VETERANS HEALTH ADMINISTRATION
OFFICE OF PATIENT CARE SERVICES
TECHNOLOGY ASSESSMENT PROGRAM

Brief Overview:

Complementary and Alternative Therapies for Post Traumatic Stress Disorder

Prepared by
Elizabeth Adams, MPH

November 2009

TECHNOLOGY ASSESSMENT PROGRAM

An Effective Resource for Evidence-based Managers

VA's Technology Assessment Program (VATAP) is a national program within the Office of Patient Care Services dedicated to advancing evidence-based decision making in VA. VATAP responds to the information needs of senior VA policy makers by carrying out systematic reviews of the medical literature on health care technologies to determine "what works" in health care. "Technologies" may be devices, drugs, procedures, and organizational and supportive systems used in health care. VATAP reports can be used to support better resource management.

VATAP has two categories of products directed toward filling urgent information needs of its VA clients. VATAP assigns a category to each new request based largely on the availability of studies from results of initial searches of peer-reviewed literature databases:

- The ***Short report*** is a self-contained, rapidly-produced qualitative systematic review of between 5 and 20 pages. It provides sufficient background information and clinical context to its subject technology to be accessible to a wide audience, including non-clinician managers.

- The ***Brief overview*** originated as an internal memo to VA clients with both well-defined and urgent information needs. It usually comprises 2 to 10 pages and assumes sufficient existing knowledge regarding clinical context and technology issues by its readers to omit these components of other VATAP products. It often requires some additional reading of documents (provided with the overview for the client) to obtain a full and comprehensive picture of the state of knowledge on the topic.

All VATAP products are reviewed internally by VATAP's physician advisor and key experts in VA. Additional comments and information on this report can be sent to:

VA Technology Assessment Program • Office of Patient Care Services
Boston VA Healthcare System (11T) • 150 S. Huntington Ave. • Boston, MA 02130
Tel. (857) 364-4469 • Fax (857) 364-6587 • vatap@va.gov

A SUMMARY FOR HTA REPORTS
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VATAP is a member of the International Network of Agencies for Health Technology Assessment (INAHTA) [www.inahta.org]. INAHTA developed this checklist© as a quality assurance guide to foster consistency and transparency in the health technology assessment (HTA) process. VATAP added this checklist© to its reports in 2002.

This summary form is intended as an aid for those who want to record the extent to which an HTA report meets the 17 questions presented in the checklist. It is NOT intended as a scorecard to rate the standard of HTA reports – reports may be valid and useful without meeting all of the criteria that have been listed.

Brief Overview:
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for Post Traumatic Stress Disorder
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Item	Yes	Partly	No
Preliminary			
1. Appropriate contact details for further information?	√		
2. Authors identified?	√		
3. Statement regarding conflict of interest?	√		
4. Statement on whether report was externally reviewed?	√		
5. Short summary in non-technical language?			√
Why?			
6. Reference to the question that is addressed and context of the assessment?	√		
7. Scope of the assessment specified?	√		
8. Description of the health technology?	√		
How?			
9. Details on sources of information?	√		
10. Information on selection of material for assessment?	√		
11. Information on basis for interpretation of selected data?	√		
What?			
12. Results of assessment clearly presented?	√		
13. Interpretation of assessment results included?	√		
What Then?			
14. Findings of the assessment discussed?	√		
15. Medico-legal implications considered?			√
16. Conclusions from assessment clearly stated?	√		
17. Suggestions for further actions?	√		

CONTRIBUTORS TO THIS REVIEW

[*]VATAP projects draw on expertise within VA nationally; physical locations provide contact guidance for contributors.

[†]No contributors to this review report conflicts of interest.

