



## Frequently Asked Questions (FAQs)

### 1. What intervention targets are supported by EMBRACE?

EMBRACE supports four levels of intervention target (as shown in the socioecological model below): individuals with dementia, caregivers, living environment, and/or neighborhood/community settings.

EMBRACE does not support trials targeting service systems or policy. Please note that while assisted living facilities settings are considered an eligible home and community-based setting supported by EMBRACE trials, skilled nursing care facilities (nursing homes) are not.

### Socioecological Model



Adapted from: Gitlin LN, Hodgson N. Better Living with Dementia: Implications for Individuals, Families, Communities, and Societies. Elsevier Academic Press; 2018.

### 2. What is a mechanism?

Mechanisms are processes (i.e., biological, behavioral, social, and/or environmental) through which an intervention influences a key outcome. Some example mechanisms you may consider include constructs representing self-regulation, stress resilience, or social/interpersonal processes that influence a desired behavior change. The mechanisms are also shown in the figure below, categorized into the four target levels of intervention influence supported by EMBRACE.

## Examples: Tailoring Mechanisms of Action



**Neighborhood/community:** safety; community-based agencies; transportation, religious outlets; access to shopping, care, and services; social capital



**Living environment:** type of housing; accessibility; safety/security; level of stimulation; adaptive equipment; home repairs; persons in living space



**Caregivers:** health, physical, emotional, cognitive; knowledge, skills, motivation; social supports; employment/financial status; location in life course; relationship/closeness; values, beliefs, style



**Individual with dementia:** neurobiological (cognitive status, executive function, disease stage); health (comorbidities, health status); behavioral/psychological (behavioral symptoms, affect/depression/anxiety); social (social compartment, interests, hobbies, occupations, socio-cultural background)

From: Gitlin LN, Hodgson N. *Better Living with Dementia: Implications for Individuals, Families, Communities, and Societies*. Elsevier Academic Press; 2018.

Additional information on mechanisms and behavior change can be found on the EMBRACE website, including:

- EMBRACE’s webinar recordings. Each webinar is focused on important aspects of mechanistic research, including the EMBRACE Executive Committee’s presentation “Why and How a Behavioral Intervention Works: A Panel Discussion Exploring Mechanisms.” [z.umn.edu/EMBRACEwebinars](http://z.umn.edu/EMBRACEwebinars).
- Dr. Gitlin and Dr. Hodgson, co-leaders of the Behavioral Intervention Development Core have written a series of five guidance documents on mechanistic research as well [z.umn.edu/EMBRACEresources](http://z.umn.edu/EMBRACEresources).

Also see:

Nielsen, L., Riddle, M., King, J. W., NIH Science of Behavior Change Implementation Team, Aklin, W. M., Chen, W., Clark, D., Collier, E., Czajkowski, S., Esposito, L., Ferrer, R., Green, P., Hunter, C., Kehl, K., King, R., Onken, L., Simmons, J. M., Stoeckel, L., Stoney, C., ... Weber, W. (2018). [The NIH Science of Behavior Change Program: Transforming the science through a focus on mechanisms of change](#), 101, 3-11.

Gitlin, L. N., Corcoran, M., Martindale-Adams, J., Malone, C., Stevens, A., & Winter, L. (2000). Identifying mechanisms of action: Why and how does intervention work? In R. Schulz (Ed.), *Handbook on dementia caregiving: Evidence-based interventions for family caregivers* (pp. 225–248). Springer Publishing Company.

**3. Will EMBRACE support evaluation using a physiological mechanism?**

Yes, however, the mechanism needs to be aligned/directly linked to public health outcome measure.

**4. Can we identify more than one mechanism?**

Yes, you can specify more than one mechanism. All mechanisms need to be aligned/directly linked to specified outcome measures. Please consult with your statistician regarding how this may impact your power analysis.

**5. The aims page specifies a 1-page limit. Can I use references?**

Feel free to use a second page for your references.

**6. Should I expect to receive a confirmation of my LOI submission?**

Yes, all applicants will receive an email confirmation upon submitting an LOI. If you do not, please contact [EMBRACE@umn.edu](mailto:EMBRACE@umn.edu).

**7. Who can apply for EMBRACE funding?**

Eligible PIs for Roybal clinical trials include junior, mid-career, and established investigators. Per NIH regulations, we are unable to support international researchers at this time. See Section III for eligible applicants [HERE](#).

**8. Does an EMBRACE award include both direct and indirect costs?**

Yes, EMBRACE awards reflect *total* costs, inclusive of both direct and indirect costs.

Since EMBRACE is funded by NIH, we honor your use of any negotiated rates or the Modified Total Direct Cost (MTDC). We defer to you, as the applicant, to determine whether you or your organization wishes to waive, modify, or rely on your standard indirect cost rate. Additionally, if your application involves a subaward to another site, that site/sub may use whatever their federally negotiated indirect rate is.

**9. Who is the sponsor organization?**

The Establishing Mechanisms of Benefit to Reinforce the Alzheimer's Care Experience (EMBRACE) Alzheimer's Disease and Alzheimer's Disease Related Dementia (AD/ADRD) Roybal Center Trial Research Grant Program is funded by

the National Institutes of Health - National Institute on Aging. Awardees will be issued a subaward from the University of Minnesota.

**10. How do I prepare for an EMBRACE consultation and who should attend?**

- Please send any questions in advance of your consultation, so that our leadership team can prepare for your consultation. Questions can be sent to [EMBRACE@umn.edu](mailto:EMBRACE@umn.edu).
- Anyone from your team is welcome! We *highly recommend* having your statistician attend the consultation as well.
- During the consultation, be prepared to give a brief overview of proposed trial.