

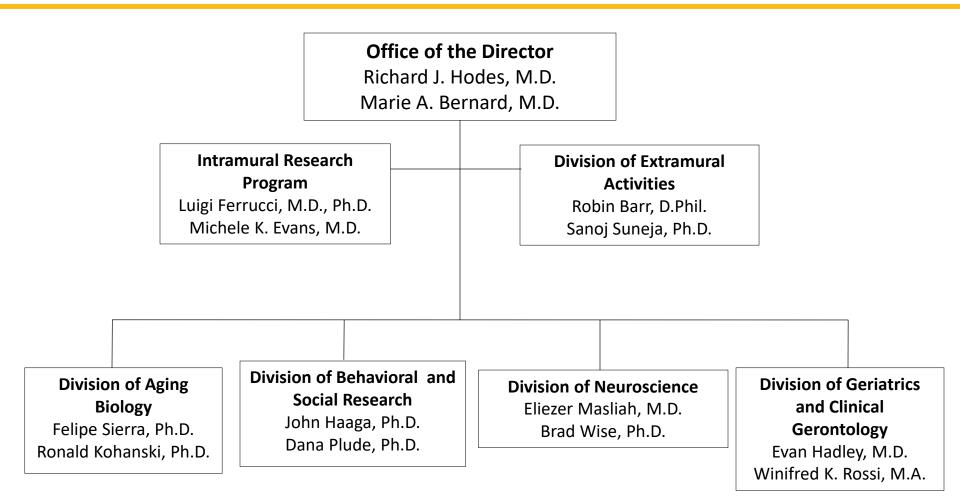
NIA Science Advances 2019 Update

Visit from Friends of the NIA

Richard J. Hodes, M.D. October 7, 2019



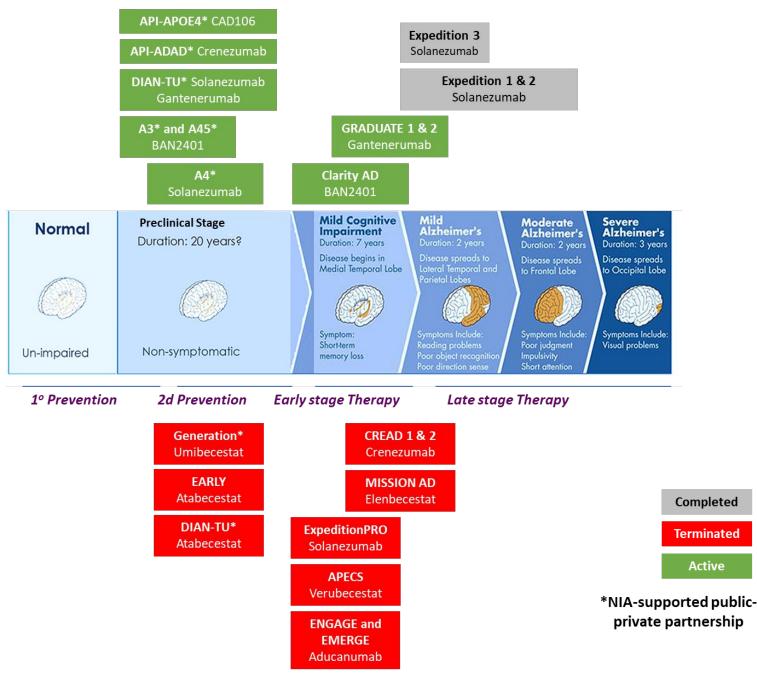
NATIONAL INSTITUES OF HEALTH National Institute on Aging Organizational Structure



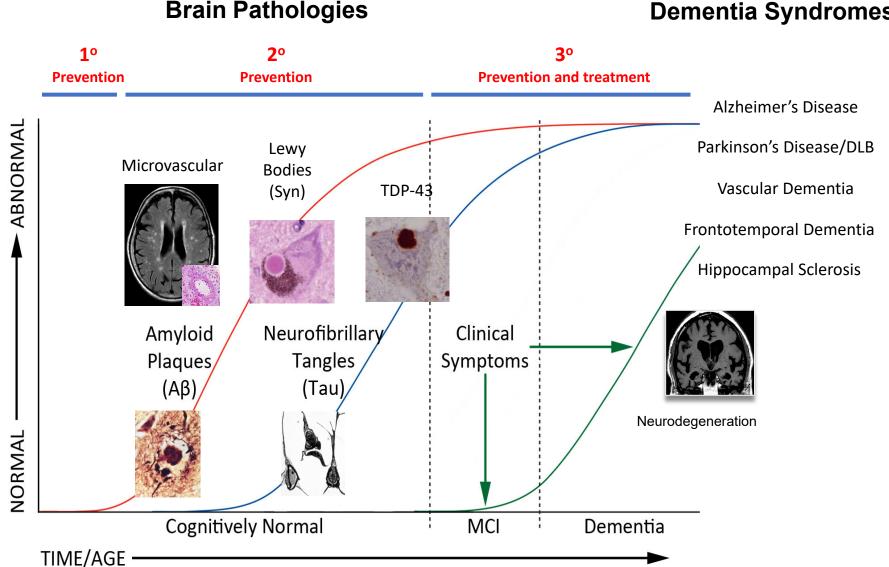
Diversity of AD Clinical Studies



AD Immunotherapy and BACE Inhibitor Phase III Trials



The Progression of Alzheimer's Disease and Related **Dementias**

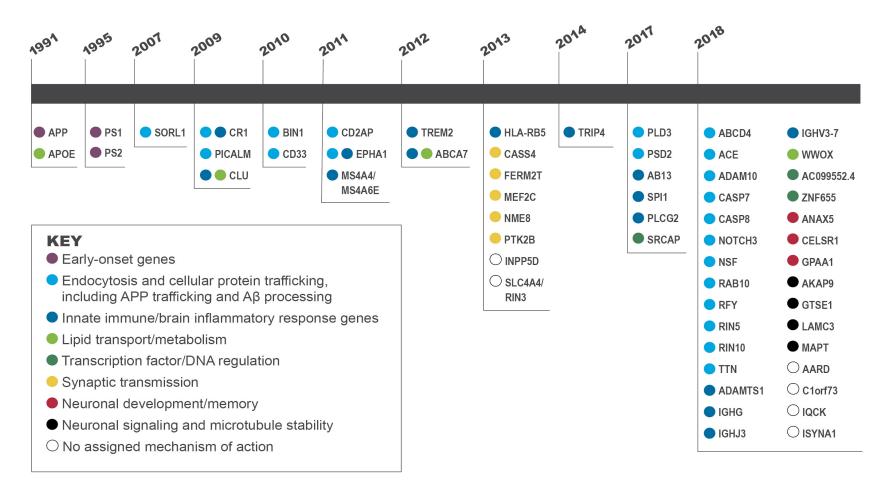


Dementia Syndromes

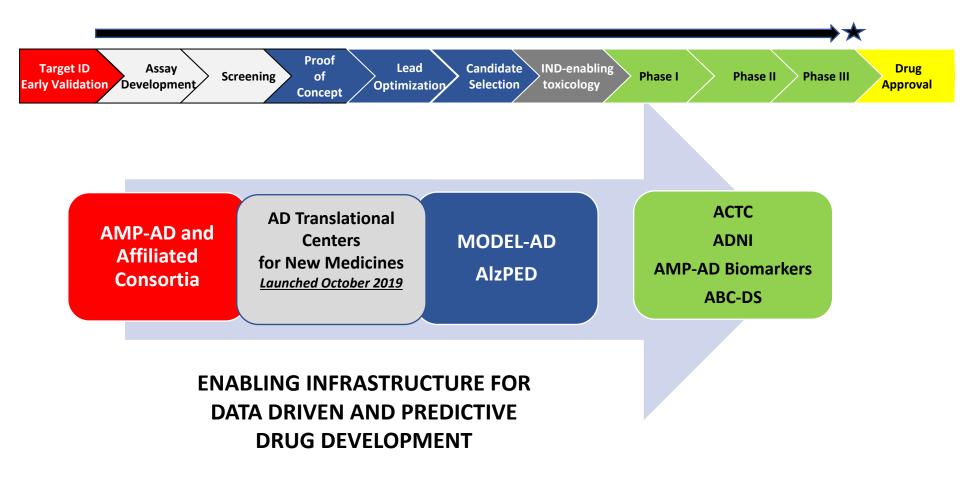
Genetic Regions of Interest in Alzheimer's Disease

By year of discovery

NOTE: Color indicates mechanism of action in the body. See key below.



