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The Relationship Between Diabetes and Cognition

Many people get concerned about their memory as they age and ask if there is anything that can be done to prevent memory loss and Alzheimer's disease. Although there are currently no easy answers to this question or simple pills to take, research studies do show that another common condition in older people—diabetes—may cause or worsen memory problems. What if, by preventing or controlling diabetes, patients could also protect their brains in the process? While we don't have a clear answer to this and other questions about how to prevent dementia, research currently being done at Mount Sinai could help us better understand the links between diabetes and memory loss and what doctors can do about it.

Diabetes is a condition that causes blood sugar levels to go too high, leading to a cascade of related problems that affect the heart, kidneys, nervous system, and eyes, among other problems. It is an extremely common disease and leads to substantial healthcare expenditure, illness, and disability for millions of Americans. We are beginning to learn how much diabetes also affects the brain, something most of us want to protect at all costs!

Researchers at Mount Sinai are currently recruiting individuals to participate in a study looking at the relationship between diabetes and memory in minority patients. Minorities are often poorly represented in studies of memory, and given the high rates of diabetes in these communities, learning more about how diabetes affects memory will ultimately help treat these patients and keep them healthy. The main idea of the study is to test the memories of people with diabetes and compare the results with patients who do not have diabetes. In addition, researchers will also obtain brain scans and get lab tests to better understand the connection between diabetes management and markers of Alzheimer's disease and other forms of severe memory loss.



Corbett Schimming, MD

For more information about the Memory and Diabetes Study (MADS), contact research coordinator, Jorge Ginory-Perez at 718-584-9000 ext. 1706 or by email at jorge.ginory-perez@mssm.edu.

La Relación entre La Diabetes y Cognición



Corbett Schimming, MD

Al envejecer una de las preocupaciones que enfrentamos es la posible pérdida de la salud de nuestra memoria. Al envejecer la gente se pregunta si habrá medidas que se puedan tomar para prevenir la pérdida de memoria y la Enfermedad de Alzheimer's. Actualmente no hay respuestas definitivas para estas preguntas ni tampoco hay soluciones efectivas. Los estudios de investigación indican que otra condición común en las personas mayores que puede causar o empeorar la memoria, es la diabetes. ¿Qué pasaría si a través de la prevención o el control de la diabetes también pudiésemos lograr proteger la salud del cerebro y por lo tanto de la memoria? Aunque todavía no hay una respuesta clara, los estudios de investigación que se están realizando en Mount Sináí podrían ayudarnos a comprender si existe alguna conexión entre la diabetes y la pérdida de memoria. Estos

estudios de investigación también nos podrían ayudar a entender mejor las medidas a tomar con respecto al tratamiento y a la prevención no solo de la diabetes y si no también de la pérdida de memoria.

La diabetes es una enfermedad metabólica que le impide al cuerpo producir suficiente insulina y por esta razón aumenta los niveles de glucosa en la sangre. La diabetes ocasiona una cascada de problemas relacionados con el corazón, los riñones, y el sistema nervioso, además puede afectar la visión y definitivamente aumenta el riesgo de desarrollar otras enfermedades. La diabetes tiene un alto costo para los millones de estadounidenses que la padecen.

Recientemente estudios de investigación han demostrado que la diabetes también puede afectar la forma en que funciona el cerebro, incluyendo cómo funciona la memoria. A medida que las personas con diabetes van envejeciendo el riesgo de desarrollar problemas de la memoria puede aumentar. Un grupo de investigadores en Mount Sináí se ha interesado en estudiar y entender a fondo cómo afecta la diabetes al cerebro. El cerebro es un órgano muy importante de manera que hay que protegerlo a cualquier costo.

El objetivo central del estudio que se lleva a cabo actualmente en el Centro Médico de Mount Sináí es entender mejor la relación entre la memoria y la diabetes. Con este propósito se van a evaluar las facultades de memoria en dos grupos, personas con diabetes, y personas que no padezcan de la condición. Los resultados de ambos grupos se compararan para a ver si existen diferencias entre ambos. Se invitara a miembros de grupos minoritarios, tales como a personas de origen latino, de 50 años o más, sin problemas de memoria grave a participar en este estudio. Como la incidencia de diabetes es alta entre los latinos y otras minorías, es crucial lograr que personas de origen latino y de otros grupos minoritarios participen. Como parte del estudio también se obtendrán imágenes del cerebro y pruebas de laboratorio.

