

Study Document

Project Title: Caring for Dementia Caregivers in Ethnic Immigrant Communities

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The project will include three sites (CA, TX, FL), which represent a continuum of Korean population density; 30%, 6%, and 3% of the total Korean residents in the United States live in the respective states.⁸⁵ These are the sites included in the PI's NIA R01 SOKA study, and community partnerships and collaborations among site PIs have been firmly established. Given that ethnic population density and the availability of ethnic resources fundamentally shape the lives of older immigrants,^{86,87} site variations will be an important context for service delivery. We recognize the need to accommodate these variations during the project phase. As described earlier, we will employ FRAME as a tool for decision-making and documentation of modifications. Each site will be directed by its site PI (CA by Jang, TX by Kwak, FL by Park). All site PIs are originally from Korea and experienced with the use of FRAME. They have also been actively engaged in community-based research in their respective local Korean communities and established a long history of collaborations with one another. For example, Park served as a Co-I on Jang's NIA R01 SOKA study and coauthored more than 70 peer-reviewed articles with Jang. The new leadership in the TX site includes Kwak and Fingerman, whose combined expertise in dementia care, family relationships, and cultural diversities strengthens our team. Both of them have a record of collaboration with the PI Jang and Co-I Haley. The PI, Jang, was formerly affiliated with the University of South Florida and the University of Texas at Austin and had built an initial foundation for community partnerships in Tampa and Austin. The PI also developed a series of Area Resource Databases in the target metropolitan areas (Los Angeles, Austin, Tampa), listing all resources and services specific to Korean communities. With an administrative supplement from NIA, she also developed a database of AD/DRD-related resources and services in general and in Korean communities in the Los Angeles area. These databases will be updated and used for the continuing community engagement effort.

Formation of Community Advisory Boards. At each site, we will invite 7-8 members for a Community Advisory Board (CAB), including community leaders and social service providers. Given the site variations in ethnic communities and service environments, it is imperative to establish regional CABs. Unique to the CA site, two K-Savvy graduates from the R21 will join the CAB. We will engage the CABs throughout the project phase, actively seeking their input on planning, reconciliation, implementation, evaluation, and dissemination. The PI will develop a protocol for the CAB discussion along with other site PIs, and the standardized protocol will be used. At each site, in-person CAB meetings will be held quarterly throughout the project phase. Each site PI will lead the CAB discussion, and another bilingual research staff will be present to prompt the discussion. PI Jang will consolidate the input from each site and share the key issues at monthly investigator Zoom meetings. Investigators' feedback will be solicited to make an immediate accommodation to the plans.

Savvy Trainer Selection and Training. Using the protocol from our previous effort, which was based on the SCP protocol and the Center for Disease Control's model of community health workers,^{69,70} two individuals at each site who are bilingual in English and Korean ($n = 6$) will be selected and trained to serve as K-Savvy trainers. Consultant Han, who has successfully completed CHW-based health promotion interventions in Korean American communities, will assist with the process. We will recruit the interventionists from ongoing community engagement efforts and CAB referrals. Training will be conducted with the SCP Trainer Certification Program offered by the SCP authors in English, which is an established asynchronous online program, and the K-Savvy TTT Program offered by the PI in Korean via real-time Zoom meetings. Using the pre/post-test design, each trainer will be evaluated for the improvement in knowledge, role competence, and satisfaction with program with the measures successfully used in Jang's R21 project.¹³ As the K-Savvy TTT program is in a formative stage, input from trainers will be actively sought. Given the positive training outcomes observed in the pilot-testing, along with the fact that an additional training with cultural relevance is to be augmented, we are confident that the trainers will be well-equipped for program delivery. We will host a retreat where all trainers meet with the Savvy originator (Hepburn) and two K-Savvy former trainers (S. Yoon and J. Kim) who had worked on K-Savvy pilot-testing and TTT content development. We will make every

effort to ensure the retention of all trained trainers throughout the project phase. However, in a potential case of trainer attrition, the former trainers will serve as reserves. All sessions will be observed upon agreement with trainers and caregiver participants, and fidelity will be monitored using the Trainer Performance Checklist. Incorporating trainer feedback, the TTT program will be refined and digitalized. We believe that the K-Savvy Online TTT Program production will help foster workforce development of competent K-Savvy trainers and enhance program sustainability. This effort will be led by Jang, Hepburn, and Haley who have expertise in SCP, K-Savvy, and training program development.

