Advances in Alzheimer's Diagnosis, Staging and Treatment: A New Era of Research, Treatment and Care

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Disclosures

Heather M. Snyder, Ph.D. is a full-time employee of the Alzheimer's Association. Spouse is an employee of Abbott Labs in an unrelated field.

Alzheimer's Association

The Alzheimer's Association forges partnerships with all those with the shared commitment to end Alzheimer's and other dementia, including Alzheimer's organizations around the globe, the National Institutes of Health, National Institute on Aging, universities, corporations and the pharmaceutical, biotech and device industries. With our broad partnerships, we are committed to transparency. Additional information can be found at www.alz.org/about/transparency.

Vision: A world without

Alzheimer's disease

and all other dementia.™



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Our Research Strategy

Dynamic, Durable, Multi-dimensional, Multi-faceted

SEED
new ideas

SPEED
the development of new therapies

SCALE
to accelerate the science

ISTAART
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14,000
members



130+
countries

$450M currently active

1,200 projects

59 countries

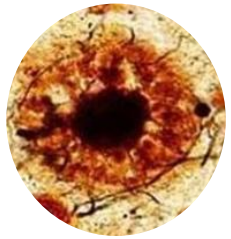
Objectives for Today's Talk

1. Identify at least two (2) avenues of research for biomarkers for early detection or diagnosis.
2. Describe emerging trends in the clinical pipeline for AD/ADRD therapeutic development
3. Discuss research directions and clinical considerations for brain health, aimed at risk reduction and future research questions.

Timeline of Tools for Detection of AD-specific Pathology

1906–2004

Neuropathology: brain examination after death



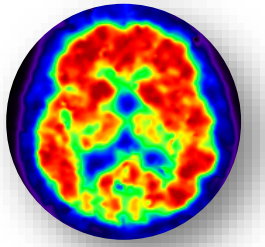
Early 2000s

CSF testing for amyloid and phosphorylated tau



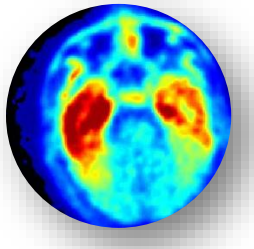
2004

Amyloid PET imaging to detect amyloid plaques



2010s

Tau PET imaging to detect tau neurofibrillary tangles



2020s

First detectable, reasonably accurate blood biomarker

2025

U.S. clearance of the first AD blood test, for people with cognitive impairment

U.S. FDA Cleared Four Blood Based Biomarker Tests: Supporting Faster, More Accessible Tools for Diagnosis

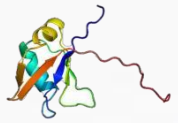
Test (Company, Date of FDA Clearance)	**What it measures**	**Where Used**	**Who is eligible**
Lumipulse G pTau217/ Aβ1-42 Plasma Ratio Fujirebio · May 2025	Ratio of pTau217 to Aβ1-42 in plasma	Specialty care; aids detection of amyloid plaques	Adults 55+ with signs and symptoms of Alzheimer's
Elecsys pTau181 Roche · Oct 2025	pTau181 in plasma	Primary care; rules out amyloid pathology	Adults 55+ with symptoms of cognitive decline
PrecivityAD2 C2N · Aug 2026	Plasma Aβ42/40 ratio + %pTau217, combined into a probability score	Providers experienced in cognitive evaluation; aids in diagnosis	Adults 40+ with signs or symptoms of cognitive impairment
Elecsys pTau217 Roche · Aug 2026	pTau217 in plasma	Primary and specialty care; rule-in and rule-out	Adults 55+ with signs, symptoms or complaints of cognitive decline

No single test diagnoses Alzheimer's. Results are used alongside a full clinical evaluation.

Mixed Pathology is Common

Endolysosomal dysfunction (SORL1)

TDP-43 (LATE)



Vascular contributions (VCID)

α-Synuclein (Lewy body)

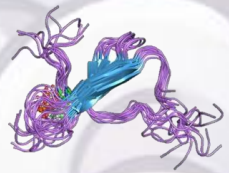


Microglial dysfunction (TREM2)

