

Pilot Trial Evaluating the Mediterranean Diet Vs. Modified Mediterranean Ketogenic Diet Using a Scalable Community Program

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1. The ICAN platform was feasible, acceptable, and effective for supporting adherence to both Mediterranean and modified Mediterranean ketogenic dietary interventions in high-risk older adults.
2. Both diets were associated with clinical benefits, but MMKD showed greater improvements in select cognitive and cardiometabolic outcomes through 12-month follow-up.

INTRODUCTION	METHODS	RESULTS	CONCLUSIONS	REFERENCES
- Dietary interventions are promising for reducing Alzheimer’s disease and related dementia (ADRD) risk, particularly through vascular, metabolic, inflammatory, and brain energy pathways.¹⁻³ - The Mediterranean diet (MED) is a well-established dietary pattern for cognitive health and may confer up to a 30% reduction in risk for ADRD.⁴ - Modified Mediterranean ketogenic diets (MMKD) may provide additional metabolic and cognitive benefits by combining Mediterranean-style foods with nutritional ketosis, but they are more complex and difficult to implement.⁵⁻⁷ - Scalable behavioral programs are needed to help high-risk older adults initiate and sustain evidence-based dietary change in real-world community settings.⁸ - The Improving Cognitive Aging through Nutrition Program (ICAN) was designed as a flexible adherence-focused nutrition and lifestyle platform that can support multiple brain-health dietary patterns. - This pilot trial evaluated ICAN using a regionally modified MED and an MMKD as two dietary test cases to evaluate the acceptability and feasibility of the ICAN program, as well as compare preliminary clinical effects of the two diets.	Design: Multi-arm randomized clinical trial (N=30 in MMKD arms; N=31 in MED arms). Assessments completed at baseline, weekly monitoring, post-intervention (10-weeks), & 12-month post. Participants: 65 older adults (55-85) with and without mild cognitive impairment, over-recruited from rural and underrepresented populations Measures: - Feasibility was assessed based on retention rates, session attendance, and dietary adherence. - Acceptability was measured at 10-weeks using the 8-item Client Satisfaction Questionnaire (CSQ-8, range=8-32).⁹ - Adherence was measured using food logs, self-rated (0-10), and the MEDAS. - Cognitive change across the intervention was assessed using age and education adjusted t-scores from select measures of the NIH Toolbox. - Cardiometabolic change was assessed using blood pressure, HbA1c, blood cholesterol, blood glucose, and blood triglycerides levels. Analyses: Descriptives, T-test, & ANOVA	Feasibility and Acceptability - Retention: 93.4% of participants were retained at the 10-week assessment, and 88.5% remained in the study through the 12-month follow-up. Slightly higher retention at 6 and 12-months in MED and support group arms. - Attendance: 84.5% overall, no significant differences between groups - Adherence: No significant differences in self-reported and MEDAS-based adherence ratings; however, MMKD arms had higher dietary adherence based on food logs (p<.001). - Acceptability: CSQ-8 M=29.31, high satisfaction with no group differences. Clinical Outcomes - MMKD and MED groups both showed significantly lower weights, BMI, and better sleep quality at week 10 (ps<.05). - Compared with the MED group, the MMKD group exhibited greater improvements in RAVLT at week 10 (p = .015), DCCS at month 6 (p = .048), and Flanker (p = .007) and RAVLT (p = .028) at month 12. - Compared with the MED group, the MMKD group exhibited reduced SBP, weight, BMI, and visceral fat at month 6 (ps<.05), and greater decrease in triglycerides (p = .006) at month 12.	- The ICAN program demonstrated <u>strong feasibility and acceptability</u> for delivering brain-health dietary interventions in a diverse, community-based sample of high-risk older adults, with high retention, attendance, satisfaction, and dietary adherence. - Both the Mediterranean diet and the MMKD were associated with meaningful improvements in weight, BMI, and sleep quality following the intervention. - Compared with the Mediterranean diet, <u>MMKD demonstrated greater improvements in multiple cognitive domains</u> (episodic memory, executive function, and inhibitory control) and cardiometabolic outcomes, including blood pressure, adiposity, and triglycerides. - These findings support the feasibility of disseminating intensive dietary interventions through scalable behavioral programs and provide preliminary evidence that MMKD may offer additional benefits beyond a Mediterranean diet alone.	1. 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Assessment of client/patient satisfaction: Development of a general scale. <i>Evaluation and Program Planning</i>, 2(3), 197–207. https://doi.org/10.1016/0149-7189(79)90094-6 CONTACT Julia L. Sheffler, PhD, ABPP Assistant Professor Florida State University College of Medicine Julia.sheffler@med.fsu.edu  