

## APPENDIX A. SEARCH STRATEGIES

Step	Goal	Terms	Result <sup>a</sup>
1	<b>PTSD terms</b>	Stress Disorders, Traumatic[MeSH] OR stress disorders, post-traumatic[MeSH] OR (post AND traumatic AND stress AND disorder[All Fields]) OR (post-traumatic AND stress AND disorder [All Fields]) OR (post traumatic stress disorder[All Fields]) or (post-traumatic stress disorders[All Fields]) OR ptsd[All Fields] <b>AND</b>	1069
2	<b>Interventions</b>	Acupuncture Therapy[Mesh:noexpl] OR Acupuncture Analgesia[Mesh] OR Acupuncture, Ear[Mesh] OR Electroacupuncture[Mesh] OR Acupuncture[Mesh] OR Acupressure[Mesh] OR Auriculotherapy[Mesh] OR acupuncture[All Fields] OR (acupuncture[All Fields] AND therapy[All Fields]) OR (acupuncture therapy[All Fields]) OR acupressure[All Fields] OR auriculotherapy[All Fields] OR Mind-Body Therapies[Mesh:noexpl] OR Breathing Exercises[Mesh] OR Hypnosis[Mesh] OR Imagery (Psychotherapy)[Mesh] OR Meditation[Mesh] OR Mental Healing[Mesh] OR Relaxation Therapy[Mesh] OR Tai Ji[Mesh] OR Therapeutic Touch[Mesh] OR Yoga[Mesh] OR Mind-Body Relations, Metaphysical[Mesh] OR breath[All Fields] OR breath[All Fields:expl] OR Complementary Therapies[Mesh:noexpl] OR Holistic Health[Mesh] OR Medicine, East Asian Traditional[Mesh] OR Reflexotherapy[Mesh] OR Spiritual Therapies[Mesh] OR acoustics[MeSH] OR acoustics[All Fields] OR acoustic[All Fields] OR aromatherapy [MeSH] OR sensory[All Fields] OR aromatherapy[All Fields] OR art[MeSH] OR art[All Fields] OR colour[All Fields] OR color[MeSH] OR color[All Fields] OR dance[All Fields] OR music[MeSH] OR music[All Fields] OR play and playthings[MeSH] OR (play AND playthings[All Fields]) OR play and playthings[All Fields] OR play[All Fields] OR sensory art therapies[MeSH] OR reflexotherapy[All Fields] OR craniosacral[All Fields] OR magnet[All Fields] OR light[MeSH ] OR light[All Fields] OR feldenkrais[Tiab] OR Alexander[Tiab] OR pilates[All Fields] OR trager[All Fields] OR movement therapeutic[All Fields] OR movement therapies[All Fields] OR movement therapy[All Fields] OR healers[All Fields] OR energy[All Fields] OR therapeutic touch[MeSH] OR (therapeutic[All Fields] AND touch[All Fields]) OR therapeutic touch[All Fields] OR reiki[All Fields]) OR ayurvedic[All Fields] <b>AND</b>	83692
3	<b>Study designs</b>	Randomized controlled trial[publication type] OR clinical trial[publication type] OR Comparative study[Publication type] OR clinical trials as topic[MeSH] OR (randomized AND controlled AND trial[Tiab]) OR (clinical AND trial[Tiab] OR trial[Tiab:expl]) <b>AND</b>	13973
4	<b>Combine results and apply limits</b>	#1 <b>AND</b> #2 <b>AND</b> #3 LIMITS: English and Human and Adult	353

<sup>a</sup>Numbers reflect the result of the PubMed search only.

## APPENDIX B. STUDY SELECTION FORM

**Citation Screening Instructions:** Turn on revision marks and label each citation with your decision. For studies that you can definitively exclude ( $\geq 90\%$ ), mark with “E.” For studies that are relevant to CAM for PTSD but not eligible (e.g., a review article), mark with a “B” for background. For an article that appears to meet eligibility criteria, mark with “IN” for include. We will need to be able to identify comparative studies that appear to meet our eligibility criteria but are excluded because they are not RCTs. Mark these studies with “F” for flag, and in the absence of RCTs for a therapy, we will give these studies further scrutiny.

### **Inclusion criteria:**

- Study must be an RCT
- Sample population must have diagnosis of PTSD using DSM criteria, validated severity measures (e.g., PTSD Checklist), or clinical diagnosis by a physician
- Sample population is  $\geq 19$  years of age
- Setting: Patients are recruited from community or outpatient mental health or general medical settings
- Any of the following eligible treatments:
  - Mind-body therapies: Acupuncture, meditation, yoga, deep-breathing exercises, guided imagery, mindfulness-based stress reduction, hypnotherapy, progressive relaxation, qi gong, and tai chi
  - Manipulative and body-based therapies: spinal manipulation, massage therapy
  - Other CAM therapies:
    - Movement-based therapies: Feldenkrais method, Alexander technique, Pilates, Rolfing Structural Integration, and Trager psychophysical integration
  - Manipulation of various energy fields to affect health: magnet therapy, light therapy, qi gong, Reiki, and healing touch
- Comparative studies:
  - Studies that compare an eligible treatment to a control condition—such as usual care (including no treatment, supportive therapy), an attention control, sham intervention, or a waitlist—will be included
  - Studies that compare an eligible treatment to an empirically based treatment such as CBT, PE, or antidepressant medication
- Outcome is reported at  $\geq 6$  weeks after treatment initiation
- Patients are in acute phase treatment (i.e., not selected for treatment-resistant PTSD)
- Study must be published in a peer-reviewed publication

### **Exclusion criteria:**

- Study is a non-English language publication
- Study is conducted outside of North America, Western Europe, Australia, or New Zealand. Studies conducted outside of these countries are unlikely to be applicable to a VA population because of important differences in culture and the health care system.
- Study populations are patients with complicated PTSD: psychosis or acute suicidality

