Duke Dementia Family Support Program

Caregiver Connections
An Educational Webinar Series With The Experts

The presentation will begin shortly. Thank you for your patience!

dukefamilysupport.org
919-660-7510
Advances in the Prevention and Treatment of Alzheimer’s Disease

Presenter: Kathleen A. Welsh-Bohmer, PhD, ABPP
Professor of Psychiatry & Neurology
Duke Clinical Research Institute
NC Registry for Brain Health &
Duke / UNC Alzheimer’s Disease Research Center

October 17, 2023
Affiliation and Disclosures

**Dr. Welsh-Bohmer** directs the Coordinating Center for the NC Registry for Brain Health at Duke University.

She consults with pharmaceutical companies, including Roche/Genentech and Biogen.

And she has a contract with the biotechnology company WCG-VeraSci to assist in the development of technologies for clinical trials of Alzheimer’s disease.
Brain imaging, fluid biomarkers, retinal imaging, & genetics allow enhanced detection of disease
New treatments target the underlying cellular mechanisms and slow the disease progression
Where we are today ….

**Bad News**
- There is no cure for Alzheimer’s disease once the disease has started
- No treatment that allows us to prevent the disease from occurring

**Good News**
- Have disease biomarkers allowing earlier diagnosis
- New treatments that slow disease progression in brain
- Evidence based approaches to lower risk and promote healthy cognition
Biomarkers for early detection
Alzheimer’s Disease: Two Problems
Amyloid Plaques and Neurofibrillary Tangles

Amyloid “plaques”
(ß amyloid protein)

Brain immune response
inflammation/glial cells

Cell loss “neurodegeneration”
Atrophy

Neurofibrillary Tangles
(p-Tau protein)
Biomarkers of Alzheimer’s Disease - Amyloid

- Measure abnormal amyloid and tau in cerebrospinal fluid (CSF)
  — and —

- Amyloid and tau brain imaging using Positron Emission Tomography (PET)

  Amyloid or tau is tagged with a fluorescing imaging agent, F18 florbetapir seen here

  Doing this allows us to then visualize areas of high accumulation on imaging with PET

  Three different agents FDA are approved for detecting abnormal levels of brain amyloid.

Increased Precision with Combined Biomarkers

Confirm & stage disease

- Large prognostic study with prospectively collected data (clinical and imaging) from 8 cohorts of AD, MCI, healthy controls from South Korea, Sweden, and the US (n=1431)

Showed

- Abnormal amyloid points to a diagnosis of Alzheimer’s disease
- Tau abnormalities in the context of abnormal amyloid points to greatest risk for decline
- Together this information can be used to guide therapeutic decisions in early stages of silent disease (i.e., when to start therapy)

Blood Biomarkers- Improving Accessibility for All

- Research suggests that a form of tau called p-Tau217 is very specific to Alzheimer’s and, when measured in the blood, is highly accurate in distinguishing Alzheimer’s from other neurodegenerative disorders.

- Advantages of convenience and cost
  - Starting to be used to screen for disease

- Disadvantages in accuracy compared to PET imaging & CSF methods
  - Not yet covered by insurance

New Breakthroughs- Gut Microbiome & Brain AD pathology

Novel biomarker improves accuracy in disease detection
(Ferreiro et al. Science Translational Medicine, June 14 2023)

- Seven types of bacteria found in gut are correlated with AD pathology in preclinical AD
  - Suggests that bacteria in the gut and our exposures over our lifetime can influence what is happening in the brain
- Adding microbe data to all types of biomarkers nudges up accuracy in diagnosis
  - Could be used to screen people to identify those who should go on to have a lumbar puncture or PET scan
  - And could help physicians in the future personalize medicines to prevent disease based on our unique biology & health history

**Improving Diagnostic Accuracy.** Including the prevalence of certain gut bacteria (green) improved the accuracy of most models used to diagnose preclinical AD, including clinical variables only (CC), clinical information plus polygenic risk score and ApoE4 status (CC + G), those plus biomarkers of neurodegeneration, tau and amyloid (All), or all the markers minus Ab (All – A). [Courtesy of Ferreiro et al., Science Translational Medicine 2023.]
Digital tools, including wearable devices, increase the reliability of measuring cognition and highly nuanced changes in behavior:

