# Currents



# The Shiley Gift: Bringing Discovery and Hope to the ADRC



"We chose to support UCSD's Alzheimer's efforts because of its national leadership in this area"

Donald and Darlene Shiley are no strangers to the University of California, San Diego. Longtime supporters of UCSD healthcare and

neuroscience initiatives, the couple has generously given to Leon J. Thal, M.D.'s Alzheimer's disease research, experimental Alzheimer's brain cell therapy research, and to the world-renowned Shiley Eye Center at UCSD. This past fall, the Shileys' benevolence touched UCSD yet again. In November 2004, UCSD announced a \$4 million pledge from Donald and Darlene Shiley to support the UCSD Alzheimer's Disease Research Center (ADRC), bringing their commitment to the university to more than \$8 million. In recognition of their gift, and in honor of Darlene's mother Dee Marcos, UCSD has renamed the ADRC the Shiley-Marcos Alzheimer's Disease Research Center.

Donald and Darlene Shiley are personally invested in Alzheimer's disease research and treatment. Explaining this commitment, Darlene

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#### Vitamin E and Alzheimer's Disease by Leon Thal, M.D.

"...it is difficult
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or make
recommendations."



A recent publication (Ann Intern Med 2004; 142:1-10) examined the number of deaths in 19 clinical trials of vitamin E, including a total of 136,000 subjects. These trials varied in the characteristics of the subjects enrolled, the dose of vitamin E used, the duration of treatment, and the outcome measures studied. Many of the subjects enrolled in these trials had coronary artery disease or risk factors for cardiovascular disease. In about half of the studies, the active treatment under investigation was a combination of vitamin E plus other vitamins or minerals.

None of the individual studies showed an increase in risk of death for subjects on vitamin E alone. Similarly, when all 19 studies were examined together, there was no increase in the risk of death. However, when the studies were arranged by dose of vitamin E (above or below the 400 IU/day median

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### The Shiley Gift: Bringing Discovery and Hope to the ADRC (Continued from Page 1)

This gift will help give families hope in caring for their loved ones afflicted with this disease.

says, "The disease has hit my family very hard. I have lost several close family members to the disease, including my mother. We chose to support UCSD's Alzheimer's efforts because of its national leadership in this area." In 2004, in honor of her devotion to finding a cure for this invasive disease, Darlene Shiley was named to the National Alzheimer's Association Board. The Shileys have also supported other local Alzheimer's disease organizations, including the Glenner Center building campaign, the San Diego Alzheimer's Association, and Alzheimer's research at the Salk Institute.

Dr. Thal, Professor and Chair of the UCSD Department of Neurosciences and Director of the Shiley-Marcos ADRC, believes "This gift will enable us to continue to recruit the most talented clinicians and researchers to UCSD to further expand our patient care, clinical trials and basic research efforts." The Shiley-Marcos ADRC has been instrumental in making a number of discoveries regarding biological and clinical aspects of the disease, including identifying new targets for therapy. As part of its mission, the Shiley-Marcos ADRC also provides patient evaluation, community outreach and education, and access to clinical trials for various interventions. Thanks to the ongoing generosity of the Shileys, the ADRC will continue as a major contributor to solving the challenge of Alzheimer's disease. Most importantly, this gift will help give families hope in caring for their loved ones afflicted with this disease.

#### **Roulla Drego Receives 2004 Diversity Award**



Roulla Drego, one of our UCSD work-study employees, has been an integral part of our team since 2001. She was recently selected as one of the 14 campus-wide recipients of the Equal Opportunity/ Affirmative Action and Diversity Award for 2004. Frances Martinez-Goodrich, MSW, coordinator of our Hispanic Component at the ADRC, nominated Roulla for this award in gratitude for the essential contributions that have made her an asset at the Center.

In 2004 she effectively handled with minimal supervision the responsibility of coordinating the Hispanic Caregiver Conference, an event that caters to the needs of monolingual Spanish-speaking caregivers. She helped obtain \$6,214.00 in funding from pharmaceutical companies and community agencies, which enabled us to offer this event for free. Utilizing her sharp computer skills, she organized a resource binder for participants and caregivers that assisted the conference.

