Supplement 1. Trial protocol

Lay-delivered Behavioral Activation in Senior Centers for Older Adults with Depression: Protocol for a Non-inferiority Randomized Trial

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Summary of Changes

Version	Date	Summary of Revisions Made	Rationale
1	10/21/2020	Initial Study Review	
2	2/25/2021	Addition of assessment measures; no currently enrolled participants.	Assessments added during start up
3	4/7/2021	Broad edits during start up procedures including addition of PHQ-9 to client screening interview.	Assessment added during start up
4	6/15/2021	Changed baseline assessment from a single 2-2.5 hour appointment to two 1 hour and 15 minute appointments.	Modification to assessment schedule to reduce burden
5	7/19/2021	Modified language in consent regarding sharing of information between staff and senior centers; corrected protocol to state the CSQ-3 will be administered at week 9 only.	Clarification regarding sharing of information; correction to assessment schedule
6	9/15/2021	Edited consent form clarifying release of information section.	Clarification regarding release of information
7	12/1/2021	Eligibility criteria changed from mTICS ≥19 to mTICS ≥20.	Correction to eligibility criteria
8	3/17/2022	Updated consent form regarding audio recordings; clarified CPT cases can be 50+ years old.	To clarify audio recording consent and CPT client inclusion criteria
9	5/3/2022	Corrections made to client and clinician consent; corrected number of clinician trainings from 4 to 2; updated DSMB language regarding meeting frequency; added 5 non-UW investigators; updated CPT participant inclusion criteria (HAM-D >0).	To correct an error regarding required number of clinician trainings, update DSMB language as requested in RNI00001817, update personnel, and clarify inclusion criteria for CPT clients
10	2/14/2023	Protocol updated following supplemental NIH funding received to serve Spanish-speaking clients; clarified geographic area referred to as Tampa or Tampa area.	To update procedures following receipt of NIH supplemental funding
11	2/28/2023	Updated contact information on Spanish consent forms.	Updated contact information

Version	Date	Summary of Revisions Made	Rationale
12	3/29/2023	Updated clinician consent form to reflect change in reimbursement.	Increased clinician compensation to account for travel expenses
13	5/5/2023	Updated recruitment procedures regarding social media advertisements for volunteer participant recruitment.	To expand outreach
14	6/16/2023	Updated protocol and consent forms to permit assessment administration to participants by staff across collaborating research institutions.	To allow for cross-institutional staff support to reduce burden
15	8/3/2023	Added 5 non-UW investigators.	Personnel update
16	8/23/2023	Updated protocol regarding procedures with senior center staff. Staff survey consent form submitted.	To gather insights on successful implementation of the program
17	8/31/2023	Updated recruitment procedures regarding social media advertisements for client participant recruitment.	To expand outreach
18	10/11/2023	Added 5 non-UW investigators; removed one non-UW investigator.	Personnel update
19	10/18/2023	Added 5 non-UW investigators.	Personnel update
20	12/4/2023	Updated exclusion language around dementia; submitted staff surveys; updated staff consent form language.	To exclude clients with cognitive impairment
21	1/19/2024	Removed 3 Individual Investigators.	Personnel update
22	3/14/2024	Updated language around the use of social media and online advertisements to recruit client and volunteer participants.	To expand outreach
23	4/12/2024	Uploaded missing IIA agreement.	IIA submission
24	5/10/2024	Added 3 non-UW Individual Investigators.	Personnel update
25	5/24/2024	Updated language around recruitment location of clients, volunteer coaches, and clinicians from Tampa area to Florida.	To allow USF to recruit from a wider catchment area (the whole state)
26	6/12/2024	Updated language around recruitment location of clients, volunteer coaches, and clinicians from Seattle and NYC to Washington and New York, respectively.	To allow UW and Cornell sites to recruit from a wider catchment area (the whole state)
27	10/4/2024	1) Added study team member to project. 2) UW site team will conduct a survey of individuals who work in aging service organizations. Protocol has been modified, and draft survey and flyer template have been uploaded.	To gather input on depression need, organization interest, and organization resource needs for delivering DMFB
28	5/16/2025	IIA requested.	IIA request
29	8/18/2026	Minor corrections to dissemination plan to reflect final dissemination procedures.	To clarify dissemination procedures

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1 Protocol Summary

Title: Lay-delivered Behavioral Activation in Senior Centers

Grant Numbers: R01MH124975, R01MH124956, R01MH124966

Study Description: In response to large numbers of senior center clients who suffer untreated depression and the dearth of geriatric mental health providers, we have partnered with senior center stakeholders to simplify Behavioral Activation (BA) to match the skill set of lay volunteers ("Do More, Feel Better"; DMFB). The lay delivery model: (1) makes use of existing volunteer resources that can address the insufficient workforce; and (2) has potential for being an acceptable and sustainable delivery model. However, the capacity of this model to engage the same target (increased activity) and to yield comparable clinical outcomes as professionally-delivered interventions has yet to be determined in a fully powered trial. This collaborative R01 is a fully powered randomized effectiveness trial testing the effect of DMFB in comparison to clinician-delivered BA on increased activity level and decreased depressive symptoms.

Objectives: The specific aims are to: (1) test the effectiveness of DMFB, in comparison to clinician-delivered BA, for depressed (Patient Health Questionnaire-9 [PHQ-9] ≥10 and 24-item Hamilton Rating Scale for Depression [HAM-D] ≥14) older adults (≥60 years) on increasing overall activity level (target) and reducing depression symptoms; and (2) test whether increased activity level predicts greater reduction in depression severity and whether increased activity's impact on depression is non-inferior across conditions.

Endpoints: The multiple primary outcomes are activity level (Behavioral Activation for Depression Scale; BADS) and depression symptom severity (HAM-D).

Study Population: Client participants will be a total of 288 older (≥60 years) non-psychotic, non-demented individuals with elevated depressive symptoms. Eligible clients will be randomized within senior center to either DMFB (n=144) or clinician BA (n=144).

Description of Sites/Facilities Enrolling Participants: Sites include 18 senior centers, including 6 Washington, 6 New York, and 6 Florida senior centers serving economically and ethnically diverse communities.

Description of Study Intervention/Experimental Manipulation: DMFB, a simplified version of Behavioral Activation (BA) delivered by lay volunteers to depressed senior center clients, involves 9 weekly 45-50 minute in-person sessions.

Study Duration: The study is 5 years in duration.

Participant Duration: Enrolled participants will participate in sessions for 9 weeks and will be administered assessments for 36 weeks.

2 Introduction

2.1 Study Rationale

In response to large numbers of senior center clients who suffer from untreated depression and the dearth of geriatric mental health providers, we have simplified Behavioral Activation (BA) to be delivered by lay volunteers ("Do More, Feel Better"; DMFB). The focus of BA is to guide clients to reengage in daily pleasant and rewarding activities and reduce depressive symptoms. If we can show that the lay delivery model has positive impact in comparison to clinician-delivered BA, we will have identified an effective intervention that can be used by a large, untapped workforce of older adult volunteers across the nation.

The lay delivery model: (1) makes use of existing volunteer resources that can address the insufficient workforce; and (2) has potential for being an acceptable and sustainable delivery model. However, the capacity of this model to engage the same target (increased activity) and to yield comparable clinical outcomes as professionally-delivered interventions has yet to be determined in a fully powered trial.

2.2 Background and Significance

The IOM report "Mental Health and Substance Abuse Workforce for Older Adults" highlighted the dearth of mental health providers for older adults and the need to develop a workforce of nontraditional providers to serve this growing population.[1] An expanding evidence base supports the feasibility and effectiveness of lay providers' delivery of brief psychosocial interventions for geriatric mental health disorders.[2] Our early pilot work partnering with New York City (NYC) senior centers[3] and our current UW R34-supported work with Seattle senior centers[4] supports the feasibility and preliminary effectiveness of DMFB and lays the groundwork for a definitive effectiveness trial. Our and others' work has demonstrated the need for such an intervention given the high rate of elevated depressive symptoms in aging service settings[4,5,6] and the lack of available and acceptable mental health services for older adults.[7,8]

Senior center clients have high rates of depression and are underserved: Older adults who attend senior centers across the country represent large numbers of mid to low-income seniors with multiple social service needs, nutritional insecurity, and financial vulnerability.[9-12] The Older Americans Act (OAA) in 1965 spurred the growth of senior centers, with more recent amendments calling on increased accessibility and services for those with low income and limited resources.[13] There are approximately 10,000 senior centers in the U.S. that are part of a national, multilevel aging services network overseen by the Administration for Community Living. The mission of senior centers is to help older adults live in their community as independently as possible. Centers provide a variety of social, health promotional, nutritional, case assistance, and recreational services to an average of 125 members a week. Centers also support volunteer services, including health promotion, social, and educational programs.[10] We have documented that 10-25% of older adults experience clinically significant depression in NYC, Seattle, and Tampa-area senior centers.[4-6] In response to the deleterious effects of untreated depression, many aging service settings have begun to screen for depressive symptoms and offer mental health referrals. Moreover, the NYC Department for the Aging (DFTA) has received funds to embed mental health services into 20-25 NYC senior centers. Even when treatment is available, however, older depressed individuals rarely accept a referral,[7] and few engage in evidence-based treatment.[8] The unmet need our team has documented in this population is due to lack of available depression treatments within senior centers as well as poor client satisfaction with available community services.

Untreated depression is associated with poor health and mental health outcomes, and with excessive and costly service use: Depression is the leading contributor to the overall burden of disease around the world,[14] reflecting both its pervasiveness and consequences. Beyond personal suffering, late-life depression increases the risk of medical illness, disability, social isolation, institutionalization, health care costs, suicide, and non-suicide mortality.[15,16] Even milder forms of depression are associated with diminished quality of life among older adults.[17,18]

Brief community-delivered interventions can improve rates of mental health evaluation and treatment adherence: Raue and Sirey developed a conceptual model of personalized treatment engagement for depressed older adults[19] and tested targeted interventions in community settings to improve treatment adherence. Sirey et al. developed a 3-session intervention for community settings called Open Door. Open Door facilitates client follow-through on mental health evaluation following a positive depression screen by addressing concerns about stigma and other barriers to care. In an RCT, Sirey demonstrated that 75% of Open Door participants vs. 51% attention controls attended a mental health visit over a 6-month follow up.[20] Program evaluation of Open Door delivered by senior center social workers showed an increased pre-post connection rate from 35% to 63%.[21] Raue et al. developed a brief Shared Decision-Making (SDM) intervention conducted by primary care nurses without mental health background.[22] The aim of the intervention was to involve untreated older depressed patients in decisions about mental health care, increase adherence to treatment, and reduce depressive symptoms. Patients from an inner-city municipal hospital randomized to SDM were significantly more likely to receive a mental health evaluation or initiate some form of treatment (39% versus 21% in usual care), and to adhere to psychotherapy visits over 12 weeks.[23] In the context of real-world depression treatment available in primary care, we have shown that we can train non-mental health professionals in a brief intervention that almost doubles treatment initiation rates. SDM, however, did not show an impact on clinical outcomes, which combined with relatively low treatment adherence across both groups highlights the importance of providing accessible mental health services to patients choosing active treatments.