VATAP staff person/position	Role	Tasks
Karen Flynn Program Manager Boston	Consultation throughout project	Internal content and format review of draft.
Elizabeth Adams Health System Specialist Boston	Primary author	Conception and conduct of review: • Communication with client; • Interim information; • Analytic framework; • Draft review; • Final review.
Elaine Alligood Information Specialist Boston	Literature database searches	Database searches: • Design strategy; • Choose/manage databases; • Strategy text and bibliography for report; • VATAP library/archive of information resources.
Bernard Spence Administrative Officer Boston	Administrative support	• Budget/resources; • Project tracking.
Sarah Curran Library Technician Boston	Article retrieval	Information retrieval: • Full text from print journals and electronic resources; • Manage reference lists.
Valerie Lawrence Physician Advisor San Antonio	Content and methods review	Final review: • Internal consistency, • Clarity; • Clinical context; • Methods.
VA Complementary and Alternative Medicine Field Advisory Group	Advisory group	• Design strategy; • General draft content review; • Clarity.

ABBREVIATIONS

ACU,	acupuncture treatment
BSI-18,	Brief Symptom Inventory-18
CAM,	complementary and alternative medicine
CAM-FAC,	Complementary and Alternative Field Advisory Committee (VA)
CAPS,	Clinician-Administered PTSD Scale
CBT,	cognitive-behavioral therapy
CI,	confidence interval
d,	Cohen's d
DSM-III (IV),	Diagnostic and Statistical Manual of Mental Disorders, Third (Fourth) Edition
F,	F-statistic
FAC,	Field Advisory Committee
FACIT-SpEx4,	Functional Assessment of Chronic Illness Therapy—Spirituality-Expanded Version 4
HSCL-25	Hopkins Symptom Checklist-25
HTA	Health Technology Assessment
ICD-9 (10),	International Statistical Classification of Diseases and Related Health Problems, 9th (10th) Revision
ITT,	intent-to-treat
IOM,	Institute of Medicine
MAAS,	Mindfulness Attention Awareness Scale
MANOVA,	Multivariate Analysis
NCCAM,	National Center for Complementary and Alternative Medicine
NLM,	National Library of Medicine
OEF	Operation Enduring Freedom
OIF,	Operation Iraqi Freedom
PSS-SR,	Post traumatic Symptom Scale-Self Report
PTSD,	post traumatic stress disorder
Q-LES-Q:SF,	Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form
RCT,	randomized controlled trial
RR,	relative risk
SCI,	Sheehan Disability Inventory
SD,	standard deviation
STAXI-2,	State-Trait Anger Expression Inventory-2
USPTF,	US Preventive Services Task Force
VA,	Veteran Administration
VATAP,	VA's Technology Assessment Program
WLC,	waitlist control

BRIEF OVERVIEW:
Complementary and Alternative Therapies for Post Traumatic Stress Disorder

BACKGROUND

Post Traumatic Stress Disorder (PTSD) is an anxiety disorder triggered by exposure to an extreme traumatic event. PTSD is characterized by persistent reexperiencing of the traumatic event, persistent avoidance of stimuli associated with the trauma, numbing of general responsiveness, and persistent hyperarousal (Diagnostic and Statistical Manual 2000). The most recent National Comorbidity Survey Report, published in 2005, estimated lifetime prevalence of PTSD among adult Americans at 6.8% (Gradus 2009).

Survivors of military combat are among those groups at higher risk for PTSD. Thirteen percent of OEF/OIF Veterans who were new users of VA health care between September 2001 and December 2005 received a diagnosis of PTSD, and the youngest Veterans (age 18 to 24 years) were at greatest risk of receiving one or more mental health and PTSD diagnoses (RR=1.72, 95% CI=1.63 to 1.80) compared with Veterans age 40 years or older (Seal 2003). Therefore, PTSD is an important health issue among Veterans for which the VA offers a continuum of services to address their needs, including early identification and treatment (Gradus 2009).

In 2007, the VA commissioned the Institute of Medicine (IOM) to conduct a qualitative systematic review of the evidence on drug therapies and psychotherapies for PTSD in adults. The IOM concluded that significant knowledge gaps remain regarding the efficacy for most treatments of PTSD (Institute of Medicine 2008). Only exposure therapies were found to effective for treating PTSD. The report further identified important research considerations needed to inform clinical care and made recommendations for future research.

