A Pilot Online Mindfulness Intervention to Decrease Caregiver Burden and Improve Psychological Well-Being

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Abstract
Interventions to reduce caregiver burden are of great interest as the number of informal family caregivers continues to grow. The purpose of this study was to test the feasibility of an online mindfulness meditation intervention for community-dwelling older adult caregivers and to evaluate its impact on quality of life, caregiver burden, and psychological well-being. A total of 40 caregivers were recruited from 2 community center support groups to participate in an 8-week online mindfulness intervention. Pre and post surveys were administered. Retention rates were high with 55% completing the post surveys and attending at least 5 out of 8 sessions. Matched pairs t test indicated that the intervention reduced caregiver burden, perceived stress, anxiety, and loneliness and improved mental well-being. Online interventions offer flexibility for caregivers regardless of their responsibilities. Future research should expand this opportunity and explore the scalability of online mindfulness interventions.

Keywords
caregiving, mindfulness meditation, aging

Demographics in the United States are shifting as Baby Boomers age and the older adult population continues to grow. Estimates suggest that up to 92% of older adults have at least 1 chronic condition and 77% have 2 chronic conditions.1 The presence of multiple chronic conditions increases older adults’ likelihood for limitations in their daily activities and need of assistance.2 Meanwhile, today’s older adults have unique health risks as they are expected to live longer while managing an increasing number of chronic conditions.3 In 2015, the AARP Public Policy Institute and the National Alliance for Caregiving published a report on caregiving in the United States and found that 34.2 million Americans had provided unpaid care to an older adult in the previous year.4 These unpaid caregivers are often family members who provide assistance both formally and informally, often with significant emotional and financial difficulties.5

Caregiver Burden
Caregiver stress occurs when the responsibility of caregiving, particularly for family members, becomes overwhelming. Caregiver burden occurs when caring for the family member negatively affects the caregiver’s life in any domain (eg, social, emotional, financial, or physical).6 It is estimated that up to 32% of caregivers experience caregiver burden.7 Caregiver burden is a serious concern associated with a number of negative mental and physical health outcomes including reduced quality of life and high levels of depression, anxiety, heart disease, loneliness, social isolation, and mortality.8-10 Predictors of caregiver burden include being female, number of hours spent caregiving, being employed, and caring for someone with dementia.11 In addition, one study found about a third of caregivers are older adult vulnerable caregivers, meaning they were...
also personally in poor health, with high caregiver burden and negative health outcomes.12

Caregiver burden can have negative effects on the care recipient as well.13,14 Care recipients whose caregivers experience high levels of burden have more frequent hospitalizations, lower quality of life, and higher levels of mortality.13,14 Therefore, interventions to reduce caregiver burden are of great importance for the well-being of both the caregiver and the care recipient.

Mindfulness

Mindfulness meditation is the practice of moment-to-moment awareness without judgment; it is a meditative state focusing on one’s presence; a cognitive state of self-awareness that promotes emotional regulation and change in self-perspective.15,16 Mindfulness has been studied in the context of stress reduction, anxiety, and psychological distress and has demonstrated consistent health benefits.17-19 A meta-analysis by Khoury et al19 found that mindfulness-based therapy was consistent in reducing stress, anxiety, and depression. Research has also demonstrated that the practice of mindfulness can improve focus, increase immune functioning, and promote well-being.18,20

The benefits of mindfulness meditation are potentially significant for older adult caregivers with high levels of stress or burden. Although existing studies have focused on small study populations of older adults, research has found that the practice of mindfulness meditation can reduce loneliness, inflammatory responses due to loneliness, psychological distress, and blood pressure.21-23 Similarly, studies focusing on the benefits of mindfulness for caregivers have found them to be successful in reducing caregiver burden.24,25 However, a key limitation of these interventions is the requirement for frequent in-person sessions, which may not be conducive to the lifestyle or schedule of an older adult caregiver. In addition, these studies require intensive practice and demonstrate limited long-term effects.24,25

Research on mindfulness is somewhat limited as most studies have been conducted within the context of a specific illness (eg, cancer, bipolar disorder), many have focused only on women, and they often have limited efficacy outside research settings.17,26 Delivering a mindfulness intervention for older caregivers would require them to have access to the program regardless of their caregiving responsibilities. Therefore, considering modes of delivery beyond the scope of typical in-person sessions would be of great value for this population.

