Feasibility and Pilot Testing of a Mindfulness Intervention for Frail Older Adults and Individuals With Dementia

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ABSTRACT
Mindfulness interventions have been beneficial for healthy adults and individuals experiencing a stressful medical or mental health diagnosis. The purposes of the current study were to: (a) determine feasibility of mindfulness for older adults in long-term residential settings, and (b) examine differences in outcomes between a mindfulness and cognitive activity. The current study is the first mindfulness study to include individuals in moderate and severe stages of dementia, and included 36 individuals with a range of cognitive abilities. A crossover design was used, and the intervention was feasible for continued practice by individuals with cognitive impairment. Statistically significant short-term changes in agitation, discomfort, anger, and anxiety were found. Nighttime sleep did not improve, but participants slept less during the day. Long-term changes in outcomes were not found. Mindfulness may be useful in decreasing emotional reactivity and improving well-being of older adults in long-term care.

Targets: Individuals with multiple chronic conditions, including cognitive impairment.

Intervention Description: The Present in the Now (PIN) intervention is a mindfulness intervention with three components: attentional skill exercises, body awareness activities, and compassion meditation.

Mechanisms of Action: Mindfulness acts to decrease emotional reactivity through cognitive and affective mechanisms of action and neural activation of the cingulate cortex, amygdala, and hippocampus.

Outcomes: Agitation, affect, stress, sleep, discomfort, and communication of need.

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Over the past 2 decades, mindfulness has gained increasing popularity in the West as a means to develop a deeper sense of happiness and personal calm. Mindfulness is proposed as a potentially useful practice for an array of health conditions, including anxiety disorders, chronic pain, overeating, depression, and attention-deficit/hyperactivity disorder (Didonna, 2009). Mindfulness research is a current funding priority of the National Center for Complementary and Integrative Health at the National Institutes of Health (U.S. Department of Health and Human Services, 2017).

On the surface, mindfulness-based activities for people with dementia (PWD) seem illogical. Alzheimer’s disease (AD) and other illnesses associated with irreversible dementia progressively and profoundly change neurons, synapses, and neurochemical transmitters in the cortical and subcortical regions of the brain. The pathology impacts attention span, recall, abstract thinking, and judgment (Lyketsos et al., 2000). In addition, there are changes in communication, motivation, affect, mobility, tolerance for external stressors, and ability to comprehend changes in the physiological condition of the body (Giebel et al., 2014). These impairments make it much more difficult for PWD to continue to be comfortable, functional, and fully feeling of a range of positive and negative mood states that typify the human condition. However, loss of memories from the past as well as inability to plan for the future may make PWD naturally more focused on the present. Present moment awareness is one of the foundational skills of mindfulness activities.
Although neuroimaging research on the effects of mindfulness is in the nascent stages, multiple studies of healthy adults have shown activation responses in regions of the brain that are potentially beneficial for PWD. The anterior cingulate cortex is involved in preparation for task performance, decision making, emotional regulation, and regulation of physiological processes, such as blood pressure and heart rate (Etkin, Egner, & Kalisch, 2011). The anterior cingulate cortex, which governs thinking and emotion, is the primary region implicated in decreased stress reactivity seen following mindfulness practice. One randomized controlled trial of 14 adults with mild cognitive impairment (MCI) found less hippocampal volume atrophy and increased functional connectivity between the posterior cingulate cortex and bilateral medial prefrontal cortex and left hippocampus compared to controls (Wells et al., 2013). Although this was a small study, findings suggest that a mindfulness intervention may positively impact regions of the brain most related to MCI and AD (Wells et al., 2013).

Several preliminary studies of mindfulness meditation interventions for individuals with MCI and early stage dementia have shown promising positive changes in outcomes, including perceived stress, mood, depression, sleep, retroactive memory function, and blood pressure (Innes, Selfe, Brown, Rose, & Thompson-Heisterman, 2012; Lenze et al., 2014; Moss et al., 2012; Reig-Ferrer et al., 2014). In addition, research on subjective states of cognitively intact mindfulness practitioners includes reports of decreased anxiety, depression, eating disorders, physical impairment, and chronic pain, and improved functional quality-of-life estimates (Fiocco & Mallya, 2015; Goldin & Gross, 2010; Grossman, Tiefenthaler-Gilmer, Raysz, & Kesper, 2007; Hofmann, Sawyer, Witt, & Oh, 2010; Schirda, Valentine, Aldao, & Prakash, 2016; Tapper et al., 2009; Young & Baime, 2010; Zeidan, Johnson, Gordan, & Goolkasian, 2010).

