Does mindfulness and self-compassion integrated with education for the management of neuropsychiatric symptoms reduce caregiver stress? Protocol for a stress management intervention for caregivers of individuals with dementia

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Abstract

Background: Stress related to Alzheimer's Disease and Related Dementias (ADRD) is common, particularly among those who care for persons with challenging behaviors and personality or mood changes. Mindfulness and self-compassion programs are efficacious for managing stress. The skills of mindfulness and self-compassion, however, must be integrated with behavioral management skills in order to effectively improve caregiver stress.

Objective: We describe the development of the Mindful and Self-Compassionate Care program (MASC), the first program that combines mindfulness and self-compassion with behavioral management skills to decrease caregiver stress, and its evaluation in the Supporting Our Caregivers in ADRD Learning (SOCIAL study).

Methods: The SOCIAL study has two phases, both within the NIH stage 1 model. Phase 1 (NIH stage 1A) includes focus groups and the development of MASC. Informed by these results, Phase 2 (NIH stage 1A) will include an open pilot with exit interviews of MASC. Phase 3 (NIH stage 1B) will consist of a feasibility RCT of MASC versus a time and dose matched Health Education Program control. Primary outcomes include feasibility of recruitment and data collection. Secondary outcomes include acceptability, credibility, fidelity, and signals of preliminary efficacy.

Results: Phase 1 has been completed. Findings from rapid data analyses (5 focus groups, N=28 stressed individuals who cared for persons with ADRD and challenging behaviors) informed the development of MASC (6 sessions). Caregivers reported interest in a brief, virtual stress management program. They had misconceptions of mindfulness and self-compassion but after detailed explanation thought these skills would be helpful. Formal qualitative analyses are in progress. Phase 2 and phase 3 will be completed over the next 2 years.

Conclusions: We describe the protocol for the SOCIAL study, as well as the development and feasibility testing of the MASC intervention. Future work will include a fully powered efficacy-effectiveness RCT. Clinical Trial: This trial is registered with ClinicalTrials.gov: #NCT05847153, #NCT06276023

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Does mindfulness and self-compassion integrated with education for the management of neuropsychiatric symptoms reduce caregiver stress? Protocol for a stress management intervention for caregivers of individuals with dementia

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Abstract

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Conclusions: We describe the protocol for the SOCIAL study, as well as the development and feasibility testing of the MASC intervention. Future work will include a fully powered efficacy-effectiveness RCT.

Trial Registration: This trial is registered with ClinicalTrials.gov: #NCT05847153, #NCT06276023

Key words: Mindfulness; Caregiver; Self-Compassion; ADRD; Mental Health

Introduction

Over 11 million nonpaid caregivers care for people with dementia in the United States (US) [1]. The extent of care provided by caregivers often results in a great deal of psychological, physical, emotional, and functional stress: 40% have reported experiencing stress that interferes with their ability to care for themselves and their loved one [2,3]. Despite their critical role in supporting people with ADRD and the healthcare system, caregivers can be described as “hidden patients” since their healthcare needs often go under-recognized and under-treated [4]. A growing body of literature suggests that caregivers are at risk for negative health outcomes [4], and most caregivers lack effective non-pharmacological interventions to manage stress associated with caregiving and their care recipient's behavioral and mood symptoms. For instance, individuals living with ADRD may present with challenging behaviors such as aggression, agitation, and apathy [5,6]. Such behaviors have been associated with heightened emotional distress (e.g., symptoms of depression and anxiety), decreased well-being, and increased risk for morbidity and mortality in both caregivers and care recipients [2,3].

Addressing caregiver stress has the potential to mitigate risk for the exacerbation of caregiver chronic health problems and to improve emotional and health outcomes for people living with ADRD [2,3]. Preliminary data [6] indicate ADRD caregivers desire real-time guidance and support to learn about emotional regulation, self-compassion, and behavioral management skills that can help them navigate stress related to their care-recipients’ challenging and developing needs.

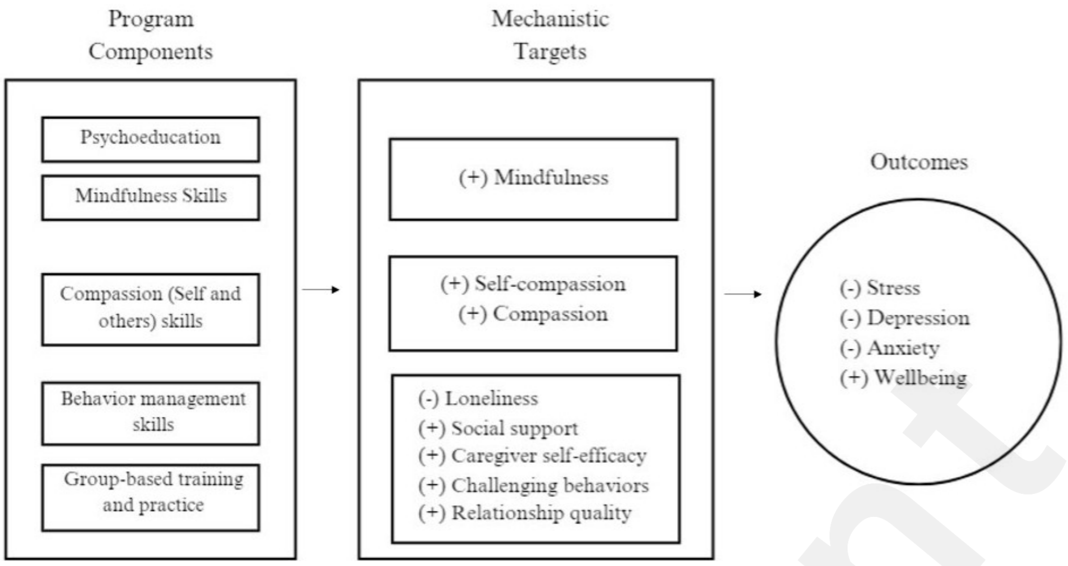
Many of the current caregiver support programs do not fully meet the psychological and social needs of stressed caregivers for three main reasons. First, support groups may not teach evidence-based behavioral management skills that caregivers report they need to manage the challenging behaviors of people living with dementia (PLWD) successfully. Second, behavioral management skills interventions, while available, often do not teach emotional regulation skills, which are necessary to foster the caregiver’s ability to manage their care recipient’s behaviors. Third, though mindfulness and self-compassion interventions are theoretically based, effective solutions for managing stress and distress among caregivers, they have rarely been applied to managing common challenging behaviors experienced by care recipients [7,8].