Caregiver Recruitment. We will recruit a total of 150 caregiver participants across the sites (72 in CA, 48 in TX, 30 in FL). The proportional sample size was based on the Korean population density: about one third of all Korean immigrants in the U.S. reside in California, 6% in Texas, and 3% in Florida.⁸⁵ In the NIA R01 SOKA survey, our sample size also proportionately reflected the ethnic density. Eligibility criteria for caregiver participants include self-identified Korean Americans who provide care for a family member with AD/DR as a primary caregiver, speak English less than “very well,” and can attend virtual classes through an electronic device and the Internet. Primary caregiver is defined as someone who provides weekly minimum of 10 hours of in-home caregiving to a family member. Given the underutilization of health services in the target population,⁸⁸ we decided not to include dementia diagnosis by a medical professional in the eligibility criteria. Instead, we will use the AD8[®] Dementia Screening Interview^{89,90} to ascertain the cognitive impairment status of care-recipients ($AD8^{\circ} \geq 2$). The scale is for an informant-based cognitive rating known to have good discrimination (sensitivity of 74% and specificity of 86%),⁸⁹ and the PI has obtained a license for the use. In the R21 caregiver sample, the AD8 scores reported for care-recipients ranged from 6 and 11 with a mean of 7.90 ($SD = 1.22$). Because K-Savvy is not a mental health treatment program, individuals with severe depression (PHQ-9 score ≥ 20) will be excluded. For those individuals, a list of local mental health service providers, including Korean-speaking counselors, will be provided. Recognizing the concern about the overall high levels of depressive symptoms of caregivers, we will carefully monitor participants’ PHQ-9 scores. As part of the participant safety protocol, mental health-related data and observations will be shared with our Consultant, Benjamin Hochang Lee, MD, who is a Korean-speaking Psychiatrist with a long record of research and clinical service with Korean Americans. It should also be noted that participant safety-related issues on depression, suicidality, and elder mistreatment will be an important part of the trainer training. We are also mindful of the exclusion of caregivers who are digitally disadvantaged and plan on conducting a subsequent ancillary study on in-person and technologically accommodated delivery modes.

We will recruit participants via multiple sources, including previously established area resource databases, public advertisement, and referrals through community networks and the CABs. In the CA site, it is expected that the referrals from former K-Savvy participants will be impactful (we have already received several referrals). We also learned from the R21 project that primary doctors, social workers, and senior housing service coordinators in Korean communities would be useful sources of participant recruitment. These lessons will be incorporated in our recruitment strategies. We believe the proposed sample size at each site is feasible to achieve. However, if encountered any recruitment challenges, we will expand our sites to such locations as Irvine/Gardena, Dallas/Houston, and Orlando/Miami where each site PI has community connections. Considering sex as a biological variable and reflecting the nature of caregiving, we anticipate that more than 70% of the caregiver participants will be women.

Intervention Design. We will employ a three-arm design, randomly assigning participants to (1) active treatment with K-Savvy ($n = 60$), (2) attention control with Healthy Living ($n = 60$), and (3) usual care ($n = 30$). Our goal is to enroll 150 participants across 25 classes, each consisting of 6 participants, proportionately representing three areas with varying Korean population densities: CA ($n = 72$), TX ($n = 48$), and FL ($n = 30$). All participants will be assessed at five points: baseline, and at 3, 6, 9, and 12 months. Following the baseline

assessment, those assigned to the active treatment group will participate in K-Savvy immediately, while participants in the attention control and usual care conditions will begin K-Savvy after a delay of 6 months, following the 6-month data collection. At each site, there will be two K-Savvy trainers. K-Savvy implementation will be phased to have each trainer lead one class at a given time. The three-arm randomization with a 2:2:1 ratio, protocols for control conditions, and assessment plans are adapted from Co-I Hepburn’s successful RCT with Tele-Savvy (R01AG054079).

