Study Protocol

Title: Creating a Faith-Based Toolbox for African Americans Living With Moderate and Severe Dementia

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Creating a Faith-Based Toolbox for African Americans Living with Moderate and Severe Dementia

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PI: Fayron Epps, PhD, RN

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Research Protocol

(A) Background and Significance

African Americans (AAs) are more likely than other racial/ethnic groups to be diagnosed with Alzheimer's disease and related dementias (ADRD) and will account for 20% of persons living with dementia (PLWD) by 2050.[2] PLWD experience progressive distress and confusion, which decreases their quality of life and also contributes to the emotional strain, burden, social isolation, and depression experienced by caregivers.[16] Research indicates that religiosity (the inner commitment to one's faith through integration of religious beliefs and practices into one's life) can serve as a protective factor against the stressors associated with caregiving and living with ADRD.[5] Religiosity affirms the significance and sacredness of life and the value of a person, even in the face of loss.[34] The progression of ADRD often restricts the person and the caregiver from participating in religious communities and familiar church-based religious practices.[12,16] Religion is usually defined by individuals identifying with an organized system of beliefs, practices, rituals, and symbols concerning the sacred.[35] Religious beliefs shape family values, motivations and behaviors toward the commitment to care for their loved ones.[5] Religious involvement and practices are associated with religious coping that positively influences health outcomes.[36,37] Through religious coping, religiosity frequently provides the basis for hope and a framework for finding meaning, even when navigating difficult life events and transitions.[38,39] Religious coping encompasses a wide array of religious behaviors, activities, and beliefs (e.g., praying, reading scriptures, attending religious services, seeking congregational and clergy support, relying on faith in God) that are used to manage the psychological perception and consequences of an unfavorable situation.[38]

Religiosity has been shown to be beneficial in improving the quality of life of PLWD and family caregivers.[40-42] Engaging in personal faith and prayer can help enhance positive attitudes in PLWD by increasing feelings of security, support, and meaning in their lives.[34,43] Meditative practice contributes to psychological and physiological well-being by bringing self-control, inner peace regardless of outer conflicts, and patience and joy even in difficult circumstances.[23,44,45] In addition to private religious practices, religious engagement can occur via television, podcast, and live streaming connections from faith communities.[41] There is evidence that, for a PLWD, the spiritual connectedness (internal feelings and beliefs to the sacred) related to personhood does not disappear as ADRD progresses, but the relationship with and expression of one's own spiritual life changes over time with illness-produced decreases in cognitive functioning.[12,15,26-28] If caregivers cannot find ways to facilitate spiritual connectedness and engagement in pleasant and meaningful activities, such as religious activities, a PLWD may experience an unmet emotional need that could lead to behavioral problems due to loneliness, sadness and frustration; [19,29] such problems can adversely affect caregiver well-being. This association underscores the need to strengthen support services and identify resources, nonpharmacological approaches, and meaningful activities, including faith-based ones, that promote the well-being of AA family caregivers and community-dwelling PLWD.

The majority of older adults in the United States consider religion to be significant in their lives.[1,2] Indeed, 75% of AA older adults deem religion to be substantially important to their well-being[1] and have a stronger presence of religiosity compared to other racial/ethnic groups.[3-8] Historically, faith communities have been the backbone of support for AA families when in distress.[9,10] AAs living with ADRD may particularly benefit from engaging in religious practices.[41] Overall, religious practices and activities serve a common good for AA older adults living with ADRD.[23,45] Participation in organized religion provides meaningful connections and enhances spiritual connectedness and quality of life for AA older adults through accepting diagnoses and life situations, maintaining relationships, maintaining hope, and finding meaning in their lives.[11-15] Participating in religious traditions and belonging to a faith community provides a positive sense of identity and continuity as circumstances change in life and reduces stress by providing stability.[46,47] Physical health may diminish, financial and social circumstances may change, but religious and spiritual engagement may contribute to the preservation of personhood.[34] However, many faith communities, AA faith communities included, do not have programs to support the families and congregants living with ADRD.

The goal of this clinical feasibility trial and NIH stage 1 intervention development project[48] is to go beyond the four walls of the church to find ways to meet the spiritual needs of persons living with moderate and severe ADRD "where they are" in order to help them remain religiously and spiritually engaged. This study is premised on the notion that religious/spiritual engagement is possible and beneficial for PLWD[19,28] and that this beneficial effect will extend to their caregivers. Robust evidence suggests that family caregivers have poor health outcomes and significantly higher rates of psychological and physiological difficulties, relative to age-matched noncaregiver adults.[49-51] This relationship is even more pronounced among AA caregivers.[50,52-54] Dementia caregiving is stressful and associated with negative effects on caregivers' health including high caregiver burden, physiological as well as psychological stress, depression, poor sleep, and poorer quality of life.[50,51,55,56] Thus, caregivers observing the beneficial effects and engaging in meaningful religious and spiritual activities with their family member living with ADRD may potentially improve their psychological and physiological well-being.[3,4,19,30-33,36] Despite the growing evidence of the benefits of meaningful activity engagement,[18-20,24,25] a gap exists about the kinds of faith-based activities that might be acceptable to and useful for engaging AA adults living with moderate and severe ADRD. Meaningful engagement in faith-based home activities could provide a culturally organic way for PLWD to retain a spiritual connection and decrease behavioral symptoms while enhancing caregiver well-being. [11,12,18-20,42] The purpose of this project is to design and test the feasibility of employing components of a **Faith**-based **H**ome **A**ctivity **T**oolbox (Faith-HAT) and create intervention tools for a full-scale randomized controlled trial (RCT) to test the efficacy-effectiveness of faith-based programs on patient and caregiver outcomes. This faith-based, family-oriented, highly person-centered approach to enhancing a greater quality of life for families draws on powerful Christian principles from within the AA community. This toolbox will be a readily scalable strategy for planning successful activity engagement and enabling faith communities to continue to support persons living with moderate and severe ADRD.