To address the need for a feasible, acceptable, effective, and scalable stress management program to reduce stress of ADRD caregivers, we created the Supporting Our Caregivers In ADRD Learning (SOCIAL) study which aimed to develop, optimize, and establish proof of concept for the Mindful and Self-Compassionate Care Program (MASC), a 6-week live program which utilizes psychoeducation, mindfulness, self-compassion, and behavioral management skills to identify and manage stressful situations and reactions to care recipients' dementia-related behaviors. The SOCIAL Study will compare MASC to a Health Education Program control condition.

Conceptual Model

Our multi-component program integrates principles and skills from Kabat Zinn's Mindfulness Based Stress Reduction Program (MBSR) [9], Kristin Neff's Mindful Self-Compassion Program (MSC) [10], and Laura Gitlin's caregiver guide to manage challenging behaviors [11]. We propose that: (1) mindfulness skills (observe, describe, mindful action, non-judgement, and non-reactivity) will teach emotional regulation necessary to remain calm and nonreactive to challenging dementia behaviors; (2) compassion and self-compassion skills (self-kindness and common humanity) will help caregivers be kind to themselves and feel connected with their care recipient and others; and (3) behavioral management skills will teach caregivers the specific actions they should take to navigate patient behavioral symptoms. Psychoeducation and group-based training and practice will provide rationale for program skills and an opportunity to role play and integrate skills within the daily caregiver role and interaction with the care recipient and others. Together, the program skills are hypothesized to increase mindfulness, compassion toward self and others, social support, caregiver's self-efficacy, ability to manage challenging patient behavioral symptoms, relationship quality, and decrease loneliness. The MASC program's mechanistic targets are hypothesized to act synergistically, leading to reduced stress, symptoms of depression and anxiety, and improved well-being (Figure 1).

Figure 1. Mindful and Self-Compassionate Care Program (MASC) intervention model.



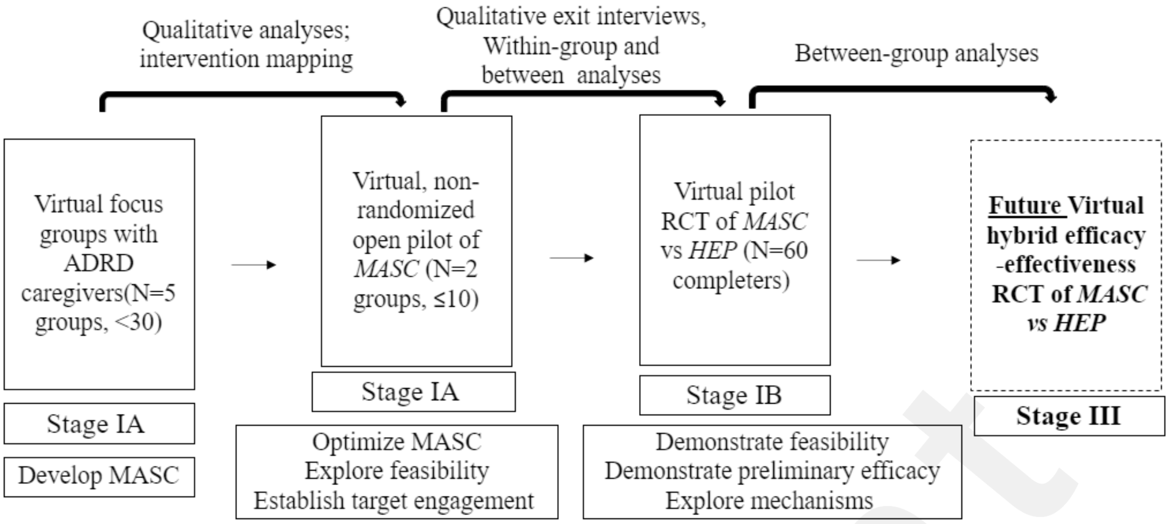
This paper describes preliminary qualitative input from 28 caregivers in five focus group interviews (Phase 1) used to guide intervention development. We go on to describe the design of the open pilot (Phase 2) and the feasibility RCT (Phase 3). Ultimately, we aim to provide a framework for increasing access to evidence-based psychoeducation interventions for caregivers of people with ADRD.

Methods

Study design

This study consists of three phases: a qualitative phase, an open pilot phase, and a feasibility randomized controlled trial (See Figure 2).

