Complementary and Alternative Treatments for Late-Life Depression, Anxiety, and Sleep Disturbance: A Review of Randomized Controlled Trials

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Objective: We reviewed randomized controlled trials of complementary and alternative medicine (CAM) treatments for depression, anxiety, and sleep disturbance in nondemented older adults.

Data sources: We searched PubMed (1966–September 2006) and PsycINFO (1984–September 2006) databases using combinations of terms including *depression*, *anxiety*, and *sleep*; *older adult*/*elderly*; *randomized controlled trial*; and a list of 56 terms related to CAM.

Study selection: Of the 855 studies identified by database searches, 29 met our inclusion criteria: sample size ≥ 30, treatment duration ≥ 2 weeks, and publication in English. Four additional articles from manual bibliography searches met inclusion criteria, totaling 33 studies.

Data extraction: We reviewed identified articles for methodological quality using a modified Scale for Assessing Scientific Quality of Investigations (SASQI). We categorized a study as positive if the CAM therapy proved significantly more effective than an inactive control (or as effective as active control) on at least 1 primary psychological outcome. Positive and negative studies were compared on the following characteristics: CAM treatment category, symptom(s) assessed, country where the study was conducted, sample size, treatment duration, and mean sample age.

Data synthesis: 67% of the 33 studies reviewed were positive. Positive studies had lower SASQI scores for methodology than negative studies. Mind-body and body-based therapies had somewhat higher rates of positive results than energy- or biologically-based therapies.

Conclusions: Most studies had substantial methodological limitations. A few well-conducted studies suggested therapeutic potential for certain CAM interventions in older adults (e.g., mind-body interventions for sleep disturbances and acupressure for sleep and anxiety). More rigorous research is needed, and suggestions for future research are summarized.

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The use of unconventional medical practices in the United States is widespread and continues to grow, exceeding a prevalence of 60% in a nationally representative survey conducted by the National Center for Health Statistics in 2002.[1] Often labeled as *complementary and alternative medicine* (*CAM*), these practices encompass a diverse range of therapies and techniques but have in common a general lack of acceptance and/or use in traditional medical settings. The historical lack of rigorous scientific study of CAM significantly impedes its incorporation into mainstream medicine. Nonetheless, the public health issues raised by its increasing use and the desire to identify its potentially valid therapeutic elements have spurred interest in CAM-related research.

Although national surveys indicate that CAM use is greater in younger than in older age groups,[2] many elderly people also use CAM therapies.[3–5] Older adults in particular often use spiritual health practices (e.g., prayer) and vitamin supplements.[1,6] Yet, even excluding prayer and megavitamins, Barnes and colleagues[1] found that 33% of U.S. adults in their sixties had used CAM within the preceding year. Other studies have identified ethnic and geographic subpopulations of older adults that may use CAM even more frequently.[7,8] Cohort effects also likely influence differences in CAM use, such that aging baby boomers may continue to incorporate CAM into their healthcare practices.

CAM use in older adults presents several important and unique issues. CAM therapies are usually tried

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concurrently with conventional medical treatments, although often without the knowledge of conventional practitioners.[5,9] In 2000, 6% of older Americans were taking both an herbal remedy and a prescription drug.[5] Because older Americans frequently take multiple prescription drugs, and given evidence that some CAM treatments can adversely interact with prescription medications,[10,11] CAM use among older adults may pose important safety risks.[12] Additionally, age-related differences in health beliefs and declining cognitive abilities could influence the effects of CAM mind-body interventions on older adults. Despite recent increases in CAM research, studies with older adults are still relatively scarce.

The motivations for CAM use are varied and multidetermined. Both younger and older individuals often cite chronic pain and psychological distress (including insomnia, depression, and anxiety) as reasons for using CAM.[2,13] Unfortunately, depressive and anxiety symptoms affect large numbers of older adults—as many as half of institutionalized elderly persons.[14,15] Likewise, nearly half of older adults report sleep difficulties.[16] Some older adults, who view mental illnesses and psychotropic medications as stigmatizing, may be more receptive to CAM therapies because they prefer "natural" treatments that can be self-initiated without divulging embarrassing symptoms.

CAM treatments for dementia-related symptoms in older adults have been previously reviewed,[17] as have CAM therapies for anxiety and depression among general adult populations.[18,19] We could not find any review of CAM for psychological symptoms in nondemented older adults. Notably, 85% or more of older adults are cognitively intact,[20] and their use of CAM to treat psychological symptoms is likely to increase. We reviewed randomized controlled trials (RCTs) of CAM treatments for cognitively intact older adults with depression, anxiety, and/or sleep disturbance. We limited the review to studies of at least moderate sample size and trial duration, systematically assessed each study's quality, and sought to identify study characteristics associated with positive versus negative outcomes.