Need to develop the geriatric workforce of nontraditional providers: At the national level, SAMSHA and the National Council on Aging have issued briefs promoting the integration of mental health programs into aging service settings.[13,24] These recommendations follow the lead set by primary care initiatives where mental health treatment is brought to the patient via Collaborative Care and other integrated models.[25,26] As the geriatric mental health workforce is currently too small to meet the needs of older adults, the IOM report and others identify nontraditional providers as a viable solution.[1,2] Given reviews supporting the effectiveness of nontraditional providers for a variety of conditions, further research is called for given the limited number of professional therapists, patient preferences for alternative treatments, cutbacks in third-party payments, and the opportunity to investigate the theoretical underpinnings or mechanisms by which different interventions have their effect.[2,27] Expanding the network of nontraditional providers also offers the opportunity to enhance the racial and ethnic diversity of the geriatric workforce, benefiting the growing population of culturally diverse older adults across the U.S.

The impetus for examining lay-delivered models of depression care: Lay-delivered interventions may be less costly than professionally-delivered interventions, may be equally or more acceptable to older adults, and may show similar effectiveness in improving target and clinical outcomes. We developed a lay-delivered Behavioral Activation intervention ("Do More, Feel Better"; DMFB) to grow the field capable of providing geriatric mental health services. We have demonstrated the feasibility of: screening, recruiting, training, and certifying a select group of older lay volunteers; volunteer fidelity in administering DMFB to depressed senior center clients; and ability to conduct 2 small RCTs exploring target and clinical outcomes.[3] Our work demonstrates the promise of transferring such an evidence-based intervention to the hands of lay providers as supervised by professionals or aging service staff, calling for a definitive effectiveness trial.

Information from this study will have the following impact on science: We will have information on the effectiveness on two delivery models of BA for depressed senior center clients: lay-delivery and professional-delivery. This is important to the field because of the growing problem in healthcare today, as documented by the IOM report on the scant mental health workforce for older adults. Depression detection has increased in many aging service settings due to screening initiatives, but without the capacity to meet the steady increase of individua ls in need or the services that depressed clients are willing or able to accept. Our lay-delivered model of care: (1) makes use of volunteer resources that can address the insufficient workforce providing geriatric mental health services; (2) is a feasible and acceptable model of care; and (3) has potential for being an effective and sustainable real-world delivery model.

Relationship to NIMH Strategic Plan: Objective 3 (Strive for Prevention and Cures). This project responds to Strategy 3.3 by "testing interventions for effectiveness in community practice settings" and "enhancing the practical relevance of effectiveness research, taking into account how patient-, provider-, and organizational level factors impact the outcomes of interventions in practice settings." Objective 4 (Strengthen the Public Health Impact of NIMH-Supported Research). This project responds to Strategy 4.3 by "developing innovative service delivery models to improve dramatically the outcomes of mental health services received in diverse communities and populations."

3 Study Aims

Primary Aims: The primary aims test the effectiveness of DMFB, in comparison to clinician BA, on increasing overall activity level (target) and reducing depression symptoms. We will test whether increased activity level predicts greater reduction in depression severity and whether increased activity's impact on depression is non-inferior across conditions.

Aim 1. Tests non-inferiority of DMFB, in comparison to clinician BA, for depressed (Patient Health Questionnaire-9 [PHQ-9][28] ≥10 and 24-item Hamilton Rating Scale for Depression [HAM-D][29] ≥14) older adults (≥60) on increasing overall activity level (target) and reducing depression symptoms.

- (H1) Activity level. DMFB is non-inferior to clinician-delivered BA in increasing overall activity level (Behavioral Activation for Depression Scale; BADS[30,31]) over 9 weeks.
- (H2) Depression. DMFB is non-inferior to clinician-delivered BA in reducing depressive symptoms (HAM-D) over 9 weeks.

Aim 2. Tests whether increased activity level predicts greater reduction in depression severity and whether increased activity's impact on depression is non-inferior across conditions. If our non-inferiority hypothesis in Aim 1 is confirmed, we will not proceed with a mediation analysis.

- (H3) Mechanism. Change in activity level (BADS) at each assessment time (baseline-2 weeks, 4-5 weeks, 7-8 weeks) predicts severity of depression (HAM-D) at next assessment time (3, 6, 9 weeks) across conditions.

Secondary Aims. Secondarily, we will test hypotheses associated with overall functioning, satisfaction with treatment, and client-level moderators. We will test hypotheses associated with three areas: (S1) Functioning. DMFB is non-inferior to clinician BA in reducing disability (World Health Organization Disability Assessment Schedule; WHODAS 2.0[32]) over 9 weeks. (S2) Satisfaction with treatment. DMFB and clinician BA subjects will report similarly high satisfaction scores (3-item Client Satisfaction Questionnaire; CSQ-3[33]). (S3) Client-level moderators. The effect of DMFB vs. clinician BA will be moderated by client baseline characteristics, including sociodemographic factors, diagnostic status (MDD vs. subthreshold), depression severity, and disability.

Exploratory Aims: (E1) Longer-term benefits. Outcomes of DMFB are non-inferior to those of clinician BA at 24 and 36 weeks: BADS, HAM-D, WHODAS 2.0. (E2) Delivery cost. We will explore whether delivery is less costly for DMFB than clinician BA. (E3) Preparing for sustainability. We will explore client, provider, and center factors related to intervention fidelity.

4 Study Team

4.1 UW, Cornell, and USF Collaboration

This project brings together three research groups with the complementary expertise necessary for the conduct of the proposed project and a history of effective collaboration: the University of Washington (UW), the Weill Cornell Medicine group (Cornell), and the University of South Florida group (USF). Our decision to collect data at three sites was as follows:

1. This trial requires a sample size that no one site can successfully recruit on its own; and
2. We wish to increase sociodemographic diversity and geographical representation of senior center participants.

For over 16 years, the team of investigators at UW, Cornell, and USF has shown that brief psychosocial interventions for depressed community-dwelling older adults can increase engagement in treatment. We have created innovative psychotherapeutic interventions for late-life depression and tested their effectiveness in both clinic and community settings. We have also conducted educational and training programs to develop the workforce of aging care providers to meet the mental health needs of older adults. Dr. Raue developed DMFB while at Cornell in collaboration with Dr. Sirey and Dr. Berman, Director of Research at the NYC DFTA. They have a long history of collaboration. Dr. Gum's team has conducted complementary research on the mental health needs of older adults and delivery of care in aging service settings. We streamlined and simplified BA into a highly structured intervention that lay providers can learn and administer. In addition to a written Manual, we developed scripts, agendas, and supporting materials that retain key elements of BA. Drs. Raue and Sirey collaborated with Dr. Berman (DFTA) and 2 NYC senior centers on an RCT pilot; and Dr. Raue completed an R34 funded pilot of this protocol.

4.2 Administration

The three site PIs developed a multi-site protocol that will allow us to leverage our respective and complementary expertise to test our hypotheses. All three PIs will be responsible for the implementation of the scientific procedures, the leadership plan and the specific aims, and ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including biosafety, human research, data and facilities.

University of Washington: UW will serve as the Coordinating Study Center and Data Management Unit and will be responsible for overall coordination of all aspects of the study across sites. UW will have primary oversight

responsibility for participant retention and data collection, including protection of human subjects, scientific integrity, personnel training, data collection and analysis, and preparation of reports and manuscripts and reports. UW will have primary responsibility for ensuring that milestones are met according to schedule and on budget. In Year 1, UW will oversee study start up activities. In subsequent years (years 2-5), UW will oversee data management, meet regularly with the data collection and recruitment team, and troubleshoot recruitment and retention. UW will also be the single IRB of record for this project.

As the Data Coordination Unit, UW will guide the design of protocols for standardizing the uniform implementation of the study. The Data Coordination Unit will standardize the data entry procedures, expand the direct data entry programs, and implement a quality control system. The Unit will convene meetings across sites to review descriptive statistics (quarterly), inter-rater reliability (quarterly), missing data (monthly), and to plan data analysis practices (monthly). The Data Coordination Unit will provide consultation and assist investigators in data analysis using the most appropriate analytic techniques. The Data Coordination Unit will provide interim data needed by site PIs and the DSMB in order to review the progress of the study and will submit reports to NIMH.

Weill Cornell Medicine: Cornell will serve as the Intervention Coordination Unit. Cornell will coordinate and supervise the following activities across the three sites: 1) Training in DMFB and clinician BA; 2) ongoing monitoring of intervention implementation and its fidelity; 3) supervision for therapists; and 4) cross-site coordination to proactively address problems arising during the course of treatment. The Intervention Unit will convene meetings across sites to review adherence to DMFB and clinician BA (monthly). At the Cornell site, Lay-delivered Behavioral Activation in Senior Centers will draw upon the training resources of the Weill-Cornell Institute of Geriatric Psychiatry and build upon its existing partnership with the NYC Department for the Aging.

University of South Florida: USF will serve as the Assessment Coordination and Dissemination Units. USF will coordinate and supervise the following activities across the three sites: 1) assessment procedures, including selecting instruments, training and supervising interviewers, conducting inter-rater reliability studies, and monitoring instrument performance; 2) procedures aimed at reducing subject burden and increasing satisfaction and adherence to research procedures; and 3) coordination of interactions between sites to proactively address problems related to systematic assessment. The Assessment Unit will convene weekly meetings across sites to review cases at risk, subject flow, attrition, subject burden, and psychiatric diagnoses.

USF will also serve as the Dissemination Unit and coordinate efforts to disseminate DMFB by tracking its implementation, collaboration with senior centers and oversight organizations, and progression of reports about DMFB. The Dissemination Unit will convene meetings of the Advisory Council and individual consultation, monitor publication progress, describe adaptation to senior centers, and work towards the sustainability of the for convening the Advisory Council and implementing other aspects of the Dissemination Plan (see Section 10.2).

4.3 Communication

The PIs will hold weekly meetings using Zoom, which allows for archiving video meetings. This ability to archive meetings will serve to memorialize how decisions are made. The UW site will manage the Zoom account. Meeting agendas will include (but not limited to): (1) recruitment and retention at each site; (2) sample representativeness; (3) prevention of procedural drift; (4) review of clinician protocol adherence; (5) review of finances; (6) report development; (7) adverse events reporting; (8) IRB renewals; and (9) publications and communications.

4.4 Study Roles

Trainer/Clinical Supervisor: Assist study PI in training volunteer and clinician participants, provide ongoing supervision to volunteer and clinician participants. Extensive experience in intervention research, specifically lay delivered interventions with older adults.

Program Manager: Responsible for all regulatory and budget activities; direct management of other study team members.

Research Study Coordinators: Obtain consent, perform all study assessments, process study incentive payments. Will have completed CITI and other applicable research trainings. Experience in research administration and clinical assessments.

Mental Health Clinicians: Master's level mental health clinicians will provide BA to client participants at senior centers.

Volunteer Coaches: Trained senior center volunteer coaches will provide the DMFB intervention to client participants at participating senior centers.

5 Study Design

5.1 Overall Design

Design: This multi-site study is a collaborative, randomized effectiveness trial.

Randomization: Depressed clients (N=288) will be randomized via REDCap within each senior center to DMFB (n=144) or clinician-delivered BA (n=144) using a 1:1 allocation ratio, and blocked randomization with randomly selected block sizes using a randomization scheme developed by the study analyst. Thus, the unit of randomization for analytic purposes will be the client in order to ensure equivalent distribution of client characteristics.

