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**Due to online journal publication in advance of presentation at AAIC 2016**

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**FROM THE ALZHEIMER'S ASSOCIATION INTERNATIONAL CONFERENCE 2016**

**A 6-YEAR TRIAL WITH A VASCULAR CARE INTERVENTION  
TO PREVENT DEMENTIA**

TORONTO, WEDNESDAY, JULY 27, 2016 – Important clinical trial results in Alzheimer's disease and dementia are being reported at the 2016 Alzheimer's Association International Conference (AAIC 2016) in Toronto, Canada.

Scientists from the Netherlands found that a six-year, nurse-led vascular care intervention did not lead to a reduction of all-cause dementia in a cognitively healthy population. However, fewer cases of non-Alzheimer's dementia were observed in the intervention group compared to the control group. In addition, they saw fewer cases of incident dementia in a subgroup of people in the study with untreated hypertension who were adherent to the intervention.

"The preDIVA Study was negative on the primary outcomes. However, the other study observations suggest once again the benefits – for the head and the heart – of assessing, treating and managing heart health risk factors as we age," said Maria C. Carrillo, PhD, chief science officer, Alzheimer's Association.

Alzheimer's is the most common form of dementia, a general term for memory loss and other intellectual abilities serious enough to interfere with daily life. Alzheimer's disease accounts for 60 to 80 percent of dementia cases. According to Alzheimer's Association's 2016 [\*Alzheimer's Disease Facts and Figures\*](#), of the 5.4 million Americans with Alzheimer's, an estimated 5.2 million people are age 65 and older, and approximately 200,000 individuals are under age 65 (younger-onset Alzheimer's).

According to the World Alzheimer Report 2015 from Alzheimer's Disease International, an estimated 46.8 million people worldwide are living with dementia in 2015. This number will almost double every 20 years, reaching 74.7 million in 2030 and 131.5 million in 2050.

**Six-Year Vascular Care Intervention May Reduce New Cases of Dementia**

Heart health and lifestyle-related risk factors are associated with risk of cognitive decline and dementia, but it is not fully known whether targeting these risk factors prevents dementia. In an article published in May 2015 in *Alzheimer's & Dementia: The Journal of the Alzheimer's Association*, Baumgart et al wrote "there is sufficiently strong evidence, from a population-based perspective, to conclude that regular physical activity and management of cardiovascular risk factors (diabetes, obesity, smoking, and hypertension) reduce the risk of cognitive decline and may reduce the risk of dementia."

In the Prevention of Dementia By Intensive Vascular Care (preDIVA) trial, researchers in the Netherlands co-led by Dr. Edo Richard tested whether a multicomponent intervention targeting vascular risk factors can prevent new cases of dementia. Richard is a neurologist in the department of neurology at the Academic Medical Center in Amsterdam and the Radboud University medical center in Nijmegen.

The researchers conducted a six-year, open cluster-randomized controlled clinical trial in primary care where 3,526 cognitively healthy persons age 70-78 were randomized to either usual care (1,636 participants) or usual care plus three additional visits per year led by a nurse and focused on vascular care (1,890 participants). Primary outcomes were cumulative dementia incidence and disability. Main secondary outcomes were incident cardiovascular disease, mortality and dementia by subtype.

Vascular risk factors were assessed and addressed with medical and non-medical strategies in all study participants based on primary care guidelines in the Netherlands. The study intervention under investigation involved meeting with a nurse every four months to monitor and encourage compliance and to optimize treatment of vascular risk factors. Attending at least two-thirds of appointments with the nurse over the course of the study was considered adherence to the intervention.

In results reported at AAIC 2016, after a median follow-up of 6.7 years:

- New cases of all-cause dementia and of Alzheimer's disease specifically did not significantly differ between groups.
- Dementia other than Alzheimer's occurred significantly less frequently in the intervention group (11 (1%) of 1,743) than in the control group (23 (2%) of 1,512) (HR 0.37; p=0.007).
- In a per-protocol analysis, in a subgroup of study participants with untreated hypertension who were adherent to the intervention, new dementia cases were significantly fewer in the intervention group (22 (4%) of 512) compared with the control group (35 (7%) of 471) (HR 0.54; p=0.02).

