Title: A Church-based Intervention for Increasing Screening for Dementia Among African American Older Adults (ADC Pilot): Project Grace

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RESEARCH PLAN

Specific Aims

African Americans (AA) are at increased risk for dementia-related diseases and experience significant differences in diagnosis and other health outcomes regarding dementia and dementia care (e.g., Bonds & Lyons, 2018), including delayed dementia diagnosis and treatment. Along the chronic disease continuum of care, early screening is one of the first critical steps to reduce diagnosis delays. However, AA experience many multi-layered barriers to dementia screening and follow-up services including limited access to care, mistrust of health professionals, dementia-related stigma, and limited cultural appropriateness of dementia services (Bonds & Lyons, 2018; Epps et al, 2018). Despite growing calls to increase the reach of dementia screening in nonmedical settings with older adult AA to address disparities, no screening studies exist using culturally-tailored approaches in AA community settings, particularly AA churches.

AA churches have extensive influence and reach in Black communities, high attendance rates especially among older adults, strong emphasis on health, and outreach ministries that serve community members who may be at greatest risk for dementia (e.g., Pew Forum on Religion and Public Life, 2009; Pew Research Center, 2015; Taylor et al, 2004; Berkley-Patton et al., 2012). Our AA church-based pilot and RCT health screening studies have demonstrated: a) church leaders can and will expertly deliver screening interventions using prepackaged, supportive tools, b) tailored tools and church-based screening were highly acceptable/feasible and increased reach to church members and community members using outreach services, and c) use of this approach and such toolkits significantly increased screening for highly stigmatized diseases, including HIV and other sexually transmitted diseases (Berkley-Patton et al., 2010, 2013, 2016, 2018a). We also established that AA churches can reach high risk groups, including older adults with low levels of education, income, and insurance, and who suffer from diseases (e.g., diabetes, heart disease) that put them at greater risk (Berkley-Patton et al., 2018b).

The **primary aim** of this study is to conduct an exploratory pilot study to examine feasibility and outcomes of a culturally/religiously-tailored church-based dementia screening intervention among older adult AA church members and community members who use church outreach services in 2 AA churches (N=100). Our secondary outcomes are dementia-related stigma and linkage to care (LTC). Intervention *content* is based on the Theory of Planned Behavior (TPB), intervention *delivery* is based on the Social-Ecological Model (Ajzen, 1991; Bronfenbrenner, 1979) – both guided by a faith community engagement approach. Trained faith leaders will deliver the tailored intervention through multilevel church outlets: individual self-help resources (e.g., risk checklist, commitment to screening cards); group ministry discussion guides about dementia; church-wide services using sermon guides, responsive readings, and church bulletin inserts; and church-community level text messages, dementia screening, and linkage to care services. Two screening events will be held at each church. We will also conduct a process evaluation that will include post-test study focus groups.

Specific Aim 1. Test a religiously/culturally-tailored, church-based dementia screening intervention on **receipt of dementia screening**, stigma, and LTC use among an older adult AA church-populations at 4 months. **Hypothesis**. The tailored church-based dementia screening intervention will evidence increased screening and LTC rates, and lower dementia-related stigma beliefs at 4 months.

Specific Aim 2. Evaluate predictors of receipt of dementia screening at 4 months among older adult AA church-populations to determine modifiable screening facilitators/barriers.

Specific Aim 3. Conduct a process evaluation to examine study intervention implementation facilitators, barriers, and dose along with exposure and satisfaction to identify essential intervention components.

Developing culturally-tailored approaches to address this disparity will permit earlier dementia diagnosis, assist in eliminating disparities and provide timely opportunities to make lifestyle changes and take advantage of available treatment, make appropriate plans, seek support from family and friends, and maintain a desired quality of life for as long as possible. Findings from this study could provide a feasible, acceptable, sustainable dementia screening and LTC approach for older adult AA church-affiliated populations in faith community settings. Findings could contribute to understanding how to increase the capacity of AA churches to assist delivering and improving use of dementia services with underserved AA populations, and thereby assist in reducing dementia AA health disparities.

