

Inclusion of Individuals Across the Lifespan

This feasibility study will enroll older adults aged 75 years and older. The lower age boundary is intentional and is consistent with the established I-CONNECT operational criteria used in prior work with socially isolated older adults at elevated risk for cognitive decline. We will not exclude participants on the basis of advanced age alone; instead, eligibility will be based on cognitive status, social isolation criteria, safety screening, and ability to provide informed consent. Because the scientific objective is to evaluate feasibility of an artificial intelligence-delivered conversational protocol in this high-risk older population, excluding younger age groups is a scientific design choice rather than a convenience-based restriction.

The investigative team includes experts in neurology, gerontology, biostatistics, and computer science with prior experience conducting conversational intervention studies in older adults. Recruitment and study procedures will be supported through the Memory Division at Mass General Brigham (MGB) and the Massachusetts Alzheimer's Disease Research Center (MADRC), with staff oversight for weekly emotional status and safety check-ins during participation. The available facilities and staffing structure are appropriate for older adults with mild cognitive impairment (MCI) and normal cognition (NC), including those with limited prior technology experience.

The planned age distribution supports meaningful analysis because the target population for this project is older adults with limited social interaction, the group for whom scalable home-based delivery is most needed. The balanced enrollment target across cognitive strata (MCI and NC) will support feasibility interpretation across two clinically relevant subpopulations while remaining within the scope of this feasibility study.

For existing resources, we will use prior I-CONNECT conversation data for model adaptation and protocol translation. In Table 1 of the published I-CONNECT topline report, the randomized sample size was 186, including 130 women (69.9%) and 56 men (30.1%); race was reported as 149 White participants (80.1%) and 37 participants who were not White (19.9%). Ethnicity categories were not reported separately in that table. We will account for these characteristics when interpreting generalizability and will report prospective enrollment through the Inclusion Enrollment Report (IER), with separate report entries prepared as needed for distinct study components.