**PURPOSE**

The purpose of the current preliminary study was to: (a) determine the feasibility of older adults with multiple chronic conditions and a subset with cognitive impairment participating in a mindfulness intervention, and (b) compare short- and long-term changes in agitation, affect, sleep, stress, and interoception when participating in a mindfulness intervention and therapeutic cognitive activity intervention. Researchers also examined differences in outcomes based on cognitive ability for what researchers called the Present in the Now (PIN) intervention group. Although other studies have researched mindfulness in individuals with MCI and mild stages of dementia, the current research is the first to include individuals with moderate and severe stages of dementia.

**COMPONENTS OF THE INTERVENTION AND MECHANISMS OF ACTION**

Experts recommend that mindfulness programs for older adults be pragmatic, foster emotional well-being, and have a secondary influence on functional outcomes (Prakash, De Leon, Patterson, Schirda, & Janssen, 2014). The level of effect depends on depth and length of practice (Lutz, Slagter, Dunne, & Davidson, 2008). Hence, components of the PIN intervention, which included attentional skills exercises, body awareness activities, and compassion meditation, were those deemed feasible by the research team for continued practice by individuals with cognitive impairment. The PIN intervention was developed by a mindfulness expert who led the PIN sessions (L.S.) and was based on activities commonly used by mindfulness teachers and practitioners. **Table 1** provides an overview of the interface between theory, components of the PIN intervention, evidence for neural circuitry activated, and explanations for mechanisms of action and hypothesized outcomes. Because

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### TABLE 1

**Interface of Theory With the Present in the Now (PIN) Intervention and Outcomes**

<table>
<thead>
<tr>
<th>Theory</th>
<th>Self-Regulation</th>
<th>Homeostatic Interoception</th>
<th>Competing Models: Cognitive Reappraisal and Perspective Taking or Self-Generated Affective Systems</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention component</td>
<td></td>
<td>Neural circuitry activated</td>
</tr>
<tr>
<td></td>
<td>Attentional skill exercises</td>
<td>Body awareness exercises</td>
<td>Insula; cingulate cortices</td>
</tr>
<tr>
<td>Neural circuitry activated</td>
<td>Dorsal and ventro medial prefrontal cortex</td>
<td>Anterior cingulate cortex</td>
<td>Insula; cingulate cortices</td>
</tr>
<tr>
<td></td>
<td>Cingulate cortices</td>
<td>Amygdala</td>
<td>Amygdala</td>
</tr>
<tr>
<td></td>
<td>Amygdala</td>
<td>Hippocampus</td>
<td>Right temporo-parietal junction</td>
</tr>
<tr>
<td></td>
<td>Hippocampus</td>
<td>(Zeidan et al., 2010)</td>
<td>Right posterior superior temporal sulcus</td>
</tr>
<tr>
<td></td>
<td><strong>Explanation for underlying mechanisms of action</strong></td>
<td></td>
<td>(Fan, Duncan, de Greck, &amp; Northoff, 2011; Lutz, Brefczynski-Lewis, Johnstone, &amp; Davidson, 2008)</td>
</tr>
<tr>
<td></td>
<td>Guided attention leads to distraction and disengagement from stress-inducing thought processes, which calms the mind</td>
<td>Guided attention, curiosity, and openness to sensing current experience leads to increased ability to connect sensation to awareness</td>
<td>Guided attention to emotional states with kindness, openness, and tolerance leads to increased empathy</td>
</tr>
<tr>
<td></td>
<td>Sustained practice leads to decreased emotional reactivity</td>
<td></td>
<td>Sequential direction of compassion meditation activities (e.g., toward oneself, a friend, a stranger, a “difficult” person, the world) leads to decreased self-centeredness and increased positive thoughts toward self and others</td>
</tr>
<tr>
<td></td>
<td>Guided attention without judgment or emotion causes a change in meaning, which leads to decreased automatic affective responses in appraisal systems and decreased emotional reactivity</td>
<td></td>
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<tr>
<td></td>
<td><strong>Proximal outcomes</strong></td>
<td></td>
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<tr>
<td></td>
<td>Increased statements that are self-referential without associated negative affect or appraisal</td>
<td>Increased symptom report</td>
<td>Decreased negative affect</td>
</tr>
<tr>
<td></td>
<td>Decreased agitation</td>
<td></td>
<td>Decreased stress</td>
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<tr>
<td></td>
<td>Decreased negative affect</td>
<td></td>
<td>Decreased agitation</td>
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<tr>
<td></td>
<td>Decreased stress</td>
<td></td>
<td>Increased nighttime sleep and decreased daytime sleep</td>
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<tr>
<td></td>
<td>Increased engagement</td>
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<tr>
<td></td>
<td>Increased nighttime sleep and decreased daytime sleep</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Distal outcomes</strong></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Increased positive affect</td>
<td>Earlier treatment of new problems and symptoms</td>
<td>Increased socialization</td>
</tr>
<tr>
<td></td>
<td>Increased regulation of hypothalamic–pituitary–adrenal axis</td>
<td>Decreased pain, symptoms, and comorbid problems</td>
<td>Increased compassion for self and others</td>
</tr>
<tr>
<td></td>
<td>Health</td>
<td></td>
<td>Decreased negative affect and increased positive affect</td>
</tr>
</tbody>
</table>
there is insufficient evidence regarding effects of meditation for PWD, Table 1 is based primarily on theory and evidence from studies involving adult practitioners.