- Studies in which the eligibility criteria require a diagnosis of PTSD comorbid with another mental illness (e.g., PTSD and substance abuse)
- Intervention is used in a continuation phase or maintenance phase
- Excluded interventions:
  - cognitive processing therapy
  - eye movement desensitization and reprocessing (EMDR)
  - generic counseling
  - life review therapy
  - psychoeducational therapy
  - social support or supportive therapy
  - standard psychodynamic therapy
  - “third wave” cognitive and behavioral therapies: mindfulness-based cognitive therapy, dialectical behavioral therapy, and acceptance and commitment therapy
  - other treatments that are a direct extension of an established conventional therapy (e.g., Imagery Rehearsal Therapy)
  - incident stress debriefing, psychological debriefing
  - trauma-focused therapy
  - present-focused therapy
  - seeking-safety treatment
  - relaxation therapy used as a control arm or not described in sufficient detail to understand the key components

## APPENDIX C. SAMPLE DATA EXTRACTION FORM

**Study Information** (Author/Year/EN#): \_\_\_\_\_

Other linked studies? (1) No (2) Yes: \_\_\_\_\_

1. **Study objective:** \_\_\_\_\_  
\_\_\_\_\_

2. **Study location (1-4 sites):**  NA

a. Location 1: City \_\_\_\_\_ Country: \_\_\_\_\_

b. Location 2: City \_\_\_\_\_ Country: \_\_\_\_\_

c. Location 3: City \_\_\_\_\_ Country: \_\_\_\_\_

d. Location 4: City \_\_\_\_\_ Country: \_\_\_\_\_

3. **Study location (If > 4 sites):**  NA Sites (#): \_\_\_\_\_ Countries/regions(#): \_\_\_\_\_

Names of regions (e.g. Western Europe) \_\_\_\_\_

4. **Treatment setting (all that apply):**

(1) Mental Health (2) Gen. Medical (3) Non-Medical (4) NR

5. **VA settings:** (1) Yes (2) No (3) Mixed (4) NR

6. **Active duty military settings:** (1) Yes (2) No (3) Mixed (4) NR

7. **Academic affiliation:** (1) Yes (2) No (3) Mixed (4) NR

8. **Study design:**

(1) Patient level RCT (2) Non-randomized controlled trial (3) Cross-over trial

(4) Prospective cohort study (5) Case Series (6) Other: \_\_\_\_\_

9. **Subject recruitment (all that apply):** (1) Screening (2) Clinician referral

(3) Advertisement (paid) (4) Other (list): \_\_\_\_\_ (5) NR

**Characteristics of the participants** 1. Total enrolled: \_\_\_\_\_

Characteristic	Total Enrolled	Intervention	Control
2. Mean age (SD)			
3. Sex: Men (n)			
4. Sex: Women (n)			
5. Race: White (n)			
6. Race: African American (n)			
7. Race: Latino (n)			
8. Race: Asian (n)			
9a. Mean (SD) education (years) or			
9b. ≥ High school education (n)			
10. Mean (SD) PTSD severity: _____			
11. Mean (SD) Functional status: _____			
12. Mean (SD) Years since trauma			

**1. Eligibility Criteria:**

- a. Diagnosis: (1) DSM3R (2) DSMIV (3) ICD (4) Clinical-nonstandardized  
(5) Severity measure (e.g., PCL) (6) Patient self-reports diagnosis
- b. Trauma exposure (all that apply): (1) Combat (2) Natural disaster  
(3) Rape/sexual assault (4) Childhood abuse (5) Physical assault (6) Transportation  
accident (7) Other \_\_\_\_\_
- c. Age range: \_\_\_\_\_
- d. Suspend other psychological treatment: (1) Yes (2) No
- e. Keep psychotropic medications stable: (1) Yes (2) No
- f. Other 1: \_\_\_\_\_
- g. Other 2: \_\_\_\_\_

**2. Exclusion Criteria:**

- a. Alcohol or substance abuse: (1) Yes (2) No (3) Not reported
- b. Psychotic disorder: (1) Yes (2) No (3) Not reported
- c. Reason 1: \_\_\_\_\_ Reason 2: \_\_\_\_\_
- d. Reason 3: \_\_\_\_\_ Reason 4: \_\_\_\_\_

**Intervention**

- 1. Intervention: \_\_\_\_\_
- 2. Sessions planned (#): \_\_\_\_\_ Mean (SD) Sessions delivered: \_\_\_\_\_
- 3. Duration planned (minutes/session): \_\_\_\_\_
- 4. Discipline: (1) Physician (2) PhD MH professional (3) Masters train MH professional  
[All that apply] (4) Physical therapist (5) Chiropractor (6) Trained research assistant  
(7) Trained acupuncturist (8) Other: \_\_\_\_\_
- 5. Mean years of experience (SD): \_\_\_\_\_
- 6. Study-specific training: \_\_\_\_\_
- 7. Intervention components:
  - a. Component 1: \_\_\_\_\_ (allowed | given)
  - b. Component 2: \_\_\_\_\_ (allowed | given)
  - c. Component 3: \_\_\_\_\_ (allowed | given)
  - d. Component 4: \_\_\_\_\_ (allowed | given)
  - e. Component 5: \_\_\_\_\_ (allowed | given)
- 8. Is the intervention described in sufficient detail for a trained practitioner to replicate?  
(1) Yes (2) No

**Comparator** (If active comparator choose PE or CPT > EMDR > Other)

- 9. Basic descriptor: (1) Usual Care (2) Sham (3) Attention Control (4) Waitlist  
(5) CPT (6) Exposure therapy (7) Other: \_\_\_\_\_
- 10. Sessions planned (#): \_\_\_\_\_ Mean (SD) Sessions delivered: \_\_\_\_\_
- 11. Duration planned (minutes/session): \_\_\_\_\_
- 12. Clinician same discipline as for the intervention? (1) Yes (2) No (3) NR

13. Comparator Components:

- f. Component 1: \_\_\_\_\_ (allowed | given)
- g. Component 2: \_\_\_\_\_ (allowed | given)
- h. Component 3: \_\_\_\_\_ (allowed | given)
- i. Component 4: \_\_\_\_\_ (allowed | given)
- j. Component 4: \_\_\_\_\_ (allowed | given)