Technology and Interventions

Attendance and attrition are common challenges in intervention research. As a way to reduce their impacts, the use of technology is becoming an effective tool of intervention delivery. In particular, online interventions can be ideal as they are accessible, flexible, and have demonstrated effectiveness.27 Although research emphasizes the importance of multiple modes of delivery, the ease of online interventions makes them particularly attractive.28 Research has demonstrated that an online mindfulness intervention can be effective.29 In 2016, Spijkerman et al29 published a meta-analysis analyzing 15 online mindfulness interventions. Findings demonstrated small to moderate effects on mental and psychological health. However, none of these interventions were tested among caregivers nor were they specific to older adults.

Meanwhile, the use of technology, including online interventions, among older adults is increasing. A 2012 Pew Research Report found that more than half of older adults are online using smartphones, email, and social networking sites.30 Feasibility studies aimed at recruiting older adults for online interventions have also been successful and have demonstrated their ability to improve loneliness and social isolation.31 Similarly, an online intervention for caregivers may be particularly effective as many of these individuals may not have the ability or flexibility to attend frequent in-person sessions. Therefore, an online mindfulness meditation intervention to reduce caregiver burden and improve quality of life and psychological well-being may have significant potential.

Statement of Purpose

The purpose of this study was to target community-dwelling older adult caregivers for a pilot online mindfulness intervention with in-person mindfulness sessions (described in the intervention), to determine if this could be a feasible intervention approach for this population. Community-dwelling generally refers to older adults who are, for the most part, living independently. Feasibility was initially assessed by the ability to attract participants and sustain engagement in the intervention. A secondary goal of this study was to measure with repeat surveys the impact of the intervention on caregiver burden, quality of life (mental and physical well-being), and psychological well-being measures, including stress, loneliness, anxiety, and social support.

Methods

This study was approved by the New England Institutional Review Board, an independent institutional review board that reviews protocols and studies for nonacademic institutions. This study was unique in that it was a collaboration between AARP Services, Inc (ASI), UnitedHealth Group (UHG), and 2 local community centers in South Florida. This study was part of a larger effort, where ASI and UHG partnered with local community health resources to improve the lives of older adults in nontraditional ways. This program was also unique as not all participants were UHG insureds or AARP members.

Recruitment

Participants were recruited from caregiver support groups at 2 local senior community centers in the South Florida area that provide caregiver services to older adults. These centers were chosen as convenience recruitment sites with the assumption that those attending the support groups may be faced with greater challenges than other caregivers in the community. Eligibility criteria for participation in this study included the following: membership in the community center support group, ability to access the online modules of the intervention, and agreement to complete baseline and post surveys. Members of the
support group could participate in the mindfulness program without participating in the study but no data were collected on these individuals. About 40 members attended each of the 2 support groups for a total of approximately 80 potential participants. A total of 40 members (from both sites) agreed to participate in the study and completed a baseline assessment (pre-survey; Table 1). There was no compensation for participation.

### Intervention

The 8-week intervention was designed as a combination of education, mindfulness meditation, and self-care, which primarily focused on self-compassion. The intervention facilitator was a certified mindfulness facilitator with extensive knowledge and experience in both mindfulness practice and teaching. Eight modules were delivered twice weekly online, utilizing phone and web interface to an online learning platform that contained session materials, downloadable brief meditation practices, access to short learning videos, and other support tools. Participants had the choice of which session to join during the week. In addition, 3 of the modules were also delivered in-person to provide alternative touch points if participants were able to attend and preferred this method. These in-person modules were delivered at the kickoff, a midpoint session, and the final session. Topics covered were the following: Why Putting Yourself Last Doesn’t Work, Just Breathe, Mindfulness and Sleep, Compassion for Self and Others, Eating Mindfully, Working with Difficulties, Appreciating the Good, and Putting a Plan into Action (Table 1). Participants joined the program via a link provided by the intervention staff, which they accessed most often on a home computer. The intervention facilitator was live at the community center and guided participants through the 60-minute intervention during the initial kick-off meeting. In-person meetings included staff from the community center and the research staff from UHG.