Theoretical Framework: The Meaningful, Enjoyable, and Doable Approach (MED) will serve as the conceptual basis for this proposed intervention.[25] This approach draws primarily on the Selective Optimization with Compensation (SOC)[57] and the Needs-Driven Dementia Compromised Behavior (NDB)[29] models. The SOC has been useful in explaining how to support optimal development in the face of losses that occur across the lifespan.[57] The NDB is specific to supporting adaptation in the context of living with ADRD as all behavior is a result of an unmet need arising from the interactions between a person's functional abilities and their immediate personal state and their physical or social environment.[29] Activities tailored to both functional abilities and personal preference result in higher levels of engagement as the activities are viewed as meaningful and enjoyable.[25] Thus, meaningfulness of activities that reflect an individual's values can lead to positive benefits of a sense of normalcy for a PLWD.[25,58]

Innovation

This project is innovative and moves beyond existing interventions that merely provide ADRD-related education to church leaders and congregants within the AA community. The proposed project will provide a framework for religious practices specific to engaging PLWD to be used in the home setting. This project is innovative in that stakeholder engagement is significant to the design of the toolbox, allowing those affected by ADRD to influence design and implementation of the toolbox. Addressing one of the main recommendations of the Research Summit on Dementia Care,[59] we are including caregivers and PLWD on the research team. Stakeholder engagement will occur throughout the project as caregivers and PLWD will be members of the design team, along with church leaders. The design team will routinely meet throughout the project to advise on the design and implementation of the Faith-HAT.

To date, no evidence has been published to correlate meaningful faith and spiritual activities on the physiological health of caregivers. Exposure of an individual to a physical or mental stressor activates their stress response through the sympathetic nervous system (SNS) axis.[60] The SNS response involves increased heart and respiratory rate and a shift in blood flow delivery toward the heart, brain, lungs, and skeletal muscles at the expense of other organs, thus preparing the host to fight or flee from the stressor.[60] This project is innovative in that we are proposing to introduce physiological measures of stress response in AA caregivers related to engaging in Faith-HAT which adds promise to advancing the field of caregiving research. We include an ecologically and stress response measure through the use of a wearable wristband. To measure stress, we have traditionally relied on standard questionnaire instruments whose capacity to measure similar concepts across racial/ethnic groups has been problematic.[61-64] Further, such instruments are subjective, confounded by the participant's willingness to disclose, and are able only to capture stress perception and exposure[65] and not truly stress response. In this study, we measure both aspects of this construct (exposure/response). Additionally, measuring stress response unobtrusively in the participant's home-setting adds a novel dimension not previously tackled in ADRD. In the essence of moving science forward, we hope that objectively assessing the physiological measures of stress response in caregivers will corroborate (or not) these standard questionnaire instruments and allow scientists and clinicians to precisely tailor and test interventions to improve the health and well-being of caregivers.[66]

(B) Aims

The project will have 3 aims:

Aim 1. Develop a prototype Faith-HAT for AA families living with moderate and severe ADRD. Brainstorming workshops with a purposefully created design team and at least 15 semi-structured interviews with faith leaders, caregivers, and PLWD will be used to explore capabilities and resources available to support faith-based home activities and the key spiritual and religious practices families and PLWD consider essential, engaging, and meaningful. Results will be used to develop the content of Faith-HAT. Member checking will occur to validate fittingness and readiness of Faith-HAT for testing.

Aim 2. Test the feasibility and explore preliminary effectiveness of employing Faith-HAT. Our feasibility outcomes include success in recruitment, engagement, and retention in a purposive sample of 30 dyads. Our effectiveness outcomes include: caregiver-reported behavioral problems in PLWD; caregivers' self-reported psychological well-being (stress, burden, depression); and objective physiological measures of stress response (heart rate variability, skin conductance) to be measured at baseline and 12 weeks.

Aim 3. **Construct a refined toolbox of meaningful faith-based home activities.** Using integration and refinement of quantitative and qualitative data, results from Aim 2 will be matched, compared, and validated with the design team to refine the meaningful Faith-HAT for AA families living with moderate/severe dementia. The goal of this aim is to have materials ready for deployment for a fully powered clinical trial.

(C) Study Designs

Preliminary Studies: My previous qualitative work showed that families view participation in religious activities as a way to promote the physical and emotional health of AA older adults living with ADRD.[17,41] The results of this study with 18 AA older adults living with ADRD and their family caregivers stressed the importance of religiosity to the well-being of PLWD.[17,41] In fact, many PLWD were unable to physically attend church to worship as the disease progressed to the later stages, and families were left to come up with meaningful religious activities to do at home with their family member (i.e., singing gospel songs, praying, watching worship on the television).[17,41] In my current work with the Atlanta-based Ministerial Alliance, we have found that families affected by ADRD do not attend church due to fear of embarrassment and uncertainty about the PLWD's behavior (Alzheimer's Association Research Diversity Grant 18-56229). These findings support the need for further exploration of religions' impact on AA families affected ADRD.

