



Notice of Funding Opportunity: Testing Mechanisms of Benefit in Tailored Home and Community-Based Dementia Care Interventions

The Establishing Mechanisms of Benefit to Reinforce the Alzheimer's Care Experience (EMBRACE) AD/ADRD Roybal Center ([RFA-AG-24-007](#)) will support trials that test mechanism-driven, tailored interventions in home- and community-based contexts. Our Center is particularly interested in dementia care interventions that:

- 1) Tailor their intervention components to the needs of individuals living with AD/ADRD, their care partners, or others);
- 2) Target one or more levels of influence (e.g., individuals living with AD/ADRD; the living environment; the family/social network/provider; and/or the neighborhood and community); and
- 3) Identify, measure, and test mechanisms of action (i.e., causal drivers that specify why an intervention works, such as constructs representing self-regulation, stress resilience, or social/interpersonal processes that influence a desired behavior change).

EMBRACE requests applications to support a 1- to 2-year award for a clinical trial that tests mechanisms of action for tailored home- and community-based dementia care interventions. Proposed trials should demonstrate high potential to advance to later stages of the [NIH Stage Model for Behavioral Intervention Development](#) for further testing, dissemination, and/or implementation. EMBRACE will support one trial in the upcoming year of funding with a maximum total cost of \$200,000 per year. Pending approval from the National Institute on Aging (NIA), EMBRACE trials will begin on June 1, 2025.

Eligibility

Per [RFA-AG-24-007](#), "Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the PI(s) for Roybal clinical trials is invited to work with his/her organization to develop an application for support. The eligible PIs for Roybal clinical trials include, but are not limited to, junior investigators, investigators from diverse backgrounds including those from underrepresented groups, and established investigators at the Center institutions or at outside institutions, or in association with academic and/or corporate partners."

As stated in [RFA-AG-24-007](#), EMBRACE will support preliminary clinical trials in any stage of the [NIH Stage Model for Behavioral Intervention Development](#). Supported trials may: "1) leverage a

Stage 0 basic research finding to create a potent implementable intervention, defined by its principles; 2) examine the principles, or mechanism of action underlying a behavioral intervention, in all Stages of research); 3) create and/or modify, and conduct preliminary testing of real-world-friendly training procedures (Stage I) and further test these procedures (Stage III), as appropriate, before progressing to Stage IV; and 4) create and/or modify and pilot test and test methods to maximize real-world fidelity (Stage I and III) to maximize successful later-Stage real-world clinical trials.”

An important consideration for any funded EMBRACE trial is the presence of *adequate statistical power to test the proposed mechanism of action and/or efficacy of the dementia care intervention*. EMBRACE values trials that are inclusive; trials “may involve creating, adapting, and/or testing interventions that are designed to be feasible and acceptable across multiple races and ethnicities; conducting studies that seek to determine the mechanisms through which an intervention may have efficacy for one group of individuals, but not for another, where the elucidation of mechanisms informs the development of precision interventions targeting the specific processes requiring modification” ([RFA-AG-24-007](#)).

Evaluation Criteria

We will apply the following criteria when considering EMBRACE trial applications: a) significance/innovation of idea; b) clearly identified and measurable mechanism of action (e.g., Science of Behavior Change mechanisms such as self-regulation; stress resilience; and/or interpersonal/social processes); c) clearly-specified intervention target level (individual living with dementia; caregiver; living environment; and/or neighborhood community); d) inclusion of a tailored intervention delivered within home and/or community settings; e) potential of the trial to yield high-quality data leading to future extramural funding at a subsequent stage of the NIH Stage Model; f) scientific merit and feasibility of design/analysis; and g) a focus on diverse samples.

Application Process

The first step in applying for EMBRACE funding is to complete our Letter of Intent (LOI) form, available [here](#). A traditional LOI is not required. Please provide the following information via the LOI form:

- Principal Investigator (PI)/Multiple Principal Investigator (MPI) name(s), institution(s), and background information
- Title of proposed project
- The dementia care/caregiving challenge addressed
- Intervention proposed and hypothesis
- Mechanism of action targeted
- Level of influence targeted
- A Specific Aims page
- An NIH-formatted biosketch for PI. For formatting guidelines and examples, please see [here](#).

The EMBRACE Behavioral and Intervention Development Core would be happy to discuss proposal ideas or answer related questions from potential applicants. Please email embrace@umn.edu to schedule a time to do so.

Completed Letters of Intent (again, via the LOI form [here](#)) are due on November 20, 2024, at 5 PM CST. Applicants with highly promising LOIs will be invited to submit a full EMBRACE trial application no later than December 15, 2024.

These select applicants will have the opportunity to consult with the EMBRACE Behavioral and Intervention Development Core to review design, innovation, and alignment before submitting a full application, which is due February 1, 2025.

EMBRACE trials will be selected no later than March 1, 2025, with an anticipated start date of June 1, 2025, contingent on NIA approval.