



HEALTH AND AGING
POLICY FELLOWS



The Case for Delivering Complementary and Integrative Therapies for Mental Health and Aging

Policy Brief with Annotated Bibliography of Research

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The Case for Delivering Complementary and Integrative Therapies for Mental Health and Aging

The Issue: The global population is aging rapidly. Over the next several decades the number of persons aged 60 and older will triple to more than 2 Billion in 2050. The burden and costs of chronic disease will escalate worldwide. In the United States in 2050, the population aged 60 and over is projected to be 84 million, almost double its 44 million estimated population in 2014. The projected growth of the older population in the USA will present extraordinary challenges to policy makers, programs, businesses, and health care providers. (Ortman, et al, 2014).

This brief describes the issues and treatment of aging-related neuro-degenerative diseases and the compelling need for Complementary, Alternative, and Integrative Medicine & Health (CAIMH) options and deliverable interventions. As a society, we must recognize that prevention of neuro-degenerative diseases of aging will improve the quality of life for aging individuals and their families. It is imperative that we combine evidence-based integrative, alternative and complementary health-promoting use of CAIMH interventions with standard “treat the disease” mainstream Western medicine.

The Problem Today: As of 2016, there are an estimated 45 million people worldwide with dementia, including Alzheimer’s and Parkinson’s disease. This number will increase to an estimated 76 million in 2030, and 136 million in 2050. There are 7.7 million new cases of dementia/Alzheimer’s each year, inferring that there is a new case of dementia every 4 seconds. In 2016 in the USA, there are an estimated 5.6 million cases of Americans with Alzheimer’s disease in persons age 65 and older; and millions more with other neuro-degenerative disorders, which is expected to increase 15% by the year 2020.

In the USA, every year an estimated 100,000 people die from Alzheimer’s disease, the 6th leading cause of death and the most common brain disorder responsible for 60%-70% of neuro-degenerative diseases. There is no known cure. However, there are preventive dementia fighting strategies that every one of us can take to avoid and to ultimately stave off Alzheimer’s, and other neuro-degeneration of aging.

There are easy, concrete steps every single person can take to avoid adding to the ranks of Alzheimer’s sufferers and their families. There is an alternative that includes: educating populations of dietary intake of specific foods that lower the risk of developing dementia, incorporating specific daily body and brain exercise programs, intake of only GMP US Pharmacopeia professional brands vitamins and nutritional supplements that cross the blood-brain barrier, and consuming an anti-inflammatory diet and cholesterol-lowering drugs.

Waiting passively for a cure for Alzheimer’s is not an option as Alzheimer’s rates are spiraling upward at out-of-control. We really cannot afford to take a passive approach. Individuals must have the knowledge, as well as easy and affordable access and options to full life CAIMH disease prevention and protective alternatives.

Options: The aging of the population in the United States (the 3rd most populous country in the world) is unprecedented in human history. In 2016, there are nearly 50 million persons age 65 and older. In 2050, the population aged >65 is projected to be 90 million or more. The current mainstream “Western Medicine” approach to “treat the disease” is not a medical option. Why not? At this time, there are no disease-modifying drugs to stop, delay or reverse progression of Alzheimer’s disease.

Alzheimer’s disease remains one of the most critical unaddressed and underfunded public health issues in America. (ALZ.org, 2016). Why should prevention of Alzheimer’s disease and CAIMH preventive measures be a national priority? The costs for Alzheimer’s care and services continue to rise, straining the United States’ overwhelmed health care system and threatening to bankrupt Medicare and Medicaid. (Ortman, et al, 2014).

Unless public policy changes, the health care system will be overwhelmed and the future bleak. Nursing homes will be overloaded. Caregivers will be overworked. The healthcare system will be overwhelmed. Federal and state budgets will be overtaxed. The US Dept. of Health & Human Services National Institutes of Health (NIH) National

Center for Complementary and Integrative Health (NCCIH)¹ has recognized the importance of exploring and providing empirical research-based complementary, alternative and integrative interventions to prevent or delay the onset of neuro-degenerative diseases of aging, such as dementia, Alzheimer's, Parkinson's. (NIH-NCCIH, 2016).

