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Development and evaluation of a health care decision-making intervention for African American parent-adult daughter dementia dyads: A mixed-methods study protocol

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Kenneth Hepburn, PhD, FGSA, ORCID:0000-0002-3498-6272

khepbur@emory.edu

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Article Summary

Strengths and limitations of this study

- The structural culturally responsive prototype intervention will be co-created with African American persons living with ADRD, their care partners, and a community advisory board, which consists of African Americans with lived experience and/or clinical expertise with ADRD.
- The structured culturally responsive prototype intervention will be designed using an explanatory sequential mixed methods approach.
- Because the study is entirely remote, there may be individuals who are not able to participate. We developed protocols to support collecting data via phone or paper instead of videoconferencing.
- Using a single-group clinical trial design is a limitation, but we will gain insights into feasibility, acceptability, and preliminary efficacy.

Keywords: explanatory sequential design; health care; Black American; Alzheimer's disease and related dementias, self-efficacy, culturally responsive

person when making health care decisions [3]. This concern is further exacerbated for African American care partners by their understandable distrust in the healthcare system due to known differences in their health care experiences [17, 18]. Research suggests shared decision-making approaches can reduce these dilemmas for care partners [19].

In addition to lifecourse influences, family dynamics within African American parent-adult daughter dementia dyads (hereafter referred to as dementia dyads) affect the quality of life of both members of these dyads. For African American care partners specifically, the relationship between care partners and African American persons living with ADRD matters; non-spouse care partners experience significantly worse quality of life [4]. In addition, family dynamics influence the quality of life of African American care partners; greater reports of dyadic strain within African American dementia dyads were significantly associated with worse quality of life for African American care partners [4]. In a literature review focused on African American women care partners of individuals with chronic illnesses, including ADRD, African American women care partners who reported poor family functioning experienced worse quality of life [8].

Involvement of African American persons living with ADRD in daily care decision making (e.g., what to eat, what to wear) significantly contributes to a better quality of life for African American persons living with ADRD [4, 20]. Yet, to our knowledge, the influence of health care decision-making processes within African American dementia dyads on their quality of life has not been examined. In the broader context of health care decision making within dementia dyads, persons living with mild to moderate ADRD desire to be included in health care decision making regarding their care [21]. Care partners often overlook this desire and focus on the person living with ADRD's capacity to participate in the healthcare process [21]. Supporting health care decision-making for African American persons living with ADRD by meeting the educational and psychosocial needs of African American dementia dyads may hold promise in improving their quality of life.

Structured programs focused on education and support have positively influenced quality of life [10, 22]. Specifically, structured programs have been found to improve the quality of life of both members of dementia dyads [10]. In a systematic review of structured intervention programs for dementia dyads, participation in these programs was suggested to be particularly beneficial for underrepresented groups [22]. However, few structured intervention programs address racial differences in ADRD caregiving, are culturally responsive, and include dyadic research [10, 23].

The proposed study aligns with the recommendation of the National Institute on Aging's Dementia Care Summit [24] to "use theory-driven frameworks" and "address the complex heterogeneous and interacting challenges experienced by persons living with ADRD and their caregivers." This study is guided by three frameworks: the National Institute on Aging's Health Disparities Research Framework[5], the Black Family Socio-Ecological Context Model [25], and the Superwoman Schema [26]. The National Institute on Aging's Health Disparities Framework [5], highlights levels of analysis (i.e., behavioral, sociocultural, and environmental) relevant to health disparities in African American dyads and families. The Black Family Socio-Ecological Context Model [25] provides a conceptual basis for examining societal and lifecourse influences including health disparities within individual, dyadic, and family spheres. Finally, the

Superwoman Schema [26] specifically focuses on influences of cultural characteristics of African American women, which will be applied to the African American adult daughter care partners (referred to as care partners beyond this point).

METHODS AND ANALYSIS

Study design and study setting

The study is being conducted at Emory University Nell Hodgson Woodruff School of Nursing with enrollment occurring across the United States. Recruitment across the United States was chosen purposively to strengthen heterogeneity in the sample. This National Institutes of Health Stage 0-1B study [27] will use a mixed-methods explanatory sequential design [28] to identify key factors that will lead to the development and piloting of a structured culturally responsive prototype intervention (referred to as prototype intervention beyond this point) for African American dementia dyads and/or families of persons living with ADRD. This explanatory sequential mixed-methods study will first collect and analyze quantitative data from surveys and then collect qualitative data from semi-structured interviews to explain the quantitative findings, which will build upon each other [28].

The study will be implemented in two phases (Figure 1). The first phase or preintervention phase will consist of both quantitative and qualitative data collection and analysis. The first phase will end with the integration of data that will inform the development of a prototype intervention. The second phase is divided into two parts—intervention development and piloting of the prototype intervention.

Familiarity with technology

We anticipate technology will be used during all phases of this study. If needed to improve familiarity with the proposed technology, the first author or a member of the research team will schedule a time to orient participants. This orientation will include any of the following: 1) an interactive demonstration of the steps of using REDCap and the Zoom videoconferencing platform and 2) a demonstration of using Zoom as a conference call line for those with telephone access only.

Culturally responsive research

The Center for Health and Healthy Aging, which is housed in the University of Minnesota’s School of Public Health defines culturally responsive research as research that “incorporates the knowledge and unique cultural experiences of individuals, children, families, organizations, and communities served” and is “driven by first-hand knowledge and an understanding of the varied needs of diverse families and communities—their choices, not by cultural stereotypes or generalized assumptions [29] (citation).” This study protocol is culturally responsive in two ways. First, key informants are an integral part of the design thinking and intervention mapping approaches for the development of the prototype intervention (described below) in the design thinking and intervention mapping approaches we will use to develop the prototype intervention. Second, the D.E.C.I.D.E. Research Lab, which is led by the first author, has a community advisory board (described in greater detail below) associated with it. The community advisory

board their lived experience to the first author during quarterly meetings, which guide all the projects coming from this lab.

Key informants

Key informants will be used in phase 2 of this study. Key informants will consist of up to 6 African American dementia dyads who did not participate in any of these phases of the study. All key informants must meet the above inclusion criteria for the parent living with ADRD and care partner, respectively. In addition, key informants must have experience navigating at least 2 of the following health care decisions: getting a formal diagnosis of ADRD for the parent living with ADRD, finding and/or changing a healthcare provider of the parent living with ADRD, managing the parent living with ADRD's medications under the guidance of a healthcare provider, deciding the parent living with ADRD will receive a treatment or have a procedure, participating in conversations about hospice, palliative care, and/or end-of-life care with a healthcare provider for the parent living with ADRD. Key informants will be provided an honorarium for their participation.

Design Thinking

Design thinking is often described in 5 iterative steps: empathize, define, ideate, prototype, and test. We will use the 5 steps of experimentation based on design thinking approaches [30]. These five steps are 1) framing testable ideas, 2) defining evidence, 3) selecting your test, 4) building the prototype, and 5) executing, analyzing, and iterating [30]. The design thinking will be carried out at the Design Studio at Emory University Roybal Center for Dementia Caregiving Mastery. The Design Studio uses the design thinking process to challenge and refine an emerging product, which is grounded in the early and frequent involvement of key informants or end users in product design [31]. Through a facilitated process by a design thinking specialist of divergent-convergent fast track engagement of appropriate intellectual resources to clarify ideas and design testable user-centered prototypes. The design studio sessions will be conducted in three study visits with the same participants using focus group methods. A member of the research team will attend and document nonverbal cues during each session.

Intervention Mapping

Intervention mapping is a 6-step iterative process, which consists of developing a logic model of the problem; program outcomes and objectives (e.g., logic model of change), program design, program production, program implementation plan, and evaluation plan [32]. Intervention mapping sessions will be facilitated by the first author using the Intervention Mapping Workbook and accompanying textbook [32]. During this facilitated process, the prototype intervention will be developed, piloted, and evaluated.

A total of six sessions (i.e., three design thinking sessions and three intervention mapping sessions) are planned to occur over a 6-month period for prototype intervention development. A fourth session of both will occur after piloting to evaluate the prototype intervention. The size of each design thinking session will be limited to 8-10 participants and include key informants and research team members. Intervention mapping sessions will have members of the research team

Interested participants are guided to the study's REDCap prescreening survey by an IRB study flyer or after contact with the research team. Completion of the prescreening survey takes approximately ten minutes. Once the prescreening survey is completed, the research team is notified and contacts the potential participant within 3-5 business days via email or phone based on the potential participant's preference. After this initial contact is made, all interested, eligible participants must participate in a scheduling call. The scheduling call was implemented for four reasons: 1) to schedule the study visit, 2) to begin to build rapport with the daughter, 3) to answer study questions, and 4) to screen for fraudulent participants. The scheduling call has become an important element in the recruitment process because the daughters learn more about the study, get to speak to the first author directly, and can provide additional information to help the study visit run smoothly for the parent.

The study visit is scheduled for 2.5 hours, and participants are instructed to have their camera on for the duration of the visit. This time was determined after the first few study visits lasted at least this long due to lengthy conversations with the participants and/or technical concerns. A waiver of documentation of consent was applied to this study. Verbal consent is obtained at the beginning of the study visit. To determine if the parent can provide consent, the parent answers six questions from the University of California, San Diego Brief Assessment of Capacity to Consent tool [33]. Parents must answer at least four questions correctly to be able to independently consent. Otherwise, their daughter or other family member provides verbal consent, and the parent provides verbal assent.