NIA AD Translational Research Program: Diversifying the Therapeutic Pipeline



7



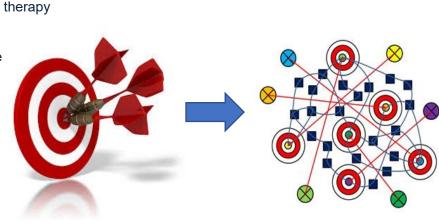
NIA Alzheimer's Translational Research Program – since 2006 Diversifying the Therapeutic Pipeline

Next-gen anti-Aβ therapeutics:

Sigma receptor – anti A β oligomer therapy Gamma secretase modulators Anti-A β oligomer immunotherapy A β immunotherapy – DNA vaccine A β aggregation inhibitors A β catalytic antibodies

Cytoskeleton/Tau:

Microtubule stabilizers CDK5-tau phosphorylation Calpain Inhibitors Tau aggregation inhibitors DYRK1A



Neuroinflammation:

EP2 receptor P38 MAPK CRAC Channel NLRP3 Inflammasome TNFα

Neurotransmitter Receptors and Growth Factors:

mGluR5 Receptor GABA Receptor A alpha5 TrkB P75 Neurotrophin Receptor

Synaptic Plasticity/Neuroprotection:

Calcineurin Ryanodine Receptor Excitotoxic Amino Acid Transporter Somatostatin Receptor subtype-4

Oxidative Stress:

Nrf2 γ-ketoaldehyde Glutathione S-transferase

Vasculature:

Angiotensin II receptor Mas receptor

<u>αSyn</u>

Heavy chain α Syn antibodies α Syn aggregation inhibitors

Multi-target therapeutics:

p38αMAPK GABA Receptor and NO production Neurogenesis Proteostasis

Metabolism and Bioenergetics:

Insulin Receptor Mitochondria **ApoE4**

ApoE-antibodies Antisense oligonucleotides

Heat Shock Proteins:

HSP 90

Cell therapies:

Neural Stem Cell transplantation

Cell Death: CDK4/6 OMA1

ACCELERATING MEDICINES PARTNERSHIP (AMP)

Progress over 4 years:

- <u>Centralized data resource</u> established- AMP-AD portal
- <u>All data sharing deliverables met</u>
- <u>A variety of experimental</u> validation models developed
- Novel biomarker discovery initiated
- <u>Over 100 candidate targets</u> nominated; currently undergoing data-driven prioritization for further preclinical validation



Candidate Targets

SNRNP70	TGFBR1	CCDC85C	RGS4
U1-A	TGFBR2	CIC	SCN2A
U1-C	BMPR1A	CSRP1	OLFM3
SNRPN	BMPR1B	DAB2IP	SLC22A10
SNRPB	CRHR1	FAM63A	ENAH
PLCD1	TREM2	FURIN	WWTR1
PTRHD1	TYROBP	HMG20B	LRP10
SFRP1	S100A8	IGFBP5	SYP
PPP1R7	S100A9	ISYNA1	PCSK1
DNM3	P2RY2	KIF1C	кмо
RTN4	P2RX7	PADI2	PTTG1IP
EPB41L3	P2RY12	SLC38A2	MLIP
TUBB3	P2RY13	SNAP25 STX1A	DLGAP1 MOAP1
PLEC	OSMR		
ANXA5	TLR4	STXBP3	PRKCB
MSN	CR1	SV2B	YAP1
CD44	CSF1R	SYT1	GNA13
LMNA	CX3CR1	SYT12	TRIM56
	SPI1	ZBTB47	
	TNFRSF10A	VGF	
	TNFRSF10B	PLXNB1	

agora.ampadportal.org

Search for a gene

Please type a gene symbol in the search box below.

Search by gene name

PIAS2

View nominated target list

list of genes nominated by AMP-AD groups as targets of interest. Each AMP-AD team has deployed state of the art systems biology methods to integrate across genomic, transcriptomic, and proteomic data from over 2000 participant brains. Each target epresents a gene with multiple lines of evidence and is a candidate driver of Alzheimer disease etiology.

National Institute on Aging



Popular community searches

APC SNX2

View all nominated targets

Ongoing NIA AD/ADRD and Related Intervention and Prevention Trials (~200)

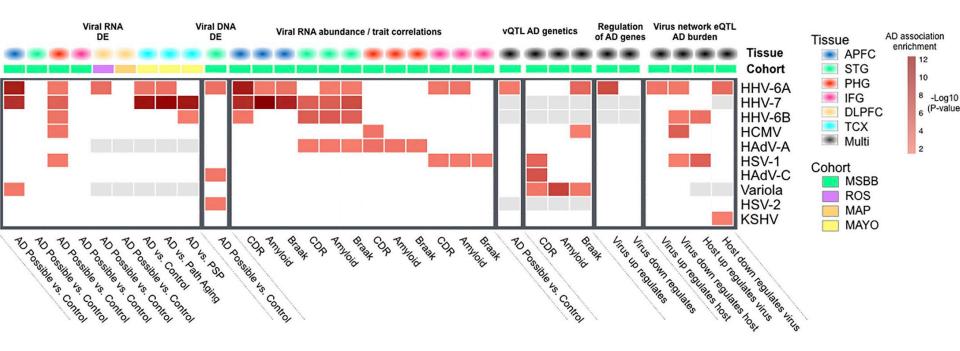
36 Early- stage Clinical Drug Development (Phase I and Phase II Clinical Trials)	8 Late-stage Clinical Drug Development (Phase II/III and Phase III Clinical Trials)	90 Non- Pharma- cological Interventions	8 Clinical Therapy Development for the Neuro- psychiatric Symptoms of AD/ADRD	61 Care and Caregiver Interventions
Amyloid (10) Receptors (4) Neuroprotection (4) Metabolism and Bioenergetics (2) Vasculature (2) Growth Factors and Hormones (2) Multi-target (2) Inflammation (2)	Amyloid (6) Neuroprotection (2)	Exercise (19) Diet (6) Cognitive Training (22) Assistive Tech. (9) Sleep (5) Combination Therapy (11) Other (18)	Pharmacological (5) Non- Pharmacological (3)	Improving Care for PWD (25) Improving care provided by family or informal caregiver (36)
Oxidative Stress (2)	www.nia.nih.gov/research/ongoing-AD-trials			10

Other (6)

Research on Mechanisms of AD



Data Sharing Enables Researchers to Find New Evidence Linking Viruses to AD Biology

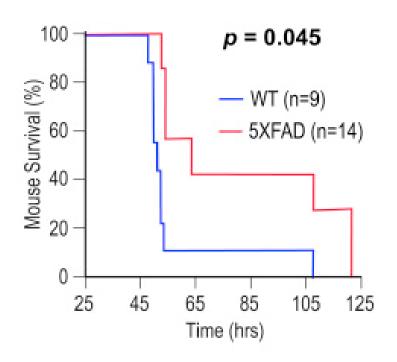


Human herpesvirus 6A and 7 were more abundant in Alzheimer's disease samples than non-Alzheimer's

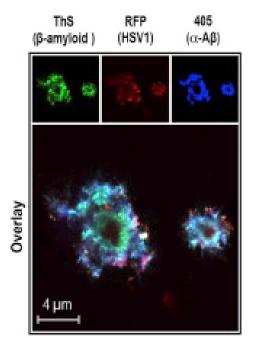
Readhead et al. (2018). Neuron 99: 64-82.



Amyloid-beta aggregates as a protective response against infection in a mouse model of Alzheimer's disease



Alzheimer's disease model mice survive longer than control mice after infection with herpes simplex virus 1.



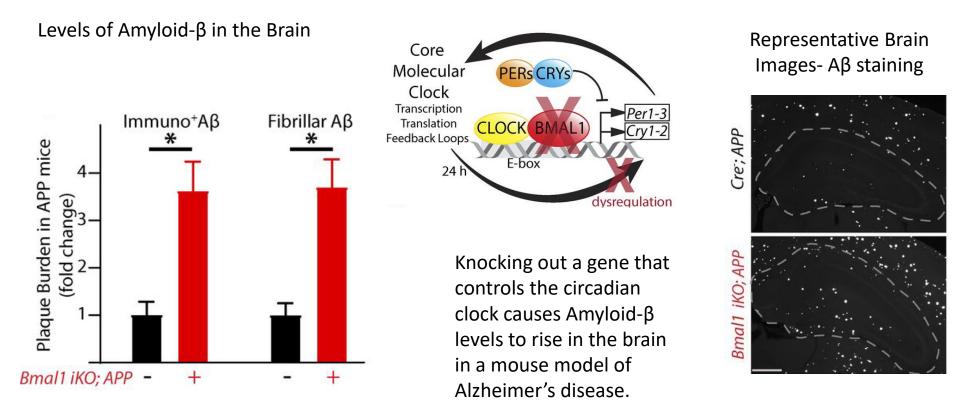
5XFAD 21 days post-infection

Herpes simplex 1 is sequestered by amyloid-beta, generating plaques in a mouse model of Alzheimer's disease.

Eimer et al. (2018). Neuron 99: 56-63



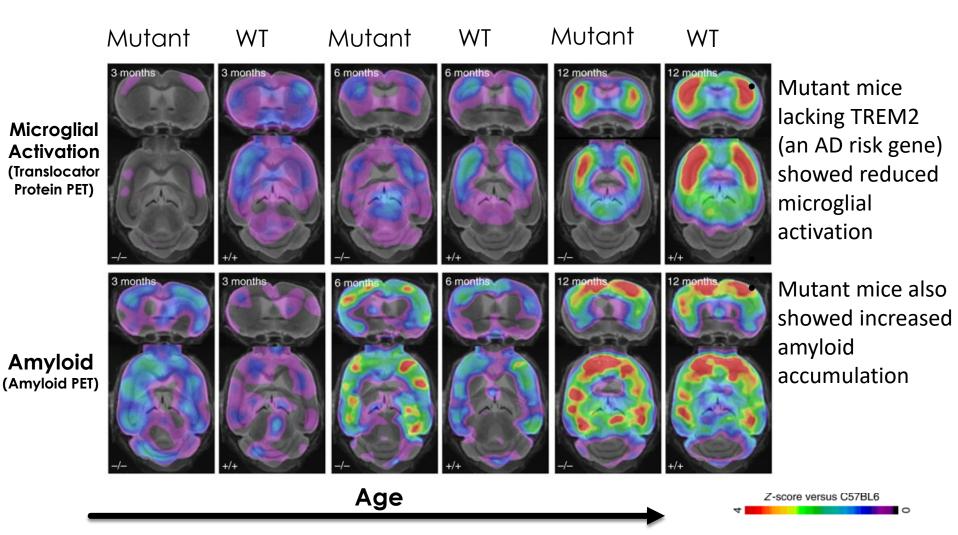
Disrupting the Circadian Clock Causes an Increase of Amyloid-β in the Brain