With this report in mind, the VA Complementary and Alternative Field Advisory Committee (CAM-FAC) agreed to address the efficacy of complementary and alternative medicine (CAM) therapies for PTSD to support general guidance for the credentialing and privileging of CAM practitioners in VA. The FAC modeled its guidance process after an earlier VHA Executive Decision Memo that made evidence-based recommendations for the use of acupuncture in the Veteran population. The CAM-FAC asked the VA Technology Assessment Program (VATAP) to provide a systematic review of the evidence to inform this guidance process.

Definition of CAM

The National Center for Complementary and Alternative Medicine (NCCAM) is the federal government's lead scientific research agency on CAM, which they define as follows (NCCAM 2009):

> *"CAM is a group of diverse medical and health care systems, practices, and products that are not generally considered to be part of conventional medicine [as practiced in the United States]."*

NCCAM groups CAM practices into four (sometimes overlapping) domains. These are mind-body medicine, biologically-based practices, manipulative and body-based practices, and energy-based interventions. NCCAM also studies CAM whole medical systems, which cut across all domains. Definitions of the four domains and whole medical systems are as follows:

- Whole Medical Systems are built upon complete systems of theory and practice. Often, these systems have evolved apart from and earlier than the conventional medical approach used in the United States. Examples are homeopathic medicine, naturopathic medicine, traditional Chinese medicine and Ayurveda.
- Mind-Body Therapy uses a variety of techniques designed to enhance the mind's capacity to affect bodily function and symptoms. Some techniques that were considered CAM in the past have become mainstream (eg. patient support groups and cognitive-behavioral therapy). Mind-body techniques that may be considered CAM include meditation, prayer, mental healing, and therapies that use creative outlets such as art, music, or dance.
- Biologically-Based Practices in CAM use substances found in nature, such as herbs, foods, and vitamins. Some examples include dietary supplements and herbal products.
- Manipulative and Body-Based Practices in CAM are based on manipulation i.e. the application of controlled force to a joint and moving it beyond the normal range of motion in an effort to aid in restoring health. Examples include chiropractic or osteopathic manipulation and massage.
- Energy Therapy involves the use of energy fields to heal. The two types are biofield therapies (eg. qi-gong, Reiki and therapeutic touch) and bioelectromagnetic-based field therapies.

METHODS

Refining the scope of the review

Some mainstream psychotherapy interventions, such as cognitive behavioral therapy and patient support therapy, have their origins in CAM. In addition, many manipulative and body-based practices are already provided by licensed and credentialed VA practitioners. Therefore, a critical first step was to identify a comprehensive list of CAM interventions deemed appropriate for inclusion in this report.

Initial scoping searches were conducted in December 2007 to find the range of potential CAM interventions for PTSD found in the literature. To do this, VATAP updated the results of scoping searches for CAM interventions (described in detail in an earlier VATAP report, Adams 2007), with terms and keywords for additional CAM synonyms, related terms in the National Library of Medicine (NLM) thesaurus, Medical Subject Headings, and terms and concepts gathered from searches on Internet search engines. These scoping searches produced 650 unique citations, from which VATAP identified a list of 29 potential CAM interventions. A second round of

searches were carried out employing terms for PTSD and stress disorders crossed with synonyms, text and keyword phrases for the 29 identified CAM modalities.

VATAP then solicited input from the CAM-FAC and national VA mental health experts in PTSD to refine the list of CAM modalities. This report will classify CAM interventions as follows:

- Whole medical systems and CAM practices in mind-body therapy and energy therapy carried out by unlicensed practitioners of CAM.
- Spiritual practices carried out by a CAM practitioner as a medical intervention.

This report will not consider the following as CAM:

- Interventions performed by licensed practitioners of conventional Western (allopathic) medicine, as they are already bound by requirements for state licensure for their health professions and would not be subject to new VA rules for credentialing and privileging of CAM.
- Manipulative and body-based practices that are currently provided by licensed and credentialed practitioners.
- Spiritual practices carried out by a chaplain or traditional healer for the purposes of general spiritual health and well-being.
- Biologically-based practices, as VA does not regulate the use of herbal or dietary supplements for medical care.

