Mindful Self-Compassion Training to Improve Retention, Job Satisfaction, and Attitudes toward Dementia among Long-Term Care Nursing Assistants:

Certified Nursing Assistants' Wellbeing

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MINDFUL SELF-COMPASSION TRAINING TO IMPROVE RETENTION, JOB SATISFACTION, AND ATTITUDES TOWARD DEMENTIA AMONG LONG-TERM CARE NURSING ASSISTANTS

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Study Title

Mindful Self-Compassion Training to Improve Retention, Job Satisfaction, and Attitudes toward Dementia among Long-Term Care Nursing Assistants: Certified Nursing Assistants' Wellbeing Program

Objectives

This preliminary study will modify, refine, and test a MSC training intervention, otherwise to be known as the CNA Wellbeing Program, for CNAs who care for nursing home residents. The proposed research will be conducted in 3 similarly rated and structured community NHs.

Aim 1: Determine the feasibility, acceptability, and adaptations of the CNA Wellbeing Program by conducting 8-week course in one NH with a goal of 15 CNAs, and up to 20 CNAs per NH. Evaluation will focus on a) participation (including home practice adherence); b) attendee evaluation of training; c) barriers/facilitators of participation; d) use and retention of session materials by participants; and e) recommendations for improvement.

Aim 2: Conduct a pilot test of adapted protocols and intervention in sample of 30 CNAs from 2 NHs to reexamine feasibility and acceptability. Evaluate fidelity and impact of training by measuring a) attendance, b) satisfaction with training, c) pre-post measures of self-compassion, intent to leave job, perceived stress, job satisfaction, burnout, and attitudes towards persons with dementia.

Interventions and Duration

Mindful Self-Compassion has been developed and validated in other populations as a course of eight 2.5- hour weekly sessions. A modified version of this program will be tested in Aim 2, which is also a validated version of the MSC program. This version is six, 1-hour weekly sessions. Each session begins with meditation, follows with discussion of previous week's home practice, introduction of main theme of session and new formal and informal practices. Each session will be offered in a location convenient to the NH, outside of work hours, at times convenient for participants, and offered at two different times to accommodate schedules.

Sample Size and Population

Eligibility to this study will include: Certified Nursing Assistant employed by participating nursing homes; over the age of 18; able to speak and write in English; works at NH 20 or more hours per week; expects to be employed with NH for the duration of the course; and expects to be able to attend 75% of the sessions. Up to 20 CNAs per NH will be able to participate, with a goal of 15 participants. If over 20 CNAs are interested, the study will enroll the 20 CNAs who score highest on the Screening Questionnaires' Perceived Stress Scale who are interested in participating.

STUDY TEAM ROSTER

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1 STUDY OBJECTIVES

This preliminary study will modify, refine, and test a MSC training intervention, to be known as CNA Wellbeing Program, for CNAs who care for nursing home residents. Our goal is to increase CNA coping skills and well-being, thereby reducing intent to leave the job, reducing burnout, and improving job satisfaction and attitudes toward people with dementia. The proposed research will be conducted in 3 similarly rated and structured community NHs.

1.1 Aim 1 Objective

Determine the feasibility, acceptability, and necessary adaptations of the CNA Wellbeing Program needed to meet the diverse cultural background, limited literacy, and job and family challenges of the nursing home CNA workforce, including the unique challenges of caring for persons with dementia, and of the data collection methods.

A. Conduct a field trial of the standardized 8-week CNA Wellbeing Program with 15 CNAs within a single community NH. Evaluation will focus on: (a) participation (including home practice adherence and attendance); (b) attendee evaluation of the training; (c) barriers to and facilitators of participation; (d) use and retention of session material by participants; and (e) recommendations for improvement of training.

B. Field test the feasibility and acceptability of our study recruitment and evaluation strategy.

C. Use data collected from the field test to modify recruitment strategies, protocols, and course structure, content and materials so as to be maximally feasible, acceptable and effective in a CNA population.

1.2 Aim 2 Objective

Conduct a pilot test of the adapted protocols and intervention in a sample of 30 CNAs from 2 similarly rated and structured community NHs to reexamine feasibility and acceptability, identify trends in key intermediate and long-term outcomes, and estimate effect size in preparation for a future randomized trial.

A. Evaluate the fidelity and immediate impact of the modified training by measuring (a) training attendance; (b) satisfaction with the training; and (c) pre-and post-training measures of self-compassion, perceived stress, job satisfaction, job burnout symptoms, and attitudes towards persons with dementia.

B. Evaluate the sustained impact of the training by comparing baseline, 3-and 6-month post-training measurements of: intent to leave job, self-compassion, perceived stress, job satisfaction, job burnout symptoms, and attitudes towards persons with dementia.

2 BACKGROUND AND RATIONALE

Critical role of certified nursing assistants (CNAs) in nursing homes (NHs). U.S. NHs serve approximately 1.6 million complex and vulnerable persons daily, the majority of whom have Alzheimer's disease or a related cognitive disorder, require extensive help with activities of daily living, and have multiple chronic illnesses.[1] In these settings, most hands-on care is provided by an estimated 634,000 certified nursing assistants (CNAs) – a workforce that is racially diverse, predominantly female, with a high school or lower education, and an annual income equivalent to the poverty threshold for a family of four.[2]

CNA workforce experiences high stress and turnover, compromising resident care. Demand for CNAs is high and projected to grow;[2] however, retaining CNA staff is a major challenge. National turnover rates average 65% annually.[3] Equally concerning is CNA absenteeism, as nearly 10% do not report to work as scheduled.[4] Turnover, absenteeism, and staff shortages have been linked to poor care, including negative resident outcomes such as pressure ulcers, infections, pain, and reduced overall quality of life.[3-8]