**Attentional Skills and Emotion Regulation**

Emotion regulation processes play a crucial role in health, illness, and well-being (Berking & Wupperman, 2012). Mindfulness meditation cultivates the ability to spend more time in the silent space between thoughts. In this state of just being, the part of one’s thoughts that makes judgments is not engaged. Trait levels of mindfulness in older adults were associated with fewer self-reported depressive symptoms, better quality of life, and decreased stress (Fiocco & Mallya, 2015). Emotion regulation has been found to mediate the relationship between trait mindfulness and reduced perceived stress in older and younger adults (Prakash, Hussain, & Schirda, 2015). The process model of emotion regulation highlights the importance of distraction and reappraisal (Gross, 2015). Distraction draws attention away from emotionally provoking stimuli to decrease negative emotion and anxiety (Karademas, Tsaliou, & Tallarou, 2011). Reappraisal changes the meaning of a stimulus, which decreases the affective reaction to the stimulus (McRae, Ciesielski, & Gross, 2012).

Some ability to regulate attention is needed to stay engaged in meditation activities. The strengthening of attention regulation and accompanying anterior cingulate cortex activation may be particularly important mediators of emotional response to stimuli in PWD (Fountain-Zaragoza, & Prakash, 2017). Sustaining attention to an object or event in the present may distract individuals from emotionally provoking stimuli and thoughts and calm the mind.

Reappraisal practices disrupt or inhibit automatic ruminative affective responses in appraisal systems and aid in development of more efficient mechanisms to engage and then disengage from aversive emotional stimuli (Lutz, Slagter, et al., 2008; Zeidan et al., 2010). If a disruptive thought or emotion emerges, the individual is taught a form of reappraisal that “releases” the momentary event without affective reaction (Lutz, Slagter, et al., 2008).

Examples of activities include focusing attention on something in the natural world, such as a flower or cloud. After some degree of attention regulation is mastered, practitioners can be taught to focus on a positive experience, such as the smell of coffee or the touch of silk. Practitioners can attach positive emotion to experiences such as having enough food to eat and being in a comfortable chair with individuals who care about them. When a negative thought arises, practitioners can note it, and let it go. Practitioners then practice paying attention to the present in a manner that is nonjudgmental and not attached to an emotional reaction.

**Body Awareness and the Homeostatic Interoception Systems**

Body awareness is needed for human functioning and survival. The term *intereception* is used to describe the awareness of internal body sensations (Mehling, Hamel, Acree, Byl, & Hecht, 2005). Although heightened body awareness would seem to lead to maladaptive somatosensory amplification and hypochondriasis, findings from numerous studies suggest that it may be useful in management of chronic diseases, such as chronic low back pain (Afrell, Biguet, & Rudebeck, 2007; Mehling et al., 2005), congestive heart failure (Baas, Beery, Allen, Wizer, & Wagoner, 2004), and irritable bowel syndrome (Eriksson et al., 2007). Increased connection between body and mind may make individuals more aware of aversive and positive sensations and help individuals self-regulate physical relaxation.

Improving body awareness has the potential to attenuate and modulate symptoms and changes in physical and emotional states. For PWD, diminished states of self-referential interoception can delay treatment, which can worsen health and well-being. Multiple studies of pain experiences of PWD suggest that physical pain sensations are not or only mildly diminished; rather, the ability of individuals to connect the sensation to awareness is diminished (Scherder et al., 2009).

Various mind–body techniques are designed to enhance body awareness, including yoga, tai chi, mindfulness, qigong, and body awareness therapy (Daubenmier, 2005; Sherman, Cherkin, Erro, Miglioretti, & Deyo, 2005). Curiosity, openness to sensing, and a nonjudgmental and nonelaborative awareness to the current experience are cultivated. A focus group study demonstrated wide agreement among experienced mind–body practitioners that a focus on breath is central to increasing body awareness (Mehling et al., 2005). Body awareness exercises during PIN include focusing on breath, relaxation of various body parts, and taste and smell exercises.

**Compassion Meditation: Two Theoretical Explanations**

Many contemplative traditions emphasize generating compassion and the wish of happiness and well-being for self and others. *Compassion* is defined as a feeling of concern for others accompanied by motivation to help or have suffering relieved (Kanske, Böckler, Trautwein, & Singer, 2015). There is some evidence that self-compassion may moderate reactions to negative events and decrease rumi-
Compassion for others could help individuals, especially those living in close quarters that involve interdependence, view others with kindness and wish well-being for those whom they perceive as annoying, demanding, or expressing distress. One study showed that during meditation, expert meditators had greater activation in the insula and dorsal anterior cingulate cortex than novice meditators in response to sounds of human distress (Lutz, Brefczynski-Lewis, Johnstone, & Davidson, 2008).

