

A Multidomain Approach to Preventing Dementia in African
Americans: Cognitive Prescriptions

Study Protocol and Statistical Analysis Plan

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Pariya Wheeler, Associate Professor, Principal Investigator
University of Alabama at Birmingham
Birmingham, AL 35294

Participants and Procedure

Data collection for this study took place from January 2020 until December 2021. Due to the COVID-19 pandemic, a hybrid data collection model was employed beginning in March 2020, which transitioned to a hybrid of in-person, phone, and mail assessment modality. This study was approved by the UAB Institutional Review Board (protocol # 300003029; ClinicalTrials.gov #: NCT03864536). All participants provided written informed consent. B/AA adults aged 45-65 were recruited from the community using flyers, targeted postcards, an online ad of university studies, and targeted social media ads. A telephone screener was used to determine the following self-reported basic eligibility criteria: AA, aged 45 to 65, able to walk, and having a cell phone with unlimited texting. Exclusion criteria were: major neurological (including dementia) or psychiatric (e.g., schizophrenia or bipolar disorder) disorders; insomnia; and moderate to severe cognitive impairment as determined by the Telephone Interview for Cognitive Status (TICS)(Brandt J 1988) (score ≤ 23 was excluded).

Participants meeting these basic criteria then completed an assessment to determine their risk factor profile across the five CogRx domains (physical activity, cognitive activity, diet, sleep, social activity) (Table 1). To be eligible, participants were required to be deficient in at least two of five CogRx domains (as detailed below). Those who were fully eligible were randomized (matched on age, education, gender) to one of the following groups: no-contact control, Psychoeducation, or CogRx (detailed below). All participants completed baseline and follow-up visits at 3- and 6-months and were compensated \$50 for each of the three assessment visits. Psychoeducation and CogRx groups received an additional \$50 for the one-time intervention visit.

Measures:

The measures listed below were administered at the baseline, 3-month, and 6-month follow-ups (with the exception of the demographic questionnaire).

Demographic Questionnaire. Demographic information was obtained via a study designed measure, which asked about age, gender (male, female), household income before taxes, occupation, employment status, highest level of education, and relationship status.

Dementia Knowledge Assessment Scale. The Dementia Knowledge Assessment Scale (DKAS)(Annear et al. 2015) is a 27-item measure including statements about dementia (e.g., “Having high blood pressure increases a person’s risk of developing dementia.”) covering four domains (causes and characteristics, communication and engagement, care needs, and risks and health promotion). Responses range from *strongly agree* to *strongly disagree*, as well as *I don’t know*. Scoring includes a percentage of the total number of correct responses (0-100%), with higher scores indicating higher knowledge.

Dementia Risk/Prevention Attitudes, Beliefs, and Knowledge. A 5-item measure adapted from prior measures(Smith, Ali, and Quach 2014; Marcum et al. 2019) assessed attitudes, knowledge, and beliefs toward ADRD prevention. Participants report the extent to which they agree with statements regarding: importance of having thinking abilities checked like physical checkups, degree to which brain health can be improved, usefulness of physical activity for protecting brain health, if it’s possible to reduce ADRD risk, and confidence in oneself to take action to reduce ADRD risk. The scoring includes a sum of Likert scale items with higher scores (possible range 5-24) indicating greater degree of confidence and belief that preventive action can be taken to reduce ADRD risk.

Five CogRx Domains. Table 1 details information for the measures used to assess deficiencies in the five CogRx domains, as well corresponding intervention recommendations. While the cutoff scores in this table were used to determine deficiencies in each domain, total scores for

these measures (and additional measures) were used to examine changes over time. Specifically, for the International Physical Activity Questionnaire (IPAQ) (Craig et al. 2003), total minutes per week for walking, moderate, vigorous, and total physical activity as well as average minutes sitting per day was examined. For the Mediterranean-DASH Intervention for Neurodegenerative Delay (MIND) Diet Questionnaire (Morris, Tangney, Wang, Sacks, Barnes, et al. 2015; Morris, Tangney, Wang, Sacks, Bennett, et al. 2015), total MIND diet scores were examined (possible range from 0-15), with higher scores reflecting greater adherence to MIND diet foods (e.g., green leafy vegetables, berries, nuts, olive oil). The Social Network Index (SNI) (Cohen et al. 1997) examines 12 types of social relationships (e.g., spouse, parents, children, friends, coworkers, schoolmates, members of groups [e.g., social, religious]), and higher total scores indicate how many relationship categories in which one speaks to someone (in person or on the phone) at least once every 2 weeks, which reflects greater diversity of one's social network. A second social activity measure was the 11-item Duke Social Support Inventory (DSSI), in which we examined the total scores for social interactions and social satisfaction subscales, where higher scores reflect greater levels. For the Pittsburg Sleep Quality Index (PSQI), we examined total PSQI Scores, as well as the individual items from that scale assessing self-reported hours of sleep per night (sleep quantity) and self-reported sleep quality, with higher total PSQI scores reflecting greater sleep disturbances (e.g., other items on PSQI include factors disrupting sleep, daytime sleepiness), higher scores reflecting poorer sleep quality, and higher hours reflecting greater hours of sleep per night. Finally, for cognitive activities, the Leisure Activity Questionnaire (LAQ) (Verghese et al. 2003) was used, a 30-item survey asking about frequency of activities across 4 domains (cognitive, physical, social, and passive), in which higher scores reflect greater engagement in each type of activity (physical and social activity scores were used as secondary outcomes for their respective domain). We also administered a secondary cognitive activity measure, the Florida Cognitive Activities Scale (FCAS) (Schinka et al. 2005), which is a 25-item measure assessing frequency of activities with

a range of cognitive effort required (e.g., playing games, preparing meals from new recipes, going to social clubs), with higher scores reflecting greater engagement. Though the LAQ and FCAS have similar items, we included both as the LAQ includes subscales for activity domains.