Figure 2. MASC intervention development, optimization, and testing following the NIH stage model and Science of Behavior Change principles.[12]



Phase 1: Qualitative Interviews

To guide the development of the intervention, we conducted five, 60-minute qualitative focus groups on our proposed intervention with caregivers currently providing care to someone with dementia. The sessions were conducted via secure live videoconferencing to elicit feedback on proposed content, skills, and logistics (length and duration of sessions, virtual vs. in person).

Setting and Participants

The inclusion criteria for the focus groups consisted of English-speaking adults (ages 18+) who identified as an informal caregiver (e.g., family or friend of a care recipient living with dementia who provides unpaid care). Eligible caregivers must have lived and cared for a patient with ADRD and provided more than four hours of supervision or direct assistance to the care recipient per day (average) in the past six months. Caregivers also had to endorse stress (PSS-4> = 6) and self-report that they managed one or more behavioral symptoms in the past month. Caregivers were ineligible to participate if they had had a recent change in psychiatric medications, had used a mindfulness app or any meditation for more than 60 minutes per week in the past six months, or were participating in another clinical trial for caregivers.

Recruitment, Screening, and Enrollment

Caregivers of people with ADRD were recruited from local sources, including the Dementia Care Collaborative (DCC) program at MGH, the Massachusetts Alzheimer's Disease Research

Center (MADRC), the Massachusetts General Brigham research posting site, nationally, through the National Alliance of Caregiving (caregiving.org) and ADRD caregiver-specific social media pages (i.e., Facebook, Instagram, and Twitter). All recruitment efforts were documented in REDCap to solidify the recruitment plan for subsequent phases of the study.

Focus Groups

Five focus groups consisting of twenty-eight caregivers were conducted. Participants responded to prompts about general caregiver needs, the proposed content of the MASC intervention, and barriers and facilitators to participation, content, and structure of the web platform companion. Focus groups also included a modeling of mindfulness and self-compassion skills as well as discussions on a case-based scenario to gauge interest in and reactions to tailoring the program content. Focus group sessions were recorded on an MGB-secured computer. All audio recordings were transcribed verbatim. Focus group participants were given the opportunity to complete an optional exit survey comprised of the secondary outcome measurement tools planned for use during Phases 2 and 3 of the study, and to share additional confidential feedback in writing. Twenty-four caregivers completed the exit survey and twenty-one caregivers provided additional written feedback.

Data coding and analysis

Rapid data analysis (RDA) guided immediate refinement of the intervention. Analysis comprised of three researchers coding data into superordinate themes and subthemes using hybrid deductive-inductive analysis [13]. Our RDA template was organized into the following domains: 1) population-specific caregiver experiences (difficult aspects of caregiving, experience with challenging ADRD behaviors), 2) program content (e.g., feedback on mindfulness and self-compassion exercises), and 3) barriers and facilitators for program implementation (e.g., barriers and facilitators to caregiver participation, homework completion). The completed RDA template was reviewed by another member of the study team and entered into a matrix of responses which informed manual and procedure adaptations prior to the open pilot. The matrix was organized in a hybrid inductive-deductive manner based on a combination of the domains from the RDA template and the information that emerged from qualitative focus groups that was most useful in guiding program adaptations.

Formal qualitative analyses will be used to provide an in-depth synthesis of the qualitative data and is forthcoming. These analyses will involve the transcription of audio recordings, followed by data analysis supported by NVivo 12. A codebook will be developed using a hybrid deductive-inductive approach wherein codes are created based on a priori categorizations using the Framework method [14] and then revised based on novel content identified from the data. New codes will be created directly from the data and through the analysis process. Two trained research assistants will code the transcripts under the guidance of the investigative team. Discrepancies between coders will be discussed until consensus is reached.

Phase 2 and 3: Open Pilot of MASC (Phase 2) and RCT of Supporting Our Caregivers in ADRD Learning (SOCIAL)

Phase 2 and 3 Study Design

The open pilot (Phase 2) of MASC will be comprised of a 6-session open pilot delivered via live video to ADRD caregivers who meet eligibility criteria (see Phase 1). MASC will be delivered by a trained clinical social worker in up to two groups of 6-10 caregivers. Upon provision of informed consent, caregivers will complete a questionnaire packet focused on mental well-being as well as questions about their experiences as a caregiver for someone living with dementia. Participants will next be enrolled in a weekly, 60-minute virtual group training session for 6 weeks followed by an exit interview. The open pilot will be used to refine the intervention and the manual used in the Phase 3 feasibility RCT of MASC versus a Health Education Program (the Supporting Our Caregivers in ADRD Learning—SOCIAL Study).

Phase 2 and 3 Setting and Participants

The inclusion and exclusion criteria for the Phase 2 open pilot study and the Phase 3 RCT will be identical to the criteria for study participants in Phase 1.

Recruitment, Screening, and Enrollment

Initial recruitment, screening, and enrollment procedures will be identical to those described for the focus groups. Potential participants recruited nationally will indicate their interest by completing the REDCap screener using the QR code on the flyer or by emailing the research assistants who will provide more information about the study and schedule a screening phone call. Research assistants will reach out to eligible caregivers and engage in a discussion in which they will be read the study factsheet which includes an explanation of study procedures, potential risks and benefits of participation, and contact information for further questions. They will also be informed that participation is voluntary, they can refuse to answer any questions, and they can withdraw from the study at any time.