DMFB intervention: DMFB involves 9 weekly 45-50 minute in-person sessions. The DMFB Manual provides structured agendas for each session, including use of Daily Activity Scheduling worksheets. While effective BA programs vary in length,[34] we chose 9 sessions given our pilot Case Series data suggesting that improvements were made in both BADS and HAM-D prior to the 12-week duration we had originally designed. We will allow 4 months to complete the intervention to accommodate client and provider schedules, preferences, illness, and other unexpected life events.

Clinician BA (comparison condition): Clinician-delivered BA will be provided in 9 weekly sessions and will utilize similar training, supervision, and fidelity assessment methods as DMFB. We chose traditional brief BA for depression (BADT-R)[35] as delivered by clinicians as the comparison condition to control for receipt of the BA intervention, and to allow us to determine whether lay delivery of the intervention leads to comparable engagement of target variables and clinical outcomes. In addition, clinician-delivered BA is a service that would be useful to our senior center partners and could potentially be supported by existing staff.

5.2 Setting

Participating sites: Six senior centers located in Seattle, 6 in NYC, and 6 in Tampa will participate.
These centers, or their oversight organizations if applicable, have agreed to collaborate with the PIs. We chose these regions and centers to represent diverse geographical areas and client sociodemographic characteristics.
Site: University of Washington

1. Central Area Senior Center
2. Southeast Seattle Senior Center
3. Greenwood Senior Center
4. Wallingford Community Senior Center
5. GenPRIDE Senior Center
6. Ballard NW Senior Center

Site: Weill Cornell Medicine

1. Stanley M. Isaacs Neighborhood Center
2. Edie Windsor SAGE Center
3. Goddard Riverside Community Center
4. Sage Center Brooklyn at Stonewall House
5. Hudson Guild
6. Lincoln Square

Site: University of South Florida

1. Brandon Senior Center

2. Progress Village
3. Oaks Senior Center
4. JL Young
5. Gardenville Dining Center
6. Ruskin Senior Center

With additional funds from an NIH supplement to expand to senior centers that serve Spanish-speaking clients, each site will work with 2 additional senior centers.

6 Study Population

6.1 Participants

Client Participants: Client participants will be representative of older depressed adults who attend senior centers. Client participants will be a total of 288 older (≥60 years) non-psychotic, non-demented individuals with elevated depressive symptoms (PHQ-9 ≥10 and HAM-D ≥14) from 6 Seattle, 6 NYC, and 6 Tampa area senior centers serving economically and ethnically diverse communities.

- Spanish supplement estimated sample size: 96

Certification Participants (CPTs): We will recruit certification participants who are age 50+ with symptoms of depression (PHQ-9 score >5 via routine screening) from participating senior centers in Seattle, NYC, and the Tampa Bay area. HAM-D does not need to be ≥14 for CPT cases.

Volunteer Participants: We will recruit 36 volunteers age 60+ that attend senior centers as interventionists for this study. Our rationale for these inclusion criteria is that our study aims center around testing a lay-delivered intervention for depressed senior center clients by volunteers of similar background in age and attendance at senior centers. No volunteers will be excluded or included based on race or gender.

- Spanish supplement estimated sample size: 12

Clinician Participants: We will recruit 36 clinician participants. We have no deliberate restrictions on clinician participants by gender, race or ethnicity although we expect them to reflect the general characteristics expected in the broader population of mental health clinicians available for employment in geriatric aging service agencies in Seattle, NYC, and the Tampa Bay area.

- Spanish supplement estimated sample size: 12

6.2 Client and Certification Participant Recruitment

Recruitment Materials: Recruitment flyers will be used across all sites to recruit client participants. These same materials will be used by senior center staff and study staff to describe the study to potential participants. Talking points and information about the study will be included in the targeted social media and online advertisements; however, compensation amount will not be listed on the social media and online advertisements themselves. Instead, compensation will be discussed during the initial phone screening with the potential participant after they have completed the secure REDCap (Research Electronic Data Capture)[36,37] survey that potentially interested individuals will complete after clicking on the advertisement link. We are removing compensation amount from the REDCap survey link because it has been flagged by Meta's Advertisement review team as meeting the "Unrealistic Outcomes" policy and we have been unable to run advertisements on the platform.

Recruitment: Older clients with elevated depressive symptoms will be recruited from 18 participating senior centers (6 from Seattle, 6 from NYC, and 6 from the Tampa Bay area), using identical procedures across sites. Each site PI is able to recruit other senior centers if necessary as a backup to ensure recruitment goals. Many senior centers routinely screen for depression using measures such as the PHQ-9 when older adults begin their programs. Any individual who screens positive will be approached by senior center staff to assess their interest in being contacted by research staff. We will enhance recruitment by conducting additional screening by Research Coordinators at regular social and health promotion events (e.g., blood pressure screening; health and wellness lectures) at the senior centers. Additionally, we will enhance recruitment by posting on local message boards (online and physical) and by

including information in neighborhood and senior center newsletters. We will also begin using targeted social media and online advertisements (e.g. Facebook, Instagram, Google) to identify potentially eligible clients for the study.

Prior to the RCT, 4 clients per center will be recruited as part of the certification process, one for each interventionist. Following certification, each interventionist will deliver the intervention to 4 randomized participants. Thus, 20 client participants will be recruited from each center over approximately a 15-month period. Each site will stagger recruitment by first working with 2 senior centers, followed by 2 other centers 12 months later, and the final 2 centers 12 months later.

Certification participants (CPTs) will be recruited using the same materials and procedures as client participants.

Data obtained for recruiting and screening procedures prior to enrollment: Potential participants will complete PHQ-9 screening with senior center or study staff. Individuals with scores meeting inclusion criteria will receive additional information about participating. For those individuals that agree to continue to the research assessment, their PHQ-9 score will be maintained as part of the study record.

6.3 Strategies for Client Recruitment and Retention

Recruitment procedures across senior centers: Our collaborators at each site will assist in recruiting other senior centers as a backups to ensure recruitment goals. While we are expanding our recruitment catchment area to Washington, New York, and Florida, we still expect most of our client participants to be recruited via senior centers in Seattle, NYC, and the Tampa Bay area. This allows us to recruit and retain client participants even if they move to another geographical location within the state they are recruited in.

Procedures to monitor client enrollment: The site PIs will provide oversight and assistance of the Research Coordinator (RC) responsibilities to recruit and consent participants. The RC and Data Managers will create study reports to track the recruitment, assessment, and follow-up of the participating subjects. These reports will be reviewed weekly. As Coordinating Study Center and Data Management Unit, the UW site PI will track and provide oversight of cumulative projected vs. actual recruitment of all sites.

To minimize attrition, we will accommodate participants' needs. For example, RAs will telephone clients to remind them of their appointments and attempt to continue assessments even with those who stop the intervention. We will also offer telephone-delivered DMFB and clinician BA sessions to participants who have difficulty attending the sessions in person, i.e., for patients with severe disability, ambivalence about treatment, and repeated missed appointments. We will request back-up contact information of clients' family members or friends to minimize clients lost to follow-up.

Strategies to ensure a diverse, representative sample: Seattle senior center clients are estimated to be 65% women, 1.3% Hispanic, 9% Asian, and 3.5% African American. NYC clients are estimated to be 79% women, 14.5% Hispanic, 7% Asian, 12.5% African American, and 5% other minorities. Tampa clients are estimated to be 55% women, 19% Hispanic, 13% African American, and 2.5% other minorities.

Enrolled client participants in our pilot RCT in NYC (n=18) had mean age of 76; 83% female; 11% non-Hispanic Black, 11% Hispanic. Enrolled client participants in our pilot RCT in Seattle (n=42) had a mean age of 70, 79% female, 18.6% Black, 7% Asian, 8.4% other race, and 2.3% Hispanic.

We expect to recruit a similar sample of client participants for the proposed study. To ensure recruitment of a diverse, representative sample, we will work closely with senior center partners to ensure depression screening among diverse client members. We will also draw on the training and support of the Cornell Clinical & Translational Science Center (CTSC) that provides training in community engagement. In addition, Cornell has a Cultural Sensitivity Committee with representation from the Cornell Institute of Geriatric Psychiatry to inform the PIs about its training and aging-related issues in various cultures. Our Enrollment Reports specify the anticipated rates of minority participants for the proposal. If the minority distribution falls below our anticipated targets, we will conduct additional targeted recruitment efforts within each of our senior centers.

In Dr. Raue's R34, volunteers did not see client participants at the same center that they attended. During preparation of the R01 application, Dr. Raue received an ethics consult from UW's Institute of Translational Health Sciences (ITHS) which found that using lay counselors (i.e., volunteer participants) is ethically allowable. This will be applied across all sites.

Potential recruitment challenges and strategies in event of enrollment shortfalls: Recruitment of client participants will be facilitated by the routine depression screening of participating senior centers with the PHQ-9. Any individual who scores ≥10 on the PHQ-9 will be approached by senior center staff to assess their interest in being contacted by study research staff. We will enhance recruitment by conducting additional screening by the Research Coordinator at regular social and health promotion events (e.g., blood pressure screening; health and wellness lectures) at the senior centers.

6.4 Volunteer and Clinician Participant Recruitment

Recruitment Materials: Potential volunteer participants will be approached by senior center staff with the support of study staff. We have drafted talking points that will be used by senior center staff to describe the study to potential participants. In addition to recruiting volunteers via senior centers, we will also use targeted social media and online advertisements (e.g. Facebook, Instagram, Google) to identify potentially eligible volunteers for the study. Talking points and information about the study will be included in the targeted social media and online advertisements.

Recruitment: Each site will recruit and certify 2 senior center volunteers per 6 center sites (12 per site; 36 across all 3 sites). Consistent with our pilot data, we plan to recruit approximately 4 volunteers per center to allow for both failure to certify and attrition throughout the study. Volunteers not needed for the RCT will be offered opportunities to participate in study outreach activities and supervision sessions. Senior centers will approach volunteers they feel have good interpersonal skills and capacity to learn a structured intervention and will describe the project to gauge their interest in participating as peer volunteers. The Centers will facilitate a meeting with study investigators, in which we will describe the program and use a structured Interview Guide to determine their capacity to learn and deliver the interventions effectively (i.e., possess interpersonal skills such as ability to listen and convey warmth and understanding; and capacity to follow structured agendas). Our interview guide was modeled after guides used in peer specialist programs, and uses behavioral examples (e.g., "Can you give me an example of how your experience has helped you to help another person going through depression, or having a difficult time emotionally?") that reflect key competencies (e.g., "Experience/Service to Others"). We iteratively developed this guide throughout the R34 by reviewing with center staff based on: (1) key qualities they believed volunteers must possess to make effective lay coaches; and (2) a guide they would find acceptable to use themselves. While we expect that most volunteers will be connected to the same senior center in which they serve, trained volunteers can see a client at any center. If attrition of certified volunteers occurs during the trial, we will replace from the pool of certified volunteers. If needed due to unanticipated further attrition, we will train new volunteers as replacements. Investigators will obtain informed consent for eligible volunteers and administer a demographic and depression knowledge and attitudes questionnaire.

