Experiences of Family Caregivers and the Use of Non-Pharmacologic Care Strategies for Community Dwelling Older Adults with Dementia

by

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DEDICATION

This dissertation is dedicated to the families that participated in this research and all families affected by Alzheimer’s disease and other dementias. Families that participated were generous to share their personal stories, their knowledge, their experiences, and their time during a particularly challenging time in history. Without their commitment, this dissertation would not have been possible.

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ABSTRACT

People living with dementia (PLWD) often experience behavioral and psychological symptoms of dementia (BPSD) which are burdensome to those diagnosed, their families, and society. Many non-pharmacologic interventions have demonstrated efficacy in reducing BPSD in research but have had limited uptake in the community, possibly due to lack of feasibility and limited acceptance by PLWD and their family caregivers. Acutherapy and weighted blankets are non-pharmacologic interventions that have improved outcomes among older adults, but few studies have focused on PLWD and BPSD. The purpose of this research was to explore the potential of acutherapy and weighted blankets as non-pharmacologic interventions to reduce BPSD in PLWD. The research presented in this 3-paper dissertation was guided by 6 specific aims:

1. Identify, examine, and synthesize the state of the science relating to the effects of acutherapy on BPSD. (Paper 1)
2. Explore perspectives of family caregivers of community dwelling older adults with Alzheimer's disease or related dementias (ADRD) regarding BPSD and use of non-pharmacologic interventions for BPSD management. (Paper 2)
3. Explore perspectives of family caregivers of community dwelling older adult family members with ADRD regarding changes in their caregiving experiences, BPSD displayed by their relatives with ADRD and BPSD management strategies used during the COVID-19 pandemic. (Paper 2)
4. Explore initial perceptions of family caregivers regarding weighted blankets as an in-home care strategy for community dwelling PLWD following a brief description and visual presentation of weighted blankets. (Paper 3)
5. Examine feasibility and acceptability of a virtually delivered, in-home weighted blanket intervention for older adults with ADRD living in the community as perceived by the family caregiver and the person with ADRD. (Paper 3)

6. Examine feasibility of collecting outcome measures of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health status of family caregivers. (Paper 3)

Aims were addressed using: a scoping review methodology (Aim 1); a qualitative approach using semi-structured interviews with 21 family caregivers living with community dwelling PLWD (Aims 2, 3, and 4); a prospective, within subjects, pre-post design study with 21 community dwelling PLWD and their family caregivers (Aims 5 and 6). This dissertation research had 6 key findings: 1) Acutherapy is a safe non-pharmacologic care strategy for PLWD and a potential treatment for BPSD, but additional research is needed to determine efficacy; 2) The caregiving experience of family caregivers of community dwelling PLWD was described as an interdependent partnership between the caregiver and the PLWD; 3) Family caregivers and PLWD experienced challenges to in-home care prior to the COVID-19 pandemic, many of which were compounded by it; 4) The virtually delivered, in-home weighted blanket intervention was feasible and acceptable to PLWD and their family caregivers; 5) Collecting outcome measures of care recipient cognitive function, caregiver well-being and caregiver self-reported health was feasible; 6) Collecting outcome measures of care recipient BPSD and quality of life was feasible through measures completed by caregiver report, but not by care recipient self-report. The efficacy of feasible and acceptable care strategies for community dwelling PLWD must be determined to promote broader uptake by clinicians, support service providers, and families. As BPSD are overwhelming for PLWD, their families, and society, we are in dire need of evidence-based non-pharmacological interventions to reduce the burden and improve the quality of life of PLWD and their families.

CHAPTER I

Introduction

Nearly 47 million people worldwide live with Alzheimer’s disease or other related dementias (ADRD), and nearly 10 million more will be diagnosed each year as the population continues to age (World Health Organization, 2020). Of the 5.8 million Americans over the age of 65 living with ADRD, over 4 million (~70%) live in the community and receive most of their care (83%) from unpaid, informal caregivers such as family members and friends (Lepore et al., 2017; Spillman et al., 2014).

Behavioral and psychological symptoms of dementia (BPSD) are experienced by virtually all community dwelling people living with dementia (PLWD) and have devastating effects on the health and quality of life of not only those diagnosed, but also on caregivers (Banerjee et al., 2006; Cerejeira et al., 2012; Fonareva & Oken, 2014; Majer et al., 2019). BPSD represent a major societal issue as they account for a large portion (~30%) of the $305 billion in total annual healthcare costs of ADRD care in the United States (Alzheimer's Association, 2021; Hurd et al., 2013; Schnaider et al., 2002).

Background

Although ADRD are typically considered cognitive related conditions, ADRD can have devastating effects on many other components of life including physical, functional, behavioral, and social health. BPSD is a distinct cluster of symptoms that is considered one of the most debilitating aspects of ADRD that has proven to be very difficult to treat by clinicians and is a major contributing factor to early institutionalization (Stall et al., 2019). Throughout this dissertation BPSD is conceptualized as a multidimensional cluster of many different types of non-cognitive symptoms and behaviors that result from changes in and interactions between cognitive, environmental, social, functional, neurologic, physiologic, and psychologic factors (Cloak & Khalili, 2020). In this way, BPSD are multifactorial and distinct from other symptoms of ADRD such as declining memory and impaired comprehension. As BPSD are known to significantly increase the burden of having ADRD and of caring for someone with the disease (Majer et al., 2019), this dissertation focuses specifically on BPSD as opposed to other hallmark symptoms of ADRD such as cognitive decline.

BPSD include a variety of symptoms and behaviors including agitated, aggressive, depressive, psychotic, manic, and apathetic types (McShane, 2000). Psychotropic medications are commonly prescribed to manage BPSD but have minimal effectiveness and are associated with several life-threatening risks including, falls, fractures, injuries and in worst cases, death in older adults with ADRD (Defrancesco et al., 2015; Jeste et al., 2008; Seyfried et al., 2011; Van Strien et al., 2013). Due to the ineffectiveness and many dangers associated with pharmacologic interventions, current practice guidelines and recommendations emphasize non-pharmacologic care strategies as first line treatment of BPSD (Austrom et al., 2018; Reus et al., 2016). Many non-pharmacologic strategies have demonstrated effectiveness in reducing BPSD experienced by PLWD in controlled clinical trials (e.g., caregiver education, training and skills building programs, multicomponent interventions comprised of 2 or more non-pharmacologic interventions, psychological and psychosocial support interventions) (Dyer et al., 2018; Trivedi et al., 2018). Despite the availability of research in support of non-pharmacologic interventions for treating BPSD, there has been limited implementation and sustained use in the community. This limited use may be due to inadequate use of theory in the development and testing of non-pharmacologic interventions, limitations in the feasibility of these interventions for the community setting and the degree of acceptance by PLWD and their family caregivers (Gitlin et al., 2015). Further research is needed to evaluate safe, feasible, effective, theory-based non-pharmacologic interventions that will be accepted and used by PLWD and their caregivers in real world, community settings (Gitlin et al., 2016; Gitlin et al., 2010).

This dissertation focuses on a specific class of non-pharmacologic interventions, that being sensory stimulation therapies. Sensory stimulation uses objects and tools to arouse at least one of the five sense (i.e., hearing, sight, smell, taste, touch) with the intent of promoting positive feelings and well-being (Strøm et al., 2016). Even more specifically, this dissertation explores the potential of acutherapy and weighted blankets as non-pharmacologic care strategies for PLWD. Acutherapy involves stimulation of multiple points across the body with manual hand pressure, needles, or other tools to promote healing and comfort. Weighted blankets are similar to traditional comforters but have added weight (they typically weigh between 10-15 pounds) and are designed to apply stimulation to broad areas of the body (these therapies are further described in the Theoretical Foundations section of this chapter).

Acutherapy has been shown to be a safe care strategy for older adults with ADRD and has demonstrated improvements in psychological outcomes among non-cognitively impaired adults, including those with psychiatric conditions (Kim et al., 2013; Smith et al., 2018). Despite the high degree of safety and potential for therapeutic effects, there is limited research on acutherapy among community dwelling PLWD (Zhou et al., 2015). Additionally, the overall effects of acutherapy on BPSD demonstrated in prior research has not been synthesized, likely precluding further research and widespread implementation.

Weighted blankets have been shown to be safe for use by older adults (Parker, 2016), and have demonstrated improvements in psychological outcomes and well-being among older adults without cognitive impairment (Eron et al., 2019). Yet no previous studies have explored the effects of weighted blankets on BPSD. As this population has the potential to benefit from safe in-home care strategies, there is a critical need for research to explore the potential of these sensory stimulation therapies for community dwelling PLWD.

A critical step to intervention development is to first understand the needs and preferences of the target population (Sekhon et al., 2017). As community dwelling PLWD receive most of their care from family caregivers, understanding the lived experiences of family caregivers represents a key piece of the puzzle to identifying the needs of PLWD. Although the experiences of family caregivers' of PLWD are known to be distinct from caregivers of people with other chronic conditions, prior research demonstrates that there is a gap in the prioritization of insights, perceptions, and needs of family caregivers of PLWD in BPSD management research (Feast et al., 2016).

The COVID-19 pandemic that began in the Spring of 2020 added another layer of complexity to in home care for families affected by ADRD, given that restrictions were placed on many of the in-person support services, healthcare programs, and community resources often used by PLWD and their families. Given this decreased access to care supports, older adults with ADRD and their family caregivers have experienced unique pandemic-related stress (Cohen et al., 2020). To further inform intervention development designed for the home setting, it is necessary to identify care needs both in general, and those that emerged due to the pandemic. It is essential to reach a deeper understanding of unique experiences of PLWD and their caregivers to inform intervention development as well as community focused ADRD research more broadly.