CNAs are predominately female; nearly half are racial/ethnic minorities; and 75% have a high school degree or less.[9] Two thirds live on a family income near or below poverty level and nearly a third receive public assistance and/or head a single-parent household. Given limited resources, hardships such as inconsistent childcare, personal illness or injury, or transportation issues can be large sources of stress.[10]

CNAs also face emotionally and physically demanding job tasks, particularly when working with persons with Alzheimer's disease and related dementias. Challenging behaviors such as verbal aggression and physical assault are common, especially during personal care[11-13] with 56% of CNAs reporting at least one work-related injury in the prior year, including scratches, open wounds or cuts, back injuries, bruises, black eyes and human bites.[9] Additionally, CNAs report distress due to unappreciative residents and unhappy family members.[14]

Job burnout, defined as a response to prolonged work-related stress that reduces job satisfaction, productivity, performance, turnover and well-being, is high among CNAs.[15] In dementia care, CNA burnout has been correlated with reduced empathy and fewer positive attitudes towards persons with dementia.[16] In contrast, our previous work and that of others found that positive attitudes towards persons with dementia are associated with increased job satisfaction.[17,18]

Current strategies to decrease job stress and improve job satisfaction have significant drawbacks. Driven by a desire to improve CNA recruitment and retention, many interventions have been identified, including increased compensation and benefits, organizational culture change, improved staffing ratios, and career advancement opportunities.[3] Although these address important issues, most require significant financial resources and organizational change. Moreover, none address the adaptive skills necessary for an individual worker to effectively respond to inevitable job, life, and interpersonal stressors. Furthermore, healthcare provider well-being and resilience are a priority focus,[19] given that optimal resident care is impossible without provider self-care.[20] The current project proposes to arm CNAs with larger life skills useful in difficult situations, many of which are beyond the person's immediate control. These skills are an important adjunct to organizational change interventions and can yield positive effects beyond the workplace.

Mindfulness-based stress reduction (MBSR) is a proven strategy for stress reduction and promotion of well-being in heterogeneous populations. Mindfulness has been described as paying attention to the present with nonjudgmental awareness.[21] MBSR training is a standardized approach that promotes well-being in a wide variety of populations, including healthy individuals,[22] persons with chronic conditions,[23] and family caregivers.[24] Taught in a series of classes, MBSR is inexpensive and highly accessible. In health care professionals, MBSR training decreases burnout, perceived stress, anxiety, and depression, while increasing well-being, empathy and compassion for others.[25,26]

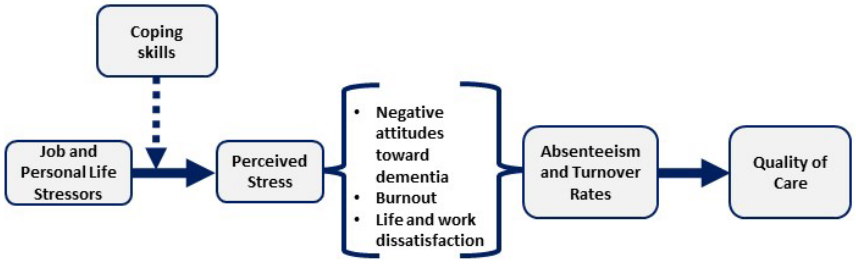
MBSR has been extensively studied in nurses.[27,28] In the limited research that has been conducted on CNAs, sample sizes were small and results mixed.[29] No published research has been conducted in NHs – where CNA roles are most extensive (although a pilot study in dementia care homes is underway in Wales).[30] Given the magnitude of job-related stress among NH CNAs and the success of MBSR with professionals, further exploration is needed. Indeed, the relative simplicity and low cost of mindfulness training coupled with high potential impact has led to calls for formal and informal mindfulness practices to be incorporated into CAN educational programs,[31] and for research on the downstream effects of mindfulness on patient care.[32]

Self-Compassion (SC) and Mindful Self-Compassion (MSC): an enhanced, focused training that is promising yet largely unexplored. SC – a closely related construct to mindfulness – is a particularly powerful new tool to reduce stress and burnout.[32,33] Compassion is "sensitivity to the experience of suffering, coupled with a deep desire to alleviate that suffering," and SC is this same concept focused inward, often described as "like treating oneself as one would a good friend when they are struggling."[34] SC has three main, interrelated components: self-kindness (responding to challenges with self-support and understanding); common humanity (recognizing hardships are part of the shared human experience), and mindfulness (responding to negative thoughts and emotions with a balanced rather than "catastrophic" response). Since its initial description in 2003, SC has been positively linked to multiple measures of well-being;[35] inversely correlated to stress, depression and anxiety;[36] and associated with resilience in the face of stressful life events.[37] There is also evidence that persons with greater levels of

self-compassion experience better interpersonal relationships and express more empathy and compassion for others.[32,38–40] Furthermore, in nurses and nurse midwives, self-compassion protects against job burnout and compassion fatigue.[41–43] A current training format for SC integrates it with mindfulness in an 8-session program entitled MSC which, in the limited intervention studies conducted to date, has demonstrated large, positive effects on compassion for others, stress, anxiety, depression and life satisfaction in community-based, mainly white, female, educated populations.[44] MSC interventions have also been successfully adapted for adolescents by our research team,[45,46] and for those with diabetes.[47] MSC interventions in NH CNAs have not, however, been studied.