Si se comprueba que la diabetes afecta la memoria los investigadores continuaran estudiando con detalle la relación entre la diabetes, los marcadores biológicos de la enfermedad de Alzheimer, y de otras enfermedades de la memoria.

Para obtener más información acerca de este estudio que comenzará pronto por favor póngase en contacto con el coordinador de investigación Sr. Jorge Ginory-Pérez en 718-584-9000 Ext. 1705 o por correo electrónico a

Jorge.ginroy-perez@mssm.edu.

The ADRC Welcomes New Associate Director, Dr. Alison Goate

Welcome to Dr. Alison Goate, a new associate Director of the Alzheimer's Disease Research Center (ADRC)! As a Professor of Neuroscience, Dr. Goate and her lab study the molecular genetics of dementia and addiction. At this year's Alzheimer's Association International Conference (AAIC), Dr. Goate received the 2015 Lifetime Achievement Award in honor of her significant and lasting contribution to the field of Alzheimer's research. We asked Dr. Goate few questions about her work and collaboration with the ADRC.



Alison Goate, PhD

ADRC: Early on in your career, what drew you toward the study of neurological disorders and Alzheimer's disease in particular?

AG: I started working on Down syndrome during my post-doctoral years, looking at the link between the amyloid beta precursor protein (APP) gene and chromosome 21 in early onset familial Alzheimer's disease. Extending from my background with Down syndrome, I became interested in examining the genotypic (the collection of an individual's genes) and phenotypic (the expression of those genes) overlap between these two diseases. For instance, individuals with Down syndrome have a significantly higher risk of developing AD later in life. While at Washington University School of Medicine in St. Louis, I was a part of the Dominantly Inherited Alzheimer Network (DIAN), an international research collaboration seeking to better understand Autosomal Dominant Alzheimer's Disease (ADAD), a rare form of Alzheimer's disease caused by an inherited gene mutation. Those born with this gene mutation develop Alzheimer's disease between the ages of 30 and 60 and have a 50-50 chance of passing the gene along to each of their children. Working with families affected by this disease made me want to see this through. You develop an emotional connection that goes beyond the science, and by identifying mutations and developing treatments we can begin to repay their generosity.

ADRC: What is your research about?

AG: The major focus of my research is to identify risk and protective factors for late onset Alzheimer's disease (AD). For example, in a group of individuals diagnosed with AD, 50% may not have an e4 allele (a gene that may present an increased risk for developing late onset AD). Collaboration with the Genome-Wide Association Study (GWAS) allows us to look for both common and rare genetic patterns as we seek to better understand their associations with risk for developing the disease. Taking a 10,000-foot view of the genome, we are asking whether new AD risk factors fall in certain cell pathways. For instance, there is evidence that certain genes may be overrepresented in certain immune responses. We can also learn so much by looking at cognitively healthy individuals, where nature has done the work for us. People with normal cognition in their 80s who have APOE e4 alleles must possess some protective factors. Within families where Autosomal Dominant Alzheimer's Disease (ADAD) is present, those who do not develop the disease amidst such strong mutations can provide a wealth of important information. By identifying and understanding these protective mechanisms, we can develop targeted therapies and potential treatments for AD.

ADRC: How do you see collaborating with the ADRC, and what are you most excited about?

AG: It is exciting to be able to work with a new and diverse cohort for genetic studies. Most current research is conducted amongst populations of predominantly European ancestry. This is very limiting because different genetic risk factors may have different impacts among different populations. As our population continues to grow in size and diversity, research like Richard Mayeux's genetic studies on Alzheimer's disease among individuals of African-American and Caribbean Hispanic descent becomes even more important. Taking advantage of Mount Sinai's location in such a culturally rich area, we hope to better understand genetic risk factors across a wider segment of the population. Being involved with the ADRC's clinical core and longitudinal follow-up program is beneficial to the research community at large. Genome-Wide Association Study (GWAS) samples from this cohort will allow us to look at factors that have yet to be analyzed and determine how these findings might overlap with those of the Neuropathology Core. (ADRC note: The Neuropathology Core analyzes brain tissue samples from ADRC participants who determined they wished to be part of the Brain Tissue Donation Program).

ADRC: What is your favorite thing about living in New York?

AG: Having moved from St. Louis, Missouri, living in an urban locale is very different. My favorite thing has been the variety of food and restaurants, and I have been trying to take advantage of it on a weekly basis!