Kress GJ, et al. (2018). J Exp Med 215(4):1059–1068



TREM2 helps microglia clear amyloid plaques in mouse model

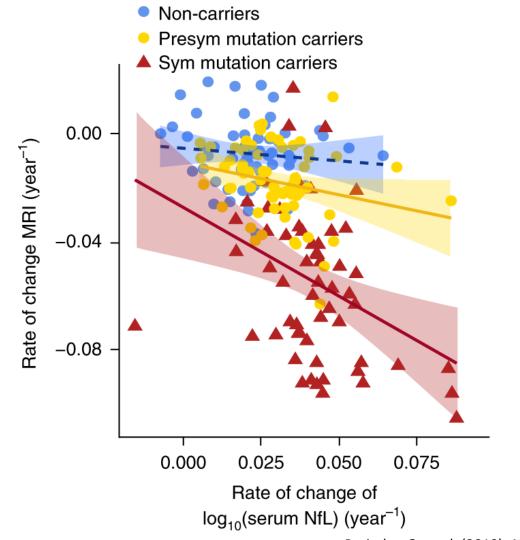


Parhizkar et al. Nat Neurosci 2019 22(2):191-204

Dementia Biomarker Studies



Blood Test Shows Promise in Predicting AD

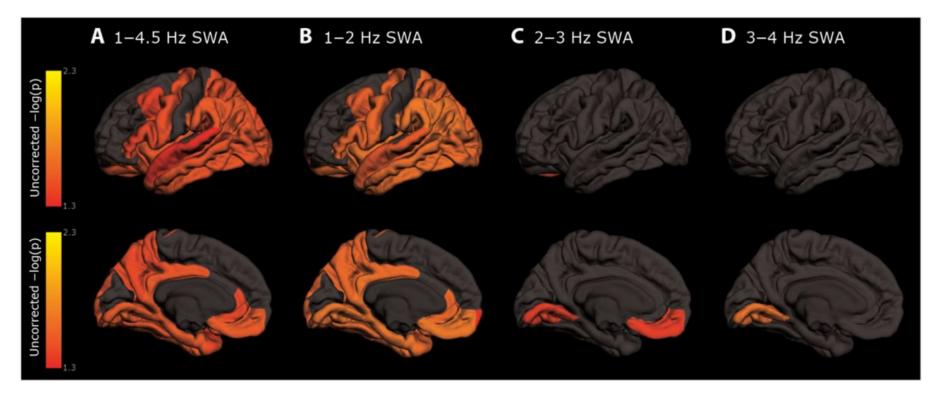


Preische, O. et al. (2019). Nature Medicine, 25(2):277-283.



Reduced NREM Sleep is associated with increased tau

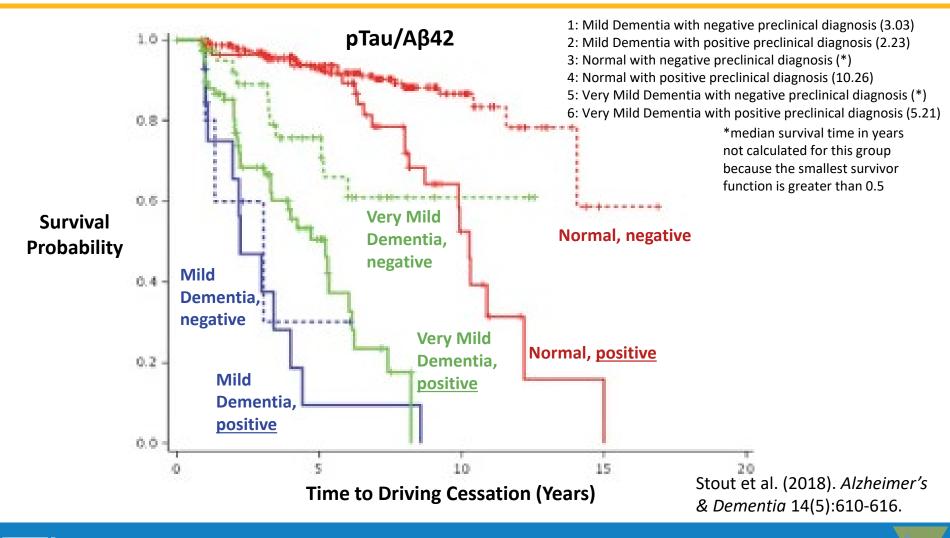
Regional differences in the relationship between non-rapid eye movement (NREM) slow wave activity (SWA) and tau PET



Lucey et al. (2019) Science Trans Med. 11(474):191-204

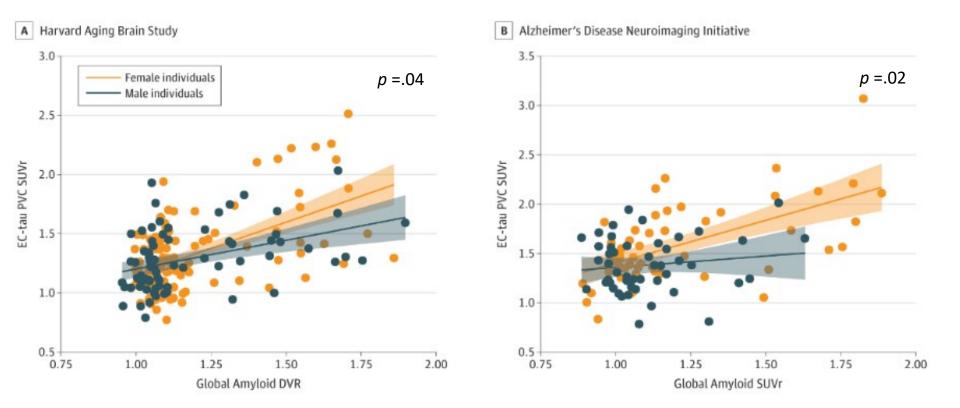


Positive AD Biomarkers Predict More Rapid Driving Cessation





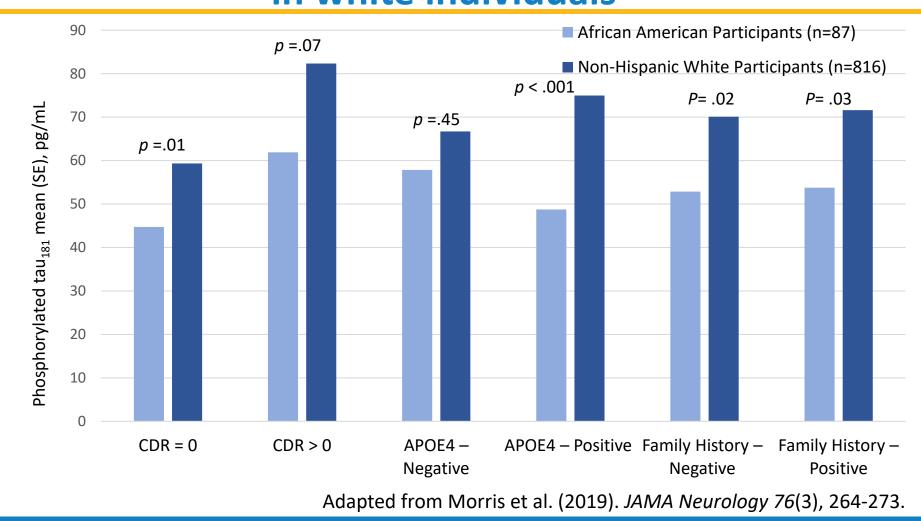
Women Have Higher Levels of Tau at Same Level of Amyloid Burden



Buckeley et al. (2019). *JAMA Neurology 76*(5), 542-551.

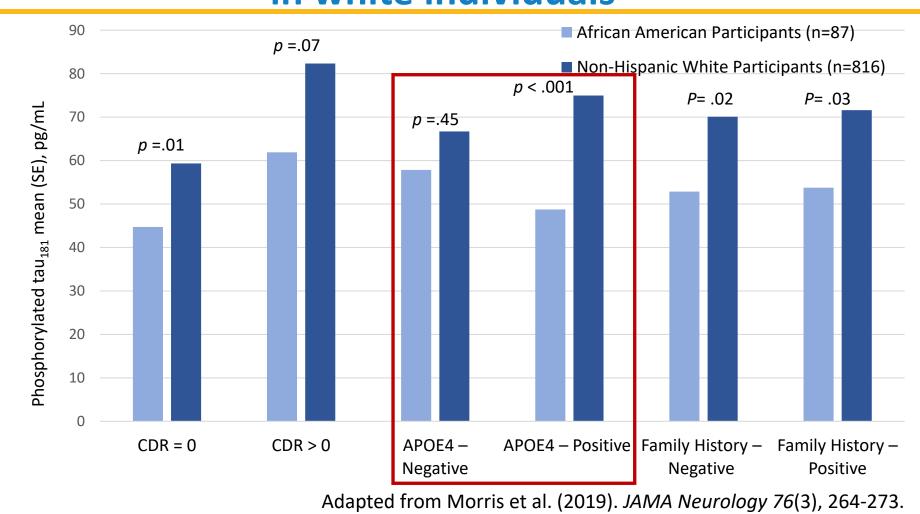


Interactions of APOE ε4 with tau in African American individuals may differ from its interactions with tau in white individuals





Interactions of APOE ε4 with tau in African American individuals may differ from its interactions with tau in white individuals