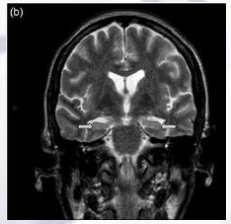
Amyloid-β



Tau



Neocortical tau

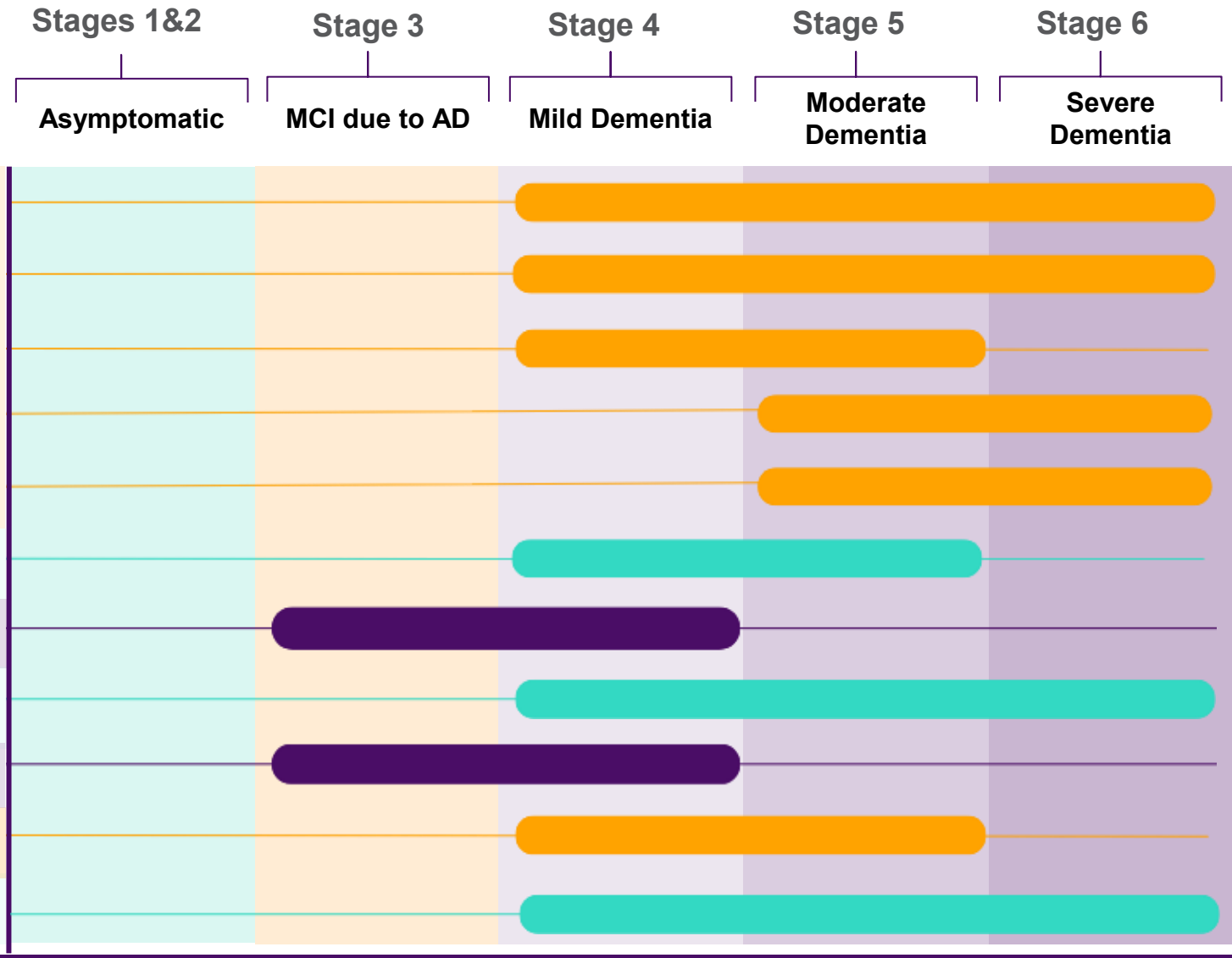


Dementia

A positive AD biomarker does not exclude co-pathology — or establish that AD explains the full clinical picture

FDA-Approved Therapies for Alzheimer's

Year	Drug
1996	donepezil (Aricept)
2000	rivastigmine (Exelon)
2001	galantamine (Razadyne)
2003	memantine (Namenda)
2014	memantine + donepezil (Namzaric)
2020	suvorexant* (Belsomra)
2023	lecanemab (Leqembi)
2023	brexpiprazole (Rexulti)
2024	donanemab (Kisunla)
2024	benzgalantamine (Zunveyl)
2026	dextromethorphan-bupropion (Auvelity)



* Suvorexant approved for insomnia not AD, but safe and effective in AD population.