We will recruit as many volunteers as necessary to yield our final projected numbers of certified volunteers. The senior centers will facilitate a meeting with the study team in which we will describe the program and use our interview guide to determine capacity to learn and deliver DMFB effectively.

Clinician Participant Recruitment: We will recruit 2 per diem clinicians per senior center and administer the above questionnaires. We may recruit clinicians employed by participating senior centers, as well as from the community by tapping into local networks of aging professionals.

Prior to recruiting clinicians, study investigators will discuss with senior center administrators the voluntary nature of clinician participation; protection of clinician confidentiality regarding their fidelity to BA, certification status, or ongoing performance; and the possibility of hiring clinicians from the community if necessary. Senior center administrators must agree to the above terms as a precondition for study participation. Senior center administrators will approach center clinicians and will facilitate a meeting with UW investigators, in which we will describe the aims and procedures of the study. Investigators will obtain informed consent for eligible and interested clinicians and administer a demographic survey and depression knowledge and attitudes questionnaire.

Data obtained for recruiting and screening procedures prior to enrollment: Potential volunteer participants recruited via social media will or online will complete an initial screening REDCap form which captures full name, date of birth, contact information, and interest level in the study. Those who meet initial eligibility criteria will receive additional information about participating. Ineligible individuals will be notified by the study team that they do not meet eligibility criteria for the study. Information collected on the screening form will be maintained as part of the study record.

Each volunteer and clinician participant will by design see 5 depressed clients over the course of the study (1 certification and 4 RCT clients). Investigators may remove volunteers or clinicians from ongoing participation if they judge them to be harmful to client participants in any way. Volunteers and clinicians may also withdraw participation at any point. While we do not anticipate significant attrition based on our pilot work, we will train new volunteers and clinicians as replacements as necessary. In the event of difficulties meeting recruitment goals at any of our participating senior centers, our collaborators at each site will assist in recruiting other senior centers as a backup to ensure recruitment goals.

6.5 Screening

Client Eligibility screening: To reduce client burden, we will administer the HAM-D and Modified Telephone Interview for Cognitive Status (mTICS)[38] to consenting candidates and only administer the rest of the measures to those with HAM-D ≥14 and mTICS ≥20. Recruitment will last ~4 years. Research assessments and each intervention will be delivered at senior center sites. Some sessions may be conducted by phone when logistic problems arise.

Intervention Weeks		1	2	3	4	5	6	7	8	9		
Assessment Weeks	Baseline			3*			6*			9*	24	36

**This assessment will occur during the week following the intervention session (e.g., assessment 3* occurs between weeks 3 and 4). Week 3 assessment should happen no later than session 5; week 6 assessment should happen no later than session 8; week 9 assessment should always fall after the 9th intervention session and can be extended as long as 4 weeks late (no more than 13 weeks after intervention session 1), but no longer, regardless if the 9th intervention session has been completed; weeks 24 and 36 assessments should be at their fixed schedule (i.e., at weeks 24 and 36, respectively), regardless of whether sessions were pushed out or rescheduled. If weeks 24 and 36 assessments are out a week of the fixed schedule, note that the assessment was out of the window.*

6.6 Inclusion and Exclusion Criteria

6.6.1 Client and Certification Participants

Client participants: Client participants in this study will be representative of older depressed adults who attend senior centers. Only senior center clients (60+) with depression will be recruited for this study. Participants may be in active treatment for depression or other psychiatric disorders, including psychotropic medication and psychotherapy.

Inclusion criteria, Referral to study (stage 1):

- Living in the Seattle, New York City, or Tampa surrounding areas
- PHQ-9 score of ≥10 via routine screening
- 60 years old or older
- English speaking (parent grant)
    - NIH Spanish Supplement sites: Spanish as preferred language

Inclusion criteria, Research assessment (stage 2):

- Modified Telephone Interview for Cognitive Status (mTICS) ≥20
- Elevated symptoms of depression as indicated by PHQ-9 score of ≥10
- Score of 14 or higher on the 24-item Hamilton Rating Scale for Depression (HAM-D)
- Off antidepressants, or on a stable dose for at least 12 weeks
- Capacity to provide consent for both research assessment and the BA intervention

Exclusion criteria: No clients will be excluded or included based on race or gender. Client participants who are under the age of 60; do not speak English (parent grant) or Spanish (supplement sites); report current active suicidal ideation (Raue Suicide Risk Protocol[39]); meet criteria for psychiatric diagnoses other than unipolar, non-psychotic depressive disorders or generalized anxiety disorder; have severe or life-threatening medical illness (e.g. end stage organ failure); or are unable to provide consent. Individuals who are receiving regular psychotherapy (e.g., weekly therapy) will be excluded. Individuals will be excluded if they disclose a diagnosis of dementia and are prescribed or taking medications approved by the FDA for the treatment of dementia.

We will allow clients to continue or initiate psychotherapy or antidepressants during the trial's course due to: (1) ethical concerns about offering lay-delivered interventions alone to clients with clinically significant depression; (2) a minority is expected to receive evidence-based psychotherapy, or "adequate" antidepressant treatment (in dosage, duration, and adherence) in the community;[40-42] (3) older adults who remain depressed after 12 weeks of therapy or on a therapeutic dose of antidepressants are unlikely to benefit further; and (4) the DMFB and clinician-delivered BA arms will have about equal percentages of clients receiving treatment at entry. We will classify receipt of psychotherapy and intensity of antidepressant use[43] prior and during the RCT.

Certification participants (CPTs) will meet the same inclusion/exclusion criteria as client participants except for a CPT participant is eligible if they report a lower PHQ-9 score allowed for inclusion, the HAM-D score is >0 (does not need to be 14 or higher), and/or they are age 50+. CPTs may have a PHQ-9 score of 5 or higher and will meet all other inclusion criteria outlined for client participants. Individuals who are receiving regular psychotherapy (e.g., weekly therapy) will be excluded.

6.6.2 Volunteer Participants

Only volunteers 60+ who attend senior centers will be recruited as interventionists for this study. Our rationale for these inclusion criteria are that our study aims center around testing a lay-delivered for depressed senior center clients by volunteers of similar background in age and attendance at senior centers. No volunteers will be excluded or included based on race or gender. The demographic profile of volunteers will be the same as the above profile for clients.

Inclusion criteria: 60 years old or older; English-speaking (parent grant); bilingual Spanish/English-speaking (NIH Spanish Supplement sites); attends one of 18 participating Washington, New York, or Florida senior centers; capacity to provide consent for all study procedures; willing to audio record study sessions for supervision and evaluation.

Exclusion criteria: Under 60; not English-speaking (parent grant) or not bilingual Spanish/English-speaking (Spanish Supplement sites); and/or unable to provide consent.

6.6.3 Clinician Participants

We will have no deliberate restrictions of clinician participants by gender, race or ethnicity. We anticipate that clinician participants will reflect the general characteristics expected in the broader population of clinicians available for employment in geriatric aging service agencies in the Seattle, NYC, and Tampa regions, respectively. We expect the demographic profile of such clinicians in Seattle to be: 8% Black, 6% Hispanic; and 80% female. We expect the demographic profile of such clinicians in NYC to be: 16% Black, 8% Hispanic; and 67% female. We expect the demographic profile of such clinicians in Tampa to be: 17% Black, 14% Hispanic; and 85% female.

Inclusion criteria: Master's degree in social work, counseling, marriage/family, or other clinical mental health degree; English-speaking (parent grant); bilingual Spanish/English-speaking (NIH Spanish Supplement sites); capacity to provide consent for all study procedures; willing to audio record study sessions for supervision and evaluation.

Exclusion criteria: Not English-speaking (parent grant) or not bilingual Spanish/English-speaking (Spanish Supplement sites); does not hold a Master's degree in social work, counseling, marriage/family, or other clinical mental health degree; and/or unable to provide consent.

6.7 Costs and Payment to Participants

Costs to Participants: There will be no financial costs to participants for participating in this study.

Payments to Client Participants: Client participants may receive up to $130 for time spent in assessment interviews throughout the study ($15 for baseline 1, $15 for baseline 2 and $20 each for 3, 6, 9, 24, and 36-week follow-ups). We will not compensate client participants for volunteer-delivered DMFB or clinician BA sessions.

Payments to Certification Participants (CPTs): Certification participants may receive up to $50 for the completing both the baseline assessment ($30) and a follow-up assessment at 9 weeks ($20). We will not compensate CPTs for volunteered-delivered DMFB or clinician BA sessions.

Payments to Volunteer Participants: Volunteer participants will receive $10 per meeting that they have with a client participant (CPT or RCT).

Payments to Clinician Participants: Clinician participants will receive $100 per session, including documentation and supervision time (CPT or RCT), or $125 if they are seeing client participants in person to compensate for travel expenses. Clinician participants will receive $50 per missed sessions.

Payments to Senior Center Staff Administrator Participants: Senior Center Staff Administrator participants will receive $150 for completing the Staff Survey with a member of the study team.

Non-monetary Compensation: See section 8.1.4 Potential Benefits.

6.8 Study Enrollment Procedures

Client Enrollment Procedures: Potential participants complete a PHQ-9 with senior center or study staff. Prior to initiating the PHQ-9, the senior center or study staff will obtain verbal consent for the continuing to the PHQ-9 alerting the individual of clinical procedures. This text will include a brief description of the PHQ-9 and telling the potential participant of mandatory reporting requirements. Here is an example: "Thanks for your interest in talking with us. Let's take a few moments to talk about your sleep, mood, and how you've been feeling lately. Before we get started, I want to let you know that everything we talk about will be kept confidential, unless there are any concerns about your safety or the safety of a vulnerable individual. If any concerns about safety come up, we'll talk about that and how to get you connected with appropriate supports." While the exact language may shift due to the conversational nature of these interactions, all elements (verbal consent, alerting to topic, limits of confidentiality) will be present in these conversations.

Once an eligible client subject is identified and gives verbal permission to be contacted, an RC will contact the client to describe study goals and procedures. If the client is interested, a time will be set up to review informed consent. This may take place via video-chat (e.g., Zoom), telephone, or in-person. Following informed consent, RAs will administer assessments to establish diagnostic criteria and other inclusion/exclusion criteria at the Baseline 1 appointment. The Research Coordinator will then randomize clients to treatment condition to protect blinding of RAs and will facilitate scheduling meetings with the appropriate provider. Based on our pilot experiences, recruitment will last ~18 months per center.

Informed Consent: Study staff at each site (UW, Cornell, and USF) will be responsible for obtaining consent from participants in their areas. Each site will use the same procedures outlined below.

Once an eligible client is identified through our recruitment/screening procedures outlined in previous sections, staff will obtain verbal permission from the client to be contacted by an RC. The RC will describe study goals and procedures. If the client is interested in participating, the RC will review informed consent either via video-chat (e.g., Zoom), telephone, or in-person. The RC will review the consent form with the client and provide plentiful opportunities for questions and discussion.

The informed consents will stipulate that information provided to the researchers will remain confidential. Access will be limited to the investigators and, when applicable, state or federal regulatory personnel, for example, in cases

of an audit. In the client informed consent, we will include discussion of the possibility of uncovering incidental findings (e.g., client reported untreated medical conditions, suicidal ideation, manic, psychotic, or substance or alcohol abuse). Included in these consent forms will be a statement that we will inform clients about the nature of these findings and that we will encourage them to follow through on referrals given to contact their primary care physician or local medical or psychiatric services. We will include in client consent forms that investigators may access and use data from Seattle, NYC, or Tampa-area senior centers' databases. As with all client-level data, we will ensure that client participants understand that they may grant permission to study investigators to access such data, or that they may refuse such access. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents.

