Supplemental Table 2. Summary of U.S. randomized controlled trials examining the use of complementary health approaches for Fibromyalgia[a].

Complementary approach	Study	Participants	Methods	Interventions	Primary Measures	Primary Outcomes	Conclusion
Biofeedback	Buckelew et al.[64], 1998	59 adults with diagnosed FM according to Yunus' criteria for diagnosis. Age: 44.1 (Biofeedback), 44.3 (Attention Control); Duration of symptoms: 11.6 (Biofeedback), 10.0 (CTR); % Female: 96.6 (Biofeedback), 90.0 (Attention Control). Baseline: Tender Pt. Ind: 1.5 (Biofeedback), 1.6 (CTR); Myalgic: 20.0 (Biofeedback), 15.7 (Attention Control); Disease severity: 5.7 (Bio), 5.0 (Attention Control); VAS: 5.8 (Biofeedback), 6.3 (Attention Control); Pain : 5.0 (Biofeedback), 4.0 (Attention Control); Phys activity: 6.0 (Biofeedback), 4.0 (Attention Control); Global severity: 69.0 (Biofeedback), 72.5 (Attention Control); CES-D: 16.0 (Biofeedback), 15.0 (Attention Control); Self efficacy function: 74.4 (Biofeedback), 48.0 (Attention Control); self-efficacy pain: 55.0	Biofeedback vs. Attention Control.	Biofeedback vs. Attention Control. 6-week individual training (once/week for 90-180 min.) then 2-year group maintenance (once/month for 1 hour). Assessments taken posttreatment, 3-month, 1-year, and 2-year follow-ups.	TPI; Myalgic score; Physician rating of disease severity; VAS (pain); Pain behavior observation; AIMS, SCL-90-R; CES-D; ASES; 4 4-point questions on sleep (falling asleep, waking tired, waking frequently, sleeping poorly)	The biofeedback group saw significant improvement in the TPI verses the attention control. No other group differences were seen. No mention of adverse events.	Supports use

		(Biofeedback), 50.0 (Attention Control); Self-efficacy other: 55.0 (Biofeedback), 50.0 (Attention Control); Sleep: 7.0 (Biofeedback), 4.0 (Attention Control)					
Acupuncture	Assefi et al.[65], 2005	100 persons diagnosed with FM; average age=47; had pain for about 10 years; 95% female; 93% white; Average VAS baseline scores: 7.0 cm for pain intensity, 7.7 cm for fatigue intensity, 3.3 cm for sleep quality, and 4.0 cm for overall well-being.	RCT of acupuncture compared to sham acupuncture	Acupuncture designed to treat FM or 1 of 3 sham acupuncture treatments. Treatment sessions were twice weekly for 12 weeks (24 treatments)	Pain VAS; Fatigue VAS; sleep quality VAS; overall well-being VAS;	Directed acupuncture for FM was no better than sham acupuncture at relieving pain. No significance influence of treatment was found on any of the outcomes. Minor adverse events reported by 89 participants.	Does not support use
Acupuncture	Harris et al.[66], 2005	114 persons diagnosed with FM for at least 1 year and reported widespread pain on more than 50% of days; 8 male and 106 female; Mean age: 46.0 (T/S), 44.5 (T/O), 51.3 (N/S), 48.1 (N/O); years of diagnosis: 5.50 (T/S), 5.26 (T/O), 5.17 (N/S), 5.77 (N/O); Week 0 mean pain scores: 55.38; fatigue: 16.60; function: 36.12	2 X 2 factorial design. Four intervention arms: (1) traditional site with deep invasive stimulation (T/S), (2) traditional site without stimulation (T/O), (3) nontraditional site with stimulation	Investigation of needle placement, needle stimulation, and treatment frequency in acupuncture for fibromyalgia (each group received treatment once weekly for 3 weeks, then twice weekly for 3 weeks, then 3	Clinically meaningful change in Pain NRS (either 20-point reduction or 30% improvement from baseline); physical functioning (SF-36); fatigue (MFI)	No significant differences between any groups were seen. However, 25-35% of subjects had clinically significant decrease in pain independent of needle stimulation or location. No serious adverse events reported.	Does not support use