METHOD

Data Sources

We searched PubMed (1966–September 2006) and PsycINFO (1984–September 2006) databases using multiple combinations of the following search terms: (Group A) *complementary medicine*, *alternative medicine*, *massage*, *reflexology*, *aromatherapy*, *music therapy*, *art therapy*, *dance therapy*, *pet therapy*, *yoga*, *Tai Chi*/*taiqi*, *qigong*, *meditation*, *relaxation*, *hypnosis*, *biofeedback*, *mindfulness*, *acupuncture*, *acupressure*, *herbal*, *supplements*, *vitamin*, *folate*, *B12*, *s-adenosylmethionine*, *tryptophan*, *ginseng*, *garlic*, *ginkgo*, *hypericum*, *St. John's wort*, *valerian*, *kava*, *soy*, *melatonin*, *omega-3 fatty acid*, *ginger*, *huperzine*, *Choto san*, *black cohosh*, *light therapy*, *magnet*, *polarity therapy*, *spiritual healing*, *prayer*, *reiki*, *therapeutic touch*, *Snoezelen*, *chiropract**, *osteopath**, *homeopath**, *naturopath**, *Ayurved**, *traditional Chinese medicine*, *curander**, and *chelation;* and (Group B) *mood*, *depression*, *anxiety*, *sleep*, and *insomnia*. Additionally, we performed PubMed searches with and without the following search limits: age 65 or older, English, and randomized controlled trial. We combined each term from group A with each term from group B. We selected the terms in Group A after reviewing the National Center for Complementary and Alternative Medicine (NCCAM) website (www.nccam.nih.gov) and the Institute of Medicine report on CAM.[21] Additional articles for consideration were identified via manual review of the references in articles retrieved from the database searches.

Study Selection

This review included RCTs that met the following criteria: (1) prospective design ≥ 2 weeks in duration; (2) mean participant age ≥ 60 years; (3) sample size ≥ 30 (approximate median sample size of studies identified); (4) at least 1 primary outcome measure assessing mood, depression, anxiety, sleep, or some combination of these; (5) no primary diagnosis of dementia or cognitive disorder among participants; (6) availability in English; and (7) inclusion of participants other than "healthy" or "normal" adults (i.e., not prevention trials). Six RCTs of CAM treatments among asymptomatic, healthy older adults that assessed changes in mood, anxiety, and sleep were excluded.[22–27] Although not necessarily described or designed as such, these appeared to be more prevention than treatment trials; notably, all 6 had negative results.

While cognitive disorders and their associated neuropsychiatric symptoms are prevalent among older adults, we deemed the efficacy of CAM in this group to be a different issue beyond the scope of this review. We also did not include studies testing cognitive-behavioral therapy (CBT), including those that incorporated relaxation techniques as a component of CBT, or studies of repetitive transcranial magnetic stimulation (rTMS). Although CBT and rTMS are sometimes listed among CAM treatments, we believed these treatments are sufficiently evidence-based and accepted in conventional medical settings to be excluded from this review.

Data Extraction

The heterogeneity of study outcomes, populations sampled, and therapies implemented precluded combining data for meta-analysis. In order to evaluate the methodology of the individual studies, we adopted a modified version of the newly developed Scale for Assessing Scientific Quality of Investigations (SASQI) (Table 1). This 19-item scale (score range, 0–20) was derived from an

Table 1. Scale for Assessing Scientific Quality of Investigations-Complementary and Alternative Medicine Version (SASQI-CAM)[a,b]

Item	Criterion	Scoring
	Research Design	
1	Were there clearly stated a priori hypotheses?	0,1
2	Was the sampling procedure adequately described?	0,1
3	Was the method used to generate the sequence of randomization described (eg, random numbers table or computer-generated list of random numbers)?	0,1
4	Was randomization successful in eliminating significant differences between groups (eg, demographics, baseline outcome measures)? If not, were randomization failures controlled for in data analysis? (Yes on either = 1)	0,1
5	Were subjects adequately blinded to treatment assignment (by use of a credible placebo/active control, sham treatment, or psychosocial control)? (Yes = 2) If *not*, did the comparison group involve an active intervention (ie, other than waiting list or treatment as usual)? (Yes = 1, No = 0)	0,1,2
6	Were subjects' expectations of benefits from a given treatment, attitudes toward treatment assignment, or sense of the treatment's credibility assessed?	0,1
	Experimental Treatment Condition	
7	Was the active treatment standardized for all participants (eg, was a reproducible protocol described or the source of a biological compound listed)?	0,1
8	Was the fidelity of the treatment intervention assessed (eg, assessing therapist adherence to treatment protocol or assays of biological substances to ensure equivalence among doses administered)?	0,1
9	Was treatment adherence assessed and factored into data interpretation if rates differed significantly between groups?	0,1
10	Were side effects/adverse events monitored and reported?	0,1
	Subjects and Measures	
11	Were the inclusion and exclusion criteria described clearly?	0,1
12	Were inclusion/exclusion criteria standardized so as to make them reliably reproducible?	0,1
13	Were the number of dropouts and their reasons for leaving described?	0,1
14	Were outcome measures appropriate to assess the hypotheses and well validated?	0,1
15	Were outcomes obtained from independent assessors blinded to treatment assignment?	0,1
	Statistical Analysis	
15	Was there appropriate statistical analysis?	0,1
16	Did analysis attempt to control for possible confounding variables?	0,1
17	Were type I and/or type II errors adjusted for?	0,1
	Discussion	
18	Did the data justify the conclusions?	0,1
19	Were the limitations of the study discussed?	0,1
	Total Score	0 to 20

[a]Adapted with permission from Jeste et al.[28]
[b]Yes = 1 and No = 0, unless otherwise indicated.

article by Jeste et al.[28] Several items were adapted or added for this review, based on expert suggestions for improving the quality of CAM research.[29,30] For example, the difficulties in CAM research of masking group assignment and employing appropriate control conditions prompted expanded items to differentiate studies on these methodological issues. Other new items evaluated studies according to treatment standardization, assessments of treatment credibility, and reporting of adverse effects.

