Web Program Connects Players in AD Trials

BY MICHELE G. SULLIVAN

FROM THE INTERNATIONAL CONFERENCE ON ALZHEIMER'S DISEASE

An interactive telephone- and Web-based service now lets Alzheimer's patients, caregivers, and their physicians connect more easily with ongoing clinical trials.

The service – Alzheimer's Association TrialMatch – has the potential to greatly enrich the research into more effective treatment options and the ultimate goal of an Alzheimer's cure, William Thies, Ph.D., chief medical officer of the Alzheimer's Association, said at a press briefing.

"Alzheimer's disease is clearly the No. 1 health challenge of the 21st century, and research is the only way to solve this problem," Dr. Thies said at the meeting in Honolulu. "If patients are not enrolling in trials, there can be no advances in diagnosis, treatment, and prevention, making the lack of study participants a significant health issue. TrialMatch provides a first-of-its-kind service in Alzheimer's by delivering a user-friendly and individualized guide to clinical trials for people with Alzheimer's, their health care professionals, caregivers, and healthy volunteers."

There are about 150 clinical studies for Alzheimer's and dementia ongoing. Unfortunately, not enough patients volunteer for them – a problem that slows recruiting and drags out the overall length of the trial, Dr. Reisa Sperling said in an interview.

"At the rate we have people signing up now, it takes 12-18 months just to complete enrollment for a study," said Dr. Sperling, director of clinical research at the Memory Disorders Unit, Brigham and Women's Hospital, Boston. "Since each one of these trials lasts for 18-24 months, that means each one takes 3-4 years to get an answer. This is not doable with the current scale of research." Currently, there are 10 drugs in large-scale clinical trials and another 20 in preclinical studies.

Even when patients do volunteer for trials, screening eliminates many possible candidates, she said. "For every patient we enroll, we typically need to screen three or four. TrialMatch will collect detailed information in a confidential way, online, and that will speed up the matching process considerably."

Interested parties visit the TrialMatch Web site (www.alz.org/TrialMatch) and identify themselves as a patient, caregiver, physician, researcher, or health volunteer. The program then creates a user name, password, and a personal profile that matches the user to trials for which he may qualify.

At any time in the process, users can also call a toll-free number (800-272-3900) to speak with a volunteer who will walk them through the process. Specialists who are available 24 hours a day help to match individuals to clinical trials for which they are eligible, based on study inclusion/exclusion criteria, diagnosis, treatment history, and location. While they won't be able to recommend particular trials, they will be able to describe all the studies for which a user may be eligible.

One of TrialMatch's biggest benefits is education, Dr. Sperling said. "Patients need more information about what being in clinical trial requires, and physicians need to understand why it's important to take the time to direct patients into studies."

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The studies included on TrialMatch include large, industry-sponsored drug trials, natural history and imaging studies, federally funded trials, and smaller, investigator-initiated studies. All of them are important, Dr. Sperling noted. "We need to rapidly enroll for all these studies, even the smaller ones, which often form the basis for larger studies."

She expressed the hope that accelerating recruitment will also speed up answers to the problem of Alzheimer's disease – a condition that threatens to overwhelm the national health care scene in the next 50 years. By the middle of this century, there could be 1 million new cases diagnosed each year in the United States alone.

"I'd like to take a page from the success some of my oncology colleagues have seen," Dr. Sperling said. "For example, as soon as 80% of children with certain pediatric tumors began enrolling in research, there were huge leaps forward in finding treatment. Finding answers is directly proportional to research."

Entering a clinical trial also is an important way for both physicians and patients to claim some power in a situation that can make them feel quite helpless, she added. "I hope this can change the landscape of thinking about what patients and doctors can do to be proactive about this disease. Instead of hiding from it, let's agree to fight it tooth and nail."

Dr. Eric Tangalos, codirector of education for the Mayo Clinic Alzheimer's Disease Research Center in Rochester, Minn., agreed. "TrialMatch is a wonderful innovation and excellent opportunity for more patients and families to get involved with Alzheimer's research," he said in an interview. "I want my patients and families to run toward a diagnosis rather than away from it. Moreover, people who volunteer for research studies tend to do better than people who do not volunteer.