All caregivers who consent and can be available during the designated time and date for the next group cohort will be emailed a link to the baseline questionnaire in REDCap and offered assistance with questionnaire completion. Caregivers who provide consent but are unavailable to participate in the next available group will be placed on a waitlist for the next group cohort. The research assistant will encourage everyone to write the date and time of the baseline session in their phone, in their calendar, or on paper displayed on their refrigerator. Once the program begins, participants will receive weekly email reminders of the session times, as well as daily email reminders for home practice. Additionally, prior to the first intervention session, caregivers will have the opportunity to attend a Zoom practice session with the Research Assistant to problem-solve any technical challenges. All baseline assessments will be completed within one week of the first group session.

Phase 2 and 3 MASC Intervention Content

Participants in the open pilot group(s) will receive the 6-week MASC intervention including the manual, web resources, and live intervention. MASC teaches: (1) mindfulness skills, (2) compassion and self-compassion skills, and (3) behavioral management skills. MASC also provides psychoeducation and group-based training and skill practice to facilitate skill uptake and integration with the caregiver experience and tasks. MASC session content is detailed in Table 1. Broadly, each session will include psychoeducation on each program skill, skill practice, strategies to incorporate the skill into the caregiver experience, and strategies for sustained practice. To access the weekly sessions, participants will be asked to use their tablet or computer to join the scheduled Zoom meeting. Participants will be encouraged to use the video feature, if possible, so that they can interact with the instructor and other group members "face-to-face" during each video session. Participants will complete weekly "homework" consisting of skills practice audio exercises that allow them to continue to engage with the skills that they are learning outside of the sessions.

Table 1. Mindful and Self-Compassionate Care (MASC) Program Content

Session	MASC Topic	Content and Skills
1	Getting To Know Your Stress Response	Psychoeducation on stress response and sources of stress. Overview of program goals, skills and conceptual model, goal settings.
2	Introduction to Mindfulness	Benefits of mindfulness and meditation for managing caregiver stress. Incorporation of mindfulness into caregiving tasks and daily life.
3	The Skill of Compassion and Managing Challenging Behaviors	Identifying sources of support and self-care. Incorporation of compassion into caregiving tasks and daily life. Introduction to challenging behaviors.
4	The Skill of Self-Compassion While Caregiving	Integrating mindfulness and self-compassion with behavioral management skills.
5	Communication Skills	Reframing challenging behaviors as a form of communication as the brain degenerates. Anticipating and problem-solving communication and behavior challenges.
6	Putting It All Together	Program review and strategies for continued practice (skills practice; continuing to work on individual goals).

Phase 2 and 3 Treatment Fidelity

Session content adherence checklists will be used to ensure all components of the intervention are delivered in compliance with the study protocol. Clinicians will complete an adherence checklist and a session note summarizing the session content and any issues that arise regarding individual concerns and progress, as well as any information that is important for case conceptualization. Sessions will be recorded, and 20% will be reviewed for fidelity. Feedback will be provided in weekly supervision, led by one of the study's Principal Investigators (AMV). Participants who miss a session will be offered one-on-one make-up sessions. Home practice will be logged manually by participants and tracked through the completion of online surveys sent either through email or discussed in each session by the clinicians. Issues with compliance will be discussed in supervision. Procedures will follow the NIH Science of Behavior Change recommendations and have been used by the MPIs in prior clinical trials.[12]

Phase 2 and 3 Primary Outcomes

The primary outcomes for the open pilot (phase 2) and the RCT (phase 3) include feasibility of recruitment, assessments, and quantitative measures, credibility, accessibility, and fidelity (Table 2). Our secondary outcomes will explore indicators of preliminary efficacy of the same quantitative measures. The feasibility of recruitment and retention will be assessed using proportions. Satisfaction and credibility will be assessed with proportions of scores over the midpoint of the Client Satisfaction and Credibility and Expectancy questionnaires. Additional assessment will focus on caregivers' perceptions regarding quantity of emails and text message reminders. Data are gathered on the proportion of caregivers who complete weekly home practice and the completion of the quantitative measures. Fidelity of the therapists' ability to deliver the content of each session is assessed through therapist-completed adherence checklists and an independent review of recorded sessions.

Table 2. Phase 2 and 3 Outcome Benchmark Definitions

Measure	Brief Description
Feasibility of recruitment	Assessed by the proportion of caregivers who were eligible to enroll, proportion of caregivers recruited from each recruitment source, and the proportion of racial and ethnic minorities recruited and enrolled across the entire sample.
Feasibility of randomization	Assessed by the proportion of randomized caregivers that completed the post-test.

Feasibility of assessment measures	Assessed by the proportion of participants with less than 25% of their questionnaires missing.
Adherence to treatment	Assessed by the proportion of randomized caregivers that attended at least 4 of the 6 sessions for both the intervention (MASC) and control group (HEP).
Therapist fidelity	Assessed by therapist's ability to deliver the content of each session (through therapist completed adherence checklists) and therapist fidelity (through co-therapist's review of recorded sessions).
Credibility and Expectancy	Assessed with the Credibility and Expectancy Questionnaire (CEQ) [15] which captures participants perceptions on whether treatment will work after learning about the study.
Satisfaction with the program	Assessed by the proportion of participants that score above the Client Satisfaction Questionnaire (CSQ-3) [16] midpoint which assesses caregivers' satisfaction with the intervention.
Patients' perception of improvement	Assessed by the proportion of caregivers that report improvement in stress, depression, anxiety, and well-being [17].
Adherence to home practice	Assessed by the proportion of caregivers that have completed more than 50% daily home practice exercises (assessed via REDCap).