Statement of the Problem

Many non-pharmacologic interventions tested among community dwelling PLWD have demonstrated improvements in BPSD but these interventions have had minimal uptake and sustained use in the community (Gitlin et al., 2015). This limited use in the community may be due to the lack of feasibility and acceptability of these interventions by PLWD and their family caregivers. Sensory stimulation therapies, including acutherapy and weighted blankets are safe non-pharmacologic care strategies that have shown improvements in a variety of outcomes among non-cognitive impaired older adults, but there is a paucity of studies examining these interventions for community dwelling PLWD and limited focus on BPSD outcomes (Eron et al., 2019; Strøm et al., 2016; Smith et al., 2018). Exploring the perceptions of family caregivers has not always been prioritized in BPSD management research but is necessary to understand the needs of community dwelling PLWD and their families. This information is needed to maximize the potential of developing interventions that will be accepted and used by families affected by ADRD, particularly during the COVID-19 pandemic which has posed new challenges to in-home care.

The Purpose

The purpose of this research was to explore the use of non-pharmacologic care strategies, specifically acutherapy and weighted blankets as potential interventions for treating BPSD among PLWD, with a specific focus on community dwelling PLWD and their family caregivers. To accomplish this overarching goal, this research was carried out in three phases and is presented through 3 papers of this dissertation. The first phase (Paper 1) was to identify, examine and synthesize the state of the science relating to acutherapy and its effects on behavioral and psychological symptoms among older adults with ADRD using a scoping review methodology (Aim 1).

The second phase (Paper 2) explored perspectives of family caregivers of community dwelling older adults with ADRD regarding their caregiving experiences, BPSD displayed by the person with ADRD, and their use of non-pharmacologic interventions for BPSD management in the home (Aim 2). Also explored were the changes in family caregivers' experiences, BPSD displayed by their family members with ADRD, and BPSD management strategies used during the COVID-19 pandemic (Aim 3).

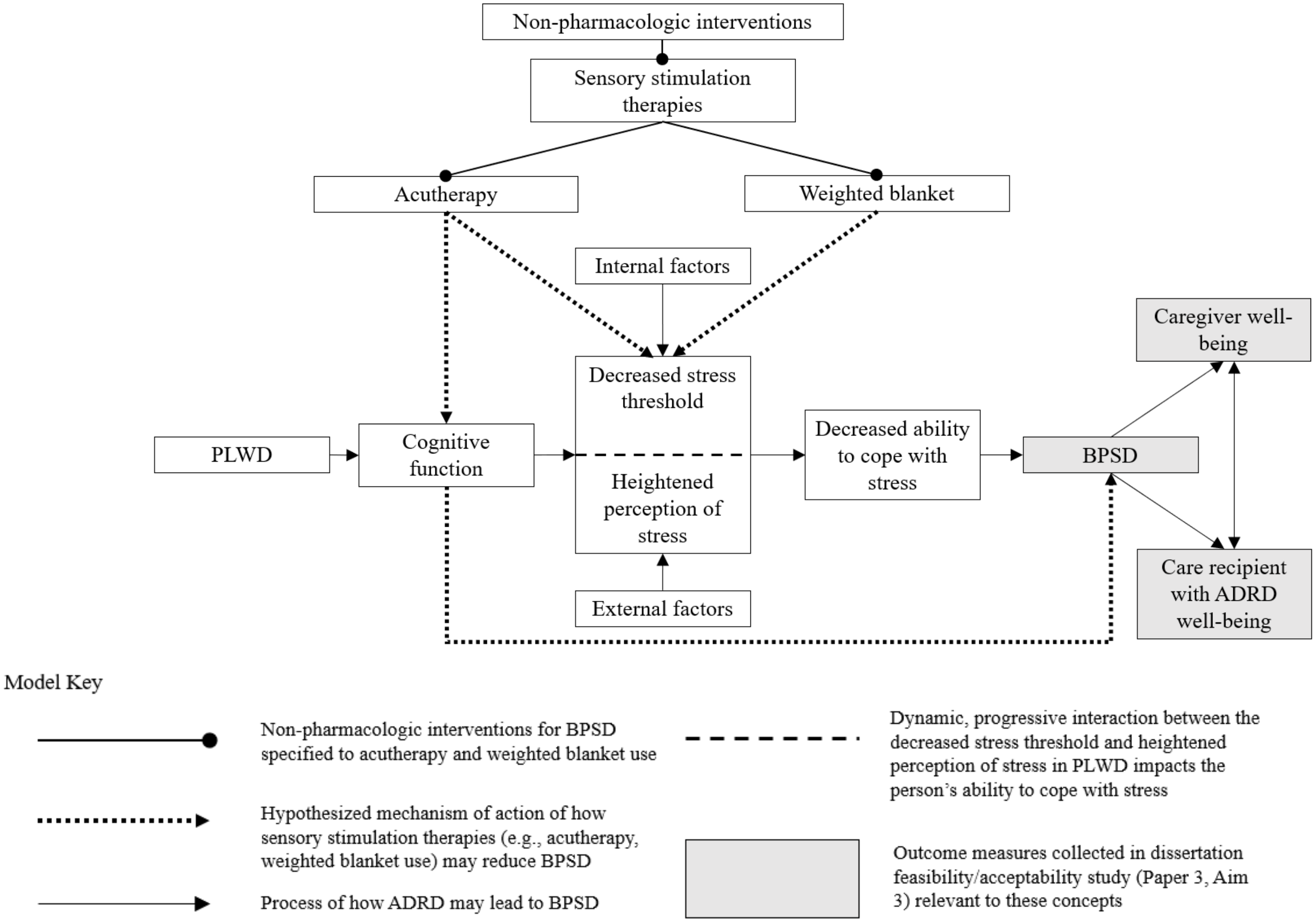
The third phase (Paper 3) was comprised of three components. First, to explore the initial perceptions of family caregivers regarding weighted blankets as an in-home care strategy for PLWD following a brief description and visual presentation of weighted blankets (Aim 4). Second, to explore the feasibility and acceptability of a virtually delivered in-home weighted blanket intervention for older adults with ADRD living in the community as perceived by the family caregiver and the person with ADRD (Aim 5). Third, to examine the feasibility of collecting outcome measures of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health status of family caregivers (Aim 6).

Theoretical Foundations

Theoretical and conceptual frameworks are important for intervention research to help identify related factors, predict, and interpret behaviors, and evaluate potential relationships among variables (Foy et al., 2007). There has been limited research focused on sensory stimulation therapies among community dwelling individuals with ADRD and no universal theory exists on the use of these therapies for reducing BPSD in this population. A conceptual framework was developed for this dissertation research (See Figure 1.1) that is based on prior theoretical models used to understand the occurrence of BPSD (Algase et al., 1996; Hall & Buckwalter, 1987), and current research on non-pharmacologic interventions for reducing BPSD among community dwelling PLWD, as well as sensory stimulation therapies for improving outcomes among PLWD (Haigh & Mytton, 2015; Kwan et al., 2016, 2017; Strøm et al., 2016). This framework also incorporates research focused on the effects of BPSD on family caregivers and the relationship between the well-being of care recipients with ADRD and their caregivers (Campbell, J., 2009; Griffin et al., 2019; Kershaw et al., 2015; Lyons & Lee, 2018; Noel et al., 2015).

Figure 1.1

Conceptual Framework of Sensory Stimulation Therapies for Reducing Behavioral and Psychological Symptoms of Dementia



Note. ADRD, Alzheimer's disease and other related dementias, BPSD, behavioral and psychological symptoms of dementia, PLWD person living with dementia

Table 1.1
Concepts and Conceptual Definitions Included in Framework of Sensory Stimulation Therapies for Reducing Behavioral and Psychological Symptoms of Dementia

Concepts	Conceptual Definitions
Person living with dementia (PLWD)	An individual diagnosed with Alzheimer's disease or related dementias (e.g., vascular dementia, frontotemporal dementia, dementia with Lewy bodies, Parkinson's disease dementia and mixed-type dementia), defined as chronic, progressively debilitating, neurodegenerative diseases that affect not only cognitive function, but also physical, psychological, behavioral, and social function (National Institute on Aging, 2019).
Cognitive function	A mental action or process of acquiring knowledge and understanding through thought, experience, and the senses, which includes interrelated functions including attention, memory, language, perception, decision making and problem solving (Glisky, 2007).
Decreased stress threshold	Decreased ability to tolerate stress due to neurocognitive changes resulting from the progression of cognitive decline in ADRD (Hall & Buckwalter, 1987; Smith et al., 2004).
Heightened perception of stress	Increased reception and perception of stressful stimuli due to neurocognitive changes resulting from the progression of cognitive decline in ADRD (Hall & Buckwalter, 1987; Smith et al., 2004).
Decreased ability to cope with stress	Decreased ability to manage and respond to stress due to the Progressively Lowered Stress Threshold inherent in dementia, which results from the dynamic interaction between the decreased stress threshold and heightened perception of stress in people with ADRD (Hall & Buckwalter, 1987; Smith et al., 2004).
Internal factors	Individual level characteristics, conditions and behaviors that can impact a person's stress threshold and perception of stress (e.g., health status, demographics, psychosocial characteristics, physiologic needs, psychosocial needs) (Algase et al., 1996; Judge et al., 2009).
External factors	Characteristics, behaviors, and conditions that are external to the individual that can impact a person's stress threshold and perception of stress (e.g., physical environment, caregiver behaviors, contextual characteristics, social environment) (Algase et al., 1996; Judge et al., 2009).
Behavioral and psychological symptoms of dementia (BPSD)	Non-cognitive symptoms of disturbed perception, thought content, mood, and/or behavior resulting from the decreased ability to manage and respond optimally to stress (Cerejeira et al., 2012; Steinberg et al., 2008)
Caregiver well-being	Multicomponent concept comprised of caregiver health status, assets, and resources from a strength-based perspective. Health status encompasses physical and mental well-being, while assets and resources include a basic needs dimension and an activities of daily living dimension (George & Gwyther, 1986; Tebb, 1995).
Care recipient with ADRD well-being	Multifaceted concept reflective of the quality of life of the person with ADRD, which is composed of interpersonal, environmental, function, physical and psychological domains (Lawton, 1997).
Non-pharmacologic interventions	Methods and approaches to managing symptoms and disease without the use of drugs or medications
Sensory stimulation therapies	Therapies that use everyday objects and tools to arouse at least one of the five sense (i.e., hearing, sight, smell, taste, touch) with the intent of promoting positive feelings and well-being (Strøm et al., 2016).
Acutherapy	Any therapy that involves the stimulation of acupoints with the intent of having a therapeutic effect on an individual's experience of symptoms or disease
Weighted blanket	The use of weighted blankets, which are deep pressure, tactile stimulation tools that are similar traditional comforters with added weighted that typically weigh between 10-15 pounds