14. If 3-arm trial, other comparator: \_\_\_\_\_

**Outcomes**

1. Subjects randomized: \_\_\_\_\_ Number Analyzed: \_\_\_\_\_
2. Time 1 f/u (weeks): \_\_\_\_\_ Time 1 f/u (n): \_\_\_\_\_
3. Time 2 f/u (weeks): \_\_\_\_\_ Time 2 f/u (n): \_\_\_\_\_
4. Other time points reported: (1) No (2) Yes (weeks): a. \_\_\_\_ b. \_\_\_\_ c. \_\_\_\_
5. Response definition (% change): \_\_\_\_\_
6. Remission definition: \_\_\_\_\_
7. Symptom measure 1: \_\_\_\_\_  Self-report  Interviewer rated
8. Symptom measure 2: \_\_\_\_\_  Self-report  Interviewer rated
9. HRQOL measure: \_\_\_\_\_  Self-report  Interviewer rated
10. Outcome measure 4: \_\_\_\_\_  Self-report  Interviewer rated
11. Adherence measured: (1) sessions completed (2) homework (3) both
12. Outcomes reported as dichotomous results – time point 1 (weeks): \_\_\_\_\_  
OR  No dichotomous results reported

Outcome	NR	Intervention		Comparator	
		Events (n)	At risk (n)	Events (n)	At risk (n)
AE: Discontinuation					
AE: Any					
Clinical response					
Clinical remission					
Completer					

13. Time point 2 Results (weeks): \_\_\_\_\_ OR  No time point 2 dichotomous results

Outcome	NR	Intervention		Comparator	
		Events (n)	At risk (n)	Events (n)	At risk (n)
AE: Discontinuation					
AE: Any					
Clinical response					
Clinical remission					
Completer					

14. Continuous results – time point 1 (weeks) \_\_\_\_\_ give mean (SD) or mean (95% CI; x to y)  
 No continuous results reported

Outcome	Intervention baseline	Comparator baseline	Intervention followup	Int “n”	Comparator followup	Comp “n”	F/U Code
Adherence	NA	NA					
Sx score 1							
Sx Score 2							
HRQOL							
Patient satisfaction							
Social functioning							

F/U Code: U=Unadjusted Mean (e.g., ANOVA); A=Adjusted mean (e.g, ANCOVA); C1=Change score for treatment arm (T2-T1); C2=Change score for treatment arm (T1-T2); D1 = Difference in means between groups at followup (intervention – comparator, e.g., estimate from mixed model); D2 = Difference in means between groups at followup (comparator - intervention); P=only a p value given (record p value in the Intervention f/u field)

15. Continuous results – time point 2 (weeks): \_\_\_\_\_ give mean (SD) or mean (95% CI; x to y)

No Dichotomous results reported at time point 2

Outcome	Intervention baseline	Comparator baseline	Intervention followup	Int “n”	Comparator followup	Comp “n”	F/U Code
Adherence	NA	NA					
Sx score 1							
Sx Score 2							
HRQOL							
Patient satisfaction							
Social functioning							

F/U Code: U=Unadjusted Mean (e.g., ANOVA); A=Adjusted mean (e.g., ANCOVA); C1=Change score for treatment arm (T2-T1); C2=Change score for treatment arm (T1-T2); D1 = Difference in means between groups at followup (intervention – comparator, e.g., estimate from mixed model); D2 = Difference in means between groups at followup (comparator - intervention); P=only a p value given (record p value in the Intervention f/u field)

## APPENDIX D. CRITERIA USED IN QUALITY ASSESSMENT

### General Instructions:

For each risk of bias item, rate as “Yes,” “No,” or “Unclear.” After considering each of the quality items, give the study an overall quality rating of good, fair or poor.

### Detailed Quality Items:

If an item is rated as “No,” describe why in the comments column.

1. *Randomization adequate?* Was the allocation sequence adequately generated? **Yes/No/Unclear**
2. *Allocation concealment adequate?* Was allocation adequately concealed? **Yes/No/Unclear**
3. *Incomplete outcome data adequately addressed?* **Yes/No/Unclear**  
Consider Attrition bias: Were there systematic differences between groups in withdrawals from a study or high overall loss to followup? (Even small differences could be important when rates are low.) Were subjects excluded from the analysis – if so, were the exclusions sensible?
4. *Subjects Blinded?* Were subjects blind to treatment assignment? **Yes/No/Unclear**
5. *Outcome assessor blinded?* (This may be recorded separately for each critically important outcome.) Were Outcome assessors blind to treatment assignment? **Yes/No/Unclear**
6. *Provider (treating clinician) blinded?* Were providers blind to treatment assignment?  
**Yes/No/Unclear**
7. *All outcomes reported?* Are reports of the study free of suggestion of selective outcome reporting (systematic differences between reported and unreported findings)? **Yes/No/Unclear**
8. *Intention-to-treat analysis?* All eligible patients that were randomized are included in analysis; note- mixed models and survival analyses are in general ITT **Yes/No/Unclear**
9. *Adequate power for main effects?* **Yes** (if power analysis or sample size calculation given and recruitment met needs or if post-hoc power calculation shows adequate power)/**No** (did not meet projected sample size needs) /**Unclear** (no power or sample size calculation given)
10. *Other Selection bias?* Were there methods that could lead to differences or were there systematic differences observed in baseline characteristics and prognostic factors of the groups compared?(e.g., failure of randomization): **Yes/No/Unclear**
11. *Comparable groups maintained?* (Includes crossovers, adherence, and contamination.) Consider issues of crossover (e.g., from one intervention to another), adherence (major differences in adherence to the interventions being compared), contamination (e.g., some members of control group get intervention) **Yes/No/Unclear**
12. *Lack of Performance bias?* Were there no important systematic differences in the care that was provided, other than the intervention of interest? **Yes/No/Unclear**
13. *Lack of Measurement bias?* Were the measures used reliable and valid – and therefore, “yes” no important measurement bias? **Yes/No/Unclear**
14. *Absence of Detection bias?* Were there systematic differences between groups in how outcomes are determined? If no systematic differences answer “yes” – no important detection bias.  
**Yes/No/Unclear**
15. *Was there the absence of potential important conflict of interest?* The focus here is financial conflict of interest. Therefore if no financial conflict of interest (e.g. funded by government or foundation and authors do not have financial relationships with drug/device manufacturer), then answer “yes.” **Yes/No/Unclear**

### **Overall rating**

Please assign each study an overall quality rating of “Good,” “Fair,” or “Poor” based on the following definitions:

A “**Good**” study has the least bias, and results are considered valid. A good study has a clear description of the population, setting, interventions, and comparison groups; uses a valid approach to allocate patients to alternative treatments; has a low dropout rate; and uses appropriate means to prevent bias, measure outcomes, and analyze and report results.