- Discrete measures that can be repeated over time
- Can be used to help clinicians detect subtle changes in real time to guide management decisions; &
- Potentially some forms of this could be used for people to self-monitor their everyday function to know how well interventions are helping

DIGITAL TECHNOLOGY: DUKE/UNC ADRC  
DRIVING NEW INSIGHTS IN NEUROCOGNITION

- Virtual Reality Functional Capacity Assessment Tool (VRFCAT)
  - Used to detect subtle changes in function in the preclinical stage of Alzheimer’s disease
  - performance based instrument
  - assesses the ability to complete instrumental activities associated with a shopping trip
  - normed (18-85) & sensitive to subjective cognitive complaints and MCI

J Prevention of Alzheimer's Disease (JPAD), 5(4): 216-224
Technology can enable broader access to services and facilitate accuracy/clinician insights by linking electronic health records.
Treatment Advances
Medications approved for symptomatic treatment of Alzheimer’s disease

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<th>Mechanism of Action</th>
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## Medications approved for symptomatic treatment of Alzheimer’s disease

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- **Provide symptomatic relief**
- **Do not change the underlying disease course**
- **Latest AD drug approval occurred in 2003**
Monoclonal antibodies aimed at lowering toxic forms of Aβ (protein found in amyloid plaques).

- Typically these drugs involve monthly infusions in order to reduce the aggregation of amyloid plaques in the brains of treated patients, as shown here with the first generation drug, Aduhelm.

Goal is to not only lower amyloid in brain but to, of course, also improve patient function and cognition.

Success 1: Aducanumab “Aduhelm”

- FDA granted early “accelerated” approval to the anti-amyloid drug Aduhelm in June 2021
- Controversial decision because of the drug’s mixed results in two large studies and mistakenly ending the study early
- Limited availability rarely used but paved the way for accelerated approval for future AD drugs
Phase 3 “Clarity” trial tested an experimental amyloid-targeting antibody, lecanemab (BAN2401) in mild stage Alzheimer’s disease (n=1795)

- significantly slowed the progression of dementia symptoms among people with early Alzheimer’s disease
- slowed the rate of cognitive decline by 27% over 18-months
- reduced blood biomarkers of progression (pictured)
- adverse events (microbleeds) 17.3% on treatment compared to 9.3% on placebo. 12% had brain swelling (edema) on drug.
- ~25% of the U.S. participants were Hispanic and African American
Success 2: Lecanemab or “Leqembi”

○ U.S. Food and Drug Administration (FDA) granted “accelerated approval” January 6th 2023

○ July 2023 the drug received full FDA approval for use in mild AD
  • Significant adverse reactions in 20%+ patients treated;
  • High costs for treatment and medical procedures;
  • Medicare coverage provided for qualifying patients.
Success 3: Within Reach

- May 3, 2023 Phase 3 donanemab trial results released.
  - Demonstrated a 35% slower decline in memory, thinking, and ability to perform daily activities
  - Reduced brain plaque associated with Alzheimer’s disease (shown here)
  - Like the other immunotherapies, donanemab carries significant adverse risks for brain edema (swelling) and micro-bleeds that can be managed

- Moving forward towards traditional FDA approval with additional data for patients on drug for 12 months

“Trail Blazer 2” Study recruited 1736 patients with either MCI or mild Alzheimer’s disease who also had abnormal levels of both AD proteins: amyloid and tau
CONCERNS - AMYLOID THERAPIES

SAFETY
- ARIA-e: Brain edema/swelling detected on MRI imaging
  - 47% aducanumab (vs 5% control)
  - 27% donanemab
  - 12% lecanemab
- Typically asymptomatic and occurs in first 3 months & resolves
- Monitor closely
- If asymptomatic, discontinue dosing until resolves

FEASIBLE/ AFFORDABLE/ ACCESSIBLE
- Typically administered with monthly infusions for 18 months or much longer
- Costly at ~$27,000 per year
- Medicare coverage contingent on physicians entering treatment and outcome data into an electronic database
2023 Drug Development Pipeline Alzheimer’s Disease

141 unique agents
187 clinical trials
36 in Phase 3 studies

Published March 14, 2023
2023 Drug Development Pipeline for Alzheimer's Disease

- 141 unique agents
- 187 clinical trials
- 36 in Phase 3 studies

Non amyloid targets: tau, inflammation, synapse and neuronal protection, vascular factors, and new neuron formation “neurogenesis.”