Because CNAs have particularly high work and life stress burdens and fewer opportunities than more educated populations to learn stress management techniques, MSC skills hold particular promise for improving outcomes. Indeed, one study of residential dementia care found that CNAs employ a range of strategies, many of which are unhelpful, such as defensiveness/shutting down, unhealthy distraction (e.g., overeating), and psychological distress (e.g., anxiety or depression); and the authors suggested that mindfulness training might have a "preventive focus" by promoting self-care.[48] Additionally, there is evidence that people with high levels of self-compassion more often use "positive cognitive restructuring" or changing one's view of a negative situation to more a positive one,[49] a reaction that has been found to buffer against burnout in CNAs.[15]

Conceptual Model and Potential Impact. Figure 1 (below) illustrates our conceptual model. Among NH CNAs, work and life stress combine with low coping skills to result in high levels of perceived stress, which in turn lead to negative attitudes toward the people they care for, life and work dissatisfaction, and burnout, culminating in high rates of absenteeism and turnover, leading to impairment on the quality of care they provide. The intervention we propose has been proven in other settings to improve performance by enhancing coping skills. If successful, MSC could be incorporated into the curricula of CNA training programs, thereby helping create a more resilient, stable, competent workforce, and one better able to provide dementia-sensitive care.



3 STUDY DESIGN

This is a single-arm feasibility trial that will refine an existing MSC intervention in preparation for a future, randomized controlled trial with the primary goal of improving CNA job retention. We will recruit 15 CNAs from a single nursing home (NH), pilot the 8-week intervention, and collect feedback via questionnaires, interviews and a semi-structured focus group at the end of the course. Data from this cohort will be used to refine study protocols and course structure/materials for maximum feasibility and acceptability. A refined intervention will subsequently be tested in 30 CNAs from two NH settings (15 CNAs per home), with pre, post, and follow-up measurements of stress, burnout, self-compassion, job satisfaction, attitudes towards dementia, and intent to leave their job.

4 SELECTION AND ENROLLMENT OF PARTICIPANTS

In nursing home settings, most hands-on care is provided by an estimated 634,000 certified nursing assistants (CNAs) – a workforce that is racially diverse, predominantly female, with a high school or lower education, and an annual income equivalent to the poverty threshold for a family of four. The participants of this study will include only CNAs employed with the partnering three Nursing Homes.

The three nursing homes that have been chosen for participation fit the following criteria: overall quality (as defined by receiving a 4 or 5 star rating on CMS compare), bed size (80-120 beds), non-profit status, and within 30 miles of the research team.

4.1 Inclusion Criteria

Participants must meet all of the following inclusion criteria to participate in this study:

- *Certified Nursing Assistant working at 3 participating NHs*
- *Works at least 20 hours a week (on average) with participating NHs*
- *Speaks and reads English*
- *Over 18 years old*
- *Intends to work with NH for the duration of the MSC course*
- *Expects to be able to attend a majority (75%) of the sessions*

If over 20 CNAs are interested in the course, and we are not able to accommodate all whom would like to participate, an additional inclusion criteria will be scores on the Perceived Stress Scale portion of the Screening Questionnaire (see Appendix D1). The 20 CNAs with the highest scores on the PSS will be eligible for the intervention course. As of the completion of this trial, this measure was unnecessary.

4.2 Study Enrollment Procedures

All candidates will be identified and recruited from the three participating Nursing Homes. The recruitment process will be a multi-step process, and will gather input from the participating NHs, as well as meeting with CNA representatives from the nursing homes to gather their thoughts on recruitment materials and strategy. See Table 1 (below) for details.

Table 1. Recruitment/Enrollment Schedule

Week -10	Meet with CNA representatives/leaders
Week -9, -8, -7, -6	Finalize logistics RE CNA Wellbeing Program times, locations, etc. Finalize/Submit materials
Week -5	• Begin posting flyers, Version 1 in Week -5 and Version 2 in Week -4 around NH to advertise. • Have available phone version of the Screening Questionnaire for interested CNAs to complete • Begin adding interested CNA's information the interest list
Week -4	
Week -3	• Hold information sessions during shift changes • Hold presentation during staff meeting ○ Shift changes/days to hold will be determined by discussions with CNA representatives. • Collect the in-person Screening Questionnaire. • Collect the interest sheet from interested participants

	• Post additional round of flyers
Week -2	• Hold an additional 2 information sessions • Continue to collect interest sheet of interested CNAs • Continue to collect Screening Questionnaire • Begin consenting CNAs one-on-one, in person. • Begin administering baseline interview after consent process
Week -1	• Hold additional information sessions as needed, based on enrollment. • Continue to collect interest sheet of interested CNAs as needed. • Continue to collect Screening Questionnaire as needed. • Continue consenting CNAs one-on-one, in person. During consenting session, also administer baseline interview. • Begin to finalize final program participant roster.
Week 0	• CNA Wellbeing Program begins • Finish any last consenting and administering of baseline interview as needed.

5 STUDY INTERVENTIONS

5.1 Interventions, Administration, and Duration

CNA Wellbeing Program and Measures Intervention

The study will take place over the course of 8 months for each participant – this includes the duration of the intervention as well as follow up measures (see details below).

Before the onset of the intervention, interested participants will complete the Screening Questionnaire, in order to gather their scores on the Perceived Stress Scale. If over 20 CNAs are interested in joining the course, this screening data will be used to choose the 20 CNAs with the highest scores on the Perceived Stress Scale, and invite these participants to join the full study. Otherwise, all eligible CNAs will be included. This Screening Questionnaire will be administered in person, at the recruitment sessions. Alternatively, for CNAs unable to attend the recruitment sessions and who choose to reach out to the study staff directly instead, an option to have a verbal consent and phone version of the Screening Questionnaire will be provided.

Once the final program list has been determined, the study will begin with informed, written consent, and an initial Baseline Interview, no more than 2 weeks before the onset of the course.