Searches

Comprehensive searches were carried out in March 2009, and then updated in September and October 2009 on MEDLINE, EMBASE, and CurrentContents via Dialog Information Services, using a VATAP-created search filter for evidence: RCTs, Clinical Studies, meta-analyses, systematic reviews, and guidelines, combined with extensive strategies for all 29 CAM modalities. The results were in turn combined with two additional strategies containing PTSD terms combined using the Boolean term OR with a second strategy containing combat terms: war, terror, combat, OIF, OEF, torture, deployment, aftermath, consequence, psycho-social, intrusive memory, and outcome/consequences. Searches were limited further to human studies and articles published in English. Hand searching of the end references of retrieved articles was performed by the author (Adams).

Inclusion criteria

The following inclusion criteria were applied:

- CAM interventions (as defined above) carried out by practitioners whose profession does not require state licensure or whose educational programs may not be recognized by the Secretary of the US Department of Education;
- Adult subjects with a clinical diagnosis of PTSD;
- Controlled studies;
- Study size greater than 10 with the diagnosis of PTSD;
- Health Technology Assessment, systematic reviews or Cochrane systematic review reports and protocols of CAM interventions for PTSD;
- The largest or most comprehensive study from the same study group on the same objective (to avoid redundancy);
- Full text published in English.

Grading the evidence
VATAP applied to each study the U.S. Preventive Services Task Force (USPSTF) classification for grading the strength of policy recommendations based on the quality of the evidence. This framework is designed to ensure that the critical appraisal process and final product are, *"…methodologically sound, scientifically defensible, reproducible, and well documented*."(AHRQ 2008). The framework includes:

- Classifying individual studies according to a revised hierarchy of research design;
- Assessing internal validity of individual studies and assigning to one of three categories—"good," "fair," and "poor";
- Assessing external validity and applicability;
- Assessing both the certainty of the evidence about, and the magnitude of, the net benefits of an intervention;
- Assigning a recommendation grade for that intervention.

A detailed description of the USPSTF framework is available at www.ahrq.gov. A modified summary is presented in Appendix 2.

One author (Adams) reviewed the search results, applied inclusion criteria, and abstracted and graded each article included in this report.

RESULTS

The electronic and hand searches yielded a total of 249 citations. Review of title and abstract information identified 47 articles as potentially relevant to the review. Upon retrieval and review of full text, five articles met the inclusion criteria. They are: two empirical studies (Bormann 2008; Hollifield 2007); one systematic review (Jorm 2004); and two Cochrane review protocols (Joyce 2007; Lawrence 2008) (See summary Table 1; abstracted details in Appendix 1).

Table 1. Summary of included studies of CAM for PTSD

Citation	Intervention(s)	Outcome(s)	Findings	USPSTF Grade
Bormann 2008 (RCT)	• Mantram repetition • Delayed treatment control	• PTSD symptoms (self reported & clinical), • Psychological distress • Quality of life • Patient satisfaction	• Large effect sizes found for reducing PTSD self-reported symptom severity (d = -.72), psychological distress (d = -.73) increasing quality of life (d = -.70), and mindfulness (d = .72). • Medium effect sizes found for improving clinician assessed PTSD symptoms (d= -.33), anger expression (d = -.55), and spiritual well-being (d = .67),	**I statement**
Hollifield 2007 (RCT)	• Acupuncture • Group cognitive-behavioral therapy (CBT) • Waitlist control (WLC)	Measures at baseline, end-treatment, and 3 months follow-up • Self-reported PTSD symptoms • Anxiety and depression symptoms • Daily functional impairment	• Compared with the WLC condition in the ITT model, acupuncture provided large treatment effects for PTSD (F [1, 46] = 12.60; p < 0.01; Cohen's d = 1.29), similar in magnitude to group CBT (F [1, 47] = 12.45; p < 0.01; d = 1.42) (ACU vs. CBT, d = 0.29) • Improvements were maintained at	**I statement**