Quantitative data collection

The quantitative aim of this study is to identify behavioral, sociocultural, and environmental influences associated with the health care decision-making processes and quality of life of African American dementia dyads. Primary data collection is through online surveys using REDCap [34]. Refer to (Table 1) for a list of surveys. Data collection will take about 30-40 minutes for the parents and 40-50 minutes for the daughters. During each study visit, the parent is questioned first to minimize fatigue. The first author reads the questions and marks the answers using the paper-pencil method. The answer choice options for each survey are displayed on the shared videoconferencing screen, so the choices remain visible for the parent. After the parent completes their portion of the surveys, the first author emails the REDCap survey to the daughter to complete during the allotted study visit or at their earliest convenience. Each member of the dyad will be compensated with a \$25 gift card for their time (total \$50 per dyad). Dyad members choose between three retail gift card options.

Table 1. List of measures used in screening and preintervention phase.^{a-c}

Domain	Measure	Concept of interest	Target ^a (PLWD/ D)
Cognition and General Health			

	Dementia Severity Rating Scale	To quantify the stage of cognitive impairment for screening	D
	Montreal Cognitive Assessment	To screen for cognitive impairment	PLWD
	Self-Rated Health	To assess general health	PLWD, D
Behavioral Lifecourse Influences			
	Family Assessment Device	To assess communication, problem solving & family functioning	PLWD, D
	Family Decision Process	To assess family decision making:	PLWD, D
	Resource Utilization in Dementia	To assess health care decision utilization of both dyad members	D
Sociocultural Lifecourse Influences			
	Giscombe Superwoman Schema Questionnaire	To assess cultural identity regarding gender	D
	Cultural Justifications for Caregiving Scale	To assess cultural identity regarding caregiving	D
	Dyadic Relationship Scale	To assess relationship quality regarding dyadic strain	PLWD, D
	Duke Social Support and Stress Scale	To assess their social networks	D
Environmental Lifecourse Influences			
	Rapid Estimate of Adult Literacy in Medicine-Short Form	To assess health literacy	PLWD, D
	Alzheimer's Disease Knowledge Scale	To assess Alzheimer's disease specific health literacy	D
	Perceived efficacy in patient-provider interactions	To assess the patient-provider relationship	PLWD, D
Outcomes	Quality of Life-Alzheimer's Disease	To assess the quality of life of both dyad members	PLWD, D
	Decision Self-Efficacy Scale	To assess self-confidence in one's ability to make	PLWD, D

		informed health care decisions	
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^a PLWD= parent living with dementia ^bD= daughter

Sample size estimation

Based on G*Power [35] analysis to conduct a multiple linear regression with a two-sided $\alpha = 0.05$, 80% power, and 6 predictors, a projected sample size of 60 dyads is needed to detect a moderate-to-large effect (Cohen's $f^2 = 0.26$). The rule of 10 participants (i.e., dyads) per degree of freedom has been applied based on a similar sample size used in previous dyadic research [4, 36]. Our proposed sample size of 70 African American dementia dyads will allow for a 10% attrition rate of participants or missing data.

Quantitative data analysis

Preliminary bivariate analysis will be conducted in Stata IC [37] to determine predictors of quality of life and health care decision self-efficacy from the data. No more than six predictors will be used in linear multiple regression models. Multilevel modeling, specifically Actor-Partner Interdependence Modeling [38, 39], will be conducted in HLM software [40]. If the sample size is less than our anticipated goal, we analyze parents and daughters separately using within-group effect sizes. Descriptive statistics will be computed through Stata IC to examine sample characteristics. Quantitative data analysis will be completed before qualitative data collection. We will match the domains of the surveys that are statistically significant to the interview questions for qualitative data collection.

Qualitative data collection

The qualitative aim of the study is to describe the decision-making processes of members of African American dementia dyads. After quantitative data analysis, we will connect the sample by choosing a subsample of the dyads to complete the qualitative interviews using maximum variation sampling based on diverse neighborhoods (e.g., rural, urban, suburban), relationship of parent (e.g., mother, father, in-law), and acute care visits of the parent living with dementia (e.g., none vs. one or more).

Each qualitative interview visit will be scheduled to last 1 hour. The visit will be conducted virtually using Zoom. The first author or a member of the research team will conduct the qualitative interviews using a semi-structured interview guide. Both members of the African American dementia dyads will be interviewed together (about 30 minutes). Then, each member of the dyad will be interviewed separately (about 15 minutes for each) [41], with the interviews of the parent occurring before the daughters to prevent fatigue of the parent. This process was successful in the first author's preliminary research study [42].

There are two reasons for dyadic interviewing [43]. First, having the participants together initially will help with building rapport, assuage possible apprehension with the interview process, and allow for the first author to observe the interactions between the dyad members. Second, separating the dyads will allow for more in-depth interviewing to enhance

trustworthiness, validity, and comparison and contrast. Individual interviews also allow either a member of the dyad to speak more freely and confidentially about their role or the other member of the dyads' role in decision making.

Participants will be notified of the recording of interviews before consenting to the study and will be reminded prior to the recording at the start of the semi-structured interview. Audio/video-recordings will be generated via Zoom. Recordings of the semi-structured interviews will be transcribed verbatim. Following each interview, the first author will create field notes and conduct reflexive journaling during this portion of the study [44, 45]. Sampling will continue until saturation (i.e., no new information or themes emerge from the data) is achieved [46]. Each member of the dementia dyad will receive a \$25 gift card after completing the semi-structured interview as compensation for their time (totaling \$50 per dyad). There is potential for up to 2 follow-up visits to clarify questions and for member checking the themes generated from the data for reliability and validity of the results. Each follow-up interview will last no more than 1 hour. No other information will be collected from the participants during the follow-up visits.

Qualitative data analysis

Using de-identified data, all transcripts will be managed in MAXQDA software [47]. The transcripts will be analyzed using directed qualitative content analysis to provide a more structured approach to identifying relationships among variables [48], which will lead to the identification of key components of the health care decision-making processes from the perspectives of the dyads. The research team will independently review transcripts and identify codes. Other members of the research team who are not a part of the initial coding of the data will be brought in to resolve any discrepancies among the independently developed codes. Member checks will occur to serve as validation of the interpretation (if the participants agree to future contact by the research team).

Integration of preintervention data

The integration of the phase 1 preintervention data will allow the explanation of the quantitative survey items with the qualitative results, themes, and quotes, through use of a joint display. Following steps 1-3 of design thinking and steps 1-2 of intervention mapping, this phase will end with the prototype intervention program outcomes and objectives.

PHASE 2: DEVELOPMENT OF PROTOTYPE INTERVENTION AND PILOTING

Phase 2a: Intervention development

The second phase of this study begins with the development of a prototype intervention (2a). Integrated findings from the phase 1 preintervention phase of this study will be used to develop the prototype intervention following step 4 of design thinking and steps 3-4 of intervention mapping. An outline for the prototype intervention will be developed. This outline will consist of the prototype intervention program plan (e.g., themes, scope, and mechanisms of action), program materials and messaging, and program use (e.g., adoption, implementation, and

maintenance). The outline will serve as the basis for course design activities with the Roybal Center instructional consultants and specialists. The outline will be used to create mockups of the curriculum and materials. These mockups will be shared with the key informants through an iterative process. This process will capture the feedback of the key informants, integrate the changes, and result in the presentation of new mockups. Other prototype intervention specifics (e.g., number of sessions, which member of the dementia dyad will participate in these sessions, psychoeducational vs. counseling, synchronous vs. asynchronous, in-person vs. online) will be determined during these sessions. Once the key informants, CAB, and research team come to a consensus, the prototype intervention will be finalized, and then the first author will start a second recruitment.

Phase 2b: Intervention

Implementation and evaluation

Phase two will end with the implementation and evaluation of the prototype intervention (2b). The implementation of the prototype intervention will consist of 20 African American dementia dyads who have not previously participated in this study. A \$25 gift card will be given to each member of the dementia dyad at each data collection time point and after completing the semi-structured interview as compensation for their time (totaling \$200 per dementia dyad).

Eligible dyads will be scheduled for one baseline study visit and three follow-up visits post intervention (Refer to Table 3). The three follow-up visits will consist of a 1-month study visit and two 3-month study visits. Quantitative data collection will be collected at baseline and the two follow-ups post intervention. The parents will complete the Montreal Cognitive Assessment at baseline only. The Quality of Life-Alzheimer's Disease Scale and Decision Self-Efficacy Scale will be completed by both members of the dyad at baseline (e.g., pretest) and at the two follow-up visits (e.g., posttest) to examine changes in quality of life and health care decision self-efficacy. Given our current success with dyadic data collection, we anticipate baseline and follow-up visits should last no more than 30 minutes for the parents and 40 minutes for the daughters except the follow-up visit part two at 3-months post intervention.

