A black background with white text

Description automatically generated

**Clinical Trial LOI and Proposal Template**

Writing Template and Guidance

* LOI is limited to 2-single spaced pages with 1-inch margins.
* Full Proposal is limited to 6-single spaced pages with 1-inch margins.

1. **Study Goals and Specific Aims**

*Briefly describe the goals of the proposed clinical trial. List the study Specific Aims and whether each aim is fully-powered, qualitative, or exploratory.*

1. **Study Rationale**

*Succinctly describe the rationale for the proposed clincial trial and relelvance to older adults living alone with cognitive decline.*

1. **Study Design/Stage of Behavioral Intervention Development**

*Describe the study design (e.g., RCT, MOST design, single-case within-subjects design), and study arms or conditions.*

**Stage of Behavioral Intervention Development**

1. *What Stage (*[***Stage 0, I, II, III, IV, or V***](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development)*of the NIH Stage Model) of research is being proposed?*
2. *Is more than one* [*Stage*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *of research being proposed? If so, please indicate all of the proposed* [*Stages*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *and proposed stopping rules before proceeding to a subsequent* [Stage](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development)*.*
3. *For each* [*Stage*](https://www.nia.nih.gov/research/dbsr/nih-stage-model-behavioral-intervention-development) *proposed, please explain why the research activities proposed fall under the specific Stage suggested.*
4. *Describe the plan to advance to the next Stage research and the NIH funding mechanism(s) to support it*

**Masked or Blinded Design?**

*If yes, list who is masked or blinded (e.g., considering participant, care provider, PI, statistician, other study team members).*

1. **Study Protocol including duration of participant involvment and study timeline.**

*Briefly describe the protocol (e.g., how participants are enrolled, key procedures, proposed timeline of study). Indicate time (e.g., in months) it will take for each individual participant to complete all study-related tasks after enrollment.* ***Example:*** *Each participant will complete a baseline screening, 8 weekly intervention sessions, and 2 follow-ups at 6 months and 12 months. Total anticipated time for a participant to complete the study is 15 months.*

1. **Study Population, Sample Size & Statistical Power**

*Specify who will be recruited, providing key characteristics like general health status and demographics (e.g., age range, gender, race/ethnicity) and enrollment of populations with health disparities.*

*State target accrual and estimated dropout rate.* ***Example:*** *300 participants will be enrolled to meet a final sample of 240 participants, estimating a 20% drop-out rate.*

*Has a power analysis been completed? Describe whether there is sufficient statistical power to answer the primary research question(s). If different from the primary research question(s), describe whether there is sufficient statistical power to test for: a) efficacy outcomes, b) mechanistic target outcomes, and c) core or essential component outcomes.*

1. **Description of Behavioral and Lifestyle Intervention(s)**

***New Intervention:***

* **Brief Description of Intervention**
* *Briefly describe all interventions in the proposed CT. Example: Intervention # 1(Replace with name) is intended to improve emotion regulation skills and ultimately to improve mood. It is a 12-session (four 3-week modules) intervention, delivered over a 12-week period by community-based social workers. The four 3-week modules are: 1), 2), 3), 4).*
* **Core or Essential Elements**
  + ***For interventions with multiple components:*** 
    - *Specify the hypothesized core elements/components/ingredients of the intervention.*
    - *Specify the proposed method to determine the essential elements/components/ingredients of the intervention.*
    - *Identify the hypothesized mechanism(s) of behavior change of each core element/component, and the proposed method to test the hypothesized mechanism(s)*
  + ***For single component interventions:*** 
    - *Identify the hypothesized mechanism(s) of behavior change of the intervention, and the proposed method to test the hypothesized mechanism(s)*