We will assess the secondary outcomes of stress [18], depression [19], anxiety [20], and wellbeing [21] through the mechanistic targets of mindfulness [22], caregiver self-efficacy [23], social support [24], loneliness [25], compassion for self [26] and others [27], behavioral symptom management [28], and relationship quality[29]. Study assessments are presented in Table 3. Briefly, we will assess depression using the Center for Epidemiological Studies-Depression Scale (CES-D) [19] which measures how often caregivers have experienced depressive symptoms within the past week; anxiety will be measured through the State Trait Anxiety Inventory (STAI) [20] survey that asks caregivers to report whether they are experiencing a series of state or trait anxiety symptoms; caregiver stress will be measured by the Perceived Stress Scale (PSS-10) [18] which asks participants to indicate the degree of stress that they are experiencing due to different life stressors. Overall wellbeing will be measured using the World Health Organization-Five Well-Being (WHO-5) [21] scale which asks caregivers questions about current level wellbeing within the past two weeks; the Interpersonal Support Evaluation List (ISEL-12) [24] will be used to measure individuals' perceived level of social support; the UCLA Loneliness Scale [25] asks questions about participants' feelings of isolation and loneliness; and the Caregiver Distress Scale (NPI-Q) [28] asks caregivers about the presence and level of severity of neuropsychiatric symptoms that are commonly seen within individuals with dementia. Mindfulness will be assessed using the Applied Mindfulness Scale (AMPS) [22], which asks individuals to respond to a list of scenarios and indicate if they have utilized mindfulness in the situation. Self-compassion and compassion are being measured using the Self-Compassion Scale-Short Form (SCS-SF) [26] and Compassion Scale (CS) [27]. The Revied Scale for Caregiver Self-Efficacy (RSCSE) [23] will be used to assess caregiver's perceptions of self-efficacy. Finally, relationship quality will be assessed through the Dyadic Relationship Scale (DRS) [29]. Pre- and post-changes in our intervention targets and outcomes will be analyzed using t-tests and explore correlations between change scores in targets and outcomes. Associations will be explored in the pre-, post-, and 3-month follow-up surveys.

Table 3. Study Measures

Measure	**Time Frame**	**Brief Description**
Symptoms of depression	Baseline, post-intervention, follow-up	The Center for Epidemiological Studies-Depression Scale (CES-D) [19] is a 20-item scale widely used with ADRD caregivers to assesses depression.
Mindfulness	Baseline, post-intervention, follow-up	The Applied Mindfulness Process Scale (AMPS) [22] is a 15-item scale that assesses caregivers' ability to apply mindfulness to everyday challenges.
Perceived stress	Baseline, post-intervention, follow-up	The Perceived Stress Scale (PSS-10) [18] assesses perceived stress using a 5-point Likert scale.
Symptoms of anxiety	Baseline, post-intervention, follow-up	The State Trait Anxiety Inventory (STAI) [20] form Y (20 items) assesses anxiety symptoms in response to stressful situations. STAI has been successfully used with ADRD caregivers.
Self-compassion	Baseline, post-intervention, follow-up	The Self-Compassion Scale-Short Form (SCS-SF) [26] has 12 items that assess self-kindness.

Compassion	Baseline, post-intervention, follow-up	The Compassion Scale (CS) [27] has 16 items assessing common humanity, kindness toward others and ability to understand the suffering or challenges of others.
Distress due to challenging behaviors	Baseline, post-intervention, follow-up	The Neuropsychiatric Inventory Caregiver Distress Scale (NPI-Q) [28] has 12 items assessing distress associated with dementia patient's behaviors.
Caregiver self-efficacy	Baseline, post-intervention, follow-up	The Revised Scale for Caregiver Self-Efficacy (RSCSE) [23] (8-items) assesses domains of self-efficacy including obtaining respite, responding to disruptive patient behaviors, and controlling upsetting thoughts.
Well-being	Baseline, post-intervention, follow-up	The World Health Organization-Five Well-Being Index (WHO-5) [21] has five items assessing emotional well-being.
Loneliness	Baseline, post-intervention, follow-up	The UCLA 3-item loneliness scale [25] assesses relational connectedness, social connectedness, and self-perceived isolation.
Social support	Baseline, post-intervention, follow-up	The Interpersonal Support Evaluation List short form (ISEL) [24] has 12 items assessing appraisal, belonging and tangible social support.
Relationship quality	Baseline, post-intervention, follow-up	The Dyadic Relationship Scale (DRS) [29] has 11 items that assess negative and positive interactions between caregivers and their care recipient.

Phase 2 Data analysis

The feasibility of recruitment and retention will be assessed using proportions defined in Table 2. Satisfaction and credibility will be assessed with proportions of scores over the midpoint of the Client Satisfaction [30] and Credibility and Expectancy [15] questionnaires. Qualitative data from exit interviews will be analyzed using procedures outlined in Phase 1. We will also explore pre/post changes in our intervention targets and outcomes using t-tests and explore correlations between change scores in targets and outcomes. Given the exploratory nature of this open pilot, we do not anticipate statistical significance [31]. For all outcomes we will report 95% confidence intervals consistent with recommendations for pilot trials [32]. Overall, these activities and statistical analyses are consistent with NIH stage 1A and the overall goal of intervention development, optimization, and target engagement. We will revise our procedures, conceptual model, and measures based on quantitative and qualitative data as needed. We expect that modifications will be required before the Phase 3 RCT to maximize feasibility, target engagement and potential for preliminary efficacy.

Phase 2 Open Pilot Intervention Refinement

The MASC intervention will be refined based on overall findings of feasibility, acceptability, credibility, fidelity, preliminary efficacy outcomes, and 30-minute exit interviews from study participants.