If the informed consent process takes place remotely (e.g., via video chat or telephone), the RC will gather verbal consent and document that consent in REDCap. If the informed consent process happens face-to-face, the participant will sign the informed consent form. Regardless of whether or not the consent process takes place remotely or in-person, the participant will receive a copy of the consent form either a hard copy given in-person, mailed, or emailed to the participant depending on their preference.

Certification Participants: Certification participants (CPTs) will follow the same recruitment, screening, and baseline procedures. CPTs will complete a specific CPT consent form outlining separate assessment procedures for CPTs.

Coach Volunteer Participants: After clicking on the link, potential volunteers that respond to a social media or online advertisement will see a brief description of the study and be told that they will be asked for contact information, basic demographic information, and to respond to some brief questions about their interest in the program. Prior to moving forward with the questions, potential volunteers will be asked to respond 'Yes' or 'No' to the following question: "Would you like to proceed?"

Once a potential volunteer has been identified by senior center staff, the potential volunteer will meet with study investigators during which time the investigators will describe the program and use the interview guide to determine their capacity to learn and deliver BA effectively. The interview will include the PHQ-9 and the Brief 6-Item Memory Cognition Screen[44]. Study team members will obtain informed consent for eligible and interested volunteers by reviewing the consent form and allowing plentiful opportunities for questions and discussion. Consent will be obtained either remotely via video-chat technology (e.g., Zoom) or telephone, or in-person.

Volunteers will be asked to sign consent indicating their agreement to have their performance reviewed by study investigators and by an external rater who is not a member of the research team. The informed consents will stipulate that information provided to the researchers will remain confidential. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents.

If the informed consent process takes place remotely, the study team member will gather verbal consent and document that consent in REDCap. If the consent process happens in-person, the participant will sign the informed consent form. Regardless of whether or not the consent process takes place remotely or in-person, the participant will receive a copy of the consent form either as a hard copy given in-person, mailed, or emailed to the participant depending on their preference.

Clinician Participants: Similar to the volunteer participants, study team members will meet with identified potential clinician participants to describe the aims and procedures of the study. Study team members will obtain informed consent for interested clinicians. Study team members will obtain informed consent for eligible and interested volunteers by reviewing the consent form and allowing plentiful opportunities for questions and discussion. Consent will be obtained either remotely via video-chat (e.g., Zoom) or telephone, or in-person.

In recruiting clinicians, study investigators will approach clinicians already contracted to work at each senior center site and discuss their interest in participating in the study. We will describe the study protocol and review common concerns that clinicians might have about evaluations and productivity review. If clinicians are interested, investigators will obtain informed consent, indicating their agreement to have their performance reviewed by study investigators and by an external rater who is not a member of the research team. The informed consents will stipulate that information provided to the researchers will remain confidential. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents. Clinicians

will be supervised by a member of the research team on a weekly basis and will be able to contact their supervisor outside of that time whenever necessary.

If the informed consent process takes place remotely, the study team member will gather verbal consent and document that consent in REDCap. If the consent process happens in-person, the participant will sign the informed consent form. Regardless of whether or not the consent process takes place remotely or in-person, the participant will receive a copy of the consent form either as a hard copy given in-person, mailed, or emailed to the participant depending on their preference.

Staff and Administrators: Participating senior center staff and administrators will be invited by a study investigator to review all aspects of the study and invite him/her to sign a written consent. The informed consents will stipulate that information provided to the researchers will remain confidential. Access will be limited to the investigators and, when applicable, state or federal regulatory personnel, for example, in cases of an audit.

Electronic Presentation of Consent Information: The participant will have a copy of the consent form in either electronic or physical form. Participants may receive the consent form via email if they prefer; otherwise, the study team will mail a hard copy to the participant. If the informed consent process is completed via videochat technology (e.g., Zoom), study staff will share their screen with the consent form to facilitate review.

Comprehension: Study staff will evaluate and confirm confirmation during the informed consent process by answering questions, repeating sections of the form, and asking questions of the participants when necessary.

Ongoing Process: Participants will be asked at each study visit whether they have questions and are reminded the participation is completely voluntary and that they may change their mind about participating at any time. If applicable, participants will receive updated information sheets, which will be submitted to IRB for approval prior to distribution.

7 Procedures

7.1 Client Participant Procedures

Each site (UW, Cornell, and USF) will use these same procedures; each site will be responsible for administering these procedures for participants and senior centers in their areas. All procedures may take place via video-chat (e.g., Zoom), telephone, or in-person.

Baseline Eligibility: Following informed consent, the Research Coordinator will administer assessments to establish diagnostic criteria and other inclusion/exclusion criteria at the Baseline 1 appointment. We anticipate that this appointment will last 60-75 minutes.

Assessment Procedures: If a potential participant meets all diagnostic and other inclusion/exclusion criteria, they will complete a Baseline 2 appointment to complete remaining study measures. We anticipate this Baseline 2 appointment will take 60-75 minutes.

Randomization: After a client is determined to be eligible for participation, they will be randomized to receive either 9 sessions or either volunteer-delivered "Do More, Feel Better" (DMFB) or clinician-delivered Behavioral Activation (BA).

Session Procedures: We anticipate that each session will last 45-50 minutes. Sessions may be delivered remotely via video-chat (e.g., Zoom), telephone, or in-person. Clients will complete a PHQ-9 at each session. These sessions will be audio-recorded to allow for assessment of fidelity, training, and future research purposes. Clients give specific consent for recordings being used for these purposes.

Communication: Email, phone, text, or letter communication regarding scheduling, appointment reminders, discussing other study protocols, and requests to confirm contact information.

Withdrawal of Participants: Clients who develop active suicidal ideation, or manic or psychotic symptoms will be removed from the study and referred to their PCP by study investigators.

7.2 Volunteer and Clinician Participant Procedures

Coach Volunteer Training Procedures: Volunteers will receive training in the "Do More, Feel Better" (DMFB) intervention. The DMFB Manual will be used during training. Site PIs and designated study staff will lead training in group format for volunteers at each senior center. We anticipate volunteer training to consist of four 2-hour sessions over 1 month. Training consists of didactic on late-life depression, the DMFB intervention, and step-by-step role playing.

Clinician Training Procedures: Clinician participants will receive training in the Behavioral Activation (BA) intervention. The BA Manual will be used during training. Site PIs and designated study staff will lead training in group format for volunteers at each senior center. We anticipate clinician training to consist of two 2-hour sessions over 1 month. Training consists of didactic on late-life depression, the BA intervention, and step-by-step role playing.

Certification Procedures: Trainees achieve preliminary certification if they successfully complete an initial session role play (minimum=1 attempt, maximum=5 attempts), defined as ≥3 (satisfactory) on the DMFB and BA Fidelity forms. We used this threshold for the UW R34 and for the Engage R01 in which community clinicians were monitored for fidelity as a primary study aim.

Approved trainees then see a "practice case" meeting study eligibility criteria and must achieve fidelity scores ≥3 on 2 sessions. Each volunteer and/or coach will see at least 1 certification participant (CPT) in order to complete training procedures. Their fidelity scores will be assigned by external consultants who are not members of the research team. If trainees do not achieve certification (maximum sessions allowed=5), they will be dropped from the study and will not serve as volunteers or clinicians for the RCT. We will record training time of volunteers and clinicians and proportion who achieve certification to inform delivery cost information.

Sessions with Client Participants: After certification, volunteers and clinicians will be assigned client participants. We expect that each volunteer and client participant will see approximately 4-5 client participants for 9 sessions each throughout the course of the study. We anticipate that these sessions will last 45-50 minutes and will be audio-recorded to allow for assessment of fidelity.

Cultural Sensitivity: We train our Research Coordinators to assess for depression and other variables, and we train our volunteer coaches and clinicians to deliver each intervention in a non-judgmental manner and with knowledge of and respect for clients of different cultural backgrounds. We will draw on Dr. Gum's Assessment Coordination Unit and her team's expertise teaching courses on cultural diversity and behavioral health and conducting cultural competence and cross-cultural counseling trainings across the country. We will also draw on the training and support of the Cornell CTSC that provides training in community engagement. Cornell has a Cultural Sensitivity Committee with representation from the Cornell Institute of Geriatric Psychiatry to inform the PIs about its training and aging-related issues in various cultures. Cornell has adopted a patient-centered approach to cultural competency, known as the "Culture of One," which recognizes that it is the provider's responsibility to ensure clear communication and understanding with each unique patient. These approaches are aligned with the National Quality Forum's (NQF) Cultural Competency framework.

Supervision: Investigators will provide weekly supervision of volunteer coaches throughout the study period, and separately for the clinicians. We will provide ad-hoc supervision as needed and will record additional supervision time for volunteer coaches and clinicians as part of delivery cost information. Volunteer coaches and clinicians will be able to contact their supervisor outside of that time whenever necessary.

Withdrawal: Volunteer coach or clinician participants may be withdrawn from the research without their consent if study investigators should judge them to be harmful to client participants in any way. Volunteer coaches and clinicians may also withdraw participation at any point.

Attrition: While we do not anticipate significant attrition based on our pilot work, we will document how many withdraw and their reasons. We will train replacement volunteers or clinicians as necessary.

7.2.1 Fidelity Assessment

We will assess fidelity in two ways in order to document overall fidelity as well as to identify methods that have scalability in senior centers following the project:

1. After completing the intervention, we will ask client participants to report the extent to which interventionists used intervention techniques (e.g., "helped me complete a weekly activity list", "followed up on my activity plans and discussed any difficulties with me").
2. Experts who are not part of the study team will assess fidelity to DMFB and clinician-delivered BA using the respective fidelity forms on 10% of randomly selected audiotaped sessions.

Ratings are made on a 6-point scale ranging from "very poor" to "very good". Individual items reflect key elements of the DMFB and clinician BA interventions and consist of review of progress, assistance in scheduling daily activities, process tasks, and communication and interpersonal skills, with a final global rating integrating all sets of skills. A global rating of 3 for interventionists will be used to indicate overall "satisfactory" fidelity for a session. All sessions will be recorded, and neither volunteers nor clinicians will be aware of which sessions will be rated. We will examine associations between each method of assessing fidelity, with a particular focus on the correlation of the first three methods with the "gold standard" method of expert audiotape ratings. We recognize the challenges of audio-recording in community settings but draw on our successful experiences obtaining audiotapes from community providers in our pilots and other work. To enhance interventionist and client comfort, the Research Coordinator will facilitate audiotaping and uploading tapes to the computer.

7.3 Study Assessments

7.3.1 Client and Certification Participant Study Assessments

Assessments will be conducted by trained and blinded Research Coordinators. We have chosen measures successfully used in the PIs' community-based studies of older adults, and a length of time acceptable to these individuals. Diagnosis will be based on DSM-V after review by investigators of the depression section of the Structured Interview for DSM-5 (SCID-5)[45] and gateway questions for other disorders.