Advocating on behalf of patients with Alzheimer's disease seems to come naturally to her. Her many skills enable her to be an effective and compassionate communicator, recently making a strong impact on hundreds of high school students she spoke to at a health fair in South Bay.

This young lady is beyond her 22 years of age; she is a phenomenal human being and outstanding worker gifted with the winning combination of skills, ethics and talent.

#### Vitamin E and Alzheimer's Disease

(Continued from Page 1)



A cautious interpretation of the risk reported in the new publication would be that cognitively individuals and those with MCI should limit their intake of vitamin E. For individuals with AD, the

normal



results are much

less clear.

dose), it appeared that individuals on low to moderate doses of vitamin E had a very slight protection against death while those on high dose vitamin E were at a very slightly higher risk of death. The majority of the deaths occurred in individuals who had known coronary artery disease. Further, only 30% of the metaanalytical sample was in high dose studies and 12 studies with fewer than 10 deaths were not included in the analyses. Since publication of this paper, a number of methodological issues have been raised and the conclusions have been questioned; further statistical analysis is in progress.

Two Alzheimer's Disease Cooperative Study trials have been completed looking at the effects of high dose vitamin E in patients with Alzheimer's disease (AD) or mild cognitive impairment (MCI). In the AD study, patients that were on high-dose vitamin E for up to 24 months reached functional milestones more slowly than individuals on placebo. Vitamin E was not associated with increased risk of death; an identical number of subjects on vitamin E died (12) during the course of the trial compared to patients on placebo (12). In a second study looking at the effects of vitamin E for up to 36 months in patients with MCI, there was no overall benefit or increase in risk; the death rate was also identical for individuals on placebo (5) and vitamin E (5).

Based on the pooled data in the recent publication, it is difficult to draw firm conclusions or make recommendations. The benefits of vitamin E supplements for AD prevention are unproven, and individuals with MCI have not shown benefit from vitamin E. A cautious interpretation of the risk reported in the new publication would be that cognitively normal individuals and those with MCI should limit their intake of vitamin E. For individuals with AD, the results are much less clear.

The single randomized clinical trial of vitamin E in AD showed that high-dose vitamin E is beneficial, without increased mortality, in the treatment of individuals at the moderate stage of disease. Since this trial was much smaller than the published cardiovascular trials, a small degree of increased risk might have been missed. Lower doses of vitamin E have not been tested in AD. It is thus unclear whether the riskbenefit ratio warrants continued use of 2000 IU of vitamin E for AD, or whether a lower dose should be recommended. An additional caution is that the protective effects of statins on cardiovascular disease may be attenuated by co-administration of anti-oxidants, suggesting that individuals who are on statins should be cautious about using vitamin E. In our view, it is reasonable at present to maintain AD patients on 2000 IU of vitamin E per day unless coronary artery disease is present, in which case a reduction in dose might be considered by the treating physician.

Research studies will continue to investigate vitamin E at various doses, as well as combinations of antioxidants, and will take appropriate precautions to monitor the well being of research participants.

> Leon Thal, MD Mary Sano, PhD

Ronald Petersen, MD, PhD Douglas Galasko, MD

Paul Aisen, MD Fred Schmidt, PhD

Pierre Tariot, MD

# New Vaccine May Be On The Horizon

by Ingrid Padilla, BA

Therapeutic options for treating Alzheimer's disease (AD) have focused thus far on regulating transmission of acetylcholine, a neurotransmitter found in lower concentrations in the brains of Alzheimer's patients. It is believed that lower levels of this chemical leads to some of the neuronal death observed during the course of this illness. Currently prescribed medications belong to a category of drugs called acetylcholinesterase inhibitors. They exert their action by limiting the amount of enzymes (acetylcholinesterase) available for reuptake (reducing the amount of acetylcholine available in the brain), thus rendering higher levels of available acetylcholine and preserving neuronal function. The problem with this type of treatment is it provides only temporary relief of symptoms without addressing the underlying disease process.

The precise cause of nerve cell death in AD is not known. Some recent advances in genetic studies suggest high levels of beta-amyloid (protein that accumulates and forms the hallmark AD feature called plaques) may be responsible for starting the disease. Some scientists believe the key to slowing down the progression of AD may lie in regulating levels of this protein.