Significance

African Americans (AA) have double the risk of developing dementia as whites. Dementia risk factors include diabetes, smoking, poor diet, obesity, hypertension, physical inactivity, and depression (e.g., Crous-Bou et al, 2017; Deckers et al, 2018, Baumgart et al., 2015) – health conditions that significantly burden AA. AA are also diagnosed later in the disease than their white counterparts (Gleason et al, 2017). These disparities put older AA with cognitive impairment at risk for a variety of negative health outcomes such as falls, malnutrition, frailty, dehydration, and mortality (Fogg et al, 2017, 2018; Blackwood & Martin, 2017) because they do not receive disease-relevant supports for maintaining their health.

Past research suggests that a critical step in addressing unmet dementia care needs is to improve capacity for early dementia screening in primary care (e.g., Tan et al., 2016) and in the community (e.g., Han et al.2013). Despite continued calls for earlier ~~s~~screening of AA (e.g., Goldstein et al, 2014; Grober et al, 2016, Jackson et al, 2017), many screening barriers exist for AA – and are multilayered. These include limited access to dementia information and screening (e.g., Epps, 2018), stigma associated with cognitive decline (e.g., Epps, 2018; Gleason et al., 2016; Gupta et al., 2016; Tappen et al, 2011), and mistrust of healthcare professionals to consider AA cultural needs (e.g., Bond & Lyons, 2018). In addition, only half of those who screen positive receive follow-up care (Dale et al., 2008). There is great need to increase acceptable and accessible dementia screening as well as timely *linkage to care (LTC)* to improve access to dementia services and confront disparities.

Dementia intervention studies with AAs are slowly beginning to appear in the literature (e.g., Cothran et al., 2017; Owusu et al., 2019; Rovner et al., 2018). For example, Cothran et al. reported that a physical activity intervention for AA caregivers of family members living with dementia successfully reduced caregiver subjective burden. Rovner et al. (2018) found that a culturally-tailored intervention focused on behavioral activation (e.g., social, cognitive, and physical activity) slowed cognitive decline in AA older adults with mild cognitive impairment. This study indicated the inclusion of cultural aspects (social relationships, spiritual/religious activities) as key activators. These studies highlight the need for tailoring materials and strategies to AA, including social support and religiosity, to improve acceptability and impact of such interventions. However, none of these studies have addressed dementia screening with older adult AA. *Our pilot intervention will address screening barriers with culturally-appropriate strategies in AA church settings to enhance screening acceptability and accessibility.*

AA churches are highly influential institutions that have many untapped strengths to extend the reach, influence, and impact of dementia screening interventions with older adult AA. For example, AA churches have high attendance rates, especially among older adults, strong emphasis on health, provide highly valued social support from fellow church members, and include outreach ministries that serve community members who may be at greatest risk for dementia. Thus, AA churches are well-positioned to serve church and community members who might benefit most from dementia education, early screening, and LTC opportunities.

Additionally, past research has demonstrated that the AA church can be a practical setting for health screening interventions with older adult AA (e.g., Campbell et al, 2007). Critical intervention components in AA church studies have included church leaders' delivery of culturally/religiously-tailored health messages via naturalistic church activities (e.g., sermons, testimonials, ministry group meetings). Our own past church-based studies have demonstrated older adult AA are highly represented (> 40%) and believe the church plays an important role in providing health services (Berkley-Patton et al, 2018a). *We will engage faith leaders in implementing our proposed intervention using culturally-religiously tailored materials/activities packaged in a supportive, church-based Dementia Screening and Compassion Tool Kit.*

Innovation

To our knowledge, no community-based, culturally and religiously-tailored dementia screening intervention studies have been conducted with older adult AA in their churches. Our church-based dementia screening and LTC intervention study is innovative and fills gaps in the literature by:

1) being the first to study dementia screening, including related risk factors, and LTC among AA church populations;
2) uniquely including community members using church outreach services (e.g., food/clothing programs, social services) – an underserved population with limited access to health services;

3) being the first to use a culturally/religiously-tailored Dementia Screening and Compassion Tool Kit with content designed to encourage dementia screening, reduce stigma, be socio-ecologically and theoretically-grounded, and be delivered by church leaders;
4) using a multilevel approach for intervention delivery via peer-to-peer, group ministries, church-wide services, and community level church outlets; and
5) using religiously-tailored text messages to increase reach of screening messages with church-community members.

