

ISU STOP LOSS PARTNER NEWSLETTER

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Intensive Lifestyle Change Linked to Improved Alzheimer's Symptoms

By: Medscape

Healthy behaviors have been linked to a lower risk for Alzheimer's disease (AD) but may also benefit patients already diagnosed with mild cognitive impairment (MCI) or early AD, new research suggested.

After 20 weeks, patients following an intensive multimodal lifestyle intervention showed significant improvements across three measures of cognition and function and less progression on one measure when compared with usual care.

Beneficial changes were also observed in several biomarkers, including plasma amyloid beta ($A\beta$) 42/40 ratios, which increased by 6.4% in the intervention group and dropped by 8.3% in the control group ($P = .003$).

"I'm cautiously optimistic and very encouraged by these findings, which may empower many people with new hope and new choices," Dean Ornish, MD, clinical professor of medicine, University of California, San Francisco, and founder and president, Preventive Medicine Research Institute, Sausalito, California, said in an interview.



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Ornish and colleagues previously reported that the lifestyle program led to regression of coronary atherosclerosis, but this is the first randomized controlled trial to show intensive lifestyle changes can significantly improve cognition and function in early Alzheimer's, he said.

The findings were published online on June 7, 2024, in Alzheimer's Research & Therapy.

An Extensive Lifestyle Intervention

For the phase 2 study, 51 patients, aged 45-90 years, with MCI or early dementia due to AD and a Montreal Cognitive Assessment score of ≥ 18 were enrolled between September 2018 and June 2022.

Patients were randomly assigned to receive the intervention or usual care for 40 weeks, with the control group able to crossover to the lifestyle program after 20 weeks. The 40-week results will be available later this year, Ornish said.

The intervention was delivered via Zoom after March 2020 due to COVID-19 and included a minimally processed vegan diet low in harmful fats, sweeteners, and refined carbohydrates with eight selected supplements. All meals and snacks were provided at no cost to the participant and spouse or study partner.

An exercise physiologist led strength training at least three times per week and encouraged at least 30 minutes per day of aerobic exercise such as walking. One hour per day was devoted to supervised stress management practices such as meditation and yoga.



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Participants and spouses/partners also attended 1-hour group support sessions 3 days per week, supervised by a licensed mental health professional. Two patients dropped out of the intervention arm. All 49 remaining patients had plasma A β 42/40 ratios < 0.0672 at baseline.

Meaningful Lifestyle Changes

After 20 weeks, 10 of the 24 intervention patients had minimal improvement, seven were unchanged, and seven had minimal worsening in the Clinical Global Impression of Change test. No one in the control group improved, eight were unchanged, 14 had minimal worsening, and three had moderate worsening (P = .001).

The Clinical Dementia Rating Global (CDR Global) scores improved in the intervention group from 0.69 to 0.65 and worsened in the control group from 0.66 to 0.74 (mean group difference = 0.12; P = .037).

Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAS-Cog) scores improved from 21.55 to 20.53 in the intervention group and worsened in the control group from 21.25 to 22.16 (mean difference = 1.92 points; P = .053).

CDR Sum of Boxes (CDR-SB) scores worsened significantly more with usual care (from 3.34 to 3.86) than with the lifestyle intervention (from 3.27 to 3.35). The mean group difference was 0.44 (P = .032).

"Not everyone got better, but many people did, and if you can stop it or improve cognition, that can give people a sense of hope, not false hope but real hope, as opposed to telling people they're only likely to get worse," Ornish said.



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He noted that the risk for suicide 3 months after a diagnosis of Alzheimer's is seven times higher than it normally is and that minimal improvement doesn't necessarily capture clinically the impact of the lifestyle changes on these patients.

"One patient said it used to take weeks to finish a book, but after being in the study, he was able to do so in just 3 or 4 days and remember most of what he read," said Ornish. "One guy wasn't able to play the bagpipes because he couldn't remember the notes, and now he can, and he's actually teaching a student to do so."

Larger, More Diverse Trials Needed

Commenting on the study for Medscape Medical News, Heather M. Snyder, PhD, Alzheimer's Association vice president of medical and scientific relations, said, "This is an interesting paper in an important area of research and adds to the growing body of literature on how behavior or lifestyle may be related to cognitive decline."

"However, because this is a small phase 2 study, it is important for this or similar work to be done in larger, more diverse populations and over a longer duration of the intervention," she added.

Results are expected in summer 2025 from the Alzheimer's Association's US POINTER Study, the first large-scale study in the United States to explore the impact of comprehensive lifestyle changes on cognitive health in about 2000 older adults at risk for cognitive decline, Snyder said. More than 25% of participants are from groups typically underrepresented in dementia research.



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"For now, there is an opportunity for providers to incorporate or expand messaging with their patients and families about the habits that they can incorporate into their daily lives," Snyder said. The Alzheimer's Association offers [10 Healthy Habits for Your Brain](#) — everyday actions that can make a difference for brain health.

Of note, the current study showed that higher adherence to the multimodal lifestyle intervention was required to improve cognition and function in participants. In the primary analysis, this ranged from 71.4% adherence for ADAS-Cog, 95.6% for CDR Global, and 120.6% for CDR-SB at 20 weeks.

As to whether such substantial lifestyle changes are possible outside a clinical trial, Ornish said a plant-based diet is accessible and exercise, walking, and spending more time with friends are free. For patients that need extra support, he noted that Centers for Medicare and Medicaid Services already provides Medicare coverage for the exact same lifestyle program for people with heart disease.

"I'm hopeful that at some point they might extend that coverage to people with Alzheimer's disease so they can have that support as well," Ornish said.

The study was funded by the Preventive Medicine Research Institute and others.



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Ornish has consulted for Sharecare, has received book royalties and lecture honoraria, and has equity in Ornish Lifestyle Medicine. Co-author Miia Kivipelto is one of the editors in chief of Alzheimer's Research & Therapy and recused herself from the review process. Complete study funding and other authors' disclosures are listed in the paper. Snyder is a full-time employee of the Alzheimer's Association, and in this role, she serves on the leadership team of the US POINTER study. Her partner works for Abbott Labs in an unrelated field.

CompanionCARE Gene Therapy Program

The high cost of a single gene therapy poses a major challenge for all payers, especially self-funded employers. Employers are faced with a dilemma — ensuring that their members receive potentially life-changing treatments while trying to protect themselves financially. In response, Companion Life Insurance Company has developed the CompanionCARE Gene Therapy Program, a solution that will reduce the financial exposure for employers and help them confidently provide access to these therapies.

The program will automatically be included in all new and renewal stop loss policies exclusively through Companion Life's direct distribution divisions starting January 1, 2025. We believe our program stands out as a high-quality, value-add solution for self-funded employers, reinforcing Companion Life's commitment to develop solutions to emerging health care trends that affect our employer groups.



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- Stop-loss coverage for any gene therapy that is FDA-approved after the effective date of the stop loss policy.
- No new lasers for claimants identified as a candidate for gene therapy on renewal.
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- Access to negotiated facility contracts for gene therapy centers of excellence.
- Access to gene therapy clinical guidelines and resources.

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References:

1. *Intensive Lifestyle Change Linked to Improved Alzheimer's Symptoms - Medscape - June 18, 2024.*