

Reducing neuropsychiatric symptoms in persons with dementia and associated burden in family caregivers using tailored activities: Design and methods of a randomized clinical trial[☆]



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ABSTRACT

Among over 5 million people in the USA with dementia, neuropsychiatric symptoms (NPS) are almost universal, occurring across disease etiology and stage. If untreated, NPS can lead to significant morbidity and mortality including increased cost, distress, depression, and faster disease progression, as well as heightened burden on families. With few pharmacological solutions, identifying nonpharmacologic strategies is critical. We describe a randomized clinical trial, the Dementia Behavior Study, to test the efficacy of an activity program to reduce significant existing NPS and associated caregiver burden at 3 and 6 months compared to a control group intervention. Occupational therapists deliver 8 in-home sessions over 3 months to assess capabilities and interests of persons with dementia, home environments, and caregiver knowledge, and readiness from which activities are developed and families trained in their use. Families learn to modify activities for future declines and use strategies to address care challenges. The comparison group controls for time and attention and involves 8 in-home sessions delivered by health educators who provide dementia education, home safety recommendations, and advanced care planning. We are randomizing 250 racially diverse families (person with dementia and primary caregiver dyads) recruited from community-based social services, conferences and media announcements. The primary outcome is change in agitation/aggression at 3 and 6 months. Secondary outcomes assess quality of life of persons with dementia, other behaviors, burden and confidence of caregivers, and cost and cost effectiveness. If benefits are supported, this activity intervention will provide a clinically meaningful approach to prevent, reduce, and manage NPS.

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1. Introduction

Of 5+ million Americans with Alzheimer's disease or related disorders, most are cared for at home by over 15 million family caregivers [1]. A hallmark of dementia, and its most challenging and costly aspect, is neuropsychiatric symptoms (NPS). NPS, including agitation, aggression, irritability, apathy, rejection of care, depression and others, are almost universal, occurring across disease types and stages [2]. If untreated, NPS hasten disease progression, worsen daily functioning, impair quality of life, increase healthcare utilization, and accelerate nursing home placement [3,4]. For caregivers, NPS are associated with depression, worse quality of life, and increased time caregiving [5,6]. NPS account for a significant portion of the estimated \$152 billion spent annually in dementia care [7,8].

NPS are consistently under-detected and undertreated. If treatment occurs, it typically involves antipsychotics [9]. However, pharmacological options have modest to no benefits compared to placebo, with serious risks, including mortality in older adults with dementia [10]. One exception, Citalopram, reduced agitation in 186 patients [11], although with some adverse effects and further study is underway. Nevertheless, there are no medications for behaviors of most concern to families (e.g., rejection of care).

As dementia will affect over 16 million Americans in 2050 (Alzheimer's Association, 2015), a critical public health priority is reducing disease burden on families. Developing and testing behavioral care strategies provide an alternative treatment approach to prevent, reduce and/or manage NPS.

One promising nonpharmacologic approach is use of activities that capitalize on preserved capabilities and life-long social roles and interests. Evidence suggests that persons with dementia can effectively engage in activities graded to their abilities [12], resulting in reduced NPS ([13–15]). Tailored activities may afford engagement and positive affect, thus minimizing or preventing build-up of frustration and

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agitation, or other NPS [59]. Moreover, activities may fill a void, help to maintain roles, and enable positive expressions in persons with dementia [16]. Additionally, instruction to caregivers to effectively involve persons with dementia in activities may minimize supervisory time and enhance their own wellbeing. However, limitations of previous activity-based research include small sample sizes, lack of randomized trial methodology, poorly characterized samples, inattention to fidelity and caregiver abilities, and lack of control of therapeutic processes (e.g., attention) inherent in providing activity [17].

The Dementia Behavior Study tests the efficacy of a novel activity intervention to reduce NPS among community-dwelling persons with dementia and to enhance caregiver well-being. The intervention is compared to an intervention that controls for effects of empathy, validation, and attention. Unique to this trial is an analysis of cost, and cost-effectiveness and treatment fidelity, both of which are necessary for translation and wide-scale implementation if the intervention is effective. In addition to describing the study design, this paper highlights the interventions.

2. Study design

In a pilot randomized trial of 60 families, we demonstrated that tailoring activities to the capabilities and interests of persons with dementia, and training families in their use, can reduce the overall occurrence of NPS, specifically agitation, as well as reduce time spent caregiving by family members and improve confidence and wellbeing [14,18]. Building on our previous work, the Dementia Behavior Study is a randomized two-group parallel design with an expected enrollment of 250 community-dwelling persons with dementia and their primary caregivers (dyads).

Fig. 1 displays the study design and design elements are described below.