<u>Previous work in stress and physiological monitoring.</u> For the past year, I have worked with my proposed mentor, Dr. Hajjar, and his research team for the Brain, Stress, Hypertension and Aging Research Program (BSHARP) to measure stress in adults. Preliminary results using simultaneous wristband and standard measures of skin conductance and 3-chest ECG lead HR data (EDA100C and ECG100C, Biopac Systems, Goleta, CA) were collected from 16 participants (mean age=64 (SD=7); 7 women; 4 AA; 9 with mild cognitive impairment). Moving average was plotted for the SCL (by applying a lowpass filter on the EDA signal) and HR derived from RR interval from ECG or Peak-to-Peak (PP) intervals from the photoplethysmography (PPG) volume tracing from the wristband. The correlation between the 2 methods ranged from $\rho = 0.99$ for SCL EDA (**Figure 1A**) 0.8 for the HRV (**Figure 1B**) all $p < 0.0001$.

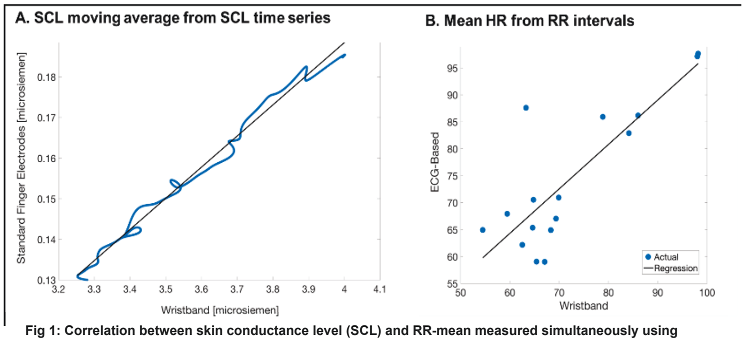
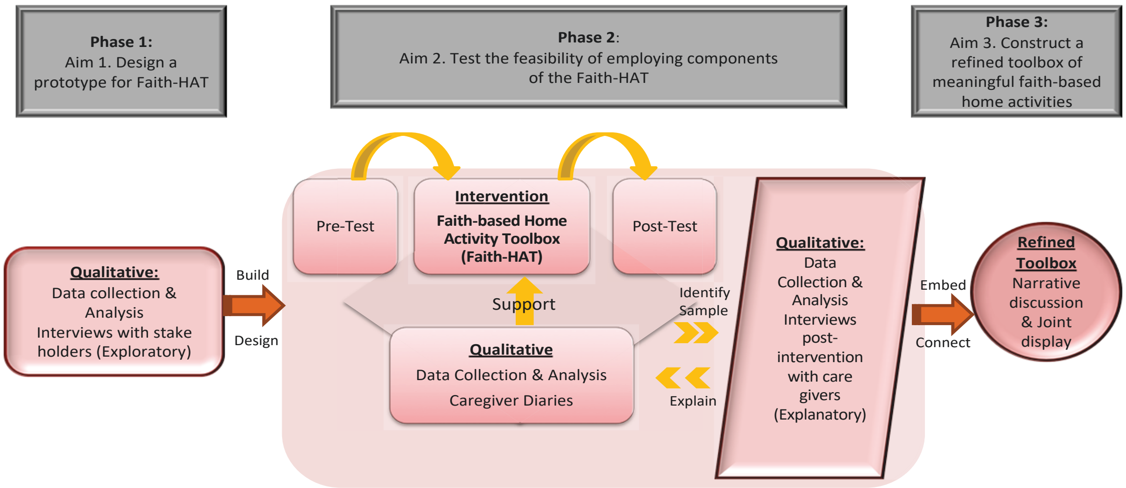


Fig 1: Correlation between skin conductance level (SCL) and RR-mean measured simultaneously using wristband and standard method (chest ECG and EDA using finger electrodes). A: SCL correlation: $R^2=0.99$, $p<.0001$; B: HR $R^2=0.7$, $p<.0001$.

Design: A multi-phase mixed methods intervention design[67] with iterative member checks will be used to design, test, and refine a faith-based home activity toolbox for AA older adults living with moderate and severe ADRD (**Figure 2**). This NIH stage 1 intervention development project will include intervention generation and refinement.[48] Using a mixed methods approach in this project allows the research team to evaluate the acceptability and utility of intervention components and the potential barriers to adherence and behavioral change.[68] The mixed methods design will maximize study strengths and counterbalance single approach weaknesses.[67,68] For this clinical feasibility trial, the aims will be implemented in phases. Initially, brainstorming workshops with a purposefully created design team and at least 15 semi-structured interviews with faith leaders, caregivers, and PLWD will be conducted to design the Faith-HAT. Next, the Faith-HAT will be assessed for feasibility and preliminary effectiveness, examining psychological and physiological outcomes that will be measured through surveys, online caregiver diaries, an automated BP monitor, and a wearable wristband. Finally, integration and refinement of quantitative and qualitative data will be used to refine the Faith-HAT. This project will further build on the collaborative relationship with Emory Alzheimer's Disease Research Center's (ADRC) Minority Engagement Core, Registry of Remembrance (coalition of 20 AA churches and community organizations). Additionally, selected church leaders from South Fulton Ministerial Alliance that have supported prior research projects will be actively engaged in the development of the Faith-HAT.

