STATISTICAL ANALYSIS PLAN

Refinement and Pilot Testing of the "My Health Priorities" Program for Rural and Underserved Older Adults with Multiple Chronic Conditions in the Deep South (MyHP-South)

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Sponsor: The University of Alabama at Birmingham

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NCT Number: Not Available

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4.3 STATISTICAL DESIGN AND POWER

This study is a Stage 1a/1b pilot designed to refine and assess the feasibility and acceptability of the My Health Priorities (MyHP) Program. Consistent with NIH guidance for early-stage intervention development, formal power calculations are not appropriate, as the primary objectives are feasibility, acceptability, and usability rather than hypothesis testing or estimation of intervention effects.

The planned sample includes 20 older adult–family caregiver dyads and 4 clinicians, which is appropriate for evaluating feasibility metrics, identifying implementation challenges, and obtaining in-depth qualitative feedback to inform intervention refinement. This sample size is sufficient to assess recruitment and retention rates, session completion, usability, and data collection procedures, as well as to identify patterns in participant experiences.

Quantitative data will be analyzed using descriptive statistics, including frequencies, proportions, means, and standard deviations, to summarize feasibility outcomes (e.g., recruitment, retention, and completion rates) and usability ratings. Pre- and post-intervention measures will be examined descriptively to assess patterns of within-person change and to evaluate the performance and burden of candidate outcome measures.

Qualitative data from semi-structured interviews will be transcribed and analyzed using an iterative constant comparative approach and thematic content analysis to identify themes related to acceptability, usability, and cultural and contextual relevance of the intervention.

No formal hypothesis testing or effect size estimation will be conducted. Findings from this pilot will be used to refine the intervention and inform the design and power calculations of a future, fully powered randomized trial.