Socially Isolated Older Adults Living with Dementia

Study Protocol

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1. Overview
    a. Study Title: Socially Isolated Older Adults Living with Dementia
    b. Research site: University of Washington, Seattle
    c. Objectives: Healthy People 2020 identified sexual/gender minority (SGM) older adults as a health disparate population. The lack of efficacious research-based interventions for such vulnerable older adults with Alzheimer's disease and related dementias (AD/RD) is a significant public health problem. AD/RD will affect up to four million SGM older adults by 2050.[1,2] SGM older adults are at elevated risk of social isolation and experience significant barriers to healthcare access.[3] Existing interventions for older adults with dementia have been found to be effective for caregiving dyads.[4] Yet, SGM older adults, compared to heterosexuals, are significantly less likely to be married or to have biological family members to support them,[1] and a significant proportion of SGM older adults living with dementia have no caregiver or care network.[5] The goal of the proposed research is to design and pilot test an innovative translation of a modified version of Reducing Disability in Alzheimer's Disease (RDAD) to support those living with dementia without a family caregiver, directly addressing unique SGM-specific risk factors for sustainable and comprehensive dementia care including social stigma, marginalization, identity management, and increased need for social support. Given that the RDAD[6,7] has been evaluated in a randomized controlled trial and has shown to successfully train community-dwelling care-recipient (CR) and care-giver (CG) dyads to increase the physical activity and functioning of individuals with AD/RD and their CGs and to teaches CGs techniques for managing behavioral symptoms of CRs, this study adds a modification that will provide an intervention for SGM older adults with AD/RD without caregivers. Building on the success of two previous NIH-funded studies (NHAS: 2R01 AG026526; K. Fredriksen-Goldsen, PI; RDAD: R01 AG10845; L. Teri, PI), we will address the following aims: Aim 1. Develop a personalized RDAD intervention (hereafter referred as Personalized Care Network suitable for SGM older adults living with dementia without caregivers; Aim 2. Implement a preliminary randomized controlled trial (RCT) of 30 participants with 2 arms (routine medical care vs. the Personalized Care Network approach) to assess the acceptability, feasibility, and initial efficacy of the intervention.
    d. Study design: This study will utilize a 2-group randomized controlled trial design including two assessments, i.e. a pre-treatment and a post-treatment
    e. Background: Lesbian, gay, bisexual, and transgender (LGBT) older adults are an at-risk, underserved, and rapidly growing population with elevated risk for Alzheimer's disease and related dementias (AD/RD). RDAD, which is grounded in social-learning and gerontological theories, is a present-focused cognitive-behavioral intervention aimed on increasing physical activity and problem-solving while engaging both members of caregiver (CG)-care recipient (CR) dyad. The focus of problem-solving in RDAD is specific to the needs of the CR and CG. RDAD, however, has not been translated to a highly stigmatized and marginalized population, such as LGBT older adults. Discrimination and stigma across the life course necessitate continual identity management for many LGBT older adults (e.g., nondisclosure), which may be complicated by cognitive decline in ways that increase stress. For example, with advanced memory decline the CR may inadvertently disclose to an intolerant family member or provider from whom they had previously concealed their identity, resulting in conflict or interpersonal discomfort that the CG must manage and negotiate. Thus, it is essential to address the unique characteristics in RDAD to improve treatment effects. In addition to these unique situations, LGBT older adults are significantly less likely to be

married or to have biological family members, and a significant proportion of LGBT older adults living with AD/RD has no caregiver or care network. This study adds a modification to RDAD that will deliver the intervention to LGBT older adults with AD/RD who do not have caregivers. Building off of the study that is to extend and test the RDAD intervention with a growing underserved and stigmatized population (IRB STUDY00003076), this study pilot-tests feasibility and efficacy of Aging with Pride: Innovations in Dementia Empowerment and Action (IDEA), a modified version of RDAD tailored to better respond to distinct risks, particularly among LGBT older adults living with AD/RD without a caregiver. In this pilot study the modified version of RDAD intervention is referred to the Personalized Care Network.