After the client signs consent, the Research Coordinator will begin the assessments to establish diagnostic criteria and other inclusion/exclusion criteria. The SCID and mTICS will be administered to consenting clients initially, with the rest of the instruments only being administered to those without an exclusionary SCID diagnosis and with mTICS score ≥20.

Baseline 1 (60-75 minutes): Following informed consent, the Research Coordinator will administer assessments to establish diagnostic criteria and other inclusion/exclusion criteria at the Baseline 1 appointment. The following assessments will be administered at this appointment, which may be split into multiple sessions for participants who cannot tolerate a long session:

- Demographics
- Hamilton Rating Scale for Depression (HAM-D)[29]
- Modified Telephone Interview for Cognitive Status (mTICS)[38]

Baseline 2 (60-75 minutes): If a potential participant meets all diagnostic and other inclusion/exclusion criteria, they will complete a Baseline 2 appointment to complete remaining study measures. The following assessments will be administered at this appointment, which may be split into multiple sessions for participants who cannot tolerate a long session:

- Behavioral Activation for Depression Scale (BADS)[30,31]
- World Health Organization Disability Assessment Schedule (WHODAS 2.0)[32]
- World Health Organization Quality of Life Scale (WHOQOL)[46]
- Charlson Comorbidity Index (CCI)[47]
- Chronic Disease Score via medication review

- Camberwell Assessment of Need for the Elderly (CANE)[48]
- Cornell Service Index[49]
- Composite Antidepressant Score (CAD)[50]
- General Self-Efficacy Scale (GSE)[51]
- Previous Treatment Scale
- Treatment Preferences Scale
- PANAS Positive Affect Scale[52]
- PROMIS Emotional Support measure[53]
- PROMIS Instrumental Support measure[53]
- Structured Clinical Interview for Diagnosis (SCID-5)[45]
- Self-reported items related to positive affect derived from positive activities
    - "Please rate the sense of pleasure you experienced from your *activities* by selecting a number from 0 (no pleasure) to 10 (great pleasure)."
    - "Please rate the sense of accomplishment you experienced from your *activities* by selecting a number from 0 (no pleasure) to 10 (great pleasure)."

Sessions (45-50 minutes): Clients will complete a PHQ-9 at each session. These sessions will be audio-recorded to allow for assessment of fidelity, training, and future research purposes. At Session1, clients will complete the Treatment Rationale Scale.[54]

Follow-up Assessments (30-45 minutes): Client participants will complete follow-up assessments at weeks 3, 6, 9, 24, and 36. The following assessments will be administered at those time points:

- Hamilton Depression Rating Scale (HAM-D)
- Behavioral Activation for Depression Scale (BADS)
- General Self-Efficacy Scale (GSE)
- World Health Organization Disability Assessment Schedule (WHODAS 2.0)
- World Health Organization Quality of Life Scale (WHOQOL)
- Cornell Service Index
- Composite Antidepressant Score (CAD)
- New Medical Events
- Reason for Drop Out (if the participant does not complete intervention sessions)

Follow-up Assessments (weeks 3, 6, and 9): The following assessments will be administered at weeks 3, 6, and 9:

- Working Alliance Inventory - Short Form (WAIS)[55]

Week 9 Assessments: After baseline, the Camberwell Assessment of Need for the Elderly (CANE) will be asked at the 9-week assessment only. The 3-item Client Satisfaction Questionnaire (CSQ-3) will be administered at the 9-week assessment only.

Additional Data: We may also collect data on client participants' engagement in senior center activities from senior center databases.

Certification Participants: Certification participants (CPTs) will only complete the baseline and a 9 week follow up assessment, containing the same measures as described above for client participants.

Non-English-speaking or -reading: The study received supplemental funding from NIH to expand the study into senior centers that serve Spanish-speaking clients. Each site (UW, USF, and Cornell) will work with 2 additional centers. Each site will hire a bilingual trainer/supervisor to provide training and supervision to bilingual clinicians and volunteers. Each site will have bilingual research staff to administer all study procedures to Spanish speaking participants. All materials including recruitment materials, consent forms, assessments, and intervention materials will be professionally translated by ARGO Translation (https://www.argotrans.com/).

For English-speaking participants, we anticipate that all assessments will be completed by RAs at the same institution that enrolled the participant. Research Coordinators at other institutions may complete assessments when specific requests have been made (assessor gender) or a lack of assessor availability. For Spanish speaking

participants, we anticipate that follow-up assessments will be completed by Research Coordinators at institutions other than the one that enrolled the participant due to availability of Spanish speaking staff.

Interpretation: No interpretation will be necessary as all study materials will be translated. Research staff who speak Spanish are either native Spanish speakers or are bilingual due to family background or academic/professional language acquisition.

Translations: All materials including recruitment materials, consent forms, assessments, and intervention materials will be professionally translated by ARGO Translation (https://www.argotrans.com/). ARGO is ISO and ATA (American Translators Association) certified, meeting or surpassing industry standards.

Audio Recordings: Participants will be asked to allow us to audio record assessment interviews and intervention sessions. The recording is completely voluntary and participants may still participate in the study whether they agree to be recorded or not. With the participant's consent, recordings will be used for training and/or research purposes. No personal information will be attached to the recordings. Recordings will be kept on a secure server which requires two passwords to access. If participants agree to have their study sessions recorded for training purposes only, their recordings will be destroyed at the end of all relevant record retention requirements.

7.3.2 Volunteer and Clinician Participant Study Assessments

Volunteer Coach Participants: We will administer a survey to consenting volunteers on their demographics, current and past volunteer experience, willingness to learn and use DMFB among depressed senior center clients, comfort level working with depressed individuals and administering such an intervention; desired timing of sessions and weekly time commitment; desired frequency of contact with supervisors; willingness to commit to volunteer to see at least 4 clients over a 1-year period; and acceptability of reimbursement amount for DMFB sessions. Volunteer coaches will complete the following measures at baseline:

- Demographics
- Generativity Scale[56]
- General Self-Efficacy Scale (GSE)
- Morrow-Howell Scale[57,58]
- 12-item Short Form Health Survey (SF-12)[59]
- Volunteer Drop Out form (if the volunteer drops out of the study)

After seeing all assigned client participants, volunteer coaches will complete the measures administered after consent. If a volunteer coach does not complete their time the study (i.e., if they drop out), we will gather information on the reasons why they left the study and document their progress up until they decide to leave the study. Volunteers will complete the following measures at follow-up:

- Volunteer Coach Questionnaire
- Generativity Scale
- General Self-Efficacy Scale (GSE)
- Morrow-Howell Scale
- SF-12 Health Survey
- Volunteer Open-ended Questions
    - "What is the primary benefit you have received from this program?"
    - "Have you experienced any other personal benefits from serving as a volunteer coach for this program?"
    - "Have you experienced anything negative as a result of serving as a volunteer coach?"
        - "If yes, please explain."
- Volunteer Drop Out form (if the volunteer drops out of the study)

Clinician Participants: Clinician participants will be administered the Clinician Questionnaire at baseline to assess attitudes concerning treatment approaches for depression in older adults, and to understand their experiences participating in the Behavioral Activation training.

7.3.3 Senior Center Staff Administrator Study Assessments

We plan to survey 18-36 senior center staff administrators. The survey will take 2 hours to complete and will be conducted remotely (e.g., Zoom) or telephone, or in-person. Study team members will identify interested staff administrators and contact them to see if they're interested in participating. Investigators will obtain informed consent for eligible and interested senior center staff administrators and administer the survey which includes a demographic section and questions related to their center's participation in the DMFB program (e.g., "What barriers do you foresee regarding outreach and recruitment for clients?"). We plan to ask follow-up questions to get more information about DMFB implementation.

8 Safety and Data Management

8.1 Risk/Benefit Assessment

8.1.1 Potential Risks

Client Participants: Clients participating in this study may be exposed to the following risks:

1. The burden of responding to standardized assessments.
2. The distress associated with discussing personal concerns with research personnel.
3. Breach of confidentiality of personal information by volunteers.
4. Clinical deterioration and suicide risk.

Volunteer Coach and Clinician Participants: Volunteer coach and clinician participant risk consists of possible personal distress while speaking with depressed older adults about their psychological symptoms and mood; medical or psychiatric emergencies that may arise during interactions with client participants; and inadvertent breach of confidentiality related to information about their performance and fidelity.

8.1.2 Adequacy of Protection Against Risks

Client Participants: Candidate clients will be invited by a Research Coordinator to review all aspects of the study and invite him/her to sign a written consent. The informed consents will stipulate that information provided to the researchers will remain confidential. Access will be limited to the investigators and, when applicable, state or federal regulatory personnel, for example, in cases of an audit. In the client informed consent, we will include discussion of the possibility of uncovering incidental findings (e.g., client reported untreated medical conditions, suicidal ideation, manic, psychotic, or substance or alcohol abuse). Included in these consent forms will be a statement that we will inform clients about the nature of these findings and that we will encourage them to follow through on referrals given to contact their primary care physician or local medical or psychiatric services. We will include in client consent forms that investigators may access and use data from senior centers' databases. As with all client-level data, we will ensure that client participants understand that they may grant permission to study investigators to access such data, or that they may refuse such access. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents.

After the client signs consent, the Research Coordinator will begin the assessments to establish diagnostic criteria and other inclusion/exclusion criteria. The SCID and mTICS will be administered to consenting clients initially, with the rest of the instruments only being administered to those without an exclusionary SCID diagnosis and with mTICS score ≥20.

Volunteer Coach Participants: Volunteer coaches will be asked to sign consent indicating their agreement to have their performance reviewed by study investigators and by an external rater who is not a member of the research team. The informed consents will stipulate that information provided to the researchers will remain confidential. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents.

Volunteer coaches will also be supervised by a member of the research team on a weekly basis and will be able to contact their supervisor outside of that time whenever necessary.

Clinician Participants: Prior to recruiting clinicians, study investigators will discuss with senior center administrators the voluntary nature of clinician participation; protection of clinician confidentiality regarding their fidelity to BA, certification status, or ongoing performance; and the possibility of contracting with external per diem clinicians if necessary. Senior center administrators must agree to the above terms as a precondition for study participation.

In recruiting clinicians, study investigators will approach clinicians already employed or contracted to work at each senior center site and discuss their interest in participating in the study. If no existing clinician at any given senior center is willing to participate, we will use funds to pay an external per diem clinician. We will describe the study protocol and review common concerns that clinicians might have about evaluations and productivity review. If clinicians are interested, investigators will obtain informed consent, indicating their agreement to have their performance reviewed by study investigators and by an external rater who is not a member of the research team. The informed consents will stipulate that information provided to the researchers will remain confidential. We will ensure that all participants will understand and consent to future use of their data; this will be stated within the consent documents.

Clinicians will be supervised by a member of the research team on a weekly basis and will be able to contact their supervisor outside of that time whenever necessary.

