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Date of Document: 07.22.2025

Official Title: Intervention to Improve Diabetes Outcomes in Older African American Women with Multi-Caregiving Burden

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NCT Number: NCT04831697

Unique Protocol ID: R21 DK 123720

Study Document(s) Included:

- Procedural Protocol (including statistical analysis plan)

Title: Community-Based Intervention to Improve Diabetes Outcomes in Older African American Women with Multi-Caregiving Burden

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Procedures Protocol

Background:

AA women (AAW) are particularly burdened by diabetes, having a prevalence more than twice that of White women (13.2% vs. 6.0%). Several studies have established that **multi-caregiving responsibilities**, or the provision of care (emotional, physical/tangible, financial, spiritual) to parents/grandparents, children/grandchildren, significant others and their larger community, is a significant barrier to effective diabetes care and contributes to the higher disease burden and increased mortality in AAW with type 2 diabetes (T2DM). An important gap in the literature is a lack of comprehensive and culturally sensitive interventions that address multi-caregiving burden in AAW with T2DM. Therefore, we propose to test the feasibility and preliminary efficacy of a multi-caregiving intervention (using a pilot randomized design compared to diabetes enhanced usual care) on improving outcomes among AAW, ages 40-64 years with T2DM (hemoglobin A1c (HbA1c) ≥8%) and multi-caregiving responsibilities recruited from communities in Milwaukee, Wisconsin and randomized to either: 1) a telephone-based, social support, health educator-facilitated 1-on-1 intervention to address multi-caregiving responsibilities, or 2) telephone-based, health educator-facilitated 1-on-1 diabetes education and skills training and general health education.

Study Design and Aims without hypotheses:

Aim 1: To determine the feasibility of the multi-caregiving intervention as measured by recruitment, session attendance, retention, and treatment adherence in AAW with T2DM

Aim 2: To test the preliminary efficacy of the multi-caregiving intervention on glycemic and blood pressure control in AAW with T2DM compared to telephone-delivered, 1-on-1 health educator led diabetes enhanced usual care at 6 months

Aim 3: To test the preliminary efficacy of the multi-caregiving intervention on self-care behaviors and quality of life in AAW with T2DM compared to telephone-delivered, 1-on-1 health educator led diabetes enhanced usual care at 6 months

Study Overview:

- Target population:
  - N=60 African American women 40-64 years of age
- Eligibility Criteria (inclusion and exclusion criteria):
  - *Inclusion criteria*: 1) Age 40-64 years; 2) Self-identifies as female; 3) Self-identifies as African American or Non-Hispanic Black; 4) Self-reports multi-caregiving responsibilities (as defined above); 5) Clinical diagnosis of T2DM based on HbA1c≥8% at the screening/baseline assessment; 6) Access to a telephone (i.e., landline, mobile device, smart device, etc.); and 7) Able to communicate in English.
  - *Exclusion criteria*: 1) Mental confusion at screening/baseline assessment suggesting significant dementia, active psychosis, or acute mental disorder; 2) Participation in other diabetes trials; and 3) Life expectancy <6 months based on screening questionnaire.
- Number of visits: 3
  - Baseline, 3-months, 6-months
- Incentive/Reimbursement amount and schedule (# of study visits):
  - Participants will receive $25 (gift card) for completion of the screening/baseline, 3-, and 6-months assessments for a total payment of $75 (gift card). Those considered ineligible at the screening visit will receive $10 (gift card) and not be enrolled in the study.

Detailed Recruitment Strategies:

After obtaining approval from the Institutional Review Board, AAW will be recruited from communities in the greater Milwaukee area. We will use four complementary approaches:

1) Recruitment through community outreach and engagement in collaboration with our community partners (i.e., leveraging current and former community partners and study participants). The PI will share the goals of the study and inclusion/exclusion criteria with community partners, and community partners will be asked to display the IRB-approved flyer within their facilities, with their members, and within their respective communities. For referrals, a recruitment letter on center letterhead and signed by the study PI will be sent to AAW referred to the study as an invitation to learn details about the study and assess eligibility for study participation. The letter will provide information about the study, explain the study requirements, and clarify that only individuals meeting certain criteria will be eligible to participate in the study. The letters will also include addressed and stamped postcards that individuals can mail back to indicate interest in participating in the study. The letter will provide a telephone number and email address that interested individuals can call or contact to receive detailed information about the study. Individuals that mail the postcard back and/or express interest by calling or emailing the provided telephone number or email address will receive detailed information about the study. Individuals who agree to participate will be asked to provide written consent and will be scheduled for the initial screening assessment.

2) Placement of recruitment flyers in prominent locations within the community (i.e., grocery and convenience stores, libraries, post office, sports venues, etc.). IRB approved recruitment flyers will be posted in prominent locations in community sites and within printed and electronic media (i.e., newsletters, bulletin boards, websites, etc.), as applicable, after approval by the appropriate personnel.