The two models explaining how compassion meditation works involve either a cognitive or affective mechanism of action. According to the cognitive perspective, compassion is fostered through reappraisal and perspective taking processes (Dahl, Lutz, & Davidson, 2016). Cognitive reappraisal refers to regulating emotional responses by changing what is thought about an emotional stimulus. Perspective taking is the act of considering feelings of oneself or others in a particular situation (Dahl et al., 2016). A competing perspective is that compassion meditation could largely bypass the cognitive route and instead directly operate via self-generated affective systems in which positive affect and prosocial motivation are cultivated (Engen & Singer, 2016).

During compassion meditation within PIN, feelings of kindness and compassion were initially directed toward oneself, and then broadened to an ever-widening circle of others. This process of focused and compassionate attention to emotional states may disrupt negative judgments and develops patterns of response within the neuroendocrine circuitry and broader autonomic system (Hofmann, Grossman, & Hinton, 2011).

Based on the theoretical and empirical literature, it was hypothesized that agitation, negative affect, and cortisol stress levels would decrease, and sleep quality would increase after PIN intervention. Decreased emotional reactivity was hypothesized to improve regulation of the hypothalamic–pituitary–adrenal (HPA) axis, as evidenced by an increase in the slope of diurnal cortisol secretion. Changes in interception through the body awareness component of the PIN intervention were hypothesized to increase communication of needs and change levels of observed discomfort.

**METHOD**

**Design**

A controlled crossover repeated measures experimental design was used in which participants received a random-
The convenience sample size of 36 participants (12 from independent apartments, five from assisted living, 13 from skilled memory care, and six from general skilled care) included 29 females and seven males with an average age of 87 years ($SD = 10.2$ years; range = 56 to 98 years). Twenty participants were cognitively impaired (seven mildly, seven moderately, six severely impaired) and 16 had no cognitive impairment according to the Mini-Mental Status Examination (MMSE). The majority had post high school education ($n = 24, 67\%$), and median length of stay was 39 months (range = 2 to 117 months). The sample had an average of 9.44 ($SD = 2.43$; range = 1 to 13) chronic illnesses and an average of 4.03 ($SD = 2.14$; range = 1 to 10) of these conditions were severe or moderately severe.

**Measurement**

Agitation, discomfort, and engagement were assessed through observation. One trained data collector (C.-R.E.) collected all observational data after interrater reliability testing was ≥0.85. Short- and long-term measures were collected to increase likelihood of capturing changes resulting from the intervention. Table 2 provides an outline of all measures, the possible range of scores, and when and by whom data were collected. To decrease participant burden, long-term saliva samples were collected only for the PIN study arm.

**Agitation.** Agitation was scored along a visual analog scale that measures the number, duration, and intensity of the 29 behaviors in the Cohen-Mansfield Agita-

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**TABLE 2**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Measure</th>
<th>Long-Term Measurement Time Points</th>
<th>Short-Term Measurement Time Points</th>
<th>Possible Score Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agitation</td>
<td>Cohen-Mansfield Agitation Inventory—Adapted for observation (observations by RA)</td>
<td>1 week before and 1 week after PIN and COG</td>
<td>20 minutes before, during, and 20 minutes after PIN and COG</td>
<td>0 to 100</td>
</tr>
<tr>
<td>Affect</td>
<td>Observed Emotion Rating Scale (observations by RA)</td>
<td>1 week before and 1 week after PIN and COG</td>
<td>20 minutes before, during, and 20 minutes after PIN and COG</td>
<td>1 to 5 per item</td>
</tr>
<tr>
<td>Engagement</td>
<td>Arousal States in Dementia Scale (observations by RA)</td>
<td></td>
<td>20 minutes before, during, and 20 minutes after PIN and COG</td>
<td>0 to 4</td>
</tr>
<tr>
<td>Stress</td>
<td>Salivary cortisol assay</td>
<td>1 week before and 1 week after PIN only</td>
<td>20 minutes before and 20 minutes after PIN and COG</td>
<td></td>
</tr>
<tr>
<td>Sleep</td>
<td>Actigraphy</td>
<td>Week 1 of PIN and COG with the first 2 days and nights serving as pre measures and the next 2 nights as post measures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interoception:</td>
<td>Discomfort—Dementia of the Alzheimer’s Type scale (observations by RA)</td>
<td>1 week before and 1 week after PIN and COG</td>
<td>20 minutes before and 20 minutes after PIN and COG</td>
<td>0 to 900</td>
</tr>
<tr>
<td>Interoception:</td>
<td>Communication of need (social worker report)</td>
<td>1 week before and 1 week after PIN and COG</td>
<td></td>
<td>0 to 48</td>
</tr>
</tbody>
</table>

Note. RA = research assistant; PIN = Present in the Now; COG = cognitive therapeutic activity.
tion Inventory during multiple 3-minute observations (Cohen-Mansfield, Werner, & Marx, 1989). Examples of agitated behaviors included restlessness, pacing, repetitive questioning, and hitting. Measures of agitation using these procedures have been responsive to change in previous intervention studies (Kovach et al., 2006; Kovach et al., 2012).