In an attempt to hinder production of beta-amyloid and plaque formation, Élan Pharmaceuticals pioneered a vaccine aimed at boosting the body's immune response to beta-amyloid and stimulating clearance of plaques. Élan

launched clinical trials of AN-1792, an active inoculation of beta-amyloid that had stimulated antibodies and almost entirely prevented the AD-like amyloid plaques in lab mice. Unfortunately, clinical trials were suspended in January of 2002 due to adverse events - namely incidence of meningioencephalitis in some human subjects, believed to be a result of immune response overstimulation.

Scientists have since been working on developing a new vaccine, one that would induce clearance of amyloid plaques without inciting the immune response of their previous attempt.

Despite these adverse events, an autopsy case suggested disappearance of amyloid plaques. Furthermore, patients who developed antibodies showed a slower decline in the course of the illness than those who did not develop antibodies. Based on these findings, scientists believed immunization therapy deserved further exploration. They have since been working on developing a new vaccine, one that would induce clearance of amyloid plaques without inciting the immune response of their previous attempt. For years they experimented with "passive" vaccines on lab mice in the hopes of eventually reducing or halting the progression of AD in humans.

These new passive immunizations consist of directly injecting beta amyloid antibodies into the brain. Peripheral injection of moderate levels of antibodies showed these antibodies were able to enter the central nervous system, surround plaques, and induce clearance of preexisting amyloid. These studies also show an increase in synaptophysin, a chemical that indicates proper synaptic function (enabled cell communication). Lab results seem promising; that which was intended was accomplished without the need to stimulate an immune response, and thus less likely to actuate adverse events such as encephalitis.

We at the UCSD Shiley-Marcos ADRC will be part of the upcoming Élan Pharmaceuticals multi-center recruitment of human subjects to participate in Phase II clinical trials of AAB-001, a newly developed passive vaccine aimed at reducing beta-amyloid and amyloid plaque formation. For more information with regards to this clinical trial, please contact Karen Wetzel MPAS, PA-C at 858-622-5800 or via e-mail kwetzel@ucsd.edu.

# Honoring







Mary Sundsmo (left), receives Health Hero Award.

We are proud and honored to announce that our Program Director, Mary Sundsmo, MBA, was the recipient of one of the 2005 Health Hero Award at the Combined Health Agencies 11th Annual Health Hero Awards on March 22nd of this year. Mary was selected by the local Chapter of the Alzheimer's Association in gratitude for all her contributions to the organization, the community, and the Alzheimer's cause. She has been an active member of the Association's Speaker's Bureau and Advocacy programs since 1998; often writes feature articles for the Association's newsletter, lobbies in Sacramento and Washington, DC for increased funding for research on their behalf, and consults with their CEO on issues in common to the Alzheimer's Association and our UCSD Shiley-Marcos Alzheimer's Disease Research Center (UCSD Shiley-Marcos ADRC).

Combined Health Agencies, an association of 27 chapters of local and national organizations, was established in 1970 as a cooperative effort to provide education and services to the community and research entities. Each member of Combined Health Agencies demonstrates community-wide efforts for the health concern they are working to treat, prevent, control or eradicate. Collectively, more than 140 programs and services are offered by member agencies and over 13 million dollars invested in 190 research grants across San Diego County.

Mary has done much to deserve this award and other honors. She started her career at UCSD in 1980 in the labs of Drs. Miller and Saitoh and joined the Shiley-Marcos ADRC in 1998 as Program Director. She has since earned her MBA at UC Irvine, graduating with the best GPA in her class. Ms. Sundsmo was an integral part of the UCSD-initiated legislation of assembly bill AB 2328, bill that called for expanding research opportunities for affected individuals, and was recognized with a Certificate of Appreciation on behalf of the UC Office of the President and the California Department of Health Services for "outstanding contribution to the advancement of dementia research and services to persons with Alzheimer's disease". She has been elected to the Administrators Steering Committee of the 30 nationwide National Institute on Aging (NIA)-funded Alzheimer's Research Centers and serves as a liaison between the NIA and members of the Committee. Mary is a contributing writer for the George G. Glenner Center newsletter and serves as their Community Ambassador and on their Medical Advisory Board. In her "free time" she gives talks to community caregiver, patient support, Kiwanis, and Rotary groups. Let us not forget, she lives and breathes a plethora of responsibilities as administrator of our Center.