Clinical Trials Information

Recruiting Trials

The A4 Study

The A4 study is testing a drug known as LY2062430 (also called "solanezumab") in older individuals who have evidence of elevated amyloid build-up in their brains, but who do not yet show symptoms of AD in order to slow possible AD-related damage in the brain and to delay progression of AD-related memory loss. The purpose of this study is to test whether solanezumab can slow the progression of memory problems associated with brain amyloid. Amyloid build-up will be identified in potential participants through a special positron emission tomography (PET) scan technique. The study team is seeking healthy participants between the ages of 65 and 85, who have someone who can be a project partner (spouse, adult child, other family member, or caregiver) to provide information about their health, attend study appointments, and assist with correctly taking the study medication. Participants will not have to pay for investigational medication, and will be paid for certain clinical visits throughout the study. This research will take place at Mount Sinai's Upper East Side campus. For more information about the A4 study, please contact a study coordinator at 212-241-8329. **PI: Mary Sano, PhD; GCO#: 91-0208(0018) and 91-0208(0019); HSM#: 14-00067; ISMMS IRB approved through 03/17/2017.**

The Connect Study

The Mount Sinai Alzheimer's Disease Research Center is seeking people aged 55-84 years old who have a diagnosis of mild Alzheimer's disease (AD) to participate in a study investigating the safety and tolerability of a drug called AZD0530. AZD0530 was previously developed as a cancer therapy but may hold greater promise as a treatment for AD. In this study, participants will be given either the AZD0530 pill or a sugar pill for about 2 years. Participants will need a person who they are in regular contact with (at least 10 hours per week) to attend all of the study visits with them. Participation is compensated. If you or someone you know is interested in this study, please contact us at 212-241-8329 to find out more. **Principal Investigator: Mary Sano, Ph.D. GCO 91-208(21). Currently enrolling. ISMMS PPHS approved through 5/4/2016.**

The Grapeseed Study

We're looking at grape seed extract to see if it helps people with memory and thinking problems. Grape seed extract may prevent the formation of a type of amino acid chain in the brain that may contribute to memory and thinking problems in those with AD. You need to speak either English or Spanish and must come to the Mount Sinai Upper East Side campus with someone who can act as a study partner to participate in this 12 week trial. Study participants will undergo memory and thinking tests, have their blood tested, receive physical and neurological exams, receive an MRI, and undergo a PET scan which will detect the buildup of a protein called beta-amyloid in the brain. Taking part in this study comes at no cost to the study participants. For more information about the A4 study, please contact a study coordinator at 212-241-8329. **Principal Investigator: Hillel T. Grossman, MD. Currently enrolling. ISMMS PPHS approved through 6/30/2016.**

Memory and Diabetes Study (MADS)

In the past, studies have shown that patients with diabetes are at an increased risk of developing memory loss and dementia. The relationship between memory and diabetes is, as of yet, poorly understood. Project 1 hopes to further our understanding of this important relationship. Specifically, we are seeking to compare the development of memory issues over time between those with diabetes and those without the affliction. We will focus on those aged 50 and older who belong to minority populations, an area vastly underrepresented in clinical research, especially research related to memory. We hope that the information gained during this study will stand to benefit the many who currently suffer from Type II Diabetes. **Principal Investigator: Hillel T. Grossman, MD. Currently enrolling. ISMMS PPHS approved through 1/26/2017.**

The Study of Nasal Insulin to Fight Forgetfulness (SNIFF)

This study is investigating the safety, tolerability and effectiveness of an insulin nasal spray when given to people with Alzheimer's disease (AD) or mild cognitive impairment. Insulin is a hormone in your body that helps your cells use sugar. We will be studying the effect of this insulin nasal spray on memory and thinking as well as cerebrospinal fluid (CSF) and biomarkers. In this study, subjects will be given either the insulin nasal spray or a placebo for 12 months, and for 6 months all subjects will receive the insulin nasal spray. The study needs volunteers who are 55 years of age or older, are diagnosed with mild cognitive impairment or Alzheimer's disease, are fluent in English or Spanish, can attend all study visits, participate in study testing and receive MRIs, and have a study partner who can also attend all study visits. Participation will be at no cost to the study participant and for some of the visits, lunch will be provided. For more information about the SNIFF study, please contact a study coordinator at 212-241-8329. This research study will take place at Mount Sinai's Upper East Side campus. **Principal Investigator: Hillel T. Grossman, MD GCO: 91-208 (17), HSM: 13-00768. ISMMS IRB approved through 10/29/2016.**