Affect. The Observed Emotion Rating scale rates two positive emotions (i.e., pleasure, general alertness) and three negative emotions (i.e., anger, anxiety or fear, sadness), with higher scores indicating longer duration of expression of that emotion (Van Haitsma & Klapper, 1999). The tool is designed specifically for nursing home residents with dementia and convergent and divergent validity have been established (Lawton, Van Haitsma, & Klapper, 1994).

Engagement. Engagement was observed and ranked by use of the Arousal States in Dementia Scale (Kovach et al., 2004). The ordinal scale measures participants’ most aroused state of stimulation to action in a 3-minute time period. A score of 0 indicates eyes were closed in apparent sleep for the entire observational period. A score of 4 indicates eyes were focused on a particular event, object, or person; activity is purposeful; and movement of limbs, head, or trunk is ≥20° or occurs for ≥1 minute.

Stress. Assays of salivary cortisol was used as a marker of stress. Cortisol is a hormone secreted by the adrenal glands in response to stress, and has been found responsive to stress-reducing interventions (Clow, Thorn, Evans, & Hucklebridge, 2004). A normal circadian rhythm of cortisol is characterized by a negative slope created by a peak in cortisol after waking followed by a decline in levels throughout the day (Oster et al., 2017). Cortisol is commonly used in mindfulness research and has been recommended as an objective marker for evaluating improvement from mindfulness-based stress reduction interventions (Matousek, Dobkin, & Pruessner, 2010). Salivary cortisol was measured using Salimetrics® Cortisol Enzyme Immunoassay Kit and all samples from the same participant were run in duplicate in the same batch to avoid between-batch variability.

Sleep. Sleep was measured in 1-minute epochs with the Basic Motionlogger® wrist actigraph from Ambulatory Monitoring, Inc. The actigraph indirectly measures sleep by detecting absence of movement, and is useful for studying PWD because of low invasiveness and ease of monitoring sleep and activity cycles in ecological environments. Diffuse slowing on the electroencephalogram makes sleep polysomnographic assessment difficult for PWD (Riemersma-van der Lek et al., 2008).

Variables measured and analyzed were total sleep time, sleep efficiency, wake after sleep onset (WASO), and the sleep fragmentation index. Total sleep time is the period in minutes of nighttime sleep (Moore, Schmiege, & Matthews, 2015). Sleep efficiency is the proportion of time spent sleeping (Enderlin et al., 2011). Sleep latency is the time in minutes to fall asleep or the first period of persistent inactivity (Moore et al., 2015). WASO is the total minutes awake during nighttime from sleep onset to final awakening (Moore et al., 2015). The sleep fragmentation index is an index of restlessness during the designated sleep period expressed as a percentage (Knutson, Van Cauter, Zee, Liu, & Lauderdale, 2011).

Interoception. Interoception was measured through an assessment of discomfort and the ability to communicate needs. The Discomfort–Dementia of the Alzheimer’s Type scale (Discomfort–DAT) requires a 5-minute observation period to measure overall level of discomfort. Items in the Discomfort–DAT scale include assessments of facial expression, body tension, fidgeting, and negative vocalization. Internal consistency alpha coefficients ranged between 0.63 to 0.82 in earlier studies, and measures have been responsive to change in previous intervention studies (Kovach et al., 2006; Kovach et al., 2012).

Communication of need was assessed with the Communication of Need–Dementia of the Alzheimer’s Type (CON–DAT) survey designed for the current study. Four experts in dementia care (C.R.K. and others) reviewed the literature and developed an initial list of nine items to capture different ways in which individuals with dementia communicate physical and emotional needs. Content validity was determined by six additional experts (four nurse researchers and two social workers). Experts were asked to rate the relevance of items to communication of physical and emotional needs. Three items that had a content validity index (CVI) of ≤0.83 were omitted. Another item with a CVI ≤0.83 was retained, but reworded from “Specific descriptive language” to “A clear verbal statement.” Based on expert feedback, one additional item and instructions were reworded. The resulting 12-item Likert scale required caregivers to state how often a resident communicates physical and emotional needs, respectively, via a clear verbal statement, nonspecific vocalizations, decreased engagement in activities performed in recent past, increased motor activity, facial expression, and withdrawing from individuals and activities. Cronbach alpha reliability for the four testing times ranged from 0.80 to 0.90.