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Treat Symptoms: Cognition and Function
Treat Symptoms: Mood or Behavior
Slow Disease Progression: Cognition, Function, and Behavior

A New Phase of Treatment

Targets *amyloid*

2023

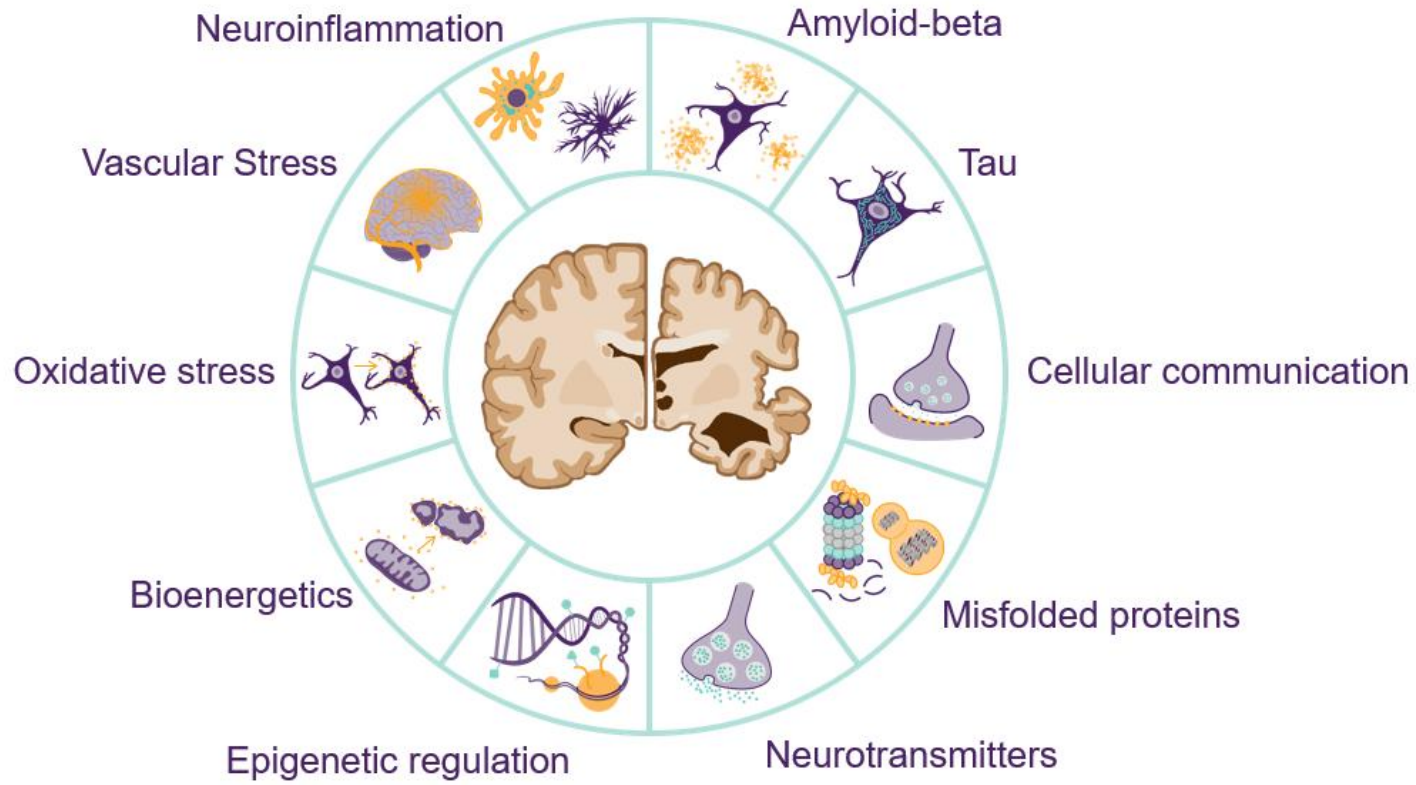
lecanemab (Leqembi™)

Targets *amyloid*

2024

donanemab (Kisunla ™)

Today, Over 158 Unique Therapies Being Tested in Clinical Trials that Target Multiple Aspects of Alzheimer's Biology



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Cummings et al. **Alzheimer's disease drug development pipeline: 2026** Alz & Dementia: TRCI

PART THE CLOUD

Advancing 5 New Approaches

83 clinical studies funded to date | **$100M+** raised by Part the Cloud

COMBINATION TRIAL	**Carbonic anhydrase inhibitors + anti-amyloid** Silvia Fossati, Temple University · Phase 1/2	**$2.0M** PTC-CTP
COMBINATION TRIAL	**Insulin and vascular function + anti-amyloid** Suzanne Craft, Wake Forest University	**$2.0M** PTC-CTP
INFLAMMATION TARGET TRIAL	**EC5026, a first-in-class sEH inhibitor** Walter Swardfager, Sunnybrook Research Institute · Phase 1b	**$1.0M** PTC-REG
REPURPOSED TARGET TRIAL	**Bumetanide, a decades-old diuretic** Kyan Younes, Stanford University · Phase 2a	**$1.0M** PTC-REG
AI-DESIGNED DRUG DEVELOPMENT	**AI-designed nanobody therapeutics** Binita Rajbanshi, Nanil Therapeutics	**$1.0M** PTC-EM-AI