NCCIH was established in 1999; in 2007 NCCIH established a Complementary and Integrative Medicine Consult Service at the NIH Clinical Center; in 2014 NCCIH omnibus legislative funding established several primary areas of focus for CAIMH research and therapies: (1) Whole medical systems such as homeopathy, naturopathy, traditional Chinese medicine, Ayurveda. (2) Mind-body medicine such as meditation, prayer, mental healing, art therapy, music and dance therapy. (3) Biologically based practices GMP US Pharmacopeia dietary supplements that cross the blood-brain barrier to reduce oxidative stress, reduce brain inflammation, prevent brain-cell damage, increase full-body and brain exercises, and eliminate fats that accelerate the development of Alzheimer's.

Policy and Recommendations: On January 4, 2011, President Barack Obama signed into law the National Alzheimer's Project Act (NAPA), requiring the Secretary of the U.S. Department of Health and Human Services to establish the National Alzheimer's Project [NAP] to include: (HHS, 2013)

- Create and maintain an integrated national plan to overcome Alzheimer's disease.
- Coordinate Alzheimer's disease research and services across all federal agencies.
- Accelerate the development of treatments that would prevent, halt, or reverse the course of Alzheimer's disease.

In 2016, NAP research has expanded in the following areas underlying Alzheimer's disease: (1) molecular and cellular mechanisms to target interventions, including drug, diet, and nutritional supplements, (2) genetic epidemiologic research to identify high risk persons and medical and lifestyle factors, (3) increase enrollment in the most promising pharmacologic drugs and naturopathic interventions of Alzheimer's clinical trials, (4) Identify imaging and biomarkers to monitor disease progression, (5) increase clinical trials on the most promising lifestyle interventions. In 2016, state and federal governments are expected to spend a combined \$40 to \$50 Billion in Medicaid/Medicare costs to care for people with Alzheimer's. This devastating disease is a public health crisis and cannot be ignored.

In the past decade research studies of CAIMH therapies in the elderly for dementia and Alzheimer's have shown significant evidence of efficacy with the following natural substances and for those age > 60 seeking prevention of neurodegenerative disease, health balance, and quality of life. The most popular natural remedies with effective impact on dementia and Alzheimer's are (1) Gingko Biloba for dementia; (2) Rhodiola Rosea Extract for Depression and Dementia; (3) Folate, a water soluble B vitamin for Depression and Dementia with the active form of folate, 5-methyltetrahydrofolate (5-MTHF) that has the capacity to cross the blood-brain barrier; (4) Omega-3 Fatty Acids EPA/DHA; (5) Phosphatidylserine enriched with docosahexaenoic acid (PS-DHA+ EPA) for dementia..

The reader is referred to **Appendix A "Annotated Bibliography CAIMH Research of Neuro-Degenerative Disease" Pages 1 - 3** for detailed information of natural remedies and definitive results of their potential benefits for mood stabilization, energy restoration, and positive effects on memory, free-recall in persons diagnosed with psychiatric depression, dementia and Alzheimer's

The challenge for the future **must** include significant increase in funding behavioral and risk reduction, high-impact, scientific empirical research in multi-modal complementary, alternative, integrative strategies and therapies for mental health and aging, including lifestyle brain-health protection and therapeutic strategies that are key to reducing the risks, the occurrence, and the impact of neuro-degenerative diseases. Lawmakers must increase educational funding and incentives to increase licensed geriatric mental health specialists knowledgeable in both mainstream medicine and holistic entire life CAIMH risk-reduction strategies and therapies to reduce the risks and occurrence of Alzheimer's and other neuro-degenerative diseases to ameliorate its impact to all persons.

¹ The National Center for Complementary and Integrative Health (NCCIH) is the Federal Government's lead agency for scientific research on the diverse medical and health care systems, practices, and products that are not generally considered part of conventional medicine. Fiscal Year 2015 Budget \$127.5 Million.