Phase 3 Health Education Program

Unlike the Phase 2 open pilot, the Phase 3 SOCIAL study will include a Health Education Program (HEP) as the comparator. HEP will have 6 sessions that will deliver educational information and will mimic the dose and duration of MASC. HEP will not teach any of the mindfulness, self-compassion and behavioral management skills that are hypothesized to be responsible for improvements in the mechanistic targets and through them, improvements in outcomes. HEP sessions will also be delivered virtually in a group format in the same way MASC is delivered. The topics of each session will contain information readily available to all caregivers adapted from the National Alliance of Caregiving. HEP will have 6 sessions: 1) education about the stress of caregiving along with common behaviors seen in dementia; 2) education and conversations on sleep hygiene for caregivers; 3) education and conversation on staying physically active as a dementia caregiver; 4) education and conversations on nutrition; 5) conversations and education on developing healthy eating habits; and 6) overall reflections on program content and discussion about post-program plans. This control condition ensures that caregivers will remain blind to intervention or control and increases confidence that improvement in outcomes is due to the active ingredients of the intervention and not to engagement with study clinicians, group support, or basic education accessible through online resources.

Phase 3 Randomization Strategy

After informed consent and collection of baseline information, caregivers will be randomized to either the MASC intervention or to the Health Education Program. We will use a 2:1 randomization to the MASC intervention or to the Health Education Program. The randomization schedule prepared by an unmasked statistician will use REDCap to create permuted blocks stratified by gender. To maintain blinding/masking, the programs will be labeled as SOCIAL 1 (MASC) and SOCIAL 2 (HEP). Both MASC and HEP groups will be run by an experienced clinical social worker trained in the intervention and the HEP and will work from updated facilitator manuals. The same social worker will run the intervention and comparison groups to control for nonspecific factors.

Phase 3 Analysis

The RCT will follow the same general analysis plan as the Phase 2 open pilot with expansion to include feasibility of randomization. Required benchmarks are depicted in Table 4. We will report benchmarks for both MASC and the HEP, including 95% confidence intervals, consistent with recommendations for stage 1B trials [12]. We will estimate between-group differences in change from baseline in intervention targets and outcomes to post test and 3 months as proof of concept. Variance components and effect sizes will be estimated for each outcome. The study will not be powered for stringent inferential testing of efficacy (two-tailed $p < 0.05$) unless an overwhelming benefit is observed from the MASC program. We will use variance estimates from repeated-measures analysis of data on PSS-10 scores in tandem with the minimal clinically significant difference (MCID) to guide the design and power calculations for the future hybrid efficacy-effectiveness trial [33]. We will compute effect sizes of change in these scores along with 95% confidence intervals. Analyses will be repeated for all targets and outcomes. For example, proofs of concept/preliminary efficacy will be demonstrated if decrease in stress (PSS-10) in the intervention group from baseline to post-test is greater than in the educational control and the 95% confidence interval includes the MCID. We chose this benchmark because PSS-10 will be the primary outcome in the future R01. If the benchmark is not met, revisions will be required before conducting a fully powered RCT. We will assess the correlation of changes in the mechanistic targets (mindfulness, caregiver self-efficacy, social support, loneliness, compassion, self-compassion, behavioral symptom management, and relationship quality) with changes in the outcomes (stress, depression, anxiety, wellbeing). We hypothesize that the intervention (targeting mindfulness, self-efficacy, coping, social support, and interpersonal bonds) is a mechanism for effecting change in outcomes. Showing association in this pilot study will provide further support for this hypothesis. Finally, we will summarize changes at 6 weeks and 3 months in each intervention group by demographic and clinical factors (gender, age, etc.) to see if the data suggests that clinical improvement does vary by these factors.

Table 4. Phase 3 Outcome Benchmarks

Measure	Brief Description
Feasibility of recruitment	≥70% of caregivers who are eligible will enroll. ≥38% of caregivers are racial and ethnic minorities.
Feasibility of randomization	≥70% of caregivers randomized will complete the post-test.
Feasibility of assessment measures	≥70% of caregivers will have less than 25% missing questionnaires.
Adherence to treatment	≥70% of randomized caregivers will attend at least 4/6 sessions for both MASC and HEP.
Therapist fidelity	≥75% fidelity (checklists and audio recordings) for ≥70% caregivers
Credibility and Expectancy Score	> 70% of caregivers with score over the scale midpoint.
Client Satisfaction Score	> 70% of caregivers with score over the scale midpoint.
Patients' perception of improvement	> 70% of caregivers report improvement in stress, depression, anxiety, and well-being.
Adherence to home practice	>70% of caregivers will complete more than 50% daily home practice exercises (assessed via REDCap).

Results

Phase 1 is complete. Findings from our rapid data analysis include confirmation from care providers that caregiving was rewarding but also difficult. Caregivers spoke of difficulties associated with the emotional toll on caregivers, these were 1) linked to their emotions (sadness and grief) prompted by seeing their care recipient decline mentally and physically or 2) impact of the difficulty in managing the rapidly changing emotions or moods of their care recipients. Caregivers affirmed the challenges of caregiving for a person with ADRD, including navigating behavioral symptoms and their impact on daily activities, such as bathing, taking medications and going to doctors' appointments. Caregivers primarily cited using music and touch as ways they addressed challenging behaviors and expressed that they would like to learn more skills to use in the moment.