Part two of the 3-month follow-up visit will consist of a qualitative interview that will last about 45 minutes, which will occur within two weeks of the quantitative 3-month follow-up part one. The dementia dyads will first be interviewed together and then separately. The interviews held with both members will focus on their perceptions of the prototype intervention. The individual interviews will allow for feedback about the prototype intervention but will focus on their perceptions of their quality of life and decision self-efficacy. Questions on the interview guide will focus on the usability and acceptability of the prototype intervention to help with future refinements. The first author in collaboration with the CAB and research team will develop an interview guide to conduct the qualitative interviews. Interviews will be recorded and transcribed verbatim.

Recruitment and consenting process

The recruitment, consent, and scheduling processes that were used in the preintervention process will be the same for the piloting of the prototype intervention with one exception. The 20 dementia dyads piloting the prototype intervention will not have participated in the preintervention phase of this study.

Sample size estimation

The rule of ten participants (i.e., dyads) per degree of freedom will be applied. We conducted a power calculation using G*Power to provide a comparison. If we conduct repeated measures analysis of variance with a two-sided $\alpha = 0.05$, 80% power, and 2 predictors, a projected sample size of 15 dementia dyads is needed to detect a large effect (Cohen's $f^2 = 0.39$). We will recruit twenty dementia dyads to control for a potential 20% attrition rate.

Components of the intervention

Since the prototype intervention will be created in this study, we cannot describe the prototype intervention. We anticipate the prototype intervention will be family based with a focus on issues of communication, problem-solving, health system literacy, and family systems. Once developed and evaluated, the intervention protocol will be published.

Study outcome measures

Primary outcomes

The primary outcomes of this study are feasibility, acceptability, usability, and preliminary efficacy. Feasibility will be measured based on the ability to recruit and retain the targeted number of participants within the desired timeframe with full participation. The recruitment plan is for 20 African American dementia dyads to be enrolled in ≤ 6 months. The actual number of dyads recruited will be reported as the outcome with the percentage of the goal achieved (actual/goal). Feasibility will assess the ability to recruit 60% of the sample. Acceptability will be measured based on the ability to retain participants in the intervention and in the study. Attendance of participants will be monitored during the program sessions of the prototype intervention. Retention will assess the ability to maintain 70% attendance in intervention program sessions and 80% of participants from baseline to 3-month follow-up part two. Usability will focus on the ease of use and desire to use the prototype intervention from the perceptions of the dementia dyads. Acceptability will assess the appropriateness of the prototype intervention as well as satisfaction with how it was delivered from the perspectives of the dementia dyads. Data about usability will be gathered during the qualitative interviews at the 3-month follow-up visit part two.

Preliminary efficacy will be determined by the change in the quality of life of both members of these dyads and the change in decision self-efficacy for the adult daughter of the parent. Using the Quality of Life-Alzheimer's Disease Scale, we anticipate the change from baseline to follow-up in quality of life will be significantly better ($p = .05$) or trends towards significance for both parents living with ADRD and adult daughters. To evaluate self-efficacy with health care

decision making, we will use the Decision Self-Efficacy Scale. We anticipate a significant ($p = .05$) positive change in both the parents and their adult daughters or a trend towards significance. Effect size will be examined for both analyses.

Data analysis

To evaluate the feasibility, acceptability, usability, and preliminary efficacy of the prototype intervention, we will use quantitative, qualitative, and mixed methods. Feasibility will be determined by using descriptive statistics. Usability and acceptability will be analyzed using directed content analysis [48]. Qualitative data from the interviews will be managed in MAXQDA software [47]. For the pretest-posttest preliminary efficacy analysis, longitudinal dyadic analysis will be conducted in Stata IC [49, 50]. Descriptive statistics will be computed for measures at each time point. Internal consistency reliability will be assessed for each measure by computing Cronbach's alpha for complete item responses. You could look at parents and daughters separately using within-group effect sizes or how you described it above, but I would do some combination of individual within change for daughters and parents and then some way of examining dyads where both benefited. Given the small sample size, we will conduct within-group effect sizes for the parents and adult daughters separately. There are also three descriptive approaches we can use to evaluate the dyadic benefits of the pilot—above-zero, pretest risk status, and/or pattern analysis [51]. We will evaluate the data using the above-zero approach. The data from the parent-adult daughter dyads will be coded on each outcome separately based on whether both the parent and adult daughter reported any posttest improvement (i.e., above zero change) [51]. Qualitative data from the interviews will be embedded in the quantitative data from the preliminary efficacy analysis. The goal of this mixed-methods integration is to refine the prototype intervention based on the piloting.

DISCUSSION

This study examines the feasibility, useability, acceptability, and preliminary efficacy of a culturally responsive health care decision-making prototype intervention for African American parent-adult daughter dementia dyads. We will examine the potential influence of this prototype intervention on the quality of life of both members of these African American dementia dyads and the health care decision making self-efficacy of African American parents using an explanatory sequential mixed methods design. The findings from this study will produce a more refined version of this prototype intervention, which will be implemented in a randomized controlled trial.

However, there are some anticipated challenges in conducting this study. First, recruitment may take longer than expected. Recruitment strategies will be discussed during research team meetings to determine the next steps and appropriate amendments to the recruitment plan. Second, there is the potential for incomplete data. Data missing at random will be handled with full information maximum likelihood. Lastly, given the small sample size of this study, nonsignificant findings with variables of interest are possible. We will look for trends towards significance, calculate effect sizes, and incorporate descriptive analysis approaches.

Despite these challenges, the design of this study has many strengths. First, we will identify target(s) of the prototype intervention. These targets will be determined by dyadic and mixed methods analysis. Using multilinear regression modeling, specifically Actor-Partner Interdependence Modeling [52], we will identify quantitative influences at both the individual and dyadic levels. Significant quantitative influences will be matched to interview questions. Second, the inclusion of the perspectives of both members of African American dementia dyads' is another strength. The expected outcome is to gain information about the individual, dyadic, and family dynamics that influence quality of life and health care decision-making of African American dementia dyads.

ETHICS AND DISSEMINATION

Ethical Considerations

The first phase of the study was approved by the Emory University Institutional Review Board (IRB). Once qualitative data collection is completed, a modification will be submitted to the IRB to obtain approval for the second phase of the study. The study is registered on ClinicalTrials.gov (NCT05139290).

Informed Consent

Participant interviews will be completed only after obtaining informed consent. If assent is obtained from the parent living with ADRD, consent will be obtained from their proxy. Confidentiality of participant's data will be maintained during the study.

Dissemination

Results of the research will be disseminated in both academic and community settings. Results will be published in peer-reviewed journals, clinicaltrials.gov, and scientific conferences. Community dissemination will include articles in community newspapers and/or newsletters, community forums and health fairs, and other ways identified by the community advisory board.

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Author's Statement

KBJ, KL, WP, and KH contributed to conception and study design. KBJ prepared the first draft of the study design proposal. KL, WP, and KH were involved in critical revisions of the study design proposal. All authors contributed to the finalized study proposal. All authors contributed to the preparation of the manuscript submission. All authors reviewed the manuscript and approved for publication.

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Competing interest statement. None declared

Data Statement

De-identified data and analytic methods are available by completing a data use agreement. For researchers interested in obtaining de-identified data request should be made by contacting the corresponding author.