We categorized CAM therapies based on NCCAM's organizational scheme,[31] recognizing that these categories are imperfect and overlapping. For instance, traditional Chinese medicine is considered an "alternative medical system," but incorporates aspects of biological therapies (herbs), energy medicine (external qigong), mind-body medicine (Tai Chi), and body-based treatments (acupressure). Nonetheless, these categories help organize this complex array of treatment modalities into groups that share putative therapeutic elements and common methodological challenges.

The first author (T.W.M.) independently rated all 33 studies using the SASQI. Ten articles were randomly selected via computer-generated numbers for evaluation on the SASQI by a second author (J.L.W.), who was blinded to the first author's ratings. We rated studies as "positive" if the study authors reported that the experimental CAM intervention yielded significantly ($p < .05$) better outcomes than the control group (or outcomes statistically equivalent to an evidence-based active control) on at least 1 primary outcome measure related to sleep, depression, or anxiety.

Data Analysis

Interrater reliability for the 10 SASQI scores rated by 2 authors was determined by calculating the intraclass correlation, which was 0.94.

RESULTS

We identified 885 studies via database searches, of which 29 met our inclusion criteria. Additionally, 4 eligible studies were identified from manual bibliography searches, yielding a total of 33 studies for review (Table 2).[32–64] Numerous studies related to CAM and

Table 2. Summary of Reviewed Complementary and Alternative Medicine (CAM) Studies

No.	Reference (year)	Population Sample; Country (N)	Mean Age, y	CAM Therapy	Treatment Protocol	Control/Comparison Group(s)
Mind-body treatments						
1	Manjunath and Telles[32] (2005)	Institutionalized adults aged 60+ y; India (N = 69)	71	Yoga; Ayurvedic medicine	75 min/d (?group)[a] 6 d/wk × 6 mo; 10 g Rasayana Kalpa bid (combination of 5 herbs)	Wait list
2	DeBerry[33] (1982)	Older women (aged 63–79 y) with various psychological symptoms; United States (N = 36)	…	Meditation/relaxation	30-min groups weekly × 10 wk (+/– encouraged daily home practice)	Discussion group
3	DeBerry et al[34] (1989)	Adults aged 65–75 y with various psychological symptoms; United States (N = 32)	69	Meditation/relaxation	45-min groups 2 times/wk × 10 wk	Cognitive restructuring/ assertiveness training group; discussion group
4	Lichstein et al[35] (2001)	Community-dwelling older adults with insomnia; United States (N = 74)	68	Relaxation therapy	45-min individual sessions weekly × 6 wk	Sleep compression training groups; placebo desensitization groups
5	Rybarczyk et al[36] (2002)	Adults aged 55+ y with multiple medical illnesses and insomnia; United States (N = 38)	68	Home-based audiotape relaxation treatment (HART)	7 tapes with relaxation, imagery, and nature sounds 30 min each night; guidebook; 2 times/wk staff 5-min phone calls × 6 wk	CBT groups; wait list
6	Pallesen et al[37] (2003)	Adults aged 60+ y with insomnia; Norway (N = 55)	70	Relaxation therapy (RT)	30 min individual training weekly × 4 wk	Stimulus control training; wait list
7	Hanser and Thompson[38] (1994)	Older adults with previously diagnosed major or minor depression; United States (N = 30)	68	Music therapy (MT) (therapist vs self-administered)	30–60 min individualized music daily × 8 wk with either 1-h weekly therapist visits or 20-min weekly phone contacts	Wait list
8	Pacchetti et al[39] (2000)	Outpatients with Parkinson's disease; Italy (N = 32)	63	Music therapy	2-h group weekly × 13 wk	"Traditional" physical therapy (PT)
9	Lai and Good[40] (2005)	Older adults with sleep complaints; Taiwan (N = 60)	67	Music therapy	1 of 6 self-selected audiotapes for 45 min nightly × 3 wk	TAU
10	Tsang et al[41] (2003)	Medically ill geriatric day hospital patients; Hong Kong (N = 50)	75	Qigong exercise	1-h practice (?group)[a] 2 times/wk × 12 wk	"Routine" rehabilitation (TAU)
11	Li et al[42] (2004)	Community-dwelling adults aged 60+ y with sleep complaints; United States (N = 118)	75	Tai Chi (Yang style)	1-h group 3 times/wk × 24 wk	Stretching exercise group
12	Tsang et al[43] (2006)	Adults aged 65+ y with chronic medical illness and depressive symptoms; Hong Kong (N = 82)	82	Qigong exercise	30–45 min (?group)[a] 3 times/wk × 16 wk	"Newspaper reading" group
Biologically-based treatments						
13	Elsabagh et al[44] (2005)	Postmenopausal women aged 51–67 y; Britain (N = 44)	61	Ginkgo biloba	Extract LI1370 (25% flavonoids, 6% terpenoids) 120 mg qd × 6 wk	Placebo pill
14	Hvas et al[45] (2004)	Adults with increased methylmalonic acid; Denmark (N = 140)	75	Vitamin B12	1-mg intramuscular injection weekly × 4 wk	Placebo injection
15	Garfinkel et al[46] (1999)	Community-dwelling older adults on BDZ therapy for insomnia; Israel (N = 34)	69	Melatonin	2 mg CR 2 h before bedtime × 6 wk (during self-directed BDZ taper of 50% week 2, 75% weeks 3–4, and stopped weeks 5–6)	Placebo pill
16	Cardinali et al[47] (2002)	Older adults taking BDZs; Argentina (N = 45)	71	Melatonin	3 mg IR at bedtime × 6 wk (during BDZ taper to 50% at day 14 and stopped at day 28)	Placebo pill
17	Baskett et al[48] (2003)	Adults aged 65+ y: 1/2 normal, 1/2 problem sleepers; New Zealand (N = 40)	72	Melatonin	5 mg IR at bedtime × 4 wk (crossover design with 4-wk washout intervals)	Placebo pill
18	Dowling et al[49] (2005)	Adults aged 40–80 y with Parkinson's disease and sleep disturbances; United States (N = 40)	62	Melatonin	5 mg IR 30 min before bedtime × 2 wk *and* 50 mg IR 30 min before bedtime × 2 wk (crossover design with 1-wk washout intervals)	Placebo pill
19	Harrer et al[50] (1999)	Adults aged 60–80 y with ICD mild-to-moderate depressive disorder; Germany (N = 149)	69	St. John's wort	400 mg LoHyp-57 extract bid × 6 wk	Fluoxetine 10 mg bid