Figure 2. Multi-phase Mixed Methods Intervention Design



Setting: This study will take place in the Atlanta Metropolitan area of Georgia, Fulton and DeKalb counties.The Atlanta Metropolitan area is the 9th largest metropolitan area in the U.S., and Atlanta is the 2nd largest majority AA metro area in the country[69] with 1.9 million AAs.[70] The region's population of older adults is expected to increase significantly during the next 25 years. By 2040, approximately one in five residents will be 65 years of age or older.[71] Older adults 65 and older are not only the second fastest growing age group but have increased by 45% since 2010 in this region.[71]

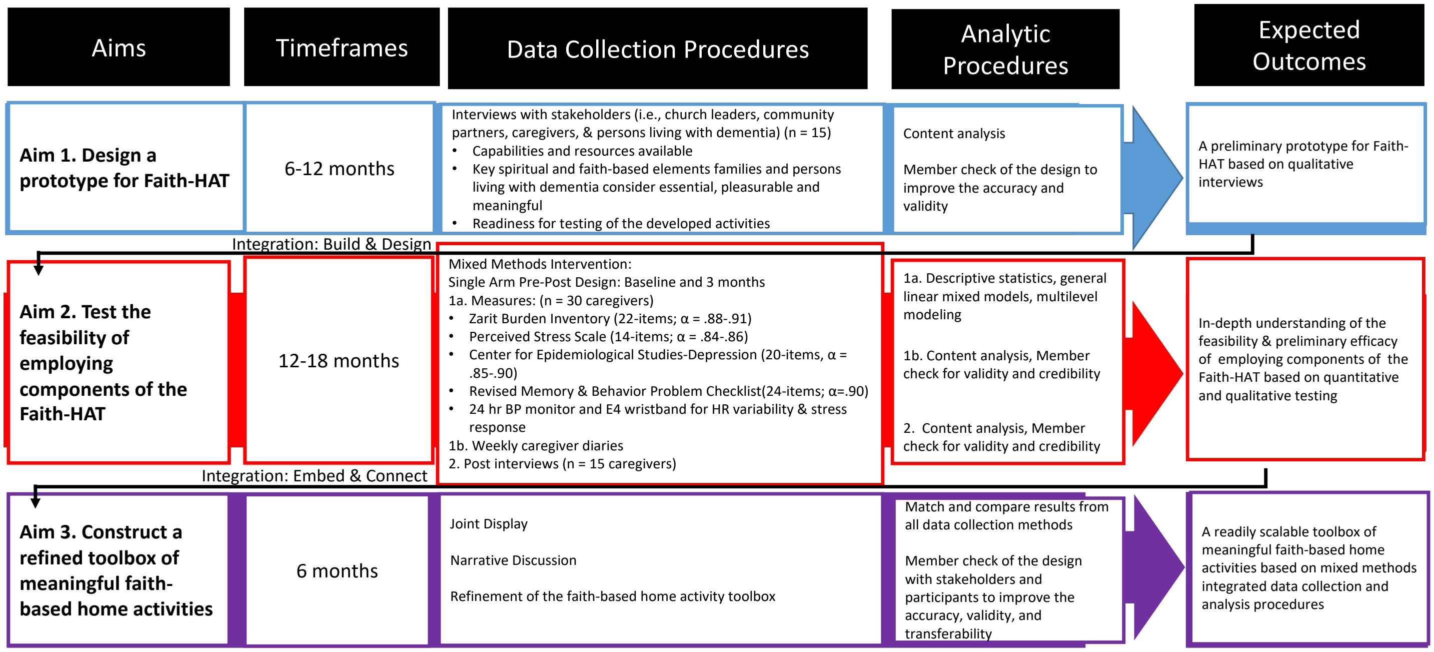
Setting:
This study will take place in the Atlanta Metropolitan area of Georgia.

Procedures: (include population, recruitment, and field methods)
Aim 1. Develop a prototype faith-based home activity toolbox (Faith-HAT) for AA families living with moderate and severe ADRD. Through leveraging existing resources, a design team (n= 10-12) will be formed consisting of family caregivers, PLWD, and members from Emory ADRC's Registry for Remembrance and South Fulton Ministerial Alliance (coalitions of AA churches in Atlanta, GA). This design team will meet quarterly (in-person or *via videoconference*) over the course of the project to brainstorm, review data, and co-design the Faith-HAT. The design team will also assist in recruiting a purposeful sample (n = 15) of stakeholders, including church leaders, community partners, dementia family caregivers, and PLWD to participate in individual 1-hour semi-structured interviews (*in person, phone, or videoconference*) to further inform the design of the Faith-HAT through an iterative process. Interested stakeholders will be consented as research subjects and receive a $25 honorarium post-interview. Initially, participants will be queried on: (a) capabilities and resources available to support faith-based home activities; and (b) key spiritual and faith-based practices families and PLWD consider essential, engaging, and meaningful. All interviews will be conducted by the PI, audio-recorded, and transcribed verbatim. Field notes and journaling will be maintained for each interview. Data will be managed in NVivo 12 software. Data collection and analysis will be performed concurrently. Qualitative content analysis will examine manifest and latent content of the interview data.[72] Content analysis of transcripts will lead to the identification of key components and delivery characteristics for Faith-HAT. Results will be shared with the design team, in which their role will be to examine the results and provide substantive feedback that will be used to design the prototype toolbox. The anticipated product for Aim 1 is a preliminary model for a faith-based home activity toolbox. We anticipate that toolbox activities will likely include devotional readings, prayer, music, religious images, and audio-

or video-recorded sermons. We anticipate that families will have up 30 activities to choose from with the average activity length to be 10 minutes. The toolbox will be placed online. Participants will be able to access the toolbox via a tablet computer that will be provided to them. Before testing, member checks will occur with the design team and stakeholders for their feedback on fittingness and readiness for testing of Faith-HAT.