How she does it, we do not know. Thank you, Mary, for who you are and ALL you do.

#### Dr. Thal Appointed to Stem Cell Committee



California Governor Arnold Schwarzenegger announced the appointment of Leon Thal, M.D., professor and chair, Department of Neurosciences, University of California, San Diego (UCSD) School of Medicine, to the Independent Citizens Oversight Committee (ICOC), which oversees the California Institute for Regenerative Medicine created by the passage of Proposition 71.

Dr. Thal becomes the second UCSD member on the faculty and the fourth San Diegan to be named to the ICOC. Additional San Diego members are Edward W. Holmes, M.D., UCSD vice chancellor for health sciences and dean, UCSD School of Medicine; Richard A. Murphy, Ph.D., president and chief executive officer, the Salk Institute; and John C. Reed, M.D., Ph.D., president and chief executive officer, the Burnham Institute.

## Clinical Trials

If you are interested in participating or would like more information, please contact the Study Coordinator listed with each trial.

- They may all be reached at the Shiley-Marcos ADRC.
- There is no cost to participate in any of these research protocols

#### Lecozotan

STUDY DIRECTOR: Jody Corey-Bloom, M.D., Ph.D.

**DESCRIPTION:** This is a study sponsored by Wyeth Pharmaceuticals to find out more about the safety, tolerability and effectiveness of an

experimental drug, Lecozotan, in patients with mild to moderate AD. This drug is considered experimental because it has not

been approved by the Food and Drug Administration (FDA).

REQUIREMENTS: 

Age 50 and older • Are not taking medications for treatment of their memory Have mild to moderate AD

**COMPENSATION:** There will be no payment for participation in this study; however, all tests, examinations, and medical care required as part of the

study will be provided at no cost.

CONTACT: Karen Wetzel, M.P.A.S., PA-C, at (858) 622-5822 and ask for the "Lecozotan Study"

#### **CLASP Study Cholesterol Lowering Agent** to Slow Progression of **Alzheimer's Disease**

#### STUDY DIRECTOR Gang Tong, M.D., Ph.D.

#### **TIME INVOLVED**

This study involves 8-9 visits over 20 months

#### **DESCRIPTION**

Statins are drugs that are used to lower cholesterol to reduce the risk of heart disease. This study will investigate the safety and effectiveness of simvastatin (Zocor) in slowing the progression of AD.

Studies in animals have shown a link between lowering cholesterol and decreased severity and risk of AD.

Participants will take a study drug for 18 months, and this drug may be simvastatin or it may be an inactive placebo.

All participants must be accompanied by someone who can answer questions about them and who can make sure they are taking the study

If you or a family mamber have AD, and are not currently taking a cholesterol drug, you may be eligible to participate.

#### **Huperzine A**

#### **STUDY DIRECTOR**

Jody Corey-Bloom, M.D., Ph.D.

#### **TIME INVOLVED**

Study participation will be 24 weeks

#### **DESCRIPTION**

This study is to determine whether huperzine A is beneficial in the treatment of mild to moderate Alzheimer's disease. Huperzine A is a natural cholinesterase inhibitor, derived from the Chinese herb huperzia serrata, used in China to treat AD. Individuals 55 years of age or older who are not currently taking cholinesterase inhibitors and have mild to moderate Alzheimer's disease are eligible for screening. Treatment with memantine (Namenda) and vitamin E is allowed.

Two-thirds of participants will be randomly assigned to receive huperzine A throughout the study; one-third will receive placebo for the first 16 weeks, followed by huperzine A for 8 weeks. An open-label extension study providing huperzine A to all participants for at least 6 months is anticipated.

There will be no payment for participation in this study; however, all tests, examinations, and medical care required as part of the study will be provided.

#### VALID **VALproate In Dementia**

#### STUDY DIRECTOR

Jody Corey-Bloom, M.D., Ph.D.

#### **TIME INVOLVED**

Study participation will be 26 months

#### **DESCRIPTION**

Can long-term treatment with valproate not only delay the time until such behavioral symptoms as agitation or psychosis emerge, but also slow the expected cognitive and functional decline of AD?