A “**Fair**” study is susceptible to some bias but probably not enough to invalidate the results. The study may be missing information, making it difficult to assess limitations and potential problems. As the fair-quality category is broad, studies with this rating vary in their strengths and weaknesses. The results of some fair-quality studies are possibly valid, while others are probably valid.

A “**Poor**” rating indicates significant bias that may invalidate the results. These studies have serious errors in design, analysis, or reporting; have large amounts of missing information; or have discrepancies in reporting. The results of a poor-quality study are at least as likely to reflect flaws in the study design as to indicate true differences between the compared interventions.

## APPENDIX E. PEER REVIEW COMMENTS/AUTHOR RESPONSES

Reviewer	Comment	Response
<b>Question 1: Are the objectives, scope, and methods for this review clearly described?</b>		
1	Yes	Acknowledged
2	Yes	Acknowledged
3	Yes - This is an excellent review and evidence synthesis.	Thank you.
4	Yes	Acknowledged
5	<p>Yes – This was a clearly and well-defined project. The authors are to be congratulated on the organization of the report which made for easy reading.</p> <p>This reviewer would appreciate a formal definition of CAM (if there is such) early in the introductory material.</p> <p>Also, I realize that natural products such as nutritional supplements were excluded from review, but there was no convincing rationale for this decision. Given the paucity of information from other CAM approaches, it might be worth reconsidering this decision.</p>	<p>Thank you.</p> <p>This definition is provided on the first page of the Executive Summary and in the background section of the Introduction of the report.</p> <p>The decision to exclude nutritional supplements was made by the stakeholders, not the research team.</p>
6	Yes	Acknowledged
<b>Question 2: Is there any indication of bias in our synthesis of the evidence?</b>		
1	No	Acknowledged
2	Yes – The exclusion criteria listed on p 12-13 show a clear bias toward western medicine centric locations. Given the paucity of studies, inclusion of a wider selection of studies particularly from countries where CAM is more common would be warranted. This would also involve non-English language publications.	The reviewer raises a valid point. Our conceptual framework was to review settings and subjects similar to the VA and Veterans—thus the focus on studies conducted in the U.S. and economically similar countries. Our staff is not resourced to include non-English publications. We note this limitation in the discussion.
3	No	Acknowledged
4	No	Acknowledged
5	No	Acknowledged
6	Yes - There is no evidence of intentional bias. The authors have done a very fair job of reporting the evidence. However, I believe the selection criteria may have limited what can be learned from the existing evidence, and therefore, have created an unintentional bias in the conclusions.	See response to Question 7, Reviewer 6

Reviewer	Comment	Response
<b>Question 3: Are there any studies of interest to the VA that we have overlooked?</b>		
1	Yes Rosenthal, et al. (2011). Military Medicine, 176:626-630	Thank you for making us aware of this article. Although it was published after our literature search date (Dec 22, 2010) and thus excluded from our formal literature synthesis, we now include a description of this study in our Results section, Key Question 4.
2	Yes - see comments above on excluded studies. since PTSD is commonly comorbid with substance abuse, exclusion of studies requiring both diagnoses limits applicability of findings  The listing of the references for the excluded studies is a plus, as the reader can draw their own conclusions. Shore 2004 is missing from that list.  Management of Operation Iraqi Freedom and Operation Enduring Freedom veterans in a Veterans Health Administration chiropractic clinic: a case series. Lisi AJ. Journal of Rehabilitation Research & Development. 47(1):1-6, 2010	Acknowledged  Shore 2004 is included in the excluded studies table in Appendix F.  Thank you for bringing this article to our attention. However, it does not meet our inclusion criteria since PTSD diagnosis was not a study inclusion criteria, nor was change in PTSD a reported outcome.
3	No – none that I am aware of, but this is not my field	Acknowledged
4	No - none that I am aware of	Acknowledged
5	No	Acknowledged
6	Yes - There is an RCT of mindfulness meditation by Barbara Niles that is relevant. I believe that the authors attempted to get a copy of the paper but could not for some reason. However, the trial was well-done and positive, so it would be helpful to try to include it if at all possible.	We have obtained a prepublication draft of this manuscript but do not include it in the current report since our literature review strategy stipulates that included studies be published in peer-reviewed journals.
<b>Question 4: Are there any clinical performance measures, programs, quality improvement measures, patient care services, or conferences that will be directly affected by this report? If so, please provide detail.</b>		
1	The findings of this report will be used while designing demonstration projects in the field, in an attempt to address some of the methodological limitations identified in the report.	Acknowledged
2	None	
3	No, the evidence base is too limited	Acknowledged

<b>Reviewer</b>	<b>Comment</b>	<b>Response</b>
4	The finding of limitations of current scientific evidence to review and the recommendation for investment in adequately powered trials may affect and push such research trials. This could result in positive results for patient care services.	Acknowledged
5	In order to facilitate health services research in this area I the VA, it would be great to have some procedure codes that could be universally adopted that would capture various CAM approaches.	Thank you for this suggestion. We have added it to our Future Research section.
6	None that I can think of	Acknowledged
<b>Question 5: Please provide any recommendations on how this report can be revised to more directly address or assist implementation needs.</b>		
1	We would like to immediately be able to provide the draft version of this report to our evaluation team from the University of Rochester, who will be designing the evaluation structure of our demonstration projects. Please advise if this is possible, or if not, when the report can be available to them. This work will begin very soon, so this is time sensitive.	Acknowledged
2	None	
3	<p>This is an excellent report and I have only a few suggestions for how to revise it to improve it.</p> <p>1. Page 15. The description of the data synthesis is somewhat difficult to understand, especially the last couple of lines. It may not be to experts in this field however. It would be nice if this could be a little clearer.</p> <p>2. I think it would be very helpful to include the quality ratings on Table 4 as well as a brief sentence or 2 interpreting the important findings in the study rather than relying on the reader either understanding the measurements or referring back to them to understand what the findings mean.</p> <p>3. On page 26, clarify that the study by Echeburua is a study of CBT/coping not of relaxation (if I understand it correctly)</p>	<p>Thank you.</p> <p>We revised the data synthesis section to more clearly describe the standardized mean difference.</p> <p>We added the quality ratings for each study in Table 4. Outcomes are summarized in text. There was not adequate space to summarize the results narratively in the table.</p> <p>Echeburúa and colleagues conducted a comparative effectiveness study of relaxation training (progressive muscle relaxation; PMR) to an intervention that included cognitive behavioral therapy, coping, and PMR. We have updated the description of the study and Table 4 to better describe the two treatment arms.</p>

