

CLINICAL PROTOCOL TO SUPPORT THE TREATMENT OF ANXIETY*

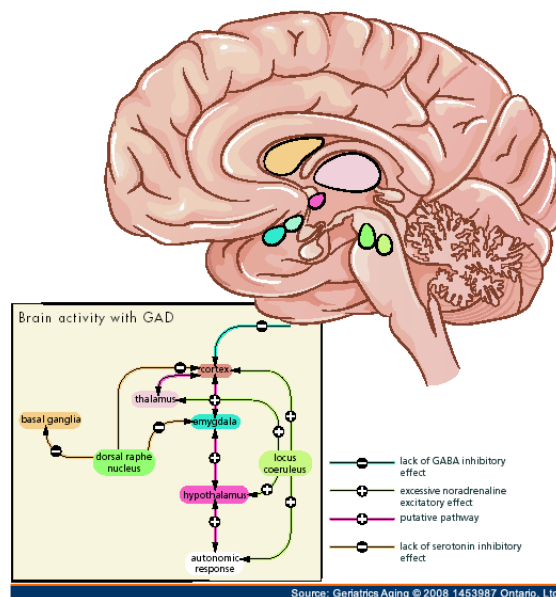
The Pathophysiology of Anxiety

Supporting mental-emotional wellness and a healthy stress response is a critical part of patient care. The biopsychosocial model of wellness demonstrates the integrated nature of physical, environmental, and psychological inputs on the individual which, if disturbed, can result in excess worry, nervousness, fear, apprehension, and anxiety.

Examples of anxiety disorders include panic attacks, obsessive-compulsive disorder, and post-traumatic stress disorder, as well as generalized anxiety disorder. Pathophysiological factors associated with anxiety include lack of inhibitory neurotransmitter synthesis/activity, excessive excitatory catecholamine activity, and elevated cytokine activity.

Developing an integrated approach to mental-emotional wellness that considers factors such as diet, nutrient deficiencies, sleep habits, interpersonal relationships, and psychological stress provides a more comprehensive care model than many conventional mono-therapies.

This protocol is designed to support patient mental-emotional wellness, stress response, and anxiety, through nutritional applications and lifestyle strategies.



Diagnostic Biomarkers / Clinical Indicators

- Organic Acid Testing - Neurotransmitter Metabolites
 - Homovanillate (HVA)
 - Vanilmandelate (VMA)
 - Kyurenate
 - Quinolinat
- Comprehensive Thyroid Panel
 - TSH
 - Free T3, T4
 - Reverse T3
 - Tg
 - Thyroid Autoantibodies (TPOAb, TgAb and TRAb)
- GenomicInsights®
 - 5-hydroxytryptamine receptor 1A (5-HT1A)
 - Monoamine oxidase A (MAOA)
 - Catechol-O-methyltransferase (COMT)
- Validated Surveys
 - State-Trait Anxiety Inventory-Trait Anxiety Scale (STAI-T)
 - Anxiety Symptoms Questionnaire (ASQ)
 - Generalized Anxiety Disorder Questionnaire-IV (GAD-Q-IV)

Lifestyle Interventions

- Guide patients in diaphragmatic deep breathing exercises
- Encourage patients to adopt practices in meditation, progressive relaxation, guided-imagery or emotional freedom technique therapy
- Promote regular exercise to improve mood and reduce stress; include Tai Chi or yoga
- Employ calming techniques such as aromatherapy, massage, or music therapy
- Optimize sleep hygiene
- Recommend patients use the Well World™ Condition Tracker to monitor their stress response and anxiety levels.

This information is provided as a medical and scientific educational resource for the use of physicians and other licensed health care practitioners ("Practitioners"). This information is intended for Practitioners to use as a basis for determining whether to recommend these products to their patients. All recommendations regarding protocols, dosing, prescribing and/or usage instructions should be tailored to the individual needs of the patient considering their medical history and concomitant therapies. This information is not intended for use by consumers.