Annotated Bibliography CAIMH Research of Neuro-Degenerative Disease

➤ Rhodiola Rosea Extract for Dementia

Fintelmann, V & Grunewald, J (2007). *“Efficacy and Tolerability of Rhodiola Rosea Extract in adults with physical and cognitive deficiencies.”* Advances in Therapy Journal 24, 929-939.

The researchers investigated in a 12-week open study R.rosea extract in combination with vitamins and minerals, including 38 women and 37 men between the ages of 50 and 89, who had physical and cognitive deficiencies in concentration, memory, and stress tolerance. The researchers found consistent improvements in alertness, concentration, mental clarity, memory, mood and energy in elderly and no adverse effects occurred. The researchers report that statistically significant improvements occurred in physical and cognitive deficiencies ($p < 1.0010$ and speed of digital connection test ($p < 0.001$)).

Darbinyan V, Aslanyan G, Amroyan, E, Gabtirlyan, E, Malmstrom C, Panossian A. (2009) *“Clinical trial of Rhodiola rosea extract SHR-5 in treatment of mild to moderate depression.”* Nord J. Psychiatry. 2009; 61(6): 503.

The researchers investigated two different doses of standardized Rhodiola rosea (SHR-5) to a placebo during 6 weeks in 89 mild to moderately depressed patients age 60 and over. The Rhodiola group showed improvement in overall depression and symptoms such as insomnia, emotional stability, self-esteem, mood stabilization and energy restoration. No side effects were reported.

Ihl R, Bachinskaya N, Vakhapova V, Tribanek M, Hoerr R, Napryeyenko O. (2011) *“Efficacy and safety of a once-daily formulation of Ginkgo Biloba extract EGb-761 in dementia with neuropsychiatric features: a randomized control trial.”* International Journal of Geriatric Psychiatry. 2011 Nov; 26(11): 1186-1194.

The researchers tested the efficacy of a once-daily formulation of EGB-761 (240 mg.) for dementia in a randomized controlled trial with patients older than 50 years. The results showed improvement in cognitive performance, neuropsychiatric symptoms, functional abilities, free-recall of appointments, and overall well-being when compared to placebo.

Van Dierman D, Marston A, Bravo J, Reist M, Carrupt PA, Hostettmann K. (2009). *“Monoamine Oxidase Inhibition by Rhodiola Rosea L. Roots.”* Journal Ethnopharmacol. March 18, 2009; 122 (2): 397-401. Doi: 10.1016/j.jep.2009.01.007. Epub 2009 Jan. 9.

The researchers tested three extracts of Rhodiola Rosea L. roots against enzymes monoamine oxidase (MAOs) A and B. They found a potent inhibitory effect on MAO-A and B, which affects serotonin and norepinephrine levels in nerve terminals that sheds light onto the treatment of senile dementia and Alzheimer’s disease. No adverse side effects were reported.

➤ **Folate and Dementia - Water Soluble B Vitamin, 5-methyltetrahydrofolate (5-MTHF)**

Mischoulon D, Raab MF. (2007) “*The Role of Folate in Depression and Dementia.*” *Journal of Clinical Psychiatry.* 2007; 68, Suppl 10:28-33.

Corrada MM, Kawas CH, Hallfrisch J, et al. (2005). “*Reduced Risk of Alzheimer’s Disease with High Folate Intake: The Baltimore Longitudinal Study of Aging.*” *Alzheimer’s Dementia.* 2005; 1:11-18.

Kado DM, Karlamangla AS, Huang MH, et al. (2005). “*Homocysteine versus the Vitamins Folate, B6, and B12 as Predictors of Cognitive Function and Decline in Older High-Functioning Adults.*” *MacArthur Studies of Successful Aging. American Journal of Medicine.* 2005; 118-161-167.

The above Researchers noted that the FDA has mandated the fortification of grains with folate due to studies that have associated folate deficiencies with a higher risk of cognitive impairment and dementia, as well as an increased risk of depression and a dampened response to anti-depressant treatment.