<b>Reviewer</b>	<b>Comment</b>	<b>Response</b>
3 (Cont'd.)	4. Page 41 last paragraph----why so much discussion about Vujanovic and their thoughts. is there data on mindfulness to support this contention? Does it deserve this much space in this report if no data and only opinion?	We agree. In the final report, we have markedly streamlined this portion of the discussion.
4	None	
5	None	
6	Given the widespread use of CAM across the VA, clinicians, researchers, and administrators may find the report to be useful in helping them understand the evidence base on CAM for PTSD.	Thank you.
<b>Question 6: Please provide us with contact details of any additional individuals/stakeholders who should be made aware of this report.</b>		
1	Dr. Madhu Agarwal, info in VA Outlook	Thank you. We will be sure Dr. Agarwal is made aware of the report.
2	None	
3	None	
4	None	
5	None	
6	None	
<b>Question 7: Please write additional suggestions or comments below. If applicable, please indicate the page and line numbers from the draft report.</b>		
1	p.10, I believe that the number who have deployed in the current conflicts is closer to 2.2 million  Overall, I am not sure why nonscientific “energy therapies” are included with movement based therapies, but since you didn’t find any efficacy, I guess it doesn’t matter.	Thank you for this comment. The report introduction now reflects an estimated 2.2 million deployed.  We included energy therapies and movement therapies within the same category, consistent with NCCAM’s classification system for these modalities.
2	None	
3	I would like to identify some features of this report that are very helpful in understanding this literature synthesis and might be applicable to other ESP reports. These include:  1. Table 1 is excellent and a nice model for our reports. It is very clear.  2. Table 5 is really nice. Very helpful.  3. Table 9 is great! again, an interpretation of the findings might be helpful to the less knowledgeable reader	Thank you!

Reviewer	Comment	Response
4	None	
5	<p>It would be terrific if there could be a parallel review of CAM therapies related to major depression and some of the non-PTSD anxiety disorders. These conditions tend to be comorbid with PTSD as well as share some symptomatology. More importantly, there are many treatments that are identical for these conditions and PTSD (e.g., SSRI's, sleep medications), so it would make sense that some CAM approaches that are successful for these conditions might also be successful for PTSD. Thus, it would be extremely useful to have such a review. In addition to the efficacy results, such a review could also point to methodological considerations as well as touch on patient acceptability.</p> <p>It would be helpful to include a brief description of the AHRQ study quality methods in the text.</p> <p>I would remove the statement on page 4 (and elsewhere in the text) that lower standards of evidence may be applicable when CAM treatments are offered as adjuncts to conventional, evidence-based PTSD therapies. Even in the context of an add-on therapy, it is important to conduct high quality studies.</p> <p>Page 6: It is problematic to omit mention of veterans of previous wars (e.g., Persian Gulf, Vietnam, etc.). Vietnam veterans are by far the most numerous in the VA system, so they and other previous war era veterans should be included in this introductory paragraph.</p> <p>At some point in the paper (perhaps when discussing future research?), it may be a good idea to discuss some of the complexities of PTSD research. These include a variety of traumas (e.g., natural disasters, combat, rape, etc) which may respond differentially to treatments, time since trauma (which may impact on symptom severity), and comorbidity (both psychiatric and medical).</p> <p>Thank you for the opportunity to review this report. I hope these comments will be useful to increase the report's utility.</p>	<p>We thank the reviewer for this suggestion. This supplementary report has already been commissioned, is underway, and should be available in the fall of 2011.</p> <p>A brief description of the AHRQ quality methods is presented in the Methods section under Quality Assessment.</p> <p>We appreciate this reviewer's comment. The Future Research section has been revised substantially and this statement has been omitted from the discussion.</p> <p>Thank you for this suggestion. We have expanded the introductory text to acknowledge Veterans of all service eras.</p> <p>We thank the reviewer for this observation. A full discussion of the complexities of PTSD research was beyond the scope of this report, but we have highlighted some key challenges and referred the reader to more in-depth discussions.</p> <p>Thank you!</p>

Reviewer	Comment	Response
6	<p>The study team did a very careful job in preparing this document. The writing is clear and thorough. However, I feel that the document could be more useful if the authors made several revisions.</p> <p>The approach, which is very strict about inclusion and exclusion, would be a better fit with a literature that was more evolved, in which there were more studies and more definitive studies. With such a small and underdeveloped literature, it would have been informative to include a broader range of studies. Doing so could have influenced the conclusions about what appears to be promising—even if those conclusions were not definitive.</p> <p>The most important example of this concerns the exclusion of studies that used relaxation as a comparison treatment but did not provide an adequate description of the relaxation protocol. At least a couple of these studies (Carlson and Marks) found that relaxation was less effective than treatments recommended in the VA/DoD PTSD practice guideline. The Marks study, which was published in the Archives of General Psychiatry, would be considered to be at least good or better quality. Although the statement about relaxation on p.29 is not very favorable, by not reviewing studies such as Carlson and Marks, it might appear that relaxation is an intervention in need of evaluation. However, its performance in the 3 studies reviewed and these 2 additional studies suggests that it may not have promise. Of course, this conclusion needs to be tempered by the absence of detail about what study participants actually received. However, the information could be presented to readers, with this caveat mentioned.</p> <p>I do not know how the criteria that caused other studies to be excluded might have affected the results. The point is a more inclusive review that extracted more information from the existing literature could provide useful guidance about future directions.</p>	<p>Thank you.</p> <p>The research team understands this observation by the reviewer. However, our conceptual framework was to review settings and subjects similar to the VA and Veterans for ease of implementation if there was strong evidence for a therapy.</p> <p>We have added text to the Limitation section to acknowledge this important point.</p> <p>Acknowledged</p>