The intervention will be administered over the course of 8-weeks for Nursing Home 1, and over the course of 6-weeks for Nursing Home 2 & 3, and follows the pre-created agenda for the Mindful Self-Compassion course (see below, Table 2). Participants will be texted weekly by study staff, with reminders of the next session, as well as a recap of the previous session. At the beginning of the course, study staff will collect Weekly Questionnaires on each participant. This will be given by the intervention instructors during the sessions. If a participant has missed a session, study staff will follow up to collect a modified Weekly Questionnaire by phone. Towards the end of the course, a half-day (4 hour) retreat was offered to participating CNAs (of Nursing Homes 1). They were encouraged to attend this retreat, however, it was not required and attendance (or non-attendance) did not impact their participation in the study. Ultimately, the retreat was not held due to difficulties with scheduling.

No more than two weeks after the termination of the course, study staff will administer an End-of-Program Interview either in person or via telephone, according to the convenience of the participant.

Additionally, there will be one shortened weekly focus group session (1 hour in length) after the last week

of the CNA Wellbeing Program in order to solicit further feedback on the course. This session will be audio recorded and transcribed, in order to collect and analyze feedback. The sessions for Nursing Home #2 & #3 were formalized into focus groups, whereas the session for Nursing Home #1 was an open discussion session.

Study staff will reach back out to all participants after the culmination of the program, in order to administer the 3/6 Month Interviews either in person or via telephone. After the 6-month interview has been completed, participation in the study will have concluded.

Additionally, in order to compare the stress levels and demographic information of CNAs who participate in the program versus those who work at the participating nursing home, we will ask CNAs present at a staff meeting to fill out a short survey with the Perceived Stress Scale and demographic information.

Table 2A: Training Course Outline – 8 Week Version

Session	Title	Content
1	Discovering Mindful Self-Compassion	Introduction and orientation to the program. The main concepts are defining self-compassion and becoming familiar with the link between self-compassion and well-being.
2	Practicing Mindfulness	Focuses on mindfulness, defined as awareness of present-moment experience. Resistance is described and presented as a source of much of our suffering. Awareness meditations are "warmed up" with affection and appreciation.
3	Practicing Lovingkindness	Participants learn the difference between lovingkindness, compassion and mindfulness, and learn how to use phrases in lovingkindness meditation.
4	Discovering Your Compassionate Voice	Lovingkindness meditation is practiced, and participants learn to self-motivate with encouragement rather than criticism. Stages of progress are identified and discussed.
5	Living Deeply	Participants discover core values (what gives their lives meaning) and learn how to re-orient themselves to them in daily life. Compassion and self-compassion are practiced through listening to others.
6	Meeting Difficult Emotions	Participants learn to transform difficult emotions using mindfulness and self-compassion practices. Self-compassion is presented as a way to alleviate shame.
7	Exploring Challenging Relationships	Self-compassion practices are used to meet unmet needs in relationships as well as to manage caregiving fatigue.
8	Embracing Your Life	Focuses on how to maintain meditation practice after the course ends, as well as how to practice savoring, gratitude, and self-appreciation as corrective measures for negativity bias.

Table 2B: Training Course Outline – 6 Week Version

Session	Title	Content
1	What is Self-Compassion?	Introduction and orientation to the program. The main concepts are defining self-compassion and becoming familiar with the link between self-compassion and well-being.
2	Practicing Self-Compassion	Focuses on the physiology of self-compassion, as well as how to practice various MSC techniques including supportive touch and self-compassion break. Also reviews mindfulness, defined as awareness of present-moment experience.
3	Discovering your Compassionate Voice	Lovingkindness meditation is practiced, and participants learn to self-motivate with encouragement rather than criticism. Stages of progress are identified and discussed.
4	Self-Compassion and	Participants learn to transform difficult emotions using

	Resilience	mindfulness and self-compassion practices. Self-compassion is presented as a way to alleviate shame.
5	Self-Compassion and Burnout	Self-compassion practices are used to meet unmet needs in relationships as well as to manage caregiving fatigue.
6	Going Forward	Focuses on how to maintain meditation practice after the course ends, as well as how to practice savoring, gratitude, and self-appreciation as corrective measures for negativity bias.

5.2 Handling of Study Interventions

This intervention will be given by Karen Bluth, PhD and Laura Prochnow Philips, both of whom are Certified Mindful Self-Compassion Trainers.

5.3 Adherence

Full participation will be encouraged and asked for all participants. Because this is a feasibility study, study staff will record adherence and non-adherence to the CNA Wellbeing Program through following attendance (including times in and times out of participants) and practice between sessions. However, participants will have the option of continuing on, even if they do not adhere completely to the program.

Study staff will continue to follow participants with the opportunity to complete questionnaires and interviews, regardless of their adherence to the program.

6 STUDY MEASURES

The following table lays out the various measures and data that will be collected from participants throughout the course of the study – including before, during, and at 3 and 6 months after the conclusion of the intervention.

6.1 Schedule of Evaluations

Measure	Pre-Course*	Course									3 Months	6 Months
		1	2	3	4	5	6	7	8	9		
Feasibility Measures												
Attendance		X	X	X	X	X	X	X	X	X		
Attrition (Withdrawal)		X	X	X	X	X	X	X	X	X		
Audio Recording										X		
Screening Questionnaire (*Demographics & PSS*)	X											
Baseline Interview (*JSS, Intent to Leave, ADQ, MBI, PSS, SCS, PROMIS*)	X											
Weekly Questionnaire (*PROMIS, Home Practice, Adverse Events*)		X	X	X	X	X	X	X	X			
End-of-Program Interview (*Acceptability Measure, JSS, Intent to Leave, ADQ, MBI, PSS, SCS, PROMIS, Adverse Events*)									X	X		
3 Month & 6 Month Interview (*JSS, Intent to Leave, ADQ, MBI, PSS, SCS, PROMIS, Adverse Events*)											X	X
Measures of Adverse Events and Safety Monitoring	**Pre-Course***	**Course**									**3 Months**	**6 Months**
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**		
PROMIS Depression Screen	X	X	X	X	X	X	X	X	X		X	X
Adverse Event Monitoring Form		X	X	X	X	X	X	X	X		X	X
Adverse Event Reporting Form					X				X		X	X
Nursing Home Level Data	**2018**				**2019**				**2020**			
Administrator Interview					X							
CMS NH Compare Website	X				X				X			
*Begins 2 weeks before onset of program												

6.2 Description of Evaluations

6.2.1 Screening Evaluation

Consenting Procedure

Two consenting processes are included in this study, an embedded consent for participation in the Screening Questionnaire and a written consent for participation in the study.