		• Satisfaction	3-month follow-up for acupuncture and CBT groups	
Jorm 2004 (Systematic review)	•Medicines & homeopathic remedies •Physical treatments •Lifestyle •Dietary changes		(Only physical treatments and lifestyle interventions for PTSD reported) • Single RCT shows effectiveness of massage in children but inconclusive in adults • Case series suggest promising results for exercise in adults, RCTs needed • Limited evidence suggests relaxation may lower anxiety symptoms relative to no treatment, but it may be less effective than other behavioral treatments	**I statement**
Joyce 2007 (Cochrane protocol)	Reiki for psychological symptoms		In progress	
Lawrence 2008 (Cochrane protocol)	Sports, games and play-based interventions for PTSD		In progress	

OVERALL CONCLUSIONS

This report was produced to help support the development of guidance for credentialing and privileging of CAM practitioners in VA, based on sound scientific evidence. It considered the best available evidence of effectiveness from controlled studies of CAM for treatment of PTSD in adults. CAM modalities included those not considered mainstream or not administered by already licensed and credentialed practitioners.

A comprehensive systematic review of a range of CAM interventions for anxiety disorders failed to identify conclusive evidence of effectiveness of CAM therapies for treatment of PTSD in adult populations (Jorm 2004). Therefore, the best available evidence found in this VATAP review is limited to two small, but rather well-designed, pilot RCTs, using mantram repetition (Bormann 2008) and acupuncture (Hollifield 2007).

Bormann (2008) found greater improvement in self-reported symptoms (medium to large Cohen's *d* effect sizes 0.40 or higher) in older Veterans using mantram repetition relative to controls, but noted a smaller improvement in clinician-assessed symptoms. Satisfaction with mantram repetition was also high, suggesting it may be a potential treatment alternative for older Veterans. However, the results would need to be confirmed in larger, robust RCTs, especially in populations of younger Veterans with recent combat experience.

Hollifield (2007) found significant improvement (large Cohen's *d* effect sizes .70 or higher) in self-reported symptoms for the use of acupuncture in treating PTSD relative to controls; the effect sizes were similar to that of cognitive behavior therapy and were sustained for at least three months after completion of therapy. Similar improvements in depression symptoms, anxiety symptoms and global impairment scores were also found. Participants were satisfied with both treatment interventions, suggesting a possible role for acupuncture as a treatment

option. However, 83% of the study participants suffered their traumatic events in childhood. Confirmation of these results is needed using other controls, interventions, outcome measures and blinded outcome assessment, as well as in a Veteran population with recent combat experience.

VATAP identified no controlled studies in the published literature (full text in English) for either Cochrane protocol topic (Reiki or sport/ play-based interventions) that met criteria for inclusion.

Given the preliminary nature of the existing evidence and lack of generalizability to a growing Veteran population with recent combat experience in need of treatment for PTSD, VATAP concludes that the current evidence for CAM therapies is insufficient to assess the net benefit of these interventions. Therefore, a USPSTF grade of an (I) statement citing insufficient evidence is warranted (Appendix 2, section 6). If offered, patients should understand the uncertainty about the balance of benefits and harms of these interventions.