Outcome Measures	Results	SASQI Score	Comments
"Sleep questionnaire"	Positive (yoga > other 2 groups)	6	Total "dose" of yoga quite high and possibly impractical for widespread use; no control for group effect; inadequately validated outcome measure
SDS, STAI	Positive (anxiety only)	6	Insufficient blinding; inadequate descriptions of instructor training; diffuse array of psychological symptoms with ambiguous inclusion/exclusion criteria
STAI, BDI	Positive (trait anxiety only): meditation > both controls	6	Limitations similar to above study by same author; no clear rationale for exclusion of "major affective disorder"; compliance may have had influence (attendance rates 100% for meditation and 65% for control group)
IIS, DBAS, FSS, ESS, PSG	Negative: relaxation = placebo groups	17	Thorough baseline comparisons/screening; unusually healthy sample; assessment for treatment delivery standards and for patient expectations of benefits between groups; use of sleep hygiene in control group may be an effective intervention itself
DBAS, PSQI, sleep logs, actigraphy	Positive: HART = CBT and both > wait list	11	Improvements seen on subjective outcomes only; suboptimal blinding and control groups; dropouts had poorer sleep measures than those retained; CBT protocol had multiple components, including some relaxation techniques; guidebook provided to HART group contained some CBT material (ie, cross-contamination between groups)
Sleep log, sleep impairment index	Positive: RT = stimulus control and both > wait list	9	Including subjects with affective and anxiety disorders increases external but decreases internal validity; use of relaxation tape was "as needed"; included evaluation of clinical significance in outcomes
GDS, POMS	Positive: MT (both versions) > wait list	7	Inadequate control group; incorporated relaxation and imagery techniques into music therapy; individualization of music but protocol used for selecting music; variability in duration of daily music therapy; improvements maintained at 9 mo
Happiness measure	Positive: MT > PT	7	Control had minimal interpersonal interactions to control for nonspecific group effect; uncommon mood measure; no description of music therapist; intervention involved "improvisation," so difficult to replicate precisely; mood improvement paralleled improvement in bradykinesia
PSQI	Positive: MT > TAU	12	Insufficient control condition and blinding; examined some relevant covariables (eg, depression, exercise); reasonable inclusion/exclusion criteria; some pretest differences in 2 PSQI subscales between groups
GDS	Negative: qigong = TAU	5	Inadequate control group; authors concluded positive findings based on changes in less validated scale devised for this study; on average participants not substantially depressed at baseline; inadequate randomization for gender between groups
PSQI, ESS	Positive: Tai chi > control	15	Clear inclusion/exclusion criteria; enrolled only inactive persons; relatively high "dose" of intervention; blinding of assessments not clearly described; reasonable control group; overall good methodology/design
GDS (15-item)	Positive: qigong > control	9	Larger version of 2003 trial above, now requiring baseline depression symptoms and with slightly improved control group, this time yielding positive results; despite requiring depression at baseline, average GDS scores were below self-described threshold for significant depression
HADS, ESS	Negative: ginkgo = placebo	11	Lower end of dose range; later menopause stage may have lessened climacteric mood/anxiety symptoms; no report of adverse events
MDI	Negative: B12 = placebo	13	Shorter duration of treatment but outcome measured at 3 mo (rationale unclear); lesser known depression measure; low depression scores at baseline
Numerical sleep quality (1–10) and self-report BDZ discontinuation	Positive: melatonin > placebo	8	Self-report of BDZ taper less reliable than administering pills and measuring pill counts or testing urine samples; no guarantee of BDZ dose equivalency between groups (only that they had similar "numbers of pills"); baseline psychiatric diagnosis not reported
VAS sleep scales and sleep logs	Negative: melatonin = placebo	6	Poorly defined inclusion/exclusion criteria (eg, excluded "organic or psychiatric disorders" but did not describe how these were identified nor why subjects were taking BDZs); heterogeneous types of BDZ and dose equivalency not reported between groups
LSQ, actigraphy	Negative: melatonin = placebo	14	No discussion of where melatonin was obtained/assurance of standardization; controlled for some confounds (eg, caffeine and alcohol intake, medications); systematic assessment of adverse effects; well-defined exclusion criteria
PSQI, ESS, GSDS, SSS, actigraphy	Positive: melatonin 50 mg > placebo for TST; 5 mg > placebo for GSDS and 2 subscales	14	Melatonin compounded at primary site, increasing standardization; clear inclusion/exclusion criteria; controlled for medication confounds; minimal description of adverse effects; excluded sleep apnea and periodic limb movement sleep disorder (common in Parkinson's disease)
SDS, HAM-D-17, CGI	Positive: St. John's wort = fluoxetine	11	Multi-center trial with relatively large sample size; systematic side effect reporting; authors' assertions of superiority of St. John's wort over SSRIs in tolerability and drug interactions not supported by their own study; no discussion of dosing considerations in older adults compared to younger adults