A. The initial consent process is for the Screening Questionnaire of eligible participants. In the event that there are over 20 CNAs interested in a course at a single nursing home, eligible participants will be chosen from the highest scores on the Screening Questionnaire (which includes the Perceived Stress Scale). This questionnaire will be collected during information sessions by the research assistant.

   While presenting on the course during the information session, the research staff will have with them a sign-in/interest sheet in the course. The interest sheet will have ID numbers preprinted (i.e. for the Nursing Home in Aim 1, 101, 102, 103, 104, etc.). The Screening Questionnaire will have the ID number pre-printed onto the questionnaire, so that when any individual chooses to sign up to the interest list, and wants to do the Screening Questionnaire, they will be immediately given an ID# and then handed the corresponding questionnaire.

   Once they've received the Screening Questionnaire, they will be able to independently read the embedded consent form and determine their interest in participating in the Screening Questionnaire. Any CNAs interested in participating in the full study and adding their name to the interest sheet will be told that the Screening Questionnaire must be eventually be completed in order to be eligible for the full study, but that by completing the Screening Questionnaire, they are not automatically enrolled.

   Alternatively, for CNAs who reach out to the study staff directly from the posted recruitment flyers, a verbal consent will be read to them to participate in the Screening Questionnaire, if they are interested.

   While study staff is recruiting CNAs, [s]he will have a folder with them in order to collect all Questionnaires. Identifiable information from the interest sheets and linking ID#s will be transferred to an electronic folder, stored on the Cecil G. Sheps Center for Health Services Research's secure servers, separately from any data.

B. The second consent process will be with all participants' who are committed to joining the intervention program. Throughout the recruitment process, participants will be able to sign up on an interest sheet to indicate their interest. These participants will be able to sign up physically, during the recruitment sessions, or reach out directly to study staff to have their name included on the interest sheet. Once CNAs have expressed interest, the study staff will reach out to them one-on-one through their preferred method of communication (telephone, text, or email), and verify their commitment to the program.

   Once commitment and eligibility have been confirmed, study staff will set up one-on-one meetings with participants in order to review the written consent form. This will take place up to 2 weeks before the start date of the program. During these in-person meetings, study staff will review the consent form with participants and answer any questions they may have. Additionally, study staff will ensure participants have their own copy of the consent form for their files. Once collected, all physical consent forms will be kept in a locked office in the Cecil G. Sheps Center for Health Services Research, where only study staff will have access.

Screening

This study will take up to 20 CNAs per Nursing Home. If 20 or fewer CNAs are interested in the CNA Wellbeing Program, all those interested will be able to participate. However, if over 20 CNAs are interested in the program (within one Nursing Home), the Screening Questionnaire administered during the recruitment process will be used to determine the 20 CNAs with the highest scores on the Perceived Stress Scale. The study's goal is to recruit 15 CNAs per Nursing Home.

In the event that there are over 20 CNAs interested and the study is not able to accommodate all CNAs, some Mindful Self-Compassion materials will be provided to those who are not able to join the program.

6.2.2 Enrollment, Baseline, and/or Randomization

CNAs will be enrolled in the screening process after they have read the embedded consent form on the Screening Questionnaire, and have chosen to fill out the questionnaire. The Screening Questionnaire involves demographic questions as well as the Perceived Stress Scale.

For the intervention portion of the study, CNAs will be enrolled after reviewing and signing the written consent form with study staff in a one-on-one process. This process will occur up to 2 weeks before enrollment in the course begins.

Once enrolled, participants complete an in-person interview (the Baseline Interview) with study staff. This baseline interview will capture their preliminary scores on:

- Stress levels
- Attitudes towards dementia
- Job satisfaction and intent to leave job
- Burnout score
- Self-compassion score
- Depression score

6.2.3 Follow-up Visits

After initial enrollment, and collection of the Baseline Interview, CNAs will begin participating in the intervention, the CNA Wellbeing Program. There will be 8 intervention sessions, as well as a 9th session for feedback (or, 6 intervention sessions, and a 7th for feedback, if taking the 6-week version of the program). Additionally, CNAs will be approached at the End-of-Program mark, and the 3/6 month mark post course, to gather additional survey responses. These interviews will continue to capture the participants' scores on:

- Stress levels
- Attitudes towards dementia
- Job satisfaction and intent to leave job
- Burnout score
- Self-compassion scores
- Depression score

See above (in section 6.1 Schedule of Evaluations) for an exact list of what will be collected from CNAs at each point, baseline, weekly, post course, 3-months, and 6-months.

6.2.4 Completion/Final Evaluation

Study staff will continue to follow up with participants until the point of the final evaluation, the 6-month Follow Up Interview.

7 SAFETY ASSESSMENTS

Potential Risks and Benefits for Participants

Potential Risks:

The potential risks to study participants include:

- Emotional discomfort caused by study questions.
- Emotional or psychological discomfort or distress (e.g., agitation, anxiety) caused by exercises, group discussion, or home practices.
- Physical discomfort during sitting exercises.
- Emotional or economic (employment-related) harm due to breech of confidentiality. This includes breech of confidentially regarding any personal information shared during the group intervention sessions, questionnaire data, or outcome data collected from administrative records.

