a validated scale; no description provided

TMAS: 50-item, true-false responses to measure anxiety – score from 0 to 50 with the higher the score representing a higher level of anxiety; administered on entry, prior to treatment, at the end of treatment and at the end of the post-treatment period

APPENDIX 4: Critical Appraisal of Clinical Studies

Author, year, study design	Strengths	Limitations
Raskin et al., 1980[15] RCT	• objectives of study stated • main outcomes clearly described • patient characteristics included • inclusion/ exclusion criteria well described • interventions described • psychologist analyzing data was blinded to interventions	• no mention on how randomization was carried out • no allocation concealment • no sample size calculation • analysis was not intention to treat • 95% confidence interval not calculated • characteristics of patients dropped out or lossed to follow-up not provided • adherence to treatment not measured (i.e., did patients practice TM every day as required?)
Brooks and Scarano, 1985[14] Non-RCT	• objectives of study stated • exclusion criteria well described • interventions described • questionnaires scored by an independent evaluator	• study is described as randomized, however an even/ odd numbered system was use which is not true randomization • inclusion criteria not well described • main outcomes not well described • not clear if all participants met diagnosis of PTSD • patient characteristics not well described • characteristics of patients not included in analysis not provided • adherence to treatment not measured (i.e., did patients practice TM every day as required?) • confounders not described • use of unvalidated scales • not specified if patients could receive other treatments during study • no follow-up period
PTSD=Post-traumatic stress disorder, **TM**=transcendental meditation		

APPENDIX 5: Summary of Results of Clinical Studies

Table 1: Patient Characteristics – Raskin et al.[15]

	TM	RT	EMG-FB
N patients	10	10	11
Age, year (mean±SD)	32±10.2	37±11.5	32±6.4
Time from onset of anxiety symptoms, year (mean±SD)	12.8±9.8	11.2±13.7	10±8.4
N receiving medication	2	2	2
Male:female	1:9	3:7	4:7
N with prior therapy for anxiety	10	10	9
EMG-FB= Electromyographic feedback, **RT**= relaxation training, **SD**=standard deviation, **TM**=transcendental meditation,			

Table 2: Taylor Manifest Anxiety Scale Scores – Raskin et al.[15]

Group	Initial	Pre-treatment (a 6-week baseline period)	End of treatment (following a 6-week treatment period)	End of post treatment (a 6-week observation period after treatment)
TM (n=10)	36.5	33.8	23.4	22.6
RT (n=10)	31.6	33.0	26.1	23.6
EMG-FB (n=11)	34.0	32.5	27.1	26.5
P value=0.05 within groups				
P value=NS between groups				
EMG-FB= electromyographic feedback, **NS**=no statistically significant, **RT**= relaxation training, **TM**=transcendental meditation,				

Table 3: TM vs. Psychotherapy – Brooks and Scarano[14]

	TM (n=10)		**Psychotherapy** (n=8)	
Mean scores ± SD	**Pre**	**Post**	**Pre**	**Post**
PVSDS	9.7±3.0	5.8±4.3	11.7±2.6	10.9±2.9
Emotional numbness	3.7±1.6	1.7±2.0	3.8±1.0	3.5±1.4
TMAS	16.5±4.7	9.1±5.3	18.3±4.4	18.6±5.0
BDI	16.6±6.8	7.6±7.5	20.6±7.9	19.8±3.8
Post-Vietnam adjustment				
Alcohol consumption	2.0±0.6	3.7±0.8	2.2±0.4	2.2±0.4
Insomnia	2.7±0.8	3.7±0.5	1.6±0.5	1.4±0.5
Employment	2.3±0.5	3.5±0.6	2.4±1.1	2.8±1.3
Family problems	2.1±0.8	3.3±0.9	2.1±0.9	2.3±0.8
BDI=Beck Depression Inventory, **PVSDS**=Post-Vietnam Stress Disorder Scale, SD=standard deviation, **TM**=transcendental meditation, **TMAS**=Taylor Manifest Anxiety Scale				