(continued)

Table 2 (continued). Summary of Reviewed Complementary and Alternative Medicine (CAM) Studies

No.	Reference (year)	Population Sample; Country (N)	Mean Age, y	CAM Therapy	Treatment Protocol	Control/Comparison Group(s)
Biologically-based treatments (cont.)						
20	Yang et al[51] (2005)	Older adults with dyssomnia; China (N = 121)	71	Traditional Chinese medicine (TCM)	Complex mixtures of 11, 15, or 20 Chinese botanicals daily × 15 d (specific mixture determined by TCM diagnosis)	Estazolam 1–2 mg daily at bedtime
21	Kok et al[52] (2005)	Postmenopausal women aged 60–75 y; Holland (N = 202)	67	Soy protein	25.6 g (52 mg genistein + 41 mg daidzein + 6 mg glycitein) qd × 1 y	Milk protein
Energy-based medicine						
22	Lee et al[53] (2001)	Older adults with chronic pain; Korea (N = 40)	73	External qigong therapy	10 min "quiet rest" + 10 min qi therapy + repeated 10 min "quiet rest" 2 times/wk × 2 wk	"Standard care" (TAU)
23	Yang et al[54] (2005)	Adults in independent-living communities with chronic pain; Korea (N = 43)	73	External qigong therapy	5 min "rest" + 20 min qi therapy + 5 min "rest" 2 times/wk × 4 wk	"Standard care" (TAU)
24	Palmer et al[55] (2003)	Older adults with self-reported symptoms of advanced sleep phase syndrome; United States (N = 47)	70	Light therapy	265 lux in the evening for 2–3 h before bedtime at 36" distance daily × 4 wk	Dim (< 2 lux) red light with same parameters otherwise
25	Kirisoglu and Guilleminault[56] (2004)	Adults aged 60+ y with chronic sleep-onset insomnia; United States (N = 30)	65	Bright light therapy	10,000 lux for 45 min in the morning at 30" distance daily × 60 d	10,000 lux for 20 min daily but otherwise with same parameters
26	Loving et al[57] (2005a)	Adults aged 60–79 y with significant unipolar depressive symptoms; United States (N = 81)	68	Bright white light therapy	8500 lux for 1 h in morning or evening at 18" distance daily × 4 wk	Dim (< 10 lux) red light with same parameters otherwise
27	Loving et al[58] (2005b)	Adults aged 60–79 y with significant unipolar depressive symptoms; United States (N = 33)	68	Bright green light therapy	1200 lux for 1 h in the morning at 24" distance daily × 4 wk	Dim (< 10 lux) red light with same parameters otherwise
28	Li et al[59] (1994)	Adults with a TCM diagnosis of "post–wind stroke depression"; China (N = 101)	63	Xingnao-Jieyo ("mind-refreshing antidepressive") acupuncture (XJA)	Specified meridians for 30 min daily × 45 d	Routine acupuncture (RAP); doxepin 25 mg bid or tid + RAP
29	Rorsman and Johansson[60] (2006)	Adults with subacute stroke; Sweden (N = 54)	76	Electroacupuncture (EA); TENS	EA = 30 min 2 times/wk × 10 wk at 2 Hz with amplitude to cause muscle contraction (over 9–10 acupoints); TENS = identical parameters to EA	"Sham" TENS (80 Hz at 0.4 mA), below sensory threshold
30	Suen et al[61] (2002)	Adults aged 60+ y in elder hostels with actigraphy-confirmed sleep disturbance; Hong Kong (N = 120)	82	Auricular treatment (AuT)	Magnetic pearls applied to 7 auricular points × 3 wk (duration of each session and frequency of sessions unspecified)	"Inactive" AuT with Junci Medulla (soft dried stem); "inactive" AuT with Semen Vaccariae (seed similar in diameter to the pearls)
Body-based/manipulative treatments						
31	Soden et al[62] (2004)	Adults with cancer in palliative care facilities; Britain (N = 42)	73[b]	Aromatherapy massage (ATM); massage alone	ATM = 30-min back massage with lavender oil weekly × 4 wk; massage alone = 30-min back massage with inert oil weekly × 4 wk	TAU
32	Chen et al[63] (1999)	Institutionalized adults aged 60+ y with sleep disturbances; Taiwan (N = 84)	79	Acupressure (AP)	15 min over head, neck, and hands 5 d/wk × 3 wk;	"Sham" acupressure (using points 1 cm away from true acupoints); conversation control
33	Wu et al[64] (2004)	Older adults with COPD and symptomatic dyspnea; Taiwan (N = 44)	73	Acupressure	16 min 5 times/wk × 4 wk	"Sham acupuncture" (using meridians not considered therapeutic for this illness)

[a](?group) = the study in question did not make clear whether their intervention was delivered individually or in groups.
[b]Median age reported in article rather than mean.
Abbreviations: BDI = Beck Depression Inventory, BDZ = benzodiazepine, bid = twice a day, CBT = cognitive-behavioral therapy, CES-D = Center for Epidemiological Studies-Depression Scale, CGI = Clinical Global Impressions scale, COPD = chronic obstructive pulmonary disease, CPRS-Dep = Comprehensive Psychiatric Rating Scale-Depression, CR = controlled release, DBAS = Dysfunctional Beliefs and Attitudes about Sleep scale, ESS = Epworth Sleepiness Scale, FSS = Fatigue Severity Scale, GDS = Geriatric Depression Scale, GSDS = General Sleep Disturbance Scale, HADS = Hospital Anxiety and Depression Scale, HAM-A = Hamilton Rating Scale for Anxiety, HAM-D-17 = 17-item Hamilton Rating Scale for Depression, ICD = *International Classification of Diseases*, IIS = Insomnia Impact Scale, IR = immediate release,