Potential Benefits:

The potential benefits to study participants include:

- Stress-management skills that may improve well-being and positively impact relationships and job performance.
- Lifetime access to resources (e.g., audio guided meditations, course materials) that may help sustain well-being and stress-management skills.

7.1 Specification of Safety Parameters

This study employs a Safety Monitoring Committee (SMC), composed of 3 members in order to monitor the safety of this study. See below for details on the process by which Adverse Events/Serious Adverse Events are defined, and will be handled.

7.2 Adverse Events and Serious Adverse Events

Adverse event (AE): Any unfavorable and unintended change in physical or mental health status (i.e. new or worsening physical or mental health signs, symptoms, or disease) or loss of employment associated with participation in the study, regardless of whether it is considered related to the study.

A **serious adverse event (SAE***):* Any AE that: results in death; is life threatening, or places the participant at immediate risk of death from the event as it occurred; requires or prolongs hospitalization; causes persistent or significant disability or incapacity; results in congenital anomalies or birth defects

Unanticipated problems (UPs): Involves risks to subjects or others to include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

7.3 Reporting Procedures

Given course content can bring up difficult emotions, study staff will monitor depressive symptoms weekly. Study staff will also ask participants to report any changes in their physical health that may be

related to their participation in the study, with the exception of transient discomfort during sitting practices. Examples of potentially relevant, although unlikely, physical health changes include: headaches, body or joint aches, or an injury occurring during mindfulness practice. These examples will be given to participants, with the caveat that they should err on the side of caution and over-reporting. Additionally, in order to monitor for participants' at risk of giving birth to a child with a birth defect, the intervention instructors will report to Principal Investigator and study staff if they learn of any pregnancy within their program participants.

In order to facilitate the reporting of potential AEs to study staff, the following procedures will be in place:

[1] During the 8-week intervention period, participants will be engaged in weekly group discussions about home practice, challenges to practice, and well-being. Any participant endorsing difficulties that the course facilitators feel are potentially beyond transient or typical will be approached privately to gather details.

[2] Participants will be given study staff contact information, including study phone and e-mail addresses. Participants will be encouraged to contact study staff in the event of psychological or potentially relevant physical health concerns.

[3] At the beginning of each weekly session, and at 3 and 6-months post-intervention, we will administer a brief adverse event form, through the Weekly Questionnaire. On this form, we will collect data on any serious adverse events in the previous week, depressive symptoms via the validated 8-question PROMIS Depression Short Form and physical health changes possibly related to study participation. Regarding depressive symptoms monitoring, we will collect the PROMIS depression screen at baseline. For the purposes of this study, any participant whose PROMIS depression score moves from a lower category into the severe category (i.e. greater than or equal to a T-score of 70) will be flagged as a potential adverse event and will prompt follow up by the study team via a phone call by the study staff to gather details. Study staff will also notify the course instructors of the increased emotional distress so that extra support can be provided as needed.

The study team member receiving information from participants about a potential AE related to the study will complete an Adverse Event Form.

7.4 Follow-up for Adverse Events

Data on AEs and UPs will be collected on an ongoing basis from study start to study completion.

General AE Procedures. The project manager or study staff will report all AEs to the PI immediately using the Adverse Event Reporting Form, after having gathered all necessary details (from the Weekly Questionnaire, as well as further communication with the participant if needed). The PI will determine the severity and the relatedness of the AE, and will confer with the SMC as needed. If the AE is serious and/or unexpected, possibly related to study participation, and suggests increased risk for participants, the procedures outlined below will also be followed.

AE reports will collected by the project manager or study staff, summarized and de- identified. A summary report of all AEs to date will be sent to the PI and the SMC in both Phases at: 1) mid-intervention (4-week mark); 2) post-intervention (8-week mark); 3) post 3-month follow-up; 4) post 6-month follow-up.

Furthermore, all AEs will be summarized as part of the Data and Safety Monitoring Report submitted post-Phase 1 and post-Phase 2 to the SMC and NIA program officer. As per UNC IRB guidelines, all AEs will reported to the UNC IRB during the yearly study review process.

Serious AE Procedures. The project manager or study staff will report all SAEs to the PI immediately using the Adverse Event Reporting Form, after having gathered all necessary details. For all deaths and for any SAE related or possibly related to study participation, the PI will send this report and any additional information, including corrective actions already taken, within 24 hours to the SMC chair, UNC IRB and NIA program officer. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or SMC.

Unexpected and Related AEs/UPs with increased risk. All AEs that are deemed 1) unexpected; 2) possibly or probably related to study participation; and 3) suggests increased risk for study participants will be reported to the UNC IRB, NIA project officer, and the SMC chair within 48 hours of study team awareness of the event, using each organizations' respective reporting formats. In these reports, the PI will identify any corrective action planned or already undertaken. The PI will follow any additional course of action recommended by the UNC IRB, NIA, and/or SMC.

The SMC will meet in person (or virtually for long-distance members as needed) at least 3 times throughout the study to review the Data and Safety Monitoring Report: 1) prior to first enrollment; 2) after completion of the field test (Phase 1) using the standardized intervention; 3) after completion of the refined intervention (Phase 2).

Additional meetings (ad-hoc) will occur as requested by the PI for review of unexpected adverse events or any SAEs that occur. Any recommended changes by the SMC will be submitted to the UNC IRB for approval.