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$7.0M awarded across five new projects

158 UNIQUE THERAPIES in 192 CLINICAL TRIALS for Alzheimer's disease

10 more trials and **20** more drugs than the 2025 pipeline

Biomarkers play an important role in determining eligibility and outcomes of current trials

35% of candidate therapies are repurposed from other diseases

54,728 Participants needed to populate all currently active clinical trials



73%
disease targeted

18%
cognition enhancement

10%
behavioral and neuropsychiatric symptoms

Source: Cummings JL, Zhou Y, Yang Y, et al. Alzheimer's disease drug development pipeline: 2026. Alzheimer's Dement. 2026;12:e70251. https://doi.org/10.1002/trc2.70251

WILEY
Alzheimer's & Dementia
Translational Research & Clinical Interventions

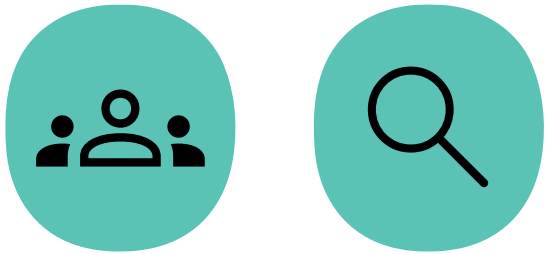
PHASE 3 CLINICAL TRIALS



45 agents

49 trials

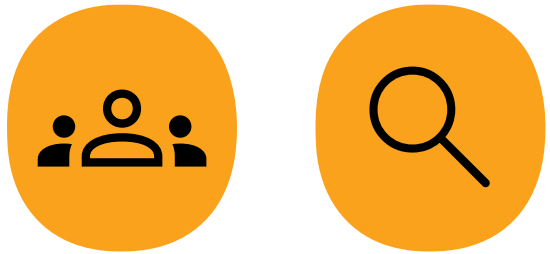
PHASE 2 CLINICAL TRIALS



84 agents

89 trials

PHASE 1 CLINICAL TRIALS



36 agents

54 trials

59 new trials entered the pipeline since 2025. This is larger than last year **(56)** and is a sign of growth.

Source: Cummings JL, Zhou Y, Yang Y, et al. Alzheimer's disease drug development pipeline: 2026. Alzheimer's Dement. 2026;12:e70251. https://doi.org/10.1002/trc2.70251

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Alzheimer's & Dementia
Translational Research & Clinical Interventions



— SPECIAL REPORT | KEY TAKEAWAY

Americans want to protect their brain health. Few know how.

88% of adults (9 in 10) age 40+ say maintaining brain health as they age is very important

99% view brain health as equally or more important than physical health

9% say they know “a lot” about how to maintain their brain health

Ref Alzheimer’s Association Special Report, 2026 Facts & Figures

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U.S.POINTER
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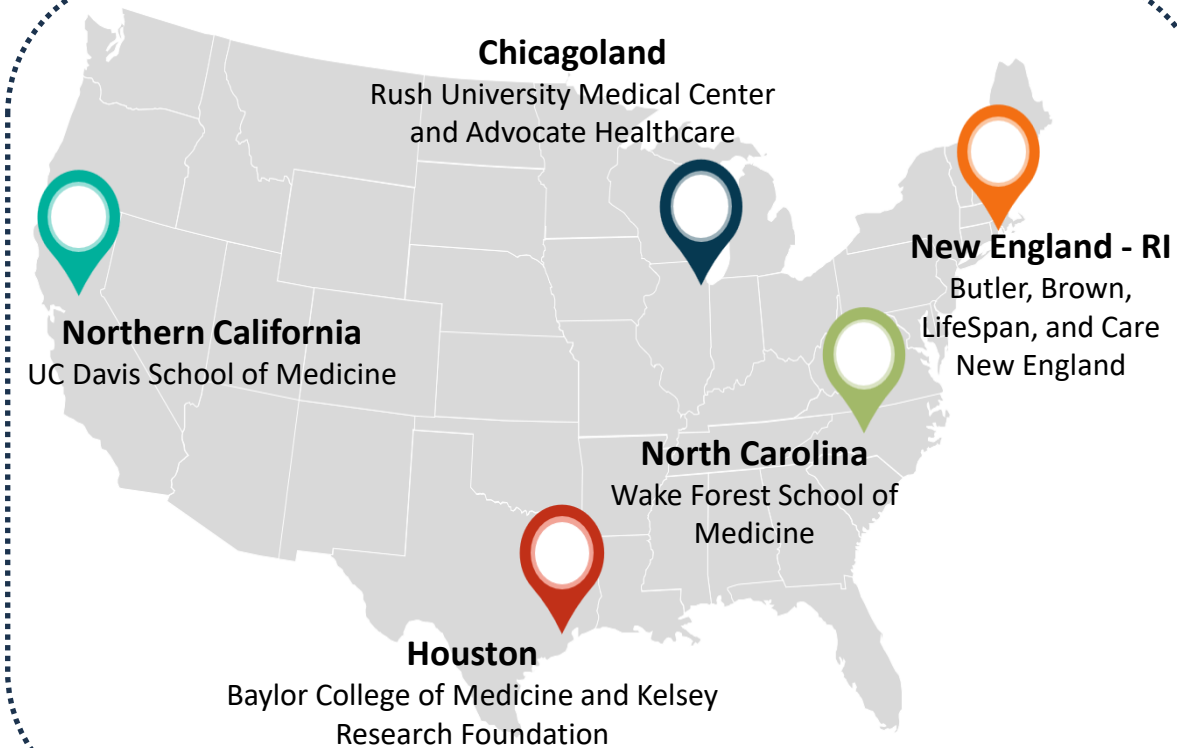
A Landmark Study for the US and Global Community