The attention control condition, developed by Hepburn’s Tele-Savvy team, utilizes Healthy Living, an educational program on exercise and nutrition drawn from publicly available resources (e.g., NIA Go4Life Program). This program provides useful information to caregivers and is structured to parallel Savvy (six-week small-group sessions led by a trained interventionist), while intentionally excluding caregiving-related and Savvy-specific content. The utility of Healthy Living as an attention control condition has been validated.¹² Our team has reviewed the content and format of the original program and made it available in Korean. Following the steps employed by our current team for the K-Savvy adaptation, we have thoroughly reviewed linguistic and cultural relevance. We now have a Korean version of the Healthy Living manuals ready for caregiver participants and interventionists.

Figure 4. Treatment and Assessment Plan

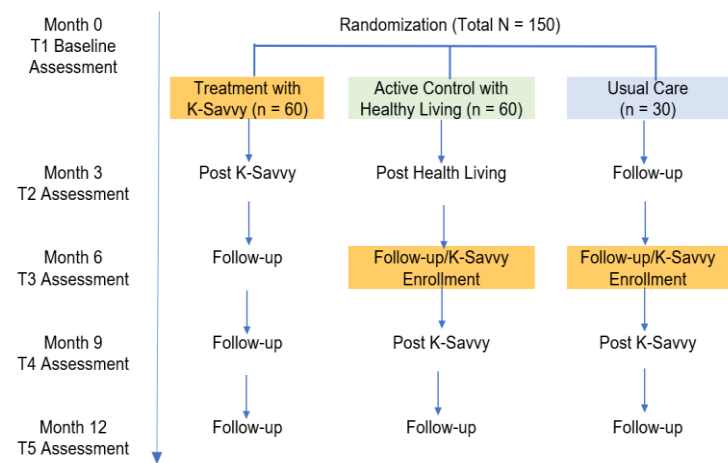


Figure 4 summarizes our new treatment and assessment plans. This design will enable us to clearly demonstrate K-Savvy’s immediate and long-term effects through group comparisons and trajectory assessments. Delayed K-Savvy participation for the active control and usual care groups will not only enhance statistical power but also fulfill ethical obligations regarding equal access to potential benefits. Additionally, the extended baseline data (T1–T3) will provide a unique opportunity to empirically address the potential placebo effect. All assessments will be conducted by trained personnel who are blinded to group assignments.

Based on our positive recruitment/retention outcomes in the R21, we expect no more than 15% attrition during the intervention phase and no more than 10% attrition at follow-ups. We would also like to note that this near perfect retention rate was also observed in the PI’s AHRQ-funded telecounseling project, which offered Korean American older adults in FL who were linguistically isolated a 4-week online CBT delivered by Korean-speaking mental health counselors in NYC.⁹¹ These exceptional retention rates reflect the high needs for behavioral interventions that have not been addressed in Korean American communities. Despite the cultural stigma associated with depression and dementia, culturally and linguistically appropriate interventions tailored to meet the community needs and characteristics seem to garner positive responses. We will continue using our culturally sensitive strategies to enhance rapport with study participants and build a sense of community.

Outcome evaluations will use the Reach, Efficacy, Adoption, Implementation, and Maintenance (RE-AIM)²³ model. Table 4 summarizes the RE-AIM contents along with assessment tools.