Description of the Model

Figure 1.1 outlines the conceptual framework, which incorporates concepts and relationships from multiple areas of study including the following: the Progressively Lowered Stress Threshold (PLST) model (Hall & Buckwalter, 1987), the need driven dementia-compromised behavior model (Algase et al., 1996), non-pharmacologic intervention research in community dwelling older adults with ADRD, intervention studies on sensory stimulation therapies for people with ADRD (Harris et al., 2019; Trivedi et al., 2018; Zhou et al., 2015), and research on family caregivers of people with ADRD (Bom et al., 2019; Kershaw et al., 2019; Norton et al., 2009). Concepts and definitions are listed in Table 1.1. The following narrative describes the concepts in the model and provides evidence to support hypothesized relationships of how sensory stimulation therapies may reduce BPSD.

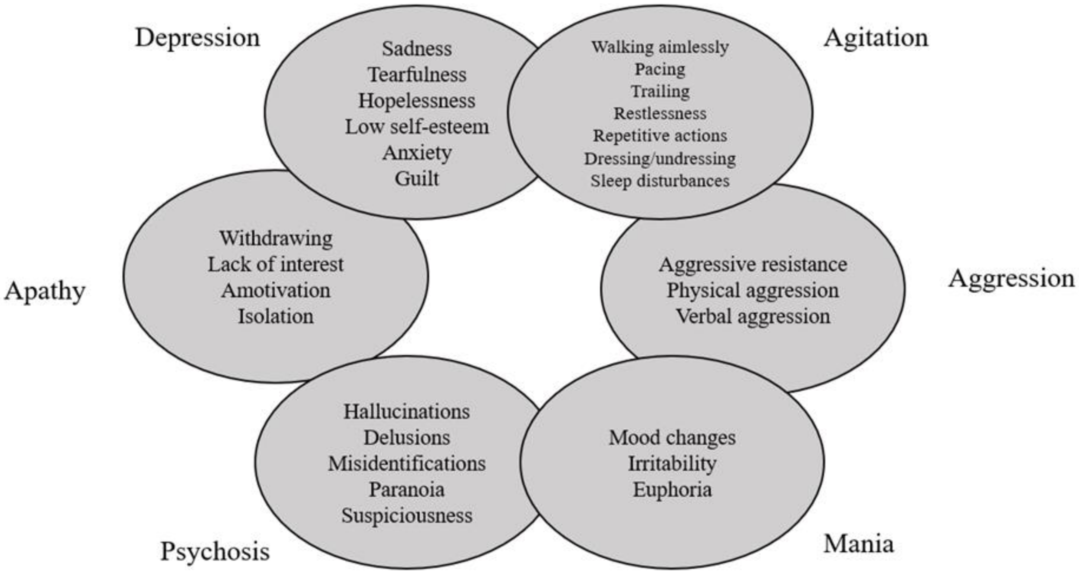
Occurrence of BPSD

BPSD is a broad, multidimensional concept composed of clusters of behaviors and symptoms such as agitation, aggression, depression, psychosis, mania, and apathy (See Figure 1.2). Even healthy people may experience behavioral and psychological symptoms at any given time, but research supports that PLWD are increasingly susceptible to such symptoms due to changes in cognitive and physiologic processes related to ADRD (Hall & Buckwalter, 1987).

Figure 1.2, modified from McShane (2000) illustrates examples of the different clusters of behaviors and symptoms of BPSD (Finkel et al., 1997; McShane, 2000). Examples of verbal aggression include those such as screaming, cursing or verbal threats, while examples of physical aggression include hitting, kicking, pushing, scratching or grabbing. Individuals may experience a single or multiple symptoms and behaviors of BPSD at the same time (e.g., physically kicking and verbally threatening to resist assistance with care). There can also be overlap among symptom and behavior types. For example, sadness and hopelessness commonly labeled as depression, may overlap with apathetic type behaviors such as isolating and withdrawing from social activities.

Figure 1.2

Clusters and Examples of Behavioral and Psychological Symptoms of Dementia



This conceptual framework supports that BPSD occur as a response to stress. According to the Progressively Lowered Stress Threshold model, individuals with ADRD have a heightened perception of stress and a decreased tolerance for stress, referred to as a progressively lowered stress threshold (Hall & Buckwalter, 1987). The progressively lowered stress threshold results from neurocognitive changes in the brain that are associated with cognitive decline, which impact a person’s ability to receive, process, and respond to stressful stimuli (Hall & Buckwalter, 1987). The need-driven dementia-compromised behavior model, another commonly used theoretical model to understand BPSD, posits that internal (e.g., unmet physiologic, psychologic and social needs, cognitive and neurological factors, health status and psychosocial factors) and/or external factors (e.g., physical environmental characteristics and conditions, social environment characteristics, sensory overload, under stimulation, interactions with caregivers, caregiver reactions) can influence manifestations of disruptive, need driven behaviors in individuals with ADRD (Algase et al., 1996; Judge et al., 2009).

When applied to the PLST model, these internal and external factors are hypothesized to influence the individual's heightened perception and decreased tolerance for stress. Together, the heightened perception and decreased tolerance for stress decreases the person's ability to cope with stress resulting in an accumulation that manifests as an array of behavioral and psychological symptoms (Hall & Buckwalter, 1987; Smith et al., 2004).

The PLST model was developed to educate caregivers and care teams on environmental and behavioral modifications that can be made to reduce environmental stress and BPSD. It has also been used to support interventions, such as massage, therapeutic touch and music therapy that are designed to affect sensory-related factors that influence the stress level among PLWD (Cheung et al., 2011; Kim & Buschmann, 1999, 2004).

Non-Pharmacologic Interventions for Community Dwelling PLWD

Many intervention studies have tested non-pharmacologic interventions for treating BPSD in community dwelling older adults with dementia, yet classification systems and definitions of non-pharmacologic interventions have been inconsistent and oftentimes unclear across prior research (Aguirre et al., 2013; Bahar-Fuchs et al., 2013; Bahar-Fuchs et al., 2019; Barreto et al., 2018; Carrion, Folkvord et al., 2018; Deshmukh et al., 2018; Huang et al., 2015; Livingston et al., 2014; Noone et al., 2019; Regan & Varanelli, 2013; Trivedi et al., 2018; Woods et al., 2018). Only one review article included acutherapy as a potential non-pharmacologic treatment option for BPSD (Oliveira et al., 2018), while no reviews included weighted blankets.

Classification System. I developed a classification system based on a database search and prior reviews of non-pharmacologic interventions for BPSD in community-based settings. In this classification system, non-pharmacologic interventions for BPSD are classified the following types: caregiver education, training and skills-building programs (e.g., behavioral management education and training, communication skills training, home safety and environmental skills building education), cognitive-theory based therapies (e.g., cognitive stimulation therapy, cognitive rehabilitation), multicomponent interventions (e.g., combined non-pharmacologic approaches such as education and psychosocial support, music and exercise programs, combined reminiscence and music therapies), physical exercise and activity (e.g., Tai Chi, individualized walking programs, chair based yoga), psychological and psychosocial support programs (e.g., reminiscence therapy, caregiver support groups, mental health counseling), sensory stimulation therapies (e.g., art therapy, music therapy, massage, therapeutic touch, acutherapy), sleep improvement programs (e.g., bright light therapy, sleep education programs), and system or organizational level programs (e.g., collaborative care planning, interdisciplinary transitional care, case management programs). Definitions for each of these classes, along with examples and relevant reviews and studies are in Table 1.2.

Sensory Stimulation Therapies

Sensory stimulation therapies, the focus of this dissertation, involve use of objects and tools to arouse at least one of the five senses (i.e., hearing, sight, smell, taste, touch) with the goal of promoting positive feelings and well-being (Strøm et al., 2016). Examples of sensory stimulation therapies tested with community dwelling PLWD include art therapy, music therapy and multi-sensory stimulation therapies (also referred to as Snoezelen therapy) (Deshmukh et al., 2018; Trivedi et al., 2018; Ueda et al., 2013).

There has been limited research conducted on sensory stimulation therapies for treating BPSD in community dwelling PLWD (Trivedi et al., 2018). Yet, there is research that supports that sensory stimulation therapies can reduce challenging behaviors and improve emotional well-being, as well as other important outcomes such as quality of life and functional ability in PLWD residing in long term care settings (Haigh & Mytton, 2015; Strøm et al., 2016). Systematic reviews have recommended additional research be conducted focused on sensory stimulation therapies in PLWD residing in the community with broader outcomes examined, such as BPSD and quality of life (Haigh & Mytton, 2015; Strøm et al., 2016; Trivedi et al., 2018).