Subsequent online sessions were delivered live via phone and WebEx connections, and included guidance from the intervention facilitator and selected videos for discussion. Participants were encouraged to continue home practice of new skills learned on their own throughout the week and were provided a CD with short mindfulness meditations to help guide personal practice. In addition, intervention staff were available outside of session time to offer participants additional one-on-one support and guidance via email or phone. No data were collected on the frequency of this contact. However, attendance of the weekly (online and in-person) modules was recorded in order to evaluate the feasibility of the intervention and to measure its impact on perceived support, other psychosocial variables, and quality of life.

After the final session was completed (Module 8), participants were asked to complete the post survey. Hard copies were available for those who attended the in-person sessions. Those who did not attend in-person sessions and those who did not wish to complete the survey in person received an emailed link to complete the survey via Qualtrics. Two reminders to complete the survey were sent via email. A total of 22 participants completed both the pre and post surveys (55% response rate).

### Data

#### Measures

Demographic information for all participants was collected during the pre-survey. Demographics collected included age (<60, 60-69, 70-79, ≥80), gender, marital status (married or other), education (high school or college), living situation (with friend or family, alone, in a structured community center), and employment (retired/home-maker or employed).

**Caregiver Burden.** The Zarit Short Burden Interview is a highly valid and reliable 12-item measure used to assess caregiver burden. Participants are asked to respond to 12 statements that reflect on their feelings on caring for another person. These feelings are then assessed on a 5-point scale ranging from 0 (never) to 4 (daily). Responses are then summed to create a score ranging from 0 to 40, with higher scores indicating higher levels of caregiver burden. Cronbach’s $\alpha$ for the Zarit Short Burden Interview was .89.

**Quality of Life.** Quality of life was assessed with the 12-item Veteran’s Rand. The 12-item Veteran’s Rand is a validated general quality of life measure that asks participants about their quality of life in the last 4 weeks. Two subscales are then derived from this measure: the Physical Component Score and the Mental Component Score. The algorithm is scored on a scale of 0 to 100, with higher scores indicating better physical and mental quality of life. Cronbach’s $\alpha$ for the 12-item Veteran’s Rand was .78.

**Psychological Well-Being.** Constructs of stress, anxiety, loneliness, and social support were used to assess psychological well-being. Stress was measured using the valid and reliable 4-item Perceived Stress Scale. In this measure, participants are asked about their ability to deal with stressful experiences in the last month on a 5-point scale from 0 (never) to 4 (very often). Responses are summed to create a score ranging from 0 to 16, with higher scores indicating higher levels of stress. Cronbach’s $\alpha$ for this measure was .82.

**Anxiety** was measured using the 7-item Generalized Anxiety Disorder Test. The 7-item Generalized Anxiety Disorder Test is a frequently used, valid, and reliable measure to screen for symptoms of anxiety. It asks participants, on a 4-point scale, about their anxiety-related thoughts in the last 2 weeks. Responses range from 0 (not at all) to 3 (every day) and are summed to create a single score ranging from 0 to 21. Higher scores indicate greater levels of anxiety. Cronbach’s $\alpha$ for this measure was .92.

**Loneliness** was measured using the 3-item UCLA Loneliness Scale. Participants are asked on a 3-point scale about their general feelings related to being lonely, left out, or isolated. Responses range from 1 (never/hardly ever) to 3 (often) and are summed to create a score ranging from 3 to 9. Higher scores indicate higher levels of loneliness. Cronbach’s $\alpha$ for this measure was .78.
Perceptions of social support were measured with the highly regarded and validated 12-item Interpersonal Support Evaluation List.\(^37\) This measure asks questions related to the amount of support individuals perceive they would have during a stressful event. Participants are asked to respond to these questions on a scale of 0 (definitely false) to 3 (definitely true). Responses are summed to create a score between 0 and 36. Cronbach’s α for this measure was .79.

**Statistical Testing.** All data were imported into SAS. To test feasibility of the mindfulness intervention, attendance was monitored at each session (both online and in-person). Then, Pearson’s \(r\) correlation analysis was used to assess the association of the number of sessions with outcome variables during the post survey. These variables included caregiver burden, quality of life (mental and physical health), and psychological well-being (stress, anxiety, loneliness, and social support). Finally, matched pairs \(t\) test was used to determine if there were changes in the continuous variables of caregiver burden, quality of life, and psychological well-being.