Aim 2. Test the feasibility and explore preliminary effectiveness of employing Faith-HAT. We will achieve this aim by conducting a feasibility clinical trial (n = 30). Our feasibility outcomes will include success in recruitment, engagement, and retention. Our effectiveness outcomes will include caregiver-reported perceived change in behavioral problems in PLWD as the primary outcome and caregivers' self-reported perceived psychological well-being (e.g., stress, burden, depression) and objectively measured physiological stress response (e.g., heart rate variability, skin conductance) as the secondary outcomes. We will use quantitative surveys, qualitative interview data, and caregiver diaries to assess psychological well-being and a wearable wristband to assess the physiological wellbeing.

Figure 3. Implementation Matrix



Aims	Timeframes	Data Collection Procedures	Analytic Procedures	Expected Outcomes
Aim 1. Design a prototype for Faith-HAT	6-12 months	Interviews with stakeholders (i.e., church leaders, community partners, caregivers, & persons living with dementia) (n = 15) • Capabilities and resources available • Key spiritual and faith-based elements families and persons living with dementia consider essential, pleasurable and meaningful • Readiness for testing of the developed activities	Content analysis Member check of the design to improve the accuracy and validity	A preliminary prototype for Faith-HAT based on qualitative interviews
Aim 2. Test the feasibility of employing components of the Faith-HAT	12-18 months	Mixed Methods Intervention: Single Arm Pre-Post Design: Baseline and 3 months 1a. Measures: (n = 30 caregivers) • Zarit Burden Inventory (22-items; α = .88-.91) • Perceived Stress Scale (14-items; α = .84-.86) • Center for Epidemiological Studies-Depression (20-items, α = .85-.90) • Revised Memory & Behavior Problem Checklist(24-items; α=.90) • 24 hr BP monitor and E4 wristband for HR variability & stress response 1b. Weekly caregiver diaries 2. Post interviews (n = 15 caregivers)	1a. Descriptive statistics, general linear mixed models, multilevel modeling 1b. Content analysis, Member check for validity and credibility 2. Content analysis, Member check for validity and credibility	In-depth understanding of the feasibility & preliminary efficacy of employing components of the Faith-HAT based on quantitative and qualitative testing
Aim 3. Construct a refined toolbox of meaningful faith-based home activities	6 months	Joint Display Narrative Discussion Refinement of the faith-based home activity toolbox	Match and compare results from all data collection methods Member check of the design with stakeholders and participants to improve the accuracy, validity, and transferability	A readily scalable toolbox of meaningful faith-based home activities based on mixed methods integrated data collection and analysis procedures

Integration: Build & Design

Integration: Embed & Connect

1-Design: A single arm pre-post design will be employed. Participants will be asked to take part in in-person survey and physiological baseline data collection, engage weekly in at least 3 activities from the Faith-HAT with person caring for living with ADRD for *6 weeks*, complete 12 weekly diary entries online through RedCap platform, and provide in-person survey and physiological endline data *immediately post-intervention and at 6-weeks post-intervention*. In addition to qualitative and qualitative measures, tracking of the enrollment and attrition rate will enable us to compute the "feasibility" of the program. Within the framework of a feasibility study,[73-75] 12 weeks is a reasonable amount of time for the behavior toward the use of the Faith-HAT to be adopted and show meaningful effects.

2. Participants: Despite AA family networks being complex and large involving blood and non-blood related individuals, there is often a family member that has the primary caring responsibility.[76] Therefore, a total of 30 dyads of AAs with moderate and severe ADRD and primary male or female caregivers will be recruited from the greater Atlanta area. Caregiver inclusion criteria*:* (a) at least 18 years of age; (b) reside with and care for (average of 4 hours/per day of unpaid assistance) for a family or friend experiencing signs and symptoms of moderate or severe ADRD as indicated through self-report or family caregiver report (c) able to read, speak, and understand English; (d) cognitively intact; (e) access to a wireless internet connection (wi-fi); and (f) access to a phone or mobile device that accepts text messages. PLWD inclusion criteria: (a) community-dwelling experiencing signs and symptoms of moderate or severe ADRD through self-report or family caregiver report; and (b) has a family caregiver that resides with them and is willing to participate; (c) no plan for institutionalization in the next month; (d) history of participating in private or public religious activities; and (e) understands English (toolbox activities will be produced in English). Family and self-reporting of the level of cognitive impairment will be identified according to the signs and symptoms of moderate and severe ADRD associated with the Alzheimer's Association[16] categorization of moderate/middle, and severe/late stages of dementia.

Caregiver exclusion criteria: does not have a history of participating in private or public religious activities; hostile to PLWD religious expression; and has active plans to move to another residence without family member with ADRD . PLWD exclusion criteria: has active plans to move from under care of primary caregiver; routinely attends church; hostile to religion; and unwilling to engage in Faith-HAT.