Table 1.2

Classification System of Non-Pharmacologic Interventions for BPSD Management in Community Dwelling Older Adults with ADRD

Classification Category	Definition	Example(s) of Intervention Types in the Classification Category	Examples of Reviews and Studies Testing These Types of Interventions *
Caregiver education, training and skills building programs	Programs designed to promote caregivers' understanding and ability to care for the care recipient with ADRD through education, training and/or skills building activities.	Functional behavioral analysis interventions Behavioral management education and training Dyadic communication skills training Home safety and environmental skills-building and education	Corbett et al. (2012) Eggenberger et al. (2013) Gitlin et al. (2001) Gitlin et al. (2003) Gitlin et al. (2005) Moniz Cook et al. (2012)
Cognitive theory-based interventions	Interventions aimed at assessing and modifying cognition as a means of changing how people think, feel, and behave (Bahar-Fuchs et al., 2013)	Cognitive stimulation therapy-engagement in a range of activities and discussions aimed at general enhancement of cognitive and social function. Cognitive training- guided practice on a set of standardized tasks designed to reflect cognitive function. Cognitive rehabilitation-individualized approach to help people with cognitive impairments to identify personal goals and devise strategies to address them.	Aguirre et al. (2013) Bahar-Fuchs et al. (2013) Bahar-Fuchs et al. (2019) Gonyea et al. (2016) Kwok et al. (2014) Paddick et al. (2017)
Multicomponent interventions	Programs that consisted of two or more non-pharmacologic approaches to manage behavior and/or improve cognitive function, without solely using medication.	Combined exercise and music therapy interventions Education or training combined with psychological support groups for caregivers Use of art and music therapy to invoke reminiscence and discussion of past life events	Brodaty & Arasaratnam, (2012) Chew et al. (2015) Han et al. (2017) Cheung et al. (2015) Fernandez-Calvo et al. (2015) Gitlin et al. (2018) Koivisto et al. (2015) Novelli et al. (2018) Oliveira et al. (2018) Prick et al. (2016)
Physical exercise and physical activity	Interventions designed to promote bodily movement by skeletal muscles that requires energy expenditure (World Health Organization, 2020).	Tai Chi Individualized walking programs Group-based chair yoga	Barreto et al. (2015) Forbes et al. (2015) Hoffmann et al. (2016) Park et al. (2019) Canonici et al. (2012) D'Amico et al. (2015)

Psychological and psychosocial support programs	Programs designed to promote the psychological and/or social factors, condition and/or experiences of individuals through individual and/or group level therapeutic processes Noone et al. (2019).	Reminiscence therapy Caregiver support groups Mental health counseling Spiritual support programs	Huang et al. (2015) Woods et al. (2018) Noone et al. (2019) Orgeta et al. (2014) Regan & Varanelli (2013) Van't Leven et al. (2013) Young et al. (2014) Robinson et al. (2018)
Sensory stimulation therapies	Therapies that use everyday objects and tools to arouse at least one of the five senses (i.e., hearing, sight, smell, taste, touch) with the intent of promoting positive feelings and well-being (Strøm et al., 2016).	Art therapy Music therapy Snoezelen multi-sensory therapy Massage Therapeutic touch Acutherapy	Deshmukh et al. (2018) Ueda et al. (2013) de la Rubia Orti (2018) Ihara et al. (2018) Holden et al. (2019)
Sleep improvement programs	Programs designed to improve overall sleep and/or sleep hygiene practices among people with ADRD	Bright light therapy Manual-based sleep education program for family caregivers	Forbes et al (2015) Kinnunen et al. (2018)
System and organizational level programs	Programs designed to provide support to diagnosed individuals with ADRD and their caregivers through interdisciplinary collaboration through hospitals and other organizational settings. (Trivedi et al., 2018).	Collaborative care planning Interdisciplinary transitional care programs Case management programs	Callahan et al., 2006 Chien & Lee, 2008 Lam et al., 2010 Spijker et al., 2011 (Studies are included in Trivedi et al. 2018 review)

*The studies listed here are only meant to provide examples of studies that evaluated the different types of non-pharmacologic interventions. This list is not exhaustive and is not reflective of all identified articles, as some reviews evaluated non-pharmacologic interventions as a whole, not specific types.

Acutherapy

Acutherapy is a specific type of sensory stimulation therapy that is rooted in Traditional Chinese Medicine that is being increasingly used in bio-medical based healthcare systems (García-Escamilla et al., 2015). Acutherapy is unique from other touch based sensory stimulation therapies, including massage and therapeutic touch, as it involves the stimulation of multiple, targeted acupoints across the body, as opposed to broad area pressure application (Smith et al., 2013). Acupoints can be targeted using manual hand pressure, threadlike needles, massage tools, electrical stimulation, or low-grade lasers. Acutherapy is an umbrella term that includes several techniques including needle acupuncture, acupressure, and laser acutherapy (Kaptchuk, 2002; Smith et al., 2013).

Weighted Blankets

Weighted blankets are comparable to traditional comforters but are filled with weighted pellets and typically weigh between 10-15 pounds. They are a safe, non-invasive form of deep pressure tactile, or touch stimulation therapy and are a tool to apply stimulating pressure to broad areas of the body (Eron, 2020). Weighted blankets are commonly used in hospital and long-term care settings, but there is no standardization for use across clinical settings. This lack of standardization may be due to limited research on weighted blankets in general which is needed to support evidence-based guidelines.

Hypothesized Mechanisms of Action. This conceptual framework hypothesizes two mechanisms by which sensory stimulation therapies may decrease BPSD. One mechanism is by decreasing stress in the PLWD, the second is by directly improving or maintaining cognitive function. Described below is the research in support of acutherapy and weighted blankets in reducing stress, as well as acutherapy for maintaining, and in some cases improving cognitive function

Acutherapy and Stress. Acutherapy has been tested with demonstrated improvement in signs and symptoms of many physiologic and psychologic stress-related conditions in non-cognitively impaired individuals. Examples of stress-related physiologic conditions improved by acutherapy include gastrointestinal motility disorders, obesity, hypertension, headaches, migraines, and infertility (Balk et al., 2010;

Cho et al., 2009; Flachskampf et al., 2007; Linde et al., 2016; Melchart et al., 1999; Sparrow & Golianu, 2014; Yin & Chen, 2010). Stress-related psychologic conditions that have demonstrated improvements include post-traumatic stress disorder, insomnia, depression, and anxiety (Cao, Pan, Li, & Liu, 2009; Kim et al., 2013; Pilkington et al., 2007; Smith et al., 2018; Sok et al., 2003). Needle acupuncture specifically has demonstrated significant reductions in depression, anxiety, and stress related symptoms among older adults (Pavão et al., 2010).

Weighted Blankets and Stress. Research demonstrates that broad, deep pressure touch stimulation increases the arousal of the parasympathetic nervous system, while also reducing sympathetic arousal (Chen et al., 2016; Reynolds et al., 2015). The increase in parasympathetic arousal is hypothesized to have a calming effect, while the decrease in sympathetic arousal is associated with changes in physiological processes that dampen the body’s physiologic stress response (Chen et al., 2016; Mullen et al., 2008; Reynolds et al., 2015). Daily use of weighted blankets has shown reductions in stress-related psychologic and physiologic symptoms among non-cognitively impaired older adults with mental health conditions (Champagne et al., 2015; Mullen et al., 2008). Regular nightly use of weighted blankets has demonstrated improvements in overall sleep maintenance, depression, anxiety and reduction in daytime fatigue in non-cognitively impaired adults with a variety of mental health conditions (e.g., insomnia, major depressive, generalized anxiety, attention deficit hyperactivity, and bipolar disorders) (Ekholm et al., 2020). As there is a strong association between stress and sleep disturbances among older adults with ADRD (Porter, 2015; Webster, 2019), the effects of weighted blankets on sleep outcomes are important to hypothesizing about how they may improve BPSD among PLWD.

Sensory Stimulation Therapies and Stress. The research in support of the positive effects of acutherapy and weighted blankets on stress-related psychologic conditions, particularly on depression and anxiety, is important to support the relationship between sensory stimulation therapies and BPSD in this model. Prior research show that a strong association exists between ADRD and depression, while depression is both a risk factor and a symptom of ADRD (Snowden et al., 2015; Enache et al., 2011; Leyhe, 2017). There is also a substantial overlap between symptoms of depression and anxiety among individuals with ADRD (Qazi et al., 2017; Sibley et al., 2021).

Stress induced chronic inflammation is proposed to play an important role in the development of depression, anxiety and ADRD (Bisht et al., 2018; Dafsari & Jessen, 2020; Hermida et al., 2012; Salim et al., 2012), which explains the association between physiologic stress-related chronic inflammatory diseases, such as cardiovascular diseases with ADRD (Cunningham & Hennessy, 2015; Newman et al., 2005). Prior research supports that acutherapy and deep pressure therapies have anti-inflammatory effects at the cellular level (Chen et al., 2016; Kavoussi & Ross, 2007; McDonald et al., 2015), which is the hypothesized mechanism by which sensory stimulation therapies affects symptoms experienced by non-cognitively impaired individuals with depression and anxiety (Lu et al., 2016; Pilkington, 2013; Sun et al., 2010).

Given the strong associations between depression and ADRD, along with the high degree of potential overlap of depressive, anxious and ADRD-related symptoms, the research in support of the effects of acutherapy and weighted blankets on depression and anxiety in non-cognitively impaired people is highly relevant. These relationships are significant to hypothesizing the potential effects on symptoms experienced by PLWD. This model posits that mechanisms similar to that of other psychologic diseases (e.g., depression and anxiety), sensory stimulation therapies can improve symptoms of ADRD through the stress and inflammatory process. In this model, the PLST framework is used to encompass the stress process, as it has been tested and is widely used in ADRD related intervention research.

