Healthy Mind, Healthy Living

Evaluation of a Mindfulness-based Intervention on Depression among Older Korean American Adults

Asian American Resource and Information Network, Inc (AARIN)
and University of Washington (UW)

Clinical Trials Registration: NCT05965349 (MBCT Healthy Mind Healthy Living (HMHL)

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Rational and Background Information

Older Asian American adults (> 65) are a rapidly growing racial/ethnic group in the United States, in which their total population is expected to nearly double from 2016 to 2030. In the context of the COVID-19 pandemic, older adults are a particularly vulnerable group as this group has an increased risk of poor prognosis due to high rates of chronic disease such as diabetes, cardiovascular disease, and cancer. In the absence of a vaccine for COVID-19, public health strategies consisted of isolation, quarantine, social distancing, and community containment. While the preventive strategies lower the risks for exposure, these strategies pose challenges for older adults who already experience isolation due to diminishing social network. For older AA & NHPI adults, these experiences are further magnified due to language barriers to accessing information and limited ability to network with culturally relevant groups. Furthermore, a survey on life satisfaction indicated that Asian American older adults reported lower satisfaction and higher unmet social and emotional needs than other race and ethnicities.[1]Finally, increased racism since the pandemic poses another layer of complexity for Asian American older adults.

Public health efforts have repeatedly marginalized older Asians' mental health needs through systematic exclusion of non-English/Spanish speakers in national surveys. Limited English proficiency (LEP) is a term used to describe individuals who do not speak English as their primary language and who have limited ability to read, speak, write, or understand English.[2] According to the 2010 Census, more than 18% of the U.S. population (47 million Americans) do not speak English as their primary language, and more than 25 million speak English less than "very well."[2] Asian immigrants are the second largest group with LEP status after Hispanics.[3] Approximately 89% of older Asian Americans are foreign-born, and 62% are LEP, with 84% of Vietnamese and Koreans reporting LEP.[4] The LEP population experiences higher burdens in health and access to care compared to their English-speaking counterparts, but surveys do not always capture these disparities.[5-8] For example, the prevalence of depression using data from the National Health and Nutrition Examination survey (NHANES) shows lower reports of depression (3.1%) among older Asians compared to non-Hispanic Whites (7.9%), Hispanics (8.2%), and non-Hispanic Blacks (9.2%).[9] NHANES is in English and Spanish only. When a large study (n=175,956) attempted to include survey reminders in Chinese, depressive symptoms among older Asians (11%–21%) were greater than non-Hispanic Whites (9%), non-Hispanic Blacks (16%), and similar to Hispanics (17%–23%).[10] Depression rates drastically escalated to 44% when surveys (n=2,609) were administered in five Asian languages (Asian Indian, Chinese, Filipino, Korean, and Vietnamese), with 55% of Vietnamese reporting depression.[11] In addition, LEP status also consistently emerges as the most prominent factor for lower mental health service use and increased unmet mental health needs among older Asians.[11] This methodologic limitation suggests that the burden of depression among non-English/Spanish speaking older Asian adults is not represented in the national health profiles of the U.S. population, and our current knowledge may be a small glimpse of a much larger health issue.

Mindfulness-based cognitive therapy (MBCT) is a group-based intervention rooted in Eastern ideology but taught from a secular perspective.[12] MBCT combines mindfulness training and cognitive therapy to improve emotion regulation and reduce negative emotions.[12] A core feature of MBCT is the cultivation of mindfulness, defined as a nonjudgmental awareness of present-moment experiences and an accepting attitude towards oneself and the surroundings.[13] Several meta-analyses have demonstrated MBCT reduces depression relapse.[14-16] and active depression.[17-19, 20] MBCT has also been embraced in Asian countries. A systematic review of MBCT intervention among Asians showed 40 studies covering diverse groups.[21] However, the effects of the MBCT among older Asian Americans remain understudied.

We will collaborate with a community-based organization named Asian American Resource and Information Network (AARIN) to implement an MBCT intervention with older Korean adults. This is a collaborative project between AARIN and the University of Washington (UW) will recruit 40 Korean Americans ages 505 and older to participate in an 8-session MBCT program delivered by staff members of AARIN.

Specific Aims

1) To implement the mindfulness-based cognitive therapy (MBCT) intervention.

2) To assess the acceptability and relevance of MBCT, as well as its impact on patient reported outcomes among older Korean adults, ages 505-89.

Overall Research Design

We will conduct a single arm, pre/post pilot intervention study to examine the effect of MBCT on depression among older Korean American adults. We will recruit older Korean adults (n=40) from AARIN to complete the 8-session Healthy Mind, Healthy Living intervention, along with periodic mental health assessments.