5 sites

2,111 participants

2 Self-Guided or Structured

2 Year Intervention

*The U.S. Study to **Pro**tect Brain Health Through Lifestyle **Inter**vention to Reduce Risk

SG

6 facilitated peer team meetings over 2 years with general support from study navigator

Education & General Support

Met with study navigator 3 times per year to receive:

- Healthy lifestyle education
- Tangible tools to facilitate self-guided plans
- General support to encourage physical activity, a healthy diet, and cognitive and social stimulation

Health Monitoring

Blood laboratory results and blood pressure measurements were provided at clinic assessment visits

STR

38 facilitated peer team meetings over 2 years, with education, goal-setting, accountability and support from study interventionist and navigator

Physical Exercise

Aerobic, resistance, and stretching & balance exercise primarily at a community facility

Nutrition

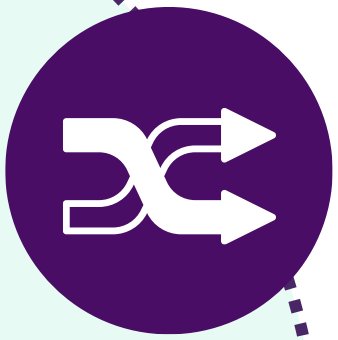
Encouragement to follow the MIND diet, with extra support through telephone contacts with the interventionist

Cognitive and Social Challenge

Home-based computer cognitive training and regular participation in intellectually & socially engaging activities

Guideline-Based Health Coaching

Medical advisor appointments every 6 months for goal-setting, and to review monthly blood pressure measurements and blood laboratory results provided at clinic visits



POINTER Rx

Aerobic: 4 days/week, 30-35 min/session

Resistance: 2 days/week, 15-20 min/session

Stretch/Bal: 2 days/week, 10-15 min/session

MIND diet: Score ≥ 9.5

BrainHQ: 3 times/week, 15-20 min/session

Labs: Biannual review

STR

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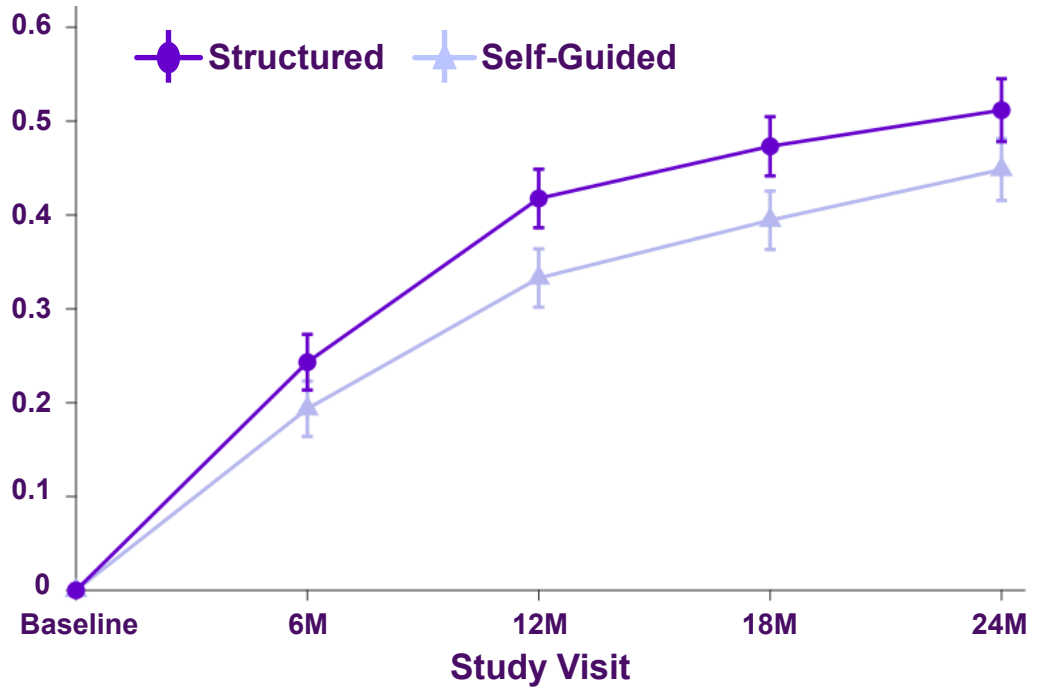
Key Takeaways