APPENDIX 1. ABSTRACTED DETAILS OF INCLUDED STUDIES

Citation	Study details	Outcome measures	Findings
Primary studies			
Bormann 2008	• Design: RCT with pre-post evaluation; • N=33 enrollees recruited from VA PTSD clinical orientation groups and invitees: 4 dropped out prior to enrollment; • Inclusion criteria: Veterans enrolled in VA, assigned a health care provider and diagnosed with PTSD; • Exclusion criteria: Persons with psychotic symptoms, severe suicidality or inability to participate in a group; • Randomized assignment; • Ave age 56 ± 6.57, range 40-76 yrs; • 66% white, 14% black, 10% Hispanic, 10% other; • No significant difference between groups in baseline demographic or outcome variable except years of military service: intervention group=3.9 yrs (SD = 1.81) vs. controls (11.1 yrs (SD = 9.90), with equivalent number of months in combat (ave 11.2 ± 6.99 mo); • Intervention: 6-week (90 min/week) mantram group sessions; • Control: usual medical care with no group sessions; • Research personnel blinded to group assignment.	• Clinician-Administered PTSD Scale (CAPS) (symptom severity); • PTSD Checklist (subjective assessment); • Brief Symptom Inventory-18 (BSI-18) (psychological distress); • State-Trait Anger Expression Inventory-2 (STAXI-2); • Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (Q-LES-Q:SF); • Functional Assessment of Chronic Illness Therapy—Spirituality-Expanded Version 4 (FACIT-SpEx4); • Mindfulness Attention Awareness Scale (MAAS); • Client Satisfaction Questionnaire.	Intervention (N=14); Controls (N= 15) Group comparisons of mean change scores pre-post intervention found that compared to controls, the intervention group showed (Cohen's d): • Large effect sizes on improving PTSD self-reported symptom severity (d = -.72), psychological distress (d = -.73) increasing quality of life (d = -.70), and mindfulness (d = .72); • Medium effect sizes on improving anger expression (d = -.55), and spiritual well-being (d = .67); • Small effect size (d = -.33) on improving clinician assessed PTSD symptoms. Additional findings: 86% of participants rated program with moderate to high satisfaction. Conclusion: Mantram is a promising, complementary intervention for treatment of PTSD in older Veterans, and Veterans were satisfied with the program. Further research in larger RCTs is warranted. Caution: Results cannot be generalized to newer OEF/OIF Veterans. Research targeted to this population is needed.
Hollifield 2007	• Design: RCT; • Sample N=90 based on power calculations: Power=0.88 with α=0.05, effect size Cohen's d=0.80, n=25 per group ; • Enrolled between March 2003 and April 2004; • Recruitment source=community, clinicians; • Inclusion criteria: DSM-IV diagnosis of PTSD, commitment to accept randomization, no active substance abuse or psychosis, no current active treatment for PTSD; • Computerized randomization; • Interventions: acupuncture (needling without electrical stimulation one hour twice per week for 12 weeks), group CBT (two hours per week for 12 weeks);	• Change in self-reported measures from baseline, midtreatment, end treatment, and at one-month and three-month follow up; • Primary measure=Posttraumatic Symptom Scale-Self Report (PSS-SR); • Secondary measures= o Hopkins Symptom Checklist-25 (HSCL-25) (for anxiety and depression); o Sheehan Disability Inventory (SCI) (for impairment in daily life; o Satisfaction scale and retention rates for measures of treatment	PTSD (PSS-SR): • Compared with the WLC condition in the ITT model, acupuncture provided large treatment effects for PTSD (F [1, 46] = 12.60; p < 0.01; Cohen's d = 1.29), similar in magnitude to group CBT (F [1, 47] = 12.45; p < 0.01; d = 1.42) (ACU vs. CBT, p = 0.29); • Symptom reductions at end treatment were maintained at 3-month follow-up for both interventions; • Results using treatment completion model were consistent with ITT model; • Treatment effects for acupuncture were similar in magnitude to CBT(p = 0.29). Depression, anxiety, impairment and satisfaction • Treatment effects from baseline to end treatment for acupuncture