Eligibility Criteria

Inclusion criteria: To be eligible, the participants must: (1) self-identify as a Korean person, (2) be between the ages 505 and 89, (3) has mild to moderate depressive symptoms (scores between 5-14 when assessed using Patient Health Questionnaire-9 (PHQ-9), (4) has limited English proficiency (responds "less than very well" when asked "how well do you speak English"?) and fluency in Korean (e.g. able to speak at a native level), and (5) willing to give a written consent to participate in the study.

Exclusion criteria include: Individuals will not be able to participate if they have any of the following criteria: (1) major psychiatric diseases that would interfere with participants' ability to participate in or receive the benefit from the mental health interventions (e.g., bipolar disorder, schizophrenia, recent history of psychosis or mania, severe depressive symptoms); (2) used drugs other than those required for medical reasons; (3) serious medical conditions (e.g., poorly controlled diabetes, severe congestive heart failure) that has not been stable for at least 3 months; (4) current active suicidal or self-injurious behavior, potentially necessitating immediate treatment; (5) general conditions that would impede participation in a group intervention (e.g., cognitive impairment, tendencies toward physical aggression); (6) prior history of engaging in formal mindfulness-based interventions including mindfulness-based stress reduction, MBCT, Acceptance and Commitment Therapy, and Dialectical Behavioral Therapy; and (7) significant current meditation practice, specifically more than three hours of insight/mindfulness/vipassana meditation per week.

Participant Recruitment

AARIN will recruit older Korean Adults through partnering organizations, social media, such as Kakao Talk which is a popular messaging application among Korean Americans.

The AARIN staff will collaborate with partnering organizations to send a study flyer (**APPENDIX A – HMHL Study Flyer**) to potential participants. AARIN staff will recruit participants directly from partnering organizations by visiting the organization or attending their scheduled activities. AARIN staff will also ask the partnering organizations to refer their potential clients who show interest in participating in the study. Potential participants will share their contact information with partnering organizations for AARIN to contact them with more information about the study.

Dr. Lee will call potential participants, speaking in the language of their preference (English or Korean), to describe the study and gauge their interest in participating in the study and their eligibility (**APPENDIX B – Phone Scripts).** Depending on the participant's capability, enrollment will take place in person, or via zoom/phone. After the eligibility of the participant is confirmed, Dr. Lee will present the Consent Information. Though this study will have a waiver of written documentation of consent, Dr. Lee will still read through the Consent Information which includes key information about the study. Dr. Lee will verify that that the participant has heard the Consent Information, was able to ask questions, and has agreed to participate in the study. Dr. Lee will administer the screener, present the Consent Information, and administer the Baseline Survey for those eligible and willing to participate. The consent process will be documented in REDCap. (**APPENDIX D – Study Consent & Baseline Variables; APPENDIX E – HMHL Screening & Consent SOP**).

Consent

Since this study is considered "minimal risk" it is exempt from requiring the written documentation of consent. However, the study staff will still present participants with the key information required for informed consent.

In-person Consent Information

Dr. Lee will read through a hard copy of the Consent Information with the participant and answer any questions that arise. If the participant has no questions and agrees to participate, Dr. Lee will mark an "X" on the Consent Information document to verify the participant has agreed to participate. Dr. Lee will track this process and update the participants Consent Information document in REDCap when she uploads the other survey responses. The participant will keep a copy of the Consent Information for themselves.

Online or Phone Consent Information

Prior to the enrollment session, participants enrolling via phone/zoom and who use email will receive an email with the Consent Information in their preferred language, those who do not use email will receive it via mail. If the screener is administered via phone/zoom, participants will provide verbal consent to confirm their participation in the study. The consent document will be read to the participants by Dr. Lee once their eligibility has been confirmed through the administration of the screener. If the enrollment is taking place over zoom, the participant will visually see a copy of the Consent Information on the screen through REDCap as the study staff member reads the Consent Information and answers questions. If it is administered via phone, Dr. Lee will read the Consent Information to the participant in the participants preferred language. If the participant has no questions, Dr. Lee will verbally confirm that the study participant agrees to participate and check's the "agree to participate" in REDCap and mark the document with an "X" to verify the participant has given verbal permission to participate. If a participant indicates they would like to receive the Consent Information via email, REDCap will automatically send the participant a copy of the Consent Information to their designated email address. If they would prefer to receive a paper copy of the Consent Information, the document will be mailed to them at their given address.

The workflow for the recruitment, consent, and data collection for the AARIN staff member and the University of Washington team member are outlined.