			(N/S), (4) nontraditional site with no stimulation (N/O)	times weekly for 3 weeks (18 total sessions)			
Acupuncture	Harris et al.[67], 2009	20 persons with diagnosed FM; all female; mean age = 44.3; 19 Caucasian, 1 African American; Duration with fibromyalgia: 7.85 (TA), 5.45 (SA); Baseline SF-MPQ total: 14.3 (TA), 16.6 (SA)	Traditional acupuncture (n=10) or non-skin penetrating sham acupuncture (n=10)	Traditional versus sham acupuncture. All participants received 9 treatments.	SF-MPQ	There were no statistically significant differences in pain between TA and SA (p>0.50). Both traditional and sham acupuncture resulted in clinically meaningful reductions in pain (TA: -4.00(6.72); SA: -2.90(8.33)). No mention of adverse events.	Does not support use
Acupuncture	Martin et al.[68], 2006	50 persons with diagnosed FM; 49 female, 1 male; mean age: 47.9, acupuncture group; 51.7, control group; all but 1 Caucasian. Baseline FIQ total: 42.4 (AC), 44.0 (Sham); baseline MPI pain severity: 40.4 (AC), 43.0 (Sham)	Real electoacupuncture (25 participants) vs. sham electroacupuncture (25 participants)	Real electoacupuncture vs. sham electroacupuncture. Patients received treatments every 2 to 4 days during 2 to 3 weeks for a total of 6 sessions.	FIQ[6] total; MPI[7]	FIQ showed significant improvement in the acupuncture group over control acupuncture during study period (p=0.01) with greatest difference at 1 month (p=0.007). Significant group effect for fatigue (P=0.001) and anxiety (P=0.003) at 1 month, but effect was lost at 7 months (P=0.05). MPI group effect showed significant improvement in pain at 1 month (P=0.03) but not at 7 months (P=0.05). Acupuncture treatments were well tolerated with vasovagal symptoms being	Supports use

						the most troubling (reported by 2 patients).	
Biofeedback	Nelson et al.[69], 2010	34 persons with diagnosed FM; 33 female/1 male; mean age=51.8; 88.2% non-Hispanic White; months since diagnosis: 159.1 (LENS); 100.2 (Sham); Months since symptoms onset: 206.2 (LENS), 223.5 (sham); Baseline: FIQ: 44.7 (LENS), 39.25 (Sham)	Low Energy Neurofeedback System (LENS), a variant of biofeedback vs. Placebo where no EM stimulation was administered	LENS vs. sham	FIQ,	There were no significant group differences. However, both groups exhibited significant decreases in the FIQ from pre- to immediate post-treatment, but were not maintained at 6 month follow-up. The trial monitored adverse events and reported that none were seen.	Does not support use
Meditation	Cash et al.[70], 2015	90 females diagnosed with FM; Baseline: PSS (MBSR: 22.0; CTR: 21.4); VAS (MBSR: 68.1; CTR: 69.2); SSQ (MBSR: 9.0; CTR: 9.4); FSI (MBSR: 6.1; CTR: 6.1); FIQ symp (MBSR: 67.5, CTR: 62.5); FIQ phys funct (MBSR: 1.3; CTR: 1.2)	Mindfulness-Based Stress Reduction (MBSR) (51 participants) vs. Waitlist (39 participants)	MBSR group met weekly for 2.5 hour sessions over 8 weeks	PSS (stress), VAS (pain), SSQ (sleep), FSI (fatigue), FIQ (symptom severity), FIQ (physical functioning); cortisol profiles.	MBSR[10] significantly reduced perceived stress (p=.000), sleep disturbance (p=.038), and symptom severity (p=.012), with gains maintained at follow-up. MBSR[10] did not significantly alter pain, physical functioning, or cortisol profiles. No mention of adverse events.	Supports use
Meditation	Hsu et al.[71], 2010	45 women with diagnosed FM; mean age=50.1; 12.7 years since pain onset; Baseline: BPI pain severity: 6.18 (ASA), 5.04 (WL)	Affective Self-awareness (ASA) vs. waitlist	90 min indiv., then 3 group sessions (2 hr) over 4 weeks (groups of 8-12) plus assigned home activities	BPI pain severity	ASA group showed significantly lower pain severity at both post treatment (p=.03) and follow-up (p=<.001) versus the control. No mention of adverse events.	Supports use

