Cognitive Function in Patients with Moderate Alzheimer’s Disease on

a Whole Food Plant Based Diet versus a Standard Diet

CNHP 6000:

Research Methods for Health Professionals

Student Name

**Introduction**

Alzheimer’s Disease (AD) impacts millions of Americans daily and the number of individuals affected is expected to triple over the next few decades.4 The disease is a progressive neurodegenerative disorder which causes problems with memory, critical thinking and behavior.4,10 AD is the most common form of dementia and is responsible for approximately 60-80 percent of cases. The formation of deposits of beta-amyloid (protein fragments) between nerve cells and the buildup of tau proteins (often times referred to as tangles) inside cells are believed to be the cause of AD as they spread through the brain’s cortex and destroy nerve cells.10As the disease progresses and cognitive abilities decline over time, recent studies have explored methods of preventing the disease.

Current scientific articles have examined the relationship between diet and the risk of developing AD. Studies have indicated a higher intake of saturated fatty acids may impair cognitive functions, while a diet in higher monounsaturated fatty acids may be related to better cognitive functions.4One study determined that when individuals are exposed to a large amount of animal-based protein daily, the oxidative stress can cause tau phosphorylation and the production of beta amyloid precursor proteins.1 Another study confirmed a diet that includes a high consumption of red meat, processed meat, refined grains, sugar and processed foods may lead to the development of AD by increasing oxidative stress and beta-amyloid deposition.4

The adherence to specific diets have been studied and determined to reduce the risk of AD. Both the Dietary Approaches to Stop Hypertension (DASH) diet and the Mediterranean diet have been examined and with their emphasis on fruits, vegetables, cereals, whole grains, beans, nuts, olive oil, fish, poultry, and reduced consumption of red meat, dairy, added sugar and sodium, their results indicate adherence to either diet may lower the risk of AD as well as the mortality in AD.4

Additionally, a study was conducted to determine if a hybrid of the Mediterranean diet and the DASH diet referred to as the Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND diet) lowered an individual’s risk for developing AD.5 The MIND diet focused on the intake of plant-based foods with an emphasis on berries and green leafy vegetables and only limited quantities of animal and high saturated fat foods. Based on the results of their study, the researchers determined modest adherence to the MIND diet “may have substantial benefits for the prevention of AD.”5

While there has been progress on examining what dietary factors may be beneficial in lowering an individual’s risk of developing AD, studies on individuals diagnosed with AD and the impact of their diet on a moderate-AD diagnosis, have not been conducted based on research of the current literature.

The purpose of this study is to determine if a whole-food plant based diet (WFPD) impacts the rate of decline on patients diagnosed with moderate-Alzheimer’s disease. Whole-food plant based diets have been studied for their beneficial impact on reversing heart disease, weight loss and glycemic control but the effect of a WFPD compared to a standard diet on AD is unknown.2 Patients with moderate-AD may exhibit difficulties in conducting simple math, forget specific details about their past, as well have problems with short term memory-loss. However, patients at this stage can continue to feed themselves independently, dress themselves and can bathe and use the bathroom independently.7,9 A WFPD is defined as a consumption of plant foods in their whole form, especially vegetables, fruits, legumes, seeds, nuts, whole grains and the exclusion of all animal products.6 This meal plan takes the MIND diet one step-further with the elimination of all animal products.By examining the relationship between diet and cognitive decline in an individual with diagnosed moderate-AD, it can be determined if adherence to a WFBD slows down the rate of cognitive decline. The hypothesis of the study is that those diagnosed individuals who consume a WFBD for a specific period of time will demonstrate a slowing of cognitive decline versus those diagnosed individuals that continue to consume a standard diet.

**Methods**

*Sample Population*

The sample population for the study includes 20 women diagnosed with moderate-Alzheimer’s Disease between the ages of 65 and 75 currently living in a skilled nursing facility. The facility selected is St. George Village in Roswell. The facility was selected based on the population of residents living in their memory care area. Patients with early-onset AD diagnosis or in the late stages of the disease are excluded from the study. It is important to have a sample population able to communicate and exhibit some independence.