For peer review only

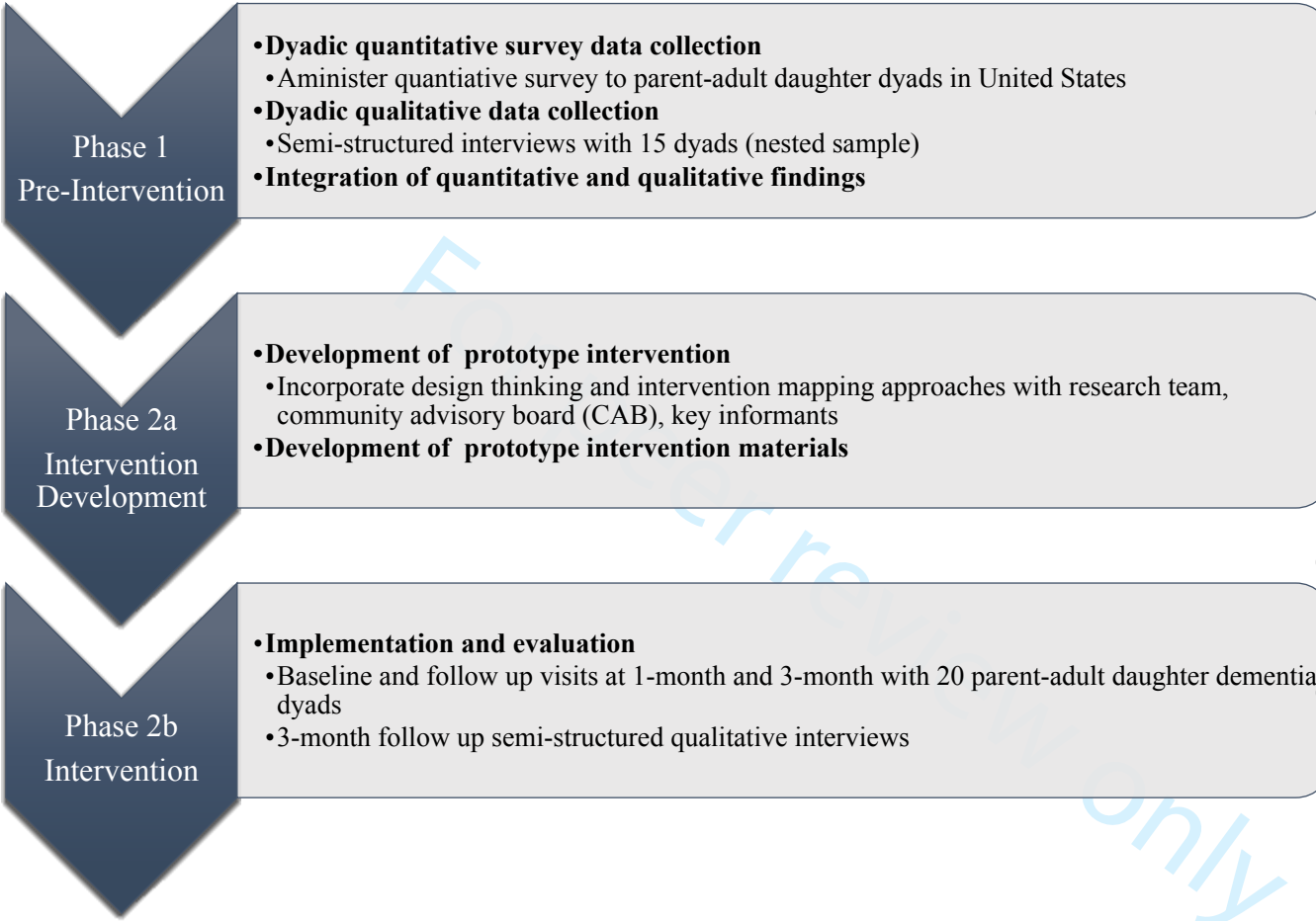


Figure 1: Summary diagram of the study design

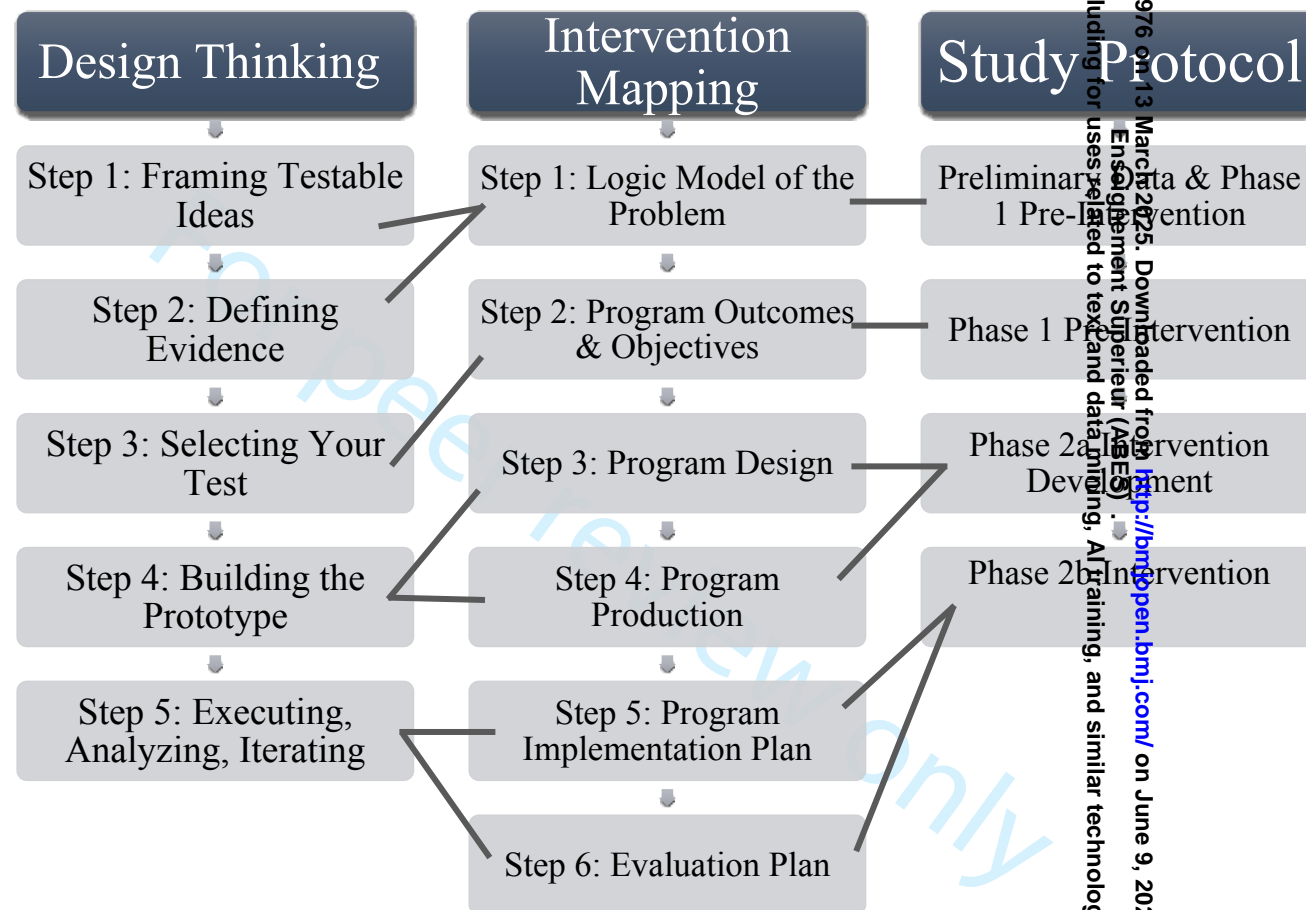


Figure 2: Alignment of design thinking and intervention mapping with prototype intervention

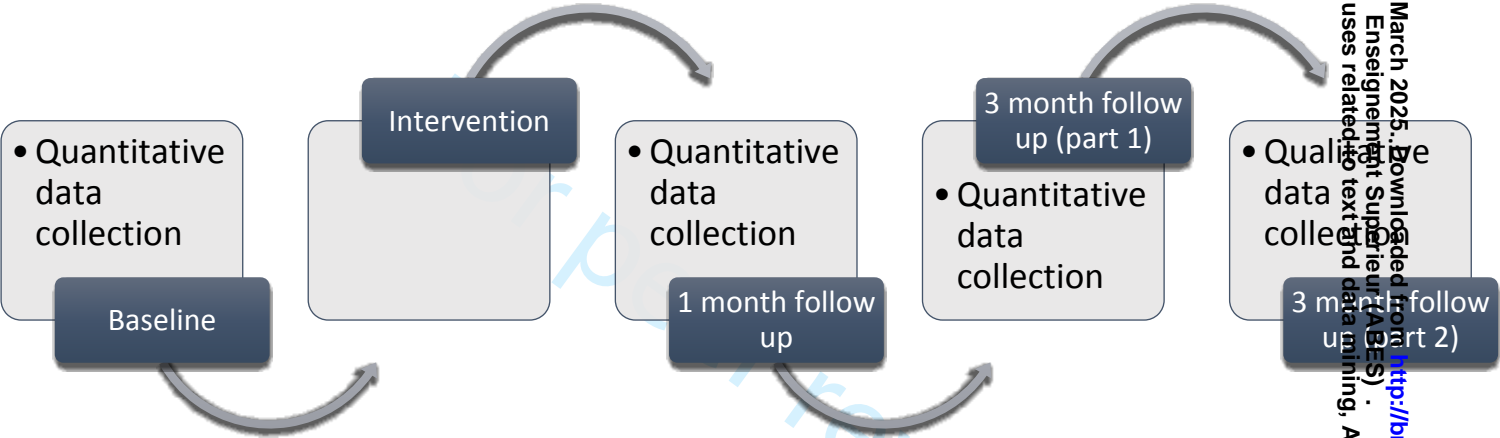


Figure 3: Timeline for intervention implementation and evaluation

BMJ Open

Development and evaluation of a health care decision-making intervention for African American parent-adult daughter dementia dyads: A mixed-methods study protocol

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Kenneth Hepburn, PhD, FGSA, ORCID:0000-0002-3498-6272

khepbur@emory.edu

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Article Summary

Strengths and limitations of this study

- The structured culturally responsive prototype intervention will be designed using an explanatory sequential mixed methods approach.
- Because the study is entirely remote, we developed protocols to support collecting data via phone or paper instead of videoconferencing.
- Using a single-group clinical trial design is a limitation, but we will gain insights about African American parent-adult daughter dementia dyads.

Keywords: aging, dementia, decision making, primary health care

person when making health care decisions [3]. This concern is further exacerbated for African American care partners by their understandable distrust in the healthcare system due to known differences in their health care experiences [17, 18]. Research suggests shared decision-making approaches can reduce these dilemmas for care partners [19].

In addition to lifecourse influences, family dynamics within African American parent-adult daughter dementia dyads (hereafter referred to as dementia dyads) affect the quality of life of both members of these dyads. For African American care partners specifically, the relationship between care partners and African American persons living with ADRD matters; non-spouse care partners experience significantly worse quality of life [4]. In addition, family dynamics influence the quality of life of African American care partners; greater reports of dyadic strain within African American dementia dyads were significantly associated with worse quality of life for African American care partners [4]. In a literature review focused on African American women care partners of individuals with chronic illnesses, including ADRD, African American women care partners who reported poor family functioning experienced worse quality of life [8].