Table 4. RE-AIM Contents and Assessment Tools

Dimension	Content	Assessment tool
Reach	What proportion of the recruited individuals participated in the intervention?	Participation rate
Efficacy	What are the benefits of the intervention?	Stressfulness, self-efficacy, burden, depressive symptoms, psychological gain
Adoption	How is the intervention accepted by the participants?	Satisfaction with the program
Implementation	What proportion of the participants completed the intervention?	Completion rate
Maintenance	Are the benefits of the intervention sustained at the follow-up?	Stressfulness, self-efficacy, burden, depressive symptoms, psychological gain

We have carefully selected the measures for major constructs, and they are listed in Table 5. Our selection was guided by the use in dementia caregiver interventions, psychometric properties, availability of a validated Korean version, sensitivity to change, and function as a repeated measure.⁹²⁻⁹⁷ Quality assurance and pilot-testing of the Korean version of the measures will be conducted before their adoption. Assessment will be conducted by trained personnel blinded to group assignments, and data will be managed through REDCap.

Table 5. Efficacy Outcome Measures

	Instrument	Description	Availability/validity of a Korean version
Perceived stressfulness	Revised Memory and Behavior Problems Checklist (RMBPC) ⁹⁸	Measurement of both frequency (stressor) and reaction (perceived stressfulness); inclusion of three domains: depression (9 items), disruption (8 items), and memory-related problems (7 items); good psychometric properties ^{98,99}	Korean version of RMBPC validated by Lee and Yoon ¹⁰⁰ ; employed in studies with Koreans ¹⁰¹ ; $\alpha = 0.90-0.93$
Self-efficacy	Revised Scale for Caregiving Self-Efficacy (RSCSE) ⁹⁵	Inclusion of three domains: obtaining respite, managing disruptive behaviors, and controlling upsetting thoughts; 5 items per each domain	Validated in cross-national samples of caregivers, including Asians ⁹⁵ ; $\alpha = 0.75-0.95$
Burden	Zarit Burden Interview (ZBI-12) ^{96,97}	Summation of 12 items (0 to 4 points per item, total score range 0 to 48), good psychometric properties, popular use in caregiving research and intervention studies	Korean version of ZBI by Yoon and Robinson ¹⁰² ; $\alpha = 0.93$
Depressive symptoms	Patient Health Questionnaire (PhQ-9) ⁸³	Summation of 9 items (0 to 3 points per item, range from 0 to 27), good psychometric properties, popular use in mental health research and clinical trials	Korean version of PHQ-9 validated by Han and colleagues ⁸⁴ ; employed in numerous studies with Koreans, including PI's work ¹⁰³ ; $\alpha = 0.86-0.92$
Psychological gain	GAIN in Alzheimer Care Instrument (GAIN) ¹⁰⁴	Summation of 10 items (0 to 5 points per item); Cronbach's $\alpha = 0.89$. two-week test-retest reliability: $\alpha = 0.79$	Validated in cross-national samples of caregivers, including Asians ¹⁰⁵ ; $\alpha = 0.85$

Quantitative Data Analysis. All multiple-item scales will be checked for internal consistency and factor structures. We will pay particular attention to the measures of perceived stressfulness and self-efficacy and decide on whether each of their subdomains should be treated separately, or a summated score should be used as a global indicator because both approaches were practiced in previous studies.^{95,98-100}

Treatment effect will be assessed via between-subject comparisons in the change of key outcome measures among the K-Savvy (KS), Healthy Living (HL), and Usual Care (UC) conditions. We will perform these longitudinal comparisons using latent growth models.¹⁰⁶ These models capture the group-level change across the study period while accounting for individual variability in measurements. The overall intervention effect will be tested by examining the effect of intervention condition (KS vs. HL, KS vs. UC) on the latent slope across the first 6 months of observation (Figure 5, Path b). Due to randomization, there is no expected effect of intervention condition on latent slope (Path a). The latent growth curve model (LGCM) approach is robust, as different (nonlinear) slope hypotheses can be tested, and as models are estimated using full information maximum likelihood (FIML), which provides unbiased estimates under the assumption data are missing at random. A secondary analysis for Aim 1 is to test the effect of K-Savvy treatment to the control waitlist period in the control groups (HL and UC). For this analysis, we will use a spline approach within the LGCM framework to estimate the slope of outcome variables within the first 6 months (i.e., waitlist), and then a latent variable that models the change in slope from 6 to 12 months (i.e., K-Savvy program). We will include a possible moderating effect of control group (HL vs. UC).