While both had benefit, the Structured intervention had a significantly greater benefit on cognitive function.

This extra benefit was the same regardless of sex, age, ApoE4 genotype, or heart health at the start of the study

Structured intervention may **slow** the cognitive aging clock **to nearly 2 years** compared to self-guided.

JAMA | Original Investigation

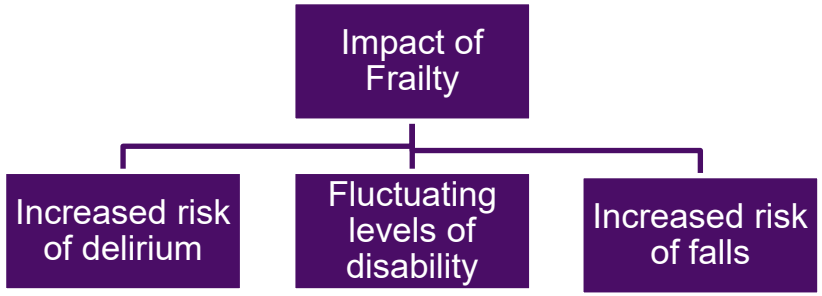
Structured vs Self-Guided Multidomain Lifestyle Interventions for Global Cognitive Function

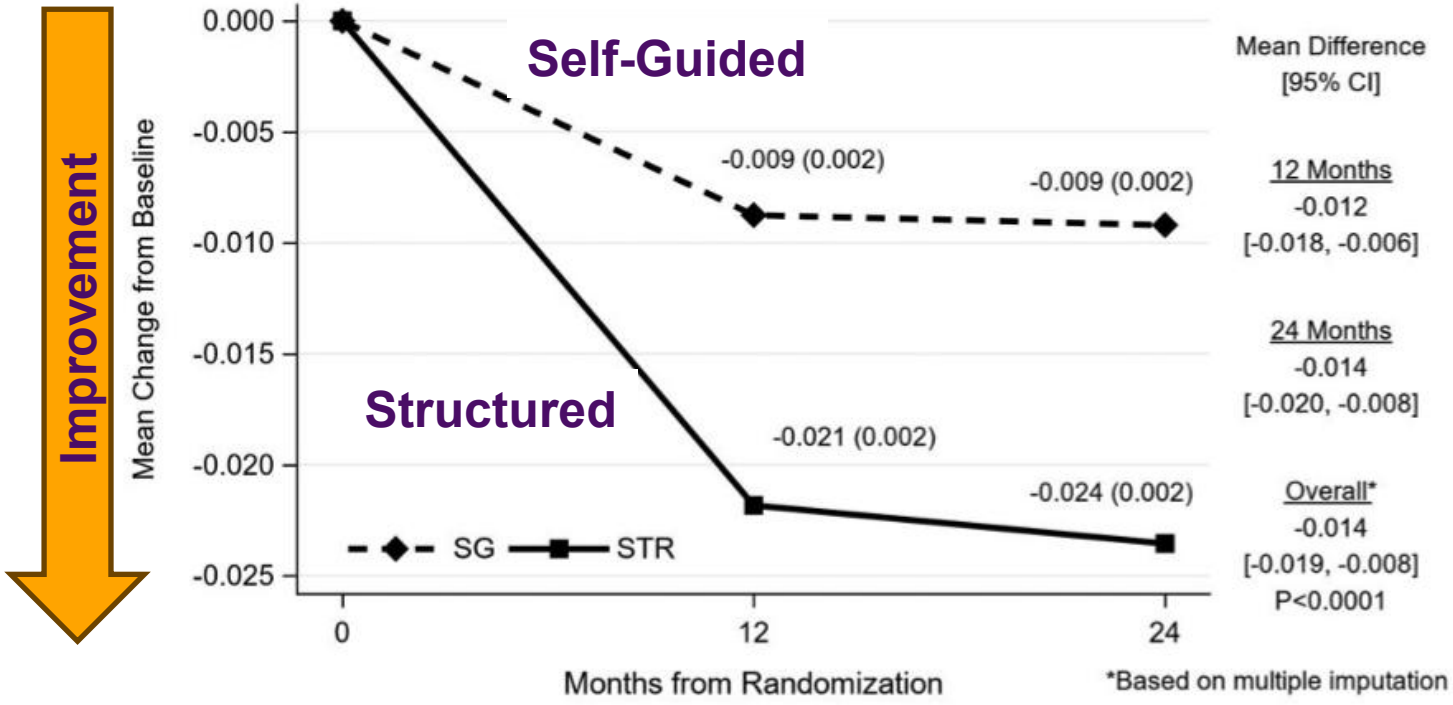
The US POINTER Randomized Clinical Trial

