

MEMORY MATTERS



OUTRUNNING ALZHEIMER'S

How Steven Blais is Beating Back Early-Onset Alzheimer's Through Fitness, Community, Research and Hope

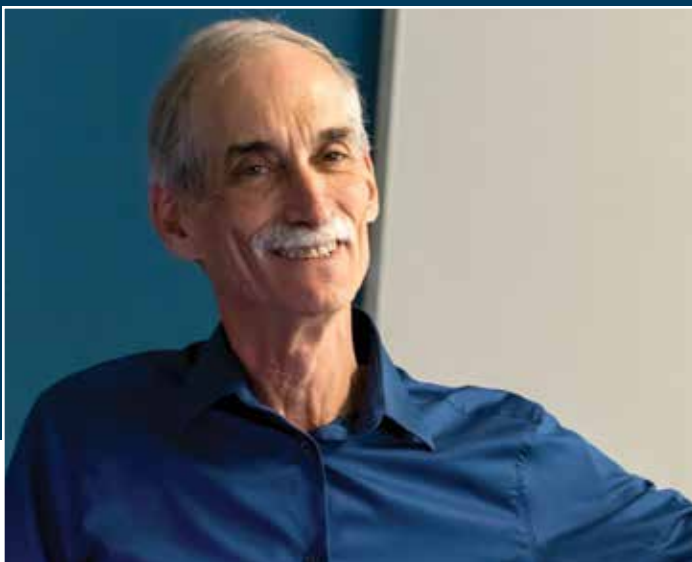
LOOKING AHEAD TO ALZHEIMER'S PREVENTION

AHEAD Study Enrolling Now

VIRTUAL EVENTS, GROUPS & ACTIVITIES



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MEMORY MATTERS

WELCOME

from Dr. Stephen Salloway
Director, Memory and Aging Program

As 2020 comes to a close, I think most would agree it sure feels good to look ahead to the new year and to focus on the future. But before we do, let's take just a moment to look back at this difficult year and give thanks.

Right now you are very likely asking yourself, "Give thanks for WHAT?!" And I wouldn't blame you one bit. But here's the thing...

Even in this year of unprecedented challenges, we have moved forward in our fight against Alzheimer's. Even when circumstance stacked obstacles in front of us, we found a way around them. We persevered. And we made progress.

Just as we were about to launch the fifth and final site of the U.S. POINTER Trial here at the Memory and Aging Program in the spring, the pandemic hit and we were forced to put the start of this promising study of lifestyle and brain health on pause. But by early summer we were able to launch and begin enrolling participants, albeit with certain parts of the study on hold.

And with stringent safety measures in place, we were able to continue our ongoing studies and clinical trials, allowing our patients and participants to continue receiving investigational drugs that have the potential to one day become a groundbreaking advancement in the treatment or prevention of Alzheimer's.

Even as I write this, one such drug studied at our program, aducanumab, is awaiting expedited review by the Food and Drug Administration and could become the first ever treatment to slow the progression of this terrible disease.

In a year when nearly all else has come to a standstill, the fight to end Alzheimer's has not only forged ahead, it has accelerated. I believe that's because all of us in the field of Alzheimer's research, and those who support that research, sense that there are big things on the horizon and we are eager to get there.

A much-needed increase in research funding has finally come to fruition. Key discoveries about the nature of Alzheimer's are happening all the time. Together, these advances point to the game-changing breakthrough we've all been waiting for. I've said this before but that doesn't dampen my excitement that the new year will be the year that breakthrough arrives. If nothing else, 2020 has taught us that we can weather difficult storms if we do so together, and that those storms are no match for the power of persistence. For that, I am grateful. Not just grateful, but energized. Inspired. Emboldened to persist through this storm we call Alzheimer's until we come out the other side, together.

I hope you are, too.



Study Spotlight: **AHEAD Trial**

A new trial that aims to prevent Alzheimer’s disease has launched at the Memory and Aging Program.

The AHEAD Study is a Phase 3 clinical drug trial for people who are at higher risk for developing Alzheimer’s disease. The study is looking to enroll men and women ages 55-80 who are not experiencing memory concerns.

AHEAD is a double blinded, placebo-controlled trial and participants will be enrolled for a four year period. Eligible participants will receive the investigational drug BAN2401, or a placebo intravenously (through a vein) every two or four weeks, depending on the group a participant is randomized to. The purpose of the AHEAD Study is to determine if the investigational medication, BAN2401, is superior to a placebo in terms of maintaining normal cognitive abilities and how effective it is in reducing levels of amyloid and tau plaques in the brain using amyloid PET and tau PET scans.