3) Use of printed and electronic media within the community (i.e., Valpak mailer, etc.). Study information, eligibility criteria, and contact information for study personnel will be detailed in the printed and electronic media of our community partners and their affiliated networks.

4) Self-referral/word-of-mouth. Individuals will be allowed to refer themselves and others to the study in response to recruitment flyers, the snowball method, and advertisements on social, electronic, and print media. For referrals, a recruitment letter on center letterhead and signed by the study PI will be sent to AAW referred to the study as an invitation to learn details about the study and assess eligibility for study participation. The letter will provide information about the study, explain the study requirements, and clarify that only individuals meeting certain criteria will be eligible to participate in the study. The letters will also include addressed and stamped postcards that individuals can mail back to indicate interest in participating in the study. The letter will provide a telephone number and email address that interested individuals can call or contact to receive detailed information about the study. Individuals that mail the postcard back and/or express interest by calling or emailing the provided telephone number or email address will receive detailed information about the study. Individuals who agree to participate will be asked to provide written consent and will be scheduled for the initial screening assessment.

Planned Procedures:

All study procedures (i.e., informed consent, screening, study visit completion, assessments, specimen collection, follow-up visits) will occur in the community setting at a location convenient for the participants. Intervention delivery is individual-based and will be delivered via telephone (i.e., landline, mobile device, smart device, etc.) by a health educator (i.e., nurse, social worker, Master's trained health educator). A total of 60 participants will be randomized to either: 1) an individual-based, telephone-delivered, social support, health educator-facilitated intervention to address multi-caregiving responsibilities (n=30 AAW); or 2) individual-based, telephone-delivered, health educator-facilitated diabetes education and skills training and general health education (n=30 AAW). There are 12 weekly sessions followed by 3 monthly booster sessions. Each session will last up to 60 minutes each. Study assessments will occur at screening/baseline, 3-months, and 6-months. All study assessments will be delivered by a Program Assistant. Please see the **Data Collection Schedule** below.

Table 1: Data Collection Schedule

Measurements	Screening/ Baseline	3 Month Visit	6 Month Visit
Primary Outcome Measures			

HbA1c	X	X	X
Secondary Outcome Measures			
Blood Pressure	X	X	X
Behavioral Skills (SDSCA)	X	X	X
Medication Adherence	X	X	X
Diet (DSQ)	X	X	X
Physical Activity (IPAQ)	X	X	X
Quality of life (SF-12)	X	X	X
Covariates			
Patient Demographics	X		
Medical Comorbidity	X	X	X
Depression (PHQ-9)	X	X	X
Diabetes Knowledge (DKQ)	X	X	X
Competing Needs	X	X	X
Social Support (MOS)	X	X	X
Self-Efficacy (PDSMS)	X	X	X
Perceived Stress (PSS)	X	X	X
Motivation (DES-SF)	X	X	X
Health Literacy	X	X	X
Locus of Control	X	X	X
Resiliency	X	X	X
Spirituality (DSES)	X	X	X
Cope (S-Form)	X	X	X
Intersectional Anticipated Discrimination (InDI-A)	X	X	X
Intersectional Day-to-day Discrimination Index (InDI-D)	X	X	X
Intersectional Major Discrimination Index (InDI-M)	X	X	X

As outlined previously, all data collection including blood draws, clinical assessments and data collection will be performed in the community at a location convenient to the study participant. Data collection will occur at baseline, 3-, and 6-months. The **primary outcome measure** is HbA1c, which will be measured at baseline, 3-, and 6-months. Trained personnel will collect a blood specimen via finger stick (using a point-of-care device) or via venipuncture to collect 10cc of blood to measure HbA1c. **Secondary outcome measures** include blood pressure, self-care behavioral skills, and quality of life. Blood pressure measurements will be obtained at baseline, 3-, and 6-months by trained personnel using automated BP monitors (OMRON IntelliSense™ HEM-907XL) with the participant seated comfortably for 5 minutes prior to the measurements. Behavioral Skills will be assessed with the Summary of Diabetes Self-Care Activities (SDSCA) scale. Self-Reported Medication Adherence will be measured with the Brooks Medication Adherence Scale (BMAS). Diet will be measured by the Dietary Screener Questionnaire (DSQ). Physical Activity will be measured using the International Physical Activity Questionnaire (IPAQ). Quality of Life will be measured by the SF-12. Diabetes Knowledge will be measured by the Diabetes Knowledge Questionnaire (DKQ). **Covariates** include**:** Demographics: Items from the 2002 National Health Interview Survey will be used to capture demographic information. Medical Comorbidity will be documented using a standardized and validated questionnaire from the National Center for Health Statistics. Depression will be measured with the PHQ-9 questionnaire. Competing Needs: This will be assessed using previously validated questions. Social support will be assessed by The Medical Outcomes Study (MOS) Social Support Survey. Self-Efficacy will be measured with the perceived diabetes self-management scale (PDSMS). Perceived Stress will be measured with the Perceived Stress Scale (PSS). Motivation will be measured by the 8-item Diabetes Empowerment Scale-Short Form (DES-SF)). Health Literacy will be measured by the Chew literacy scale. Locus of Control will be measured by the 18- item, general health locus of control scale. Resiliency will be measured using the 25-item resilience scale. Spirituality will be assessed using the 6-item Daily Spiritual Experiences Scale (DSES). Coping will be assessed using the

8-item emotional approach coping measure to allow evaluation of emotional processing and emotional expression. Intersectional Discrimination will be assessed using the InDI-A, InDI-D, and InDI-M scales. Please see references for source documents.