3. *Recruitment*: A non-probability sampling strategy will be used to recruit a modest sample of 30 dyads of AA persons living with moderate and severe ADRD and their family caregivers to participate in Phase 2 of this clinical feasibility trial. The proposed sample size is justified through Browne's[77] general rule of using a minimum of 30 participants to have the capacity to estimate a parameter in a feasibility study. We will recruit participants over a 12- month period, with a target recruitment rate of 2-3 participants per month. We will recruit participants through churches in the South Fulton Ministerial Alliance and of the Emory ADRC Registry of Remembrance coalition (see letters of support). Announcements will also be placed in church bulletins of these churches. Church leaders and congregation members may also refer a caregiver that they know who may be interested in the study. If additional family caregivers are needed, we will use snowball recruitment by asking caregivers enrolled to refer other caregivers like them to participate.

Interested participants will be screened by the PI for eligibility via phone. If eligible, times will be scheduled to consent in person prior to beginning the study. Questions posed after explaining the project during eligibility determination and the consent process will be used to gauge participants' cognitive ability to take part in the project. The cognitive capacities of the caregiver and PLWD to provide consent will be assessed by using a five-item open-ended "Evaluation to Sign Consent" questionnaire with an established interrater reliability of 0.81.[78] Caregivers who are not able to correctly answer all items will be determined not to have the cognitive capacity to provide consent and participate. PLWD who are not able to correctly answer all items will also be deemed not to have cognitive capacity to provide consent; thus, they will provide assent and their primary caregiver will provide informed consent on their behalf.

4- *Intervention*: The caregiver/PLWD dyad will engage in Faith-HAT for *6 weeks*. They will select activities from Faith-HAT at least 3 times a week. Possible examples of these activities include devotional readings, prayer, music, religious images, and video and audio recorded sermons. Results from Aim 1 will further specify delivery characteristics for Faith-HAT. Faith-HAT will be placed on online, which requires little technical know-how by users. The PI will provide training to participants on how to use the Faith-HAT and online diary on the tablet computer provided by the project. Training and implementation will be monitored with a checklist documenting the participant's ability to use the device, access the toolbox through Brightspace, implement the intervention, and understand the feedback in relation to troubleshooting. The "dose" and frequency of use of the interventions will be calculated by determining the number of days/weeks the intervention was used for *6* weeks. The quality of delivery of Faith-HAT will be assessed during weekly online diary checks.

5- Study visits: Enrollment, Baseline, and Endline: Once eligible, the PI will schedule a visit with the participating caregiver to consent and enroll, provide training and instruction on Faith-HAT, and obtain baseline data. Baseline caregiver-reported behavioral problems in PLWD; caregivers' self-reported psychological well-being (stress, burden, depression); and objective physiological measures of stress response (heart rate variability, skin conductance) will be collected. Each week for *6 weeks* the dyad will be asked to complete at least 3 activities from the Faith-HAT, and the caregiver will complete 12 weekly diary entries online. At the end of the intervention, the PI will schedule a visit and participants will provide survey and physiological endline data *immediately post-intervention and at 6-weeks post-intervention.* **Figure 3** shows the various measures collected at each visit.

6. Study procedures: **Figure 3** illustrates the project's associated procedures and analytic plan.

(a) Interview and instruments: Demographic and psychological well-being will be collected by an interview conducted by the PI with the caregiver. Measures will specifically include: (a) caregiver burden, (b) perceived stress, (c) depression, and (d) behavior and psychological symptoms of the PLWD. The following surveys will be used: (a) Zarit Burden Inventory,[79] (b) Perceived Stress Scale,[65] (c) Center for Epidemiologic Studies Depression Scale,[80] (d) Revised Memory Behavior and Problem Checklist[81], and *Sleep Scale from the Medical Outcomes Study* (see **Figure 3** for further instrument details). The demographic questionnaire will assess basic demographic characteristics (e.g., age, gender, education, caregiving length, PLWD age and gender).

Additionally, caregivers will report current chronic illnesses and medication use before and after the intervention to assist in determining the accurate effect of Faith-HAT on physiological stress response measures. Caregiver participants will be supported by receiving a $25 honorarium for each baseline, endline, and qualitative interview completed. Caregivers will also receive $5 for each weekly diary entry completed.

(b) Caregiver diary: Participants will complete weekly diary entries online the same day every week to evaluate their engagement in Faith-HAT through a survey software system (RedCap) that will be placed in Brightspace. Each entry will prompt caregivers to describe their experiences based on the following: (a) changes in your family member's condition since last week; (b) activities from the Faith-HAT that were used in the last week and frequency; (c) experience engaging in the Faith-HAT with your family member; (d) other religious activities used with your family member that were not included in Faith-HAT (e) a decrease or increase in behavioral problems of the family member this week using a 5-point Likert scale; (f) personal feelings of stress, burden, depression; (g) noticeable changes in your physical health this week using a 5-point Likert scale; and (h) experience caring for your family member this week. Recognizing the busy schedules of caregivers, weekly reminders (phone calls or texts) will be sent to caregivers to complete online diary entries on the tablet computer.

(c) Stress response using a wristband: We propose to use a wristband, a wearable-sensor (i.e., wristwatch), that detects stress reactivity in an ecologically appropriate setting (to overcome the artificial setting of the clinical site), and to collect longer-duration measurement of the physiological signals.[84-86] We will use the E4© watch (Empatica, Boston MA) which includes a photo-plethysmography (PPG) sensor for blood volume pulse and heartrate variability (HRV) measurement and a galvanic skin response (GSR) sensor activity as well as an infrared thermopile.[84-86] Caregiver participants will be asked to wear the wristband for 24 hours, simultaneously with the ABPM, prior to starting the intervention and again at the end of the intervention. Empatica® has provided validity data for the wristband suggesting a correlation with standard measures of 0.66-0.99, $p=2*10^{-11}$ for skin conductance levels (SCL)[87] and similar values 0.98-0.99, $p < 2*10^{-7}$ for HRV (time- & frequency- domains).[88] We hope to find a reduction in caregiver HRV and GSR, signifying reduced stress reactivity, post-intervention.