Participants will have imaging conducted as part of the screening process for this study, including an amyloid PET scan. They will learn if they have elevated levels of amyloid protein buildup in their brains and those that do will be invited to join the study. Amyloid is a protein that builds up in people who can go on to have memory problems and develop Alzheimer’s disease.

“The personalized treatment has the potential to be a breakthrough in Alzheimer’s prevention,” said Stephen Salloway, MD, MS, and director of the Memory and Aging Program at Butler Hospital. “This new tailored approach can potentially serve as a model to improve clinical trials in Alzheimer’s research and other diseases.”

The AHEAD Study seeks 1,165 participants from North America. The study has more than 100 study locations worldwide, including North America, Japan, Singapore, Australia, and Europe.

Interested participants can contact the Memory and Aging Program Outreach Team at **401-455-6402** or **memory@butler.org** to discuss additional eligibility criteria.

Staff Spotlight:

GINA MARIE TONINI

Looking AHEAD to a Future Free of Alzheimer's



GinaMarie Tonini has a special interest in Alzheimer's prevention, along with a deep compassion for individuals at risk of the disease who are doing all they can to create a future that's free from it.

That interest and compassion makes her an exceptional project manager of the AHEAD Trial at the Memory and Aging Program (MAP). Launched in September, AHEAD is the first clinical trial to study a drug aimed at preventing Alzheimer's disease in people as young as 55 years old.

"One of my favorite parts of working here at the Memory and Aging Program is interacting with our patients. They inspire me to be here every day," Tonini says.

"The population I work with is cognitively normal but have a higher risk for developing Alzheimer's in the future. They are continuing to work, staying active, and may even have kids at home...but they are facing this threat to their future and they are just doing whatever it takes to prevent this disease."

"Through working with them, I've become very connected to that reality and to that goal," she says. "Obviously, we want to cure this horrible disease and find effective treatment, however I think it's also so important and so wonderful that the field has become increasingly focused on Alzheimer's prevention as well."

Although Tonini feels quite passionately about her work and the field of Alzheimer's research now, it wasn't always her professional focus. She graduated from Salve Regina University with dual bachelor's degrees in Psychology and Business Administration and continued on to get her MBA as well, all with an eye toward someday open her own clinical practice.

"After I received my BA in Psychology and while I was finishing my MBA, I worked as an opioid treatment program counselor. I quickly learned that I loved counseling and connecting with patients. This position solidified my love for the field of psychology, and my desire to learn even



Tonini (left) and AHEAD Study coordinator Diane Monast, RN (right) with study participant Dave Kalberer in September, as he receives the world's first infusion of the study's investigational drug for the delay or prevention of Alzheimer's.

more. I became interested in expanding my experience within the field, so I began to look for research-based positions. However, I also became more interested in the research side of psychology as well, and so I began to look for research-based positions.”

That’s what led Tonini to join the Memory and Aging Team in April, 2018.

“I had never had any experience first-hand with Alzheimer’s up until that point but I knew as soon as I met the team that I would really enjoy it,” she recalls. “I could tell right away that it was a team-oriented environment and I could just feel all the great energy coming from everyone I met. So I decided to give it a try, and I ended up just really loving the work and being here as part of this program.”

Tonini has become so committed to the program and its goals that she volunteered to participate in Alzheimer’s research herself.

“Working in this program has truly opened my eyes to what it means to participate in research, that I have even been signing up to participate in other research studies myself. I think when people hear the word ‘research’ there’s a common misconception that it’s this sterile, impersonal environment but it’s really quite the opposite,” Tonini says.

“It’s actually all about building and keeping a personal connection. That’s one of the amazing things about the Memory and Aging Program is how much we connect on a personal level with our community and potential participants. If people feel a passion to participate in research, we help them find a study that interests them. It is their choice whether or not the individual chooses to participate or not. Either way, taking the time to have these conversations can break down common misconceptions about research.”

As Tonini works to coordinate the landmark AHEAD trial alongside MAP Nurse Coordinator Diane Monast, she says she’s looking forward to helping to break even more down boundaries in the field of Alzheimer’s treatment and prevention as part of a truly special and talented team.

“It’s a fascinating study. We are all excited to be a part of this groundbreaking prevention trial. It was incredible to watch the amount of work and collaboration that our team accomplished to get this study up and running,” she says.