Other Measures. Variables that were measured to describe the sample include age, gender, length of stay, cogni-
ative ability (using the MMSE) and baseline chronic illnesses (using The Cumulative Illness Rating Scale–Geriatric [CIRS–G]) (Cockrell & Folstein, 2002). The interventionist was asked to categorize participants into one of three groups: participative, not perceived to be participating, and low ability to understand and follow directions.

**Procedure**

Following consent, chart review was performed for eligibility, demographics, and the measure of chronic illness burden using the CIRS-G. Eligible participants were randomized to the order in which they would receive PIN and COG and given the MMSE. The communication of need surveys were completed by social work staff familiar with each resident. Baseline measures of agitation, affect, and discomfort were obtained by observing the resident mid-morning. Reports from the certified nursing assistant and/or resident were used to ensure that measures were obtained ≥20 minutes after any potential discomfort- or stress-producing event. For participants randomized to PIN, saliva samples were collected from under the tongue using three eye sponges 30 minutes after awakening, 45 minutes after breakfast, and 45 minutes before and after dinner (±15 minutes). Following collection, samples were centrifuged and frozen at –40°C.

The PIN and COG activities were held mid- to late-morning on 2 days in the first week and 3 days per week for the next 3 weeks. The 11 sessions of PIN and COG lasted approximately 45 minutes. The PIN sessions were led by an experienced mindfulness teacher/practitioner (L.S.) trained in mindfulness-based stress reduction and COG activities were led by several members of the therapeutic activity staff at the sites. Fidelity was maintained by having the PIN leader document each component of the intervention as practiced for each session. The principal investigator (PI; C.R.K.) checked fidelity to the three components of PIN by observing a session every 2 to 3 weeks. The PI also checked COG sessions to ensure sessions were solely a cognitive activity.

On Monday morning prior to the first session of PIN or COG, an actigraph was placed on participants’ non-dominant wrist and the resident or caregiver was asked to complete a log and push an event marker on the actigraph to indicate the time the individual woke up and went to sleep. The actigraph was removed on Friday.

During the third week of PIN and COG, short-term measures of agitation, affect, discomfort, stress/cortisol, and engagement were collected 20 minutes before, during (for agitation, affect, and engagement), and 20 minutes after the PIN and COG activities. Observational measures taken during PIN and COG were started 10 minutes after the session began, and the order for observing participants was based on random sequence. Saliva samples for cortisol assay were collected using established guidelines after observational measures.

One week after the conclusion of PIN and COG, long-term post measures were collected using the same procedures as at baseline. After a 2-week washout period, residents were switched to the other study arm and data collection procedures were repeated.

**Analysis**

The primary analysis was intention-to-treat and involved all participants who were randomly assigned an order for receiving the PIN and COG. Missing data were treated as missing. The percentage of missing data for variables was: agitation (1%), affect (1%), discomfort (1%), engagement (2%), sleep-actigraphy (7%), and communication of need (0%). Fifteen of 36 participants could not have cortisol samples collected because they were on a corticosteroid medication. Of participants able to have valid cortisol assays conducted, <1% of samples were missing.

Descriptive analyses included use of percentages, means, medians, standard deviations, and ranges. Agitation, affect, and discomfort were analyzed using t tests and repeated measures analysis of variance (ANOVA) procedures. The standard deviations for some agitation time points were large, but distribution of the differences from pretest to posttest were not severely skewed, allowing for parametric inferential analyses. Nocturnal sleep variables were skewed and analyzed with medians and the Wilcoxon signed rank test. Daytime sleep and wake minutes were not skewed and analyzed with means and t tests. MMSE scores were dichotomized to ≥18 and <18 to correspond with the interventionist’s rating of residents who were and were not participative in PIN. Differences between those with higher and lower MMSE scores on outcomes were examined using descriptive statistics and ANOVA.

**RESULTS**

**Participation**

Attendance records indicated that 29 (81%) of 36 PIN participants attended seven or more of the 11 sessions offered to each group and 11 (28%) participants attended all sessions. In the COG group, 18 (50%) participants attended seven or more sessions. Three individuals from the same group dropped out of the PIN intervention within the first week and all explained that the activity was not what
they expected and they did not wish to continue. One person never received the COG intervention due to hospitalization and extended rehabilitation.

The PIN and COG groups were engaged before, during, and after activities. With a possible range of 0 to 4 on the scale, means ranged from 3.47 to 3.88, with no significant differences between groups ($p = 0.274$). No participants fell asleep during PIN and only one person slept during the COG activity.

The interventionist was asked to rate her perception of how much each resident actively participated during the PIN sessions. The majority were participative ($n = 20, 56\%$) but 12 (33\%) residents were perceived to have low ability to understand and follow directions and four (11\%) residents were not perceived to be participating. The correlation between the interventionist’s rating of active participation and cognitive status was 0.69 ($p < 0.001$). The group perceived by the interventionist to be actively participating had MMSE scores that ranged from 18 to 30 (mean = 26.95, $SD = 3.66$).

