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Herbal Tranquility

For Professional Use (in integrative oncology or other areas of practice)

Eclectic choices of the top nervines, antispasmodic, sedatives, and adaptogens:^{[1], [2]} Passionflower is considered a cooling herb and may be useful for circular thinking or difficulty in letting go. Skullcap is often considered for feelings of overwhelm and body tension. Lemon balm may be associated with lifting of the mood to experience joy, when clouded by fear. Holy basil, a tonic for the body and mind, functions to restore the immune system related to HPA dysfunction.^{[1], [2], [3], [4]}

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Study	Participants and	Outcome Measures	Results	Clinical implications/	Ref.	
Design	rreatment	DASSI		incentarisin of results		
PASSIONFLOWER						
Systematic review of 9 randomized	n = 508 participants with anxiety during spinal anesthesia, dental procedures, or surgery, aged > 18 years old, 192 mg	Depressive/anxious phenotype, reactivity to stress, psychomotor functions, nervous	Passiflora incarnata may be beneficial in alleviating certain symptoms in patients with neuropsychiatric	The study indicated that the use of <i>Passiflora incarnata</i> preparations can lead to a significant reduction in anxiety levels. However, the effectiveness of these preparations appears to be less	[1]	
clinical trials	to 2 g/d of passionflower extract for 1 to 30 days.	restlessness	conditions	pronounced in individuals who experience only mild anxiety symptoms.		
Randomized, double-blind, placebo- controlled, pilot study	n = 36 patients with generalized anxiety disorder, aged 19 to 45 years. 45 drops of passionflower extract per day for 4 weeks.	Hamilton Anxiety Rating Scale (HAM-A)	A significant decrease in generalized anxiety disorder scores after treatment (<i>p</i> < 0.001) was noted after day 7 in the <i>Passiflora</i> group	The study indicate that <i>Passiflora</i> extract is a highly effective treatment option for individuals with generalized anxiety disorder. Notably, it has a significantly lower incidence of impairing job performance compared to oxazepam.	[2]	
Randomized, double-blind, placebo- controlled study	 n = 30, patients with generalized anxiety disorder, aged 18 to 50 years. 45 drops of passionflower extract per day for 1 month + 50 mg sertraline tablet. 	Correct responses, omission and substitution errors and the mean time of correct responses (reaction time) in both visual and auditory tests	A significant improvement in the HARS and a betterment in the anxiety-related symptoms (<i>p</i> = 0.039) after treatment	The study suggests that passionflower may serve as a beneficial adjunct in the treatment of generalized anxiety disorder. Its use is associated with a low incidence of side effects, making it a potentially safe option.	[3]	
		MENOPAU	SAL SYMPTOMS			
Randomized, comparative clinical study	n = 59 menopausal women, aged 51.7 ± 3.3 years. 60 drops of passionflower extract per day for 6 weeks + 160 mg <i>Hypericum</i> <i>perforatum</i> .	Improvement in menopausal symptoms like anger, palpitation, creeping sensation, depressed mood, and muscular pain	A significant improvement in the menopausal symptoms was presented during 3rd and 6th weeks of treatment (p < 0.05)	Hypericum perforatum and passionflower can effectively treat precocious menopause symptoms like hot flashes, insomnia, depression, anger, and headaches. They are suitable alternatives for those who cannot use hormone therapy.	[4]	