Finally, we will examine the extent to which cognitive appraisals mediate the relationship between intervention condition and caregiver outcomes. This will be accomplished in a similar LGCM framework as a parallel growth model. Here, we will model the effect of intervention condition (KS vs. HL, UC) on the longitudinal change in caregiver outcomes both directly (Figure 6, Path c) and as moderated by longitudinal change in cognitive appraisals (Figure 6, Paths a, b). Before implementing these models, distributions of all outcome measures will be examined for skewness; variables will be log-transformed as needed, or modeling approaches with robust standard errors will be employed. Because of the increased risk of type one error associated with multiple outcomes, we will use p-values corrected for the false discovery rate (e.g., Benjamini-Hochberg method). Bootstrapped standard errors will be estimated for the indirect path coefficients. We will examine model fit via metrics such as RMSEA, CFI, TLI, and RMSD.¹⁰⁷⁻¹⁰⁹

Because of the nested structure of the data (i.e., within classes), we will examine the ICC values for outcome measures within classes. We expect ICC to be low due to randomization of individuals to class. If the ICC is low (<.05) then we will proceed with models as planned. Otherwise, we will implement a multilevel structure within each growth curve model to account for clustering within classes. Power analyses were conducted

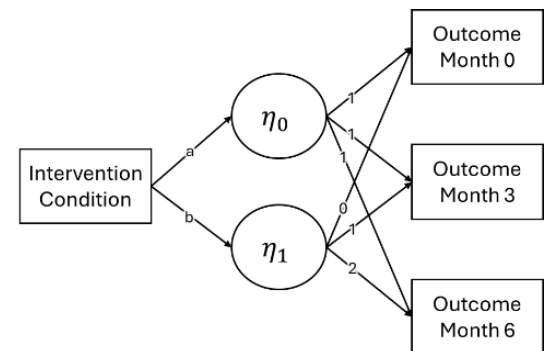


Figure 5. Latent growth model for the effect of intervention condition on change in outcomes across 6 months.

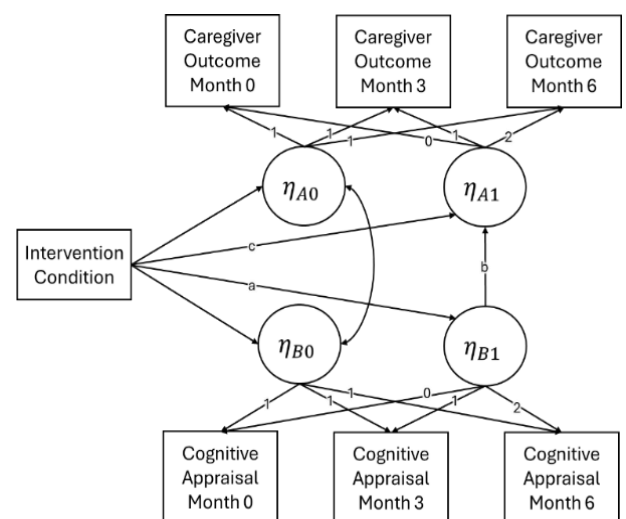


Figure 6. Parallel process latent growth model for the mediating effect of cognitive appraisals on the relationship between intervention condition and caregiver outcomes.

assuming a total of 150 participants. We estimated the minimum detectable total effect of the intervention using a Monte Carlo approach with 1000 draws per replication and 1000 replications. With an alpha of 0.05, power of 80%, and estimated missing, we would be able to detect a medium-small effect size of 0.30. This size is comparable to those reported in dementia caregiver interventions including SCP,^{1,22,29} which ranges between 0.24 and 0.45 for post- vs. pre-intervention differences. For the mediating effect, we performed a similar approach, and assuming medium standardized coefficients are observed in the structural equation model, we would be able to detect a small mediated effect ($\beta = 0.22$). Missing data will be handled via the use of FIML when estimating parameters in our structural equation models. This estimation approach produces unbiased parameter estimates under the assumption that missing values are at random or completely at random, as it estimates a likelihood function for each individual based on the variables that are present, thereby using all available data. Our power analysis was performed assuming FIML estimation and 15% missingness during the intervention and 10% missingness at follow-ups. As a way to address contextual variations, site and key individual characteristics (e.g., gender, educational attainment, acculturation level) will be introduced as potential moderators. Although exploratory in its nature, the approach will demonstrate individual variations in response to the intervention. The PI Jang and Co-I Haley conducted this line of research with the NYU Caregiver Intervention¹¹⁰ where caregivers' positive personality trait (i.e., low neuroticism) maximizes intervention benefits. All analyses will be performed using STATA version 16.0. PI Jang and Co-I Pickering will lead the analysis.