Involvement of African American persons living with ADRD in daily care decision making (e.g., what to eat, what to wear) significantly contributes to a better quality of life for African American persons living with ADRD [4, 20]. Yet, to our knowledge, the influence of health care decision-making processes within African American dementia dyads on their quality of life has not been examined. In the broader context of health care decision making within dementia dyads, persons living with mild to moderate ADRD desire to be included in health care decision making regarding their care [21]. Care partners often overlook this desire and focus on the person living with ADRD's capacity to participate in the healthcare process [21]. Supporting health care decision-making for African American persons living with ADRD by meeting the educational and psychosocial needs of African American dementia dyads may hold promise in improving their quality of life.

Structured programs focused on education and support have positively influenced quality of life [10, 22]. Specifically, structured programs have been found to improve the quality of life of both members of dementia dyads [10]. In a systematic review of structured intervention programs for dementia dyads, participation in these programs was suggested to be particularly beneficial for underrepresented groups [22]. However, few structured intervention programs address racial differences in ADRD caregiving, are culturally responsive, and include dyadic research [10, 23].

The proposed study aligns with the recommendation of the National Institute on Aging's Dementia Care Summit [24] to "use theory-driven frameworks" and "address the complex heterogeneous and interacting challenges experienced by persons living with ADRD and their caregivers." This study is guided by three frameworks: the National Institute on Aging's Health Disparities Research Framework[5], the Black Family Socio-Ecological Context Model [25], and the Superwoman Schema [26]. The National Institute on Aging's Health Disparities Framework [5], highlights levels of analysis (i.e., behavioral, sociocultural, and environmental) relevant to health disparities in African American dyads and families. The Black Family Socio-Ecological Context Model [25] provides a conceptual basis for examining societal and lifecourse influences including health disparities within individual, dyadic, and family spheres. Finally, the

Superwoman Schema [26] specifically focuses on influences of cultural characteristics of African American women, which will be applied to the African American adult daughter care partners (referred to as care partners beyond this point).

METHODS AND ANALYSIS

Study design and study setting

The study is being conducted at Emory University Nell Hodgson Woodruff School of Nursing with enrollment occurring across the United States. Recruitment across the United States was chosen purposively to strengthen heterogeneity in the sample. This National Institutes of Health Stage 0-1B study [27] will use a mixed-methods explanatory sequential design [28] to identify key factors that will lead to the development and piloting of a structured culturally responsive prototype intervention (referred to as prototype intervention beyond this point) for African American dementia dyads and/or families of persons living with ADRD. This explanatory sequential mixed-methods study will first collect and analyze quantitative data from surveys and then collect qualitative data from semi-structured interviews to explain the quantitative findings, which will build upon each other [28].

The study will be implemented in two phases (Figure 1). The first phase or preintervention phase will consist of both quantitative and qualitative data collection and analysis. This phase started in June 2022. The first phase will end with the integration of data that will inform the development of a prototype intervention. We anticipate the integration of data will occur by August 2025. The second phase is divided into two parts—intervention development and piloting of the prototype intervention. The anticipated start date for the intervention development is September 2025. The anticipated start date and end date for the pilot is September 2026 and September 2027, respectively.

Familiarity with technology

We anticipate technology will be used during all phases of this study. If needed to improve familiarity with the proposed technology, the first author or a member of the research team will schedule a time to orient participants. This orientation will include any of the following: 1) an interactive demonstration of the steps of using REDCap and the Zoom videoconferencing platform and 2) a demonstration of using Zoom as a conference call line for those with telephone access only.

Culturally responsive research

The Center for Health and Healthy Aging, which is housed in the University of Minnesota’s School of Public Health defines culturally responsive research as research that “incorporates the knowledge and unique cultural experiences of individuals, children, families, organizations, and communities served” and is “driven by first-hand knowledge and an understanding of the varied needs of diverse families and communities—their choices, not by cultural stereotypes or generalized assumptions [29].” This study protocol is culturally responsive in two ways. First, key informants are an integral part of the design thinking and intervention mapping approaches for the development of the prototype intervention (described below) in the design thinking and

intervention mapping approaches we will use to develop the prototype intervention. Second, the D.E.C.I.D.E. Research Lab, which is led by the first author, has a community advisory board (described in greater detail below) associated with it. The community advisory board their lived experience to the first author during quarterly meetings, which guide all the projects coming from this lab.

Key informants

Key informants will be used in phase 2 of this study. Key informants will consist of up to 6 African American dementia dyads who did not participate in any of these phases of the study. All key informants must meet the above inclusion criteria for the parent living with ADRD and care partner, respectively. In addition, key informants must have experience navigating at least 2 of the following health care decisions: getting a formal diagnosis of ADRD for the parent living with ADRD, finding and/or changing a healthcare provider of the parent living with ADRD, managing the parent living with ADRD's medications under the guidance of a healthcare provider, deciding the parent living with ADRD will receive a treatment or have a procedure, participating in conversations about hospice, palliative care, and/or end-of-life care with a healthcare provider for the parent living with ADRD. Key informants will receive an honorarium for their participation.

Design Thinking

Design thinking is often described in 5 iterative steps: empathize, define, ideate, prototype, and test. We will use the 5 steps of experimentation based on design thinking approaches [30]. These five steps are 1) framing testable ideas, 2) defining evidence, 3) selecting your test, 4) building the prototype, and 5) executing, analyzing, and iterating [30]. The design thinking will be carried out at the Design Studio at Emory University Roybal Center for Dementia Caregiving Mastery. The Design Studio uses the design thinking process to challenge and refine an emerging product, which is grounded in the early and frequent involvement of key informants or end users in product design [31]. Through a facilitated process by a design thinking specialist of divergent-convergent fast track engagement of appropriate intellectual resources to clarify ideas and design testable user-centered prototypes. The design studio sessions will be conducted in three study visits with the same participants using focus group methods. A member of the research team will attend and document nonverbal cues during each session.

Intervention Mapping

Intervention mapping is a 6-step iterative process, which consists of developing a logic model of the problem; program outcomes and objectives (e.g., logic model of change), program design, program production, program implementation plan, and evaluation plan [32]. Intervention mapping sessions will be facilitated by the first author using the Intervention Mapping Workbook and accompanying textbook [32]. During this facilitated process, the prototype intervention will be developed, piloted, and evaluated.

A total of six sessions (i.e., three design thinking sessions and three intervention mapping sessions) are planned to occur over a 6-month period for prototype intervention development. A

fourth session of both will occur after piloting to evaluate the prototype intervention. The size of each design thinking session will be limited to 8-10 participants and include key informants and research team members. Intervention mapping sessions will have members of the research team and community advisory board. All session will last approximately 90 minutes, be audio-recorded, and transcribed verbatim. Refer to Figure 2 for how these methods will align with the study design.

Patient and Public Involvement

Community advisory board

The community advisory board (CAB) currently consists of non-participant healthcare providers and staff, African American adult daughters, African American older adults, and African American persons living with cognitive impairment. The CAB was established in 2022 and is affiliated with the first author’s laboratory. The research questions and outcome measures were determined prior to establishing the CAB. However, CAB members acknowledge the importance of the research question and outcome measures. The CAB members provided suggestions and insights on how to conduct the study visits with the parent-adult daughter dyads often based on their own lived experiences. The CAB members are involved in developing and disseminating recruitment materials, determining the compensation of participants, and identifying inclusion and exclusion criteria. The CAB will actively participate in data analysis and interpretation of the findings to develop the prototype intervention. Specifically, CAB members will provide feedback on data collected in phase 1 the preintervention phase and phase 2 intervention development and intervention. The results of the study will be presented to the CAB members during one of our quarterly meetings as well as sent to them via email. The authors will disseminate the findings via publications, conference presentations, and community events. Community events are often recommended by CAB members. Each member of the CAB is given an honorarium for each meeting they attend.

PHASE 1: PREINTERVENTION

Inclusion and exclusion criteria of parent-adult daughter dyads

Inclusion and exclusion criteria for the study participants are provided below. Inclusion criteria for the parent living with ADRD consists of the following: (a) self identifies as African American; (b) age 50 years or older; (c) community dwelling; (d) experiences signs and symptoms of mild to moderate dementia through family care partner’s report on the Dementia Severity Rating Scale; (e) able to read, speak and understand English, and (f) willing to participate. Exclusion criteria for the parent living with ADRD (referred to as parent hereafter) is any confounding significant neurologic diseases (e.g., Parkinson’s disease) or a major psychiatric disorder (e.g., schizophrenia).

Inclusion criteria for care partners (referred to as daughter hereafter) consists of the following: (a) self identifies as African American; (b) at least 18 years of age; (c) daughter or daughter-in-law (including fictive kin individuals); (d) aids in activities of daily living and/or instrumental activities of daily living for their parent; (e) makes/takes part in health care decisions; (f) able to

read, speak, and understand English; (g) cognitively intact; (h) access to an internet connection for hosting videoconferencing; and (i) access to a phone or computer that accepts emails.