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Study Design	Participants and Treatment	Outcome Measures		Results	Clinical implications/ mechanism of results	Ref.
SLEEP QUALITY						
Double-blind, placebo- controlled, repeated- measures design study	n = 41 healthy volunteers, aged 18 to 55 years. 2 g/d of dried <i>Passiflora incarnata</i> leaves, stems, seeds, and flowers teabag for 7 days, + 2 g of dried <i>Petroselinum</i> <i>crispum</i> .	Sleep-onset latency, sleep quality, number of nocturnal awakenings, feelings of refreshment upon rising, polysomnography, sleep quality	A i ir ti	a substantial improvement in sleep was noticed after a week (p < 0.01); also, an mprovement in total sleep me was reported (p > 0.01)	Drinking a low dose of <i>Passiflora incarnata</i> tea can offer immediate subjective benefits for sleep, particularly for healthy adults who occasionally experience mild variations in their sleep quality.	[5]
Randomized, double-blind, placebo- controlled study	n = 110 participants with reported insomnia, aged 40.47 ± 11.68 years. 60 mg/d of passionflower extracts for 2 weeks.	Total sleep duration, sleep efficiency, sleep latency, total arousal, wake after sleep onset, Insomnia Severity Index (ISI), Pittsburgh Sleep Quality Index (PSQI)	A re s a	substantial improvement in total sleep time was eported ($p = 0.049$); also, a ignificant improvement in sleep efficiency ($p = 0.008$) and wake after sleep onset ($p = 0.025$).	The study states a significant increase in total sleep time measured by polysomnography. Larger clinical trials with longer treatment durations and different dosages of passionflower are needed.	[6]
		SKI	UL	LCAP		
		A	NX	IETY		
A review study including clinical trials and animal studies of herbal medicine (skullcap— randomized, controlled trial)	<i>n</i> = 19 participants with anxiety and tension, age not specified. 100, 200, and 350 mg/d of Skullcap extract for 2 days.	Acute Psycho-Activity Self-Rating Scale, anxiety levels	A	significant anxiolytic effect was noticed.	The study states skullcap was effective against anxiety.	[7]
		DEP	PRE	SSION		
Randomized, double-blind, placebo- controlled study	n = 180 participants with mild-to-moderate depressive symptoms, aged 18 to 75 years. 20 mg of <i>Scutellaria</i> <i>baicalensis</i> (SCUTELL'UP®) for 42 days, alone or in combination with 30 mg of <i>Crocus sativus</i> .	Evaluation of psychological and emotional processing, Hamilton Depression Scale, State-Trait Anxiety Inventory	T a i	he combination helped in a significant improvement in depressive and anxious symptoms and emotional wellbeing, with minimal adverse effects.	The study suggests that the extract can be an alternative for individuals in search of safer and more supportive options to enhance their mental health and wellbeing.	[8]
		MOOI	DB	ALANCE		
Randomized, double-blind, placebo- controlled, crossover study	n = 43 healthy participants aged 19 to 66 years. 1,050 mg/d of <i>Scutellaria</i> <i>lateriflora</i> extract for 2 weeks	Total Mood Disturbance, Beck Anxiety Inventory, Tension, Anger, Confusion	(p	A significant decrease in Total Mood Disturbance < 0.001) and a substantial decrease in anxiety level <i>p</i> = 0.022) were noticed in the supplemented group	Study suggests skullcap can significantly enhance overall mood while maintaining energy levels and cognitive function. However, further research is necessary to explore its potential anxiolytic effects, particularly in individuals who experience high levels of anxiety.	[9]
		LEMO	10	IBALM		
		A	NX	IETY		
Systematic review and meta-analysis of 6 randomized, controlled studies	n = 632 patients with anxiety and depression, aged 18 to 75 years. 300 mg to 5,000 mg/d of lemon balm extract for 1 to 56 days.	Acute or chronic manifestations of anxiety and depression, side effects of lemon balm		Significant improvement in the mean anxiety and depression scores (<i>p</i> = 0.0005)	Lemon balm may help alleviate anxiety and depressive symptoms, particularly in urgent or acute circumstances. However, it's important to note that the research on this subject shows considerable variability among different studies; the findings should thus be approached with caution.	[10]
Randomized, double-blind, placebo- controlled study	<i>n</i> = 60 with type 2 diabetes mellitus with symptoms of depression, aged 20 to 65 years. 700 mg/d of lemon balm extract for 12 weeks.	Beck Depression Inventory-II (BDI-II) and Beck Anxiety Inventory (BAI), Pittsburgh Sleep Quality Index (PSQI)	sco sco	A significant mean change of depression and anxiety ores ($p < 0.001$ and $p = 0.04$, respectively). Also, there vas a substantial decrease in depression and anxiety severity ($p < 0.001$ and p = 0.01, respectively).	The study demonstrated that diabetic patients experiencing symptoms of depression and anxiety benefited from holy basil extract. It also suggested that it may be an effective option for improving mental health in this population.	[11]