“When I need motivation or when I’m feeling exhausted, I just think about the team I’m working with and how they step up to the plate for their patients and each other and for the bigger goals of the field. Here, they go above and beyond. That’s the kind of team I want to be surrounded with and I’m just proud to be part of it.”

PROGRAM NEWS



World's First Dose of Investigational Drug Aimed at Delaying or Preventing Alzheimer's Administered at MAP

The first infusion of an investigational drug that aims to delay or help to prevent the earliest memory loss due to Alzheimer's disease took place in September at the Memory and Aging Program as part of the AHEAD Study. AHEAD is the first Alzheimer's disease trial to recruit people as young as 55 years old who are at risk of developing symptoms of Alzheimer's disease as they get older. It introduces a personalized medicine approach that will tailor treatment dose levels to a participant's particular risk of memory loss related to Alzheimer's disease.

"The personalized approach for people years before memory loss has begun has the potential to be a breakthrough in Alzheimer's prevention," said MAP Director Stephen Salloway, MD, MS. "This new tailored approach can potentially serve as a model to improve

clinical trials in Alzheimer's research and other diseases."

"Both of my parents were diagnosed with Alzheimer's disease. I can't run away from that, but I can help find a potential treatment," said Dave Kalberer, recipient of the first AHEAD infusion at Butler Hospital (pictured here with his wife during his first infusion). "I'm proud to be at the front of the line for this exciting opportunity and am hopeful this trial can change not just my life but millions more."

The AHEAD Study seeks 1,165 participants from North America. The study has more than 100 study locations worldwide, including North America, Japan, Singapore, Australia, and Europe. Learn more about the study on page 2.



Hwamee Oh, Ph.D. Awarded NIH Grant for Study of Neuroimaging Markers of Early Alzheimer's

Dr. Hwamee Oh, PhD, director of imaging research at the Memory and Aging Program and assistant professor in the Department of Psychiatry and Human Behavior at Brown University, has been awarded a National Institutes of Health grant for her project on novel cognitive and neuroimaging markers of early Alzheimer's disease (AD) pathologies. Dr. Oh's study is designed to identify novel cognitive and neural biomarkers of preclinical AD by using fMRI scanning to measure brain activity while participants complete tasks. This information will be used to develop new tools to assess brain function in early AD.



Louisa Thompson, Ph.D.

MAP staff Selected to Participate in Inaugural IMPACT-AD Course for Emerging Leaders in AD Research

MAP Clinical Provider Melanie Faust, APRN, FNP-C and MAP Research Scientist Louisa Thompson, Ph.D., were selected from among a large number of qualified applicants across the nation to participate in the first IMPACT-AD course for Emerging Leaders in AD Research.

Faust was selected to participate in the Professional track and Thompson was selected to the Fellowship Track.



Melanie Faust, APRN, FNP-C

IMPACT-AD is an Alzheimer's Disease and related disorders (ADRD) course offered by the Institute on Methods and Protocols for Advancement of Clinical Trials in ADRD. The course aims to educate and promote diversity among research professionals and future principal investigators in the field of ADRD research.



Athene Lee, Ph.D. Appointed Inaugural Chair, ACTC Emerging Leader Project Evaluation Committee

Dr. Athene Lee, neuropsychologist at the Memory and aging Program and assistant professor of Psychiatry and Human Behavior at The Warren Alpert Medical School of Brown University, was named the inaugural Chair of the Emerging Leader Project Evaluation Committee of the Alzheimer's Clinical Trials Consortium (ACTC), a critical new public-private partnership to fight Alzheimer's. The group of emerging leaders will help ACTC leadership evaluate clinical trial applications submitted for funding. This is an important innovative program that Dr. Lee helped to create and is now leading.



Participant Profile:

STEVEN BLAIS

Outrunning Alzheimer's through Fitness, Community, Research and Hope

Steven Blais is an avid runner and a fitness enthusiast. He's also a big believer in the power of hope and the value of community. That's what drew the Woonsocket, RI native to become founder of the Providence chapter of the November Project, a worldwide movement that brings people together for fitness and community through free group workouts.

Prior to the pandemic, he'd greet dozens of November Project members at dawn each day to run up and down Rhode Island's State House steps together. These days they work out together virtually, but the benefits to both body and mind are still just as real. And for the last few years he's also led group runs each Wednesday and at special events as a store ambassador for Lululemon, a worldwide athletic apparel company.

Steven wasn't always fit, though. Hope wasn't always easy to come by for him either, and community was a concept that existed more outside his window than in his heart. Instead, for near to a decade he lived his life under a constant shadow of dread that it would be cut short by early-onset Alzheimer's.

