Medical Foods and Diets Part 1: A Summary of the Impact on Cognition

Dr. Lauren M. Young, Geriatric Fellow, Washington University at St. Louis and Dr. David Carr, Medical Director, Parc Provence

Over the last several years, there have been a variety of dietary supplements, herbal products and medical foods that have become popular as memory boosters or even as products that slow the progression of Alzheimer's disease (AD). With approximately 5.4 million people living with Alzheimer's disease and few prescription medications on the market of which have modest effectiveness of slowing the progression of Alzheimer's and varying tolerability, the interest and use of medical foods and natural products are on the rise.

Some products currently on the market include caprylic acid, coconut oil, omega-3 fatty acids coenzyme Q10, vitamin E, polyphenols, vitamin B12 and folate. These over-the-counter supplements or vitamins may be found in common household foods in your pantry or refrigerator. Unlike their prescription counterparts, the Food and Drug Administration (FDA) does not regulate over-the-counter supplements, so the purity and concentrations of their active ingredients are not regulated. Moreover, their safety and efficacy are not monitored and adverse effects are not recorded or reported. Over-the-counter supplements are self-governed by each individual company.

Medical foods are products that are specially formulated and used for the dietary management of a disease that has specific nutritional needs that cannot be met by a normal diet. They are subject to the general food and safety labeling requirements of the FDA. In order to be considered a medical food the product must at a minimum: be a food for oral ingestion or tube feeding, be used for the dietary management of a disease with distinctive nutritional requirements, and be used under medical supervision. Approval of a medical food does not have to reach the same levels of standard of a new pharmaceutical product and typically they have been studied on smaller numbers of participants when reviewed by the FDA. At this point, over-the-counter supplements and herbal products as a whole do not have sufficient evidence to support them as equivalent alternatives to current prescription drugs/medical foods on the market for Alzheimer's disease.

An observational study published in the Archives of Neurology in 2012 indicated that individuals on low-fat diets rich in nuts, poultry, certain fruits, and leafy greens might reduce the risk of Alzheimer's disease.

These foods are rich in omega-3 fatty acids, omega-6 fatty acids, vitamin E, vitamin C, vitamin B12 and folate. It is not clear if it is the combination of several foods interacting together cause a cumulative positive effect as opposed to one supplement or vitamin in particular. Another study in the Archives of Neurology in 2010, noted that a dietary pattern of salad dressing, nuts, fish, tomatoes, poultry, cruciferous vegetables, fruits, dark and green leafy vegetables, and a lower intake of high-fat dairy products, red meat, organ meat, and butter was a associated with a lower risk prospectively of developing dementia in over 2000 older adults. Similarly, a study in 2006 of over 1800 older adults noted that those that were eating a Mediterranean diet were also at a lower risk of developing Alzheimer's disease.

Axona is a prescription medical food intended for the clinical dietary management of the impairment in metabolic processes related to glucose metabolism associated with mild to moderate Alzheimer's disease. Glucose is the primary source of energy for the brain. In patients with Alzheimer's disease, there is a dramatic drop in the brain's ability to metabolize glucose. Inadequate metabolism of glucose may lead to damage to the brain cells resulting in impaired cognition and brain disease. Axona addresses glucose deficiencies in by providing an alternative source of energy, ketones (Beta-Hydroxybutyrate), which are produced by the liver from the caprylic fatty acids. This is an alternative fuel used in the body during periods of low calorie intake or fasting states. Axona was evaluated in a double-blind,

randomized; placebo-controlled study performed at multiple US clinical centers in a population of 152 patients with probable mild to moderate Alzheimer's disease and significantly favored Axona over placebo in cognitive tests. Axona is administered orally once a day, supplied as a powder one packet (40 g) to be mixed with water or other foods/liquids. Axona is preferably administered after breakfast or lunch and can be taken with commonly prescribed AD medications. Axona's adverse effects are primarily limited to the gastrointestinal tract.

In lieu of purchasing Axona, which can cost from \$83 to \$110, and is not covered by most insurance plans or Medicare, some have opted to try the less expensive form of caprylic acid found in coconut oil. Anecdotal reports have found improvement in memory, however, coconut oil is high in saturated fat and may lead to other health complications such as heart disease, if used excessively.

Before starting any medical supplement, consult with your physician. The safest approach is to follow a healthy diet low in saturated fat including a variety of colorful fruits and vegetables, especially the cruciferous varieties, beans, nuts, wholegrains, fatty fishes and eggs, all within moderation. This is basically, a well balanced diet. A combination of these healthy ingredients just may be a recipe for a healthy brain.