Exit Survey. The Exit and Engagement Survey is a study-developed measure completed by the CogRx group at 3-month and 6-month visits. The 3-month survey collects qualitative feedback likes and dislikes about the program, as well as quantitative items on subjective improvements, difficulty adhering to goals, and likelihood of continuing to stick to goals following the program. The 6-month survey includes qualitative items on barriers and facilitators to continuing with goals in the 3-month timeframe after the initial 3-month intervention period ended. Participants are recorded with a digital audio recorder and responses are then transcribed verbatim for later qualitative analysis.

Intervention

Both the CogRx and Psychoeducation interventions were facilitated by a B/AA staff member, as a single one-on-one visit, within the week following baseline. Individuals in the Psychoeducation and CogRx groups attended a visit which included an approximately 30 to 45 minute PowerPoint presentation on general information on dementia prevalence, prognosis, and risk factors, which concluded with an opportunity for participants to ask questions. Informed by the Health Belief Model, the presentation included information on dementia severity, susceptibility (e.g., increased risk in B/AAs), and risk/protective factors (brief info on the five CogRx domains plus cardiovascular and depression management). No additional information was provided to the psychoeducation control group participants.

Following the presentation, the CogRx group received a personalized risk factor profile in which the interventionist explained which of the five CogRx domains had “optimal” or “suboptimal” levels, informed by evidenced-based criteria (Centers for Disease Control and

Prevention 2008; Morris, Tangney, Wang, Sacks, Bennett, et al. 2015; Fratiglioni et al. 2000; Verghese et al. 2003; Sabia et al. 2021) (Table 1). For domains that were optimal, participants were encouraged to maintain those behaviors. For domains that were suboptimal, participants selected between two (minimum to be eligible for the study) or three domains on which to focus, giving priority to domains that were most important to them and most feasible. The interventionist then presented examples of evidence-based strategies in their selected domains using a tailored informational presentation (Table 1 includes examples; prior work (Fazeli et al. 2022) shows stimuli provided to participants). Participants then engaged in a structured goal-setting process (Clare et al. 2012; Bandura 2004) and developed a 3-month intervention plan, consisting of SMART (Bovend'Eerd, Botell, and Wade 2009) (specific, measurable, achievable, realistic, and timely) goals to implement in their daily lives over the following 3-months. Participants also discussed ways to overcome any potential barriers they identified.

Participants also received daily automatic SMS (short message service) text-messages over the 3-month intervention period. Participants received one motivational reminder text in the morning at 8 am (i.e., *"Don't forget to do your healthy lifestyle activities today!"*) as well as one question on their perceived self-efficacy (i.e., *"I feel confident that I have the power to achieve my CogRx goals."*) to which they responded with a number (1=*not true at all* to 10=*very true*). In the evening at 8 pm, participants received up to three texts (depending on if they were assigned 2 or 3 CogRx domains goals) regarding adherence (e.g., *"Overall, how well would you say you met your diet goals today?"*) to which they responded with a number (1=*not very well* to 10=*very well*). Total adherence and self-efficacy scores for each participant were calculated as an average of their daily responses over the 3-month intervention period. If a participant was not responsive for two days, a research assistant called them to check in and encourage responding. A research assistant also called every other week to motivate participants and assess progress on engaging in CogRx goals for the duration of the 3-months.

Analysis

Directed content analysis (Hsieh and Shannon 2005) was used to generate descriptive categories from intervention feedback for open-ended questions at 3 and 6 months. An iterative and inductive approach was used to extract themes (Thomas 2006). Responses were coded by the PI (PLF) using NVivo version 12 software, which included identifying patterns in the data to structure themes representing participant feedback. Participant responses may have involved multiple themes, and therefore could have been assigned to as many themes as were applicable.

The quantitative analyses were conducted using SAS 9.4 (Cary, NC). Sociodemographic and other variables were summarized as mean and standard deviation (SD) or frequency and proportion where appropriate. Baseline comparisons were conducted using Fisher's exact test or Kruskal-Wallis Test when applicable. Outcome variables were summarized as mean and SD at each time point and each group. A general linear mixed model was conducted for each outcome variable to explore the within-group change and between-group difference. The effect sizes were calculated using Cohen's *d*. This pilot study was not powered for all the outcomes so the magnitude and estimates of intervention efficacy was of primary interest (Moore et al. 2011). Therefore, the statistical significance level was set using alpha of 0.05 without multiplicity correction.