



The University of Minnesota Establishing Mechanisms of Benefit to Reinforce Alzheimer's Care Experience (EMBRACE) AD/ADRD Roybal Center 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).

Please note the following information for your application:

Eligibility:

- 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 junior, mid-career, and established investigators at Roybal Center institutions, outside institutions, or in association with academic and/or corporate partners.
- EMBRACE will support preliminary clinical trials in any stage of the NIH Stage Model for Behavioral Intervention Development.
- Supported trials may:

- leverage a Stage 0 basic research finding to create a potent implementable intervention, defined by its principles;
 - examine the principles, or mechanism of action underlying a behavioral intervention, in all Stages of research);
 - 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;
 - create and/or modify and 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.

Number of Awards

- 1-2 awards will be issued during this funding cycle.

Award Amount

- Total Costs (direct + indirect costs): up to \$200,000

Duration

- 1-2 years, with an anticipated project start date of June 1, 2027, pending NIA approval.

Evaluation Criteria

- We will apply the following criteria when considering EMBRACE trial applications:
 - See EMBRACE Evaluation Criteria: <https://embraceroybal.wisc.edu/funding/>

Application Process:

1. Letter of Intent (LOI) Application:

- **Due Date: October 1, 2026**
- **Prior to submitting LOI applications, a 30-minute consultation with our team is strongly encouraged. EMBRACE offers applicants 1:1 consultations to discuss your LOI. To schedule a consultation, please visit: <https://z.umn.edu/EMBRACELOIConsultation>. If you are unable to**

meet during any of the available consultation times, please email embrace@umn.edu. Consults must be scheduled 48 business hours ahead of the consult date/time. The last date to request scheduling a consult is September 21, 2026.

- Your LOI application will ask for the following:
 1. Applicant Information
 2. PI(s) NIH Biosketch(es)
 3. Project Details including Study Rationale, Study Design, and description of chosen mechanism(s).
 4. Specific Aims: 1-page limit, with an additional reference page, if needed, including text detailing:
 - Title of proposed project
 - The dementia care/caregiving challenge addressed
 - Intervention proposed and hypothesis
 - Mechanism of action targeted
 - Level of influence targeted
 5. Proposed Project Duration and Study Timeline

We strongly recommend applicants:

1. Become familiar with CLIMBR. CLIMBR language should inform your aims and full application. Please view the EMBRACE co-sponsored CLIMBR webinar to learn more, if you have not already done so. The webinar recording can be found at:

z.umn.edu/embracewebinars

- Also see: Birk, J. L., Otto, M. W., Cornelius, T., Poldrack, R. A., & Edmondson, D. (2023). Improving the Rigor of Mechanistic Behavioral Science: The Introduction of the Checklist for Investigating Mechanisms in Behavior-Change Research (CLIMBR). *Behavior therapy*, 54(4), 708–713.

2. Review our executive committee’s webinar: “Why and How a Behavioral Intervention Works: A Panel Discussion Exploring Mechanisms.” The webinar is posted at:

<https://embraceroybal.wisc.edu/events/>

3. Review our series of five guidance documents on mechanistic research. They can be found at: z.umn.edu/EMBRACEresources

4. Review our LOI 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; and f) scientific merit and feasibility of design/analysis.

6. You may also wish to view our FAQ: <https://embraceroybal.wisc.edu/wp-content/uploads/sites/2289/2025/08/EMBRACE-FAQ.pdf>

2. Full Proposal Application

- **Due Date: December 7, 2026**
- If an LOI is accepted, applicants are encouraged to schedule the following consultations:
 - EMBRACE Proposal Consultation: Applicants must participate in a consultation to discuss the overall proposal prior to the submission of their full application. For EMBRACE consultations, please contact the EMBRACE team at embrace@umn.edu
 - Statistical Consultation: Applicants may elect to receive a complimentary statistical consultation on study design through the Roybal Coordinating Center. If interested in statistical consultation, please contact RoybalNIACenters@northwell.edu.

Applicants must submit a full proposal that includes the following:

1. Roybal Clinical Trial Proposal Template with project details including study rationale, study design, and description of chosen mechanism(s).
2. Specific Aims, Research Strategy, and References
 - Specific Aims: 1-page limit, including text detailing:

- Title of proposed project
 - The dementia care/caregiving challenge addressed
 - Intervention proposed and hypothesis
 - Mechanism of action targeted
 - Level of influence targeted
 - Research Strategy: All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed (R21 page limits/6 pages apply)
 - References should be placed at the end of the Research Strategy document. They are not included in the Research Strategy's page count.
- 3.** Protection of Human Subjects plan: Please submit a Protection of Human Subjects plan (PDF attachment only; see G.500 section 3.1) <https://grants.nih.gov/grants-process/write-application/how-to-apply-application-guide>
- 4.** PI(s) and Key Personnel Biosketches
- 5.** Detailed Budget and Budget Justification - Please submit in R & R format.

For additional information and questions relating to EMBRACE's application process, please contact us at embrace@umn.edu. You may also wish to view our FAQ: <https://embraceroybal.wisc.edu/wp-content/uploads/sites/2289/2025/08/EMBRACE-FAQ.pdf>

For logistical support in completing the application forms, please contact the Northwell Roybal Coordinating Center at RoybalNIACenters@northwell.edu.