Scheduling and consent process

Interested participants are guided to the study's REDCap prescreening survey by an Institutional Review Board (IRB) study flyer or after contact with the research team. Completion of the prescreening survey takes approximately ten minutes. Once the prescreening survey is completed, the research team is notified and contacts the potential participant within 3-5 business days via email or phone based on the potential participant's preference. After this initial contact is made, all interested, eligible participants must participate in a scheduling call. The scheduling call was implemented for four reasons: 1) to schedule the study visit, 2) to begin to build rapport with the daughter, 3) to answer study questions, and 4) to screen for fraudulent participants. The scheduling call has become an important element in the recruitment process because the daughters learn more about the study, get to speak to the first author directly, and can provide additional information to help the study visit run smoothly for the parent.

The study visit is scheduled for 2.5 hours, and participants are instructed to have their camera on for the duration of the visit. This time was determined after the first few study visits lasted at least this long due to lengthy conversations with the participants and/or technical concerns. A waiver of documentation of consent was applied to this study. Verbal consent is obtained at the beginning of the study visit. To determine if the parent can provide consent, the parent answers six questions from the University of California, San Diego Brief Assessment of Capacity to Consent tool [33]. Parents must answer at least four questions correctly to be able to independently consent. Otherwise, their daughter or other family member provides verbal consent, and the parent provides verbal assent.

Quantitative data collection

The quantitative aim of this study is to identify behavioral, sociocultural, and environmental influences associated with the health care decision-making processes and quality of life of African American dementia dyads. Primary data collection is through online surveys using REDCap [34]. Refer to (Table 1) for a list of surveys. Data collection will take about 30-40 minutes for the parents and 40-50 minutes for the daughters. During each study visit, the parent is questioned first to minimize fatigue. The first author reads the questions and marks the answers using the paper-pencil method. The answer choice options for each survey are displayed on the shared videoconferencing screen, so the choices remain visible for the parent. After the parent completes their portion of the surveys, the first author emails the REDCap survey to the daughter to complete during the allotted study visit or at their earliest convenience. Each member of the dyad will be compensated with a \$25 gift card for their time (total \$50 per dyad). Dyad members choose between three retail gift card options.

Table 1. List of measures used in screening and preintervention phase^{a-e}

Domain	Measure	Concept of interest	Target ^a (PLWD/ D)
Cognition and General Health			
	Dementia Severity Rating Scale	To quantify the stage of cognitive impairment for screening	D
	Montreal Cognitive Assessment	To screen for cognitive impairment	PLWD
	Self-Rated Health	To assess general health	PLWD, D
Behavioral Lifecourse Influences			
	Family Assessment Device	To assess communication, problem solving & family functioning	PLWD, D
	Family Decision Process	To assess family decision making:	PLWD, D
	Resource Utilization in Dementia	To assess health care decision utilization of both dyad members	D
Sociocultural Lifecourse Influences			
	Giscombe Superwoman Schema Questionnaire	To assess cultural identity regarding gender	D
	Cultural Justifications for Caregiving Scale	To assess cultural identity regarding caregiving	D
	Dyadic Relationship Scale	To assess relationship quality regarding dyadic strain	PLWD, D
	Duke Social Support and Stress Scale	To assess their social networks	D
Environmental Lifecourse Influences			
	Rapid Estimate of Adult Literacy in Medicine-Short Form	To assess health literacy	PLWD, D
	Alzheimer's Disease Knowledge Scale	To assess Alzheimer's disease specific health literacy	D

	Perceived efficacy in patient-provider interactions	To assess the patient-provider relationship	PLWD, D
Outcomes	Quality of Life-Alzheimer's Disease	To assess the quality of life of both dyad members	PLWD, D
	Decision Self-Efficacy Scale	To assess self-confidence in one's ability to make informed health care decisions	PLWD, D

^a PLWD= parent living with dementia ^bD= daughter

Sample size estimation

Based on G*Power [35] analysis to conduct a multiple linear regression with a two-sided $\alpha = 0.05$, 80% power, and 6 predictors, a projected sample size of 60 dyads is needed to detect a moderate-to-large effect (Cohen's $f^2 = 0.26$). The rule of 10 participants (i.e., dyads) per degree of freedom has been applied based on a similar sample size used in previous dyadic research [4, 36]. Our proposed sample size of 70 African American dementia dyads will allow for a 10% attrition rate of participants or missing data.

Quantitative data analysis

Preliminary bivariate analysis will be conducted in Stata IC [37] to determine predictors of quality of life and health care decision self-efficacy from the data. No more than six predictors will be used in linear multiple regression models. Multilevel modeling, specifically Actor-Partner Interdependence Modeling [38, 39], will be conducted in HLM software [40]. If the sample size is less than our anticipated goal, we analyze parents and daughters separately using within-group effect sizes. Descriptive statistics will be computed through Stata IC to examine sample characteristics. Quantitative data analysis will be completed before qualitative data collection. We will match the domains of the surveys that are statistically significant to the interview questions for qualitative data collection.

Qualitative data collection

The qualitative aim of the study is to describe the decision-making processes of members of African American dementia dyads. After quantitative data analysis, we will connect the sample by choosing a subsample of the dyads to complete the qualitative interviews using maximum variation sampling based on diverse neighborhoods (e.g., rural, urban, suburban), relationship of parent (e.g., mother, father, in-law), and acute care visits of the parent living with dementia (e.g., none vs. one or more).

Each qualitative interview visit will be scheduled to last 1 hour. The visit will be conducted virtually using Zoom. The first author or a member of the research team will conduct the qualitative interviews using a semi-structured interview guide. Both members of the African American dementia dyads will be interviewed together (about 30 minutes). Then, each member of the dyad will be interviewed separately (about 15 minutes for each) [41], with the interviews

of the parent occurring before the daughters to prevent fatigue of the parent. This process was successful in the first author’s preliminary research study [42].

There are two reasons for dyadic interviewing [43]. First, having the participants together initially will help with building rapport, assuage possible apprehension with the interview process, and allow for the first author to observe the interactions between the dyad members. Second, separating the dyads will allow for more in-depth interviewing to enhance trustworthiness, validity, and comparison and contrast. Individual interviews also allow either a member of the dyad to speak more freely and confidentially about their role or the other member of the dyads’ role in decision making.

Participants will be notified of the recording of interviews before consenting to the study and will be reminded prior to the recording at the start of the semi-structured interview. Audio/video-recordings will be generated via Zoom. Recordings of the semi-structured interviews will be transcribed verbatim. Following each interview, the first author will create field notes and conduct reflexive journaling during this portion of the study [44, 45]. Sampling will continue until saturation (i.e., no new information or themes emerge from the data) is achieved [46]. Each member of the dementia dyad will receive a \$25 gift card after completing the semi-structured interview as compensation for their time (totaling \$50 per dyad). There is potential for up to 2 follow-up visits to clarify questions and for member checking the themes generated from the data for reliability and validity of the results. Each follow-up interview will last no more than 1 hour. No other information will be collected from the participants during the follow-up visits.

Qualitative data analysis

Using de-identified data, all transcripts will be managed in MAXQDA software [47]. The transcripts will be analyzed using directed qualitative content analysis to provide a more structured approach to identifying relationships among variables [48], which will lead to the identification of key components of the health care decision-making processes from the perspectives of the dyads. The research team will independently review transcripts and identify codes. Other members of the research team who are not a part of the initial coding of the data will be brought in to resolve any discrepancies among the independently developed codes. Member checks will occur to serve as validation of the interpretation (if the participants agree to future contact by the research team).

Integration of preintervention data

The integration of the phase 1 preintervention data will allow the explanation of the quantitative survey items with the qualitative results, themes, and quotes, through use of a joint display. Following steps 1-3 of design thinking and steps 1-2 of intervention mapping, this phase will end with the prototype intervention program outcomes and objectives.

PHASE 2: DEVELOPMENT OF PROTOTYPE INTERVENTION AND PILOTING

Phase 2a: Intervention development

The second phase of this study begins with the development of a prototype intervention (2a). Integrated findings from the phase 1 preintervention phase of this study will be used to develop the prototype intervention following step 4 of design thinking and steps 3-4 of intervention mapping. An outline for the prototype intervention will be developed. This outline will consist of the prototype intervention program plan (e.g., themes, scope, and mechanisms of action), program materials and messaging, and program use (e.g., adoption, implementation, and maintenance). The outline will serve as the basis for course design activities with the Roybal Center instructional consultants and specialists. The outline will be used to create mockups of the curriculum and materials. These mockups will be shared with the key informants through an iterative process. This process will capture the feedback of the key informants, integrate the changes, and result in the presentation of new mockups. Other prototype intervention specifics (e.g., number of sessions, which member of the dementia dyad will participate in these sessions, psychoeducational vs. counseling, synchronous vs. asynchronous, in-person vs. online) will be determined during these sessions. Once the key informants, CAB, and research team come to a consensus, the prototype intervention will be finalized, and then the first author will start a second recruitment.

Phase 2b: Intervention

Implementation and evaluation

Phase two will end with the implementation and evaluation of the prototype intervention (2b). The implementation of the prototype intervention will consist of 20 African American dementia dyads who have not previously participated in this study. A \$25 gift card will be given to each member of the dementia dyad at each data collection time point and after completing the semi-structured interview as compensation for their time (totaling \$200 per dementia dyad).