8 INTERVENTION DISCONTINUATION

We will prepare interim analyses to evaluate the safety of the intervention after Phase 1 and again after Phase 2. One of the tasks of the Safety Monitoring Committee (SMC) will be to review preliminary data from the study and make a recommendation RE whether or not the study should continue. The following are the reasons we propose for discontinuing the study early:

- The occurrence of a serious adverse event, possibly or definitely related to the study protocol, occurring in any participant. In this study, it would include serious psychological distress causing death, suicide attempt, or hospitalization.
- Severe adverse events, possibly or definitely related to the study protocol, occurring in 3 or more participants. In this study, this would include participants who withdrew from the study due to new psychological symptoms or who were hospitalized for mental health treatment. Given the high-stress nature of the participants jobs and lives, and given MSC involves prompting participants to become aware of and attend to their own needs, it is possible that study participation prompts mental health care that had been needed previously, but was perhaps ignored or not prioritized. Thus, severe cases will be examined carefully by the PI and SMC to determine if the cases warrant study discontinuation.
- Interim analyses will provide summary data related to the above bullets and study staff will make these data available to the SMC at least 2 weeks before meeting, or within 24 hours

9 DATA COLLECTION AND QUALITY ASSURANCE

9.1 Data Collection Forms

ID# Convention:

All data will be de-identified with by using an ID# rather than names or other identifying information. This ID# will be composed of three numbers. The first number will be the Nursing Home with which

the participant is associated. The following ID#s numbers will be filled out by study staff after collecting completed Screening Questionnaires, starting with 01 and ending with 99.

ID#	Nursing Home
1	Aim 1 NH
2	Aim 2 NH
3	Aim 2 NH

A sample ID# will be as follows:

First Digit: NH	Second and Third Digit: Participant
1-3	01-99

Screening Questionnaire:

Initial data collection will begin with the Screening Questionnaire.

The Screening Questionnaire will be collected during information sessions by the research assistant. While presenting on the course during the information session, study staff will have an interest sheet, pre-printed with ID#s, as well as Screening Questionnaires, pre-printed with ID#s**.** For CNAs interested in signing into the interest sheet and participating in the Screening Questionnaire, they will sign up to a specific ID# slot, and given the corresponding Screening Questionnaire. The first page of each questionnaire will have an embedded consent form. Those present at the information sessions will be able to independently read the consent form and determine their interest in participating in the Screening Questionnaire. Any CNAs interested in participating in the full study and adding their name to the interest sheet will be told that the Screening Questionnaire must be completed in order to be eligible for the full study, but that by completing the Screening Questionnaire, they are not automatically enrolled.

While study staff is recruiting CNAs, [s]he will have a folder with them in order to collect all Questionnaires, and will instruct CNAs to bring all completed Questionnaires directly to the study staff.

Alternatively, this process will be available to CNAs over the phone if necessary (they reach out directly from flyers, are only able to stay for a few minutes at a recruitment session, but wish to complete the Screening Questionnaire at another time, etc.). In these cases, a verbal consent will be read aloud to CNAs, and the Screening Questionnaire will be read for completion.

Identifiable information from the interest sheet and linking ID#s will be transferred to an electronic folder, stored on the Cecil G. Sheps Center for Health Services Research's secure servers, separately from any data.

Baseline Interview:

This data will be collected in-person or by phone by the study staff. Study staff will bring a copy of the Baseline Interview to each in-person interview, or have a hard copy of the interview present during the telephone call. Before beginning, the study staff will write the appropriate ID# onto each interview. This ID# will have previously been assigned from the Screening Questionnaires. This interview will be done immediately after collecting consent from the participant, and will be done one-on-one, in person with the study staff. If a participant cannot complete it at the time of consenting, research staff and the participant will complete the interview at another convenient time over the phone (or in person). To aid in the data collection, study staff will provide the participant with Likert Scale cards (laminated cards with response options to various questions within the interview). This data will be collected no more than 2 weeks before the first session.

Weekly Questionnaire:

During the weekly sessions, the Weekly Questionnaire as well as the Weekly Attendance will be collected by the two study instructors.

In order to collect this questionnaire confidentially, the study instructors will have a set of manila folders – one for each participant in the program. On the manila folders, will be a Post-It note with the participants' name. Within each folder, will be a Weekly Questionnaire (with their ID# already put into their questionnaire). The instructor will hand out each folder to the study participants at the beginning of the session. Study participants will be instructed to complete the questionnaire, and put their answers back into the manila folder. At this point, the study instructor will collect all manila folders, and remove the Post-It notes with names, in order to immediately de-identify the collected data. This process will happen weekly, at each session.

For participants who need to miss a session, for whatever reason, they will be followed up with on the phone by study staff. Study staff will administer the Weekly Questionnaire – Absent Version.

For weekly sessions, study staff will meet with the intervention instructors once a week, in order to collect weekly hard copies of data from study instructors.

Semi-Structured Focus Group Guide:

The final session, a semi-structured feedback session on the Program and concepts explored in the program, includes a semi-structured focus group guide. This session will be audio-recorded.

End-of-Program Interview:

This data will be collected in phone or in person by the study staff. Research assistant will attend the final session, and bring an Sign Up for End-of-Program Interview for participants to choose when and in what form they would like to do the End-of-Program interview. Slots will be offered immediately following the session, and for immediately before and after the final semi-structured focus group. For interviews that cannot be completed at those times, study staff and participant will arrange an alternative time to either conduct a phone interview, or an in-person interview, according to the participants' convenience. Study staff will bring a copy of the End-of Program Interview to each in-person interview, or have a hard copy of the interview present during the telephone call. Once interview is confirmed (in person or phone call), study staff will arrange to either bring with them, or email or mail beforehand Likert cards (with response options for various questions in the interview) to aid in participants' responses. Before beginning, the study staff will write the appropriate ID# onto each interview. This ID# will have previously been assigned. This interview will be collected no more than two weeks after the end of the final session.