2. Participants
    a. General characteristics: 30 LGBT individuals with AD/RD aged 50 or older will participate in the study.
    b. Inclusion criteria: 1) 50 years of age or older at enrollment; 2) sexual or gender minority; 3) has early stage dementia including Alzheimer's disease; 4) lives in the community (not in a care facility). Based on the definition of dementia suggested by Alzheimer's Association and scientific literature, dementia will be determined by asking of potentially participating individuals 1) their current diagnostic status of AD/RD or 2) any difficulties in the domains of dementia AND any help needed with complex daily activities. This method has two positive aspects: (1) it precludes considerable increased costs that would be necessitated by providing a physical exam and (2) avoids unnecessary delays (and potentially loss of subjects) by scheduling an exam or waiting for receipt of patient charts.
    c. Exclusion criteria: 1) Have plans to move to a long-term care setting within 6 months of enrollment; 2) have a known terminal illness (with death anticipated within the next 12 months); 3) have had a hospitalization for a psychiatric disorder in the 12 months prior to baseline; 4) to be actively suicidal, hallucinating, or delusional; 5) have any physical limitations/chronic conditions preventing participation in an exercise program and 6) have more than early stage dementia. More than early stage dementia will be determined by 1) their current diagnostic status of AD/RD or 2) having difficulties in more than one cognitive domain AND significant difficulty in simple daily activities such as bathing, dressing, grooming, using the shower, transferring from bed to chair, using the telephone, or doing minor household chores. The final exclusion criteria will allow us to exclude individuals with severe cognitive impairment from the study.
    d. Number of subjects

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research
Personalized Care Network	15 individuals with early stage memory loss
RMC (Routine medical care)	15 individuals with early stage memory loss

3. Recruiting and Screening Participants
    a. Recruiting and screening:

Study announcements will be distributed by aging and health service agencies using organizational contact lists via mail and email. In addition, study announcements will be posted at various health, human service and community-based organizations (e.g., health clinics, support groups, buddy programs, community-based churches, and social groups) and published in community-based newspapers and newsletters. Potential participants (LGBT older adults with dementia) will be asked to contact the study directly after learning about it. Callers who contacted the Aging with Pride: Innovations in Dementia Empowerment and Action (IDEA) original study and who did not have caregivers were asked if we could contact them when this study is available. We will call or email those who responded "yes" to announce this study.

Using chain referral sampling we will send an email or letter inviting participants who have completed the study to tell their friends about the study. We will ask these participants to share the flyer provided in the email or letter. We will reimburse individuals $20 for each person that successfully enrolls in the study. We will ask those who call how they learned about the study. The caller will need to name the referring individual for us to send the referring individual $20. Callers won't be required to provide the name of the referring individual if they wish to keep their participation in the study confidential. If the caller doesn't name a referring individual, the caller may still enroll in the study if eligible. Referring individuals will be paid no more than $60 for 3 people that enroll.

b. Recruitment materials: Study announcements will be distributed by mail and email using aging and health service agencies' contact lists and will be posted at various health, human service and community-based organizations, and published in community-based newspapers and newsletters. Upon expressing interest in participating, initial screening of eligibility will be conducted by telephone using a script including the purpose and design of the study and a brief review of key elements of the consent form and an eligibility screen assessment form.
c. Payment to participants: Participants will receive $25 for each assessment they complete; there are two assessments in total: a pre-treatment and a post-treatment assessment.
d. Consent for recruiting and screening: Potential participants will be asked to contact the UW research team directly after learning about the study. 1) When a potential participant contacts the research team: A UW research staff will describe the study. If the potential participant is interested in participating in the study and determined to have decision making capacity, the research staff will ask if they are willing to voluntarily answer questions assessing eligibility over the phone and will be informed that they can refuse to answer any questions.

4. Study procedures:
    a. A total of 30 individuals with early stage memory loss will be recruited from Washington, Oregon and California and randomly assigned to one of two groups: Personalized Care Network (n=15) or RMC (n=15).
    b. <u>Pre-treatment (baseline) assessment</u>: The UW research staff will contact the 30 participants to schedule a pre-treatment assessment via telephone. They will complete

a 40-minute telephone assessment with either the study research coordinator or research study assistant.