Eligible dyads will be scheduled for one baseline study visit and three follow-up visits post intervention (Refer to Figure 3). The three follow-up visits will consist of a 1-month study visit and two 3-month study visits. Quantitative data collection will be collected at baseline and the two follow-ups post intervention. The parents will complete the Montreal Cognitive Assessment at baseline only. The Quality of Life-Alzheimer's Disease Scale and Decision Self-Efficacy Scale will be completed by both members of the dyad at baseline (e.g., pretest) and at the two follow-up visits (e.g., posttest) to examine changes in quality of life and health care decision self-efficacy. Given our current success with dyadic data collection, we anticipate baseline and follow-up visits should last no more than 30 minutes for the parents and 40 minutes for the daughters except the follow-up visit part two at 3-months post intervention.

Part two of the 3-month follow-up visit will consist of a qualitative interview that will last about 45 minutes, which will occur within two weeks of the quantitative 3-month follow-up part one. The dementia dyads will first be interviewed together and then separately. The interviews held with both members will focus on their perceptions of the prototype intervention. The individual interviews will allow for feedback about the prototype intervention but will focus on their perceptions of their quality of life and decision self-efficacy. Questions on the interview guide will focus on the usability and acceptability of the prototype intervention to help with future

refinements. The first author in collaboration with the CAB and research team will develop an interview guide to conduct the qualitative interviews. Interviews will be recorded and transcribed verbatim.

Recruitment and consenting process

The recruitment, consent, and scheduling processes that were used in the preintervention process will be the same for the piloting of the prototype intervention with one exception. The 20 dementia dyads piloting the prototype intervention will not have participated in the preintervention phase of this study.

Sample size estimation

The rule of ten participants (i.e., dyads) per degree of freedom will be applied. We conducted a power calculation using G*Power to provide a comparison. If we conduct repeated measures analysis of variance with a two-sided $\alpha = 0.05$, 80% power, and 2 predictors, a projected sample size of 15 dementia dyads is needed to detect a large effect (Cohen's $f^2 = 0.39$). We will recruit twenty dementia dyads to control for a potential 20% attrition rate.

Components of the intervention

Since the prototype intervention will be created in this study, we cannot describe the prototype intervention. We anticipate the prototype intervention will be family based with a focus on issues of communication, problem-solving, health system literacy, and family systems. Once developed and evaluated, the intervention protocol will be published.

Study outcome measures

Primary outcomes

The primary outcomes of this study are feasibility, acceptability, usability, and preliminary efficacy. Feasibility will be measured based on the ability to recruit and retain the targeted number of participants within the desired timeframe with full participation. The recruitment plan is for 20 African American dementia dyads to be enrolled in ≤ 6 months. The actual number of dyads recruited will be reported as the outcome with the percentage of the goal achieved (actual/goal). Feasibility will assess the ability to recruit 60% of the sample. Acceptability will be measured based on the ability to retain participants in the intervention and in the study. Attendance of participants will be monitored during the program sessions of the prototype intervention. Retention will assess the ability to maintain 70% attendance in intervention program sessions and 80% of participants from baseline to 3-month follow-up part two. Usability will focus on the ease of use and desire to use the prototype intervention from the perceptions of the dementia dyads. Acceptability will assess the appropriateness of the prototype intervention as well as satisfaction with how it was delivered from the perspectives of the dementia dyads. Data about usability will be gathered during the qualitative interviews at the 3-month follow-up visit part two.

Preliminary efficacy will be determined by the change in the quality of life of both members of these dyads and the change in decision self-efficacy for the adult daughter of the parent. Using

the Quality of Life-Alzheimer's Disease Scale, we anticipate the change from baseline to follow-up in quality of life will be significantly better ($p = .05$) or trends towards significance for both parents living with ADRD and adult daughters. To evaluate self-efficacy with health care decision making, we will use the Decision Self-Efficacy Scale. We anticipate a significant ($p = .05$) positive change in both the parents and their adult daughters or a trend towards significance. Effect size will be examined for both analyses.

Data analysis

To evaluate the feasibility, acceptability, usability, and preliminary efficacy of the prototype intervention, we will use quantitative, qualitative, and mixed methods. Feasibility will be determined by using descriptive statistics. Usability and acceptability will be analyzed using directed content analysis [48]. Qualitative data from the interviews will be managed in MAXQDA software [47]. For the pretest-posttest preliminary efficacy analysis, longitudinal dyadic analysis will be conducted in Stata IC [49, 50]. Descriptive statistics will be computed for measures at each time point. Internal consistency reliability will be assessed for each measure by computing Cronbach's alpha for complete item responses. You could look at parents and daughters separately using within-group effect sizes or how you described it above, but I would do some combination of individual within change for daughters and parents and then some way of examining dyads where both benefited. Given the small sample size, we will conduct within-group effect sizes for the parents and adult daughters separately. There are also three descriptive approaches we can use to evaluate the dyadic benefits of the pilot—above-zero, pretest risk status, and/or pattern analysis [51]. We will evaluate the data using the above-zero approach. The data from the parent-adult daughter dyads will be coded on each outcome separately based on whether both the parent and adult daughter reported any posttest improvement (i.e., above zero change) [51]. Qualitative data from the interviews will be embedded in the quantitative data from the preliminary efficacy analysis. The goal of this mixed-methods integration is to refine the prototype intervention based on the piloting.

DISCUSSION

This study examines the feasibility, useability, acceptability, and preliminary efficacy of a culturally responsive health care decision-making prototype intervention for African American parent-adult daughter dementia dyads. We will examine the potential influence of this prototype intervention on the quality of life of both members of these African American dementia dyads and the health care decision making self-efficacy of African American parents using an explanatory sequential mixed methods design. The findings from this study will produce a more refined version of this prototype intervention, which will be implemented in a randomized controlled trial.

However, there are some anticipated challenges in conducting this study. First, recruitment may take longer than expected. Recruitment strategies will be discussed during research team meetings to determine the next steps and appropriate amendments to the recruitment plan. Second, there is the potential for incomplete data. Data missing at random will be handled with full information maximum likelihood. Lastly, given the small sample size of this study,

nonsignificant findings with variables of interest are possible. We will look for trends towards significance, calculate effect sizes, and incorporate descriptive analysis approaches.

Despite these challenges, the design of this study has many strengths. First, we will identify target(s) of the prototype intervention. These targets will be determined by dyadic and mixed methods analysis. Using multilinear regression modeling, specifically Actor-Partner Interdependence Modeling [52], we will identify quantitative influences at both the individual and dyadic levels. Significant quantitative influences will be matched to interview questions. Second, the inclusion of the perspectives of both members of African American dementia dyads' is another strength. The expected outcome is to gain information about the individual, dyadic, and family dynamics that influence quality of life and health care decision-making of African American dementia dyads.

ETHICS AND DISSEMINATION

Ethical Considerations

The first phase of the study was approved by the Emory University Institutional Review Board (IRB). Once qualitative data collection is completed, a modification will be submitted to the IRB to obtain approval for the second phase of the study. The study is registered on ClinicalTrials.gov (NCT05139290).

Informed Consent

Participant interviews will be completed only after obtaining informed consent. If assent is obtained from the parent living with ADRD, consent will be obtained from their proxy. Confidentiality of participant's data will be maintained during the study.

Dissemination

Results will be published in peer-reviewed journals, clinicaltrials.gov, and scientific conferences. Community dissemination will include articles in community newspapers and/or newsletters, community forums and health fairs, and other ways identified by the community advisory board.

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Figure 1. Summary diagram of the study design

Figure 2. Alignment of design thinking and intervention mapping with prototype intervention

Figure 3. Timeline for intervention implementation and evaluation

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Author's Statement

KBJ, KL, WP, and KH contributed to conception and study design. KBJ prepared the first draft of the study design proposal. KL, WP, and KH were involved in critical revisions of the study design proposal. All authors contributed to the finalized study proposal. All authors contributed to the preparation of the manuscript submission. All authors reviewed the manuscript and approved for publication. Kalisha Bonds Johnson / KBJ acted as guarantor.

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Competing interest statement. None declared

Data Statement

De-identified data and analytic methods are available by completing a data use agreement. For researchers interested in obtaining de-identified data request should be made by contacting the corresponding author.