"My mother, Betty, was diagnosed with early-onset Alzheimer's in 2006," he says. "Her own mother had died from Alzheimer's, as well as some of her aunts and uncles. We lost her in May of 2017 and since then, two of her siblings have also passed from the disease."

Steven's family is afflicted with Dominantly Inherited Alzheimer's Disease (DIAD), a rare form of inherited Alzheimer's that strikes people in their thirties to fifties. Steven has a 50% chance of carrying the genetic mutation that could lead to him developing early-onset Alzheimer's himself.

"When my mom was diagnosed, I just assumed I had it too. And from that point my life just sort of stagnated," he says. "I couldn't make major

decisions. I was slow to engage in relationships or anything that really required a commitment. Eventually I decided to get the genetic testing done so I could finally know for sure one way or the other."

As it turned out, in Steven's case the testing couldn't determine if he had all the genetic markers that would indicate if he was genetically predisposed to develop Alzheimer's or not. He learned nothing new about his chances of living a long life. But he gained all the perspective he needed to live the fulfilling life he deserved in the present.

"I left there knowing nothing, and it was the most beautiful, freeing moment I've ever had in my entire life. I realized that none of us knows what the future holds and in that way, my life is just like everyone else's – so I should go live it and stop stagnating."

Steven says from the moment his mindset changed, so did his life.

"Literally from that point, things like the November Project have happened and my relationship with Lululemon took place. A lot of my community service and community leadership has taken place because of that moment," he says. "Not long after that I discovered running and fitness as a way to clear my mind and finally, I had hope. I also had so many ideas but no platform to share them from. And then these opportunities with The November Project and Lululemon came to me and grabbing on to them was like capitalizing on that hope."

Continued next page

Opposite page: Steven Blais runs (and jumps) on the Rhode Island State House steps during one of the free group workout sessions he hosts as founder of the Providence chapter of The November Project.

“Being part of a study can feel like a scary thing to do, but so is having Alzheimer’s.

For me, it’s a matter of do I want people on my side leading me through a situation like this and actively working to find a cure, or do I want to go through it alone? If you can add hope to any of it, that’s going to make the difference. It’s the catalyst to make the change and to guide you through when things get scary.”

The fitness community isn’t the only place that Steven is capitalizing on hope. He’s also participating in research to help end Alzheimer’s, at the Memory and Aging Program at Butler Hospital.

The program was founded and is directed by Stephen Salloway, MD, MS, a leading Alzheimer’s researcher who is also director of Neurology at Butler Hospital and a professor of Psychiatry and Human Behavior and Neurology at the Warren Alpert Medical School of Brown University.

The Memory and Aging Program is a founding member of the Dominantly Inherited Alzheimer’s Network (DIAN), an international Alzheimer’s research partnership focused on DIAD, and a research site of its Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU).

“My mom was part of the DIAN study. She may have even been Dr. Salloway’s first enrolled

participant in the study. I have many family members who were participants of the study before they passed as well, and many that are participants today, including myself. We’ve all decided that we want to do what we can to help get rid of this disease,” Steven says.

“I do basically anything that Dr. Salloway asks of me because I can’t thank him enough for everything that he and his team are doing on a daily basis. They’re just the most inspiring people I’ve ever met. Frankly Dr. Salloway has kind of become an extended family member.”

“He and Diane [Monast, Memory and Aging Program nurse coordinator] were present at my mom’s wake and her funeral and for my aunt and uncle’s funerals as well. They don’t consider their patients to be data. The whole team at the program are very positive and accommodating and comforting; they’re absolutely some of the most loving people I’ve ever met.”



Steven says that in addition to the fitness community, he and his family have also found a valuable sense of community among the Memory and Aging Program staff as well as among others affected by Alzheimer's disease and DIAD in particular. He says that those connections, along with the knowledge that he's contributing to research that is critical in finding effective treatment for the disease, have been instrumental in helping him to navigate his own personal fears about the disease and to keep hope alive.

"Being part of a study can feel like a scary thing to do, but so is having Alzheimer's," he says. "For me, it's a matter of do I want people on my side leading me through a situation like this and actively working to find a cure, or do I want to go through it alone? If you can add hope to any of it, that's going to make the difference. It's the catalyst to make the change and to guide you through when things get scary."

When it comes to the future of Alzheimer's disease, Steven has plenty of hope.