Feedback on skills

Many caregivers were unfamiliar with the concept of mindfulness and had not used it before. After being introduced to the concept of mindfulness and its benefits, they felt that mindfulness would help them manage caregiving stress. After being guided through a short-mindfulness exercise they reported that this skill would be feasible to learn and implement. When caregivers were presented with the concept of self-compassion, many had misconceptions about it and its applicability to caregiving. When provided with information about the meaning of self-compassion, they were unsure if it was possible to be both self-compassionate and tend to their duties as a caregiver—but they noted a willingness to try. Caregivers also expressed interest in learning practical strategies to manage the neuropsychiatric symptoms of their care-recipient. The rational for using mindfulness and self-compassion to regulate their emotions so that they could implement these practical strategies made sense to them.

Delivery and format

Participants provided feedback on the delivery and format of the group as well as ways to increase their learning and engagement in the program content. Caregivers suggested that audio recordings would be beneficial for ensuring the active practice of the skills independently. They had mixed feelings about the assignment of homework to reinforce skills. The caregivers overwhelmingly expressed a desire for the group to be online and felt one hour was a good length of time for one session.

Discussion

This paper describes the process of developing, optimizing, and testing a clinical intervention for stressed caregivers through psychoeducation and skills training in mindfulness, self-compassion, and management of behavioral symptoms of dementia. The aim of this intervention is to fill the gap in non-pharmacological interventions to meet the psychological and practical needs of stressed caregivers of persons with ADRD with challenging behaviors and personalities.

Findings from the rapid data analysis guided the development of the intervention and the group format to meet the needs expressed by dementia caregivers and prevent factors that could hinder caregivers' sustained participation. For example, MASC's development incorporated facilitators to caregiver's participation through the addition of a virtual delivery of program content, length, and duration with six sessions lasting 60 minutes. Feedback on the program format guided indicated the need to offer the program virtually at flexible times that works best for most caregivers.

To date, most caregiver support groups are either unstructured or focused on strategies to address communication and/or behavioral symptom strategies [3]. Lack of attention to the psychological needs of the caregiver in many of these interventions may contribute to their modest ability to reduce caregiver stress and behavioral symptoms. Fostering self-regulation skills and strategies as outlined in the MASC intervention may augment caregivers' ability to navigate the array of challenges faced in caring for someone with dementia and reduce their stress at the same time. Given the difficulties grasping mindfulness and self-compassion concepts, MASC directly addresses these barriers by delivering simple lay language and easy to engage exercises linked ADRD caregiving challenges. Content specifically addresses common challenging behaviors and associated stressors for both the caregiver and the care recipient. The SOCIAL study also seeks to understand the mechanisms informing caregiver outcomes but integrating a rigorous Health Education Program control condition and measuring both mechanistic (e.g., mindfulness) and proximal outcomes (e.g., caregiver stress), in addition to relevant feasibility benchmarks.

Conclusion

MASC's skills grounded in mindfulness, self-compassion, and behavioral management aim to address stress, depression, loneliness, and anxiety. Similarly, we aim to improve well-being through caregiver self-efficacy, social support, mindfulness, self-compassion, compassion, and improved relationship quality. The combination of evidence-based mindfulness and self-compassion skills with behavioral management skills within a multi-component program increases intervention potency and efficiently supports caregivers of people with ADRD. By reducing stress in caregivers of people with ADRD and evaluating this intervention with a rigorously designed control condition, the proposed work has the potential to improve caregiver well-being and elucidate the mechanisms most relevant for improving caregiver outcomes.

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Availability of data and materials

Not applicable

Author's contributions

AMV and CSR were responsible for the development of the MASC program.
AT was responsible for recruitment and data analysis. DTM assisted with facilitating the focus groups as well as completing the rapid qualitative analysis. SS and AT conducted a qualitative analysis of the focus groups transcripts.
AO was responsible for leading and facilitating groups and for supporting the write-up of this manuscript.
NGS was responsible for supporting the write-up of this manuscript.
SRA was responsible for supporting the write-up of this manuscript.

Ethics approval and consent to participate

This study is approved by the Institutional Review Board of Massachusetts General Hospital.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

List of abbreviations

ADRD: Alzheimer’s Disease and Related Dementias
Dementia Care Collaborative
HEP: Health Education Program
Massachusetts Alzheimer’s Disease Research Center
MASC: Mindful and Self-Compassionate Care
RCT: Randomized Control Trial
SOCIAL: Supporting Our Caregivers in ADRD Learning