8.1.3 Protection Against Risks

Client Participants: We have developed procedures to minimize risk to our participants and to create conditions that make study participation as comfortable as possible. The following safeguards will be implemented to increase the safety of client participants:

1. Research assessment burden: To minimize assessment-related burden, we will not use redundant inquiries. Assessment will be administered over multiple meetings if needed based on client tolerance. The burden associated with research assessments will be described in the informed consent, so that a client may refuse to enroll in the protocol if he/she considers its time commitments onerous. To minimize patient burden, only clinically experienced interviewers will administer study instruments. A small, non-coercive total fee of $130 will be paid to participants for the time spent in interviews throughout the study ($30 for baseline, and $20 each for 3, 6, 9, 24, and 36 week follow-ups). We will not compensate client participants for volunteer-delivered DMFB or clinician-delivered BA sessions.

2. Distress associated with discussing personal concerns: To limit distress, research personnel and clinicians will be trained and supervised by study investigators in procedures for helping clients cope with protocol-generated concerns, stress, and anxiety.

3. Breach of confidentiality of personal information by volunteers or clinicians: To limit the possibility of such a breach of confidentiality, we will not pair volunteers with any client with whom they have a pre-existing relationship. In addition, we will expand on training typically provided to volunteers in senior center settings concerning confidentiality and privacy (DMFB Manual). We will instruct both lay volunteers and clinicians that they must not reveal personal client information to family or friends, but only to study investigators and center clinical staff if appropriate. We will counsel both volunteer coaches and clinicians against having any type of "dual relationship" with study participants with whom they are paired, such as a friendship outside of the senior center. We will track dual relationships, breaches of confidentiality, and adverse responses in the volunteer coach Adverse Events form.

Within the consent form, volunteer coaches agree not to reveal any info about their clients. If study investigators learn that any study provider has broken confidentiality in any way, investigators will provide corrective feedback and re-training. If a study provider breaks confidentiality on a second occasion, then a replacement provider will be assigned to their current cases and they will be removed from further study participation.

The study PI received an ethics consult from UW's ITHS regarding whether or not volunteer participants could provide DMFB to client participants. Per that review, it was determined that it would be ethical for volunteers to see clients from the same senior center that they attend.

4. Suicide risk: Any client participant who endorses PHQ-9 item 9 or HAM-D item 3 (suicidal ideation) will be evaluated by a study investigator to determine the presence of suicidal ideation and level of risk. RAs will administer the HAM-D, and the Raue Suicide Risk Protocol if indicated, at follow-up assessment points. Study investigators (licensed clinicians) will follow up and evaluate all clients endorsing active suicidal ideation. The procedures for handling active suicidal ideation involve alerting the client's PCP or other health care professionals. Investigators will work with senior center staff to arrange emergency services for those clients at imminent suicide risk.

Clients who develop active suicidal ideation or manic or psychotic symptoms will be removed from the study and referred to their PCP by study investigators. Clients who develop passive suicidal ideation will be permitted to remain in the study and receive the DMFB or BA intervention; they will also be referred to their PCP by study investigators. Investigators will follow up to ensure this connection takes place. With the client's permission, investigators will contact the PCP to discuss the clinical concerns and assist the PCP in management recommendations.

Volunteer Coach Participants: To mitigate and address distress among lay volunteer coach participants, we will first incorporate such issues into our training protocols, similar to our standard training for Research Coordinators in interacting with client participants. For example, we will discuss and role play how to sensitively inquire about mood and other symptoms of depression; how to respond to client distress, including reassuring the client or facilitating contact with senior center staff or study investigators if necessary; and how to manage one's own emotions such as concern, worry, anxiety, and possible distress over clients' conditions.

We will maintain regular in-person and telephone contact with all lay volunteer coach participants. Weekly supervision will involve discussion of ways in which participants can cope effectively with client distress. Senior center staff will always be present when lay volunteers meet with client participants. In addition, as part of standard protocol the study PIs will be reachable at all times during the week, evening, and weekend if necessary via cell phone.

Investigators will train volunteer coaches in an emergency protocol developed in conjunction with participating senior centers. To ensure that the emergency protocol and training procedures are acceptable to participating senior centers, we plan to meet with clinical staff, volunteer coordinators, and administrators at each agency, review current emergency protocols, and suggest and agree on refinements for the proposed research study. We will build in additional procedures including: identification of primary emergency contact person and phone number; and how study investigators can be available to support this process.

An existing protocol we have used in pilot work with lay volunteer coaches follows: If clients report any thoughts of committing suicide or harming themselves, worsening of depressive symptoms, emergent manic or psychotic symptoms, thoughts of homicide or harming others, or elder abuse during or outside of DMFB sessions, volunteer coaches immediately contact on-site senior center clinical staff. Volunteer coaches only see clients during hours when the Center is open; center staff are always available during these times and are reachable via phone.

Staff will assess the client and arrange emergency psychiatric services, contact police, or offer a referral for elder abuse services if indicated. In addition, study investigators are available via cell phone to be contacted at any point by participating volunteer coaches or center staff to assist in this process.

If clients experience an acute medical event or accident while participating in a volunteer-led activity on site, such as choking, shortness of breath, fainting, a fall or accident, volunteers immediately contact on-site senior center staff. Center staff will arrange emergency medical services if necessary.

The research team and external raters of fidelity have agreed to abide by the confidentiality and data protection rules of the study. Investigators will not share information regarding intervention fidelity with other senior center staff and supervisors, unless volunteers are judged to be harmful to center clients. This exception will be made clear to volunteer participants in the informed consent.

Clinician Participants: To mitigate and address distress among clinician participants we will follow the same procedures outlined above for volunteer participants, namely training in responding to client distress and personal distress, and regular supervision by study investigators.

As with procedures for training in emergency psychiatric and medical protocol described for volunteer participants above, investigators will train clinicians in an emergency protocol developed in conjunction with participating senior centers. We will work with centers to ensure that the emergency protocol and training procedures are acceptable to them.

We will work with participating senior centers to identify local resources such as area hospitals to ensure that all clinician participants and relevant center staff have appropriate contact information for local medical and psychiatric services for both emergent and non-emergent client conditions. Clinician participants may make such referrals and emergency service arrangements on their own; they may work with their own clinical supervisor if applicable; or they may contact study investigators for guidance. Study investigators will be available via cell at all times.

As safeguards against coercion, clinicians who participate will be given the same protections provided to clients. Their participation will be voluntary, and their information will be confidential. Of particular importance is the need to ensure that the clinicians understand that their decision to participate (or a decision to withdraw participation) is voluntary and will have no job ramifications. Neither study participation nor performance in delivering BA will affect job stability or evaluation. As safeguards to protect clinician participants against potential risks associated with poor performance, we will not communicate with clinician supervisors or center administrators about clinician fidelity to BA, their certification status, or their ongoing performance. However, an exception to this policy will be made if study investigators should judge any clinician to be harmful to center clients. This exception will be made clear to clinician participants in the informed consent. No individual-level data will be made available to the agency or public about clinician performance (e.g., in delivering depression treatment), and all such data will be presented only in aggregate form.

The research team and external raters of fidelity have agreed to abide by the confidentiality and data protection rules of the study.

8.1.4 Potential Benefits

Potential Benefits to Client Participants: Enrolled client participants will accrue the following benefits at no cost:

1. A structured evaluation of psychopathology and an assessment of functional limitations for which interventions are needed.
2. Ongoing monitoring of clinical status and appropriate referral for clinical care in the event of deterioration.
3. Assignment to one of two potentially active interventions.

Potential Benefits to Volunteer Coach and Clinician Participants: Volunteer coach participants will learn approaches to help senior center clients with elevated depressive symptoms.

Potential Benefits to Society: The potential to expand the field capable of providing geriatric mental health services by developing a novel, sustainable delivery method of an effective intervention for late-life major depression.

8.1.5 Risk-Benefit Ratio

With the precautions taken, the likely benefits of this study outweigh the potential risks.

8.2 Adverse Events, Serious Adverse Events, and UPIRSOs

Procedures for collecting and reporting AEs, SAEs, and UPIRSOs: We will document adverse side effects that are reported to study investigators, volunteers, or clinicians, e.g., other distressing clinical symptoms; elder abuse; pursuit of activities that are unsafe or contraindicated in light of medical conditions or physical limitations.

We will report all protocol violations, AEs, and SAEs that are expected or unrelated to study participation to NIMH, at a minimum, at the time of the annual progress report. We will report all study related SAE's and UPIRSOs to the NIMH within 10 business days of the investigator learning of the event. We will report any death related to study

participation immediately (i.e., no later than within 5 business days of learning of the death). We will report the above events to the UW IRB at the same frequency. Research Coordinators will immediately report to the study PI any SAEs or UPIRSOs that they learn of from the client, lay volunteer, center clinician or other source. Research coordinators will log all AEs for weekly review by the PI.

8.3 Data and Safety Monitoring Plan

In consultation with NIMH Program officers, we will establish a Data Safety Monitoring Board (DSMB) that oversees our study activities to ensure the safety of participants, the validity of our findings, and the need for further data collection. The DSMB responsibilities will include:

1. The review of protocols, informed consent procedures, and safety plans.
2. The determination of whether the study should be continued, modified, or terminated in light of adverse events.
3. The monitoring of study progress as reflected in the rate of participant recruitment and adherence to timetables.
4. Review of baseline demographic and clinical data.
5. The evaluation of the study's risk-benefit ratio as new evidence-based treatments become available.
6. Consultations with the investigators regarding protocol measures that impose undue burden on study patients and clinicians or that pose possible ethical concerns or conflicts of interest.
7. Submission of summary reports based on meetings and review of summary information.

DSMB meetings will occur once a year following distribution of reports submitted by study investigators. Meetings may occur more frequently if requested by the DSMB or study investigators. The DSMB will be provided with summaries of adverse events (additionally, all adverse events are reported to the UW IRB within the timeframe specified by IRB regulations). The DSMB will also be provided with participant recruitment rates; investigator adherence to timetables; and baseline demographic and clinical data. The Board will also be provided with copies of all reports submitted to NIMH and manuscripts submitted for publication in professional journals. We will respond promptly to DSMB requests for data analyses.

8.4 Data Management and Protections

Data Management: Before data entry, Research Coordinators will check each other's ratings for completion and clinical consistency. We will use REDCap for data entry and management. REDCap is a secure, HIPAA compliant web-based application for quickly building and managing online surveys, data collection forms, and databases. REDCap provides an intuitive interface for users to enter data and enforces time validation rules (with automated data type and range checks) at time of entry. This platform provides an intuitive data manipulation interface, custom reporting capabilities, audit trail functionality, and real-time data monitoring/querying of participant records. REDCap has multiple data export options to common statistical packages (SPSS, SAS, Stata, R). Data from all Centers will be uploaded to UW's Secure FTP site.

Data Protections: Study data will be labeled with a unique study identification number. Only the relevant project staff will have access to the master list linking subject names to study identification numbers. The master list will be kept separate from the coded study data. All identifying information collected as part of the study will be stored in a database on a secure server which is password protected with limited access by the study team. Publications or presentation of findings will not include information identifying the subjects.

Data Security Protections:

- Level 4 for client and certification participants: Could result in serious harm (e.g., sensitive information like mental health diagnoses).
- Level 4 for volunteer participants: Could result in serious harm (e.g., sensitive information like mental health diagnoses).
- Level 4 for clinician participants: Could result in serious harm (e.g., sensitive information about their ability to provide the intervention, which could affect employment at senior centers).

Privacy Protections: Identifiable information is stored separately from study data (e.g. assessments, session notes). Study data are coded with a unique study ID number for each participant, which cannot be used to directly identify

the participant. Key members of the study team will have access to the link between the participant's identity and ID number.