(d) Qualitative Interviews: A subsample of 15 caregiver participants will be selected for in-depth interviews (1-*hour to be held in person, phone, or videoconference*) at post-test to further elaborate on feasibility, acceptability, and preliminary changes related to Faith-HAT. (i.e., *How well did using the Faith-HAT go? Did you notice a behavior change in your family member? Did your family member seem comfortable and engaged while using the Faith-HAT? How has your physical and psychological health changed? Have emotions toward caring for your family member changed? Do you feel closer to your family member? Do you have further ideas on additional religious activities that would be effective to include in the Faith-HAT? Are there any changes you would make to the program?).*

7. Data Collection and Analytical plan:

(a) Quantitative Analysis: Quantitative data will be entered at the time of each interview directly into the dedicated project tablet computer and saved on Emory's secure REDCAP platform. All data entry screens are set up in REDCAP and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data. Data will be exported into SPSS monthly and syntax run for cleaning, further data verification and file concatenation. Descriptive statistics will be computed through SPSS v 24 to examine patient characteristics. Sex as a biological factor will also be considered as a variable for analysis. While the primary expected products of this work pertain to feasibility, and our study is not powered to conduct formal hypothesis testing, we will perform preliminary analyses with a multilevel modeling framework to assess relative group changes in scores for measures of stress, burden, and behavioral problems of PLWD. Although effect sizes will not be estimated,[89] general linear mixed models will be applied to account for the repeated measurements for each study participant and a group by time term will be included in the model to gauge trends and direction of effects. In preliminary analyses, descriptive statistics and frequency distributions will be examined to identify outliers and ensure integrity of merged files. For all multi-item scales, internal consistency will be examined using Cronbach's alpha and associated statistics (e.g., item-total correlations, alpha if item deleted). Formal test-retest/inter-rater reliability coefficients will be computed as data are concatenated.

(b) Qualitative Analysis: All interviews will be conducted by the PI, audio-recorded, and transcribed verbatim. To reduce bias, field notes and journaling will be maintained during this phase. Interviews and diary entry data will be managed in NVivo 12 software. Data collection and analysis will be performed concurrently. Qualitative content analysis will examine manifest and latent content of the diary entry data.[90] The PI will work with another member of the research team to independently review transcripts and identify codes and the research team will be brought in to resolve any discrepancies among the independently developed codes. Member check will occur to serve as validation of the interpretation.

Aim 3. Construct a refined toolbox of meaningful faith-based home activities. No recruitment of participants and active data collection will occur for this aim. Qualitative and quantitative results from all data collection points from Aim 2 will be matched and compared to assist in refining the design of the Faith-HAT. The integration and interpretation of results through joint display and narrative discussion will be shared with the design team. Details of narrative discussion including caregiver discussion of activities to add, other ways to use the Faith-HAT, and circumstances under which engagement in Faith-HAT with the family member were optimal will be reviewed by the research and design team to develop a plan for program revision. Reasons for participant withdrawal and participant feedback on delivery characteristics will also be used to determine what components of the Faith-HAT will need to be revised. The research and design team will work together to produce a refined Faith-HAT program. Member checks of the refined toolbox with participants in Aims 1 and 2 will be conducted to improve the authenticity of the work and improve the accuracy, validity, and transferability of design readiness for deployment for a fully powered clinical trial.

Informed Consent Process:

Interested stakeholders and caregivers will be contacted by the PI or member of the research team to schedule a time to consent prior to data collection. Consents will be obtained at mutually agreed locations or *via videoconference platform*. *Participants will be given the option to provide verbal consent after a discussion using a videoconference platform. After the videoconference discussion and verbatim review of verbal consent document, verbal informed consent will be obtained from the participant or legal representative and a copy of the consent will be mailed to them for their records.*

Consents will be obtained at mutually agreed locations or provided by *phone/videoconference*. Consents will be obtained prior to data collection and the primary investigator will be responsible for obtaining consent.

Persons with dementia will be participating in Phase 1 and 2 of this research project. For Phase 1 and Phase 2, if the person living with dementia is unable to give a legally effective informed consent, verbal assent will be obtained with informed consent to be obtained from their legally authorized representative. If the family caregiver participating in the study is not the legally authorized representative, the PI will have to meet with the legally authorized representative for them to provide consent on behalf of the decisionally impaired adult.

For Phase 1 and 2, questions posed during the consent process will be used to gauge the person living with dementia cognitive ability to take part in the project and give consent. *For participants with dementia providing verbal consent, questions will be posed during the videoconference discussion with their caregiver or legal representative present to gauge the person living with dementia cognitive ability to take part in the project and give consent*. If there remain concern about their capabilities to consent, an "Evaluation to Sign an Informed Consent" will be completed by the primary investigator.

If the person living with dementia is determined unable to give a legally effective informed consent, verbal assent will be obtained with informed consent to be obtained from their legally authorized representative. Participant eligibility requires for caregivers to be able to read, speak, and understand English and for persons living with dementia to be able to speak and understand English. The investigator will orally review the consent form with them and answer any questions they may have. Potential participants will be asked to describe what their participation in the study will involve and what is meant by voluntary participation. Potential participants needing more time to decide whether to participate will be allowed more time as needed.