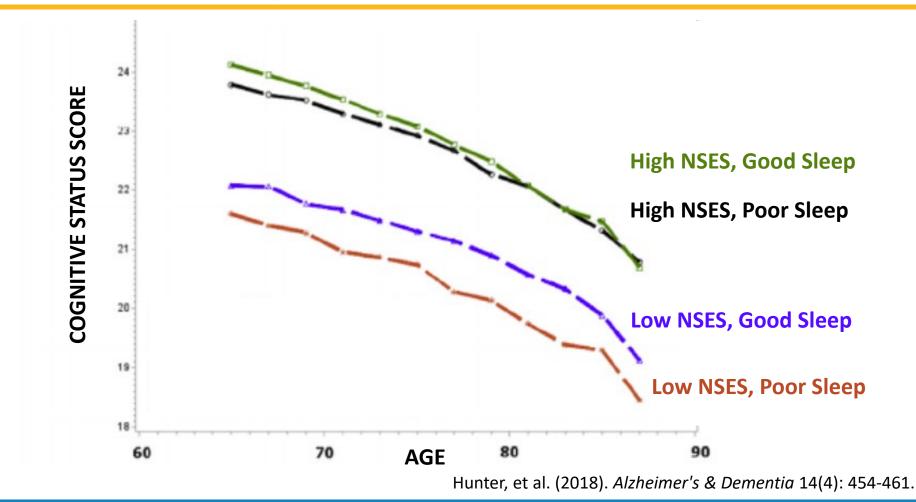




Demographic Studies

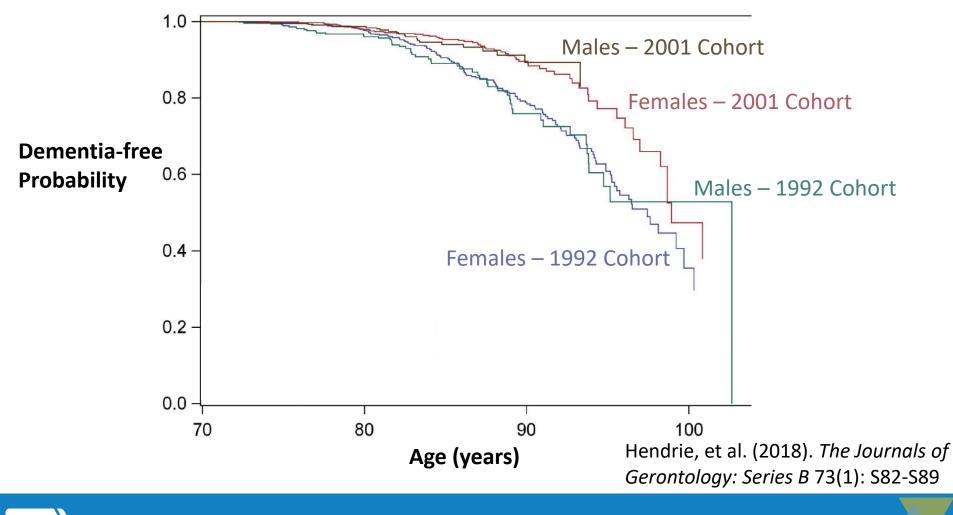


Association between Sleep and Cognition Stronger Among Individuals with Low Neighborhood SES (NSES)





Younger African American Cohorts (with Higher Educational Attainment) have Increased Probability of Being Dementia-Free

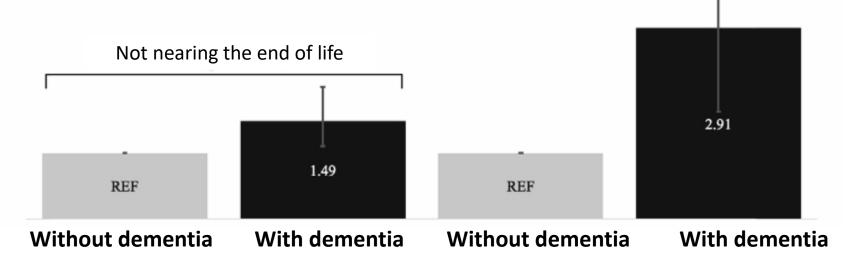


Care and Caregiver Studies



Caregivers Have Increased Strain when Person Living with Dementia is at the End of Life

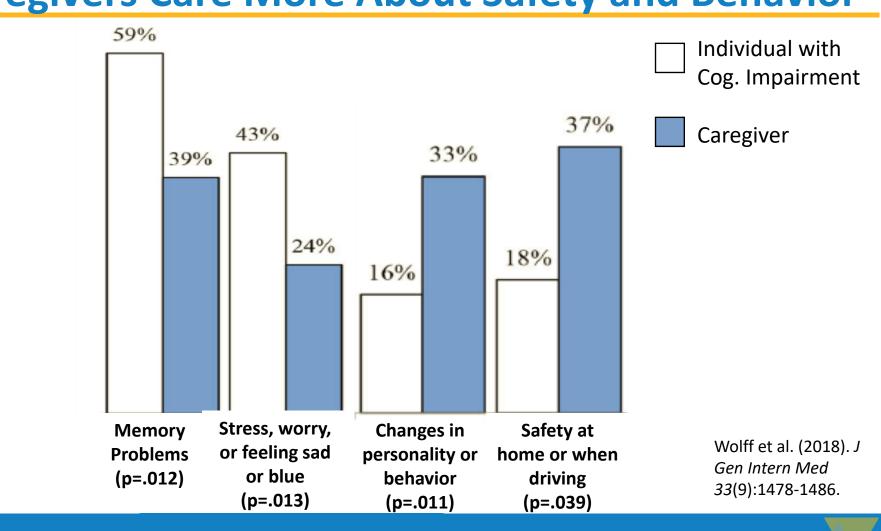
Caregiver strain: difficulty of helping in three domains—emotional, physical, and financial—as well as having no time for oneself, being overwhelmed, and being exhausted. Nearing the end of life (within 12 months of death)



Vick, et al. (2019). Pain & Symptom Mgmt 57(2): 199-208.



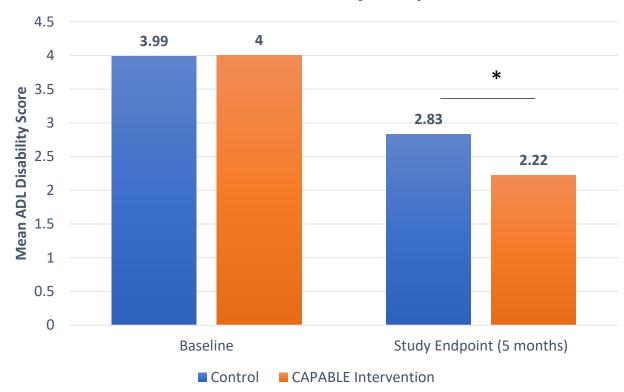
Individuals with Cognitive Impairment Care More About Memory and Mood; Caregivers Care More About Safety and Behavior





CAPABLE Intervention Reduced Disability in Activities of Daily Living by 30% for Low-income Baltimore Older Adults

Mean Activities of Daily Living (ADL) Scores at Baseline & Study Endpoint



Intervention =

- Up to 6 Home visits by OT, RN
- Implementation of personal plan based on assessments and participant goals
- Home repairs (up to \$1300)
- Significant reduction in ADL disability scores compared with participants in control group. Adjusted Effect Size: 0.70 (0.54-0.93), p = .01.

Szanton, S.L., et al. (2019). *JAMA Intern Med.,179(2***):204–211**





CAPABLE

iCare-AD/ADRD Challenge- Winners Announced Today!

- NIA received 33 applications for mobile device applications or web-based methods
- 1st place: MapHabit- mobile app that provides behavior prompts with customizable picture and keyword visual maps to assist memory-impaired people with accomplishing activities of daily living



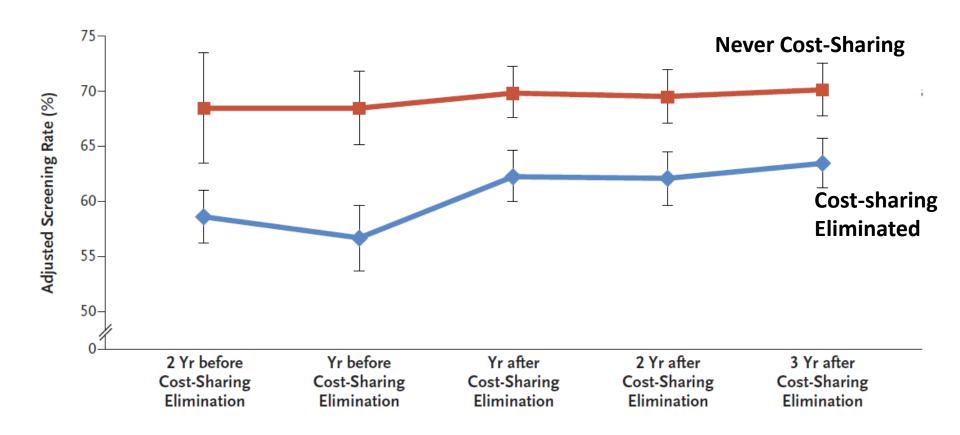
- 2nd place: Dementia Care Software System (UCLA)- case management software, which integrates with the electronic health record system
- 3rd place: Caregiver411 (N.C. A&T State)- mobile app that enables dementia caregivers to foster social connections through a messaging center and obtain tailored resources for those they care for

https://nia.nih.gov/challenge-prize

Longevity and Healthy Aging Studies



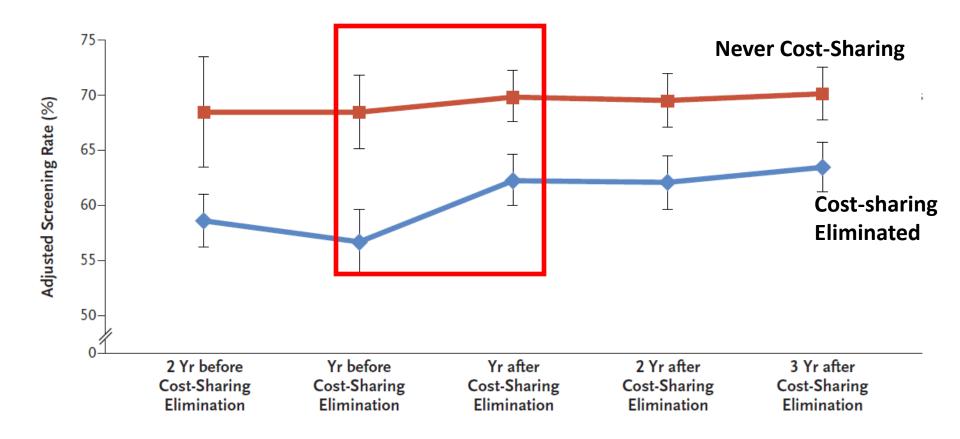
Eliminating Cost-sharing Increases Biennial Mammography Screening in Medicare Advantage