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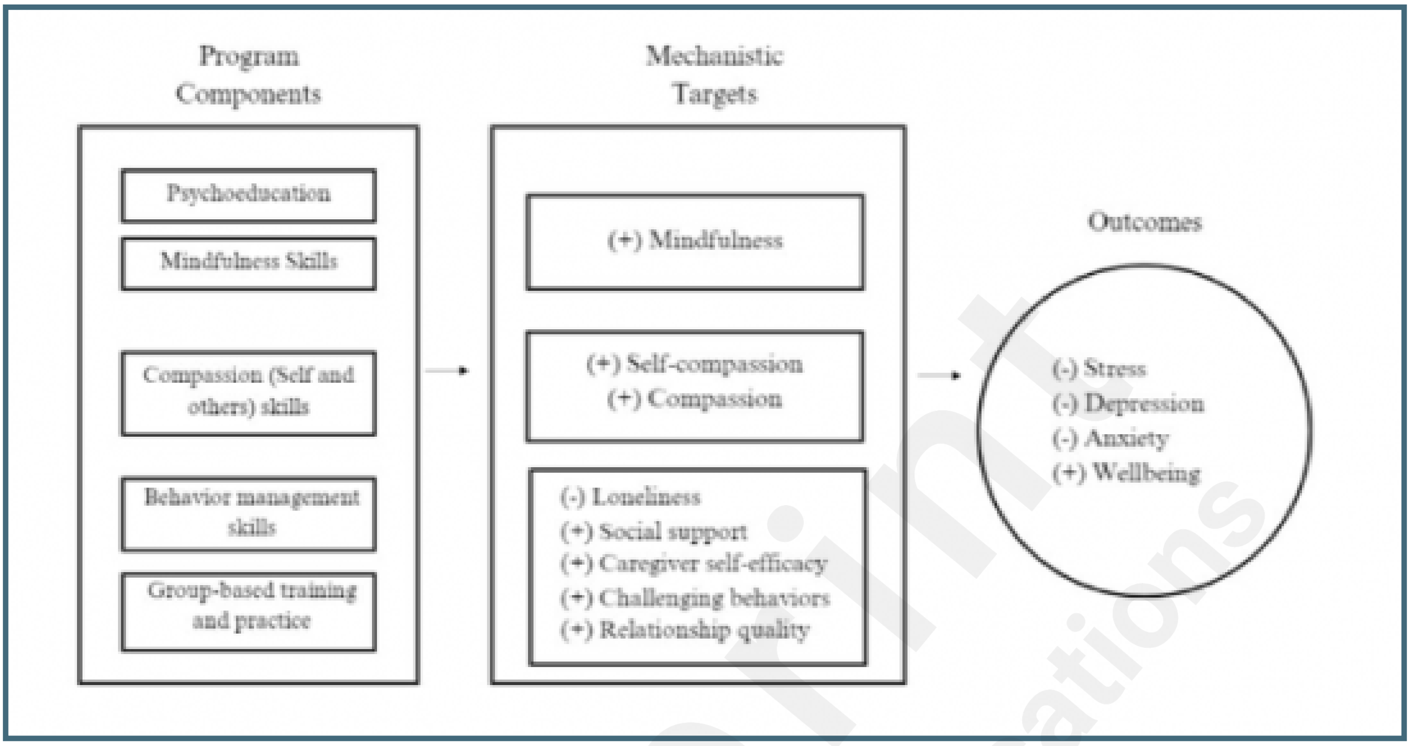
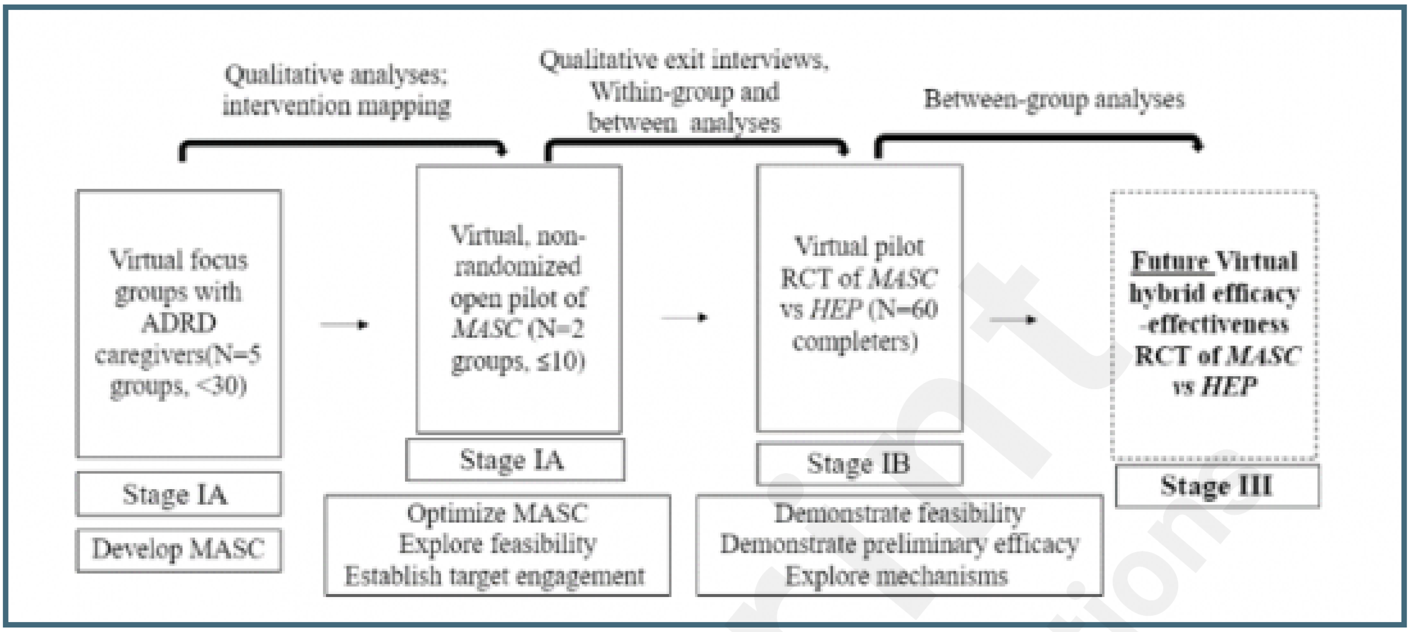
Supplementary Files

Figures

Mindful and Self-compassionate Care Program (MASC) intervention model.



MASC intervention development, optimization, and testing following the NIH stage model and Science of Behavior Change principles.



Multimedia Appendixes

Peer review from the funding agency.
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