Two acutherapy intervention studies have evaluated stress as an outcome in older adults with ADRD after receiving acupressure therapy, both showed statistically significant reductions ($p<0.05$) in cortisol levels (a biomarker for stress) during and after the therapy intervention periods (Kwan et al., 2016, 2017). These studies also demonstrated reductions in the specific BPSD of agitation. These findings, along with the PLST framework and research on acutherapy and deep pressure therapies for stress-related psychologic conditions, support the relationship between sensory stimulation therapies, the Progressively Lowered Stress Threshold (PLST), and BPSD. Although biomarkers of stress were not measured in the feasibility study (Paper 3, Aims

2 and 3) of this dissertation, stress remains an important component in the model and represents a potential area of future research to explicate the mechanism by which sensory stimulation therapies such as acutherapy and weighted blankets may reduce BPSD.

Cognitive Function and BPSD. A second hypothesized mechanism of acutherapy on BPSD is by directly improving or maintaining cognitive function. As illustrated in this model, interventions such as acutherapy that potentially improve or maintain cognitive function in PLWD may also act through other neurochemical and neuropathological processes that ultimately reduce BPSD (Casanova et al., 2011).

Acutherapy and Cognitive Function. Declining cognitive function has been consistently linked to increasing BPSD frequency and severity (Lövheim et al., 2008; Majer et al., 2019; Thompson et al., 2010). Meanwhile, non-pharmacologic intervention research, including acutherapy studies, have demonstrated improvements in cognitive function in people with ADRD specifically (Zhou et al., 2015). A study examining needle acupuncture in individuals with ADRD used functional magnetic resonance imaging to explore the physiologic mechanism of acupuncture for treating cognitive impairment in individuals with Alzheimer’s disease and mild cognitive impairment (MCI). Results showed that during and immediately after acupuncture therapy sessions, individuals with MCI and Alzheimer’s disease demonstrated activation of multiple regions of the brain, specifically the frontal and temporal lobes, which are responsible for recognition, memory, and cognition (Wang et al., 2012). Other acutherapy studies have demonstrated significant improvements in both cognitive function and BPSD (Jia et al., 2017; Kwok et al., 2013; Rodríguez-Mansilla et al., 2015; Shi et al., 2015; Wang, Qin, & Yu, 2014). This research provides support for the relationship between acutherapy and cognitive function, as well as the direct relationship between cognitive function and BPSD.

Caregiver Well-Being and Care Recipient Well-Being

Family caregivers play a critical role in providing care for PLWD in the community, but ADRD caregiving can come at a significant cost. BPSD have consistently been shown to be a major factor related to increased caregiver burden (Campbell et al., 2008; Liu et al., 2017; Matsumoto et al., 2007), worsened self-reported health of caregivers

(Son et al., 2007), and decreased quality of life of caregivers and care recipients with ADRD (Brodaty & Donkin, 2009; Hurt et al., 2008). Caregiver well-being is a concept in this model used to encompass many dimensions related to the overall health, basic needs, and functional ability. Caregiver well-being is conceptualized as a broad, multifaceted concept composed of dynamic relationships and interactions between caregiver physical health, mental health, assets, and resources (George & Gwyther, 1986).

There is an interdependent, dynamic relationship between the well-being of individuals with ADRD and their family caregivers (Harris et al., 2020; Bom et al., 2019; Kershaw et al., 2019; Graham & Bassett, 2006; Norton et al., 2009; Stall et al., 2019). Increased caregiver distress is associated with several negative care recipient specific outcomes, such as early institutionalization, worsening cognition, mood and quality of life, increased healthcare utilization and costs (Stall et al., 2019). Meanwhile, care recipient specific factors such as functional ability and degree of symptom severity are associated with overall caregiver well-being (Kang et al., 2014; Miyamoto et al., 2010). For these reasons, the concept of caregiver well-being is included in this framework, bidirectionally associated with the well-being of the care recipient with ADRD and unidirectionally linked to BPSD.

The lack of a conceptual and theoretical framework on sensory stimulation therapy for ADRD and BPSD limits the understanding of key concepts and relationships, thus restricting the development and applicability of these interventions in research and practice. This conceptual framework was developed for this dissertation research to link the current research on sensory stimulation therapies with prior theoretical models that advance the understanding of BPSD. As this framework identifies and delineates concepts and hypothesized relationships, it was used in this dissertation and will be used in future research to develop sensory stimulation therapy interventions for BPSD. This model also prioritizes family caregivers, who act as key stakeholders in understanding and advancing care for PLWD in the community, which promotes the applicability and usefulness of this research to community-based settings (White et al., 2018). This model was used to guide outcome measurement selection to ensure that key components of the framework were captured in the weighted blanket intervention feasibility and acceptability study (Paper 3) of this dissertation research.

Specific Aims

To achieve the overall purpose of this dissertation, the following aims were used to guide this research.

Aim 1

Identify, examine, and synthesize the state of the science relating to the effects of acutherapy on BPSD. (Paper 1)

Aim 2

Explore the perspectives and experiences of family caregivers of community dwelling older adults with ADRD regarding BPSD and use of non-pharmacologic interventions for BPSD management. (Paper 2)

Aim 3

Explore the perspectives and experiences of family caregivers of community dwelling older adult family members with ADRD regarding changes in their caregiving experiences, BPSD displayed by their family member with ADRD, and BPSD management strategies used during the COVID-19 pandemic. (Paper 2)

Aim 4

Explore the initial perceptions of family caregivers regarding weighted blankets as an in-home care strategy for community dwelling older adults with ADRD following a brief description and visual presentation of weighted blankets. (Paper 3)

Aim 5

Examine the feasibility and acceptability of a virtually delivered, in-home weighted blanket intervention for older adults with ADRD living in the community as perceived by the family caregiver and the person with ADRD. (Paper 3)

Aim 6

Examine the feasibility of collecting outcome measures of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health status of family caregivers. (Paper 3)

Overview of Dissertation Research Papers, Chapters and Study Designs

Chapter 2 presents the first paper of this dissertation titled, *Acupuncture and Acupressure for Dementia Behavioral and Psychological Symptoms: A Scoping Review*. A scoping review methodology was used to identify, examine, and synthesize the state of the science on acutherapy and its effects on behavioral and psychological symptoms among older adults with ADRD (Aim 1). Findings of this review were first published in the Western Journal of Nursing Research in December 2019 (Harris, Titler, & Struble, 2019).

Chapter 3 paper 2 of this dissertation titled, *Perceptions of Family Caregivers of Older Adults Living with Dementia Regarding Behavioral and Psychological Symptoms of Dementia and the Impact of the COVID-19 Pandemic.* This study used a qualitative, exploratory approach using virtual semi-structured interviews with family caregivers who lived with older adults with ADRD. The purpose of these interviews was to explore caregivers' perceptions and experiences regarding BPSD experienced by their relatives with ADRD, non-pharmacological strategies they used to address these symptoms and how helpful these strategies were to better manage challenging symptoms (Aim 2). Furthermore, interviews explored how the COVID-19 pandemic affected caregivers' experiences in caring for their family member with ADRD, the BPSD their family member experienced, and strategies they used to manage BPSD (Aim 3).

Chapter 4 is the third paper of this dissertation titled, *Examining the Feasibility and Acceptability of a Virtually Delivered In-Home Weighted Blanket Intervention for Older Adults Living with Dementia and their Family Caregivers.* This study used two designs, the first being the same qualitative approach that was used in paper 2 with the aim of exploring the initial perceptions of family caregivers regarding weighted blankets as an in-home care strategy for community dwelling older adults with ADRD following a brief description and visual presentation of weighted blankets (Aim 4). A prospective, within subjects, pre-post design was used to examine the feasibility and acceptability of a virtually delivered, in-home weighted blanket intervention for older adults with ADRD living in the community as perceived by the family caregiver and the person with ADRD (Aim 5). This feasibility and acceptability study also examined the feasibility of collecting outcomes of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health status of family caregivers (Aim 6).

Chapter 5 concludes this dissertation by summarizing and synthesizing the findings across all 3 papers (Chapter 2, 3 and 4) by linking the findings back to the conceptual framework. This chapter also presents the significance of the overall findings of this dissertation, the strengths and limitations, and future directions for this area of research.

CHAPTER II

Acupuncture and Acupressure for Dementia Behavioral and Psychological Symptoms: A Scoping Review

Introduction

The projected number of people diagnosed with Alzheimer's disease or related dementias (ADRD) is anticipated to reach 92 million by 2030 and jump to 152 million by 2050 (World Health Organization, 2020). Behavioral and psychological symptoms of dementia (BPSD) affect virtually all of people with ADRD (Lyketsos et al., 2002; Margallo-Lana et al., 2001) and have negative effects on those diagnosed, their families, clinicians, and society. Pharmacologic treatments are often ineffective at managing BPSD and can be harmful to older adults with ADRD (Jeste et al., 2008; Maust et al., 2015), thus practice guidelines encourage the use of non-pharmacologic interventions as first line treatment of BPSD.

Acupuncture and acupressure, collectively referred to as acutherapy are non-pharmacologic interventions that have demonstrated to be safe and have the potential to improve cognitive function among older adults with ADRD (Peng et al., 2007; Zhou et al., 2015). Additional research is needed to examine the efficacy for improving outcomes besides cognitive function among people living with dementia (PLWD). With the significant individual, family, and societal level costs associated with BPSD, there is a need to understand the extent and nature of the effects that acutherapy has on these distressing behaviors and symptoms.

