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SHORT COMMUNICATION

Effect of cold pressed coconut oil on cognition and behavior among patients with Alzheimer's disease - A pilot intervention study

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ABSTRACT

Background: Alzheimer's disease (AD)'s pharmacotherapy is limited, with anecdotal reports claiming some usefulness of cold pressed coconut oil. **Aims and Objectives:** To study the effect of cold pressed coconut oil on cognition and behavior of AD patients who are treatment naïve or stabilized on cholinesterase inhibitors or memantine for at least 3 months with a mini-mental state examination (MMSE) score of 10-24. **Materials and Methods:** An investigator initiated pilot randomized controlled trial studied the effect of cold pressed coconut oil on cognition and behavior of AD patients. Minimum sample size was calculated assuming an increase of 30% in MMSE scores in the experimental group with 95% confidence interval and 80% power to be 20 at each experimental and control groups. Efficacy was measured using MMSE, clock drawing test (CDT), neuropsychiatric inventory questionnaire at baseline, 3 and 6 months, with safety profile monitored by electrocardiogram, and laboratory investigations at baseline and at 6 months. **Results:** 40 individuals out of 99 screened were enrolled, with no significant differences in cognitive level between the intervention and control group at baseline. At 6 months, the control group showed significant ($P = 0.035$) improvement in CDT. Diarrhea, the most common adverse event caused high dropout in intervention group. **Conclusion:** Cold pressed coconut oil did not improve cognition or behavior in AD patients.

KEY WORDS: Alzheimer's Disease; Cognition; Behavior; Coconut Oil; Cold Compressed

INTRODUCTION

Alzheimer's disease (AD), a progressive neurodegenerative disorder affecting the ageing population, results in irreversible loss of neurons and loss of intellectual abilities such as memory, language and reasoning, and eventually impedes social and occupational functioning posing a great burden on the caregiver.[1,2] In 2006, there were 26.6 million sufferers of AD worldwide and predicted to affect 1 in 85 people globally by 2050.[3]

Around, 47 million people suffer from dementia globally, and about 9.9 million of new cases are reported every year. AD is the most common cause for dementia and contributes to about 60-70% of cases. Dementia is one of the major causes of disability and dependency among elderly population worldwide. It has physical, psychological, social, and economical impact on carers, families, and society.[4]

Currently no available treatment can stop or reverse the progression of the disease. A Cochrane review of current treatment using acetylcholinesterase inhibitors (ChEI) such as donepezil, galantamine, and rivastigmine has shown minimal improvement in cognition and behavior but none has a large treatment effect and clinical significance is questionable.[5,6]

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Memantine has shown modest benefits in cognition, function, and behavioral of AD patients either on its own, or in combination with ChEI.[7] These drugs are expensive and not available to many AD patients in Malaysia. A Cochrane review found no evidence supporting the use of Vitamin E, non-steroidal inflammatory drugs, statins, and lecithin[8-10] in the treatment of AD, with conflicting evidence in the use of testosterone and gingko.[11]

Pathologically, AD shows accumulation of senile plaques, neurofibrillar tangles, brain atrophy, and regional cerebral hypometabolism with low cerebral metabolic rates of glucose use.[2] When there is a lack of glucose (e.g., in insulin resistance), brain cells particularly neurons slowly die off. Some studies have suggested that induced ketosis may be beneficial in AD as ketone bodies is an efficient alternative source of energy for brain cells and help keep the brain cells alive and functioning.[12-15] Medium chain triglycerides (MCTs) or fatty acids are a source of ketone bodies which appears to protect neurons when glucose is not available. Coconut oil contains 66% MCT which can be neuroprotective. MCTs are metabolized directly through the liver have been found to increase high-density lipoprotein cholesterol and decreases total and low-density lipoprotein cholesterol and triglycerides.[16]

A clinical trial on Ketasyn (AC 1202) a ketogenic agent found significant differences in cognition of study participants as compared to placebo in AD assessment scale-cognitive subscale scores but not the mini-mental state examination (MMSE) scores.[17]

Anecdotal case studies reported that 35 ml of cold pressed coconut oil taken daily resulted in improvement of cognition using MMSE within weeks of starting therapy and sustained subsequently and behavior.[18,19] Cold compressed/virgin coconut oil is higher in vitamin content, antioxidant levels, minerals, medium chain fatty acids, taste, fragrance, and even the amount of protein. Since it is not subjected to heat (even if it is, it is subjected to very low heat), sunlight, and being extracted from fresh coconuts using a different process of extraction, virgin coconut oil is certainly richer in benefits than ordinary coconut oil.[20] In AD, there appears to be a pathological decrease in the brain's ability to use glucose. Research suggests that ketones are an effective alternative energy source for the brain. Studies show that raising ketone levels through an oral dose of MCTs might improve cognitive functioning in older adults with memory disorders.[21]

Since virgin (cold compressed) coconut oil is available as dietary supplements in Malaysia it would be easily acceptable for the treatment of AD if it is found to be effective.