Meditation and Qi gong	Astin et al.[72], 2003	128 adults with diagnosed FM; 127 female; 4.7% 18-29, 19.5% 30-39, 25% 40-49, 40.6% 50-59, 10.2% 60+; 87.5% Caucasian, 10.9% black, 1.6% Other race; No. comorbidities: 2.09; time since diagnosis: 5.06; Baseline: FIQ: 57.8 (MBSR), 58.7 (control); Total Myalgic Score: 17.9 (MBSR), 16.8 (control); MOS SF-36: 32.3 (MBSR), 31.4 (control); 6 min walk: 1314 (MB), 1323 (control); Beck dep inv: 16.7 (MBSR), 17.2 (control)	Combined MBSR and Tai Chi (Mind-body intervention) vs. education/support control group	Mind-body Intervention consisted of mindfulness meditation and Qi gong.	FIQ, Total Myalgic Score, SF-36; 6 min. walk; BDI	No significant between-group differences on any study outcomes. No mention of adverse events.	Does not support use
Guided Imagery	Menzies et al.[73], 2014	64 women with diagnosed FM; mean age=46.9; Race: 30% black, 64% Caucasian, 5% multiple races, 1% Other; Ethnicity: 6% Hispanic, 94% Non-Hispanic; Time since diagnosis: 8.4%; BMI: 30.0. Baseline: OSE: 47.9 (GI), 49.0 (UC); PSS: 21.0 (GI), 21.4 (UC); BFI: 6.2 (GI), 6.0 (UC); BPI severity: 5.3 (GI), 4.7 (UC); BPI interference: 5.5 (GI), 5.3 (UC); CES-D: 23.1 (GI), 22.4 (UC)	Guided imagery vs. usual care control	Guided imagery participants listened to audio-recorded scripts in 2-week increments in order for the first 6 weeks, then used tracks in any order for weeks 7 through 10.	ASES (PSE and OSE); PSS; BFI (fatigue); BPI (severity and interference); CES-D; immune biomarkers.	GI group change from baseline to 10 weeks was significantly different from the UC group change for OSE (p=.02); PSS (p=.05); BFI (p=<0.01); BPI severity (p=<0.01), and CES-D (p=.02). There was no significant difference between GI and UC for BPI interference at 10 weeks and all measures at 6 weeks except BPI severity (p=.03). After 10 weeks of daily use, guided imagery participants reported statistically significant improvements in self-efficacy (p=.02), stress	Supports use

						(p=.05), fatigue (p=<.01), pain severity (p<.01), and depression (p=.02). There were no significant improvements in pain interference or immune biomarker levels. No mention of adverse events.	
Guided Imagery	Menzies et al.[74], 2006	48 persons 18+ diagnosed with FM; mean age=49.6; 47 female; 43 white, 4 black, 1 other; Baseline: SF-MPQ total: 16.55 (GI), 16.46 (UC); SF-MPQ-sensory: 12.59 (GI), 12.54 (UC); SF-MPQ-affective: 3.96 (GI), 3.74 (UC); SF-MPQ-VAS: 5.79 (GI), 6.36 (UC); SF-MPQ-PPI: 2.32 (GI), 2.13 (UC); FIQ: 53.69 (GI), 52.99 (UC); PSE: 51.91 (GI), 52.99 (UC); OSE: 50.46 (GI), 53.61 (UC)	Guided imagery vs. usual care control	3 audiotapes practiced daily for 2 weeks each during weeks 1-6; participants chose which tapes to use daily weeks 7-10	SF-MPQ;FIQ; ASES (PSE and OSE)	The GI group had significant improvement compared to the UC group in FIQ (p=0.03) and self-efficacy for managing other symptoms (OSE) (p<0.01) from baseline to 6 weeks and from 6 to 10 weeks (p=0.03). There were no significant differences between the GI and UC groups in SF-MPQ[7], or self-efficacy for managing pain (PSE). No mention of adverse events.	Supports use
Massage therapy	Liptan et al.[75], 2013	12 women with diagnosed FM; average age=34.5 (range: 21-50); all white, 20% Hispanic; average time with fibromyalgia: 2.6 years	Quasi-RCT; head to head comparison of Swedish massage to myofascial release therapy (MFR)	90 min. massage once weekly for 4 weeks (either Swedish massage or myofascial release therapy)	FIQ-R total	There were no statistically significant between-group differences in total FIQ-R. No adverse events.	Not relevant
Tai Chi	Jones et al.[76], 2012	98 adults with diagnosed FM; mean age: 53.3 (tai chi), 54.8 (control); Race: 98.0 % white (tai chi), 95.3% white	Parallel-group RCT of 8-form Yang-style Tai chi vs.	Twice weekly tai chi for 12 weeks with 90 min. sessions based	Clinically significant change (14%) in	Tai chi group had clinically and significantly greater decrease in FIQ total compared to education	Supports use