This is one of the few large-scale rigorously designed randomized clinical trials (RCT) to determine whether participation in activities

that match interests and abilities and account for caregiver readiness and environmental factors, reduces NPS. Similar trials and demonstration projects of this intervention are also underway in the Veterans Administration [19], Australia [20] and Brazil [21]. Also, this intervention (referred to as New Ways for Better Days, Tailoring Activities for Persons with Dementia and Caregivers [TAP]), is being used and evaluated in a variety of sites (Scotland, adult day services in the United States, England). However, the study trial described here includes design elements that distinguish it from other efforts and which elevates the science of activity intervention research in important ways as described in Table 1.

3. Research aims

3.1. Primary aim

The primary study aim is to evaluate the immediate effect of the activity intervention on the frequency and severity of agitation and aggression at 3 months. Our hypothesis is that persons with dementia in the activity intervention arm, compared to those in the control group intervention arm, will have a greater reduction in agitated/aggressive behaviors (frequency and severity) from baseline to 3 months as rated by primary caregivers using items from the Neuropsychiatric Inventory–Clinician Rating (NPI-C) subscales of agitation and aggression (21 items).

3.2. Secondary aims

One secondary aim is to evaluate the effects of the activity program from baseline to 6 months on behavioral symptoms, and quality of life in persons with dementia. We hypothesize that persons with dementia in the activity treatment arm compared to those in the control group intervention arm will have a greater reduction in agitated/aggressive behaviors (frequency and severity) from baseline to 6 months as rated by

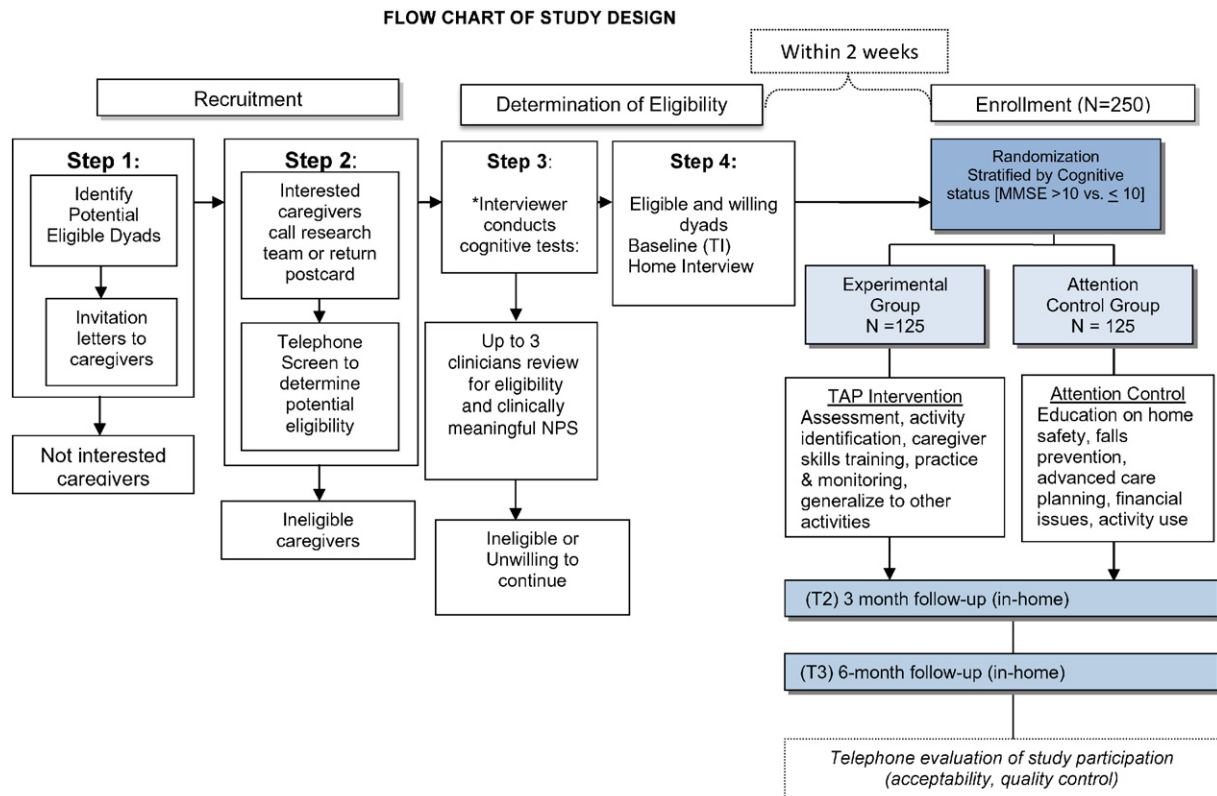


Fig. 1. Flowchart of Study Design.

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