The objective of this study was to explore whether daily dietary supplement of cold pressed coconut oil improved and/or prevented further deterioration in cognition and behavior for patients with mild to moderate AD. Specifically to determine if coconut oil supplement improves cognition using the MMSE, clock drawing test (CDT), and behavior using the neuropsychiatric inventory questionnaire (NPI-Q) and to determine if coconut oil supplement has any adverse effects on blood parameters and electrocardiogram (ECG).

MATERIALS AND METHODS

The study was funded through a short-term research grant from the University Kuala Lumpur, Royal College of Medicine, Perak (STRG No: 1205) and was approved by the University's Research and Ethics Committee.

This is an investigator initiated randomized double-blind placebo controlled trial among patients with AD who were either treatment naïve or stabilized on cholinesterase inhibitors or memantine for at least 3 months with a MMSE score of 10-24. The participants should have a stable caregiver and were recruited from the community either living in their own home or in geriatric homes. Efficacy was measured using MMSE, CDT, and NPI-Q at baseline, 3 and 6 months. Safety profile was monitored by ECG and laboratory investigations comprising of fasting lipid profile, fasting blood sugar, renal profile, and liver function test at baseline and 6 months.

Dementias of other types, AD patients with MMSE scores of <10 and >24, those with clinically significant history such as coronary heart disease, uncontrolled hypertension (BP >140/90 mmHg), uncontrolled diabetes mellitus (HbA1c >7%), hypothyroidism, renal impairment, depression, and also allergies to plant food products were excluded from the study.

Sample size was calculated assuming an increase of 30% in MMSE scores in the experimental group with 95% confidence interval (CI) and 80% power. Minimum sample size was calculated to be 20 at each arm.

After the participants signed the informed consent form (ICF) they were screened for their eligibility. The ICF and throughout the study procedure coconut oil was referred to as "coconut product" to ensure blinding of cold compressed virgin coconut oil and placebo consisting of water plus coconut essence. Both placebo and coconut oil were of the same color and smell. Eligible participants were randomized 1:1 using block randomization method to either experimental or control group (Figure 1). The study was double blinded so that the participants and the researchers were unaware of the allocation to experimental or control groups. A laboratory-based research assistant, who was not blinded, handled the packing and dispensing of coconut oil and placebo. The intervention group received 30 ml of coconut oil daily during the first 2 weeks and thereafter increased to 60 ml daily. Placebo was also dispensed in the similar manner. They were