Published March 14, 2023
Not all dementias are Alzheimer’s disease ...... or due to Alzheimer’s disease only

Mix of pathologies that overlap lead to cell injury and cell death

- Blood Flow
- Inflammation
- Cellular Metabolism
As new therapies are developed, it is important experimental therapeutics are available to all.

And, that it is clear that these drugs will be safe and effective in all populations.

- African Americans are two times more likely to develop Alzheimer’s compared to whites. And, Hispanics are at 1.5 times higher risk than non-Hispanic whites.
- Less than 10% of participants in most clinical trials are African American (Flores et al 2021)\(^1\)

\(^1\) Flores LE et al. (2021) Assessment of the Inclusion of Racial/Ethnic Minority, Female, and Older Individuals in Vaccine Clinical Trials. JAMA Network Open;4(2):e2037640
Diversity in Clinical Trials

- Reasons for the imbalance and lack of population diversity within clinical trials are complex (Franzen et al. 2022).²
- Health inequities, limited access to research, reluctance, historical trial injustices leading to mistrust, and rigid study designs that create obstacles to participation.
- FDA (April 2022) now requires all companies doing clinical trials to have a plan for increasing diversity before they start the work.

Genetics & Alzheimer’s Disease Risk

Effect sizes of disease-associated gene variants can differ between populations

**APOE**
- AA: 1.93 (1.72-2.17)
- EUR: 3.32 (3.20-3.45)
- JAP: 5.5 (4.4-6.9)*

**ABCA7**
- AA: 1.41 (1.21-1.65)
- EUR: 1.13 (1.09-1.18)
- JAP: NS

**SORL1**
- AA: NS
- EUR: 0.81 (0.76–0.88)
- JAP: 0.75 (0.66–0.85)*

- Genes related to AD may operate differently across the world populations.
- Important to understand this as we attempt to personalize treatment.

Adapted from Shea Andrews and Alison Goate, Ichan School of Medicine, Mt Sinai
Preventing Alzheimer’s Disease & Optimizing Brain Health
What can we do now until there is a treatment?

Alzheimer’s is a highly complex disease involving the demise of multiple brain systems, developing over a long period of time, the entire life course.

As is true with other complex diseases, there is not one answer or one treatment that will be effective for all.

Protecting brain health is best when started early, but it is never too late to have a positive impact.
AD Risk: Genetics accounts for ~30% risk of developing AD
Non-genetic factors account for the other 70% risk. These factors impact neuron viability, inflammation, oxidative stress, glucose metabolism, endothelial cell damage, clearance of tau and β-amyloid from brain

Lancet Commission Report 2020
Modifying risk factors across the lifespan can prevent or delay up to 40% of dementia cases.

How do we implement changes to optimize brain health?

**Seven things** that can be done now to reduce risk of disease and potentially have a positive impact on memory decline & dementia progression
Step 1: Change in Mindset - Positive & Take Control

- None of us are powerless as we age
- Responsibility to maintain health
  - Continued contributions (big or small) to the larger society, family, & friends. “Wisdom of age” and a life well-lived
- Cultural/societal supports for active aging — Europe models
  - Delay exit from employment for those who want to work and encourage an active life following retirement

European Innovation Partnership on Active and Healthy Age (EIP-AHA). Green Paper on Ageing was adopted on 27 January 2021, COM (2021) 50 final
Step 2: Treat What Can Be Treated

- Stop smoking
- Reduce alcohol consumption
- Management of medical conditions:
  - Heart disease & vascular risk conditions
    - Hypertension,* diabetes, high cholesterol
  - Thyroid disease
  - Sleep disorders (obstructive sleep apnea)
  - Pain, arthritis
  - Anxiety & depression
  - Sensory Impairments