Qualitative Data Analysis. Individual interviews with caregiver participants and interventionists will be conducted within a week from the K-Savvy completion. Through the interviews with caregiver participants, we aim to capture descriptions of how and why K-Savvy intervention may impact their perceived stressfulness and beliefs about their caregiving abilities. We will also solicit caregivers' perceptions of changes in the cognitive and affective processes and performance of key aspects of the intervention, as well as feedback on the content from each of the six sessions, the learning activities in each session, and the cultural adaptations made throughout. The interviews with interventionists will address challenges to applying the knowledge and skills or to delivering the program. We will audio-record qualitative interviews, transcribe them verbatim in Korean, and translate them into English. Using the protocol suggested for cross-language studies,¹¹¹⁻¹¹³ we will translate, transcribe, and code data. Interview materials including audio files, transcriptions, and field notes and memos will be organized and analyzed using ATLAS.ti. As employed in the team's previous qualitative work,^{80-82,114-116} we will conduct a thematic analysis with initial open coding of data, clustering of codes into categories, and identification of overarching themes from the clusters of codes. To enhance rigor and trustworthiness, we will also employ several strategies such as intensive engagement, cross-coding, regular debriefings, record-keeping, and a feedback loop for consensus.¹¹¹⁻¹¹³ PI Jang and Co-I Park/Oh will lead the analysis.

Data Triangulation. The proposed study will generate various sources of data (e.g., quantitative and qualitative data from participants and trainers, session recordings, field notes, and minutes from CABs and investigator meetings, as well as FRAME documentation). These data will be integrated for a comprehensive program evaluation and future planning. Qualitative data will be used to solicit participants' input for program refinement and to contextualize the findings from the quantitative data analysis. By combining the RE-AIM and FRAME approaches,^{117,118} the project outcomes will be consolidated, and recommended actions will be listed. Suggestions regarding program content will be processed following the feedback loop and fidelity-fit balancing strategies, resulting in refined programs and protocols. As part of our iterative process, we will share outcomes with all members of the investigative team and CABs to discuss future directions.

Anticipated Challenges and Planned Strategies. The proposed study is built upon preliminary evidence and community partnerships at multiple sites. Potential challenges and limitations may include: (1) recruitment

and retention, (2) multi-site management, and (3) the exclusion of caregivers who are not equipped for online education. To address these issues, our planned strategies are: (1) promoting our community engagement efforts, (2) using multiple recruitment sources, (3) employing culturally sensitive approaches to build trust and foster a sense of community, (4) preparing backup research sites and personnel, (5) establishing multi-site communication protocols and channels, and (6) planning an ancillary study targeted at caregivers who are digitally disadvantaged. Although the proposed study focuses on a single ethnic group, our process—firmly grounded in an understanding of and respect for the target group’s cultures and contexts—could serve as a model for cultural modification and implementation of EBIs for other groups. The study will build evidence of K-Savvy efficacy and its mechanisms of action, refine the K-Savvy protocol, and generate the K-Savvy Online TTT Program. The knowledge gained and products generated from this Stage II Efficacy Trial will provide a solid foundation for the Stage III Real-World Efficacy Trial, which will ultimately lead to the goal of establishing a self-contained K-Savvy program package that can be easily disseminated in community settings. We expect our efforts to yield societal benefits by narrowing the gap in EBI delivery.

Reference available upon request