In general, the above researchers found that the active form of folate, 5-methyltetrahydrofolate (5-MTHF), which has the capacity to cross the blood brain barrier, at 15.0 mg/day had an increased response rate to SSRI’s (Selective serotonin reuptake inhibitors), and may be prophylactic for Alzheimer’s and may suppress the formation of plaque growth. As L-methyl folate (5MTHF) can cross the blood-brain barrier, the researchers concluded that it seems to be a viable strategy in the prevention and treatment of dementia and Alzheimer’s.

No adverse effects and the dosage was well-tolerated when given to patients with poor or no response to SSRIs.

➤ **Omega-3 Fatty Acids for Mood and Improved Mental Functioning for Aging**

Omega-3 Polyunsaturated fatty acids (PUFAs) are found mainly in oily fish and seafood. Omega-3s are thought to act by altering cell membrane structure and function, particularly fluidity, cellular communication, and inflammatory pathways and support neural development and prevent nervous system disorders.

The following studies specifically investigated the effects of Omega-3s in the elderly, particularly concerning dementia, depression, and bi-polar disorder in persons 60 – 95 years of age.

Gertski L, Poland RE, Bresee C, Rapaport MH. (2012). “*Omega-3 Fatty Acid Augmentation of Citalopram Treatment for Patients with Major Depressive Disorder.*” *Journal of Clinical Pharmacology.* 2012 Feb; 32 (1):61-64.

Gertski and colleagues showed that the combination of Omega 3 with SSRIs decreases the signs and symptoms of major depressive disorders.

Rondanelli M, Giacosa A, Opizzi A, Pelucchi C, La Vecchi C, Montofrano G. Negroni M. Berra B, Polito P, Rizzo AM. (2010). “*Effects of Omega-3 Fatty Acids Supplementation on Depressive Symptoms and on Health-Related Quality of Life in the Treatment of Elderly Women with Depression.*” *Journal of the American College of Nutrition* Feb: 55-64.

In this double-blind, placebo controlled randomized clinical study with 46 depressed elderly women (66-95 years old) administered daily dose of 2.5 g Omega-3 (1.67 EPA and 0.83 DHA) and evaluated improvements of depressive symptoms with the Geriatric Depression Scale. The results showed that Omega-3 led to significant reduction in depressive symptoms and amelioration of quality of life as well, with improved physical and mental function. No adverse side effects noted.

TajalizadekhoobY, et al (2011). “*The effect of low-dose omega-3 fatty acids on the treatment of mild to moderate depression in the elderly.*” *Eur Arch. Psychiatry Clinical Neuroscience.* 2011 Dec: 539-549

In a double-blind, randomized, placebo controlled study of 66 depressed patients older than 65 years of age, researchers compared a daily low dose of Omega-3 (1 g / day) to placebo over 6 months. The researchers found that low dose Omega-3 supplements showed significant effects and efficacy in the treatment of mild to moderate depression. No adverse side effects noted.

➤ **Phosphatidylserine and Omega-3 (PS + DHA/EPA) for Dementia**

Vakhapova V, Cohen T, Richter Y, Herzog Y, Korcayn AD. (2010). “*Phosphatidylserine containing Omega-3 Fatty Acids May Improve Memory Abilities in Non-Demented Elderly with Memory Complaints.*” *Dementia Geriatrics and Cognitive Disorders*. 2010; 29(5): 467-474. doi: 10.1159/000310330. Epub 2010 Jun3. And **Vakhapova, et al 2014:**38 (1-2:39-45. doi: 10.1159/000357793. Epub 2014 Feb 20. 2914 D

Richter Y, Herzog Y, Cohen T, Steinhart Y. (2010) “*The Effect of Phosphatidylserine-containing Omega-3 fatty acids on memory abilities in subjects with subjective memory complaints.*” *Clinical Intervention and Aging*. 2010 Nov 2; 5:313-316. doi: 102147/CIA/S13432.