Background and Significance

Behavioral and Psychological Symptoms of Dementia

BPSD are defined as signs and symptoms of disturbed perception, thought content, mood, or behavior that frequently occur in PLWD (Finkel et al., 1997). Examples of BPSD include anxiety, sleep disturbance, depressed mood, hallucinations and delusions, aggression, restlessness, agitation, wandering, culturally inappropriate behaviors, screaming, wandering, sexual disinhibition, hoarding, cursing, and shadowing (Finkel et al., 1997; Kar, 2009).

Virtually all people diagnosed with dementia are likely to experience at least one specific behavioral or psychological symptom during the disease. Specific symptoms are often episodic in nature, while BPSD as a whole are present throughout the lifetime of the diagnosis (Aalten et al 2005; Steinberg et al., 2004). The causes of BPSD are diverse, complex, and multifactorial. Some individuals with ADRD may be more at risk than others to experience certain types and degrees of severity of BPSD. Research has shown that women may be more at risk for depressive symptoms (Buchanan et al., 2004; Lövheim et al., 2009; Steinberg et al., 2006), while men may be more at risk for aggressive type behaviors (Buchanan et al., 2004; Hall & O'Connor, 2004; Lövheim et al., 2009). BPSD are most common in the middle stages of the disease, with an estimated prevalence of 61%-88% (Lövheim et al., 2008; Steffens et al., 2005). Specific BPSD have been shown to vary depending on dementia type, for example, depressive and anxious type symptoms have consistently shown to be more prevalent among individuals with vascular type dementia compared to Alzheimer’s dementia (Cerejeira et al., 2012; Steinberg et al., 2006). Worse general health and increased comorbidities are associated with increased risk for many BPSD, including agitation/aggression, aberrant motor behavior, disinhibition, and irritability (Steinberg et al., 2006).

BPSD are a leading factor in worsening caregiver burden (Campbell et al., 2008), and they negatively impact the quality of life of PLWD, as well as their family caregivers (Banerjee et al., 2006; Hurt et al., 2008). Similarly, these symptoms are associated with increased stress and burden among care staff in geriatric-acute care and nursing home settings (Cocco et al., 2003). BPSD can ultimately lead to early institutionalization, or placement in long term care settings, and increased healthcare utilization (Gaugler et al., 2009) BPSD are also incredibly costly to society, as they account for up to 30% of the $305 billion in total health costs for ADRD in the United States (Alzheimer's Association, 2021; Schnaider et al., 2002).

Pharmacologic treatments for BPSD have been shown to be ineffective at managing BPSD and in many cases, dangerous to PLWD. For example, antipsychotics continue to be used as a primary treatment for severe agitation and psychosis in dementia; however, these medications have been shown to have limited efficacy and have been linked to increased mortality rates in this population (Maust et al., 2015). Current FDA black box warnings caution against the use of all antipsychotics in older adults with dementia due to the increased risk of death (Jeste et al., 2008). Anti-anxiety medications such as benzodiazepines, which are also commonly used for BPSD management, are associated with worsening cognitive function and increased falls and fractures in older adults (Defrancesco et al., 2015; Van Strien et al., 2013). Meanwhile, use of anti-depressant medications have been linked to increased risk for suicide in this population (Seyfried et al., 2011).

Due to the dangers associated with psychotropic medications in older adults with ADRD, recent practice guidelines and recommendations encourage the use of non-pharmacologic interventions for BPSD (Austrom et al., 2018; Reus et al., 2016). There is an urgent need for safe and effective non-pharmacologic treatments for BPSD to support families and clinicians to better manage these burdensome symptoms experienced by PLWD. Acupuncture and acupressure present as possible non-pharmacologic care strategies for BPSD management.

Acutherapy and Dementia

Based in Traditional Chinese Medicine, acutherapy is a non-pharmacologic intervention that emerged in China as early as first century B.C. The traditional understanding of acutherapy is based on scientifically non-detectable energy pathways called meridians. Meridians are interconnected throughout the body and thousands of acupoints that are along these pathways can be stimulated using needles, manual hand pressure, and light or electrical stimulation to correct various disturbances in the harmony of the body (Kaptchuk, 2002). Given the non-invasive nature of acutherapy and the clinical effectiveness it has had on several symptoms and diseases, it has been increasingly used in Western healthcare systems that embrace primarily bio-medical perspectives of health (García-Escamilla et al., 2015; Ma, 2007). It has been found to be a safe and effective treatment option for several symptoms and diseases such as chronic pain, migraines, depression, anxiety and weight loss (Amorim et al., 2018; Kim et al., 2018; Lee & Ernst, 2011; Wu et al., 2012).

Functional magnetic resonance imaging (MRI) has advanced the understanding of how acutherapy provides symptom relief by demonstrating that through the stimulation of acupoints corresponding areas of the brain are effectively activated that relate to disease processes (Fang et al., 2004). Despite these technological advancements, the exact mechanism of action is still not fully understood. The stimulation of acupoints is hypothesized to have a therapeutic effect on symptoms and disease through a variety of neurologic, hormonal and endocrinologic mechanisms (Han, 2003; Kou et al., 2017; Li et al., 2013; Noguchi, 2010). MRI studies have been conducted examining needle acupuncture in individuals with ADRD. Findings showed that the acutherapy interventions activated primarily the frontal and temporal lobes of the brain, which are responsible for recognition, memory and cognition (Shan et al., 2018; Wang et al., 2012). Given these findings, it is suggested that acutherapy may be beneficial for those with cognitive impairment; however, there remains no unified understanding of the mechanism of action of acutherapy for improving cognitive function, or for reducing BPSD in individuals with ADRD. The conceptual framework guiding this dissertation research hypothesizes that acutherapy may influence BPSD through the stress process, or by directly improving cognitive function (See Chapter 1, Figure 1.1, p. 6).

Systematic reviews support that acupuncture is safe for people with ADRD with very few side effects and that participants often report high satisfaction with the treatments; however, the quality of the evidence identified was low and additional research was recommended (Peng et al., 2007; Zhou, et al., 2015). Despite these recommendations, research on acutherapy in people with ADRD in Western healthcare systems has stalled, and despite its high degree of safety and potential for improving cognitive function, it has not been the focus of symptom management research in this population.

Purpose

Despite these encouraging findings, the effects of acupuncture and acupressure on BPSD specifically remain understudied. Prior to this review which was published online in the *Western Journal of Nursing Research (WJNR)* in December 2019 (Harris, Titler, Struble, 2019), no review existed on acutherapy for BPSD. The purpose of this review was to identify, examine and synthesize the science relating to the effects of acupuncture and acupressure therapy on BPSD. The research question guiding this review was, "What are the effects of acupuncture and acupressure therapy on the behavioral and psychological symptoms in persons with dementia?".

Methods

This review was guided by the scoping review methodology outlined by the Joanna Briggs Institute Reviewers' Manual (Peters et al., 2015), which is based on the scoping review frameworks of Arksey and O'Malley (2005) and Levac, Colquhoun, and O'Brien (2010).

A scoping review framework uses a systematic approach to identify, examine, and summarize available evidence and to identify gaps in knowledge (Arksey & O'Malley, 2005). Prior to this review, evidence available regarding acutherapies for managing BPSD was unknown. A scoping review is useful when the state of the science is emerging, as it allows for a broad view of the nature and range of evidence on the given topic area (Munn et al., 2018). Unlike a systematic review, a scoping review framework allows for greater breadth and inclusion of all pertinent research regarding acutherapy for BPSD, irrespective of quality (Peters et al., 2015). This approach also enables identification and examination of gaps in the evidence, which is useful to this emerging area of study.

Eligibility Criteria

Studies were included that consisted of participants with a diagnosis of ADRD. Alzheimer's disease and vascular dementia are the two most common types of dementia and were expected to be the most prevalent dementia types in this review; however, some studies did not specify the type of dementia of study participants. As the characteristics of the participants and settings were similar across studies, studies were included even if they did not specify dementia type.

Studies were included that examined the use of acupuncture and/or acupressure therapy. The studies could use multi-modal interventions that included other types of treatments including pharmacologic and non-pharmacologic approaches, but a acupuncture or acupressure treatment had to be included. Because the aim of this review was to explore the effects of acupuncture or acupressure therapy on BPSD rather than cognitive function, at least one behavioral or psychological symptom needed to be included as an outcome measure in the studies to be included in this review. Studies evaluating activities of daily living (ADLs) as an outcome were also included, as BPSD are often marked by increased ADL dependence and poor hygiene (Kar, 2009). Studies that only evaluated cognitive function or no BPSD outcomes were excluded.

Included studies had to be published in the English language. As acupuncture therapy is rooted in Traditional Chinese Medicine, studies could be conducted within or outside the United States. No exclusion criteria were applied to the setting of the studies, for example, they could be conducted in acute care, primary care and/or community settings.

Gray literature such as dissertations, theses, conference reports and proceedings, and white papers were excluded. In addition, commentaries, opinion pieces and letters to the editor were also excluded as they provided little support relevant to the research question. Reviews and meta-analyses that did not include BPSD were also excluded.

A broad range of study designs were included, due to the potential paucity in high quality research studies and unknown state of the science on acupuncture and acupressure therapy for BPSD in those with dementia. Studies were not excluded based on the date of publication, as to include studies that may add historical value to the review.

Search Strategy

An initial search was done using the MEDLINE database to briefly review the topic of interest, as to ensure no review had been done on the topic already. This was also done to gain a better understanding of keywords to be used in a more systematic search.

A systematized search strategy was then created and conducted. University of Michigan Health Science Library informationalists were involved and provided expertise in creating and conducting the search. Five databases were used in the search strategy:

PubMed, CINAHL, Embase, PsycINFO and AgeLine. Search terms and keywords, along with how they were combined for the database searches are outlined in Table 2.1.