The TAN-SNIP Study

The TAN-SNIP study is an observational study that will include taking pictures of the brain to see if there are any brain changes present in those who have the risk factors for heart disease, or whom have normal to mild cognitive impairment. The purpose of this study is to determine the presence of risk factors for heart disease such as high level of fat in the blood, high blood pressure, diabetes and obesity, and clogging of the arteries in people who have difficulty with memory, attention, and/or concentration. In addition we will determine if these risk factors for heart disease also cause problems with activities of daily living, motivation, depression symptoms and the likelihood to keep a healthy lifestyle. The study team is seeking healthy participants between the ages of 60 and 85, who can attend study appointments (with or without a study partner) and are not taking any Alzheimer's disease medications. Participants will not have to pay for investigational diagnostic procedures, and will be reimbursed for certain traveling expenses needed to attend clinical visits throughout the study. This research will take place at Mount Sinai's Upper East Side campus. For more information about the TAN-SNIP study, please contact a study coordinator at 212-241-5692. **PI: Valentin Fuster MD, PhD, FACC; GCO#: 14-0701(0003); HSM#: 15-0538; ISMMS IRB approved through 07/27/2016.**

Upcoming Trials

To find out more about our upcoming studies for participants with Mild Cognitive Impairment (MCI), please contact our study team at 212-241-8329.

Alzheimer's Research: Then and Now –Margaret Sewell, PhD

Early efforts: In 1906, German psychiatrist and pathologist Alois Alzheimer described the case of 51-year old Auguste Deter, who exhibited progressive memory loss, language changes and psychotic symptoms including hallucinations. An autopsy on her brain revealed atrophy and abnormal deposits in and around the nerve cells. In 1910, Emil Kraepelin coined the term “Alzheimer’s disease” which was regarded as a rare presenile dementia affecting those under 65 years old and considered distinct from senile dementia. Senile dementia was thought to be related to arteriosclerosis or “hardening of the arteries.” Senile dementia was regarded by many to be a normal part of aging. In the 1960’s, advances in technology enabled scientists to identify a direct relationship between pathology in the brain (plaques and tangles) and dementia severity. In the 1970’s, pioneering Alzheimer’s research by neurologist Robert Katzman identified that cell loss was the pathological characteristic that most related to dementia. The brains of those with senile dementia also had the plaque and tangles seen by Alzheimer. This finding suggested that both conditions were part of the same disease process, and not normal aging. The National Institute of Aging (NIA) initiated the first Alzheimer’s Disease Research Centers, including Mount Sinai in 1984. Important discoveries in the 1980s included the identification of two proteins, beta amyloid (associated with the development of plaques) and tau (associated with neurofibrillary tangles). Debate continues as to the relative contribution of beta amyloid and tau in the development of AD. Early research focused on the role of cholinergic deficits and their relationship to cognitive decline, which in turn led to the development of several FDA-approved medications to treat the symptoms of AD.

Genetics: In the 1990’s, researchers identified several genes (Presenilin-1, Presenilin-2 and APP) believed to cause many cases of the early-onset (before age 60) form of AD. In fact it is now believed that this is the mutation that Auguste Deter had. They are referred to as “deterministic” genes because the presence of these genes directly causes AD. Other genes have been identified, including apolipoprotein E-e4 (APOE-e4). The presence of these genes puts people at increased risk for developing the more common late-onset AD. Large-scale studies are allowing researchers to identify new genes that cause AD. Additionally, the Nerve Growth Factor (NGF) trial is a novel study that uses gene therapy to deliver NGF directly to a specific part of the brain, via surgery, to determine if NGF can help cholinergic neurons to survive.

Neuroimaging and biomarkers: While MRI and CT scans have been used to aid in the diagnosis of AD, neuroimaging techniques have become more sophisticated, and include FDG-PET, SPECT and amyloid imaging. In 2005 the large-scale Alzheimer’s Disease Neuroimaging Initiative (ADNI) study began to better understand the use of biomarkers (including neuroimaging, cerebrospinal fluid and blood tests) in the diagnosis and monitoring of AD and in research trials. In 2012 the FDA approved florbetapir (Amyvid). Florbetapir binds to amyloid plaques in the brain, so that they can be seen in a positron emission tomography (PET) scan and are primarily used for research purposes only.

Vaccines and immunotherapies: The idea of using the body’s own immunity with an “Alzheimer’s vaccine” to combat amyloid buildup has a great appeal, but the first clinical trial was terminated in 2002 after some participants developed an allergic inflammation of the brain. After this, some researchers turned to immunotherapies that rely on passive immunity (where anti-amyloid antibodies are created in a lab and infused into patients). While several recent Phase III trials have yielded disappointing results, other “second generation” active vaccines and passive immunotherapies are currently being studied.