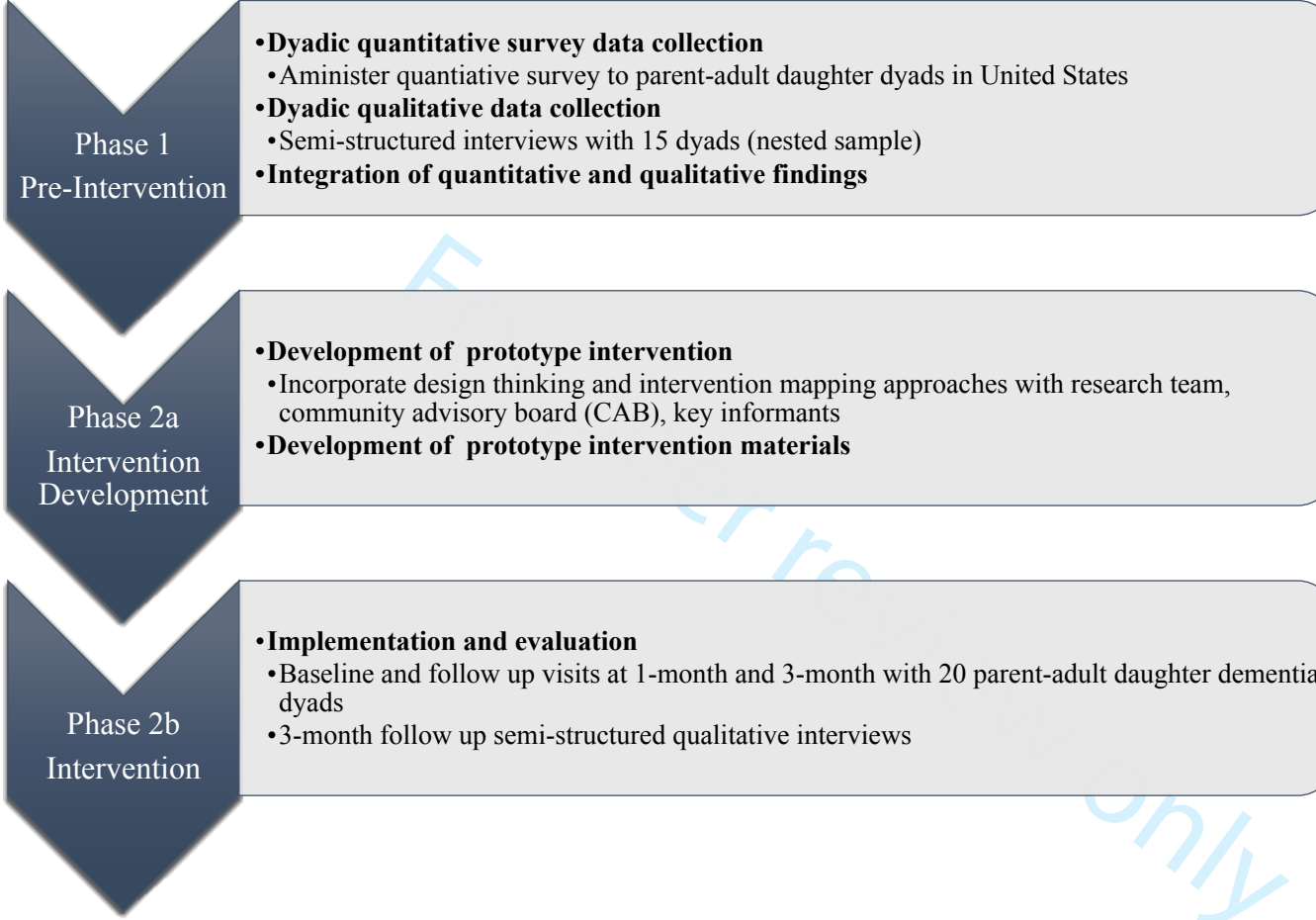


Figure 1: Summary diagram of the study design

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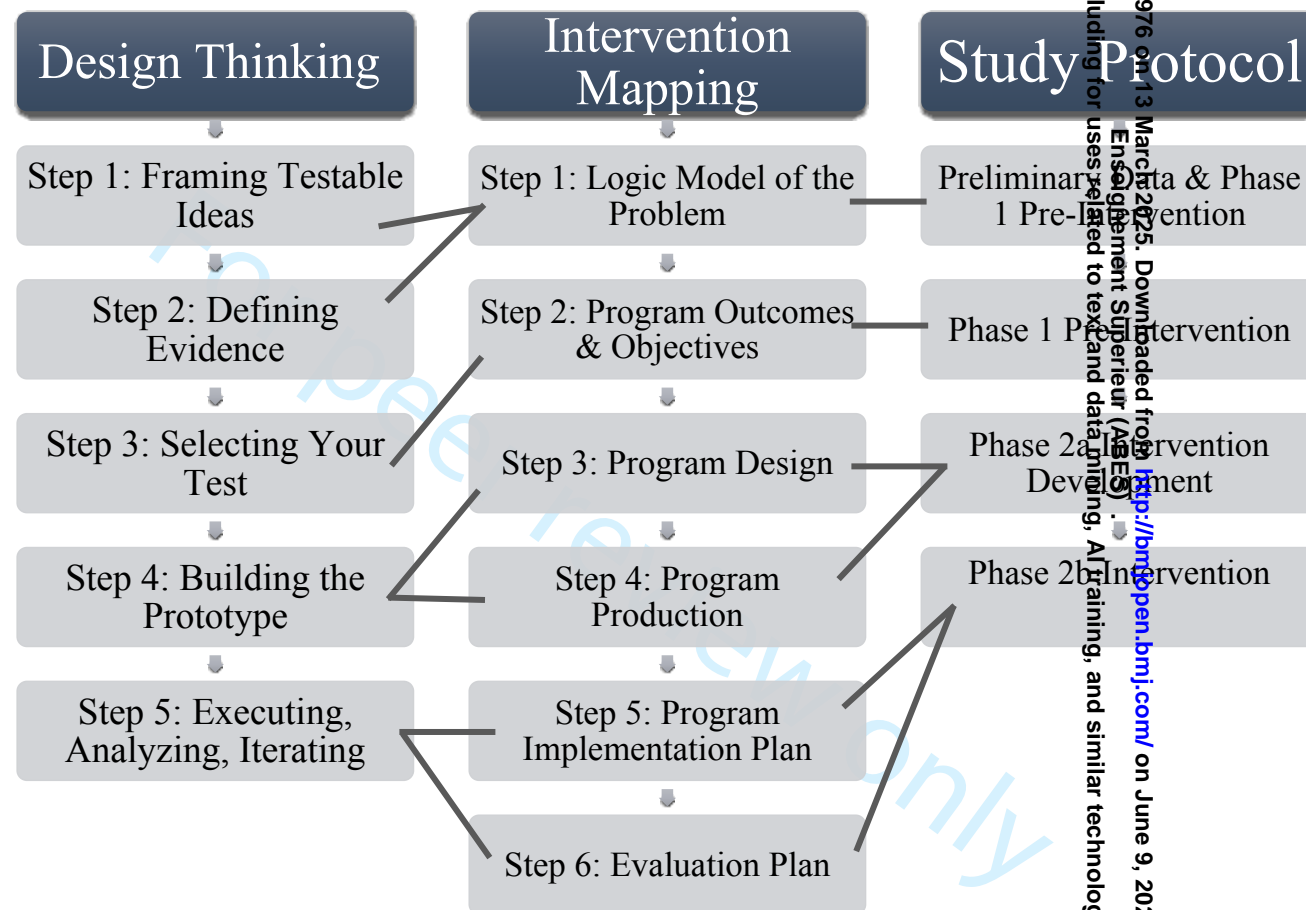


Figure 2: Alignment of design thinking and intervention mapping with prototype intervention

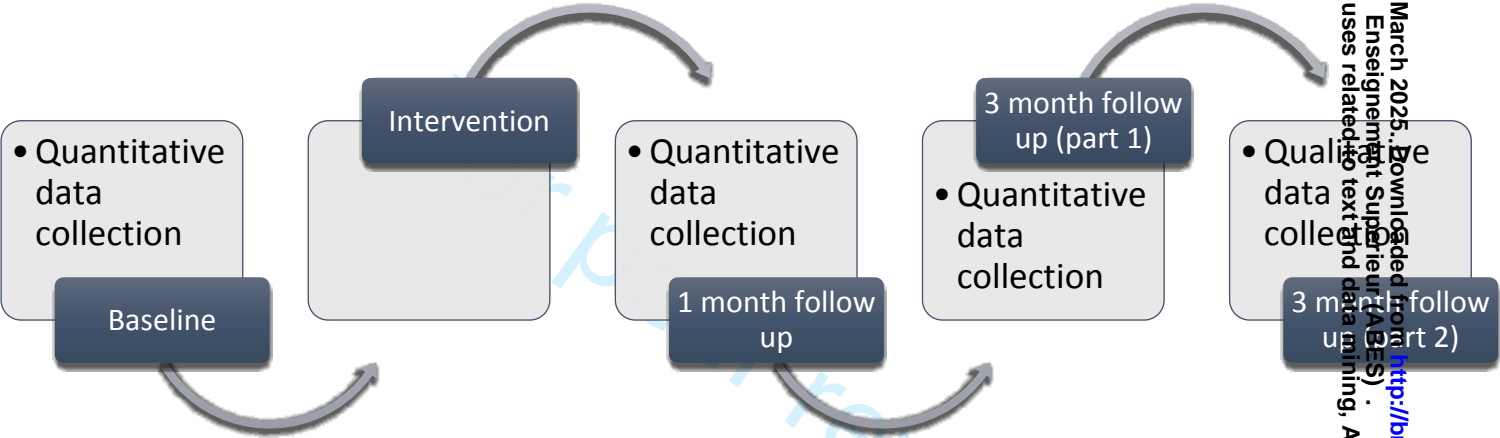


Figure 3: Timeline for intervention implementation and evaluation