This is a randomized, placebocontrolled, double-blind trial of outpatients 55 or older with AD (MMSE 10-20 inclusive) who lack agitation and psychosis and do not require treatment with psychotropic medications. Participants will be randomly assigned to receive valproate or placebo (an inactive substance).

Treatment with Aricept, Reminyl, Exelon, Namenda and/or vitamin E is allowed

There will be no payment for participation in this study; however, all tests, examinations, and medical care required as part of the study will be provided at no cost.

#### **ONO-2506**

#### **STUDY DIRECTOR**

Jody Corey-Bloom, M.D., Ph.D.

#### **DESCRIPTION**

This is a study to find out whether an experimental drug, ONO-2506, is beneficial in the treatment of patients with mild to moderate AD. This study is sponsored by ONO Pharma, Inc.

We are seeking participants who:

- Are age 50-90
- Have mild to moderate AD
- Are not taking galantamine (Reminyl), tacrine (Cognex), or memantine (Namenda).
- Treatment with donepezil (Aricept), rivastigmine (Exelon), and/or vitamin E is allowed.

Participants will be randomly assigned to receive one of two doses of the experimental drug ONO-2506 or a placebo.

#### **COMPENSATION**

There will be no payment for participation in this study; however, all tests, examinations, and medical care required as part of the study will be provided at no cost.

#### **Antioxidants**

#### STUDY DIRECTOR

Douglas Galasko, M.D.

#### **DESCRIPTION**

This study will assess the safety, tolerability, and effects related to oxidative damage on cerebrospinal fluid (CSF) biomarkers of two antioxidant treatment regimens in patients with mild to moderate AD.

We seek male and female subjects, age 60-85, inclusive, who:

- Have a diagnosis of probable AD (NINCDS-ADRDA criteria)
- MMSE score > 14/30
- No contraindications to lumbar puncture
- Medically stable, with no clinically significant abnormalities of hepatic, renal or hematologic function

STUDY DURATION: The study will last 4 months; it includes two lumbar punctures (spinal taps), three clinic visits, and six telephone interviews.

#### **COMPENSATION**

Participants will receive \$400 upon study completion (\$200 per lumbar puncture).

#### **Biomarkers** in Aging, MCI, and **Alzheimer's Disease**

#### STUDY DIRECTOR

Douglas Galasko, M.D.

#### **DESCRIPTION**

This study will measure levels of a number of different proteins in cerebrospinal fluid (CSF) and in blood in order to compare these biomarker levels amongst people who have normal cognitive ability, mild memory problems, or early Alzheimer's Disease (AD).

We are looking for male and female volunteers:

- Age 40-90 with no memory problems
- Age 60-90 with Mild Cognitive Impairment (MCI)
- Age 60-90 with early AD

Study candidates should be in general good health and without major lower back problems. The study will last 5 years, with a 2-day visit per year. Participation involves a lumbar puncture and bloodwork.

#### **COMPENSATION**

Participants will receive up to \$200 compensation per year of the study for undergoing the lumbar punctures

#### CONTACT

Susan Johnson, G.N.P. at (858) 622-5800 and ask for the "Statin Study"

Karen Wetzel, M.P.A.S., PA-C, at (858) 622-5822 and ask for the

CONTACT

"Huperzine A Study"

Karen Wetzel, M.P.A.S., PA-C. at (858) 622-5822 and ask for the "VALID Study"

CONTACT

Karen Wetzel, M.P.A.S., PA-C, at (858) 622-5822 and ask for the "ONO-2506 Study"

CONTACT

Mary Margaret Pay, R.N., C., N.P. at (858) 622-5800 and ask for the "Antioxidant Study"

**CONTACT** 

#### CONTACT

Helen Vanderswag, R.N.C., B.S.N. at (858) 622-5805 and ask for the "Biomarkers Study"





# COULD OMEGA-3 FATTY ACIDS HELP THE FIGHT AGAINST ALZHEIMER'S?



by Ingrid Padilla, BA

Fatty acids are one of the components of phospholipids, a type of fat that is a building block of cell membranes. They serve as energy for muscles, heart, organs, and as energy storage for the body as a whole. Essential fatty acids are those the body needs for metabolic functioning but cannot produce and therefore must be acquired from food. Docahexaenoic acid (DHA), a major component of fish oil, is a fatty acid

of the omega-3 type that is synthesized from essential fatty acids (such as ALA) or obtained in the diet.