Evidence that treating what we can treat works: Hypertension

- SPRINT & SPRINT-MIND trials
  - 9361 participants age 50+ with SBP > 130 + CVD risk factor
  - Randomized to
    - Standard BP control (target SBP <140)
    - Intense BP control (target SBP <120)
  - Intense BP control over 5 years lowered risk of MCI/dementia by nearly 20%

Effect of Intensive vs Standard Blood Pressure Control on Probable Dementia

- Study Population: 9361 elderly participants
- Intervention: Randomization to Intensive blood pressure control (systolic BP <120 mmHg) vs Standard blood pressure control (systolic BP <140 mmHg)
- Outcome: Reduced risk of Mild Cognitive Impairment (MCI)

- Mean Blood Pressure: 121.6 vs. 134.8 mmHg
  - Standard control: 121.8 to 122.3 mmHg
  - Intensive control: 114.3 to 135.5 mmHg

Hazard Ratio:
- MCI: 0.81 (95% CI 0.69 to 0.95)
- Probable Dementia: 0.85 (95% CI 0.74 to 0.97)

Limitation: Study terminated early due to cardiovascular benefit

2 Minute Medicine, Inc. www.2minutemedicine.com
Step 3: Get Physically Active

**World Health Organization 2020 guidelines on physical activity and sedentary behavior**

<table>
<thead>
<tr>
<th>Senior Guidelines For Physical Activity</th>
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<tr>
<td><strong>Aerobic Exercise</strong> (walking, jogging, dancing, biking, swimming, etc.)</td>
</tr>
<tr>
<td><strong>Resistance Exercise</strong> (weight lifting, calisthenics)</td>
</tr>
<tr>
<td><strong>Flexibility Exercise</strong></td>
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<td><strong>Balance Exercise</strong></td>
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Exercise & Dementia

- The World Health Organization named “physical activity” as the highest priority, non-pharmacological intervention with potential to reduce dementia risk
  - Meta-analysis of 19 studies (17 randomized clinical trials) concluded that exercise delays cognitive decline in people with MCI
  - Observational data from humans and animals point to mechanisms: improvements in:
    - brain structure
    - brain tissue function
    - biomarkers associated with dementia

Exercise & Dementia

- Inconsistent evidence on whether it is possible to **prevent** MCI or dementia by exercising.
- Meta-analysis of 5 RCTs found no significant effects:
  - Strongest evidence for aerobic exercise\(^1\)
- Recent multi-site RCT in very mild MCI & subjective concerns (EXERT;18 months)\(^2\):
  - Saw positive effects across both exercise arms.
  - Biomarker data under analysis.

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Step 4: Watch What You Eat!

- Many observational studies report lower dementia risk associated with diet types (e.g., Mediterranean diet & MIND diet) or specific nutrients.
- Mechanism unclear but these diets confer broad health benefits that protect against brain injury:
  - Anti-inflammatory effects
  - High antioxidant properties
  - Pro-metabolic effects
  - Lower lipids
  - Offer protection from cardiovascular disease
  - Modulate intestinal microbiome in healthy ways

Diet & Dementia Risk

- Meta-analysis of 15 RCTs with dietary interventions found a significant effect on cognitive performance (McGrattan et al 2018. Brit J Nutr)
  - Supplements do not confer the same advantage (Wengreen et al 2013 Amer J Nutr)
  - Effect seen across cultures (Moustafa et al 2022 JAMA)
  - World Health Organization recommends vitamins and nutrients obtained from balanced diet, not supplements
Step 5: Work Your Brain—Engage it in Novel Ways

- Learning new things creates new brain connections
- If it involves movement & activity with others, all the better!
- Protects brain, buffering against damage in the same circuits affected by disease

http://doi.org/10.1002/trc2.12047
Cognitive & Social Engagement and Dementia Risk

- Engaging with others is a natural way to cognitively engage
  - Social engagement taps multiple cognitive domains (e.g., attention, memory, planning, language) and can bring with it positive emotional elements
- Low social engagement and loneliness are both linked to dementia risk & cognitive decline.
- Groups at high risk include:
  - Widows, caregivers
  - People in rural settings
  - Individuals from groups that have been targeted or marginalized

Step 6: Stress Reduction and Caring for Your Emotional Health

- Growing evidence from animal models that stress hormones contribute to risk of cognitive decline and dementia
- Sleep often affected by stress but is crucially important for reducing toxic molecules including beta amyloid
- Methods for reducing stress:
  - Social engagement
  - Outdoor activity
  - Pet therapy
  - Meditation/prayer
  - Yoga /mindfulness
  - Close personal connections/ support groups

Step 7: Be a Part of the Solution—Participate in Research!

