Reducing Agitation in Dementia Patients at Home: The Customized Activity Trial

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USA

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Reducing Agitation in Dementia Patients at Home: The Customized Activity Trial

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Alzheimer's disease & other dementias

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Acquired Cognitive Impairment... Aging... Alzheimer's Disease... Alzheimer's Disease including Alzheimer's Disease Related Dementias (AD/ADRD)... Behavioral and Social Science... Brain Disorders... Burden of Illness... Caregiving Research... Clinical Research... Clinical Research - Extramural... Clinical Trials and Supportive Activities... Dementia... Effectiveness Research... Mental Health... Neurodegenerative... Neurosciences... Patient Safety... Translational Research

Research Abstract
DESCRIPTION (provided by applicant): Over 5 million Americans have Alzheimer’s disease or a related dementia, a progressive and irreversible neurodegenerative condition, affecting also close to 15 million family caregivers (CG). A hallmark of the disease and one of the most significant challenges in dementia care is neuropsychiatric symptoms (NPS) of which agitation is the most disabling and frequently occurring. It is associated with increased health care costs, reduced life quality, heightened caregiver burden, disease acceleration and nursing home placement. Treatment typically involves pharmacologic agents; however, these are at best modestly effective, carry serious risks including mortality, and may not reduce family distress. Recently issued position statements from medical organizations suggest nonpharmacologic strategies as first-line treatment. Nevertheless, nonpharmacological strategies for agitation remain understudied. We propose a Phase III efficacy trial to test a novel 8-session patient-centric intervention, the Customized Activity Program (CAP). We will test CAP using a randomized two- group parallel design of 250 people with dementia (PwD) and their CGs (dyads) who will be randomly assigned to CAP or a control intervention of equivalent in-home attention and social contact. CAP assesses PwDs’ preserved capabilities, deficits, previous roles, habits, interests and home environment from which activities are developed to match PwD profiles. Families are trained to implement activities and modify them for future decline. A pilot phase with 60 dyads showed clinically meaningful and statistically significant reductions in agitation, with no adverse effects. Our primary study aim evaluates the effect of CAP at 3 months on agitation (Hypothesis: PwD in CAP will have lower clinician rated agitation compared to the control intervention condition. Three secondary aims evaluate: 1) 6-month effects of CAP on agitation and quality of life in PwD (Hypothesis: PwD in CAP will manifest lower clinician rated subscale severity scores at 6 months and better quality of life compared to PwD in the control intervention); 2) Immediate effects of CAP at 3 and 6 months on CG wellbeing, and time spent providing care (Hypothesis: CGs receiving CAP will report enhanced wellbeing and less time caregiving compared to the control intervention (3 and 6 months); and 3) Cost effectiveness of CAP expressed as an incremental cost outcome achieved in the form of CG burden reductions and willingness to pay for burden reductions (3 and 6 months; Hypothesis: CAP will be cost effective compared to the control intervention at each test occasion). Five exploratory aims will evaluate treatment effects on psychotropic medication use and other troublesome behaviors, if effects differ by cognitive status, if CGs receiving CAP use activities a 6 months and with what frequency, how time gained is spent, and if frequency/duration of treatment and activity use affects outcomes. If proven efficacious and cost effective, CAP has potential to transform clinical practice by offering a proven nonpharmacologic treatment for agitation of PwDs at home. This trial addresses a critical clinical need and public health priority identified by recent legislative activity.

Lay Summary
We propose an efficacy trial of a novel home-based nonpharmacologic intervention to reduce one of the most common, costly and troublesome neuropsychiatric behaviors of dementia,

agitation. The Customized Activity Program provides activities systematically customized to the unique cognitive, physical, social and interest profile of individuals with dementia in order to reduce agitation, enhance quality of life and improve caregiver wellbeing. As there is no cure for dementia or standard of care for treating agitation, developing and testing this novel nonpharmacologic approach to minimize the devastating consequences of this disease, is a major public health priority that can positively impact dementia care in the United States.

Further information available at:

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