Outcome Measures	Results	SASQI Score	Comments
SDRS, HAM-A	Positive: TCM = estazolam	8	Not blinded, and possible cultural beliefs or experience of taking herbal concoction could alter outcome expectancies; combined Western concept of dyssomnia with TCM diagnosis to decide TCM regimen; statistics poorly described
GDS	Negative: soy = milk protein	16	Lengthy follow-up with large sample; accounted for several confounds (eg, food intake); no report of adverse effects; older age may lower baseline climacteric symptoms; baseline depression scores were relatively low
POMS (depressed and anxiety subscales)	Positive: external qigong > TAU	6	Inadequate control group; duration of chronic pain unspecified; no mention of baseline psychiatric illness or analgesic/psychotropic use; decrease in pain intensity in active treatment
POMS (depressed and anxiety subscales)	Positive: external qigong > TAU	9	Similar in many ways to above study by same investigators; differences include explicitly defined duration of chronic pain (3 mo) and higher "dose" of treatment (longer duration of treatment sessions and longer duration of trial)
GDS, sleep log, actigraphy	Negative: bright = dim light	11	Systematic diagnosis of advanced sleep phase syndrome lacking; hypotheses include active treatment improving depressed mood but low depression scores at enrollment and depression not part of inclusion criteria; good assessment of compliance and expectancy measure (similar between groups)
SDQ, VAS fatigue, ESS, sleep logs, actigraphy	Positive: 45 min > 20 min light therapy for SL, TST, and fatigue	10	Benefits maintained at 3- and 6-mo follow-up; admit some patients "question if 20 min was long enough" (inadequate blinding); assert no clinical depression in sample but no procedure to screen for this; both groups included sleep hygiene instructions, which may be beneficial alone
GDS, HAM-D-17, sleep log, actigraphy	Negative: bright white = dim red light	15	Established threshold of depression severity for entry; excluded those with high natural light exposure; used partial sleep deprivation in all subjects on initial night of trial (with poor compliance rates); systematic assessment for adverse effects; innovative assessment of expectancy differences between active treatment and placebo; trend for better response in those *not* taking antidepressant during trial
GDS, HAM-D-17, sleep log, actigraphy	Negative: bright green = dim red light	14	Many strengths/weaknesses similar to above study; adequacy of control assessed by expectancy measures; 30/33 patients had major depressive disorder on SCID; not clearly described that outcome assessments were blinded
CES-D (modified)	Positive: XJA = doxepin + RAP > RAP alone	5	Use of TCM diagnosis for inclusion makes results more authentic but also difficult to apply to Western medicine; little detail about treatment providers, standardization of treatments, statistical design, or duration of treatment; dosing of doxepin is relatively low; control with no acupuncture intervention might have been more informative
HADS, CPRS-Dep	Negative: EA = TENS = sham TENS	13	Excluded known psychiatric diagnoses; standardized EA protocol; psychotropics allowed during trial (possible confound); included expectancy measures of outcomes (which favored TENS at baseline); blinding imperfect as "sham" TENS delivered no detectable sensation
Unspecified sleep questionnaire, sleep log, actigraphy	Positive: AuT > both controls	12	Rationale for treatment protocol given; standardization of magnetic strength and interpractitioner reliability; asserted subjects blinded to treatment but not well described; duration and frequency of treatment sessions not well described; comprehensive inclusion/exclusion criteria but methods for making diagnoses not described; unclear age was equivalent among groups and age was a predictor of outcome measures in regression analysis
HADS, VSH	Positive: massage > ATM and TAU for depression; ATM and massage combined > TAU for sleep	8	Therapist training and standardization of treatments insufficiently described; some baseline differences between groups (failed randomization); control group inadequate; negative for aromatherapy component of treatment (ie, added nothing to massage)
PSQI	Positive: AP > both controls	12	Not clear sham acupressure subjects adequately blinded; inadequate detail on blinding of outcome assessments; subjects matched at randomization on use of naps, exercise, and hypnotics; good assessments of treatment standardization
STAI	Positive: AP > sham AP	12	No description of therapist training; clear inclusion/exclusion criteria; matched at randomization on several variables (eg, age, pulmonary function, steroid use); very standardized protocol; inadequately described blinding

Abbreviations continued: LSQ = Leeds Sleep Questionnaire, MDI = Major Depression Inventory, POMS = Profile of Mood States, PSG = polysomnography, PSQI = Pittsburgh Sleep Quality Index, qd = daily, SASQI = Scale for Assessing Scientific Quality of Investigations, SCID = Structured Clinical Interview for DSM-IV-TR, SDQ = Sleep Disorders Questionnaire, SDRS = Sleep Dysfunction Rating Scale, SDS = Zung Self-Rating Depression Scale, SL = sleep latency, SSRIs = selective serotonin reuptake inhibitors, SSS = Stanford Sleepiness Scale, STAI = Spielberger State-Trait Anxiety Inventory, TAU = treatment as usual, TENS = transcutaneous electrical nerve stimulation, tid = 3 times a day, TST = total sleep time, VAS = visual analogue scale, VSH = Verran and Snyder-Halpern Sleep Scale.
Symbol: … = unknown.

psychological symptoms in older adults were identified that did not meet inclusion criteria, with the most common reasons being lack of prospective randomized controlled design, inadequate sample size, and inclusion of participants with known cognitive impairments.