DHA is a vital component of the phospholipids in human cell membranes, particularly those in the brain and retina. It is needed for regulation of all bodily functions and the breakdown of dietary fats within the body, as well as necessary for optimal neural development and visual acuity. DHA-containing phospholipids in nerve cells are believed to be critical for cell signaling (communication), and are the prominent structural fatty acid in the gray matter of the brain. Deficient levels of DHA have been associated with cystic fibrosis, some congenital metabolic diseases, attention deficit disorder, and may be a risk factor for Alzheimer's disease (AD).



A number of studies have implicated high DHA intake as a preventative measure and/or possible therapeutic approach for several illnesses. A large body of scientific research suggests that increased dietary omega-3 fatty acid intakes are associated with significantly reduced risks of cardiovascular diseases, prompting the American Heart Association to recommend all adults eat fish at least twice weekly. Some studies have suggested that increasing DHA intake may be beneficial to diabetic individuals, especially those with high triglyceride levels, as DHA supplementation reduces triglyceride levels. Fish oil supplementation for at least 12 weeks has consistently decreased the number of tender joints and reduced morning stiffness in individuals with rheumatoid arthritis.



Various observational studies have also documented correlations between high DHA intake and lower incidence of Alzheimer's and other dementias. Researchers at the Lipid Metabolic Lab in Tufts University found diets rich in DHA reduced risk of developing dementia by 48% compared to those diets containing low amounts of DHA. *Neuron* published an article on a UCLA study where high DHA intake was observed to help prevent memory loss and brain damage in mice genetically engineered to get AD-like disease. Furthermore, the *British Medical Journal* published an article last year which reported elderly people who consumed fish at least once weekly were at lower risk of developing dementia, including AD.

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#### Currents

Should we increase our DHA intake to lower our chances of developing AD?



It probably wouldn't hurt.

Should we increase our DHA intake to lower our chances of developing AD? It probably wouldn't hurt. Boosting your dietary intake of omega-3s is easy. Foods rich in omega-3s include eggs, organ meats, fish (especially fatty fish such as salmon, mackerel, sardines, tuna, halibut, trout, herring, catfish, cod), shrimp, clams, spinach, flaxseed oil (linseed oil), walnuts, and canola oil. Try eating fish a couple of times per week, adding flaxseed to your morning oatmeal, and/or adding walnuts to your cereal or baked goods. The possibilities are endless.







Although serious side-effects from fish oil and omega-3 fatty acid supplements have not been reported, pregnant or breastfeeding women, individuals on anticoagulant medications (Coumadin, warfarin), and individuals with compromised immune systems should consult their physician before starting supplements.



A nutritional powerhouse, packed with omega-3s from the canola oil, egg, flaxseed (richest source of omega-3s amongst plant foods), and walnuts. As if this wasn't enough, they have both soluble and insoluble fiber from the whole wheat flour and flaxseed respectively, vitamin E and folic acid from the wheat germ; and last, but not least, antioxidants from the blueberries and honey. What a way to start your morning!

¼ cup canola oil
¾ cup milk (or soymilk)
1 egg (or ¼ cup egg replacement)
2 tbs honey
1 tsp vanilla
¼ cup sugar
1 ¾ tsp baking powder

1 cup whole wheat flour
¼ cup wheat germ
¼ cup ground flaxseed
1 tsp cinnamon
½ cup chopped walnuts (optional)
1 cup blueberries
additional wheat germ or oat flakes
for dusting

Preheat oven to 375 degrees. Spray muffin pan with non-stick spray.

In a medium bowl mix canola oil, milk, egg, honey, and vanilla. Add sugar, flour, wheat germ, flaxseed, salt, cinnamon, and chopped walnuts; mix until just blended. Fold in blueberries and baking powder (do not over mix - this makes the muffins harder and less fluffy).

Spoon mixture into muffin pan. Sprinkle a little wheat germ over the top of the muffins. Bake for 15-20 minutes (or until toothpick comes out clean after inserted in the middle of one of the muffins).