Workflow for Development, Recruitment, and Data Collection

#	Responsibility	Activity
1	University of Washington	Develop the research protocol and consent.
2	University of Washington	Submit the IRB application
3	University of Washington/Dr. Visvanathan	Create the MBCT training protocol, the survey instrument and semi-structured interview guide.
4	Dr. Visvanathan	Provide training on MBCT and provide implementation support.
5	AARIN	Recruit 40 participants for the MBCT program.
6	AARIN	Receive training on MBCT.
7	AARIN	Implement the MBCT program with 40 participants, 5 groups.
8	AARIN	Conduct baseline and post assessment survey – in-person or telephone survey.
9	AARIN	Enter survey data to REDCap.
10	AARIN	Send incentives to participants.
11	AARIN	Conduct and record semi-structured interviews with 12 participants.
12	University of Washington	Transcribe the interviews
13	University of Washington & AARIN	Analyze the data.
14	University of Washington & AARIN	Collaborate on conference presentations and manuscript preparation.

HMHL Intervention

A telephone-based MBCT will be delivered by AARIN staff members. Prior to the delivery of the MBCT the staff members at AARIN will be trained by Dr. Visvanathan, a certified MBCT instructor and developer of the remote-delivered MBCT protocol. The training will include 1) **experiential training** from participating in the 8-week MBCT intervention, 2) **didactic training** on how to deliver the intervention (how to lead meditations and cognitive exercises

and conduct participants inquiry), and 3) **supervision** as the staff member at AARIN lead their first 8-week MBCT group.

Table 1 shows critical components of MBCT including: (1) learning mindfulness skills; (2) practicing mindfulness skills in class and at home; and (3) dialogue and inquiry. All sessions will be audio-recorded to allow the staff at AARIN to access them later as a resource.

Table 1: Structure and Content of MBCT

Structure	Weekly Content
• Homework review (except session 1) • In-session practice of both meditation-based and cognitive behavioral exercises • Guided inquiry • Summary of main themes and assign at -home daily practice	**MBCT-T**
	1. Awareness & Automatic Pilot
	2. Living in Our Heads
	3. Gathering the Scattered Mind
	4. Thoughts are not Facts
	5. Allowing and Letting Be (Part I)
	6. Allowing and Letting Be (Part II)
	7. Taking Care of Myself
	8. Maintenance

Dr. Visvanathan will also provide weekly supervision. We will ensure fidelity by using treatment manuals, session fidelity checklists, and weekly supervision of session audio recordings to minimize drift. Treatment fidelity will be evaluated by two independent raters, with a minimum of 85% inter-rater reliability, using the Remote-Delivered MBCT-Treatment Adherence Competence Scale (MBCT-TACS).[130] We will recruit 40 older Korean Americans. AARIN will deliver five, eight-week MBCT sessions with 8 participants per group (n=40).

Data Collection

Individual participants' mental health status will be assessed at pre and post MBCT delivery using PHQ-9 and quick inventory of Depressive Symptomatology (QIDS) across all conditions (**APPENDIX F** – **Follow-up survey**. At the end of the study, we will conduct semi-structured interviews with 12-16 older adults to understand acceptability and cultural relevance of the MBCT for older Korean adults (**APPENDIX G** – **Semi-structured Interview Guide**).

Survey data of participants include depressive symptoms, immigrant stress, sleep quality, socio-demographic characteristics, major chronic diseases, healthcare, beliefs on mental health, and medications. All measures will be collected using validated standardized measures.

Timeline with detailed activities

	2022								2023									
	APR	MAY	JUN	JUL	AUG	SEP	OCT	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT
Development Research Protocl/Consent/IRB																		
MBCT Training																		
Recruitment																		
Baseline Assessment																		
MBCT Sessions																		
Follow-up Assessment																		
Semi-Structured Interviews																		
Data Analysis																		
Write Summary Report																		
Community Presentation																		

Data Analysis

Survey data Analysis: All analyses will be done in SAS Version 9.4. We will generate frequencies for categorical variables and means for continuous variables. To assess the effect of MBCT, we will compare depression outcomes pre/post using T-test. A two-sided test with a level of 0.05 will be used.

Semi-structured Interview Data Analysis: Transcripts will be uploaded into ATLAS.ti Version 8. Two analysts will use an inductive, constant comparison approach, in which concepts will be identified and themes derived from interview data. Using an iterative process, two analysts will meet weekly to refine the codebook, adding, removing, and revising codes, as needed, to address inter-rater agreement and to compare new data with existing data. We will build consensus around themes that are identified throughout the coding and analysis process. We will compare the themes arising from the data and determine possible linkages across participants and thematic categories.

Data Safety Monitoring Plan

A detailed data safety monitoring plan is outlined in **APPENDIX H**.

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