Trivedi et al. (2018). NEJM 378(3):262-269



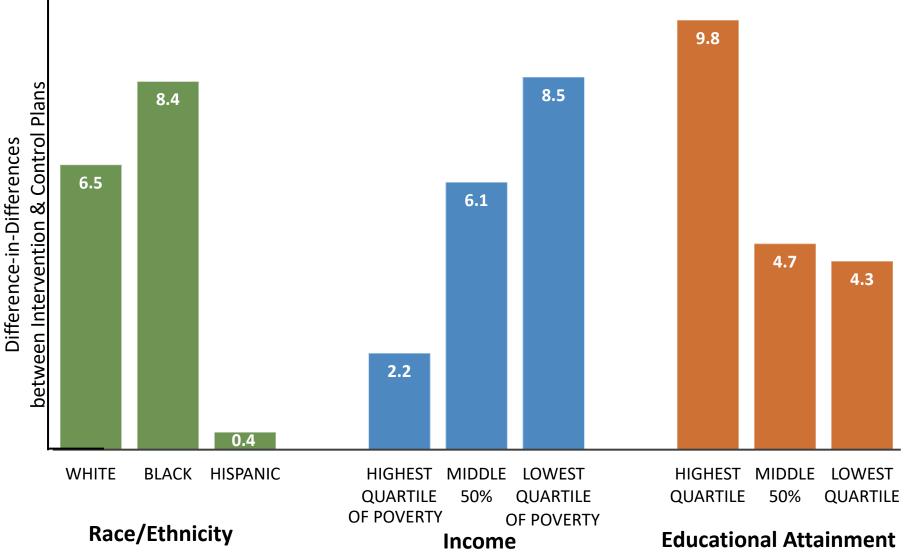
Eliminating Cost-sharing Increases Biennial Mammography Screening in Medicare Advantage



Trivedi et al. (2018). NEJM 378(3):262-269



Changes in Rates of Mammography Screening By Race/Ethnicity, Income, & Education

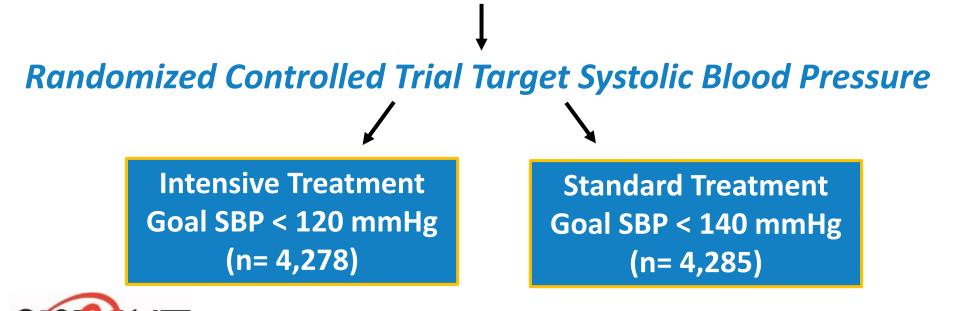


Trivedi et al. (2018). NEJM 378(3):262-269

SPRINT-MIND Research Question

SPRINT Memory and Cognition in Decreased Hypertension

Does intensive blood pressure control compared with standard control reduce the occurrence of dementia?



The SPRINT MIND Investigators for the SPRINT Research Group (2019). *JAMA, 321*(6):553–561.



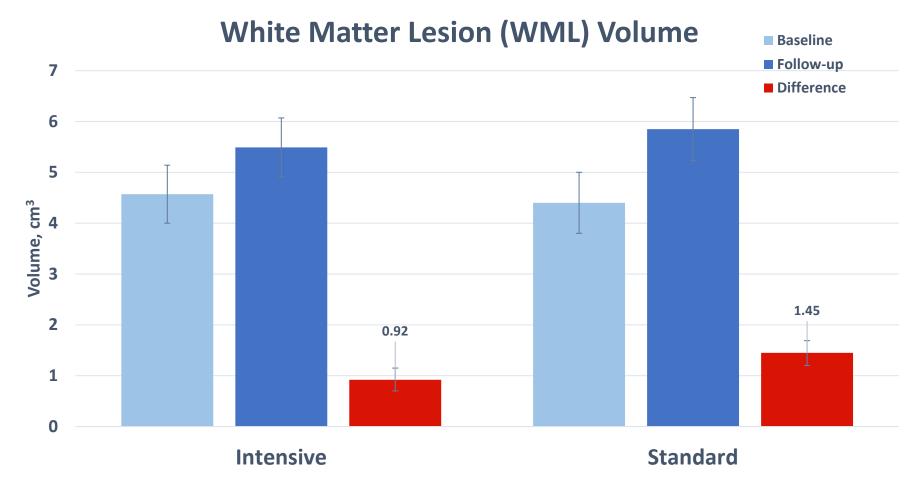
SPRINT-MIND: Secondary Cognitive Outcome

- The Intensive Treatment Group experienced a statistically significant reduction in the rate of developing MCI (19% reduction) as compared to the Standard Treatment Group
- The Intensive Treatment Group experienced a statistically significant reduction in the rate of composite MCI and probable dementia (15% reduction) as compared to the Standard Treatment Group

The SPRINT MIND Investigators for the SPRINT Research Group (2019). *JAMA*, *321*(6):553–561.



SPRINT-MIND: Structural MRI Outcomes



Adapted from The SPRINT MIND Investigators for the SPRINT Research Group (2019). JAMA, 322(6), 524-534.



Daily Low-Dose Aspirin Found to Have No Effect on Healthy Life Span in Older Adults

ASPirin in Reducing Events in the Elderly (ASPREE) - Results

- **Cardiovascular**: No substantial reduction in risk of MI and stroke
- **Mortality**: Slightly higher but not significant
- **Bleeding**: Significantly increased risk of serious bleeding
- Physical disability: No effect
- Dementia: No effect

McNeil, J.J. et al. (2018). *NEJM* 379:1499-1508. McNeil, J.J. et al. (2018). *NEJM* 379: 1509-1518. McNeil, J.J. et al. (2018). *NEJM* 379: 1519-1528.



Change in ACC/AHA Clinical Practice Guidelines re: Aspirin for CVD Prevention





Learn and Live

<u>Circulation</u>

ACC/AHA CLINICAL PRACTICE GUIDELINE

2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines

WRITING COMMITTEE MEMBERS

Donna K. Arnett, PhD, MSPH, FAHA, Co-Chair Roger S. Blumenthal, MD, FACC, FAHA, Co-Chair Michelle A. Albert, MD, MPH, FAHA* Andrew B. Buroker, Esq† Zachary D. Goldberger, MD, MS, FACC, FAHA‡ Ellen J. Hahn, PhD, RN* Chervl Dennison Himmelfarb, PhD, RN, ANP, FAHA* Amit Khera, MD, MSc, FACC, FAHA* Donald Lloyd-Jones, MD, SCM, FACC, FAHA* J. William McEvoy, MBBCh, MEd, MHS* Erin D. Michos, MD, MHS, FACC, FAHA* Michael D. Miedema, MD, MPH* Daniel Muñoz, MD, MPA, FACC* Sidney C. Smith Jr, MD, MACC, FAHA* Salim S. Virani, MD, PhD, FACC, FAHA* Kim A. Williams Sr, MD, MACC, FAHA* Joseph Yeboah, MD, MS, FACC, FAHA* Boback Ziaeian, MD, PhD, FACC, FAHA§

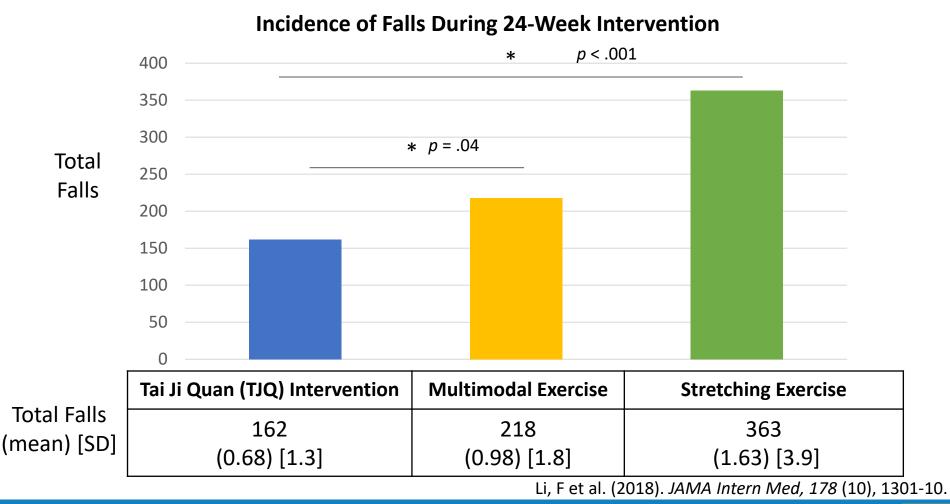
Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Geriatrics Society, the American Society of Preventive Cardiology, and the Preventive Cardiovascular Nurses Association

AC C/AHA Task Force Members, see page e577

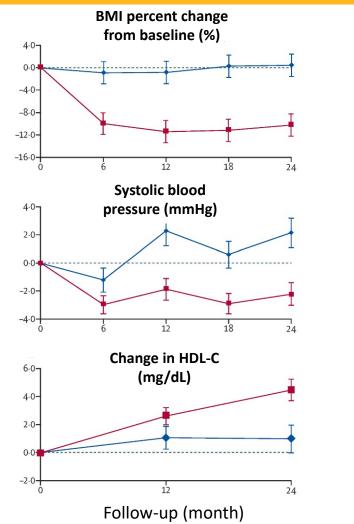
Key Words: AHA Scientific Statement guidelines = antihypertensive agents aspirin atherosclerosis atherosclerotic cardiovascular disease atrial fibrillation behavior modification
behavior therapy blood cholesterol
blood pressure body mass index = cardiovascular team-based care a cardiovascular cardiovascular disease = cholesterol = chronic kidney disease a coronary arter calcium score
coronary disease coronary heart disease a cost a diet a dietary patterns
dietary fats
dietary sodium
dyslipidemia
e-cigarettes exercise healthcare disparities health services accessibility
heart failure
hypertension
LDL cholestero diabetes mellitus
lifestyle
lipids measurement myocardial infarction nisatina = nonnharmacologies