Reviewer	Comment	Response
6 (cont.)	<p>I also recommend that the authors revise content in the section on Future Directions (p. 4), and carry these revisions into the more extensive summary on pp. 41-45. Using the p. 4 content as a reference:</p> <ul style="list-style-type: none"> <li>• The first paragraph discusses usual care and no care interventions as if they are the same, when they are not. The inferences drawn from a usual care design are different and stronger than the inferences drawn from a no care design.</li> <li>• The second paragraph suggests that “evidence of benefit from less rigorous trial designs may be sufficient” for CAM treatments for PTSD that are low costs, responsive to patient preferences, and have few adverse effects. There is nothing in the review to support this suggestion. Low cost, low risk intervention that patients like may not be a good use of resources at a system level and could interfere with the delivery of effective care. Except for the patient-centeredness of this suggestion, I do not think it fits with VA’s model of quality care. Furthermore, why would a lower standard of evidence be a good idea in any case?</li> <li>• The third paragraph concludes that medication, acupuncture, relaxation, and mind-body interventions are feasible and acceptable to patients and “may hold promise as adjunctive of monotherapies for PTSD.” Based on the literature review, it is not possible to draw such a broad, if suggestive, conclusion about the benefits of monotherapy and adjunctive therapy for all of these treatments. None of them were tested in both formats. Furthermore, the tone of the conclusion does not fit with the summary of the evidence on p. 29 or the table on pp. 39-40. Findings based on small, primarily poor or fair quality studies (for which the strength of evidence for all treatment/comparator combinations is rated as low or insufficient except for acupuncture), are not an adequate basis for concluding that the interventions tested may be promising. There is only one good-quality study, of acupuncture as monotherapy (although study participants were allowed to use medication and receive supportive therapy).</li> </ul>	<p>The text has been revised to refer to no care (waitlist) controls.</p> <p>The Future Research section has been revised substantially, and the endorsement of lower quality evidence and discussion of costs have been removed.</p> <p>We agree that the conclusions were overly broad. The conclusions have been modified and reflect the concerns raised by this reviewer.</p>

Reviewer	Comment	Response
6 (cont.)	<p>The recommendations for future research should include recommendations about completeness of reporting and fidelity monitoring, both of which are problems in the literature reviewed. Testing CAM interventions as monotherapy versus adjunctive therapies also would be helpful. There could be an argument that CAM as monotherapy should use EBT as a comparator given the strength of data now available for the EBTs.</p> <p>The content on mindfulness on pp. 41-42 seems out of place in a section on limitations. This content is not about the limitations of the report.</p> <p>I recommend that the authors standardize the level of detail provided about different studies. For example, in the section on relaxation (pp. 26-29), F and p-values are reported for the Watson study, p-values are reported for the Vaughn study, and Ms and SDs are reported for the Echeburúa study.</p> <p>I also recommend that the authors try to reduce jargon when possible. Sentences like the 3rd bullet on 0. 29 are difficult to understand.</p>	<p>Recommendations about fidelity monitoring and completeness of outcomes reporting have been specifically addressed in the revised Future Research section.</p> <p>We concur and now omit this content from the limitations section.</p> <p>Thank you for this observation. We have attempted to standardize this section.</p> <p>Thank you for this observation. We have attempted this where possible.</p>

## APPENDIX F. EXCLUDED STUDIES

All studies listed below were reviewed in their full-text version and excluded for the reason indicated. An alphabetical reference list follows the table.

Reference	Population not PTSD	Setting not outpatient, PC, MH, or community	Intervention not eligible CAM treatment	Control or comparator not eligible condition	Location not US/Europe/New Zealand/Australia	Language not English	Not peer reviewed/not primary data
Bob, 2004 (1220)	X						
Branstrom, 2010 (43)	X						
Bryant, 2005 (243)	X						
Cardena, 2000 (732)							X
Carlson, 1998 (259)			X				
Carter, 2006 (402)							X
Descilo, 2010 (357)					X		
Dunn, 2009 (950)	X						
Echeburúa 1997 (260)			X				
Frueh, 2007 (1388)			X				
Gordon, 2004 (313)				X			
Hiley-Young, 1990 (1874)			X				
Kraft, 2010 (490)	X						
Marks, 1998 (258)			X				
Nakamura, 2010 (748)	X						
Peeke, 2002 (483)							X
Salerno, 2005 (1312)		X					
Shore, 2004 (1793)	X						
Short, 2007 (1315)	X						
Spira, 2006 (758)	X						
Stapleton, 2006 (401)			X				
Stapleton, 2007 (1057)			X				
Tacón, 2009 (1137)		X					
Tarrier, 1999 (257)			X				
Taylor, 2003 (425)			X				
Taylor, 2003 (1157)			X				
Trzepacz, 2004 (1056)			X				
Valentine, 2001 (1522)						X	
Waelde, 2008 (954)	X						

## LIST OF EXCLUDED STUDIES

- Bob P. Psychophysiology of hypnotic abreaction. *Homeost Health Dis.* 2004;43(2):109-111.
- Branstrom R, Kvillemo P, Brandberg Y, et al. Self-report mindfulness as a mediator of psychological well-being in a stress reduction intervention for cancer patients--a randomized study. *Ann Behav Med.* 2010;39(2):151-61.
- Bryant RA, Moulds ML, Guthrie RM, et al. The additive benefit of hypnosis and cognitive-behavioral therapy in treating acute stress disorder. *J Consult Clin Psychol.* 2005;73(2):334-40.
- Cardena E. Hypnosis in the treatment of trauma: A promising, but not fully supported, efficacious intervention. *Int J Clin Exp Hypn.* 2000;48(2):225-238.
- Carlson JG, Chemtob CM, Rusnak K, et al. Eye movement desensitization and reprocessing (EDMR) treatment for combat-related posttraumatic stress disorder. *J Trauma Stress.* 1998;11(1):3-24.
- Carter JJ. Evaluation of a multi-component yoga intervention as adjunct to psychiatric treatment for Vietnam veterans with posttraumatic stress disorder (PTSD): A randomized controlled trial (RCT). [controlled-trials.com](http://controlled-trials.com); 2006.
- Descilo T, Vedamurtachar A, Gerbarg PL, et al. Effects of a yoga breath intervention alone and in combination with an exposure therapy for post-traumatic stress disorder and depression in survivors of the 2004 South-East Asia tsunami. *Acta Psychiatr Scand*; 2010:289-300.
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- Frueh BC, Monnier J, Yim E, et al. A randomized trial of telepsychiatry for post-traumatic stress disorder. *J Telemed Telecare.* 2007;13(3):142-147.
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- Nakamura Y, Lipschitz DL, Landward R, et al. Two sessions of sleep-focused mind-body bridging improve self-reported symptoms of sleep and PTSD in veterans: A pilot randomized controlled trial. *J Psychosom Res.* 2010.
- Peeke PM, Frishett S. The role of complementary and alternative therapies in women's mental health. *Primary Care - Clinics in Office Practice.* 2002;29(1):183-197.
- Salerno N. The Use of Hypnosis in the Treatment of Post-traumatic Stress Disorder in a Female Correctional Setting. *Australian Journal of Clinical & Experimental Hypnosis.* 2005;33(1):74-81.
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- Short A. Theme and variations on quietness: Relaxation-focused music and imagery in aged care. *Australian Journal of Music Therapy.* 2007;18:39-61.
- Spira JL, Pyne JM, Wiederhold B, et al. Virtual reality and other experiential therapies for combat-related posttraumatic stress disorder. *Primary Psychiatry.* 2006;13(3):58-64.
- Stapleton JA, Taylor S, Asmundson GJ. Effects of three PTSD treatments on anger and guilt: exposure therapy, eye movement desensitization and reprocessing, and relaxation training. *J Trauma Stress.* 2006(1):19-28.