### Results

Demographics of the baseline study sample (pre-survey) are shown in Table 2. Most caregivers in this study were older (average age of 71), married (83%), female (80%), living with a family member (72%), and retired/homemakers (85%). The demographics of the sample were similar between those who only enrolled in the intervention and those who completed the intervention. However, respondents with both pre and post surveys \((N = 22)\) were significantly older than those who did not respond to the post-survey or complete the intervention \((N = 18\) with fewer than 5 sessions; \(P < .05\)). None of the other demographic variables were statistically different.

Attendance for the intervention was high with more than half of participants \((22\) of \(40)\) attending 50% or more of the sessions. Participation rates were high even for participants who did not complete the post-survey. Although the in-person sessions were an option, overall the online sessions were the preferential mode of delivery with 60% in-person attendance at baseline, 30% in-person attendance at midpoint, and 30% in-person attendance at the final in-person module.

### Correlations

Correlation analyses demonstrated that high levels of attendance (more sessions) were significantly associated with positive changes in perceived social support scores on post-surveys compared to baseline scores \((r = .58, P < .01; Table 3)\). Higher levels of attendance were also correlated with significant changes in Mental Component Score \((r = .41, P < .05)\). In addition, significant correlations were found for decreased stress \((r = .53, P < .05)\) and anxiety \((r = .54, P < .05)\), as well as improved changes in Mental Component Score (Table 4).

### Mean Differences

The second goal of this study was to identify whether the intervention had an impact on caregiver burden, quality of life, and psychological well-being. As shown in Table 5, there were significant differences in caregiver burden, Mental Component Score, stress, loneliness, and anxiety scale scores (pre to post survey). This suggests that over the course of the intervention, mental health improved and caregiver burden, stress, loneliness, and anxiety decreased \((P < .05)\). There was no significant change in social support.

### Discussion

Our primary purpose was to determine the feasibility of enrolling participants and sustaining engagement in a primarily online mindfulness intervention (including options for 3 in-person interactions, live sessions via phone with WebEx connections, and training videos) for community-dwelling older adult caregivers. A secondary goal was to evaluate the impact of the intervention on caregiver burden, quality of life, and psychological well-being. Our findings regarding the primary purpose demonstrated that community-dwelling older adults

| Table 2. Demographic Characteristics. |
|---------------------------------------|
| Demographics                          | Baseline, \(N = 40\) | Pre and Post Surveys\(^a\), \(N = 22\) |
| Age (years)                           | 71\(^*\)             | 73\(^*\)             |
| Average age                           | 71\(^*\)             | 73\(^*\)             |
| <60                                   | 3                   | 6                   |
| 60-69                                 | 12                  | 12                  |
| 70-79                                 | 19                  | 12                  |
| 80 plus                               | 4                   | 3                   |
| Gender                                |                      |                     |
| Female                                | 32                  | 19                  |
| Male                                  | 8                   | 3                   |
| Marital status                        |                      |                     |
| Married                               | 33                  | 19                  |
| Other                                 | 7                   | 3                   |
| Living situation                      |                      |                     |
| With a friend or family member        | 28                  | 15                  |
| Alone                                 | 11                  | 6                   |
| In a structured community center      | 1                   | 1                   |
| (independent, assisted living)        |                     |                     |
| Education                             |                      |                     |
| High school diploma                   | 11                  | 5                   |
| College                               | 28                  | 16                  |
| Employment status                     |                      |                     |
| Retired/homemaker                     | 33                  | 19                  |
| Employed (full- or part-time)         | 6                   | 2                   |
| Number of sessions attended           |                     |                     |
| (total 8 sessions)                    |                     |                     |
| 1                                     | 2                   |                     |
| 2                                     | 6                   |                     |
| 3                                     | 3                   |                     |
| 4                                     | 1                   |                     |
| 5                                     | 2                   | 1                   |
| 6                                     | 4                   | 2                   |
| 7                                     | 11                  | 9                   |
| 8                                     | 11                  | 10                  |

\(^{a}\)Twenty-two members who responded to the pre and post surveys.

\(^*P < .05.\)
would successfully engage in an online mindfulness intervention. Retention and participation rates were high with over 50% completing the program. Findings related to the second goal of this study demonstrated that an online mindfulness meditation intervention could positively influence caregiver burden, quality of life, and psychological well-being.