BPSD were not included in the database search, as this concept involves a wide range of examples and could result in excluding relevant studies if a specific type of BPSD was not included in the database search. For this reason, the inclusion and exclusion criteria were applied to this concept during the review of titles/abstracts and of full text articles.

Table 2.1
Search Terms and Combinations

Boolean operator	Field	Keywords
	Title, abstract, medical subject headings (in PubMed), author defined keywords	'dementia', 'dementia, vascular', 'Alzheimer disease' and keywords and synonyms of dementia such as 'senile', 'Alzheimers', 'Alzheimer', 'Alzheimer's', 'dementia' and 'amentia'
AND	Title, abstract, medical subject headings (in PubMed), author defined keywords	like 'acupuncture', 'acupuncture therapy', 'acupuncture, ear', 'acupuncture points' and 'acupressure'
OR	Title, abstract, medical subject headings (in PubMed), author defined keywords	'shiatsu', 'pharmacopuncture', 'acupuncture', 'electroacupuncture', 'acupoints', 'meridians', 'acupressure', 'acupotomy', 'auriculotherapy', 'intradermal needling', 'Zhi Ya', 'Chih Ya' and 'Tui Na' 'acutherapy'

Data Management

Original database searches were conducted between October 2 through October 19, 2018, then updated and conducted again in January 2020. All article citations were downloaded to EndNote X8. EndNote X8 was used to filter duplications. Review of titles and abstracts and full text articles was conducted by the primary reviewer (M. Harris). Studies that seemed uncertain regarding inclusion and exclusion criteria were discussed with authors L. Struble and M. Titler until a consensus was reached. Data was extracted pertaining to reference title, author, year, sample characteristics (size, dementia types, dementia severity), study location, study design, acutherapy intervention procedures, BPSD examined and other outcomes, adverse effects of interventions, and significant results relating to BPSD. These data were charted in an ongoing, iterative manner in tables, which were then shared and discussed among the review team to synthesize the findings.

Results

Figure 2.1 provides a PRISMA diagram outlining the results of the search process. The total number of citations from the database search was 1178. EndNote X8 was used to filter duplications, which left a total of 836 citations to be reviewed by title and abstract. Common reasons for exclusion at the title and abstract screening phase were studies that evaluated alternative treatments but did not include acupuncture or acupressure therapy and studies that did include a BPSD outcome.

Fifty-seven articles were then reviewed by full text. Articles were excluded for the same reasons as the title and abstract review, in addition, some articles were commentaries (*n*=6), one was a report on a not yet completed study, one was a conference abstract and several articles reported on the same study, but in different journals (*n*=11). Ultimately, 15 articles were included based on the inclusion and exclusion criteria. The final step of the search was a review of the references of the included studies, no new studies were found.

Synthesis of the Extent and Nature of the Research on Acutherapy for BPSD

The 15 studies identified through the database search are summarized in Tables 2.2 and 2.3. The 6 studies in Table 2.2 examined the effects of acupuncture on BPSD in persons with ADRD (Jia et al., 2017; Kwok et al., 2013; Lombardo et al., 2001; Shi et al., 2015; Shi et al., 2012; Wang et al., 2014). The 9 studies in Table 2.3 includes those that tested the effectiveness of acupressure therapy on BPSD in persons with ADRD (Fung & Tsang, 2018; Kwan, Leung, & Lai, 2016, 2017; Lin et al., 2009; Rodríguez-Mansilla et al., 2015; Simoncini et al., 2015; Sutherland et al., 1999; Yang et al., 2015; Yang et al., 2007). The publication years of the articles ranged from 1999-2018. The sample sizes of all the studies ranged from 10-186, with an average of 69 participants. Sample sizes of the acupuncture studies ranged from 10 to 186 with an average of 88, and for acupressure therapy sample sizes ranged from 11-79, with an average of 40.

Figure 2.1

Prisma Flow Diagram of Acupuncture and Acupressure Therapy Studies for BPSD

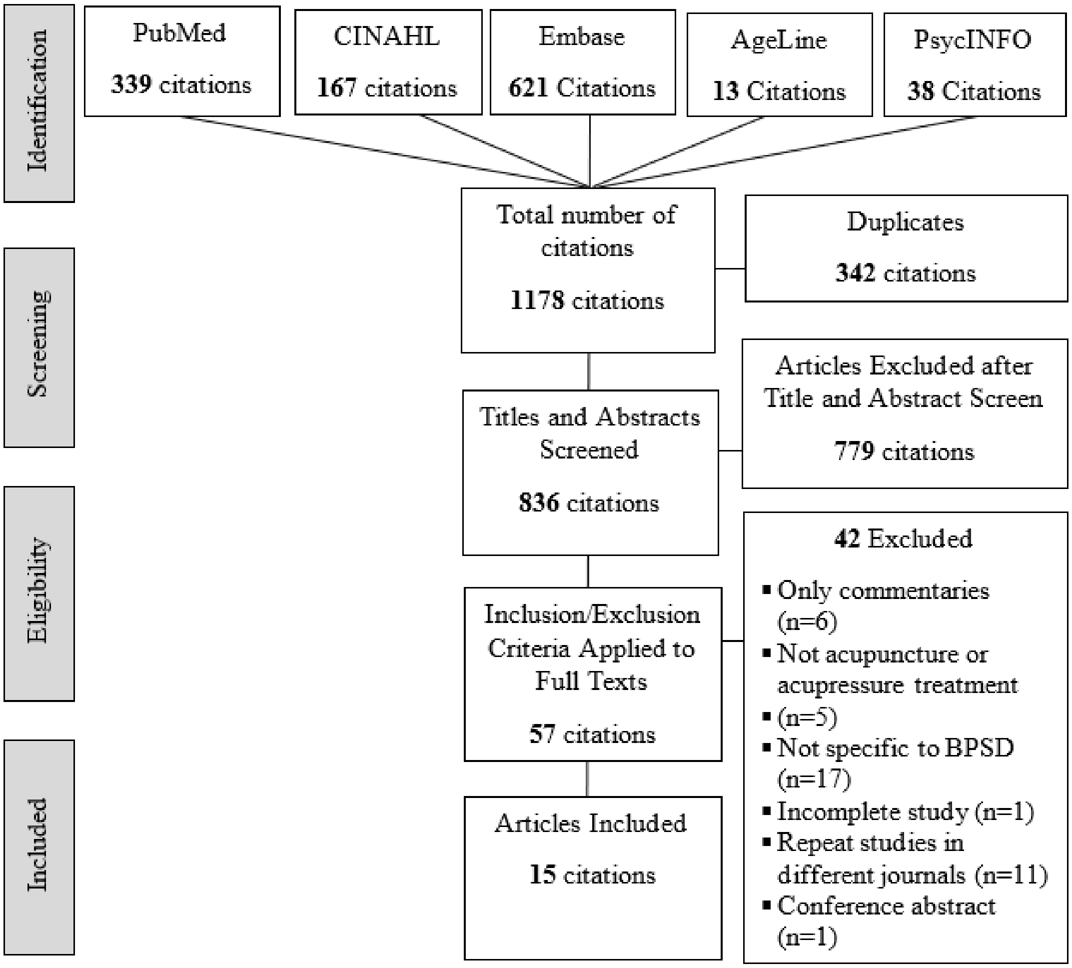


Table 2.2

Acupuncture Intervention Studies with BPSD Outcomes (N=6)

Authors (Year)	Sample Size	Location and Design (Arm Specification)	Acutherapy Intervention	Intervention Period Duration, Session Frequency and Session Duration	Acupoints Targeted	Outcomes (Measurements)	Significant Findings
Jia et al. (2017)	79	China In the home RCT, 2 arms (Acupuncture vs. daily oral donepezil)	Needle acupuncture treatments	3x per week for 12 weeks Session duration not specified	RN 17 RN12 RN6 ST36 SJ5 SP10 <u>Auxiliary points *</u> LR3 GB39 ST40 BL17 ST44 ST25 RN4	Cognitive function (ADAS-Cog) Overall clinician impression of change (CIBIC-Plus) ADLs (ADCS-ADL) Neuropsychiatric disturbances (NPI)	Improved cognitive function and clinican impression of change in acupuncture group
Kwok et al. (2013)	19	China Community centers Repeated measures design, 1 arm	6-week control followed by needle acupuncture treatments	2x per week for 6 weeks Sessions duration: ~30 minutes	HT7 DU20 EX-HN9 EX-HN3 ST36 SP6	Sleep disturbances (Wrist actigraphy) Sleep parameters Cognitive function (ADAS-Cog)	Improved sleep time and quality, and cognitive function with acupuncture therapy
Lombardo et al. (2001)	11	United States Setting not specified Repeated measures design, 1 arm	Needle acupuncture treatments	3x per week for 2 weeks, then 2-3x per week for 7-10 weeks Sessions duration: ~30 minutes	GV20 Ki3 ST36 M-HN-1 Yin Tang SP6 HT7 GB9 GV23	Depression (CSDD) Anxiety (State-trait anxiety inventory) Cognitive impairment (Medical Outcomes Survey) Mood (POMS)	Improved depression, anxiety and mood with acupuncture therapy
Shi et al. (2012)	16	China Hospital Repeated measures design, 1 arm	Needle acupuncture treatments	Every other day treatments for 6 weeks Sessions duration: ~30 minutes	GV20 EX-HN1 GV24 PC6 CV17 CV12 CV6 SP10 ST36	Cognitive impairment (MMSE) Quality of life (DEMQOL) ADLs (ADL scales) Oxidative DNA damage (Oxidative marker detection	Increased cognitive function and quality of life with acupuncture therapy