Citation	Study details	Outcome measures	Findings
	• Control: waitlist condition (WLC); • Repeated measures MANOVA was used to detect predicted Group X Time effects in both intent-to-treat (ITT) and treatment completion models at $p < .05$; • 84 were randomized, 73 began study, 61 completed treatment or waitlist assessments, 60 obtained end treatment and 58 obtained 3-month follow up; • No statistically significant differences between assigned groups with respect to gender, age, marital status or education, but there was a statistically significant difference between groups by ethnicity (X^2 [6]=14.65, p=0.02); • 83% participants suffered traumatic events in childhood.	satisfaction.	vs. WLC for depression (*d's* = 0.83 vs. 0.12, respectively, $p <$ 0.01), anxiety (*d's* = 1.28 vs. 0.19, respectively, $p < 0.01$), global impairment scores (*d's* = 0.75 vs. 0.04, respectively, $p = 0.01$), were significant; • Effects from baseline to end treatment for CBT vs. WLC for depression (*d's* = 1.08 vs. 0.12, respectively, $p < 0.01$), anxiety (*d's* = 1.28 vs. 0.19, respectively, $p < 0.01$), global impairment scores (*d's* = 0.76 vs. 0.04, respectively, $p < 0.01$), were significant; • Symptom reductions at end treatment were maintained at 3-month follow-up for both interventions; • Results using treatment completion model were consistent with ITT model; • Treatment effects for acupuncture were similar in magnitude to CBT; • Acupuncture and CBT patients expressed similar high satisfaction with their care ($p = 0.11$). Conclusion: *"Acupuncture may be efficacious for reducing symptoms of PTSD, depression, anxiety, and impairment in people diagnosed with DSM-IV PTSD."* Caution: Multisite replication of the trial with additional control groups, multiple therapists, treatment validation procedures, and blinded outcome assessment are warranted, as are confirmation of these results in a Veteran population with recent combat exposure.
Systematic reviews and protocols			
Jorm 2004	• Systematic review of the effectiveness of CAM and self-help treatments for anxiety disorders; • Searches of PubMed, PsycLit, and Cochrane Library through April 29, 2003; • Included were all study types of subjects with an anxiety disorder or a high level of anxiety symptoms; • Australian National Health and Medical Research Council levels of evidence applied; • Homeopathic medicines and remedies, physical treatments, lifestyle interventions, and dietary changes were included.	Varied	Only CAM interventions for PTSD reported here: Massage/touch therapy: "Some evidence for effectiveness with PTSD in children, but no convincing evidence for adults or on other anxiety disorders." Report identified some evidence from at least one properly designed RCT for effectiveness for generalized anxiety with acupuncture, autogenic training, exercise, meditation, music and relaxation. More evidence on specific anxiety disorders such as PTSD is needed.
Lawrence 2008 Cochrane protocol	• Sports, games and play-based interventions for PTSD and general physical health, mental health and social functioning; • Protocol to include RCTs, cross-over trials, cluster randomized trials and factorial trials of subjects age 5 or older with DSM-IV PTSD. Interventions include organized activities done alone or with a group, competitive and non-	• PTSD diagnostic status; • Self- or observer- reported PTSD symptoms; • Diagnostic status or self-report of symptoms of anxiety and/or depression; • Global assessment of functioning including quality of life and physical	In progress.

Citation	Study details	Outcome measures	Findings
	competitive sports and games compared with usual care, pharmacologics, or psychosocial interventions.	and social functioning.	
Joyce 2007 Cochrane protocol	• Reiki treatment for psychological symptoms; • Protocol to include all RCT and quasi-RCT published or unpublished with subjects age 16-65 suffering from anxiety or depressive disorders according to DSM-III, DSM-IV, ICD-9 and ICD-10 criteria, as well as selected symptomatology scales. Intervention includes any type of Reiki performed by a trained Usui initiated Reiki practitioner. Control interventions include none or placebo, sham Reiki, standard/usual care, waitlist, pharmacologics, herbals, psychological therapies, exercise therapy, other.	• Measurable symptom relief using validated scales; • Quality-of-life, self reported perceived stress, drop-out rates, side effects and treatment acceptability.	In progress.

APPENDIX 2. SUMMARY OF US PREVENTIVE SERVICES TASK FORCE PROCEDURE MANUAL

1. Classify individual studies according to a hierarchy of research design.

I:	Properly powered and conducted RCT; well-conducted systematic review or meta-analysis of homogeneous RCTs
II-1:	Well-designed controlled trial without randomization
II-2:	Well-designed cohort or case-control analytic study
II-3:	Multiple time series with or without the intervention; dramatic results from uncontrolled experiments
III:	Opinions of respected authorities, based on clinical experience; descriptive studies or case reports; reports of expert committees