3/6 Month Follow Up Interview:

This data will be collected in phone or in person by the study staff. Study staff will bring a copy of 3/6 Month Follow Up Interview to each in-person interview, or have a hard copy of the interview present during the telephone call. Once interview is confirmed (in person or phone call), study staff will arrange to either bring with them, or email or mail beforehand Likert cards (with response options for various questions in the interview) to aid in participants' responses. Before beginning, the study staff will write the appropriate ID# onto each interview. This ID# will have previously been assigned. This data will be collected as close to the 3 month and 6 month mark post Wellbeing Program as is possible within the participants' schedules. This means data will be collected either within the two weeks before the 3/6 month mark, or within the two weeks after the 3/6 month mark.

9.2 Data Management

All data will be stored on computers and secure servers in locked offices within the Cecil G. Sheps Center for Health Services Research. All hardcopies of data will be stored in locked offices within the Sheps Center, accessible only to study staff. All hardcopies of data will be de-identified, with a linking ID# (as is the case for the Screening Questionnaire, Baseline Interview, Weekly Questionnaire, End-of-Program Interview, and 3/6 Month Follow Up Interview).

Study staff will be double entering data into Access Databases housed on the Cecil G. Sheps servers to ensure mistakes are not made during data entry. Analysis will be completed by the study staff analyst with the Program on Aging, Christopher Wretman.

10 PARTICIPANT RIGHTS, REIMBURSMENT AND CONFIDENTIALITY

10.1 Institutional Review Board (IRB) Review

This protocol and the informed consent document and any subsequent modifications will be reviewed and approved by the IRB or ethics committee responsible for oversight of the study.

10.2 Informed Consent Forms

Two consenting processes are included in this study, an embedded consent for participation in the Screening Questionnaire and a written consent for participation in the study.

A. The initial consent process is for the Screening Questionnaire of eligible participants. In the event that there are over 20 CNAs interested in a course at a single nursing home, eligible participants will be chosen from the highest scores on the Screening Questionnaire (which includes the Perceived Stress Scale). This questionnaire will be collected during information sessions by the research assistant.

   While presenting on the course during the information session, study staff will have with them Screening Questionnaires with pre-printed ID#s, as well as an embedded consent on the first page of the questionnaire. For CNAs who choose to take the Screening Questionnaire over the phone, a verbal consent will be read out to them for their response.

B. The second consent process will be with all participants' who are committed to joining the CNA Wellbeing Program. Throughout the recruitment process, participants will be able to sign up on the interest sheet to indicate their interest. These participants will be able to sign up physically, during the recruitment sessions, or reach out directly to study staff to have their name included on the interest sheet. Once CNAs have expressed interest, the study staff will reach out to them one-on-one through their preferred method of communication (telephone, text, or email), and verify their commitment to the Wellbeing Program.

   Once commitment and eligibility have been confirmed, study staff will set up one-on-one meetings with participants in order to review the written consent form. This will take place up to 2 weeks before the start date of the CNA Wellbeing Program. During this in-person meeting, study staff will review the consent form with participants and answer any questions they may have. The study staff will ensure that they have one copy of the consent form, and that the participant has another copy. Once collected, all physical consent forms will be kept in a locked office in the Cecil G. Sheps Center for Health Services Research, where only study staff will have access.

10.3 Reimbursement Schedule for Participants

Each component of the study is associated with a separate compensation (refer to Table 3), and is a nominal, non-coercive amount, to reflect the time that they will be dedicating to the study.

The CNA Wellbeing Program is being administered in two different forms of the intervention:

1. Nursing Home 1 will have the standard, MSC program (8 weeks, 2.5 hours per week) administered

2. Nursing Home 2 & 3 will have the modified, MSC program (6 weeks, 1.25 hours per week)

The original compensation of $180 was awarded to persons in the NH #1, 8-week program, in which they were reimbursed $25 per interview, and $10 per class ($25 x 4, $10 x 8 = $180). This equates to $5.00 per 1.25 hours of class, and $25.00 per interview. This reimbursement amount & schedule was changed after Nursing Home #1, after receipt of feedback from participants that the reimbursement was not commensurate to their time dedicated to the project. We also readjusted our reimbursement schedule in response to feedback – rather than waiting until the end of the intervention to reimburse participants for the first time, we added in a mid-intervention reimbursement point.

In response to feedback, the compensation per time spent in class doubled. For those in the 6-week, 1.25 hour-Program, participants will be reimbursed a total of $140. This includes $80 in participation in all 4 interview ($20 each), and $60 for their participation in 7.5 hours of intervention ($10 per 6, 1.25 hours classes).

Table 3A – Reimbursement Payments/Schedule (for 2.5 Hour, 8-Week Program)		
Study Component	**Reimbursement Amount**	**Schedule**
Baseline Interview	$20.00	Reimbursed once: 1. After End of Program (up to $100)
Weekly Questionnaire	$20/per class/questionnaire	
End-of-Program Interview	$20.00	
3-Month Interview	$20.00	To be reimbursed after completion of 3-Month Interview (up to $20)
6-Month Interview	$20.00	To be reimbursed after completion of 6-Month Interview (up to $20)

Table 3B – Reimbursement Payments/Schedule (for 1.25 Hour, 6-Week Program)		
Study Component	**Reimbursement Amount**	**Schedule**
Baseline Interview	$20.00	To be reimbursed twice: 1. After mid-way point (week 3) of program (up to $50) 2. After End of Program (up to $50)
Weekly Questionnaire	$10/per class/questionnaire	
End-of-Program Interview	$20.00	
3-Month Interview	$20.00	To be reimbursed after completion of 3-Month Interview (up to $20)
6-Month Interview	$20.00	To be reimbursed after completion of 6-Month Interview (up to $20)