Information Sheet about participation in a research study titled: Effect of Stress-Busting Program on Caregivers' Quality of Life, Immunology/Stress Biomarkers and Cellular Aging

Who is conducting the study?
Lyda C. Arévalo-Flechas PhD, RN, Advanced Geriatrics Fellow, and Chih- Ko Yeh BDS, PhD , Professor, from the South Texas Veterans Health Care System and The University of Texas Health Science Center at San Antonio respectively.

What is the purpose of the research?
To study the effect on quality of life and physiological indicators of a Stress-Busting Program for Family Caregivers (SBP) of people living with Alzheimer's disease or related dementias.

Who is asked to participate?
We aim to include 75 caregivers of people living with Alzheimer's disease or related dementias. The caregiver must be at least 18 years old and be the primary care provider for the care-recipient. The caregiver does not need to be a veteran. Family caregivers include spouses, adult children, grandchildren, siblings, partners, and significant others. In addition to Alzheimer's disease, other causes of dementia include multiple sclerosis, Parkinson's, post-traumatic stress disorder (PTSD), and/or traumatic brain injury (TBI). Those wishing to participate in the Spanish- Stress-Busting Program (SBP) must speak and read Spanish.

Do you have to be in this study?
Participation in the study is completely voluntary. Not participating will not affect in any way the care that the person living with dementia will receive. You are free to stop being part of the study at any time.

Procedures
The Stress-Busting Program is a 9 week group program. You will be asked to come to the study site once a week for approximately 90 minutes. The program is focused on learning to manage the stress in caring for a person living with dementia, and learning strategies to stay healthy. There will never be more than 10 caregivers in a group. The sessions in weeks 1 and 9 will be longer as samples of saliva and blood will be collected. Saliva is collected after 90 minutes of not drinking or eating, by allowing saliva to flow freely for 3 minutes in a plastic container. Blood is collected by inserting a small needle in a vein in the arm. Blood is collected in tubes, totaling approximately 3 tablespoons of blood. After processing saliva and blood tests, remaining samples will be entered into a repository for future studies.

Risks and Benefits
Your personal and identifying information will be kept strictly confidential. You will benefit from learning stress management techniques, strategies to deal with issues common in people living with dementia, and from the group interaction. You may experience emotional distress as you share with others your experiences. Giving saliva and blood presents minimal risks, mainly slight pain or discomfort at the site where the small needle is inserted to obtain blood. Occasionally there may be bruising to the site. Other caregivers may benefit in the future from what we learn in this study. In the event that there is disclosure of abuse or exploitation, we will report it to the proper agency to seek assistance for you to resolve those issues.

UT Health Science Center at San Antonio IRB Approved July 6, 2016

Costs and Compensation
There is no cost to you to participate. All the materials for the program will be provided free of cost to you. You will be compensated with a $10.00 (ten) gift card for each session you complete.

Confidentiality
Your identifying information will remain secure in a password protected folder in the South Texas Veterans Health Care System network. Only Drs. Arévalo-Flechas and Yeh will have access to your data. Other members of the research team will have access to data stripped from your name and other identifying information. During group sessions, a request is made to all caregivers in the group to maintain the confidentiality of what is discussed during the group sessions.

Contact Information
The main contacts for questions and comments will be Dr. Arévalo-Flechas at (210) 617-5197 and Ms. Alicia Conde MA at (210) 617 -5190. The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject, and take any comments or complaints you may wish to offer. You can contact the IRB by calling 210-567-8250, or by mail to IRB, UTHSCSA, Mail Code 7830, and 7703 Floyd Curl Drive, San Antonio, TX 78229-3900.

THIS FORM IS YOURS TO KEEP.