Approach

Our pilot religiously-tailored dementia screening intervention will assess feasibility (e.g., intervention implementation dose, exposure, satisfaction, facilitators/barriers) and outcomes (self-report and objective receipt of screening and LTC; stigma) with 100 older adult AA members in 2 AA churches. The primary outcome measure will be receipt of screening (self-reported and objectively assessed) at 4 months. Guided by the Theory of Planned Behavior (TPB) and a socioecological approach, we will produce a culturally and religiously tailored intervention package appropriate for the AA church-context and delivered through multilevel church outlets. We will engage our highly active KC FAITH Community Action Board led by Calvary Community Outreach Network (CCON) in the development of the intervention components, including the Dementia Screening and Compassion Tool Kit to ensure cultural-religious appropriateness for AA churches. Our team has extensive experience in developing, implementing, and sustaining culturally-religiously tailored, church-based AA health promotion interventions using TPB and socio-ecological approaches guided by faith community-engagement (Berkley-Patton et al., 2010, 2013, 2016, 2018a, b, c; Moore et al, 2016). Our team also has extensive experience in conducting large-scale recruitment and data collection activities in church settings, especially before, during, and after Sunday morning services and during church outreach activities (Berkley-Patton, 2010, 2016, 2018a, 2018b, 2018c).

Setting and participants. Two AA churches in the Kansas City, MO urban area will participate and have already provided letters of support. Criteria for church participation includes: a) a minimum of 150 adult church members who regularly attend Sunday services; b) an active church outreach ministry (e.g., food/clothing pantry, social services, daycare); c) commitment from the pastor and two *church health liaisons (CHLs)* to assist in study activities; and d) commitment to hold 2 dementia screening/LTC events over 4 months. Impact will be tracked among 50 church and community member participants from the two participating AA churches, for 100 participants total. Church members will be recruited by study staff who provide study information during church services and flyers in participating churches. Community members will be recruited similarly during churches' outreach ministries. Participants will: a) identify as AA, b) be aged > 50; and c) regularly attend church (≥once a month) or use church outreach services (3-4 times per year). Prior screening will not be an exclusion for participation. Anyone will be able to receive free screening, regardless of their participation in the study. Participants will complete baseline and 4-month follow up surveys.

Intervention implementation. Pastors, CHLs, and KC CARE Health Center (our health agency partner; see letter of support) community health workers *(CHWs)* will participate in a pre- and midpoint training on study manualized implementation information, procedures, and brain health. The trainings will also be used to review the Dementia Screening and Compassion Tool Kit materials/activities and plan/schedule delivery of activities in targeted, multilevel church services and ministries. The project team will host an informational presentation in the churches on brain health and the importance of screening for dementia and cognitive impairment as part of a church-hosted project-prescribed Kick-off event to launch intervention implementation. Pastors and church health liaisons will deliver 2 to 3 toolkit items per month over a 4-month period through multilevel church outlets, including: a) self-help materials (e.g., educational brochures, risk checklist, screening commitment cards) (individual level); b) discussion guides (ministry group level); c) sermon guides, responsive readings, testimonials, and church bulletins (church level); and d) screening via UMKC psychology students and faculty and linkage to care (e.g., referral for diagnostic evaluation, linkage to community resources) via trained community health workers (church-community level). Two screening events will be held in each church, at 4 weeks and 12 weeks. UMKC psychology faculty and trained students will conduct the screening and provide immediate feedback via electronic-tablets.