2. Assess internal validity of individual studies and assignment to one of three categories—"good," "fair," and "poor"

Good	Meets all internal validity criteria: comparable groups are assembled initially and maintained throughout the study (follow up at least 80%); reliable and valid measurement instruments are used and applied equally to the groups; interventions are spelled out clearly; all important outcomes are considered; and appropriate attention to confounders in analysis. For RCTs, intention to treat analysis is used.
Fair	If any or all of the following problems occur, without fatal flaws noted in the "poor" category below: generally comparable groups are assembled initially, but some question remains whether some (although not major) differences occurred with follow-up; measurement instruments are acceptable (although not the best) and generally applied equally; some, but not all, important outcomes are considered; and some, but not all, potential confounders are accounted for. Intention to treat analysis is done for RCTs.
Poor	If any of the following fatal flaws exists: groups assembled initially are not close to being comparable or maintained throughout the study; unreliable or invalid measurement instruments are used or not applied at all equally among groups (including not masking outcome assessment); and key confounders are given little or not attention. For RCTs, intention to treat analysis is lacking.

3. Global rating of external validity

Good	The study differs minimally from the Veteran population, and only in ways that are unlikely to affect the outcome; it is highly probable (>90%) that the clinical experience with the intervention observed in the study will be attained in the Veteran setting.
Fair	The study differs from the Veteran population in a few ways that have the potential to affect the outcome in a clinically important way; it is only moderately probably (50%-89%) that the clinical experience with the intervention in the study will be attained in the Veteran setting.
Poor	The study differs from the Veteran population in many ways that have a high likelihood of affecting the clinical outcomes; the probability is low (<50%) that the clinical experience with the intervention observed in the study will be attained in the Veteran setting.

4. Levels of certainty regarding net benefit

Level of certainty	Description
High	The available evidence usually includes consistent results from well-designed, well-conducted studies in representative Veteran populations. These studies assess the effects of the intervention on health outcomes. This conclusion is therefore unlikely to be strongly affected by the results of future studies.
Moderate	The available evidence is sufficient to determine the effects of the intervention on health outcomes, but confidence in the estimate is constrained by factors such as: o the number, size, or quality of individual studies o inconsistency of findings across individual studies o limited generalizability of findings to the Veteran population, or o lack of coherence in the chain of evidence. As more information becomes available, the magnitude or direction of the observed effect could change, and this change may be large enough to alter the conclusion.
Low	The available evidence is insufficient to assess effects on health outcomes. Evidence is insufficient because of; o the limited number or size of studies o important flaws in study design or methods o inconsistency of findings across individual studies o gaps in the chain of evidence o findings not generalizable to routine VA care, or o a lack of information on important health outcomes. More information may allow an estimation of effects on health outcomes.

5. Putting it all together: Assigning a recommendation grade for that intervention

Certainty of Net Benefit	Magnitude of Net Benefit			
	Substantial	**Moderate**	**Small**	**Zero/Negative**
High	A	B	C	D
Moderate	B	B	C	D
Low	Insufficient (I)			

6. Defining USPSTF grades and suggestions for practice

Grade	Grade definitions	Suggestions for Practice
A	…recommends the intervention. There is high certainty that the net benefit is substantial.	Offer/provide this intervention.
B	…recommends the intervention. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this intervention.
C	…recommends against routinely providing the intervention. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this intervention only if there are other considerations in support of offering/providing the intervention in an individual patient.
D	…recommends against the intervention. There is moderate or high certainty that the intervention has no net benefit or that the harms outweigh the benefits.	Discourage the use of this intervention.
I statement	…concludes that the current evidence is insufficient to assess the net benefit of the intervention. Evidence is lacking, of poor quality or conflicting, and the balance of benefits and harms cannot be determined.	If offered, patients should understand the uncertainty about the balance of benefits and harms.

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VA Technology Assessment Program
Office of Patient Care Services (11T)
VA Boston Healthcare System
150 South Huntington Avenue
Boston, MA 02130

Tel: 857.364.4469 Fax: 857.364.6587
vatap@med.va.gov
http://www.va.gov/vatap http://vaww.va.gov/vatap

Author: Elizabeth Adams, MPH
Health System Specialist,
VA Technology Assessment Program

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