Permission to conduct the study at St. George Village is required from the facility’s board. The nursing home is a non-profit entity, owned by Catholic Care Retirement Community, Inc. and is managed by Wesley Woods Senior Living, Inc., which is affiliated with Emory Healthcare. A full review of the research proposal by the facility’s board is expected.

A signed informed consent form is required from the patients’ legal guardians. The consent form clearly states the purpose of the study, the length of the study, how the participants were selected, what meals the intervention group will receive, what benefits may occur for the participants, how any unforeseeable risks which may occur will be handled, how personal patient information will be kept confidential, the steps the patient’s guardians can take to withdraw from the study at any time and how to contact the researchers.

*Study Design*

The study is an experimental – randomized controlled trial. Patients will be selected by simple randomization to either the control group, which will continue to eat the meals and snacks provided by the facility, or the intervention group, whose WFPD meals will be created by a registered dietitian (RD).

*Dietary Intervention*

The WFPD meals will provide the recommended dietary reference intakes (DRI) of vitamins and minerals, as well as adequate fiber and hydration. A sample menu plan may be oatmeal banana muffins for breakfast, an edamame hummus-wrap for lunch, a snack of whole-grain crackers and sundried tomato and roasted pepper spread, a black bean burger with red cabbage and mango slaw, a banana peanut butter cookie for dinner. The WFPD may be deficient in protein, iron, vitamin B12, calcium and vitamin D, and fatty acids. If properly planned, persons on a WFPD are at little or no risk for protein deficiency. The consumption of beans, soy products, nuts such as walnuts, flaxseeds and grains including quinoa provide an adequate amount of protein and essential fatty acids. While iron stores may be lower in people that consume a WFPD, iron-deficiency anemia is rare. Eating foods such as beans, spinach, oatmeal and cabbage, which are rich in iron, ensure iron levels remain in the appropriate range. Vitamin B12 is produced by bacteria, not plants or animals. This vitamin requires supplementation or the consumption of fortified foods to maintain appropriate levels. A supplement of 50 mcg of vitamin B12 will be added for patients in the intervention group, unless they are currently taking a multi-vitamin or other supplement which meets the DRI for vitamin B12. Calcium and vitamin D can be adequate on a WFBD as long as foods such as tofu, mustard and turnip greens, bok choy and kale are consumed along with fortified nut-based milks and juices.6 The RD will also be aware of any food-medication reactions that may occur with a WFPD.

Patients in the intervention group will consume a WFPD diet for 180 days. Every 30 days, both the control and intervention group will complete a General Practitioner Assessment of Cognition (GPCOG) questionnaire.8 The GPCOG Screening Test is a validated dementia-screening instrument.11 Interviewers will be trained in the appropriate methods of gathering information from the patients and their caregivers and will have an opportunity to practice their interview skills prior to conducting the initial interviews. Specific details regarding the step-by-step process, how to ask the questions, how to record answers on the GPCOG and how to handle various situation or problems that may arise when conducting the interview will be included in a handbook provided to each interviewer.

The patient assessment questions on the GPCOG have the categorical variables of “correct” and “incorrect”. Questions for patients include a name and address recall test, drawing a clock, information recall, and time orientation. The informant questions answered by the patient’s lead nurse include the variables of “yes”, “no”, “don’t know” and “N/A”. Questions for the informant determine if the patient is having more difficulty remembering details, recalling conversations, using the appropriate words as well as difficulty finding the right word. The maximum total score is 9 with the following impairment categories: 9: no significant cognitive impairment, 5 – 8: more information required, 0 – 4: cognitive impairment is indicated.

Demographic and clinical characteristics of the population will be described using frequency statistis. A Chi-square test will be used to assess the association between GPCOG category and the type of diet received (2 x 3 table). All statistical analysis will be conducted with SPSS (version 25.0, SPSS Inc. Chicago, IL). Analysis of the data will occur at baseline and again at the conclusion of the 180-day study period.

**References**

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