**Agitation, Affect, and Stress**

There were statistically significant differences in short-term agitation between the PIN and COG activities ($F [1, 28] = 6.89$, $p = 0.014$), and the order in which participants received PIN and COG was not significant ($p = 0.122$). As seen in Figure 1, agitation scores decreased during and 20 minutes after PIN ($F [1, 28] = 17.50$, $p < 0.001$, partial eta squared = 0.385), and increased by a small amount during the cognitive activity ($F [1, 31] = 0.362$, $p = 0.683$, partial eta squared = 0.012). The drop in agitation during mindfulness for those with an MMSE score $\geq 18$ (i.e., 45-point drop) was similar to the decrease for those with an MMSE score $< 18$ (i.e., 40-point drop).

Changes in long-term agitation were next examined from 1-week pre- to 1-week post-intervention. Agitation did not change substantially in the PIN condition, but decreased in the cognitive activity condition from a mean of 67.16 ($SD = 33.23$) at baseline to 55.47 ($SD = 35.20$) at 1-week posttest ($t = 1.84$, $p = 0.038$, one-tailed).

Each item of the affect scale was analyzed for changes. As seen in Figure 2, anger and anxiety/fear showed decreases during the PIN intervention, and decreases were sustained 20 minutes after the intervention (anger $F [1, 31] = 2.94$, $p = 0.030$, one-tailed; anxiety/fear $F [1, 31] = 5.94$, $p = 0.004$). Pleasure increased during the PIN intervention and increases were sustained 20 minutes after the intervention ($F [1, 31] = 2.40$, $p = 0.046$, one-tailed). Sadness and alertness did not change during the
The changes in affect items during and 20 minutes after PIN were similar for those with MMSE scores <18 and ≥18. The COG group had no statistically significant improvements in negative or positive affect during or after cognitive activities.

There were no statistically significant changes in cortisol values from 20 minutes before to 20 minutes after the PIN (mean = 0.234 μg/dL, SD = 0.142; mean = 0.246 μg/dL, SD = 0.118, respectively; t = –0.352, p = 0.729) or COG interventions (mean = 0.275 μg/dL, SD = 0.235; mean = 0.229 μg/dL, SD = 0.177, respectively; t = 1.12, p = 0.280) and no significant changes from baseline to 1-week post-intervention for the PIN group for waking cortisol (p = 0.773), nadir cortisol (p = 0.254), or cortisol slope (p = 0.263).

Sleep at Night and Day Times

On average, participants had 436 minutes (SD = 70.4 minutes) of sleep per night. The percentage of time spent asleep during the nighttime was 76.9% (SD = 7.9%). Participants had an average sleep latency of 28 minutes (SD = 21 minutes). Total minutes awake during the nighttime from sleep onset to final awakening averaged 130.7 minutes (SD = 50.9 minutes). Residents were awake 532.1 minutes (SD = 268.1 minutes) during the daytime and napped 120.5 minutes (SD = 94.3 minutes). On average, 18.5% (SD = 10.9%) of the daytime was spent asleep.

There were no changes at night in either the PIN or COG groups for total sleep time (p = 0.279; 0.699), sleep efficiency (p = 0.869; 0.713), WASO (p = 0.946; 0.568), sleep latency (p = 0.576; 0.572), or fragmentation index (p = 0.689; 0.716). However, during the daytime, participants in the PIN activity decreased their daytime sleep by an average of 27 minutes (pre-activity mean = 140.53 minutes, SD = 112.15 minutes; post-activity mean = 114 minutes, SD = 87.62 minutes, p = 0.03, one-tailed). Daytime sleep minutes did not change in the COG group (p = 0.311).

Measures of Interoception

There were statistically significant differences in short-term measures of discomfort between the PIN and COG activities (F[1, 27] = 32.63, p < 0.001, partial eta squared = 0.547). As seen in Figure 3, discomfort scores decreased for the PIN group by 193 points and increased by 19 points after the COG activity. Discomfort scores dropped by 203 points for those with a MMSE score ≥18 and dropped by 171 points for those with a MMSE score <18. The order in which participants received PIN and COG was statistically significant, with the group receiving PIN before COG experiencing larger decreases in discomfort than those who received COG first (p = 0.122). There were no statistically significant differences in long-term measures of discomfort between the PIN and COG groups (t(32) = –0.293, p = 0.771).

The ability to communicate needs verbally showed a small range and little change from baseline to posttest in both the PIN and COG groups (means ranged from 0.337 to 0.347).