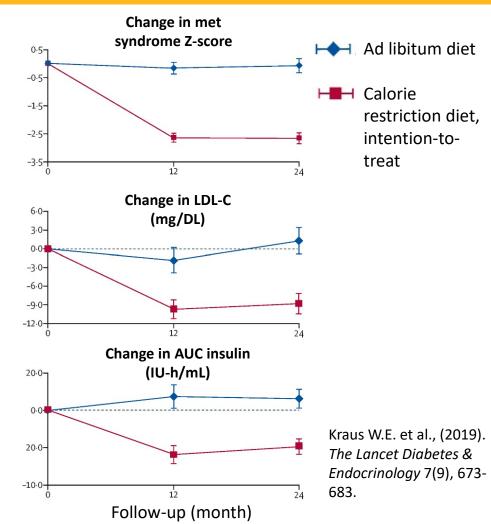


Tai Chi Intervention Reduces Incidence of Falls when Compared to MME and Stretching for Sedentary Individuals with History of Falls



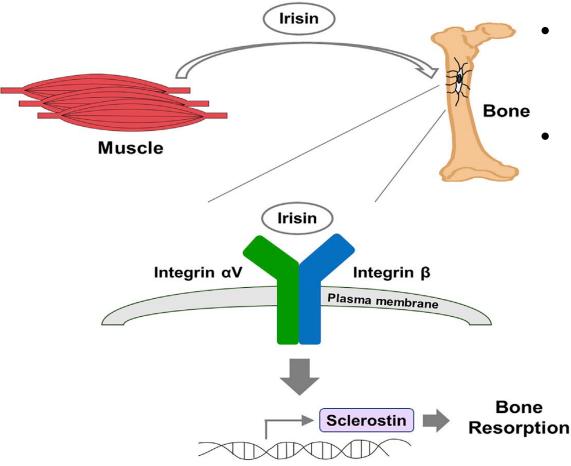
Modest Calorie Reduction Can Improve Cardiometabolic Health







Irisin Promotes Skeletal Remodeling with Implications for Stemming Bone Loss



Irisin secretion by muscle is rapidly stimulated by exercise

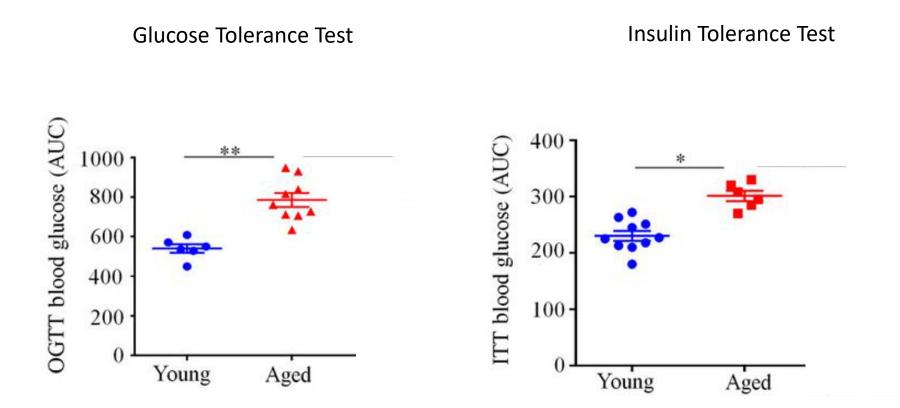
- Irisin supports bone remodeling by:
 - Protecting against • apoptosis of osteocytes
 - Promoting transcription of sclerostin, an inhibitor of osteoblast differentiation

Kim et al., 2018. Cell 175(7):1756-68.



Gut Microbiome Contributes to Insulin Resistance (IR) in Aging

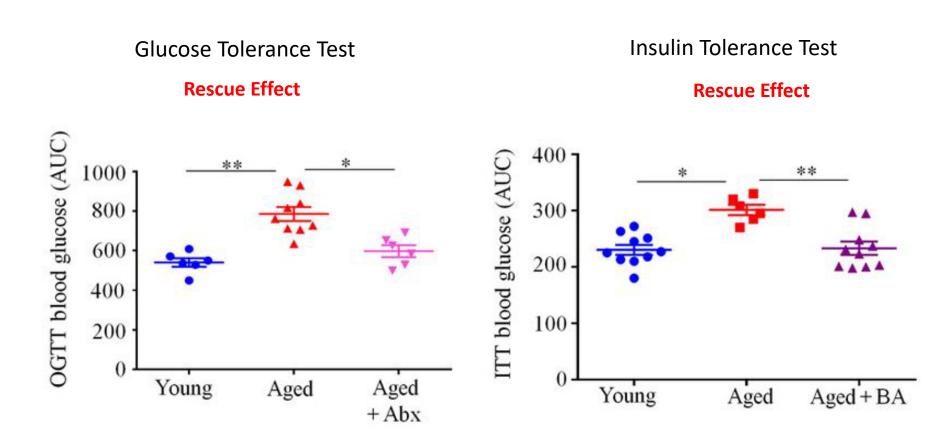
IR is attenuated in aged mice following treatment with antibiotics or butyrate



Bodogai, M et al. (2018). Science Translational Medicine, 10(467): eaat4271.

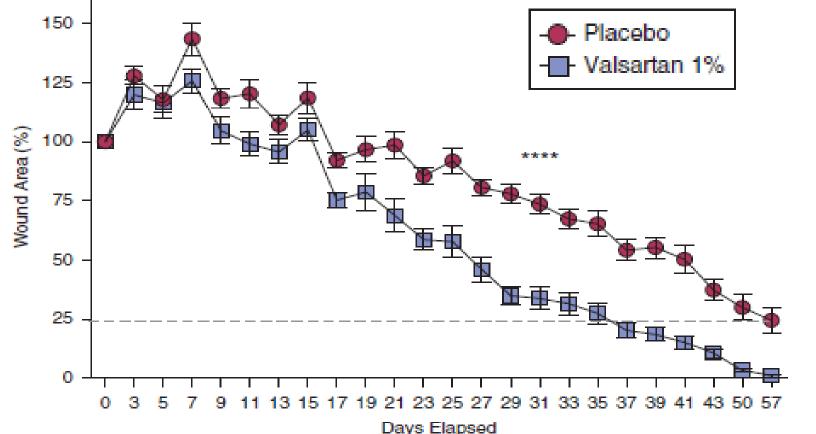
Gut Microbiome Contributes to Insulin Resistance (IR) in Aging

IR is attenuated in aged mice following treatment with antibiotics or butyrate



Bodogai, M et al. (2018). Science Translational Medicine, 10(467): eaat4271.

Hypertension Drug "Valsartan" Reformulated as Topical Treatment for Chronic Diabetic Wounds

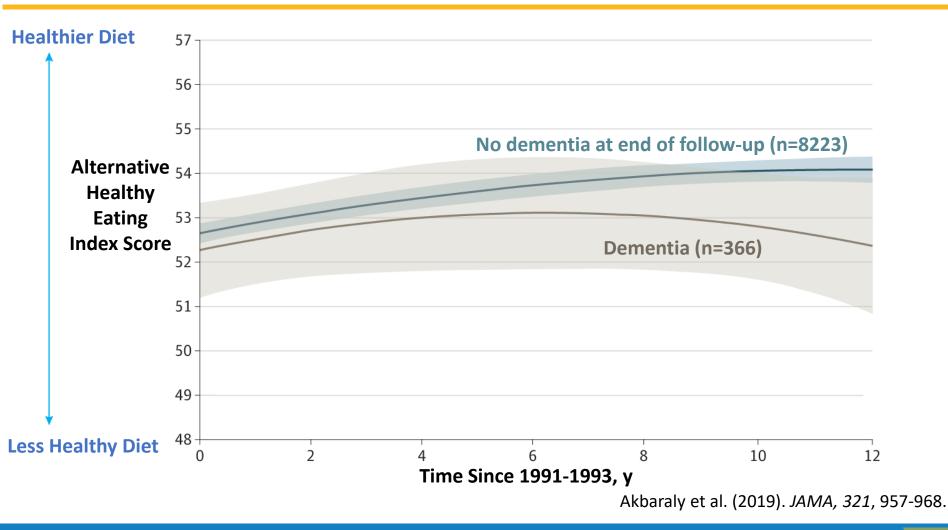


Note: Study tested Valsartan on wounds in diabetic pigs.

Abadir, P., et al. (2018). *Journal of Investigative Dermatology, 138* (2), 434-443.



No association found between diet quality in midlife and later life incident dementia





Healthy Lifestyle Associated with Lower Risk of **Dementia Independent of Genetic Risk**

Subgroup	Total No. of Participants	No. of Cases of Dementia/ Person-Years	Hazard Ratio (95% CI)
Low genetic risk			
Favorable lifestyle	26856	151/211986	1 [Reference]
Intermediate lifestyle	9114	57/72342	1.11 (0.81-1.52)
Unfavorable lifestyle	3165	29/24460	1.52 (1.02-2.26)
Intermediate genetic risk			
Favorable lifestyle	80290	635/633405	1.36 (1.14-1.63)
Intermediate lifestyle	27703	280/219777	1.70 (1.39-2.08)
Unfavorable lifestyle	9603	99/74005	1.70 (1.31-2.19)
High genetic risk			
Favorable lifestyle	26407	298/208769	1.95 (1.60-2.38)
Intermediate lifestyle	9380	111/74652	2.02 (1.57-2.58)
Unfavorable lifestyle	3373	60/26039	2.83 (2.09-3.83)

0.5

Lifestyle scores were constructed based on 4 factors- smoking status, physical activity, diet, and alcohol consumption

Lourida, I et al. (2019). JAMA, 322, 430-437.