Measures. We will assess self-reported receipt of screening (ever/past year and where/why screening received). A battery of assessments will be administered including the AD8 (Galvin et al., 2007) for dementia screening, the LIBRA Index to assess modifiable risk factors (Schiepers et al., 2017), the Lubben Social

Network Scale (Lubben et al., 2006) to assess social engagement, the Physical Activity Scale for the Elderly (PASE, Washburn et al., 1993) to assess healthy lifestyle factors, the Duke University Religion Index (Koenig & Bussing, 2010) to assess religious behaviors, the RCOPE (Pargament et al., 2011) to assess religious coping, and the Perceptions Regarding Investigational Screening for Memory in Primary Care (PRISM-PC; Boustani et al., 2008) and the Stigma Impact Scale (Fife & Wright, 2000 as modified for use with dementia by Burgener & Berger, 2008) to assess perceived dementia-related stigma. We will also assess depression using the PHQ9. Demographic factors (e.g., age, education, occupation, marital status) and chronic health conditions (e.g., diabetes, high blood pressure) will be assessed. For our process evaluation, we will assess intervention implementation with CHLs and intervention exposure/satisfaction with participants. All measures will be assessed at baseline and 4 months. We will conduct post-study focus groups with 24 participants to obtain feedback on study materials/procedures and refine study design/delivery for future projects.

Data analysis. Self-reported receipt of screening (Yes/No) is our primary outcome. We will also collect objective data on persons screened. Stigma and LTC use are secondary outcomes. To explore pilot study outcomes and hypothesized pathways with baseline/4-month comparisons, we will use frequencies (ns), percentages, and means/SDs. Referrals to care and actual care received will be documented using CHW objective records. Logistic regression analyses with demographic and psychosocial variables, including TPB, will be conducted to determine associations with receipt of dementia screening screen and LTC use. Linear regression will be conducted to examine stigma associations. Perceived acceptability of study intervention materials/process and feasibility/challenges will be assessed in our post-study focus groups. Together, this information will provide a strong basis for designing a larger, randomized study of dementia screening in African American churches. Power calculations will not be conducted since this is an exploratory pilot study.

KUADC resource utilization. We anticipate using the Outreach and Recruitment (OR) Core to tap the Core's experience in community education on the latest research in brain health and dementia. As described here, part of our project is to increase knowledge about AD and other dementias in the African-American community, which can then support our efforts to increase screening and linkage to care. As we pursue this work, the OR Core will help us build a network of colleagues and collaborators for future research projects.

Dissemination of findings and plans for additional funding. We will prepare presentations and at least 5 scholarly publications focused on study development, baseline findings, primary/secondary outcomes, process evaluation, and screening predictors. We plan to use study findings to support a future clustered, RCT NIH application and address feasibility, acceptability, and statistical power to detect a change in screening rates. Our project fits well with NIH priorities. There is a new Program Announcement (PA-18-932) titled "Increasing Uptake of Evidence-Based Screening in Diverse Adult Populations (R01 Clinical Trial Optional)". This funding opportunity "invites applications that seek to understand strategies to reduce disparities in the uptake of evidence-based screening across the adult lifespan in diverse clinical and community settings, and/or with traditional, non-traditional and/or allied health care providers". We plan to submit to this PA, June 2020 cycle.

Overview of primary intervention activities and timeline

Week 0_1: Study implementation training with pastor, CHLs, an CHWs

Week 0_2: Recruitment information via flyers and church bulletin information is distributed in churches

Week 0_3: Study introduced by study team in Sunday morning services and in outreach ministry activities, volunteering church and community members are consented, and baseline survey is administered

Week 1: Intervention Kick-off: Informational presentation on brain health and dementia screening; pastoral sermon, responsive reading, and risk checklist delivered during Sunday morning service

Week 2 – 12: Pastors and CHLs deliver dementia toolkit items to encourage screening and reduce stigma

Week 4: First screening event with linkage to care services is held

Week 7: Refresher study implementation training with pastor, CHLs and CHWs

Week 12: Second screening event with linkage to care services is held

Week 16: 4-month follow-up survey is administered

Weeks 18: Focus groups with participants and CHLs are conducted

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Project Grace Consent for Participation in a Research Study

Study Title: Brain Health Screening in African American Churches

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Request to Participate

You are being asked to take part in a research study that examines brain health education and screening projects in African American churches. The study is taking place at this church. The researcher in charge of this study is Jannette Berkley-Patton, PhD. While the study will be run by her, other qualified persons who work with her may act for her. This study is funded by the University of Kansas Alzheimer's Disease Center.