***Adaptation of Existing Intervention:***

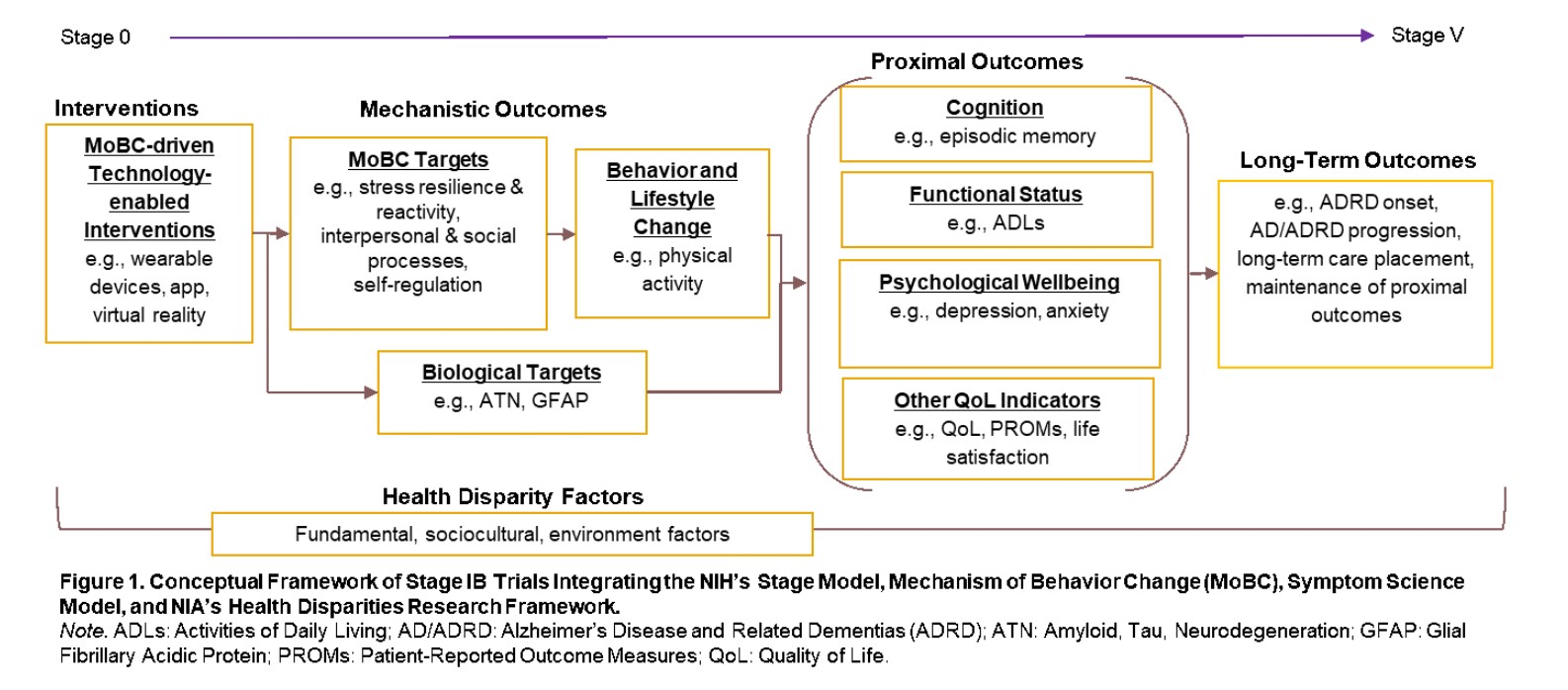
* **Adaptation*:*** *If proposing a Stage I study to adapt, modify, or refine an existing intervention:*
  + *List the existing intervention you are modifying and what specific changes you will make, including rationale for modification:*
  + *Are you proposing to adapt the core elements of an existing intervention, related to the hypothesized mechanism(s) of change of the intervention?* 
    - *If so, what are the PROPOSED CHANGES TO THE INTERVENTION?*
    - *Based on hypothesized mechanisms of behavior change, what is the rationale for this modification?*
  + *Are you proposing to adapt aspects of an existing intervention, unrelated to the hypothesized mechanism(s) of change of the intervention?* 
    - *If so, what are the PROPOSED CHANGES TO THE INTERVENTION?*
    - *Based on hypothesized mechanisms of behavior change, what is the rationale for the modification?*

***Both New Interventions and Adaptation of Existing Interventions Must Explain:***

* **How intervention(s) are enabled by technology**
* **How the intervention(s) are testing ASU Roybal Center’s Conceptual Framework**
* **Intervention dose and delivery:**
  + ***Number of Modules*** *(e.g., topics to cover in the intervention)*
  + ***Number of Sessions*** *(e.g., meetings, visits)*
  + ***Length of Sessions*** *(e.g., 60 minutes)*
  + ***Method of Intervention Delivery*** *(e.g., web-based, face to face, virtual, phone call)*
  + ***Intervention Provider*** *(e.g., M.A. level research staff, formal care providers in nursing homes, occupational therapists in community health-care settings, etc.)*
  + ***Fidelity considerations*** (e.g.,*Briefly outline how your study will address intervention fidelity. Indicate the fidelity measure you will use and the methodology you will use to collect data for this measure. For interventions that require delivery by individuals in the community, outline how and when materials will be developed to train these individuals to administer the intervention correctly and how any issues of sustained administration fidelity will be addressed.*

**Behavioral Intervention Details** (*Create a new table for each intervention.) \*****Required for full proposal, but optional for LOI.***

|  |  |
| --- | --- |
| **Intervention Name** | **Explanation** |
| **Brief Description** |  |
| **Core Elements (Essential ingredients)** |  |
| **Enablement by Technology** |  |
| **Test of ASU Roybal Center’s Conceptual Framework** |  |
| **Number of Modules** |  |
| **Number of Sessions** |  |
| **Length of Sessions** |  |
| **Method of Intervention Delivery** |  |
| **Intervention Provider** |  |

****