Would you like this column to become a regular feature? Tell us what you think! Call (858-622-5800), write (8950 Villa La Jolla Dr. Suite C-129; La Jolla, CA 92037), or e-mail us (ipadilla@ucsd.edu) with your input or suggestions.

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### HISPANIC Support

### Comprendiendo y detectando las primeras etapas de Alzheimer Por Ingrid Padilla

A muchos de nosotros se nos ha olvidado en ocasiones dónde hemos estacionado el carro o dónde hemos dejado las llaves. A veces hasta olvidamos lo que estamos diciendo a mitad de oración. Mientras que un poco de olvido es normal y aumenta con la vejez, otros cambios de memoria pueden ser más serios y requieren atención médica.

La gente que sufre de cambios memoria, capacidad mental y/o comportamiento puede que estén padeciendo de algún tipo de mal cerebral conocido como "demencia". Los pacientes con demencia no sólo olvidan dónde han puesto las llaves, puede que ni se acuerden cómo utilizarlas. Suelen repetir preguntas, perderse en lugares conocidos, olvidar nombres de personas allegadas o perder noción del tiempo y/o lugar.

Existen muchos tipos de demencia. Algunas formas de demencia son reversibles; tales como aquellas causadas por deficiencias nutricionales, enfermedades metabólicas, deshidratación o leves lesiones de cabeza. Otros tipos de demencia son causados por cambios cerebrales y no son reversibles. Uno de dicho tipo y la causa más común de demencia es la enfermedad Alzheimer.

En la enfermedad de Alzheimer, cambios en las células afectan distintas partes del cerebro. Los síntomas aparecen lentamente y crean dificultad en la ejecución de tareas comunes. Pueden presentar dificultad con el idioma y causar que las personas olviden palabras simples. Otros síntomas comunes incluyen cambios drásticos de personalidad, falta de juicio, pérdida de iniciativa y dificultad comprendiendo lo que se escucha. No todos los síntomas se presentan al mismo tiempo o progresan al mismo ritmo en las personas afectadas con esta enfermedad. Es muy importante que documenten estos cambios y consulten su médico.

Mientras que no existe prueba diagnóstica específica para determinar si una persona padece de Alzheimer, es posible que su médico le pueda referir a un neurólogo para que le hagan una evaluación extensa. Se le

diagnostica como "posiblemente padeciendo de Alzheimer" tras una evaluación minuciosa de su historial médico y varias otras pruebas. Algunas de estas pruebas pueden ser un examen físico y neurológico completo, pruebas de laboratorio, y evaluaciones de memoria y otras capacidades mentales. Este proceso por lo regular toma más de un día como paciente ambulatorio.

Aunque no existe cura para la enfermedad de Alzheimer, es posible aliviar algunos de los síntomas que acompañan este mal. Mientras más pronto se le diagnostique, mejor probabilidad de que sus síntomas respondan a tratamiento. Su médico le puede recetar una de varias medicinas existentes. La reacción a cualquiera de estos medicamentos varía entre personas.

En la actualidad se están desarrollando otros medicamentos para disminuir los síntomas de la enfermedad de Alzheimer. Estos medicamentos por lo regular se consiguen a través de pruebas clínicas en centros de investigación. Su habilidad de participar varía de acuerdo a la prueba clínica y los requisitos de participación. Los centros de investigación mantienen su información en confidencia y únicamente comparten sus datos con su doctor si usted lo autoriza.

La participación en pruebas clínicas tiene en sí sus propias recompensas. Le pudieran proveer medicamentos que aún no se recetan, seguimiento de su condición, e historial médico bien documentado que pudiera beneficiar a otros miembros de su familia. Estas investigaciones ayudan a los científicos comprender mejor esta enfermedad e identificar los factores de riesgo envueltos en el desarrollo de la misma. La información obtenida a través de su participación voluntaria pudiera ayudarnos a descubrir la causa de esta enfermedad y algún día encontrar la cura. Cada granito de información cuenta. Considere participar en investigaciones científicas si usted o algún ser querido está mostrando síntomas o tiene diagnóstico de Alzheimer, o si no tiene síntomas y está dispuesto(a) a participar como sujeto normal (para comparar resultados con aquellos de personas afectadas).