The studies included had several limitations that merit mention and restrict what conclusions can be drawn about these treatments. Sample sizes remained generally small enough to engender significant risks of type II errors. This may be especially true of studies that enrolled less symptomatic participants. Very few studies used systematic psychiatric diagnoses, and many even failed to specify symptom thresholds for inclusion. Dropouts were generally poorly accounted for, and few studies implemented intent-to-treat data analysis. Many studies failed to provide enough details about inclusion/exclusion criteria and/or treatment protocols to allow for reliable replication. Despite the frequent assertion that CAM interventions are superior to conventional treatments in tolerability, assessments of adherence and side effects were overall poor. Additionally, while financial conflicts of interest are increasingly contentious in conventional medical studies, this was seldom addressed in the studies reviewed (only 5 studies explicitly addressed this), although this could be equally problematic in CAM research. Lastly, control conditions had significant limitations, including several trials with wait-list or treatment as usual groups. Controlling for additional time and attention given to subjects in active treatment as well as for participant expectations when receiving a concrete treatment (e.g., by using a support group or mock intervention) helps substantially to separate the therapeutic effects of the experimental treatment from these other nonspecific factors.

The mean SASQI score of the studies was 10.3 (SD = 3.5). The studies ranged in sample size from 30 to 202 (mean = 67), in duration from 2 to 52 weeks (mean = 8.5), and in average participant age from 61 to 82 years (mean = 70.5 years). Only one third of the studies were conducted in the United States, with the rest coming from Europe (24%), Asia (33%), or elsewhere (9%). The most common CAM treatments studied were mind-body interventions (36.4%), followed by biologically-based (27.3%), energy-based (27.3%), and body-based/manipulative treatments (9.1%). Many of the studies examined more than 1 type of symptom domain (e.g., depression and anxiety). The proportions of trials targeting specific symptoms were as follows: depression alone, 33.3% (11/33); anxiety alone, 3.0% (1/33); sleep disturbance alone, 45.5% (15/33); depression and anxiety, 15.2% (5/33); and depression, anxiety, and sleep disturbance, 3.0% (1/33).

Twenty-two (67%) of the studies were rated as positive. Comparisons of the positive and negative studies are summarized in Table 3; statistical comparisons were not computed due to the small number of studies and lack of power to detect differences. The mean SASQI for negative studies was notably higher than that for positive studies. Also of interest, 91% (10/11) of Asian studies were positive, compared to 55% (12/22) of studies from other regions. Studies primarily targeting sleep disturbances were positive in 77% (13/17) of cases, while 59% (10/17) of those targeting depression and/or anxiety were positive. The prevalence of positive studies according to CAM type varied considerably: mind-body (83%, 10/12), biologically-based (44%, 4/9), energy-based (56%, 5/9), and body-based/manipulative (100%, 3/3). Negative studies tended to have slightly higher sample sizes and treatment durations than positive studies, but their mean participant age was very similar to that of positive studies.

Table 3. Comparisons Between Positive (22) and Negative (11) CAM Studies

Characteristic	Positive Studies Mean (SD)	Negative Studies Mean (SD)
Sample size	63.6 (36.5)	73.6 (52.0)
Age, y	70.7 (5.6)	70.1 (4.4)
Treatment duration, wk	7.7 (6.4)	10.2 (14.1)
SASQI-CAM score	9.2 (2.8)	12.3 (3.8)
	No. (%)	No. (%)
CAM category		
Mind-body	10 (45.5)	2 (18.2)
Biologically-based	4 (18.2)	5 (45.5)
Energy-based	5 (22.7)	4 (36.4)
Body-based	3 (13.6)	0 (0)
Location where conducted		
United States	7 (31.8)	4 (36.4)
Asia	10 (45.5)	1 (9.1)
Europe	4 (18.2)	4 (36.4)
Other	1 (4.5)	2 (18.2)
Target symptom		
Depression and/or anxiety	10 (45.5)[a]	7 (63.6)
Sleep disturbance	13 (59.1)[a]	4 (36.4)

[a]One positive study included all 3 symptom domains as primary outcomes; this study is represented in both marked figures, causing the proportions to add to greater than 100%.
Abbreviations: CAM = complementary and alternative medicine, SASQI-CAM = Scale for Assessing Scientific Quality of Investigations-CAM Version.

DISCUSSION

To our knowledge, this is the first systematic review of randomized controlled trials employing CAM for symptoms of depression, anxiety, and sleep disturbance among older adults without dementia. Of the 33 RCTs reviewed, two thirds were positive. The average SASQI score for included studies indicated generally modest methodological quality, as has historically been true in CAM research. Yet, the studies reviewed, by virtue of being RCTs and having sample sizes of 30 or more, were informative and worthy of examination. Strengths of this review include the use of a quantitative assessment of study quality, the

inclusion of only randomized controlled studies, and an exploration of study attributes that were associated with positive versus negative treatment outcomes.