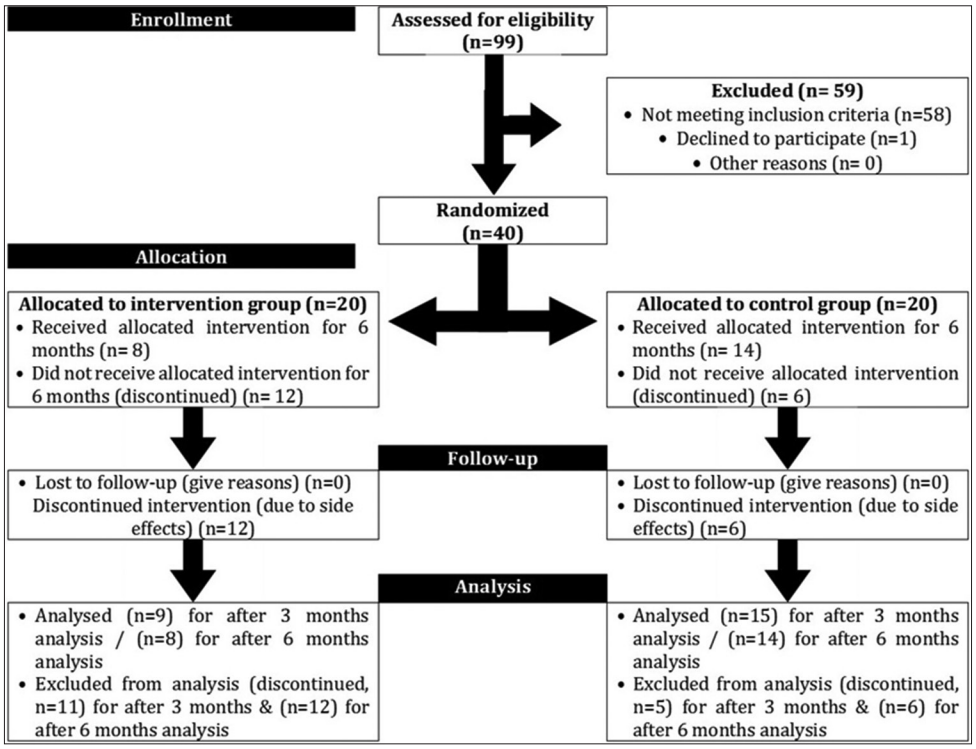

Figure 1: Consort flow chart

dispensed biweekly and instructed to be taken in two divided doses either directly or added to food.

The data were analyzed using SPSS version 19 with Student's *t*-tests and ANOVA.

RESULTS

Out of 99 patients, 41 patients screened met all the inclusion criteria. One left the geriatric home before enrolment. The majority were Chinese (85%), female (65%), aged between 70 and 79 years (58%), had primary school education (43%) and staying in a geriatric home (60%).

There was no significant difference in the mean scores in all the parameters assessed between the intervention and control group at baseline, at 3 months and 6 months. Nine from coconut oil group and 15 from placebo group completed at 3 months. Eight from the coconut oil group and 14 from placebo group completed the study at 6 months.

There was a high dropout rate among the coconut oil group primarily due to diarrhea (45%) with two of these participants also having abdominal discomfort (10%), and two unable to tolerate the smell/taste (10%). Other reasons for participants in the coconut oil group who stopped participating in the study was acquired pneumonia, poor compliance, and withdrawing consent.

From the placebo group, reasons for stopping participation in the study included relocation, starting warfarin treatment, and withdrawing consent.

Analysis showed no significant difference in all the parameters from baseline to 6 months within each group except in the placebo group showed significant improvement in CDT (difference between mean CDT −0.78571, 95% CI of difference between mean CDT: −1.50824 −0.06319; $P = 0.035$).

There was no significant changes in ECG and blood tests except in the coconut oil group, serum alanine aminotransferase and serum triglyceride were significantly increased ($P = 0.015$, $P = 0.010$ respectively). In the placebo group, serum aspartate aminotransferase was significantly increased ($P = 0.027$) while blood urea and serum uric acid was significantly decreased ($P = 0.033$, $P = 0.029$ respectively). It is difficult to interpret the blood results due to small number of participants due to high dropout.

DISCUSSION

There was no significant difference in the mean scores in all the parameters assessed between the intervention and control group at baseline, at 3 months and 6 months. There was significant improvement in CDT scores from baseline to 6 months in the control group. It was found that seven of the 14 patients of the control group (50%) were staying in their own houses with families. There was a significant difference between the 2 groups (fisher exact test [2 sided] $P = 0.041$), where those staying in their own homes significantly improved in CDT.

The findings were different from the previous anecdotal case studies which reported that cold pressed coconut oil taken daily resulted in improvement of cognition using MMSE

within weeks of starting therapy and sustained subsequently and behavior.[18,19] This might be due to the increased dropout rate and the reduction in sample available for analysis at the end of the research.

The strength of this research is that it is one of the few randomized controlled trials to test the effectiveness of cold pressed coconut oil in improving cognitive function among AD patients. High dropout was the major limitation. Diarrhea with abdominal discomfort were the most common side effect of taking coconut oil followed by intolerance to its smell/taste, resulting in a very high-dropout rate. Alternatively, capsule formulation or reduced amount of cold pressed coconut oil could be tested.

People with dementia who live in their own homes with their families and enriched with cognitively stimulating environment would logically fare better than in a geriatric home which lack such stimulation. A larger multicentric trial should be done to explore beneficial effect of coconut oil in AD patients that was claimed by anecdotal reports.

CONCLUSION

Cold pressed coconut oil supplement did not significantly improve cognition and behavior in patients with AD in this research.

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