- Medical science has come a long way in the last 30 years
  - But still no cure for Alzheimer’s disease and other dementias
  - And in all likelihood there will not be just one solution or one treatment
  - Different treatments for different stages of disease - early & late

- Preventing Alzheimer’s disease and other dementias can only come with further research
  - Need help from everyone so that answers and treatments are based on the full population at risk of dementia

- Getting involved in clinical research is a proactive step to brain health
DO ALL SEVEN THINGS!
MULTIDOMAIN INTERVENTIONS ARE EFFECTIVE TREATMENT

**US POINTER STUDY**
- Builds off of study in Finland FINGER showing merits of combined approach
- 2 year lifestyle intervention trial targets simultaneously a number of risk factors to protect cognitive function
- 2000 older adults; completed enrollment in March 2023
  - Sites in Chicago, Rhode Island, Texas, California & NC (Wake Forest!)
  - Sub-studies include sleep, neurovascular, imaging, & microbiome

Getting Involved in Research
TOGETHER
We Can Improve Brain Health and Defeat Dementia

Click Here to Join
What is a research registry?

A registry collects information from people who *might* want to be in research studies or learn more about current research that they may be eligible for.
What is the NC Registry for Brain Health?

The “Registry” is a group of people across North Carolina interested in news to improve brain health and information about research to advance the treatment of dementias such as Alzheimer’s disease and other memory disorders.

Funded by the State to increase access to information and to research studies to improve brain health

FREE!!
Who We Are: Impact Across the State of NC

THE REGISTRY - PEOPLE AND PLACES

Wake Forest School of Medicine
WINSTON-SALEM, NC
Researchers at Wake Forest School of Medicine combine medical research with community engagement at the Maya Angelou Center for Health Equity.

NC A&T State University
GREENSBORO, NC
Researchers from NC A&T University link science and community at the Center for Outreach in Alzheimer’s, Aging and Community Health (COAACH).

Duke University
DURHAM, NC
Duke University partners are building on the Alzheimer’s Disease Prevention Registry to create a new statewide registry.

UNC-Chapel Hill
CHAPEL HILL, NC
Our partners at UNC-Chapel Hill include the UNC Memory Disorders Program and the Carolina Alzheimer’s network.

East Carolina University
GREENVILLE, NC
East Carolina University combines expertise in neurology and brain disorders with commitment to improving health for future generations.
Who’s joined so far? (October 16, 2023)

Total enrollees: 11,314

Race (check all that apply)
- White: 7177 (63.4%)
- African-American/Black: 3293 (29.1%)
- Multi-racial: 205 (1.8%)
- Unknown: 193 (1.7%)
- Asian: 146 (1.3%)
- Other: 182 (1.6%)
- American Indian/Alaska Native: 115 (1.0%)
- Native Hawaiian/Other Pacific Islander: 4 (0.0%)

Do you have any Hispanic or Latino Ethnicity?
- No: 10,083 (89.1%)
- Yes: 399 (3.5%)
- No response: 605 (5.4%)
- Don't know: 227 (2.0%)

Racial Demographics

What is the highest level of school you have completed?
- Unknown: 1998 (17.6%)
- Graduate degree: 3137 (27.7%)
- 4-year college degree: 2715 (24.0%)
- Some college or Associate's: 2354 (20.8%)
- High School graduate: 967 (8.5%)
- Less than HS diploma: 168 (1.5%)
Who’s joined so far? (October 9, 2023)

**Total enrollees: 11,314**

**Gender**
- Female: 8353 (73.5%)
- Male: 2923 (25.9%)
- Nonbinary: 14 (0.1%)
- No response: 13 (0.1%)
- Transgender: 2 (0.0%)
- Transgender female: 2 (0.0%)
- Transgender male: 2 (0.0%)