Vakhapova, et al (2010) performed the first double-blind, placebo-controlled clinical trial (n = 131) to analyze the effect of phosphatidyl-serine with attached Omega-3 fatty acids (mainly DHA) for 15 weeks in patients without dementia but with memory complaints. Dosage consisted of PS 300 mg/day + DHA/EPA 79 mg/day (3:1 ratio) The supplement’s efficacy was measured by several cognitive and memory assessment tools, with objective and subjective evaluations. Results showed a better recall of immediate verbal memories in the intervention group. There was better treatment responsiveness among patients receiving PS-DHA when compared to the placebo group.

The Vakhapova, et al (clinical trial was extended as an open-label trial (n = 122). Researchers administered a lower dose of PS-DHA for another 15 weeks to the Placebo Group. Dosage was 79 mg/day and PS 100 mg/day + EPA/DHA 26 mg/day (3:1 ratio). Similarly, compared to their previous findings, they observed memory benefits and improvements in responsiveness. Vakhapova, et al (2014).

Finally, Richter, et al (2010) published a pilot open-label study in which PS with Omega-3 EPA + DHA was administered daily for 6 weeks in eight elderly volunteers with memory complaints. Dosage of PS-DHA/EPA were PS 300 mg/day + DHA/EPA 37.5 mg/day. Despite not being a placebo-controlled and double-blind trial, the results were significant and impressive, showing a 42% increase in patients’ ability of verbal recall memory.

Appendix B Glossary of Policy Brief Key Terms

Alzheimer's disease (AD): A degenerative progressive brain disease that impairs memory, language, thought, judgment and behavior. It is not just "old age," it can strike in the forties and fifties. It is the most common disorder responsible for 60%-70% of neuro-degenerative diseases. Alzheimer's starts in late middle age or in old age, that results in progressive memory loss, impaired thinking, disorientation, and changes in personality and mood, and that is marked histologically by the degeneration of brain.

CAIMH: Complementary, Alternative, and Integrative Medicine & Health

Neuro-degenerative Disease: Neurodegenerative disease is an umbrella term for a range of conditions which primarily affect the neurons in the human brain. Neurons are the building blocks of the nervous system which includes the brain and spinal cord. Neurons normally don't reproduce or replace themselves, so when they become damaged or die they cannot be replaced by the body. Examples of neurodegenerative diseases include Parkinson's, Alzheimer's, and Huntington's disease. Neurodegenerative diseases are incurable and debilitating conditions that result in progressive degeneration and / or death of nerve cells. This causes problems with movement (called ataxias), or mental functioning (called dementias).

Dementia: A neuro-degenerative disease that is responsible for the greatest burden of brain conditions where cognitive or memory impairment is severe enough to affect daily life, but it does not identify the underlying cause. Thus, not all dementia is Alzheimer's disease.

NCCIH: The National Center for Complementary and Integrative Health (NCCIH) is a sub-division of National Institutes of Health (NIH), the Federal Government's lead agency for scientific research.

NIH-Neuro-degenerative Research: The Neuro-degenerative cluster portfolio consists of research on adult onset neurodegenerative diseases of all types, broadly focusing on pathogenesis, treatment and prevention. Research on the normal structure and function of neural systems is also included to enable identification of intervention strategies.

Parkinson's disease (PD): the second most common neuro-degenerative disorder, results from loss of dopaminergic (DA) neurons in substantia nigra pars compacta, located in the mid-brain. It is a progressive disease marked by tremor, muscular rigidity, and slow, imprecise movement, chiefly affecting middle-aged and elderly people. It is associated with degeneration of the basal ganglia of the brain and a deficiency of the neurotransmitter dopamine.

Western Medicine: A system in which medical doctors and other healthcare professionals (such as nurses, pharmacists, and therapists) treat symptoms and diseases using drugs, radiation, or surgery. Also called allopathic medicine, biomedicine, conventional medicine, mainstream medicine, and orthodox medicine.

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US Dept. of Health and Human Services (HHS, 2013). "National Plan to Address Alzheimer's Disease." Retrieved from: <https://aspe.hhs.gov/national-plan-address-alzheimers-disease-2013-update>