A primary outcome in this study was reduced caregiver burden. This intervention lowered the caregiver burden score from 20 to a defined cutoff point of 16 for little or no burden in just 8 weeks with a 1-hour weekly intervention. Other studies applying this measure have often not addressed significant burden or have not reduced burden close to this cutoff point for nonburden.38-40 Overall, research has demonstrated that while the effect sizes are small, it is possible to reduce caregiver burden through education, skills training (eg, coping strategies), or therapeutic counseling.41 Similarly, while this intervention focused on mindfulness, the format also included additional components of education and self-care. Self-compassion was a key aspect of the self-care component, as many caregivers often put themselves last and may ignore their own needs, which can add to caregiver burden. However, practicing self-compassion teaches individuals to direct care toward themselves leading to improved health and well-being.42 Therefore, a multifaceted approach as demonstrated here may have contributed to the observed reduction in caregiver burden.

Our results also demonstrated a significant improvement in quality of life, specifically through mental and psychological well-being, over the course of the intervention. The mental health improvements are important to consider within the context of research elsewhere on the impacts of mindfulness.17 Specifically, other studies examining the effects of mindfulness with caregivers have not found significant improvements in quality of life for either mental or physical well-being.25,43 Meanwhile, the absence of an impact on physical well-being in this study as well as in others25,43 may be a result of the focus of the intervention on perceived caregiver burden generally associated with stress and other mental issues.

Finally, the majority of the psychological well-being constructs studied here demonstrated improvement as a result of the intervention; anxiety, loneliness, and stress all decreased over the 8 weeks. Other research confirms the benefits of mindfulness meditation in its ability to promote emotional

| Variables | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|-----------|---|---|---|---|---|---|---|---|
| 1. Number of Sessions Attended | — | — | — | — | — | — | — | — |
| 2. Physical Health | −0.15 | — | — | — | — | — | — | — |
| 3. Mental Health | 0.23 | −0.26 | — | — | — | — | — | — |
| 4. Perceived Stress | −0.02 | 0.22 | −0.43* | — | — | — | — | — |
| 5. Loneliness | −0.28 | 0.21 | −0.42* | 0.53* | — | — | — | — |
| 6. Social Support | 0.58* | −0.09 | 0.09 | −0.12 | −0.34 | — | — | — |
| 7. Anxiety | −0.17 | 0.09 | −0.58* | 0.56* | 0.31 | −0.18 | — | — |
| 8. Caregiver Burden | −0.05 | 0.08 | −0.41* | 0.59* | 0.61* | −0.39 | 0.57* | — |

*Pearson correlation test was performed.
*P < .05.

| Variables | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|-----------|---|---|---|---|---|---|---|---|
| 1. Number of Sessions Attended | — | — | — | — | — | — | — | — |
| 2. Change in Physical Health | −0.09 | — | — | — | — | — | — | — |
| 3. Change in Mental Health | −0.41* | −0.37 | — | — | — | — | — | — |
| 4. Change in Perceived Stress | −0.03 | 0.63* | −0.53* | — | — | — | — | — |
| 5. Change in Loneliness | 0.07 | −0.26 | 0.11 | 0.30 | — | — | — | — |
| 6. Change in Social Support | −0.31 | 0.13 | 0.16 | 0.01 | −0.40 | — | — | — |
| 7. Change in Anxiety | 0.11 | 0.14 | −0.54* | 0.45* | 0.11 | −0.26 | — | — |
| 8. Change in Caregiver Burden | 0.25 | 0.11 | −0.18 | 0.32 | 0.19 | −0.39 | 0.34 | — |

*Pearson correlation test was performed.
*P < .05.

Table 5. Matched Paired t Test of Survey Variables Pre and Post (N = 22)*.

| Variables   | Mean Pre | Mean Post | Difference | P Value |
|-------------|----------|-----------|------------|---------|
| Physical Health | 48.15 | 47.18 | −0.97 | .48 |
| Mental Health | 39.64 | 48.1 | 8.46 | .00 |
| Perceived Stress | 7.55 | 5.76 | −1.79 | .01 |
| Loneliness | 5.86 | 5.28 | −0.58 | .03 |
| Social Support | 35.36 | 36.32 | 0.96 | 0.33 |
| Anxiety | 8.11 | 4.62 | −3.49 | .00 |
| Caregiver Burden | 20.38 | 16.2 | −4.18 | .01 |