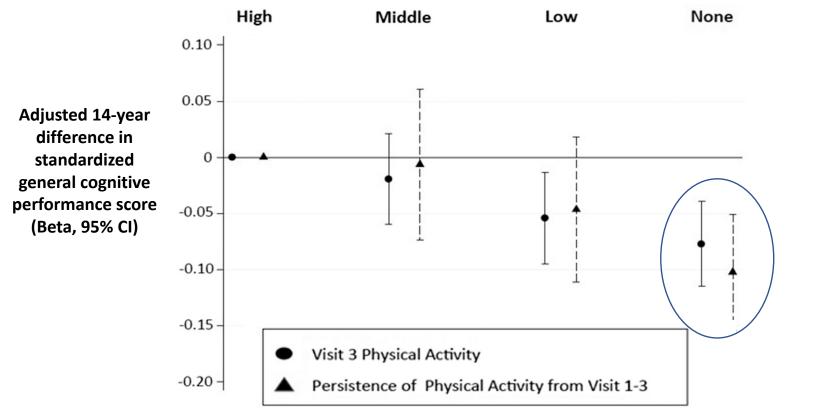
Hazard Ratio (95% CI)



5

Individuals with No Leisure-Time Physical Activity Show More Rapid Cognitive Decline

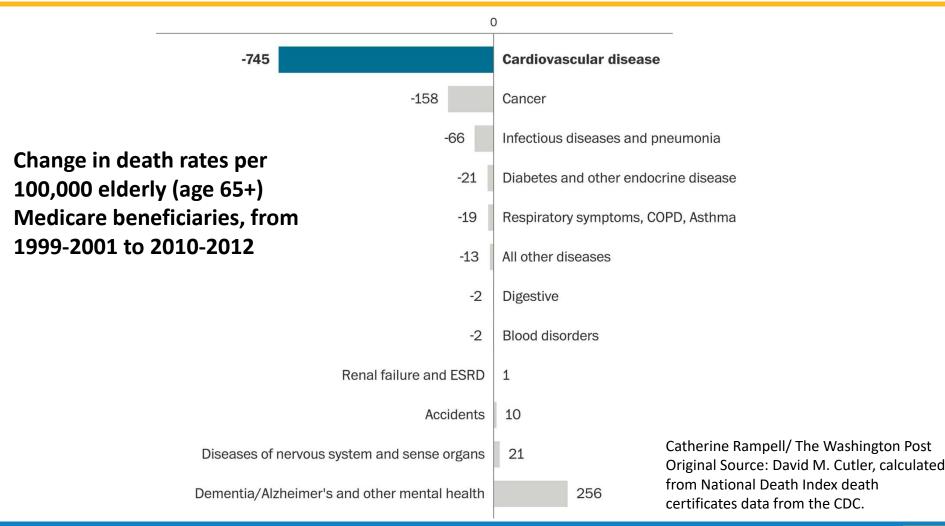
Leisure-Time Physical Activity Level



Palta et al. (2019). Alzheimer's & Dementia, 15(2), 273-281.

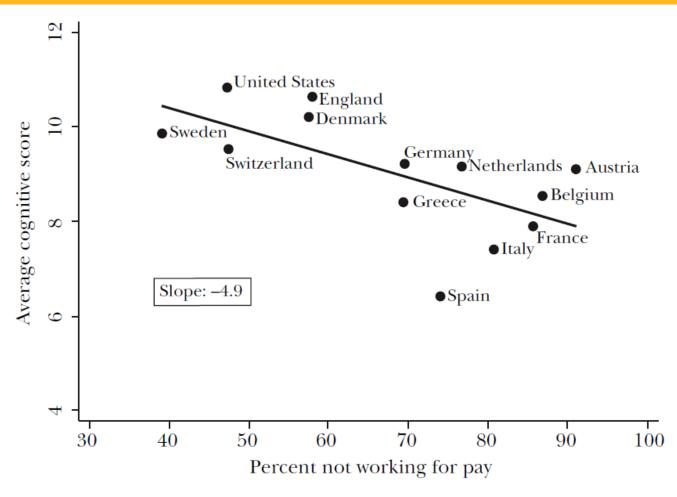


Declining Death Rates Among Older Adults Linked to CVD Improvements





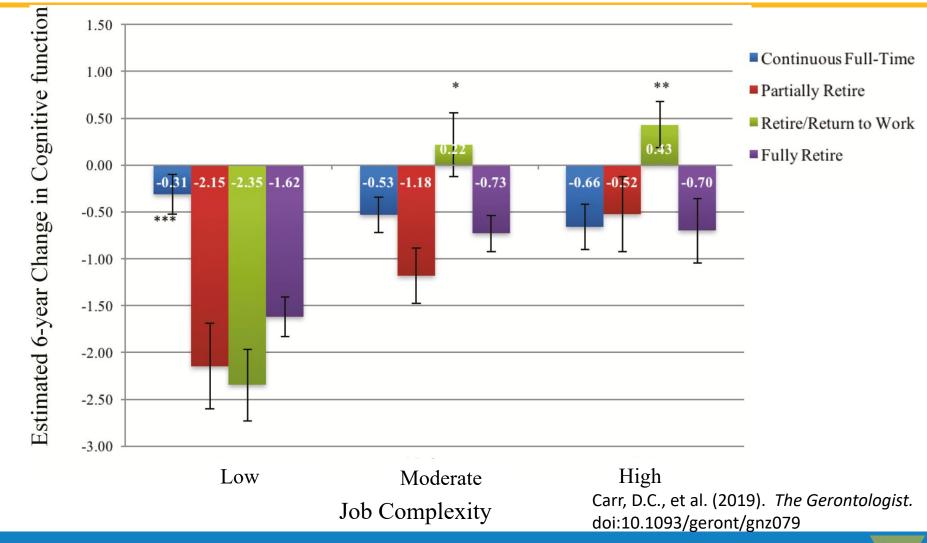
Cognitive Performance as a Function of Employment Rate (2010)



Rohwedder, S. & Willis, R.J. (2010). Journal of Economic Perspectives, 24 (1), 119-138.



"Mental Retirement" Depends on Job Complexity & Retirement Pathway

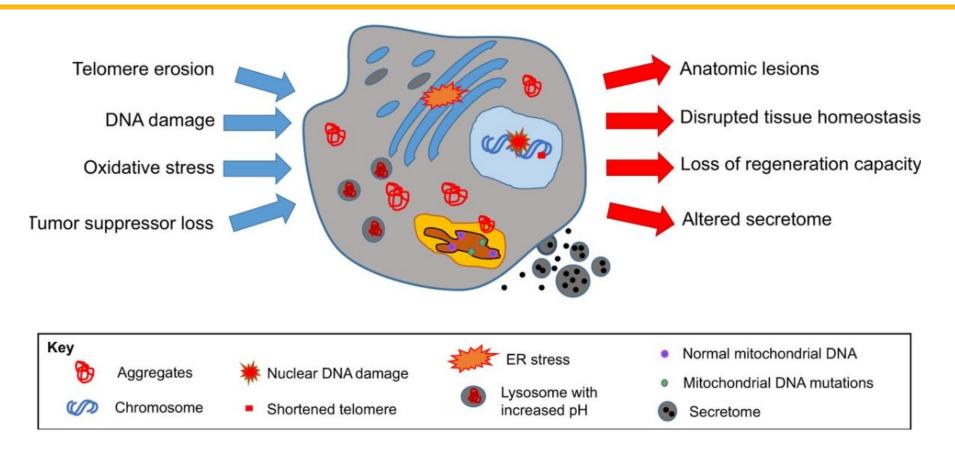




Studies Targeting Senescent Cells



What is cell senescence?

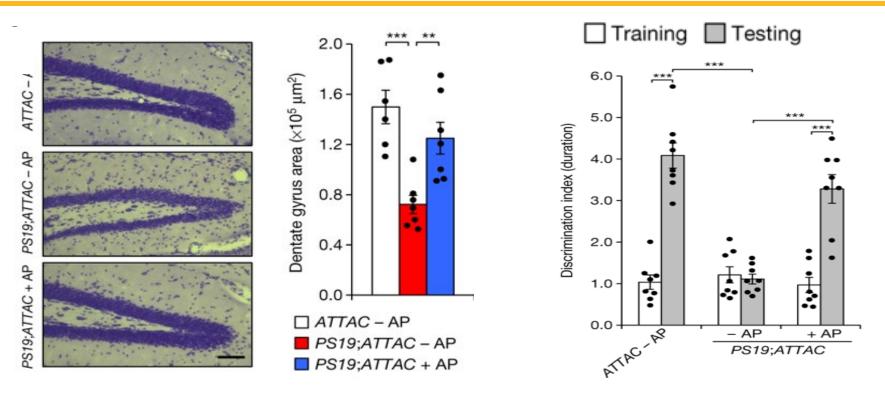


Senescent cells secrete a large number of biologically active factors which affect the function of neighboring, non-senescent cells

Ruan, L. et al. (2018). J Cell Sci 131.



Clearance of senescent glial cells prevents taudependent pathology and cognitive decline



- Senescent cells drive neurodegenerative disease
- Clearance of senescent cells through genetic manipulation or drug treatment decreases tau pathology and cognitive decline

Bussian, T. et al. (2018). Nature, 562(7728): 578-582.