The study team is asking you to take part in this research study because you are over the age of 55. You are also either: a) a church member or b) community member using this church's outreach services (e.g., church daycare/afterschool/Summer School services for your children; food/ clothing programs, other church social services) of this predominantly African American church in the Kansas City, MO, or Kansas City, KS, metropolitan area. Church and community members from several churches will be asked to participate in this study. Research studies only include people who choose to take part. This document is called a consent form. Please read this consent form carefully and take your time making your decision. The researcher or study staff will go over this consent form with you. Ask him/her to explain anything that you do not understand. Think about it and talk it over with your family and friends before you decide if you want to take part in this research study. This consent form explains what to expect: the risks, discomforts, and benefits, if any, if you consent to be in the study.

Background

This research study is being conducted to:

a) examine the health beliefs and behaviors related to brain health among African American church congregants and community members;
b) describe the capacity of Black churches to develop and implement health ministries using a church-based brain health tool kit;
c) improve the delivery of training and materials with health ministries to address brain health.

You are being asked to take part in this study because you will have an opportunity to see how this church carries out a brain health education and screening intervention named Project Grace. You will be one of about 50 subjects in the study at this church. About 200 subjects total will take part across all the churches participating in this study.

Purpose

The information from this study will be used in collaboration with Calvary Community Outreach Network, a faith-based/community-based organization serving the Greater Kansas City area, to better develop services and tools to assist African American churches in developing health ministries focused on brain health. Calvary Community Outreach Network will assist with training and providing technical assistance on mental health topics with participating churches.

Procedures

Your church/this church will receive brain health materials/activities which will be implemented by your church leaders and members. Your church/this church will also coordinate brain health screening events, which will take place at this church and will be run by UMKC and KU Medical Center professionals.

You are not required to participate in this research study in order to receive tool kit materials/activities and partake in the trainings provided by the Community Health Research Group. Your participation in any portion of this research study is completely voluntary.

If you choose to participate in this research study, you will be asked to complete a contact sheet with your name, phone number, address, email address, and contact information for two other people who know how to contact you. We will contact you to tell you when upcoming surveys will take place at this church. You will also complete a Brain Health Beliefs and Behaviors Survey that will be passed out in your church/this church. The Health Beliefs and Behaviors Survey asks questions about your: a) mental health and other health screening behaviors, b) mental health risks, and c) beliefs about mental health. The survey also asks about your religious activities, your knowledge about brain health, whether your church should be involved in brain health-related activities, and to what degree you have participated in these activities. This survey will take about 20-30 minutes to complete. You will also be given information about brain health. The survey will be administered at this church, which is participating in this research study. You will put your completed survey in unmarked envelope and then place your envelope in a sealed box. Your survey responses will be completely confidential. The survey does not ask you for any personal identification.

You are asked to complete the Brain Health Beliefs and Behaviors survey at 2 separate time points, at an initial survey event, and then again four months later. When you are done taking part in this study, you will still have access to the Project Grace intervention if this church chooses to continue to implement it as part of its health ministry.

Participation in this evaluation study is voluntary at all times. You may choose to not participate or to withdraw your participation at any time. Deciding not to participate or choosing to leave the study will not result in any penalty, loss of benefits, or other privileges at this church to which you are entitled. If you decide to leave the study, please inform the lead researcher of this study, Jannette Berkley-Patton (berkleypattonj@umkc.edu, 816-235-6362).