“Though we were not able to show an effect on the primary outcome, our study shows that long-term, nurse-led vascular care in an unselected population of community dwelling older people is safe and may reduce incidence of non-Alzheimer's dementia,” said Richard. “In addition, we saw potentially clinically meaningful effects in lowering incident dementia in people with untreated hypertension who were adherent to the intervention.”

Complete data for the primary outcome were obtained for 3,454 persons (98%). Dementia occurred in 233 participants (6.7%; 121 intervention, 112 control); 578 participants (16.4%) died. Mean blood pressure decreased significantly in both groups, but more in the intervention group than in the control group ( $\Delta$ 2.1 mmHG, p<0.001).

According to the researchers, preDIVA is the largest and longest-running randomized clinical trial with incident dementia as primary outcome.

#### **About Alzheimer's Association International Conference (AAIC)**

The Alzheimer's Association International Conference (AAIC) is the world's largest gathering of researchers from around the world focused on Alzheimer's and other dementias. As a part of the Alzheimer's Association's research program, AAIC serves as a catalyst for generating new knowledge about dementia and fostering a vital, collegial research community.

AAIC 2016 home page: [www.alz.org/aaic/](http://www.alz.org/aaic/)

AAIC 2016 newsroom: [www.alz.org/aaic/press.asp](http://www.alz.org/aaic/press.asp)

#### **About the Alzheimer's Association**

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's care, support and research. Our mission is to eliminate Alzheimer's disease through the advancement of research, to provide and enhance care and support for all affected, and to reduce the risk of dementia through the promotion of brain health. Our vision is a world without Alzheimer's. Visit [alz.org](http://alz.org) or call 800.272.3900.

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- Edo Richard, MD, PhD, et al. Prevention of Dementia By Intensive Vascular Care (preDIVA) – a Cluster-Randomized Trial. (Fundors: Dutch Ministry of Health, Welfare and Sport; Dutch Innovation Fund of Collaborative Health Insurances; Netherlands Organization for Health Research and Development)

Proposal ID: O4-05-01

Oral Session, Wednesday, July 27, 2016: 2:00 PM - 3:30 PM, #2315

Theme Selection: Clinical Therapeutics: Clinical Trials – Innovative Trials

## **Prevention of Dementia By Intensive Vascular Care (preDIVA) – a Cluster-Randomized Trial**

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**Background:** Observational studies show that cardiovascular and lifestyle related risk factors are associated with an increased risk of dementia. It is unknown whether targeting these risk factors prevents dementia. In the preDIVA trial we test whether a multicomponent intervention targeting vascular and lifestyle related risk factors could prevent incident dementia.

**Methods:** In an open cluster-randomized controlled clinical trial in primary care, with blind outcome adjudication, 3526 persons (age 70-78 years) were randomized to nurse-led vascular care (1890 participants) or usual care (1636 participants). The planned intervention and follow-up duration were six years. Primary outcomes were cumulative dementia incidence and disability. Main secondary outcomes were incident cardiovascular disease (CVD), mortality and dementia according to subtype.

**Results:** Complete data for the primary outcome were obtained for 3454 persons (98%) after a median follow-up of 6.7 years, yielding 21,341 observed person-years. Dementia occurred in 233/3453 participants (6,7%). During the study 578 participants (16,4%) died. Stroke/TIA occurred in 222/2844 participants (7,8%). Mean blood pressure decreased significantly in both groups, but more in the intervention group than in the control group ( $\Delta 2.5$  mmHG,  $p=0.02$ ). The effect was largest for participants with grade III hypertension ( $\Delta 6.2$  mmHG,  $p=0.05$ ).

**Conclusions:** PreDIVA is the largest and longest running RCT ever with incident dementia as primary outcome. The pragmatic primary outcome has resulted in a complete follow-up in a very high percentage of participants. A beneficial effect on blood pressure was recorded throughout the study. The manuscript is under review and results will be presented depending on the review process.

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