Stapleton JA, Taylor S, Asmundson GJG. Efficacy of various treatments for PTSD in battered women: Case studies. *J Cogn Psychother.* 2007;21(1):91-102.

Tacón AM, McComb J. Mindful exercise, quality of life, and survival: A mindfulness-based exercise program for women with breast cancer. *The Journal of Alternative and Complementary Medicine.* 2009;15(1):41-46.

Tarrier N, Pilgrim H, Sommerfield C, et al. A randomized trial of cognitive therapy and imaginal exposure in the treatment of chronic posttraumatic stress disorder. *J Consult Clin Psychol.* 1999;67(1):13-8.

Taylor S, Thordarson DS, Maxfield L, et al. Comparative efficacy, speed, and adverse effects of three ptsd treatments: exposure therapy, emdr, and relaxation training. *J Consult Clin Psychol.* 2003(2):330-8.

Taylor S. Outcome Predictors for Three PTSD Treatments: Exposure Therapy, EMDR, and Relaxation Training. *J Cogn Psychother.* 2003;17(2):149-161.

Trzepacz AM, Luiselli JK. Efficacy of Stress Inoculation Training in a Case of Posttraumatic Stress Disorder (PTSD) Secondary to Emergency Gynecological Surgery. *Clinical Case Studies.* 2004;3(1):83-92.

Valentine PV, Smith TE. Evaluating traumatic incident reduction therapy with female inmates: a randomized controlled clinical trial. *Research on Social Work Practice.* 2001;11(1):40-52.

Waelde LC, Uddo M, Marquett R, et al. A pilot study of meditation for mental health workers following Hurricane Katrina. *J Trauma Stress.* 2008;21(5):497-500.

## **APPENDIX G. GLOSSARY**

### **Acupuncture**

A family of procedures involving stimulation of anatomical points on the body by a variety of techniques. American practices of acupuncture incorporate medical traditions from China, Japan, Korea, and other countries. The acupuncture technique that has been most studied scientifically involves penetrating the skin with thin, solid, metallic needles that are manipulated by the hands or by electrical stimulation.

### **Alexander technique**

A movement therapy that uses guidance and education about ways to improve posture and movement. The intent is to teach a person how to use muscles more efficiently in order to improve the overall functioning of the body.

### **Ayurvedic medicine**

A system of medicine that originated in India thousands of years ago. Ayurveda is based on theories of health and illness and on ways to prevent, manage, or treat health problems. A chief aim of Ayurvedic practices is to cleanse the body of substances that can cause disease, and this is believed to help reestablish harmony and balance.

### **Biofeedback**

A technique that uses simple electronic devices to teach clients how to consciously regulate bodily functions, such as breathing, heart rate, and blood pressure, in order to improve overall health. Biofeedback is used to reduce stress, eliminate headaches, recondition injured muscles, control asthmatic attacks, and relieve pain.

### **Chiropractic care**

A type of care that involves the adjustment of the spine and joints to influence the body's nervous system and natural defense mechanisms to alleviate pain and improve general health. It is primarily used to treat back problems, headaches, nerve inflammation, muscle spasms, and other injuries and traumas.

### **Cognitive behavioral therapy (CBT)**

A psychotherapeutic approach that aims to solve problems concerning dysfunctional emotions, behaviors, and cognitions through a goal-oriented, systematic procedure. The term is used in diverse ways to designate behavior therapy, cognitive therapy, or therapy based on a combination of the two.

### **Cognitive processing therapy (CPT)**

A cognitive behavioral therapy for PTSD and related conditions. CPT conceptualizes PTSD as a disorder of "nonrecovery" in which erroneous beliefs about the causes and consequences of traumatic events produce strong negative emotions and prevent accurate processing of the trauma memory and natural emotions emanating from the event.

### **Complementary and alternative medicine (CAM)**

A group of diverse medical and health care systems, practices, and products that are not generally

considered part of conventional medicine. Complementary medicine is used together with conventional medicine, and alternative medicine is used in place of conventional medicine.

### **Energy therapy**

A practice that involves channeling of energy through the hands of a practitioner into the patient's body to restore a normal energy balance and health. It is often used in conjunction with alternative and conventional medical treatments.

### **Eye movement desensitization and reprocessing (EMDR)**

A form of psychotherapy developed to resolve symptoms resulting from disturbing and unresolved life experiences. EMDR uses a structured approach to address past, present, and future aspects of disturbing memories.

### **Exposure therapy**

A type of behavior therapy in which the patient confronts a feared situation, object, thought, or memory. Sometimes exposure therapy involves reliving a traumatic experience in a controlled, therapeutic environment. The goal is to reduce the distress, physical or emotional, felt in certain situations.

### **Feldenkrais**

A movement therapy that uses a method of education in physical coordination and movement. The intent is to help the person become more aware of how the body moves through space and to improve physical functioning.

### **Frontalis muscle tension**

Tension or pain in the muscle tissues that run vertically on the forehead.

### **Guided imagery**

A mind-body approach involving a series of relaxation techniques followed by visualization of detailed images, usually calm and peaceful in nature. If used for treatment, the individual will visualize their body free of the specific problem or condition.