Risks and Inconveniences

There are minimal risks for participating in this research study which consists of completing two surveys. The survey will ask you about your personal health status, health behaviors, and other personal health information. You may feel a bit uncomfortable answering some of the survey questions related to brain health risks, screening, and other health-related topics when completing questionnaires, particularly in the church setting. However, because your identity will be coded, your responses will be totally confidential. The survey will not ask you to write down any personal identifying information. If for whatever reasons you include personal identifying information on the survey, this information will be removed. Although information on your contact sheet will have been viewable by study staff due to the need to contact you about completing this study's surveys, that information will not be associated with your responses. Upon completion of the study, summary information gathered from participants as a group will be used in reports, presentations, and/or for grant writing purposes.

Benefits

Potential benefits from participating in this evaluation study may be an increased knowledge of brain health and resources that contribute to your prevention of brain health conditions. You may gain the ability to share this information with friends and family. You may also choose to receive a free confidential brain health screening and linkage to care services if needed. Also, other African American church and community members may benefit from the information you provide. You may also find that talking about brain health-related symptoms and better understanding symptoms and care options will be beneficial to you. This information will also assist us in improving the church-based Project Grace trainings on development of health ministries.

Fees and Expenses

There are no fees/expenses costs to you for participating in this study.

Compensation

In partnership with Calvary Community Outreach Network, your church will receive promotional items for participating in this study, including a church-based brain health Tool Kit, a monetary stipend, promotional items, and meals/snacks during training sessions.

You will have opportunities to receive $20 for completing the 1st survey and $20 for completing the post survey. This adds up to a total of $40 if you complete both surveys.

Alternatives to Study Participation

You can choose to not take part in this study, which means you will not complete the surveys. You may still partake in the use of the brain health Tool Kit material/activities, church-based brain health screening, and trainings offered through your church and Calvary Community Outreach Network while choosing not to participate in this evaluation research study.

Confidentiality

While we will do our best to keep the information you share with us confidential, it cannot be absolutely guaranteed. Individuals from the University of Missouri-Kansas City Institutional Review Board (a committee that reviews and approves research studies), Research Protections Program, and Federal regulatory agencies may look at records related to this study to make sure we are doing proper, safe research and protecting human subjects. The results of this research may be published or presented to others. You will not be named in any reports of the results. Also, church names will not be associated with any public use of the data.

Your name will not be collected at any time during the survey process. There will be no personal identifiers on the surveys. You will be asked to not put personal identifiers on the surveys. After completing your survey, you will immediately put it in an unmarked envelope and then put the envelope in a sealed box. Upon publication of survey data in reports, all collected survey responses will be combined as not to be able to detect any information about you or your church/this church. Surveys will be maintained by the lead evaluator, Jannette Berkley-Patton, PhD in a locked filing cabinet in her secured study office and will be destroyed after 7 years. Your contact sheets will also be stored in a locked filing cabinet in her secured study office and will be destroyed after all follow-up data is collected.

Contacts for Questions about the Study

The University of Missouri-Kansas City appreciates the participation of people who help it carry out its function of developing knowledge through research. You should contact the Office of UMKC's Institutional Review Board at 816-235-5927 if you have any questions, concerns or complaints about your rights as a research subject. You may call the researcher Dr. Jannette Berkley-Patton at 816-235-6362 if you have any questions about this study. You may also call her if any problems come up. Dr. Berkley-Patton is located in the School of Medicine at the University of Missouri-Kansas City, 2411 Holmes Street, Kansas City, MO 64108.

Voluntary Participation

Taking part in this research study is voluntary. If you choose to be in the study, you are free to stop participating at any time and for any reason. If you choose not to be in the study or decide to stop participating, your decision will not affect any care or benefits you are entitled to. The researchers or sponsors may stop the study or take you out of the study at any time if they decide that it is in your best interest to do so. They may do this for medical or administrative reasons or if you no longer meet the study criteria. You will be told of any important findings developed during the course of this research.

You have read this Consent Form or it has been read to you. You have been told why this research is being done and what will happen if you take part in the study, including the risks and benefits. You have had the chance to ask questions, and you may ask questions at any time in the future by calling Dr. Jannette Berkley-Patton at 816-235-6362. By accepting this this consent form, you volunteer and consent to take part in this research study. Study staff will give you a copy of this consent form.