c. Interventions: For the **Personalized Care Network group,** the intervention will be done virtually using a video conferencing platform such as Zoom. Two coaches will meet with 4-6 individuals for 9 one-hour sessions over six weeks. We will use the treatment manual developed and used for an earlier translational research (IRB STUDY00003076, Title: Older Adults Living with Alzheimer's Disease and their Caregivers, PI: Karen Fredriksen-Goldsen). The manual was modified in March 2020 in order to transition from an in-home intervention to a virtual intervention. The manual includes text for the coaches, graphic illustrations of exercises, handouts, and process/treatment fidelity forms. A video link demonstrating exercises will be provided to participants. The coaches will encourage and help participants with their exercises, and develop plans to address difficult behaviors. The exercise component includes seated exercises with aerobic/endurance activities, strength training, and exercises to improve balance and flexibility. Exercises are introduced incrementally and individualized to meet the needs of each person. Each exercise is first demonstrated by the coach, then practiced by the participants. Coaches monitor the exercises closely in order to ensure that they are practiced safely and correctly. In the behavior management component, the ABC technique is applied. Study participants are taught to identify the antecedent (A) to a behavioral issue or problem (B) as well as the consequences (C) of the behavior. Participants are instructed to identify and modify behavioral problems that can impair day-to-day function and interfere with exercise participation. They are given specific training in how to identify precipitants of problem behaviors, and how to modulate their own responses to these problems. Participants are also encouraged to identify pleasant activities that can be incorporated into the exercise program. An Exercise Coach will meet via a video conferencing platform individually with each treatment group participant once a week for 6 weeks to ensure exercises are done safely and correctly. Participants in the treatment group will be invited to participate in a focus group after their post treatment assessment is completed.

d. Participants in the **RMC group** will use the same routine medical care they are currently using as needed. Exercise and behavioral management training will not be provided to the RMC group. An online workshop will be offered to RMC participants after their post assessment. The workshop will focus on aging, memory loss and maximizing health and independence.

e. Post-treatment assessments: The UW research staff will conduct, via telephone, a post-treatment assessment after all sessions are completed to evaluate treatment effectiveness outcomes for participants. Participants will receive $25 for each assessment.

5. Outcome Measure(s):
    a. Change in Physical Activity [Time Frame: Baseline (pre-treatment) and 7 weeks (post-treatment)]
        - Minutes spent on exercising per week in the past month were calculated from the following two questions: (1) How much time did you spend on exercises (hours per day) on a typical day during the last month; (2) How many days did you spend on exercises during the last month.

b. Change in Physical Functioning [Time Frame: Baseline (pre-treatment) and 7 weeks (post-treatment)]
    - Physical functioning subscale of SF-36 (Medical Outcomes Study [MOS] 36-Item Short Form), consisting of 10 items assessing if participants' health limit them in activities such as walking, climbing, lifting, etc. on a 3-point scale ranging from 'yes, limited a lot' to 'no, not limited at all.'
c. Change in Quality of Life [Time Frame: Baseline (pre-treatment) and 7 weeks (post-treatment)]
    - Quality of Life-AD scale assessed via interviews with participants, consisting of 13 items with a 4-point response scale (1 = poor to 4 = excellent) asking about their feeling about different aspects of life. Summary scores are a sum of the 13 items.

6. Identifiability of data
    a. Each and every subject will be assigned a unique identification number. This number serves as an indirect link between the assessment data collected and any identifying information gathered as a part of the study. Only the PIs and authorized research staff will have access to the link between data and the direct identifiers.
    b. Participants' name and their contact information (home address, email address, phone numbers) will be accessed by research staff to contact participants regarding the intervention and to schedule pre and post treatment assessments with participants.
    c. The direct subject identifiers will be stored in a password-protected computer in an encrypted file. Any physical copies of direct identifiers (such as consent forms) will be stored in a secured and locked cabinet. Only the PIs and authorized research staff will have access to the link between data and the direct identifiers. Only the PIs and authorized research staff will have keys to the cabinet.

7. Consent
    a. Consent process: Once interested participants have been identified. eligibility criteria met, and they have agreed to a consent visit, the study assessment staff will schedule a virtual consent visit using Zoom. The UW office will also mail or email the consent form prior to the consent visit so the participant may review it. An electronic consent will be sent to the participants through REDCap. During the consent visit the staff person will ask the participant if they read their consent form. If not, the staff person will ask them to read the forms, or if they would like staff person to read their consent form out loud.
    b. Comprehension: after the consent form has been read the staff person will ask if they have any questions and answer all of their questions. Before signing the consent, the staff person will check in with the participants: 1) whether they understand the consent form; 2) whether they have asked all of their questions and have had enough time to discuss the study; 3) whether they have received satisfactory answers to all their questions; 4) whether they have received enough information about study to decide if they want to participate; 5) whether they understand that they are free to leave the study at any time without having to give a reason and without affecting their medical care. When the participant demonstrates an understanding of the study, they will be asked to

electronically sign the consent using a touch screen on an electronic device and to submit the consent.

c. Ongoing process: Each session of the interventions and the assessments will be preceded by a brief review of the participants' rights, including their right to withdraw from the study and the right to refuse to answer any questions
d. Documentation of consent will be obtained for all of the research procedures.
e. Cognitively impaired adults and other adults unable to consent:
    - This study includes participants with early stage memory loss who will be able to consent for themselves. Potential participants who cannot consent for themselves will not be included in the study.