Study Design	Participants and Treatment	Outcome Measures	Results	Clinical implications/ mechanism of results	Ref.	
HEART PALPITATIONS						
Randomized, placebo- controlled, double-blind study	 n = 57 volunteers with an unpleasant sensation in the heart or awareness of heartbeat, aged 18 and 60 years. 1,000 mg/d of <i>M. officinalis</i> extract for 14 days. 	Mean frequency of palpitation episodes per week, derived from patients' diaries, and mean intensity of palpitation estimated through Visual Analogue Scale (VAS), somatization, anxiety and insomnia, social dysfunction, and severe depression.	A significant decline in the frequency of palpitation episodes (<i>p</i> = 0.0001) and a substantial anxiolytic effect (<i>p</i> = 0.004) were noted.	The leaves of <i>M. officinalis</i> may offer a safe and effective herbal remedy for managing benign palpitations, providing a natural option for those experiencing this common heart-related symptom.	[12]	
		MOOD BALA	NCE AND STRESS			
Randomized, placebo- controlled, double-blind, balanced- crossover study	n = 20 young healthy participants aged 18 to 22 years. 300, 600, and 900 mg of <i>M. officinalis</i> (Pharmaton) at 7-day intervals.	Calmness, Bond-Lader Visual Analogue Mood Scales, word presentation, immediate word recall, simple reaction time, digit vigilance task, spatial working memory, attention, memory, and speed of performance.	A significant improvement in mood and calmness was observed after supplementation, (p < 0.002); also a substantial improvement in accuracy of attention was noticed (p = 0.0001). 600 mg of the extract supplement exhibited the positive effects.	This study indicates that consuming <i>Melissa officinalis</i> affects cognitive performance and mood. It is important to further investigate whether this herb can improve cognitive function in healthy young volunteers.	[13]	
Randomized, double-blind, placebo- controlled, balanced crossover study	n = 18 healthy volunteers, with a mean age of 29.11 years. 300 or 600 mg of <i>M. officinalis</i> extract for a day	Mathematical processing, visual monitoring, auditory monitoring, and memory search tasks	A significant positive effect on self ratings of calmness was reported after receiving the 600 mg dose of <i>M. officinalis</i> (<i>p</i> = 0.02). Also a substantial increase in mathematical processing task (<i>p</i> = 0.05).	A 600 mg dose of <i>Melissa</i> demonstrated the ability to enhance mood by alleviating feelings of negativity, suggesting its potential effectiveness in reducing the impact of stress.	[14]	
		ALZHEIM	IER'S DISEASE			
Randomized, placebo- controlled, double-blind study	n = 23 patients with mild dementia due to Alzheimer's disease, aged 73.42 ± 5.00 years. <i>M. officinalis</i> extract containing 500 mg of rosmarinic acid each day for 24 weeks (with 24-week extension).	Mini-Mental State Examination (MMSE) cognitive subscale of the Alzheimer's Assessment Scale (ADAS-cog), Disability Assessment for Dementia scale (DAD) clinical dementia rating (CDR), Neuropsychiatric Inventory Questionnaire (NPI-Q) score.	A significant improvement in the NPI-Q score after the supplementation, by 0.5 points when compared to the placebo group (p = 0.012).	The study indicated that RA may help manage worsening neuropsychiatric symptoms in patients with mild Alzheimer's disease with dementia. The supplement also led to no adverse reaction after 48 weeks of consumption, and thus proved to be safe.	[15]	
		SLEE	P QUALITY	-		
Randomized, placebo- controlled, double-blind study	n = 60 postmenopausal women with sleep disturbance, aged 51.7 ± 3.3 years. 500 mg/d of <i>M. officinalis</i> L. extract for 8 weeks + 30 mg citalopram.	Menopause-Specific Quality-of-Life (MENQOL) questionnaire	A significant improvement in the MENQOL domain scores after receiving <i>M. officinalis</i> (<i>p</i> < 0.001); also a substantial enhancement in vasomotor domain and psychomotor- social domains (<i>p</i> < 0.001).	The findings suggest that <i>M. officinalis</i> could be an effective option for improving the overall quality of life for menopausal women who are struggling with sleep disturbances. This herbal remedy may provide relief from insomnia and promote better sleep patterns.	[16]	
	HOLY BASIL					
ANXIETY						
Randomized, placebo- controlled, double-blind study	n = √−1 healthy male subjects aged 18–30 years. 300 mg/d of <i>Ocimum</i> <i>sanctum</i> extract for 30 days.	Reaction time (RT) and error rate (ER) of Sternberg test, RT of neutral task of Stroop, RT and ER of interference task of Stroop, P300 latency, salivary cortisol, and State-Trait Anxiety Inventory (STAI).	A significant decline in the STAI scores in the supplement group when compared to the placebo (<i>p</i> < 0.001); also, a substantial reduction of the P300 latency (<i>p</i> < 0.01).	The extract derived from the leaves of <i>Ocimum sanctum</i> appears to have promising properties that may enhance cognitive function and reduce anxiety in humans.	[17]	