"There is not only the direct benefit of being engaged but [also] a social and societal advantage that plays out positively for the volunteer."

TrialMatch is funded by the Alzheimer's Association. Neither Dr. Sperling nor Dr. Tangalos had relevant disclosures. ■

Systolic BP, Gait Linked to Cognitive Deficits in Type 2

BY DIANA MAHONEY

FROM NEUROPSYCHOLOGY

High systolic blood pressure, gait-balance deficiencies, and low self-reported health scores are linked to cognitive deficits in older adults with type 2 diabetes, a report shows.

The three health-related covariates were associated with deficits in neurocognitive speed, executive functioning, and episodic memory in diabetic vs. nondiabetic adults, based on cross-sectional data from the Victoria Longitudinal Study (VLS), an ongoing, multicohort study comprising initially healthy community-dwelling adult volunteers from Western Canada. The study participants undergo cognitive, neuropsychological, health, and physiologic assessment at 3-year intervals.

The current analysis included 499 participants, aged 53-90 years, drawn from the study's third independent sample. Excluded from the study were individuals who had been previously diagnosed with Alzheimer's disease or vascular dementia, those scoring less than 26 on the Mini-Mental Status Examination, and those with clusters of potential comorbid neurologic, cardiovascular, and psychiatric diseases (Neuropsychology 2010;24:547-62).

Type 2 diabetes was present in 41 participants who were compared with the remaining 458 participants without diabetes. The two groups were similar in age, education, and gender proportions, as well as marital and dwelling status, and no group differences were found for global cognition or visual or audio acuity, according to C. Peggy McFall of the University of Alberta, Edmonton, and colleagues.

The investigators identified from the literature 13 health-related potential covariates and identified relationships between the covariates and type 2 diabetes. Six potential covariates – systolic blood pressure, body mass index, gait-balance, depression, negative affect, and subjective health were found to be sensitive to type 2 diabetes associations with performance on seven cognitive measures. These measures were episodic memory, the Stroop Test, the Hayling Sentence Completion Test, the Color Trials Test 2, semantic speed, reaction time, and the Digit Symbol Substitution Test.

VITALS

Major Finding: Systolic blood pressure attenuated the type 2 diabetes–cognition relationship by 30%-50% for episodic memory, neurocognitive speed, and executive function.

Data Source: An analysis of 499 older Canadian adults, 41 with diabetes, drawn from the Victoria Longitudinal Study of human aging.

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In the regression analyses, systolic blood pressure, gait-balance, and subjective health were found to mediate multiple cognitive outcomes. For example, systolic blood pressure attenuated the type 2 diabetes–cognition relationship by 30%-50% for episodic memory, neurocognitive speed, and executive function. As such, systolic blood pressure may be associated with type 2 diabetes-related vascular disturbance.

The gait-balance composite mediated type 2 diabetes cognition relationships for all seven cognitive measures, with attenuation effects ranging from 32% to 62%, the authors reported. The substantial influence of this composite might reflect the impact of diabetes on specific neural mechanisms associated with gait and balance or, more broadly, it might affect the "multiple overlapping areas [of the brain] associated with gait-balance and cognition."

The subjective health composite accounted for 35%-50% of performance on five different cognitive tests. "Specifically, [type 2 diabetes] may exacerbate levels of psychosocial stress, depression, and (lower) health self efficacy – all of which may negatively affect motivation for performance on cognitive tests," the authors wrote. Further, with diabetes, "processes of interoception may detect inner biological stimuli of discomfort or nutritional deficits that could be associated with lower subjective health ratings and, by extension, cognitive performance."

The findings point to the need for "neuropsychological research on neural bases of [diabetes-related] cognitive decline, clinical research on intervention and treatment strategies, and larger-scale longitudinal epidemiological studies, all of which will help clarify the multilateral (and possibly dynamic) relationships and mechanisms of [type 2 diabetes], related comorbidities, and cognitive outcomes," the authors concluded. ■