Nonetheless, our review methodology had several limitations. Although we attempted to be exhaustive in our literature search, the volume of search results and long list of possible CAM therapies both increased the likelihood that we overlooked a publication that would have met entry criteria. Reviewing non-English publications was not feasible, but not doing so may have omitted certain studies. The definition of CAM is dynamic and subject to debate, necessitating a subjective judgment regarding the inclusion or exclusion of treatments in this broad category. Although we did not include studies that clearly enrolled persons with dementia, not all of the studies systematically excluded cognitively impaired participants. The reliability and validity of the SASQI has not been empirically evaluated, and SASQI ratings for this review cannot be considered completely impartial. Evaluating methodology and outcomes from such a diverse array of therapies makes comparisons less reliable and precludes meta-analysis, but we attempted to use SASQI items that could generalize across all CAM trials.

In spite of these methodological limitations, some general observations are possible. The higher methodological quality of negative studies was an interesting finding. This does not dismiss all positive results, however, as indeed some rigorously conducted studies yielded promising results for certain CAM therapies. Nonetheless, it draws attention to the need for careful assessment of study design before accepting the reported results. The high rate of positive studies from Asia could result from several factors: a lower SASQI score compared to American and European studies (8.7 vs. 11.1), stronger cultural expectations for CAM benefits in Asian researchers and participants, the type of CAM studied in Asia (i.e., relatively few biologically-based therapies), or better implementation of CAM therapies in cultures in which these originated.

Mind-body interventions proved effective in 10 out of 12 studies reviewed. As in younger adults,[65] these therapies appear to have promise for alleviating late-life insomnia. The Tai Chi study for sleep disturbance by Li et al.[42] was among the best in methodological quality and yielded notably positive results. A recent review of 26 controlled trials in general adult samples described relaxation therapies as generally effective for anxiety[19]; however, none of the mind-body studies we reviewed focused primarily on anxiety disorders among older adults. Mind-body studies assessing depressive symptoms were often hampered by inadequate methodology, including unclear symptom thresholds and diagnostic inclusion criteria. All 3 studies of music therapy were positive, but all had inadequate control conditions.

Controlled trials of biologically-based CAM treatments (e.g., herbs, supplements) for mental disorders are not abundant, but they are especially scarce among older adults. For instance, there is at least modest evidence for the efficacy of treatments such as St. John's wort, s-adenosylmethionine (SAM-e), and omega-3 fatty acids for depression in younger adults.[66–68] However, only one similar trial was found in older adults, a positive German study of moderate methodological quality using St. John's wort for depression.[50] The most common biological therapy reviewed was melatonin for sleep disturbance, which yielded inconsistent results. Overall, less than half of biologically-based treatment trials were positive.

Eastern treatments based on energy manipulation, such as external qigong therapy, are particularly removed from mainstream Western medicine. Although 2 studies of external qigong in this review reported positive effects on depressed mood in older adults with pain,[53,54] both studies had a SASQI score below the review's mean. Acupuncture is likewise based on concepts of manipulating bodily energy (qi) and has gained increasing acceptance for uses such as pain and nausea control.[69] A meta-analysis of 5 RCTs of acupuncture for depression in general adult samples revealed acupuncture to be equivalent to antidepressants, though caution was noted about insufficient methodology.[70] From our review, one RCT using acupuncture in older adults with stroke was negative for improving mood among minimally symptomatic participants, while another was positive for depression but fraught with methodological limitations. Another energy treatment some may no longer consider "alternative" is the use of visible light waves for treatment of circadian sleep disturbances and seasonal affective disorder.[71,72] Light therapy appeared ineffective, however, in 2 trials for late-life depression.[57,58]

The final category of CAM treatments, body-based/manipulative, had only 3 studies—all positive. Chiropractic care, a commonly employed manipulative therapy, has received little attention for mental disorders. However, massage, including acupressure massage, has been tried for psychological symptoms, especially among older or medically ill populations. All 3 trials of massage were positive (for a mixture of depression, sleep, anxiety symptoms); more rigorous studies are needed, but the acupressure trials were promising and above average in methodological quality (relative to other trials in this review).

Further study of CAM therapies among older adults with psychological symptoms is warranted but would benefit from improved methodology. CAM trials are challenging because of theoretical differences with evidence-based Western medicine, emphasis on treatment individualization and wellness, and difficulty choosing appropriate control groups. Factors related to aging, such as concomitant medications and illnesses as well as cognitive decline, also introduce some challenging confounds. Nonetheless, implementation of the criteria

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outlined in the SASQI-CAM (Table 1) would serve as a useful starting point. Additional considerations include (1) examination of mediating variables such as cognition and health beliefs, (2) use of flexible yet reproducible protocols (e.g., "toolbox approaches") when treatment individualization is a core component of the CAM therapy, (3) use of systematic psychiatric diagnoses and clear symptom thresholds in inclusion criteria, and (4) clear delineation of financial support and possible conflicts of interest.

CONCLUSIONS

Several factors argue for further study of CAM, including its widespread popularity, the potential for tapping unrealized therapeutic resources, the inability of current conventional treatments to substantially improve quality of life in many chronic illnesses, and the need for culturally competent medical care. Some CAM advocates may feel that imposing Western standards of evaluation on CAM is unnecessary, inappropriate, or culturally biased. We feel that systematic research with innovative methodologies created by both conventional and CAM researchers is crucial to reaping any widespread benefits that CAM therapies may offer and to preventing harm or deception that may come from well-intentioned or purely opportunistic CAM practices. Studies of CAM among older adults with mental disorders will be particularly important. U.S. demographic patterns are changing, and cohorts with high rates of CAM use are growing older. The number of older adults with mental illnesses is also increasing exponentially,[73] and depression, anxiety, and insomnia are likely to remain among the most prominent reasons that older adults use CAM.

Drug names: doxepin (Sinequan and others), fluoxetine (Prozac and others).

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