"The fact that right now Alzheimer's is the sixth leading cause of death in America and that in 10 years it's expected to be the second-leading cause is terrifying," he admits. "But I feel very hopeful that with the incredible research that's happening now and the funding that we're finally getting to accelerate that research, real progress is coming soon."

"We're at a point where hope and research are meeting together. We have a drug for Alzheimer's treatment going into phase 3 trials [aducanumab] at the same time that we're starting the U.S. POINTER study for prevention of the disease. And those two studies combined will hopefully show us the great gains that are to come in fighting this disease. I really think we're at the precipice of finding the first person who is going to beat Alzheimer's."

Volunteer Profile

Meet Madeline Leite

Madeline Leite knows that she wants her life's work to be centered around helping people to live their best life - physically, cognitively or maybe even both.

When she first enrolled in college, the Rehoboth, MA native and Johnson and Wales University senior thought she'd achieve that goal by becoming an occupational therapist. But the further she got in her studies, the more interested she became in psychology, mental health and research.

That bend in the road is what led Leite, who is majoring in Health Sciences, to become a volunteer at the Memory and Aging Program this past August.

"I wanted to experience what it would be like to work in the research setting," Leite says. "My sister did an internship at Butler Hospital a few years ago and really liked it, so I looked into the options available at Butler through JWU's experiential internship office and found out about the Memory and Aging Program."

Although the COVID-19 pandemic has limited the range of things that Leite has been able to do with the program thus far, she says the last few months have already been a valuable and enlightening experience.

"I'm usually in the office once per week for now, helping the study coordinators to file and organize information related to their various studies. This is my first look behind the scenes at how research actually works and it's been really interesting to see," she says.



When she's not helping on the research side, Leite is helping on the program's more public side by assisting the Outreach Team, although COVID has limited that outreach to mostly virtual settings for now.

"Right now I mostly help the team with office work, but I'm really looking forward to getting involved with their community outreach events as well, once the pandemic has passed and more in-person events are being held," Leite says.

Although Leite says she still hasn't settled on exactly what she wants to do after graduation in the spring, she does know one thing: she's looking forward to figuring it out through continued involvement at the Memory and Aging Program.

"I'm just really using this time to figure out what I like and what I don't like by trying to actually experience it," Leite says. "So far I've found the field of clinical research to be really interesting, and the entire team at the Memory and Aging Program is so kind, positive and helpful. It's been a great experience."

IN THE COMMUNITY



10th Annual Caregiver's Journey Conference Now virtual! December 2 - 4

No fee for family caregivers; CEUs available for direct care professionals.

This conference is for both caregivers and professionals who dedicate their lives to caring for people with Alzheimer's disease and related dementias. Caring for someone with Alzheimer's disease or a related dementia is truly a labor of love. We offer a variety of workshops

throughout the day that provide caregivers and professionals with the tools to carry on their journey of caring and supporting persons with Alzheimer's disease and related dementias.

The keynote speaker for this year's conference will be Laura Baker, Ph.D., Principal Investigator of the national U.S. POINTER Study. Among a variety of other presentations, the conference will also feature a panel discussion moderated by Catherine Taylor of Age-Friendly RI and featuring MAP Outreach Manager Tara Tang as well as Terry Fogarty of Rhode Island Hospital's Alzheimer's Disease and Memory Disorders Center and Annie Cerullo of the Rhode Island Memory and Mood Research Institute. To register to attend, visit alzri.org or call **1-800-272-3900**.



VIDEO: Learn the 8 Pillars of Brain Health

MAP Outreach Coordinator Tara Tang recently hosted a virtual presentation for the Cranston Senior Enrichment Center about the 8 Pillars of Brain Health. It was a wonderful opportunity for the Senior Center's constituents to learn what they can do to support brain health in everyday life - and it was recorded, so you can learn what to do, too. Visit memoryandaging.org/8pillarsvideo to watch and learn!



PODCAST: Healthy Aging with Age Friendly RI

Earlier this Fall, Age Friendly RI hosted MAP Outreach Coordinators Athena Lavoie and Lorraine Saraiva were guests on the Age Friendly RI radio show. Tune in to the recorded podcast to hear insights on healthy aging and brain health, as well as information about ongoing studies aimed at prevention and treatment.

Visit memoryandaging.org/AgeFriendlyRIpodcast to listen!