Prevention: Recently, research has focused on earlier stages of the disease. This includes the study of those with Mild Cognitive Impairment, thought to be a prodromal stage of AD, and characterized by the presence of cognitive difficulties (as measured by paper and pencil tests) that do not yet interfere with daily functioning. Very recently, scientists have discovered that the disease process (as measured by biomarkers) can begin decades before symptoms appear. These findings have prompted the development of prevention studies that aim to determine if certain medications might prevent or delay the onset of AD in those who have no symptoms but who may be at high risk for developing AD. Current studies at ADRC at Mount Sinai include the A4 and Tomorrow trials.

Other research areas: Effective strategies to help caregivers manage the burden of caring for a loved one with AD include skills training, counseling, respite care, and social support. Studies suggest interventions may not only reduce caregiver’s stress and depression, but may improve outcomes for patients, such as reduced behavioral disturbance and delay in the need for nursing home placement.

Conclusion: Considerable scientific progress has been made in the last 30 years and advocacy efforts have helped educate the public and secure funding. The National Alzheimer’s Project Act was signed into law in 2011, mandating a comprehensive plan to address AD; the first goal is to “Prevent and effectively treat AD by 2025.” Finding a cure for AD is dependent on well-designed and executed studies, significant funding and, equally important, *volunteers to participate*. With the acceleration of AD research through clinical trials of new medications, prevention, neuroimaging, biomarker and genetic studies, as well as studies that rely on brain tissue donation, there are many ways to be part of this tremendously exciting time in AD research.

In Loving Memory

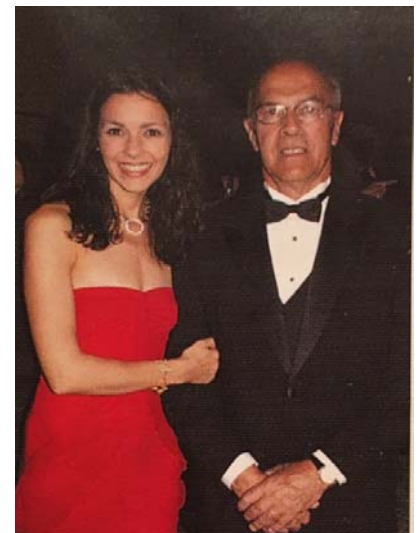


Susan Byelick's mother, Margaret Tracy Byelick (pictured to the left), had AD and passed away on September 7, 2015 at age 86. Susan Byelick is the Assistant Director of Space Planning and Management in the office of Dean Dennis Charney at Mount Sinai. Her coworkers and friends made generous donations to the ADRC in memory of Susan's mother. Mrs. Margaret Byelick lived in Westchester and Rockland County and was the mother of four children and had six grandchildren. Susan Byelick described her mother as an "energizer bunny" who loved to travel, explore and as a person who was always "positive and optimistic."

With grateful acknowledgment to the donors who included: *Rose Day, Matthew J. Di Properzio, Lillian Fojas, Rama S. Iyengar, Michelle Johnson, Mr. and Mrs. Paul Laderach, Jacqueline Lawes, David and Eleanor Muench, Paulette Moore-Akonnor, James Niles, and Eileen Wall.* The ADRC is profoundly grateful for the donations made in Margaret's memory and for the support of research to treat Alzheimer's disease.

Lori Hall's father, John Capra (pictured together to the right) recently passed away from complications due to Alzheimer's disease and was a participant in our ADRC. Ms. Hall has made a generous contribution to our ADRC in honor of her father. We are grateful to Ms. Hall and her family for all they have done to show their support for the ADRC's efforts to improve the lives of those suffering from Alzheimer's disease.

If you are interested in making a donation in memory of or in honor of a family member, please feel free to contact the ADRC at 212-241-8329. Every little bit helps. Last week we were moved to receive an envelope that contained a single dollar bill. Imagine if everyone did that?



2015 ADRC Summer Internship Program



L-R: Dr. Jane Martin; Dr. Margaret Sewell; Mr. Robert Kahen; Intern Helen Kim; Director Dr. Mary Sano; Interns Nelly Velasco and Daisy Gallegos; Dr. Judith Neugroschl

Thanks to ADRC supporter Robert Kahen, the ADRC was able to offer its fourth summer research internship program in memory of Mrs. Moussa Kahen. Mr. Kahen's support towards future aging and memory researchers allowed our interns to attend educational lectures and outreach activities, while gaining hands-on experience with clinical research methods.