8. Privacy and Confidentiality
    a. Privacy protections: Only UW research staff members will contact study subjects. All intervention sessions will be conducted by trained coaches via a HIPAA-compliant video conferencing platform such as Zoom. Assessment data collected will be available only to the project staff and investigators directly involved in with this study. No others will have access to the data. Collected data are confidential. Each subject will be assigned a unique identification number. Direct identifiers including contact information will be stored separately from the data collected through questionnaires, interviews, and assessments. The data cannot identify a subject without having access to the link between the identification number and the direct identifiers. A study subject cannot be identified by anyone except the UW lead researchers and authorized research staff members who have legitimate access to the single record identifying subjects by their research ID number. This record will be stored and maintained completely separate from all data and other information gathered. All data will be stored in secure computer files and records will be identified by a unique identification number that are assigned by the study. The data files will not contain any identifying information.
    b. All members of the research team will have completed required training in human subjects and HIPAA, including training in data management and confidentiality.
    c. Retention of identifiers and data: We will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements.
9. Risk/Benefit Assessment
    a. Anticipated risks: Subjects in the study may be inconvenienced or experience psychological discomfort related to assessment questions including previous experiences of LGBT-specific adverse experiences and everyday discrimination. Subjects may also experience mild physical discomfort related to engaging in new physical exercise activities. These problems have not previously occurred in Drs. Teri or Fredriksen-Goldsen's studies, and we estimate the risks to be minimal. Subjects are informed that they are free to not answer any question and not to participate in any exercises.
    b. Protections against psychological discomfort: To minimize the risk of distress or emotional upset, the following steps will be taken: A) The PIs are experienced in conducting interviews and assessments by phone and in-person with subjects experiencing cognitive impairment and mood or behavioral disturbance; they are also experienced with research involving LGBT older adult health. Throughout the study they

will respond in a sensitive and respectful manner, in-person or by phone, to individuals who are distressed. B) The coaches will receive training from the PIs to monitor for distress and will be advised to immediately contact the PIs with any concerns related to the intervention or assessments resulting in psychological discomfort to the subjects. All concerns will be addressed in collaboration with the PIs. Subjects will be advised of their right to not answer any question(s) and/or to withdraw from the study at any time. No adverse emotional responses have been reported in our prior experience with training staff to deliver behavioral strategies. All sensitive questions in the proposed study are worded respectfully and have been used in previous studies with no adverse consequences. C) The coaches and assessment staff receive training on how to monitor for distress and how to identify and monitor potential triggers and redirect participants to other activities with more pleasant memories. D) If psychological distress is identified, for example severe depression or anxiety, referral to a primary care provider or mental health provider will be initiated. Resources (e.g. contact information of participants primary doctor or mental health provider) will be identified at the beginning of the intervention. Distress requiring referral has never occurred in previous studies of the intervention.

c. Protections against physical discomfort: If subjects experience mild physical discomfort related to engaging in new physical exercise activities, they will be informed that they do not need to participate in any exercises. We estimate physical discomfort to be minimal in the proposed study.

d. A potential breach of confidentiality regarding subjects' sexual/gender identity and/or medical condition may cause psychological or social harm. All team members have signed a confidentiality agreement prior to being involved in the study. All participant information is to be kept strictly confidential with the only exception being incidents of abuse of a dependent adult or minor child and risks of imminent harm to others or to the subject. All researchers have completed training in research with human subjects.

10. Analysis plan

a. The point estimates of the proportions of eligible participants who agree to participate in the study and enrolled participants who comply with exercise assignments and adhere to the program sessions will be computed to test enrollment feasibility and intervention acceptability. Data from all measures at each time point will be examined utilizing univariate statistics in which psychometric properties of each variable will be determined. While random assignment is expected to produce comparable intervention groups, this will be ensured by comparing demographic characteristics and outcomes of interest at the baseline across intervention groups. To test initial efficacy of the Personalized Care Network approach and RMC on primary outcomes, we will use ANCOVA, which helps to reduce error variance, yielding a more powerful test. The proposed sample size is sufficient to detect a medium effect of the preliminary intervention,[8] which is greater than a clinically important difference level.[9] We will compute and assess confidence intervals to evaluate precision of sample estimates and effect sizes for each outcome variable so as to derive proper sample size for the next stage of the study.

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