# CLINICAL TRIALS? by Ingrid Padilla, BA

A clinical trial is a test or study of a drug or device involving human subjects. Such studies may involve testing the efficacy and safety of a medication, or developing new assessment instruments (such as tests for memory) and other diagnostic tools utilizing biomarkers (e.g. urine, blood, etc.), imaging techniques or other technologies. Clinical trials are the primary way through which scientists develop new therapies and treatment options.

Clinical trials are divided into phases of development before a new medication/treatment is presented to the Food and Drug Administration (FDA) for approval. A small number of volunteers are treated and examined to assess action, safety, and effectiveness of different doses of a particular drug during a Phase I trial. Once results from this initial phase show treatment appears to be safe, the FDA may approve Phase II and III of the research process. These subsequent phases involve a higher number of participants and last longer than the initial trial. Phase II and III focus on safety, effectiveness, and potential side effects of the treatment under investigation.

Scientists are continually looking for volunteers to participate in clinical trials. Your ability to participate may depend on variables such as your age, health status, and medications you are currently taking. It is important to be aware of the purpose of the clinical trial, responsibilities entailed, types of tests and exams, time commitment, risks and benefits, and all the particulars about medical care provided.

Upon deciding to participate in a study, you should consider your expectations and motivations, whether or not you are comfortable with the uncertainty of receiving treatment or a placebo (inactive compound), your ability to participate, and your willingness to experience potential risks or side effects. Make sure you understand the study and all it entails. Be aware your condition may or may not improve, regardless of whether you are taking an active compound or placebo; sometimes people experience improvement of symptoms solely on account of expectation and feelings of well-being brought about by the amount of attention received from study physicians. Do not be afraid to ask questions; it is your right as a study volunteer to be fully informed before you consent to participate.



You may find the experience of participating in research to be very rewarding

Once you decide to participate, there are several steps to the enrollment process. First and foremost, you will sign an *informed consent form*. This form states you understand the study, your responsibilities, the potential risks and benefits; that you have received a copy of your rights as a research subject, are aware of the extent of medical treatment provided and your option to withdraw from the study at any time, and that you agree to participate. Next, you will undergo an initial screening evaluation to determine participation eligibility. After this screen visit you will receive a baseline assessment which will serve as a frame of reference for observations made throughout the study, after which you would become an active participant in the study.

You may find the experience of participating in research to be very rewarding. Participating in research may allow you access to medications not readily available by prescription, have your condition monitored on a regular basis, maintain a well documented medical history for others in your family, and receive attention and thorough evaluations from specialized physicians and medical staff. It would help scientists gain enhanced discernment of a particular illness, enable further identification of risk factors involved in the development of the disease, devise more efficient treatments, and eventually identify cause and hopefully a cure for a given malady. Every bit of information counts. Be sure to explore the possibility of participating in research if you or someone you love is showing symptoms or has a diagnosis of Alzheimer's disease, or if you are not experiencing symptoms and are willing to enroll as a normal control subject.

#### Currents

#### Participation Opportunities with Other UCSD Affiliated Alzheimer's Research Studies

by Susan Johnson, G.N.P.

There are at least 55 ongoing ADRC affiliated AD research studies within UCSD's School of Medicine. The goal of these research studies is to enhance medical knowledge of the disease, its progression and impact on patients, families and caregivers. Like the ADRC, their ultimate goal is preventing and someday curing the disease. The ADRC longitudinal study is the backbone and primary source of volunteers for these studies. Those of you enrolled in the ADRC are asked at each annual exam if you are willing to be contacted about additional studies you may be eligible to participate in. Sue Johnson refers contact information of willing volunteers to pertinent study coordinators, ensuring each individual is referred to only one study at a time. The particular study coordinators contact potential participants to present information about their study and ask whether or not the individual would like to be involved. Please know you are selected and referred to these studies because you meet the study criteria while many other willing volunteers may not.

There have been times when the availability of research volunteers runs short of studies' needs. If you would consider participation in these affiliated UCSD AD research studies or have a friend who is, please call us to discuss your options. Don't hesitate to contact Susan Johnson, ADRC Program Representative, at (858) 622-5850 for information or answers to questions about other UCSD affiliated AD research studies. Thank you for your continued support.

### Currents

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