ALZHEIMER'S PROTOCOL

designs for health®

CLINICAL PROTOCOL TO SUPPORT BRAIN HEALTH AND HEALTHY AGING*

Alzheimer's disease (AD) is the most prevalent neurodegenerative disorder in the world affecting more than 40 million older adults. Its incidence is predicted to triple by 2050, in part, due to the aging population. AD is characterized, in particular, by lack of memory for recent events and by a progressive loss of cognitive function and memory. Currently, AD has no cure.[1-4]

The underlying pathophysiology is still not fully understood. Therefore, research has focused on understanding the hallmark features of AD, which are amyloid plaque accumulation, impaired glucose metabolism, and neuronal cell death.[5] In addition, neuroinflammation, oxidative stress, and circadian rhythm dysfunction have all been correlated with AD.[6]

Although the onset of AD primarily constitutes the patient population of those 65 years of age and older, epidemiological research suggests that as many as 3 million cases worldwide could be prevented with a reduction of 10% to 25% known modifiable risk factors in midlife, demonstrating the efficacy and importance of prevention through diet and lifestyle.[5] Additionally, many interventions have been shown to improve preclinical or early-stage AD.[7]

This clinical protocol includes evidence-based lifestyle and dietary interventions for Alzheimer's disease characteristics that are designed to support healthy aging, optimal brain function, healthy neurological integrity, a healthy response to inflammation, and healthy cognition, mood, and memory.*

Diagnostic Biomarkers and Clinical Indicators of Alzheimer's Disease

- Clinical diagnosis[8] is determined using the National Institutes on Aging and the Alzheimer's Association (NIA-AA) workgroup diagnostic criteria, DSM-5, and ICD-10
- Cognitive Assessments
  - Montreal Cognitive Assessment (MoCA)
- Assessing level of dependency
  - Katz Index of Activities of Daily Living (ADL)
  - Lawton's Instrumental Activities of Daily Living Scale
- Further testing, if indicated
  - Cerebrospinal fluid
  - MRI
  - PET
- Blood tests[8,9]
  - Complete blood count with differential
  - Complete metabolic panel
  - Thyroid-stimulating hormone
    - 0.5 to 4.0 µU/mL
  - Vitamin B12
    - 200 to 800 pg/mL
  - Homocysteine
    - 5 to 15 µmol/L
  - Erythrocyte sedimentation rate
    - Female: 0 to 20 mm/hr
    - Male: 0 to 15 mm/hr
  - C-reactive protein
    - ≤0.8 mg/dL; ≤76.2 nmol/L

Therapeutic Diet and Nutritional Considerations

- Recommend a Mediterranean diet or low-glycemic dietary approach rich in the following nutrients[10]
  - High intake of fruits, vegetables, and legumes, along with low intake of meat, high-fat dairies, and sweets are associated with lower risk of AD[5]
  - Adequate consumption of polyunsaturated fatty acids and monounsaturated fatty acids from sources such as cold-water fatty fish (salmon, sardines, mackerel), nuts (walnuts, almonds, pistachios), olive oil, and avocado
  - Adequate intake (AI) of choline (550 mg per day for men; 425 mg per day for women) through choline-rich foods, such as liver and egg yolks[11]
  - Herbs and spices that contain compounds with anti- inflammatory properties, such as allspice, cinnamon, cloves, rosemary, turmeric, ginger, and oregano
- Ensure adequate calorie intake, as proper feeding can be a challenge for some patients in this population[4]
- Consider a ketogenic diet, which could alleviate effects of impaired glucose metabolism and may possibly reduce accumulation of amyloid plaques[12]

Lifestyle Interventions

- Optimize sleep hygiene practices. Sleep disturbance is common in patients with AD, and a link between disrupted circadian rhythms and AD has been established in research[6]
- Recommend exercise, particularly cardiovascular exercise and resistance training, at appropriate intensity per patient fitness level. Regular exercise has been shown to improve brain structure and function in older adults[13-15]
- Strengthen existing connections within the brain with social activity and brain-stimulating exercises, such as crossword puzzles
- Reduce lifestyle stressors and promote stress management through techniques such as meditation, breathing exercises, and biofeedback
- Consider supporting a healthy mood and screen for common comorbidities, such as depression

SUPPLEMENT PROTOCOL/REGIMEN

Primary Support:

Brain Vitale™	
Dose	2 capsules with breakfast and lunch
Duration	Ongoing
Formula Highlights	Brain Vitale™ is a unique formulation designed to optimize brain function and to support healthy cognition, mood, and memory.* This product contains a comprehensive array of brain-supportive nutrients, including acetyl-L-carnitine, glycerophosphocholine (GPC), phosphatidylserine, Ginkgo biloba (standardized to contain 24% ginkgo flavon glycosides), and citicoline. Also included is a unique coffee fruit concentrate extracted from the whole coffee cherry, including the flesh of the berry that surrounds the coffee bean and contains several distinctive compounds not found in coffee beans themselves.*

CogniAid™	
Dose	2 capsules per day with breakfast
Duration	Ongoing
Formula Highlights	CogniAid™ is an herbal formula designed to help support healthy cognition, mood, and memory.* This product supplies herbs and extracts that have been shown to work through a variety of mechanisms, including helping to maintain proper levels of the neurotransmitter acetylcholine, as well as supporting healthy neurons and nerve impulse transmission.* CogniAid™ contains a wild-crafted blueberry complex, which in addition to blueberries, uses extracts of huckleberries and bilberries. This product also features vinpocetine, huperzine-A (a naturally occurring alkaloid compound), the green tea polyphenol epigallocatechin gallate (EGCg), and the Ayurvedic herb *Bacopa monnieri*.*

Curcum-Evail®	
Dose	1 softgel twice per day with meals
Duration	Ongoing
Formula Highlights	Curcum-Evail® is a highly bioavailable curcuminoid formulation. This product contains a unique combination of three bioactive, health-promoting curcuminoids: curcumin, bisdemethoxy curcumin, and demethoxy curcumin, along with turmeric oil. These three curcuminoids are the strongest, most protective, and best-researched constituents of the turmeric root. This product is manufactured utilizing the Designs for Health Evail™ technology process, which helps to optimize the absorption rate of the curcuminoids while reducing their absorption time.

OmegAvail™ Ultra DHA	
Dose	1 to 2 softgels daily
Duration	Ongoing
Formula Highlights	OmegAvail™ Ultra DHA is a highly concentrated docosahexaenoic acid (DHA) formulation, providing 500 mg of DHA + 110 mg of eicosapentaenoic acid (EPA) to help support optimum DHA status supporting healthy blood glucose metabolism, and neurological and brain health. This product contains lipase, a digestive enzyme to maximize absorption and to help avoid a fishy aftertaste, along with vitamin E isomers (as DeltaGold® delta- and gamma-tocotrienols) to protect from oxidation.*

NeuroMag™	
Dose	Dose 1 capsule 3 times per day
Duration	Ongoing
Formula Highlights	Several studies indicate that synaptic connections in the brain hippocampus, a critical region for learning and memory, decline during the normal process of aging. This product uses the unique, patented, chelated mineral Magtein®, which contains magnesium that is chelated to threonic acid (magnesium L-threonate). It is superior to other forms of magnesium at getting through the blood brain barrier because it is able to transport magnesium ions across lipid membranes, including those of brain cells. Researchers at MIT concluded that elevating brain magnesium content via supplementation with magnesium L-threonate may be a useful strategy to support cognitive abilities and decrease common age-related memory decline.*

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.

***These statements have not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure, or prevent any disease.**