Study Design	Participants and Treatment	Outcome Measures	Results	Clinical implications/ mechanism of results	Ref.
Observational clinical study	n = 35 healthy subjects aged 18–60 years. 1,000 mg/d of <i>Ocimum sanctum</i> extract for 60 days.	Psychological rating scale including, anxiety index, depression index, and stress index.	A significant attenuation in generalized anxiety disorders, stress, and depression (<i>p</i> < 0.001) was observed. Also, a positive effect in willingness to adjust and attention (<i>p</i> < 0.001).	Ocimum sanctum may offer significant benefits in the treatment of generalized anxiety disorder. Its potential as an effective anxiolytic agent presents a promising avenue for future therapeutic applications.	[18]
		SLEE	P QUALITY		
Randomized, placebo- controlled, double-blind study.	n = 100 volunteers aged 18–65 years. 250 mg/d of <i>Ocimum</i> extract for 8 weeks (Holixer™).	Perceived Stress Scale, Profile of Mood States, Athens Insomnia Scale (AIS), Restorative Sleep Questionnaire, and the Patient-Reported Outcomes Measurement Information System-29.	A significant improvement in Perceived Stress Scale and hair cortisol levels after receiving <i>Ocimum</i> ($p = 0.025$). Also, several other aspects substantially improved, such as salivary cortisol and salivary amylase ($p = 0.001$), and subjective stress ratings ($p < 0.001$).	Ocimum has the potential to significantly decrease both objective and subjective indicators of stress. Additionally, this supplementation may lead to enhancements in individuals' subjective assessments of sleep quality, suggesting a holistic benefit for those experiencing stress and sleep disturbances	[19]
Randomized, placebo- controlled, double-blind, parallel study	n = 60 volunteers aged 18–54 years. 500 mg/d of a a combination of Valeriana officinalis extract, Passiflora incarnata extract, Ocimum sanctum extract, Ziziphus jujuba extract, Rosmarinus officinalis extract, and Nigella sativa extract for 56 days (KaraCalm™).	Circadian rhythm sleep, cortisol levels and hs-CRP, heart rate, blood pressure, temperature, respiratory rate, and pulse rate.	A significant improvement in total sleep quality was noted in patients receiving the supplement ($p = 0.000$). Also, a substantial decrease in the stress levels that reflected with respect to the drop of serum cortisol levels ($p = 0.000$).	The supplement helped alleviate stress and enhance the quality of sleep. With its blend of natural ingredients, it promoted relaxation and good sleep quality.	[20]

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Each vegetable capsule contains:

Passionflower (Passiflora incarnata) extract,	
4% flavonoids (DHE: 1,500 mg)	150 mg
Skullcap (Scutellaria lateriflora),	
10% flavonoids (DHE: 1,500 mg)	150 mg
Lemon balm (Melissa officinalis) 10:1 extract (DHE: 1,500 mg)	150 mg
Holy basil (Ocimum tenuiflorum) leaf extract,	
10% ursolic acid (DHE: 500 mg)	50 mg
DHE: Dry-Herb Equivalent.	

Nonmedicinal ingredients: Vegetable magnesium stearate, and silicon dioxide in a non-GMO vegetable capsule composed of vegetable carbohydrate gum and purified water.

Directions of use: Adults: Take 1 capsule daily or as directed by your health-care practitioner.

Cautions and warnings: Consult your health-care practitioner if sleeplessness persists for more than 4 weeks (chronic insomnia), or if symptoms persist or worsen. Consult a health-care practitioner prior to use if you have a heart condition or diabetes, or if you are taking any heart or blood pressure medication. Avoid taking with alcohol or products that cause drowsiness.

Contraindications: Do not use this product if you are pregnant or breast-feeding.

Known adverse reactions: Some people may experience drowsiness. Exercise caution if operating heavy machinery, driving a motor vehicle, or involved in activities requiring mental alertness. Discontinue use if hypersensitivity/allergy occurs.

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