Participants have the option to opt out of answering questions if they are uncomfortable doing so. We ask permission to discuss sensitive information prior to doing so and let subjects know they are free to decline to answer. All assessments, intervention sessions, consenting and other sensitive communications may take place remotely, and participants will be encouraged to find a private space to hold those conversations.

Identifiers: Identifiable information (participant names, contact information) will be stored separately from study data.

Dissemination: The results of this study will be disseminated and have practical relevance to senior centers across the country. New aging service initiatives provide support for whichever form of BA is found to be most effective in the proposed trial. Our Dissemination Plan outlines procedures for creation of training materials for use by community partners, methods to disseminate the intervention, and use of funding provided by the Administration on Aging to support implementation of the intervention by senior center staff (see Section 10.2).

We will create an Advisory Council of dissemination experts that will guide us in: reviewing program roll out and any challenges; reviewing funding structure and opportunities for senior centers; reviewing preliminary feedback from client and volunteer participants; reviewing feedback from center staff and administrators; assisting in interpreting our findings and their implications; and providing direction on how to disseminate DMFB. We will seek feedback from ~2 staff and administrators per participating center about their experience implementing and hosting the intervention throughout the study, including their reactions to our training, supervision, and fidelity assessment procedures. We will create a website with information about DMFB and available training resources from the investigators. This will include a Train the Trainer manual and materials that can be downloaded at no cost. We will also apply for evidence-based program status from the Administration on Community Living (ACL), which will allow senior centers to receive Title IIID funding.

9 Secondary Use or Sharing of Information or Contact Information

Storage for Future Use: All study data will be stored for future use. This includes all assessment data, training information, and sessions data. All data is coded with a unique study ID number, which cannot be used to identify the participant. The ID number will be stored along with the study data for future use. De-identified Audio from intervention sessions or assessments will be used for future supervision, training, and research purposes only if the client explicitly consents to these uses.

Data Sharing: All study data may be shared with other researchers and/or with a repository/database/registry (e.g., NIMH's National Data Archive). No direct identifiers will be shared. Participants consent to the sharing of this information during the provision of informed consent. Despite using direct identifiers to generate GUIDs for the NIMH's NDA, the GUID is not identifiable. We will remove identifiers (name, date) from any audio recordings when sharing them with other researchers and/or repository/database/registry.

Oversight/management of Sharing: The oversight and/or management of the sharing will be the responsibility of the study PIs.

Possible Future Uses: Possible future uses of this data include ongoing data analysis for publication, informing grant proposals for clinical trials, and use of de-identified audio recordings as supplemental training materials for future DMFB trainings.

10 Supporting Documentation

10.1 Protocol Amendment History

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is located in the Protocol Title Page.

Version	Approval Date	Description of Change	Brief Rationale
1	10/21/2020	Initial Study Review	
2	2/25/2021	No currently enrolled participants (only clinician participants to date) will be impacted by these changes. Modification submitted to provide clarifications that we've arrived at during study start up and to add a few assessment measures.	Assessments added during start up
3	4/7/2021	This modification covers a broad range of edits as we continue start up procedures. The only participants currently enrolled are volunteer and clinician participants. One of the edits to procedures for volunteer participants (adding the PHQ-9 to the intake interview) will not impact currently enrolled volunteers.	Assessments added during start up
4	6/15/2021	Modified baseline assessment from a single 2-2.5 hour long appointment that all participants received $30 for completing to two, 1 hour and 15 minute appointments. Participants will receive $15 for completing each assessment and must meet inclusion criteria assessed at the first baseline appointment to move to the second.	Modification to assessment schedule to reduce burden
5	7/19/2021	Modified language in consent around sharing of information between study staff and senior centers. Corrected an error in the protocol where we had listed that the Client Satisfaction Questionnaire (CSQ-3) would be administered at all time points rather than just at the week 9 follow up assessment.	Clarification regarding sharing of information; correction to assessment schedule
6	9/15/2021	Edited consent form to clarify the release of information section added in the previous submission. Currently enrolled clients will not be notified as these clarifications were made verbally with those clients.	Clarification regarding release of information
7	12/1/2021	Updated protocol to reflect that participants who score ≥20 on the mTICS meet inclusion criteria. Currently, the protocol states that people who score ≥19 meet eligibility criteria.	Correction to eligibility criteria
8	3/17/2022	Updated consent forms for client participants to increase specificity around client consent to capture audio recordings for future research purposes and to clarify that CPT cases can be 50+ years old.	To clarify audio recording consent and CPT client inclusion criteria
9	5/3/2022	1) Corrected a contradictory reference that exists in the client consent template and the UW client consent form. Also edited UW clinician consent form regarding minor formatting issues. Changed number of BA Clinician trainings from 4 to 2 (this was an error). 2) Updated Data Safety and Monitoring Plan language around DSMB meeting frequency. 3) Added 5 non-UW investigators. 4) Updated CPT participant inclusion criteria in the protocol to reflect that people who score >0 on the Hamilton Depression Rating Scale (HAM-D) during their baseline assessment are eligible.	To correct an error regarding required number of clinician trainings, update DSMB language as requested in RNI00001817, update personnel, and clarify inclusion criteria for CPT clients

Version	Approval Date	Description of Change	Brief Rationale
10	2/14/2023	The study received supplemental funding from NIH to expand into senior centers that serve Spanish speaking clients. We are submitting this modification to 1) edit inclusion/exclusion criteria for participants; 2) provide information on how Spanish language materials and support will be provided; 3) upload templates for recruitment flyers for volunteer coach participants; and 4) clarify the geographic area referred to as Tampa or the Tampa area. The edits related to Spanish language apply only to the additional sites supported by the supplemental funds; all active and future sites originally included will continue to require English-speaking clinicians, volunteers, and clients, as delineated in the protocol.	To update procedures following receipt of NIH supplemental funding
11	2/28/2023	Updated contact information on the Spanish versions of the client, certification client, volunteer coach, and clinician consent forms.	Updated contact information
12	3/29/2023	Updated protocol and clinician consent forms to reflect a change in reimbursement amount decided by the PIs. We are increasing clinician compensation for in-person sessions to account for travel expenses to $125 as senior centers continue to reopen for in-person services.	Increased clinician compensation to account for travel expenses
13	5/5/2023	Modified protocol to account for new recruitment procedures. Going forward, we will be using targeted social media advertisements (Facebook, Google) to identify, screen, and recruit potential client participants. Updated recruitment procedures regarding social media advertisements for volunteer participant recruitment.	To expand outreach
14	6/16/2023	Updated protocol and consent forms to reflect more clearly that assessments may be administered to participants by research staff across the collaborating research institutions.	To allow for cross-institutional staff support to reduce burden
15	8/3/2023	Added 5 non-UW investigators.	Personnel update
16	8/23/2023	Submitted Staff Survey consent form; updated protocol to reflect this procedure. We will administer the Staff Survey to senior center staff who participated in the DMFB study.	To gather insights on successful implementation of the program
17	8/31/2023	Modified protocol to account for new recruitment procedures. Going forward, we will be using targeted social media advertisements (Facebook, Google) to identify, screen, and recruit potential client participants.	To expand outreach
18	10/11/2023	Added 5 non-UW investigators and removed one non-UW investigator who discontinued participation in the study.	Personnel update
19	10/18/2023	Added 5 non-UW investigators.	Personnel update
20	12/4/2023	1) Updated exclusion language around dementia. 2) Submitted DMFB TTT Staff Survey Pre-Interview and Survey assessments. Updated Staff	To exclude clients with cognitive impairment

Version	Approval Date	Description of Change	Brief Rationale
		consent to reflect audio recording permission change.	
21	1/19/2024	Removed 3 Individual Investigators who initially enrolled in the study but discontinued participation before conducting research activities.	Personnel update
22	3/14/2024	Submitted modification with updated language around the use of social media and online advertisements to recruit client and volunteer participants for the study.	To expand outreach
23	4/12/2024	Uploaded missing IIA agreement.	IIA submission
24	5/10/2024	Added 3 non-UW Individual Investigators.	Personnel update
25	5/24/2024	Updated language in protocol around recruitment location of clients, volunteer coaches, and clinicians from Tampa area to Florida.	To allow USF to recruit from a wider catchment area (the whole state)
26	6/12/2024	Updated language in protocol around recruitment location of clients, volunteer coaches, and clinicians from Seattle and New York City (NYC) to Washington and New York, respectively.	To allow UW and Cornell sites to recruit from a wider catchment area (the whole state)
27	10/4/2024	1) Added study team member to project 2) UW site team will conduct a survey of individuals who work in aging service organizations. Protocol has been modified, and draft survey and flyer template have been uploaded.	To gather input on depression need, organization interest, and organization resource needs for delivering DMFB
28	5/16/2025	IIA requested.	IIA request
29	8/18/2026	Minor corrections to dissemination plan to reflect final dissemination procedures.	To clarify dissemination procedures

10.2 Dissemination Plan

The UW Research Coordinator (RC), will be responsible for handling ClinicalTrials.gov requirements for this project under Dr. Raue's oversight. The RC will register the trial prior to enrolling the first subject. Once a record is established, the RC will confirm accuracy of record content, resolve problems, and maintain records including content update and modifications. The RC will also be responsible for aggregate results reporting and AE reporting at the conclusion of the project. Any changes to the protocol will be discussed with the DSMB and NIMH program officer before they are enacted and must be approved by the UW IRB.

1. We will create an Advisory Council of dissemination experts that will guide us in: reviewing program roll out and any challenges; reviewing funding structure and opportunities for senior centers; reviewing preliminary feedback from client and volunteer participants; reviewing feedback from center staff and administrators; assisting in interpreting our findings and their implications; and providing direction on how to disseminate "Do More, Feel Better." The Council will consist of 3 consultants to the grant, with expertise regarding dissemination of evidence-based programs in the aging services network, ranging from national to regional and local. We will seek feedback via annual group Council meetings and individual consultation as needed.

2. We will seek feedback from ~2 staff and administrators per participating center about their experience implementing and hosting the intervention throughout the study, including their reactions to our training, supervision, and fidelity assessment procedures. The PIs at each site will synthesize all feedback and present at Advisory Council meetings (above) to refine materials and procedures. Input from staff and administrators, along with the feedback from clients and volunteers in these areas will yield a refined Train the Trainer manual on training procedures, the certification process, and fidelity assessment instructions for use in senior centers throughout the country.

3. We will present study findings at conferences that aging service providers and policymakers attend, such as Aging in America, the National Association of Area Agencies on Aging, Age + Action, and the NCOA Center for Healthy Aging.

4. We will create a website with information about "Do More, Feel Better" and available training resources from the investigators. This will include Train the Trainer manual and materials that can be downloaded at no cost.

5. We will apply for evidence-based program status from the Administration on Community Living (ACL), which will allow senior centers to receive Title IIID funding. Title III-D of the Older Americans Act provides grants to states to implement health promotion programs, and it requires that programs be recognized by the U.S. Department of Health and Human Services as evidence-based. Currently across the ~10,000 U.S. senior centers, approximately 58% host evidence-based health promotion programs (e.g., Chronic Disease Self Management Programs) that receive Title IIID funding.

11 References

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