### **Health-related quality of life (HRQOL)**

Aspects of overall quality of life that can be clearly shown to affect health—either physical or mental.

### **Image habituation training (IHT)**

A form of exposure therapy that involves the patient in generating verbal descriptions of the traumatic event and recording these onto an audiotape.

### **Intent-to-treat analysis**

A method of analyzing results of a randomized controlled trial that includes in the analysis all cases that should have received a treatment regimen but for some reason did not. All cases allocated to each arm of the trial are analyzed together as representing that treatment arm, regardless of whether they received or completed the prescribed regimen.

### **Magnet therapy**

An approach that applies a magnetic field to the body for purported health benefits including pain control. Magnets in products such as magnetic patches and disks, shoe insoles, bracelets, and mattress pads are used for pain in the foot, wrist, back, and other parts of the body.

### **Manipulative and body-based practices**

Practices that focus primarily on the structures and systems of the body, including the bones and joints, soft tissues, and circulatory and lymphatic systems. Two commonly used therapies in this category are spinal manipulation and massage therapy.

### **Mantram**

A sound, syllable, word, or group of words used in meditation practice to focus attention and achieve a state of greater calmness, physical relaxation, and psychological balance.

### **Massage therapy**

A practice where therapists manipulate muscle and connective tissue to enhance function of those tissues and promote relaxation and well-being.

### **Mind-body medicine**

Practices that focus on the interactions among the brain, mind, body, and behavior, with the intent to use the mind to affect physical functioning and promote health.

### **Mindfulness-based stress reduction (MBSR)**

A type of meditation with origins in religious and spiritual traditions. Mindfulness meditation focuses attention on breathing to develop increased awareness of the present. The intent is to reduce stress and control emotions in order to improve health.

### **Movement-based therapy**

The psychotherapeutic use of movement to promote emotional, cognitive, physical, and social integration of individuals.

### **Musculoskeletal manipulation**

Manipulation of the bones and joints, soft tissues, and circulatory and lymphatic systems.

### **National Center for Complementary and Alternative Medicine (NCCAM)**

An agency of the NIH dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training CAM researchers; and disseminating authoritative information to the public and professionals.

### **National Institutes of Health (NIH)**

An agency of the U.S. Department of Health and Human Services that is responsible for biomedical and health-related research.

### **Olfactory hypnotherapy**

A technique that uses scents to arouse potent emotional reactions in the patient. During hypnosis, the patient learns to associate pleasant scents with a sense of security and self-control to overcome phobias and prevent panic attacks.

### **Pilates**

A movement therapy that uses a method of physical exercise to strengthen and build control of muscles, especially those used for posture. Awareness of breathing and precise control of movements are integral components of this approach.

### **Posttraumatic stress disorder (PTSD)**

A severe anxiety disorder that can develop after exposure to any event that results in psychological trauma.

### **Progressive relaxation**

A technique used to relieve tension and stress by systematically tensing and relaxing successive muscle groups.

### **Prolonged exposure**

A form of behavior therapy and cognitive behavioral therapy for PTSD characterized by reexperiencing a traumatic event through remembering it and engaging with reminders of the trauma (triggers).

### **Qi gong**

A practice with origins in Chinese philosophy involving gentle physical movement, mental focus, and deep breathing directed toward specific parts of the body.

### **Reflexotherapy**

A treatment method that uses fingers, needles, and magnet applicators to influence biologically active spots on a human body that are situated where nerve terminals and vessels are concentrated.

### **Reiki**

An energy medicine practice that originated in Japan. In Reiki, the practitioner places hands on or near the person receiving treatment, with the intent to transmit “ki,” believed to be life-force energy.

### **Relaxation therapy**

A practice that focuses on using a combination of breathing and muscle relaxation to deal with stress.

### **Rolfing Structural Integration**

A form of deep tissue massage used to realign the tissues that cover and connect all muscles and body organs (fascia). Bringing the body back into proper alignment is thought to reduce pain, improve flexibility and energy, and reduce muscle tension.

### **Sensory arts therapy**

An expressive arts therapy that encourages the patient to express and understand emotions through artistic expression and the creative process.

### **Serotonin norepinephrine reuptake inhibitors (SNRI)**

A class of antidepressant drugs used in the treatment of major depression and other mood disorders. They are sometimes also used to treat anxiety disorders. SNRIs act upon and increase the levels of two neurotransmitters in the brain that are known to play an important part in mood, serotonin and norepinephrine.

### **Serotonin reuptake inhibitor (SSRI)**

A class of medications used to treat psychological conditions including depression and anxiety disorders. SSRIs help increase levels of serotonin in the brain, thus improving mood.

### **Spinal manipulation**

A practice performed by chiropractors and other health care professionals such as physical therapists, osteopaths, and some conventional medical doctors. It involves the use of hands or a device to apply a controlled force to a joint of the spine, moving it beyond its passive range of motion; the amount of force applied depends on the form of manipulation used.

### **Stress inoculation therapy (SIT)**

A cognitive behavioral treatment for PTSD where the goal is to help a patient gain confidence in his or her ability to cope with anxiety and fear stemming from trauma-related reminders. In SIT, the client becomes more aware of reminders for anxiety and fear and learns coping skills that are useful in managing anxiety, such as muscle relaxation and deep breathing.

### **Tai chi**

A mind-body practice, originated in China as a martial art, that involves moving the body in a slow, relaxed, and graceful series of movements. Many practitioners believe that tai chi helps the flow throughout the body of a vital energy called “qi.”

### **Trager Psychophysical Integration**

A movement therapy in which practitioners apply a series of gentle, rhythmic rocking movements to the joints. The intent is to release physical tension and increase the body’s range of motion.

### **Trauma-focused therapy**

A therapy designed to reduce negative emotional and behavioral responses following child sexual abuse and other traumatic events. The treatment addresses distorted beliefs and attributions related to the abuse and provides a supportive environment in which the patient is encouraged to talk about their traumatic experience.

### **Whole medical system**

A complete system of theory and practice that has evolved over time in different cultures and apart from conventional medicine. Examples of whole medical systems include traditional Chinese medicine, Ayurvedic medicine, homeopathy, and naturopathy.

### **Yoga**

A system of physical postures, breathing techniques, and meditation practiced to promote bodily or mental control and well-being.