

## **ii. Non-Pharmacological Strategies to Ameliorate Symptoms of Alzheimer's Disease**

**Competition objectives:** The Alzheimer's Association is launching a new initiative to stimulate the scholarly investigation and development of non-pharmacological strategies to improve the care of persons with Alzheimer's disease and related disorders (ADRD). The Association's Request for Applications (RFA) is aimed at the identification, validation and investigation of non-pharmacological approaches to improve the care of older adults with ADRD. This includes the investigation of new approaches, extension of existing approaches, and development of methodological strategies to improve the conduct of clinical and translational research of non-pharmacological treatments of ADRD.

The RFA is designed to enable preliminary pilot research or proof-of-principle studies that can provide data for further research support by other funding agencies. This RFA focuses on the science of conducting and evaluating non-pharmacological interventions for the treatment of ADRD, whether independently or in conjunction with pharmacological approaches.

**Background:** Non-pharmacologic approaches to intervention have promise for ameliorating many symptoms of Alzheimer's disease. Despite this, non-pharmacological trials using state-of-the-science methodologies are few in number. This RFA therefore focuses on both proposals for trials themselves and proposals for research that moves the field forward by improving the conduct and analysis of these trials. These interventions can be formulated either independently or in conjunction with pharmacological approaches.

The Association aims to keep open the pipeline for the development of new non-pharmacological treatments as well as the investigation and translation of existing non-pharmacological treatments that have the potential to significantly improve the care of persons with ADRD.

**Potential themes:** Based on discussions with its Medical and Scientific Advisory Council, the Association puts forth several themes that may be particularly worthy of further research. These themes are each designed to move the science of non-pharmacological treatment forward and include:

- (a) research on non-pharmacological treatments (e.g., behavioral therapies, cognitive-behavioral management, exercise, environmental manipulations, etc.);
- (b) studies engaging different “targets” for treatment delivery and treatment receipt (e.g., family caregivers, staff, health care professionals, etc.);
- (c) studies using diverse methods of investigation (e.g., multimodal/multimethod design, randomized clinical trials (RCTs), efficacy, effectiveness trials, translational studies, etc.);
- (d) studies focusing on improving key aspects of methodology relevant to non-pharmacological trials (e.g., study design, outcome measures, methods of analysis, etc.); and
- (e) studies focused on translation of promising programs into the field.

Note that “non-pharmacological treatments” is broadly defined and can include any and all methods designed to improve outcomes that are not pharmaceutically based. Grant proposals could address, but are not limited to, the following areas of study:

1. **Non-pharmacological intervention studies that incorporate state-of-the-science methodologies to investigate outcomes.** Research projects in this category may include but are not limited to interventions designed to improve affected individuals’ care, quality of life, functional status or health services utilization and reduce behavioral disturbance or cost. Studies can incorporate persons with ADRD, their family care providers or staff or health care professionals involved in the treatment of individuals with ADRD.
2. **Research on improving methodologies to be employed in non-pharmacological trials.** Research projects in this category may include investigating strategies for implementation, evaluation and standardization of treatment fidelity in community-based or long-term care settings; development and testing of standardized manuals for treatment dissemination; or development or elaboration of scientific methods for investigation of non-pharmacological treatment studies of ADRD.

3. **Evaluation of new non-pharmacological approaches that have a conceptual and/or empirical basis for potential to impact patient outcomes.** Research projects in this category may focus on the development and evaluation of innovative programs that have not yet been subjected to RCTs. Such projects will develop and make available standardized protocols for treatment delivery and evaluation. They will employ outcomes that are psychometrically sound and clinically relevant in domains of value to persons with ADRD and their care providers (e.g., behavioral disturbance, cognitive impairment, health care costs, etc.)
4. **Research that moves promising non-pharmacological interventions for treatment of ADRD into the field (i.e., community or clinical practice) using state-of-the-science translational research methods.** Research projects in this category may be translational in nature, taking existing therapeutic modalities (such as environmental and behavioral) and investigating how to move these programs from research protocols to community application. Projects may include feasibility, efficacy and effectiveness studies, among others. Projects in this category would most likely depend upon partnerships between researchers and the clinical setting of interest.

**General considerations:** Any proposal must have a clear focus on ADRD and on non-pharmacological treatments. All proposals must clearly and explicitly outline the treatment to be investigated, the methods for study, sample, outcomes, etc. The ultimate goal is to move the science of non-pharmacological treatments forward and facilitate the translation of evidence-based programs into practice.

The Alzheimer's Association recognizes the need to increase the number of scientists from underrepresented groups in the research enterprise. Researchers from these groups are encouraged to apply.

**Funding and award period:** The Association anticipates funding 2 non-pharmacological approaches for ADRD awards. Each award is limited to \$400,000 (direct and indirect costs) for two to three years. Requests in any given year may not exceed \$200,000 (direct and indirect costs). Indirect costs are capped at 10 percent (rent for laboratory/office space is expected to be covered by indirect costs paid to the institution).

**Eligibility:** Researchers with full-time staff or faculty appointments are encouraged to apply. Applications from post-doctoral candidates will not be accepted.

**Deadlines and award dates:** Letters of intent must be received by 5:00 PM EASTERN STANDARD TIME, December 1, 2009. Letters of intent will not be accepted after this date. No exceptions will be made.

**Applications must be received by 5:00 PM EASTERN STANDARD TIME, January 7, 2010.** Scientific and technical review will be conducted from February through May 2010.

The second-level review by the Medical and Scientific Advisory Council will be conducted during June 2010. Funding will be awarded by July 2010.

**Mechanism of award, reporting requirements and allowable costs:** The mechanism of the award is the individual research grant. The maximum allowable duration is three years. Annual progress and financial reports are required. Continuation of the grant over the awarded duration is contingent upon the timely receipt of scientific and financial reports.

**Budget:** A “budget summary” for the proposed research project is required and must be submitted with the application and within the allowable page limits. However, if the application is to be awarded, a more detailed budget will be required and must be approved before the disbursement of funds. Your budget must not exceed the maximum amount of the award (\$400,000 for Non-Pharmacological Treatments for ADRD).

**Allowable costs under this award:**

It is required that most of the funds awarded under this program be used for direct research support.

**Allowable costs under this award include:**

- Computer equipment if used strictly for data collection
- Travel (up to \$1,000 per year)
- Salary for the principal investigator, scientific (including post-doctoral fellows) and technical staff (including interviewers, interventionists, data entry staff, technicians, and administrative support staff whose work is directly related to the funded project)
- Manual production/development/website, etc.

**Costs not allowed under this award include:**

- Tuition
- Computer hardware or software for investigators
- Rent for laboratory/office space
- Construction or renovation costs

***For more information:*** E-mail [grantsapp@alz.org](mailto:grantsapp@alz.org) or call 312.335.5747.