Therapeutic Diet and Nutrition Considerations

- Ensure adequate magnesium intake (310-420 mg/day based on age & gender)^{1,2} through rich sources such as kale, spinach, Swiss chard, pumpkin seeds, almonds, cashews, black beans, dark chocolate
- Ensure adequate zinc intake (8-11mg/day based on age & gender)³ through rich sources such as oysters, liver, beef, pork, crab, lobster, baked beans, egg yolks
- Recommend an amino-acid rich diet with emphasis on foods high in tyrosine and tryptophan: turkey, beef, chicken, salmon, cheese
- Recommend consumption of probiotic-rich foods such as sauerkraut, kefir, kimchi, kombucha, pickled vegetables; intake of fermented foods has been associated with reduced anxiety symptoms⁴
- Consider adaptogenic teas for their polyphenols and calming effects such as chamomile, holy basil or oolong
- Anxiety is thought to be correlated with a lowered total antioxidant state, with antioxidants showing promise as novel therapeutics.^{5,6} Patients may therefore benefit from supporting antioxidant status in the diet through foods of high antioxidant content:
 - Spices: clove, allspice, sweet basil, sage, rosemary, turmeric, ginger
 - Fruits: blueberries, blackberries, raspberries
 - Vegetables: artichokes, kale, spinach, beets, broccoli, garlic
 - Beans/legumes: dried small red, Pinto, black, red kidney
 - Nuts, seeds: walnuts, pecans

SUPPLEMENT PROTOCOL/REGIMEN

Primary Support:

Catecholacalm™	
Dose	3 capsules per day
Duration	Ongoing
Formula Highlights	Catecholacalm™ is designed to support healthy catecholamine levels with adaptogenic herbs and nutrients that may help mood and promote calmness and relaxation. This unique formulation addresses adrenal gland health, which may help people handle stress more effectively.*

Cannab-FS™ 600	
Dose	1 ml (1 dropperful) and hold in mouth for 30 seconds before swallowing; consider initially dosing in the evening due to potential relaxant effect
Duration	Ongoing
Formula Highlights	Cannab-FS™ 600 provides 600 mg per bottle of full spectrum phytocannabinoids, which are the beneficial compounds naturally found in the aerial parts of hemp. This product is offered in liquid form, infused in a base of organic cold-pressed hemp seed oil, and yields 20 mg active phytocannabinoids per 1 ml serving (1 dropperful). Cannab-FS™ 600 also contains natural terpenes, aromatic compounds from the hemp plant that work synergistically with phytocannabinoids, complementing their health-promoting properties.* Additional terpenes are also included for taste enhancement.

Pharmagaba®	
Dose	2 tablets per day
Duration	Ongoing
Formula Highlights	Pharmagaba® is naturally-sourced, bioidentical GABA (gamma-aminobutyric acid). It is made via a process where the amino acid glutamic acid (glutamate) is fermented using <i>Lactobacillus hilgardii</i> , the beneficial bacteria also used to ferment many foods including the vegetables in kimchi, the famous Korean dish. Pharmagaba™ provides 200 mg of GABA per serving (two tablets). Its chewable tablet delivery allows for rapid and efficient absorption and assimilation. As a result, benefits may be felt very quickly.

Adjunct Support:

Magnesium Chelate Powder	
Dose	5 grams (approx. One teaspoon) of powder mixed in eight ounces of water per day
Duration	Ongoing
Formula Highlights	Magnesium Bisglycinate chelate is one of the best absorbed forms of magnesium. Each 5 gram (1 teaspoon) serving provides 300 mg of elemental magnesium in a great-tasting, orange flavored product. This product should not cause any of the unfavorable gastrointestinal symptoms associated with magnesium supplementation due to the very stable chelate formed between two glycine molecules and each magnesium ion via a patented process.

For a list of references cited in this document, please visit:

<https://www.designsforhealth.com/protocol-references/protocol-anxiety-references.pdf>

Dosing recommendations are given for typical use based on an average 150 pound healthy adult. Health care practitioners are encouraged to use clinical judgement with case-specific dosing based on intended goals, subject body weight, medical history, and concomitant medication and supplement usage. Any product containing botanical substances has the potential for causing individual sensitivities, appropriate monitoring, including liver function tests (LFT) is recommended.

For considerations around herb/nutrient-drug interactions, please refer to reliable, evidence-based resources such as Natural Medicine Database or Stargrove, M. B., Treasure, J., & McKee, D. L. (2008). *Herb, nutrient, and drug interactions: Clinical implications and therapeutic strategies*. St. Louis, Mo: Mosby Elsevier.

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