DISCUSSION

Short-term positive changes in agitation, affect, and discomfort level that were not present during participation in the cognitive activity were seen when participants were in the mindfulness arm of the study. These findings are consistent with multiple studies showing a relationship between mindfulness activities and decreased stress reactivity (Lutz, Slagter, et al., 2008; Zeidan et al., 2013). Two studies with cognitively intact adults have shown a positive relationship between compassion training and positive affect (Fredrickson, Cohn, Coffey, Pek, & Finkel, 2008; Klimecki, Leiberg, Ricard, & Singer, 2014).

Increasing connection between body and mind may make individuals more aware of aversive and positive sensations. The large decreases in short-term discomfort...
found in the current study suggest that participants may have either become more aware of feelings of comfort; were able to physically relax, causing feelings of physical discomfort to decrease; or had decreased emotional reactivity to their discomfort. Those who received PIN before COG had greater decreases in discomfort, although no carryover effect from other activities at the facilities could be identified.

In the current study, the positive effects from PIN did not endure over time. The inability to find long-term positive changes from participating in the PIN intervention may indicate that the dose of intervention was not strong enough, that there are no long-term benefits, or that measurement error accounted for the inability to detect long-term changes.

The average number of minutes the current sample slept at night ranged from 420 to 540 minutes, which is considered adequate (Miaskowski et al., 2011). The sample's sleep efficiency was below the 80% to 85% or greater benchmark, and it took participants longer than the average <20 minutes to fall asleep (Johansson, Adamson, Edebjäck, & Edêl-Gustafsson, 2014; Miaskowski et al., 2011; Moore et al., 2015). Participants were awake for a greater percentage of time than the typical 10% of total minutes spent awake after sleep onset (Ancoli-Israel et al., 2003; Miaskowski et al., 2011). These findings may indicate that individuals are in bed too long and have fragmented sleep.

Although nocturnal sleep did not improve following PIN, daytime napping decreased. These results will need to be replicated to determine if the PIN intervention had positive benefits on sleep or wakefulness. If napping is a reaction to boredom or aversive stimuli in the immediate environment, the decreased time sleeping during the daytime could be seen as a beneficial result of PIN. Decreasing the length of daytime naps is a commonly used therapy to improve nocturnal sleep (McCurry, Gibbons, Logsdon, Vitiello, & Teri, 2005; Morin et al., 2006).

A large number of participants in the current study were taking a corticosteroid drug, which precluded obtaining valid cortisol assay results. The lack of changes in measures of stress through cortisol assay adds to a growing body of evidence showing conflicting results on the effects of participation in mindfulness-based stress reduction programs and cortisol levels (Matousek et al., 2010). Cortisol has a strong circadian rhythm and is regulated by the HPA axis. Many individuals with dementia have dysregulations of the circadian rhythm and HPA axis, which may have confounded the measures (Reppermund et al., 2007; Tranah et al., 2011).

Attendance at the PIN activity was good and participants were engaged during sessions. Future studies should collect data on length of time participants are able to stay engaged in the mindfulness activities, and whether time differs based on level of cognitive impairment. Findings based on the interventionist's ratings of participation were inconsistent with the outcome data. Although the interventionist perceived that residents with an MMSE score <18 were either not participating or having a difficult time understanding and following directions, the similarity of findings between those with higher and lower MMSE scores suggests that the intervention is feasible and beneficial even for those with advanced dementia. Perceptions regarding participation of individuals with dementia in mindfulness activities may underestimate the degree to which individuals with dementia are actually engaged in these activities.

LIMITATIONS

A crossover design was used to reduce the potential for confounding variables to influence results. Researchers also checked for the influence of order of receiving each study arm when possible. The washout period was only 2 weeks, which could have led to some carryover effect from one intervention to the other. The sample size was small. The dose of mindfulness therapy was small and could have influenced results. Attendance at COG activities was much lower than at PIN activities and could have influenced outcomes. In addition, although the data collector was instructed to be highly objective in assessments, the collector was not blinded to study arm or purpose, which could have biased results of observational measures. Furthermore, the study relied on objective measures of sleep and stress, observational measures, and caregiver report, but failed to include self-report measures. Future, larger studies should include self-report measures of variables such as mood and satisfaction with the activity.

Research with a larger sample size should examine the feasibility and benefits of specific components of PIN and other mindfulness intervention along the trajectory of cognitive decline. Future research should include a larger sample size, a randomized design, higher dose of the intervention, and blinding. The significant drop in discomfort after mindfulness practice suggests that a study of mindfulness as a treatment or combined treatment for mild and moderate chronic pain conditions is needed.

CONCLUSION

Most research on the effects of mindfulness has involved healthy adults or individuals dealing with a stressful medical or mental health diagnosis. Much of the research occurs in highly controlled clinical laboratory settings. The current
study demonstrated that mindfulness is feasible for older adults with multiple chronic conditions and cognitive impairment, can be conducted in a residential setting, and is associated with positive benefits. Mindfulness focuses on using strengths within oneself to promote well-being, comfort, and compassion, and has negligible known side effects.

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