The following measures will be implemented to minimize the possibility of coercion or undue influence: explaining the (a) voluntary nature of participation; (b) any alternatives to participating; (c) ability to withdraw at any time; and (d) fact that the decision whether or not to participate will have no impact on the availability of care through Emory Healthcare System.

All aspects of the study will be communicated to the participant or legally authorized representative.

Organizational Structure:

The study team for this K23 will be comprised of the Principal Investigator and applicant (Dr. Epps), Primary Mentor (Dr. Kenneth Hepburn), and Co-Mentors (Drs. Hajjar and Kemp). Dr. Epps will gain clinical trial research experience under the supervision of mentoring team. Dr. Hepburn will be primarily responsible for monitoring Dr. Epps implementation of all components of the study. The Co-Mentors will collaborate with and provide input to the PI in their given areas of expertise. The PI will responsible for the day to day operations of the study including recruitment and data collection management and analysis. The administrative site will be at Emory University, Nell Hodgson Woodruff School of Nursing.

Study Team Training:

All team members have completed CITI training. Study-specific training for staff who will be obtaining data by interview.

Data Management and Monitoring:

Ongoing monitoring of this clinical feasibility trial will be conducted by the PI and mentor team throughout the study to ensure the trial is conducted according to the approved protocol. Drs. Hepburn and Hajjar, both have experience with conducting clinical trials, will assist Dr. Epps in monitoring the study for safety and ensure that protection is assured throughout data collection. In addition, the Emory IRB will conduct regular reviews of study protocols, changes in study protocols, and adherence to protocols in the field. The PI is required to report any unexpected study-related adverse events to the Emory IRB and NIH. An independent safety monitor or a data and safety monitoring board will not be used.

Plans for Assuring Compliance with Requirements Regarding the Reporting of Adverse Events: The Principal Investigator is responsible for reporting serious adverse events to the Emory IRB and NIH within 48 hours of the occurrence.

A serious adverse event is defined as one that: is fatal or life-threatening (i.e., results in an immediate risk of death); requires or prolongs hospitalization; results in persistent or significant disability; is a birth defect; or is an important medical event that when based upon appropriate medical judgment, may jeopardize the participant, and may require medical or surgical intervention to prevent one of the outcomes listed above. Serious adverse events are not expected to occur during this study.

If there are instances of severe distress observed during the interviews, the we will provide the caregiver with a list of resources that the caregiver may use, such as counseling services or resources offered by Alzheimer’s association. In emergent circumstances, the we will make a referral to the local emergency room.

Plans for Assuring Data Accuracy and Protocol Compliance: Under the direction of Dr. Epps, all data will be managed in a secure fashion. All of the data will be kept on a secure server. In all of the data files, data will be coded by identification number only. Participants’ names will be separated from the data and kept on a secure server or in a locked file cabinet. Access to the secure server and the file cabinet will be strictly controlled by the Principal Investigator.

Data Maintenance: We will use REDCAP to minimize data entry errors. All data entry screens are set up in REDCAP and, where possible, include data delimiters (i.e., skip patterns, valid range limits) to ensure correctness and minimize missing data.

Confidentiality:

Interactions with participants will take place in a private setting. All data will be coded by participants' identification numbers and kept in a locked file cabinet in the investigators' office. Consent forms will be stored separately from the data and will be limited to a few key personnel (PI and research team) involved in the study. When the interviews are transcribed, any identifiable information that was inadvertently mentioned (about anyone) will be removed from the transcript.

Benefits:

We are designing and testing the feasibility of an intervention and participants may not directly benefit. However, participants may derive some benefit from an increased awareness of meaningful activities for PLWD and their family caregivers. The potential risk for emotional distress is believed to be minimal and considered reasonable in view of the potential benefits for reducing stress and promoting well-being of dementia family caregivers of persons.

Compensation:

Phase 1 participants will receive $25 honorarium upon completion of their semi-structured interview. Phase 2 caregiver participants will receive a $25 honorarium for each baseline, endline, and qualitative interview completed for a total of $75. In addition, they will also receive $5 for each weekly diary entry completion, for an additional honorarium of $60. Caregiver participants in Phase 2 possible compensation for total study participation is $135.

Limitations, Challenges, and Strategies: This clinical trial feasibility study is an early stage of intervention development. A limitation of this study is related to not incorporating a control group into the design to avoid bias. Therefore, causal inferences regarding effects will not be made from the results of implementing the Faith-HAT. Accuracy of family caregiver report of behavior changes of the PLWD might be questionable due to recall bias. To counterbalance this challenge, caregiver participants will complete weekly entries about behavioral occurrences by their family member in their caregiver diaries. Asking participants to complete diaries of their weekly experiences allows for the gathering of their perceptions, thoughts, and feelings, as well as their family member's behavior and caregiving in context. However, using weekly caregiver diaries for data collection presents a challenge of maintaining caregiver motivation to ensure the diary entries are completed. Members of the research team will send weekly text message reminders, establish good working relationships with participants, and provide positive reinforcements to maintain motivation throughout study period. Recruiting AA participants into clinical research has been an ongoing challenge. If the aforementioned recruitment strategies do not obtain the desired sample, recruitment will be extended to advertising through social media, radio, senior centers, community newsletters, and other public venues.

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