Senolytics are Being Tested in the Clinic Against a Handful of Diseases

- Small Phase 1 studies on repurposed compounds (dasatinib + quercetin; navitoclax)
- Conditions:
 - Idiopathic pulmonary fibrosis (IPF) n=26 <u>NCT02874989</u> (completed)
 - Alzheimer's disease n=5 <u>NCT04063124</u>
 - Diabetic chronic kidney disease n=16 <u>NCT02848131</u>
 - Osteoarthritis n=78 <u>NCT03513016</u> (completed)
- Feasibility and tolerability results published for IPF Phase 1 study (Justice et al. (2019). EbioMedicine; 40:554-563)

Resources and Infrastructure



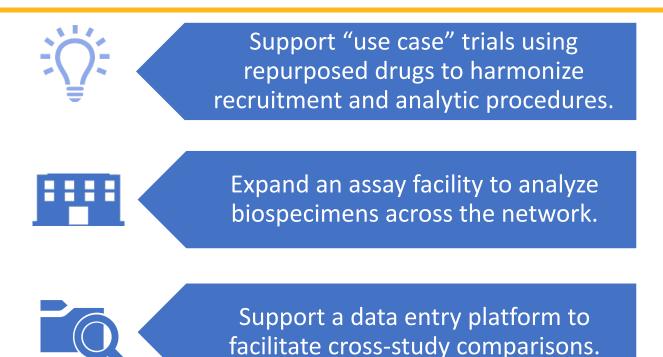
RESEARCH CENTERS COLLABORATIVE NETWORK of the National Institute on Aging, NIH <u>https://www.rccn-aging.org/</u>

Catalyzing cross-disciplinary research across the NIA Center Programs

- Alzheimer's Disease Research Centers
- Centers on the Demography and Economics of Aging
- Claude D. Pepper Older Americans Independence Centers (OAICs)
- Nathan Shock Centers of Excellence in the Basic Biology of Aging
- Resource Centers for Minority Aging Research (RCMAR)
- Roybal Centers for Translational Research on Aging 58

Translational Geroscience Network

Goal: Accelerate the development of interventions designed to treat chronic conditions (e.g., diabetes, heart disease, Alzheimer's disease) as a group by targeting biological aging.



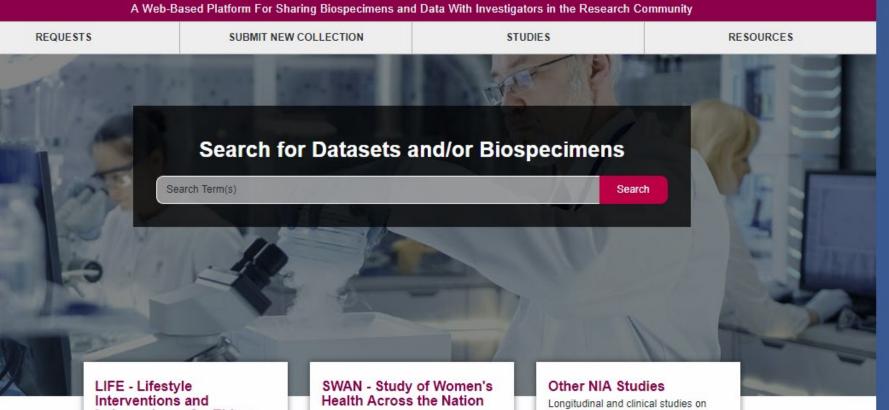


Develop a biobanking and repository network for samples from clinical trials to permit future analyses.





https://agingresearchbiobank.nia.nih.gov



Interventions and Independence for Elders FEATURED COLLECTION The primary aim is to assess the longterm effects of structured physical

term effects of structured physical activity on the primary outcome of major mobility disability, defined as inability to walk 400 m.

Learn more about the LIFE Study >>

SWAN is providing many interesting findings about the health and aging of mid-life women from diverse communities and racial and ethnic backgrounds.

Learn more about the SWAN Study >>

Longitudinal and clinical studies on aging supported by the National Institute on Aging have generated collections of biospecimens and related phenotypic and clinical data to allow better understanding of the aging process and to promote advances in the development of prognostics, markers, and therapeutics for agingrelated conditions.

AgingResearchBiobank

Main Purpose:

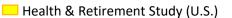
- Provide a state-of-the-art inventory system for the storage and distribution of biospecimens and data collections from NIA-funded studies to broader scientific community.
- Accelerate science to help extend the healthy, active years of life for the world's fast-growing population of older adults.



HRS Family Studies Around the World

https://hrs.isr.umich.edu/data-products

- Mexican Health and Aging Study
- Costa Rican Longevity and Healthy Aging Study
- Health and Aging in Africa: Longitudinal Studies of INDEPTH Communities (Agincourt, S. Africa)
- The China Health Aging and Retirement Longitudinal Study
- Indonesia Family Life Survey
- The Scottish Longitudinal Study of Ageing
- The Irish Longitudinal Study on Ageing
- * The Northern Ireland Longitudinal Study of Ageing



- The Brazilian Longitudinal Study of Aging
- English Longitudinal Study of Ageing
- Survey of Health, Aging, and Retirement in Europe
- Longitudinal Aging Study in India
- Korean Longitudinal Study on Ageing
- Japanese Study of Aging and Retirement



The Healthy Cognitive Aging Project (HCAP) Dementia Assessment in HRS-Family Studies

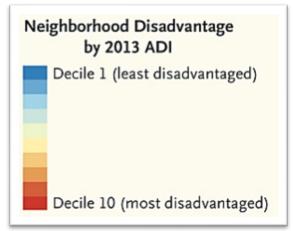
 The now-global consortium of studies (HRS-sister studies) collecting rich cognitive data using the Harmonized Cognitive Assessment Protocol

https://hrs.isr.umich.edu/data-products/cognition-data

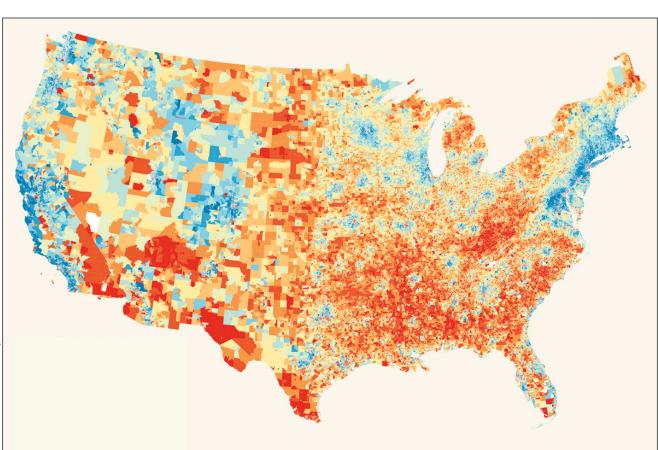




Assessing Neighborhood Disadvantage on a National Scale



<u>www.neighborhoodatlas.</u> <u>medicine.wisc.edu</u>



Kind, A.J.H., & Buckingham, W.R. (2018). NEJM 378(26):2456-8.



New research collaboratory designed to spur innovation and improve dementia care



NIA IMPACT will:

- Develop and disseminate technical, policy, and best practices
- Enhance research development and investigator capacity:
 - Fund/guide pilot ePCTs, support transformation into full-scale ePCTs.
 - Resource for NIA-funded investigators conducting ePCTs in PLWD.
 - Support training through career award, workshops, and on-line modules.
- Engage stakeholders



IMPACT Collaboratory







Alzheimer's and Dementia Outreach, Recruitment, and Engagement Resources

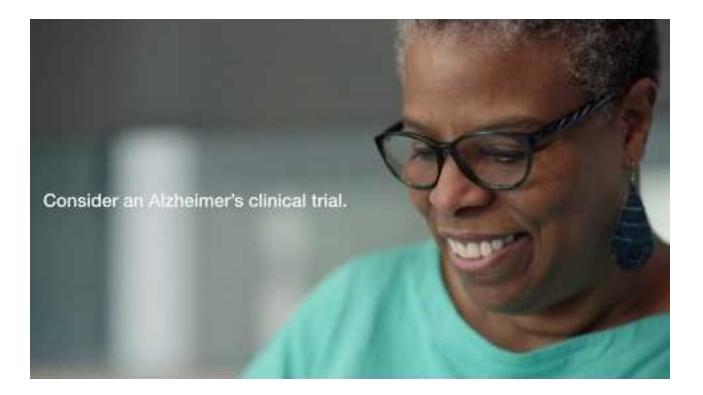
www.nia.nih.gov/research/ADORE

A searchable collection of materials for clinical trials recruitment and retention:

- **Find** flyers, toolkits, recruitment plans, and more from Alzheimer's Disease Research Centers, NIH, and others.
- **Browse** by goals, participant characteristics, and dozens of focused topics.
- **Get** tips for strategy from the Alzheimer's Disease and Related Dementias Clinical Studies Recruitment Planning Guide.
- View, download, and share participant testimonial videos.



Recruitment Video



Alzheimer Centers for the Discovery of New Medicines

- Two new research centers with funding expected to total more than \$73 million
- Designed to diversify and reinvigorate the Alzheimer's disease drug development pipeline
- Will provide added infrastructure for developing high-quality research tools and technologies needed to validate and advance the next generation of drug targets

<u>https://www.nia.nih.gov/news/nih-funded-</u> <u>translational-research-centers-speed-diversify-</u> alzheimers-drug-discovery

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Save the Dates



The third **Geroscience Summit** organized by the Trans-NIH GeroScience Interest Group:

Targeting Chronic Diseases Through Geroscience



Geroscience Summit 2019

The Summit will be held on **November 4 & 5, 2019** in the NIH Natcher Building, Bethesda, MD.

> Registration is now open at <u>www.nia.nih.gov</u>! Questions? <u>Sierraf@nia.nih.gov</u>



Join NIA in celebrating its 45th anniversary! Friday, 11/15/19, 10:00a.m – 11:30 a.m. The GSA meeting, Austin TX – Room TBD

- Hear from division directors, scientific director, and NIA director
- See the unveiling of the new Strategic Directions
- Enjoy light refreshments (*not at government expense*)



Dementia Care, Caregiving, & Services Summit March 24-25, 2020 Natcher Conference Center Bethesda, MD

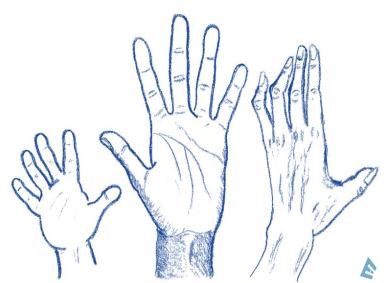


CALL FOR POSTERS: Submit an abstract by **NOVEMBER 15th**. Registration will open soon!

https://www.nia.nih.gov/2020-dementia-care-summit



NIH's 2nd Inclusion Across the Lifespan Workshop



September 2-3, 2020

A Request for Information (RFI) will be published soon!

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