THANK YOU

We are grateful to the following organizations for partnering with us to raise awareness about Alzheimer's disease and our program, and for hosting educational presentations and events:

Age Friendly RI

La Mega 94.9 FM

Rhode Island Elder Info

Cardi's Furniture & Mattress

NAACP Providence Chapter

Wingate Healthcare

Cranston Senior Center

Progreso Latino

RESOURCES



Educational Webinars & Virtual Activities

The Alzheimer's Association Rhode Island Chapter offers virtual support groups that individuals can participate in online or by phone, as well as a variety of on-demand educational webinars, including:

- Healthy Living for Your Brain and Body
- Know the 10 Signs of Alzheimer's
- COVID-19 and Caregiving
- Understanding and Responding to Dementia-Related Behavior
- *and many others!*

The Association also offers a variety of activities that can be accessed and enjoyed online, including virtual religious services, virtual tours of museums, aquariums and tourist attractions around the world, and links to craft activities, free streaming movies and audio books, and more. Visit alz.org/ri to explore these resources and more.



Flu, Pneumonia Vaccines Linked to Lower Risk of Alzheimer's Dementia; Here's Where to Get Yours

Study results announced at the Alzheimer's Association International Conference (AAIC) in July showed that:

- Having had at least one flu vaccination was associated with a 17% reduction in Alzheimer's incidence
- More frequent flu vaccination was associated with another 13% reduction in Alzheimer's incidence
- Vaccination against pneumonia between ages 65 and 75 reduced Alzheimer's risk by up to 40% depending on individual genes. What's more, individuals with dementia have a higher risk of dying (6-fold) after infections than those without dementia (3-fold)

Particularly in the midst of the COVID-19 pandemic, this study provides further reason why it's important to receive an annual flu vaccine. Your PCP is an excellent place to get your annual flu shot. But if you don't have a PCP or you're looking for walk-in service, the CDC provides a Flu Vaccine Finder where you can find vaccine providers near you, at vaccinefinder.org.



FEATURED STUDIES

The Memory and Aging Program is currently recruiting for a number of ongoing studies, including the studies featured here. If you're interested in participating, please join the Butler Hospital Alzheimer's Prevention Registry at butler.org/ALZregistry or contact the Outreach Team at memory@butler.org or (401) 455-6402.

ARIAS Study

The ARIAS study seeks to understand what changes to the retina can detect AD risk 10 to 20 years before memory symptoms occur, and to develop a 3-D imaging atlas of AD-related changes in the retina for use by researchers worldwide. Participants will be evaluated at four time-points during the 36-month study period. At each study visit, participants will undergo basic eye exams, medical history, assessment of vital signs, neuropsychological assessment, full retinal imaging scan, and blood sample for measurement of plasma beta-amyloid and tau levels.

Digi-Cog AD Study

This study will evaluate how to use smartphone (app-based) and online cognitive tests, as well as other digital assessment tools, to detect subtle changes in memory and thinking that occur prior to the onset of major clinical symptoms of Alzheimer's. The project's goal is important to developing more effective strategies for the early detection of Alzheimer's disease to facilitate treatment research, and give patients and providers a greater window for treatment and care planning.

LEADS Study

The LEADS (Longitudinal Early-onset Alzheimer's Disease) study is an observational research study aimed at exploring the development of early-onset Alzheimer's disease and how it compares to the more common late-onset AD. Study activities include general medical and neurological exams, cognitive testing, blood and spinal fluid collection and neuroimaging (MRI and PET scans).

US POINTER Study

The U.S. Study to Protect Brain Health through Lifestyle Intervention to Reduce Risk (U.S. POINTER) is a Phase 3, two-year clinical trial to evaluate whether lifestyle interventions such as increased physical and cognitive exercise, healthier diet, and social activity can protect cognitive function in healthy older adults who were at increased risk of significant memory loss.

MEMORY MATTERS

Thank you!

Without our participants, their families, and caregivers, Alzheimer's research would not advance. The Memory and Aging Program staff is continually inspired by the families who decide to join clinical research studies. We would like to express our deepest gratitude to all of our registry participants and their families for their contribution to the science that will lead to the end of Alzheimer's disease.

You are receiving the **Memory Matters** newsletter because of your current or past relationship with Butler Hospital's Memory and Aging Program, our research program or with the patients and family members we serve. If you would like to be removed from the mailing list and not receive future editions, please contact us at memory@butler.org or (401) 455-6402.

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Can changing to a healthy lifestyle protect memory in older adults?

We need your help to stop memory loss and Alzheimer's disease! Learn more about the opportunity to participate in this national study, open to qualifying individuals between the ages of 60 and 79:

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 **butler.org/POINTER**