Laura D. Baker, PhD; Mark A. Espeland, PhD; Rachel A. Whitmer, PhD; Heather M. Snyder, PhD; Xiaoyan Leng, MD, PhD; Laura Lovato, MS; Kathryn V. Papp, PhD; Melissa Yu, MD; Miia Kivipelto, MD, PhD; Ashley S. Alexander, MHSA; Susan Antkowiak, BS; Maryjo Cleveland, MD; Claire Day, BSW; Richard Elbein, MS; Sarah Tomaszewski Farias, PhD; Deborah Felton, BS; Katelyn R. Garcia, MS; Darren R. Gitelman, MD; Sarah Graef, DC; Marjorie Howard, MSPH; Jeffrey Katula, PhD; Katherine Lambert, BA; Olivia Matongo, MPH; Anne Marie McDonald, MEd, MBA; Valory Pavlik, PhD; Rema Raman, PhD; Stephen Salloway, MD, MS; Christy Tangney, PhD; Jennifer Ventrelle, MS; Sharon Wilmoth, BA; Benjamin J. Willliams, MD, PhD; Rena Wing, PhD; Nancy Woolard; Maria C. Carrillo, PhD

U.S. POINTER Structured Intervention Significantly Reduced Frailty

Measured by a **Frailty Index (FI):** quantitative, multidimensional tool to measure biological age rather than chronological age.





Months Post Randomization into U.S. POINTER Trial

MA Espeland et al, *The Journals of Gerontology: Series A*, Volume 81, Issue 5, May 2026

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LatAm Fingers

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- U.S. POINTER sister study tested structured (systematic) and self-guided (flexible) interventions in at risk population in 11 countries
- 73.7% female
- 36.9% had primary education and 63.1% had secondary education
- 58.6% Mestizo; 27.0% White; 6.8% Mulato; 1.3% Indigenous; 1.7% Black; 4.6% Other or Prefer not to say
- Adherence and retention remained 70.0%+ (ranging from 73.4-87.9% for cognitive outcome data)

References:
Crivelli et al 2023 A&D
Crivelli et al 2026 The Lancet

Primary Outcome: Global Cognitive Composite
mean rate of change per year (slope)