		(control); Female: 92.1% (tai chi), 93.6% (control); BMI: 30.9 (tai chi), 30.1 (control); Yrs with symptoms: 17.0 (tai chi), 19.8 (control); FIQ total: 64.1 (tai chi), 63.6 (control)	education control	on Yang style with modifications for FM patients; education group had same time and attention	FIQ total	group (-16.5 vs. -3.1 points (95% CI)). No adverse events.	
Tai Chi	Wang et al.[77],2010	59 persons with diagnosed FM; Female: 85% (tai chi), 88% (control); Mean age=49.7 (tai chi), 50.5 (control); White race: 61% (tai chi), 52% (control); Mean BMI: 33.9 (tai chi), 31.5 (control); Duration of pain: 11.8 (tai chi), 10.0 (control); FIQ total: 62.9 (tai chi), 68.0 (control)	RCT of tai chi vs. wellness education and stretching	Twice a week for 12 weeks, each session lasted 60 min.; same time for control group	FIQ total	At 12 weeks, tai chi group had significantly greater decrease in total FIQ than control (-27.8 points [95% CI]; -33.8 to -21.8) vs. -9.4 points [95% CI]; -26.9 to -9.8). Significantly greater decrease also seen at 24 wks. No adverse events noted.	Supports use
Yoga	Carson et al.[78], 2010	53 women with diagnosed FM for at least 1 year; mean age = 53.7; 92.5% white, 5.7% native American, 3.8% Other race; mean time since diagnosis: 11.6 years; Baseline FIQ-R total: 48.32 (Yoga), 49.26 (control)	RCT of yoga of awareness program vs. waitlist	8 classes, once per week for 120 min.	FIQ-R total	FIQ-R total score group differences were significant favoring yoga group (effect=15.28; p=.0003). No mention of adverse events.	Supports use

Footnotes

[a] Abbreviations:

AIMS = Arthritis Impact Measurement Scales

ASES = Arthritis Self-Efficacy Scale
BDI = Beck Depression Inventory
BFI = Brief Fatigue Inventory
BPI = Brief Pain Inventory
CES-D = Center for Epidemiological Studies-Depression scale
FIQ = Fibromyalgia Impact Questionnaire
FIQ-R = Fibromyalgia Impact Questionnaire Revised
FSI = Fatigue Symptom Inventory
VAS = Visual Analog Scale (0 to 10 and 0 to 100)
LEMS = Low Energy Neurofeedback System
MBSR = Mindfulness-Based Stress Reduction
MFI = Multidimensional Fatigue Inventory
MPI = Multidimensional Pain Inventory
MPQ = McGill Pain Questionnaire
MOS = Medical Outcomes Study 36-Item Short Form Health Survey
NPR = numeric Pain Rating scale
OSE = Self-efficacy for managing other symptoms subscale of ASES
PSE = Self-efficacy for pain management subscale of ASES
PSS = Perceived Stress Scale
SCL- 90 = Symptom Checklist-90-Revised
SF-MPQ = Short-Form McGill Pain Questionnaire
SSQ = Stanford Sleep Questionnaire
TPI = Tender Point Index