**Age (approximate)**
- 18-29: 23 (0.2%)
- 30-40+: 315 (2.8%)
- 50's: 3297 (29.1%)
- 60's: 3008 (26.6%)
- 70's: 1568 (13.8%)
- 80's: 1275 (11.3%)
- 90-100+: 707 (6.3%)
- 403 (3.6%)
- 30s: 403 (3.6%)
- 263 (2.3%)
- 18-29s: 455 (4.1%)
- Unknowns: 2 (0.0%)
Some Types of Studies

- Studies of how lifestyle change may reduce risk and slow down disease
- Clinical trials examining medications that might work to improve memory functioning or slow decline
- Studies of new technologies to help better identify early signs of disease
Duke/UNC Memory & Aging Study

You may be eligible to participate if you:

- are between the ages of 45 and 80, with or without memory loss.
- are willing to attend yearly visits that include brain imaging (MRI) and memory evaluations.
- have a study partner who knows you well and can answer questions about your memory and daily activities.
- are willing to provide a one-time spinal fluid donation. Watch our informational videos at https://dukeuncadrc.org/join-our-study.

You and your study partner will be paid for participating.

FOR MORE DETAILS OR TO FIND OUT IF YOU MAY BE ELIGIBLE TO PARTICIPATE, PLEASE CONTACT:

(919) 668-0281
adrc@duke.edu
Duke Studies: Retinal Imaging to Detect AD

We are recruiting cognitively healthy adults over 18 years old for a study to take non-invasive pictures of the retina in your eyes. No X-rays and no eye drops. Compensation for time/travel.

You may be eligible for this research study if you:

- Do not have Alzheimer’s, frontotemporal dementia, mild cognitive impairment, Parkinson’s, Down syndrome, multiple sclerosis, PTSD, traumatic brain injury, or another dementia or neurodegeneration
- Have not had prior retina surgery
- Are willing to have some undilated pictures of your retina
Volunteers needed for the PACT research study to see if computerized training exercises reduce risk of Alzheimer’s disease.

Study participation takes about three years and includes 3 study visits of up to 2 hours each. You will also complete 45 hours of computerized training exercises.

You may qualify if you:

☐ Are 65 years of age or older
☐ Do not have any neurological disorders
☐ Have not had a stroke or brain injury
☐ Do not have mild cognitive impairment or dementia such as Alzheimer’s disease

Please contact the PACT study location nearest you for more information:

919.668.3154
Durham
www.PACTstudy.org

Pt: Brenda Plassman, WIRB® Protocol #20182630

Duke Health

NC Registry for Brain Health

NC Research Consortium for Brain Health in Aging
NC Registry for Brain Health - Challenges

- Mostly Women
- Mostly Educated
- Need more ethnically diverse populations
- Need to assure we are reaching rural, communities with disadvantage
- Those who successfully enroll in research are White - 89%
- Sex and Gender Minorities
- Indicate need for science of enrolling and recruiting into studies
CONCLUSIONS

After 30 years of investment, we now have

- **Diagnostic tools**, imaging & fluid biomarkers, opening up the opportunity for early identification of Alzheimer’s disease and early intervention

- **Disease modifying therapies** to slow the disease once it has started and many more compounds in the pipeline targeting different biological mechanisms offering the potential to treat patients from early to late stage disease
CONCLUSIONS

○ Evidence based life-style approaches that we each can use to improve brain health
  • Positive mindset & taking control of health; treat what can be treated; maintain healthy diet; get regular daily exercise; attend to stress reduction, emotional health & sleep; remain socially and cognitively engaged

○ Continuing research to accelerate a cure
  • Partnering in research includes a need for everyone to get involved. With better diversity and inclusion in research, we will have scientifically well informed treatments positioned to benefit all people affected
BE INFORMED
GET INVOLVED
JOIN THE NC REGISTRY FOR BRAIN HEALTH

GO TO NCBRAINHEALTH.ORG
THANK YOU

QUESTIONS AND DISCUSSION
Duke dementia family support program

Caregiver Connections
An Educational Webinar Series With The Experts

Thank you for joining us today!

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