LatAm FINGERS
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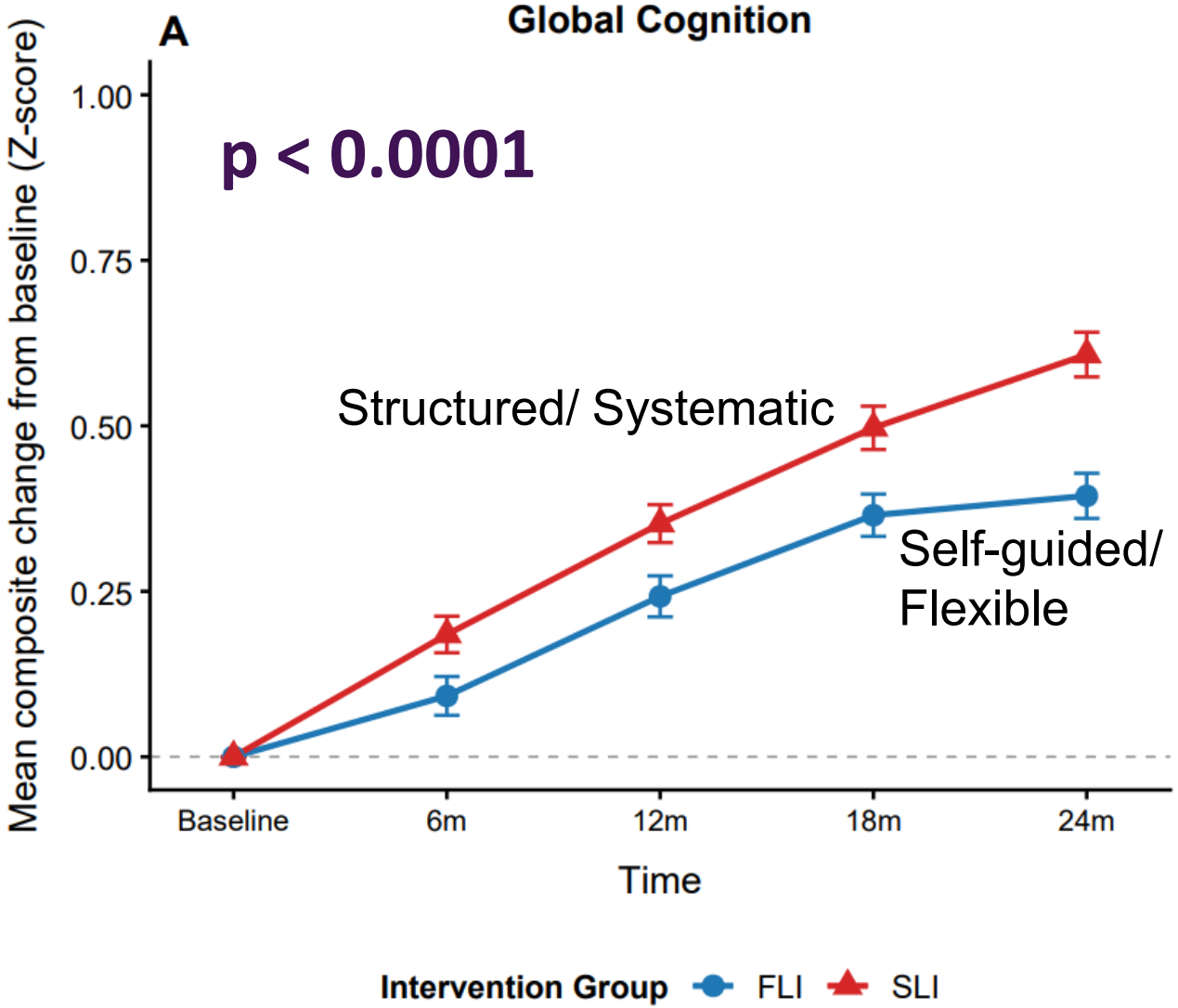
Systematic Lifestyle Intervention
0.31 SD per year [95% CI 0.28 to 0.34]
Flexible Lifestyle Intervention
0.20 SD per year [95% CI 0.17 to 0.23]

Between-Group Difference in Mean Annual Change (95% CI)
0.11 SD per year [0.06 to 0.15]

55% **cognitive benefit of the Structured/ Systematic over Self-Guided/ Flexible**



Slide courtesy of Dr. Lucia Crivelli and the LatAm FINGERS team, Crivelli et al. Lancet 2026

The Need:

Memory concerns start in the doctor's office



Primary care (PCP) is the first stop. People and families usually raise memory worries with their regular doctor.

PCP visits are short and busy. There's little time for memory testing and waits to see a specialist are long.

Science is moving fast. New blood tests and treatments are available today at the earliest stages of symptomatic disease; detecting early changes matter and have implications on care.

MindCare365 builds brain health into everyday clinical care

The team developed a screening pathway and care bundle to help PCPs identify patients with memory changes early and guide each person to the right next step.

- **Mostly virtual,** from home
- **Expert team** reviews every result
- **One simple order** for the doctor



Developed by Wake Forest University School of Medicine and Atrium Health, with principal funding from the Alzheimer's Association

Five steps to MindCare: Ensuring the right care, for every patient



Doctor refers → **Memory check by phone** → **Video visit + tests** → **Expert panel review** → **Care plan visit**

Each person leaves with a care path matched to them:

No impairment, at risk	→ Brain health education + risk reduction discussion
Early-stage impairment	→ Education, coaching + treatment options
Advanced or atypical	→ Referral to a memory specialist

Source: Skiles R et al., MindCare 365 Overview at AAIC, July 2026.

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Developed by Wake Forest University School of Medicine and Advocate Health, with principal funding from the Alzheimer's Association



The science has momentum.
Collaboration and Partnership gives it reach.

Momentum in the science

A fast-shifting diagnostic landscape.

Expanding clinical pipeline and diversification of targets and approaches.

From association to cause and effect

Lifestyle intervention – USP and LatAm FINGERS- shows cognitive benefit in at-risk populations — translate this to communities.

Working together

One ecosystem, driving understanding, faster progress, and research into care.

Resources at alz.org


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AAIC 27
SAVE THE DATE
THANK YOU?
Questions?
JULY 18-21 ANNUAL CONFERENCE > CHICAGO, UNITED STATES AND ONLINE
Abstract Submissions open in Fall 2026. Registration opens at alz.org/AAIC in Spring 2027.