Sample Size and Statistical Analysis:

Analysis for Aim 1: Dichotomous measures of intervention feasibility are recruitment, compliance, and dropout proportions. We will compare dropout proportions between the intervention and usual care using logistic regression analyses to inform feasibility. Preliminary descriptive analyses will be conducted to assess the similarity of the treatment arms at baseline based on demographic, clinical, and other collected variables. Univariate descriptive statistics and frequency distributions will be calculated.

Analysis for Aim 2: Repeated measures analysis of covariance will be used to compare HbA1c measurements and BP between the intervention and usual care at 6 months, with baseline HbA1c as a covariate.

Analysis for Aim 3: Six-month quality of life measurements and self-management will also be compared using the model-based approach with baseline quality of life as a covariate. In secondary analyses, additional covariates will be added to the basic models if indicated in preliminary descriptive analyses.

Human Subjects:

- Potential Risks: Potential risks to the participants include possible violation of each participant's privacy, discomfort with questions on the research questionnaire, discomfort and bleeding from blood collection, discomfort with BP measurement, and psychological distress.
- Protection against Risk: Participants will be protected against potential risks as follows:
    - Confidentiality: This will be maintained by keeping participant folders in locked file cabinets in the investigator's locked office. Only participants' unique identification numbers will be recorded in folders and on data forms. The database will remain on the MCW computer system using unique ID numbers, rather than names, and will be password-protected.
    - Administration of Research Questionnaires**:** Some participants might feel uncomfortable or be offended by detailed questions about emotional or physical health status and impairment. All participants will be informed during the consent process that they may terminate participation at any point. Past research suggests that data collection using these measures can be conducted without undue psychological distress or exacerbation of symptoms among study participants.
    - Blood Draw/Collection: To reduce the risks of discomfort and bruising, finger sticks or venipuncture will be performed by trained personnel with used equipment and supplies discarded per routine lab policy/procedures at the appropriate laboratory or facility. To reduce the risk of fainting, blood will be drawn while participants are in a seated position. The amount of blood that will be drawn (maximum ~10cc) is not considered to pose a health risk for most adults. If deemed appropriate, the medical monitor will be contacted to assist with reducing risks associated with the finger sticks or venipuncture.
    - Blood Pressure Measurement: To lessen any associated risks, BP measurements will be performed only by trained personnel utilizing a standardized protocol. The medical monitor will be notified of all elevated blood pressure readings. Participants with elevated BP will be advised to contact their Primary Care Provider (PCP). Those with potentially life-threatening BP readings will be sent to a local emergency room for treatment.
    - Psychological Distress: Because we will be administering a questionnaire that measures the presence of depression, we will take several steps to ensure the safety of research participants. The Program Assistant will be trained by the PI to identify participants who meet criteria for depression on the PHQ-9 and will be advised to call the medical monitor with questions and concerns and for guidance. Participants who screen positive for depression will be notified during the visit and verbally instructed to seek care from their PCP. They will also be given the contact information for the Suicide Prevention National Hotline: 1-800-SUICIDE (784-2433) and told to call if they experience acute worsening of symptoms before they can be seen by their PCP.
    - Unknown risks: Participation in research may have other unknown risks. The researchers will advise participants if they learn of emerging information that might alter participants' decisions to participate.

- Participants requiring medical or other professional intervention for study-related events will be provided with appropriate and timely medical guidance by the PI or the designated medical monitor. If adverse events occur during the conduct of this study, they will be reported to the MCW IRB.
- To protect against the potential risk of loss of confidentiality and/or breach of privacy, data will be compiled using codes in lieu of personal identifiers. Access to study data will be limited to research personnel. Development of and security oversight for the electronic database for this study will be performed by the PI and Program Assistant. Paper documents pertaining to this study will be stored in locked file cabinets, and electronic data will be entered into secure, password-protected databases developed for this study by the Program Assistant. The PI will perform periodic review of the data entry process to ensure accuracy of recording. When study results are published or presented, only aggregate reports of the results will be used, and participants' identities will not be revealed. A file of names, contact addresses, telephone numbers, and other research identification numbers will be stored separately on paper and on computer, for purposes of audit by the sponsor (NIH/NIDDK and MCW IRB, if necessary.

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