*Means of the score variables and their change from Pre and Post (total N = 22). Variables and means in bold are the variables that have significant decrease from pre to post.
regulation and a sense of calmness. However, few studies have measured the impact of these constructs for older adult caregivers, making this study particularly unique. Stress is the typical outcome measured and has consistently been reduced as a result of mindfulness interventions. Elsewhere, interventions not specifically designed for older adults or caregivers have found that mindfulness exercises reduce self-reported anxiety (measured by the 7-item Generalized Anxiety Disorder Test) and anxiety measured through neuroimaging. Meanwhile, other research on the benefits of mindfulness for older adults demonstrates that mindfulness improves loneliness and its related inflammatory responses. Although to our knowledge these outcomes have not been studied specifically within the context of older caregivers with high burden, our outcomes in this study are consistent with existing literature reporting the benefits of mindfulness meditation. We do recognize the need to be cautious regarding these interpretations on improvements of mental and psychological well-being, as the pilot program did not include a control group.

Of note, this intervention was also unique in requiring less time and lower intensity from participants as compared with similar interventions that have measured the impact of mindfulness on caregivers. In our study, participants logged in for 60 minutes per week from their homes and practiced at their convenience. Other mindfulness intervention studies for caregivers have found that higher intensity levels of mindfulness practice are required in order to have an impact. In contrast, the current study, while small in nature, suggests that lower levels of intensity and time commitment may be sufficient. This study also demonstrated a high retention rate, suggesting an opportunity to expand the intervention in a number of different community settings such as local community centers or support groups. Finally, the intervention represented a unique collaboration between AARP Services Inc., UHG, and local community resources, as part of their efforts to establish a presence to improve the lives of older adults at the local level. Participants were aware of this collaboration and were able to participate in this study or in the mindfulness program independent of the study regardless of their affiliation with either organization.

**Strengths and Limitations**

An important feature of this intervention was the inclusion of additional psychological variables, which added a mechanism for the impact of reduced caregiver burden and mental and psychological well-being. This is an important consideration in terms of expanding the intervention for older adults who may not identify themselves as caregivers, or may have low caregiver burden but also other stressors that affect their quality of life or psychological well-being. Furthermore, this intervention demonstrated that consistent with the literature, the use of technology is a feasible intervention for older adults. Therefore, the online availability of this intervention offers an opportunity for older adults who may not have access to transportation or have other limitations (eg, ability to leave their care recipient) affecting their ability to attend in person. Overall, this intervention was relatively low in cost and utilized resources allowing flexibility, such as the CD for home practice and videos delivered via WebEx accessed on home computers. Therefore, scalability to larger populations of caregivers may be feasible and cost-effective.

**Limitations**

Limitations of this feasibility study included the small sample size and lack of a control group, limiting the generalizability of the intervention. Other published studies on mindfulness have had small sample sizes and lacked control groups. In addition, the study participants were recruited from an existing caregiver support group, implying a need for support and a willingness to participate and thus would not generalize to all caregivers. However, the high participation rate and positive intervention results would indicate that additional value was realized by those caregivers who engaged. A larger pilot study would be required to confirm these engagement rates and mental health outcomes. In addition, some individuals may prefer an opportunity to utilize resources outside of their homes; thus, this intervention may not be ideal for all older caregivers.

**Conclusions**

Caregiving involves a number of responsibilities especially for older adult caregivers, many who are primary caregivers and who may be vulnerable themselves. Therefore, the opportunity for older caregivers to participate in an online program, focusing on mindfulness meditation, in their own homes is a unique resource with the potential to be scalable. Online mindfulness meditation programs also have the potential to significantly reduce caregiver burden in a number of other settings. Thus, future studies could expand on the current intervention by testing with a larger sample size, longitudinal cohorts, targeting caregivers of older adults with specific needs, or targeting caregivers with young children.

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**Author Contributions**

Drs Tkatch and Musich and Ms MacLeod contributed significantly to the writing of the article. In addition, Dr Tkatch contributed to the development of the survey and the research design of this project. Dr Bazarko developed the intervention and implemented the intervention and collected the data. In addition, she contributed significant background information to the article. Dr Wu was the lead analyst on this project. Dr Hawkins provided significant input on the design of the project and the article. Ms Keown was the clinical and scientific lead on the intervention and contributed significantly. Ms Wicker was the client scientific lead on the project and contributed significantly.

**Declaration of Conflicting Interests**

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**Ethical Approval**

This study was approved by the New England Institutional Review Board (120160377).

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