All three interns were supervised by senior ADRC faculty on a variety of research projects that culminated in a presentation on to an audience of students and faculty members. We look forward to following the careers of these young academics!

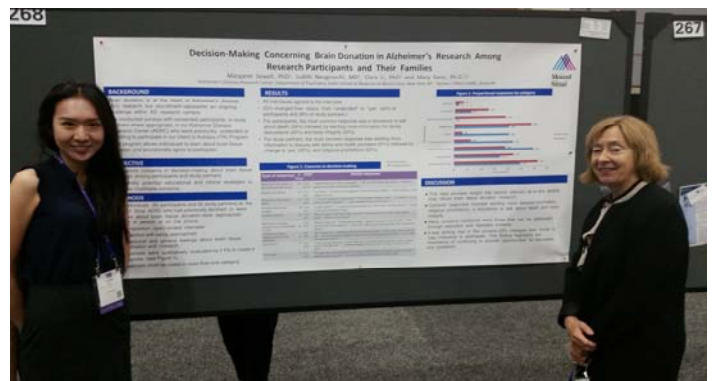
2015 Alzheimer's Association International Conference



Several ADRC faculty/staff traveled to Washington D.C. to present at the annual Alzheimer's Association International Conference. Clinical research coordinator, **Christopher Van Hise, BA** (pictured to the left), presented a poster entitled "Challenges of Recruiting Individuals with Mild Cognitive Impairment (MCI) for Biomarker studies in a Veteran Population." The poster, a collaboration between

several ADRC researchers, analyzed recruitment methods at the James J. Peters VA Medical Center in the Bronx. Their findings highlighted patient concerns about research participation and recommended best practices for engaging with prospective study participants.

Clara Li, Ph.D. and Mary Sano, Ph.D. (pictured below) presented a poster entitled "Decision-making concerning brain donation in Alzheimer's research among research participants and their families" based on results from an Education Core project. Brain donation is at the heart of Alzheimer's disease (AD) research but recruitment to the program represents an ongoing challenge in the ADRC and a sensitive issue for family members. Nearly 100 ADRC study participants and family members who had previously declined or were unsure about brain tissue donation were asked open-ended questions about what went into their decision-making. Our primary goal was to identify potential strategies to address concerns about brain tissue donation. Common responses included *needing more information, religious prohibitions, reluctance to talk about death, concerns about body integrity, and practical concerns*. Many concerns mentioned were those that can be addressed through education and more conversation. Furthermore, it was striking that in this process 23% changed their minds from "undecided" or "no" to "yes," intending to participate. This finding highlights the importance of continuing to provide opportunities for discussion and questions. If you want to hear more information about our Brain Tissue Donation Program or if you are unsure about your brain tissue donation status, please do not hesitate to contact us at (718) 584-9000 ext. 1704. Our staff will always be happy to discuss brain tissue donation with you and your family.



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2015 Walk to End Alzheimer's



This year, our ADRC joined forces with Dr. Alison Goate's lab to form one of the largest teams to participate in the annual Walk to End Alzheimer's. Sponsored by the Alzheimer's Association, this annual event held at Riverside Park provides a wonderful opportunity to support this important cause. Thank you to all who came out to join us, and we look forward to seeing you next year!

ADRC News and Resources

ADRC faculty were honored to be speakers at **Mount Sinai's 2015 Women's Health Day of Learning** and Luncheon held at the Plaza in November. Our session was called "Where Did I Put My Keys?" Guests learned about normal aging, tips to improve memory and cutting edge research. More information for patients and caregivers can be found using the resources listed below.

- **Telephone Support Group** — Family caregivers of AD research participants will receive support and information, as well as the opportunity to discuss issues of concern and share coping and adaptation strategies for managing the demands of daily life when caring for a family member with AD. If you would like more information, please contact Mari Umpierre, Ph.D. at (212) 659-8872 or email mari.umpierre@mountrysinai.org
- **Sobre el AD:** <http://www.alz.org/espanol/>
- **Centro de asistencia para personas y con AD y desordenes relacionados (ADAC):** 212-659-8872

We hope to see you at our annual Participant Appreciation Day, which will be held Wednesday April 13, 2016 from 10:00 am to 2:00 pm. Invitations coming soon!



L-R: Dr. Jane Martin, Dr. Margaret Sewell, Stacy London, Dr. Judith Neugroschl, and ADRC Director Dr. Mary Sano