					Auxiliary points * GB39 ST30 LR3 ST44 ST25 CV4	through urine samples)	
Shi et al. (2015)	63	China Hospital RCT, 2 arms (randomized vs. non-randomized)	Needle acupuncture treatments	Every other day treatments for 6 weeks Sessions duration: ~30 minutes	GV20 EX-HN1 GV24 PC6 CV17 CV12 CV6 SP10 ST36 Auxiliary points * GB20 ST40 LR3 SP6 ST25	Cognitive impairment (MMSE) ADLs (ADL scales) QOL (DEMQOL)	Increased cognitive function and ADL function in acupuncture group
Wang et al. (2014)	55	China Inpatient and outpatient neurology units RCT, 2 arms (daily oral donepezil vs. daily oral donepezil + acupuncture)	Needle acupuncture treatments combined with medication	Combined daily dosage of donepezil with once-daily acupuncture treatments for 20 days Sessions duration: ~30 minutes	Not specified	Cognitive impairment (MMSE) ADL's (ADAS-ADL) Brain activity (EEG)	Improved cognitive function and ADL function in acupuncture group

Note. ADLs activities of daily living, ADCS-ADL Alzheimer's disease cooperative study activities of daily living scales, ADAS-Cog Alzheimer's Disease Assessment Scale-Cognitive subscale, BPSD behavioral and psychological symptoms of dementia, CSDD Cornell scale for depression in dementia, DEMQOL Dementia Quality of Life Scale, EEG electroencephalogram, MMSE Mini-Mental Status Exam, NPI Neuropsychiatric Inventory, PMS Profile of Mood States PWD person with dementia, RCT randomized controlled trial

*Auxiliary points could be added to the treatment based on the individual's condition at the acupuncturist's discretion. Treatments were individualized for each person for each session.

Table 2.3
Acupressure Intervention Studies with BPSD Outcomes (N=9)

Authors (Year)	Sample Size	Location/ Design (Arm Specification)	Acutherapy Intervention	Intervention Period Duration, Session Frequency and Session Duration	Acupoints Targeted	Outcomes (Measurements)	Significant Findings
Fung et al. (2018)	60	China 3 RCH RCT, 3 arms (aroma-massage with acupressure + exercise vs. cognitive training + exercise vs. aroma-massage with acupressure + cognitive training)	Aroma-massage combined with acupressure treatments	2x per week sessions for 3 weeks Session duration: 20 minutes	HT4 HT5 HT7 PC6 GV20 GB20 GV24 EX-HN5 EX-HN3 SP6	Agitation (CCMAI) Neuropsychiatric symptoms (NPI) Cognitive function (CMMSE) ADLs (Barthel Index)	Reduced neuropsychiatric symptom distress and improved ADL function in aroma-massage + acupressure groups compared to non-acupressure group
Kwan et al. (2016)	24	China 3 LTC Repeated measures, non-randomized design, 8 dosage-combo groups	Acupressure treatments	1-4 weeks, 1-2x per day depending on dosage group Session duration: 9 minutes	EX-HN3 GV20 GB20 HT7 PC6	Agitation (CMAI) Stress (Salivary cortisol levels)	Reduced agitation and stress. Optimal dosage was determined to be 2x/day for 2 weeks
Kwan et al. (2017)	119	China 12 RCHs RCT, 3 arms (acupressure vs. sham vs. usual care)	Acupressure treatments	5 days per week for 2 weeks with 6-week follow up Session duration: 9 minutes	EX-HN3 GV20 GB20 HT7 PC6	Agitation (CMAI) Stress (Salivary cortisol levels)	Reduced stress and agitation in acupressure group (agitation was reduced at 5th week follow up)
Lin et al. (2009)	133	China Dementia units RCT, cross-over design, 3 arms (acupressure vs. Montessori methods vs. presence therapy)	Acupressure treatments (participants received four weeks of the each of the three therapies, implemented in 3 different sequences, with weeklong pre-post measure periods and 2-	6 days per week for 4 weeks Session duration: 15 minutes	GB20 DU20 HT7 PC6 SP6	Agitation (CMAI) Ease of care with ADLs (Ease of care inventory) Emotional expression (Apparent Affect rating scale) Need for restraint (Unit log) Number of family visits (Unit log)	Reduced agitation and improved ease of care and ADLs in acupressure and Montessori group compared to presence group

			week wash out periods between therapy types)				
Rodríguez-Mansilla et al. (2015)	111	Spain RCHs RCT, 3 arms (usual care vs. ear acupressure vs. massage therapy)	Ear acupressure	Continuous ear acupressure for 3 months	MA-TF1	Pain (DOLOPLUS2 scale) Depression (CSDD) Anxiety (Campbell scale) Cognitive impairment (MMSE)	Reduced depression, anxiety and pain seen in acupressure group with greater improvement in pain and depression with ear acupressure compared to massage therapy
Sutherland et al. (1999)	10	Location not specified Dementia unit Quasi-experimental, 2 arms (foot acupressure vs. usual care)	Foot acupressure treatments	10 minutes per day for 10 days Session duration: 10 minutes	Not specified	Wandering (Behavioral documentation instrument created by researchers) Pulse Respirations Quiet time behaviors	Decreased wandering in acupressure group
Simoncini et al. (2015)	129	Location not specified Dementia nursing homes Longitudenal prospective study, 1 arm	Acupressure treatments	Continuous 8-hour overnight stimulation of the HT7 acupoint applied for 8 weeks	HT7	Cognitive impairment (MMSE) Anxiety (State-trait anxiety inventory) Neuropsychiatric symptoms (NPI) ADLs (ADL scales) Disease stage QOL (Global health quality of life scale) Subjective sleep quality (Pittsburgh sleep quality index)	Neuropsychiatric symptoms, health quality ADL, and sleep improved with acupressure therapy
Yang et al. (2007)	20	China LTF dementia unit Repeated measures, 1 arm	Acupressure treatments	2x per day for 5 days per week for 4 weeks Session duration: 15 minutes	GV20 GB20 HT7 PC5 SP6	Agitation (CMAI, daily records of agitated behaviors) Ease of care with ADLs (Ease of care inventory)	Reduced agitation and improved ease of care with ADLs with acupressure therapy
Yang et al. (2015)	186	China Dementia care facilities RCT, 3 arms (aroma-acupressure	Aroma–acupressure treatments	1x per day, 5 days per week for 4 weeks Session duration: 15 minutes	GV20 GB20 HT7 PC5 SP6	Agitation (CCMAI, heart rate variability)	Reduced agitation in acupressure group

	vs. aromatherapy only vs. usual care)	

Note. ADL activities of daily living, ADAS-Cog Alzheimer’s Disease Assessment Scale-Cognitive subscale, BPSD behavioral and psychological symptoms of dementia, CCMAI Chinese version of Cohen-Mansfield Agitation Inventory, CMAI Cohen-Mansfield Agitation Inventory, CSDD Cornell Scale for Depression in Dementia, LTF long-term care facilities, MMSE Mini-Mental Status Exam, NPI Neuropsychiatric Inventory, PWD person with dementia, RCHs residential care homes, RCT randomized controlled trial

Participants, Diagnoses and Cognitive Impairment Severity

A total of 1,035 participants were included across the 15 studies. Four studies included participants with Alzheimer's disease (Jia et al., 2017; Simoncini et al., 2015; Sutherland et al., 1999; Wang et al., 2014), one of which tested acupuncture (Jia et al., 2017), the other three tested acupressure interventions. Two acupressure studies included participants with vascular type dementia (Shi et al., 2015; Shi et al., 2012) and the remainder of the studies did not specify the type of dementia. Fifty-seven percent of the participants were female, although two studies did not report the gender of participants (Simoncini et al., 2015; Sutherland et al., 1999). The age range of participants in all studies was 50-96. Across acupuncture studies specifically, a total of 243 participants were included, while 792 were included across acupressure studies.

Table 2.4 summarizes the baseline severity of cognitive impairment of study samples for the 12 studies that reported cognitive function and the cognitive measures used (Fung & Tsang, 2018; Jia et al., 2017; Kwan et al., 2016; Kwan et al., 2017; Kwok et al., 2013; Lin et al., 2009; Lombardo et al., 2001; Rodríguez-Mansilla et al., 2015; Shi et al., 2015; Shi et al., Simoncini et al., 2015; 2012; Wang et al., 2014). The Mini-Mental Status Exam (MMSE) and the Alzheimer's Disease Assessment Scale-Cognitive subscale (ADAS-Cog) were the tools used to measure cognitive function across the studies with the majority (83%) using the MMSE. The overall cognitive impairment severity of study samples was determined based on standardized MMSE scores which range from 0-30, scores greater than 25 indicate no cognitive impairment, 19-23 mild cognitive impairment, 10-18 moderate cognitive impairment and ≤ 9 severe cognitive impairment (Folstein et al., 1983). The ADAS-Cog subscale scores range from 0-70, with higher scores indicative of greater impairment (Rosen et al., 1984).

The degree of cognitive impairment severity ranged from mild to severe, with most samples having moderate severity (58%) (Table 2.4). Across the 6 acupuncture studies, one had a sample with mild impairment (Lombardo et al., 2001), and 5 with moderate cognitive impairment (Table 2.4). Across the 6 acupressure studies that reported baseline cognitive impairment scores, 2 had samples with overall moderate cognitive impairment, 3 were severe, and 1 had a sample that included participants with moderate and severe dementia (Table 2.4).

Table 2.4

Cognitive Measures and Cognitive Impairment Severity of Study Samples in Acutherapy Intervention Studies with BPSD Outcomes

Author (Year)	Measurement Tool	Baseline CF Mean (SD)	Sample (n)	Cognitive Impairment Severity
□ Fung et al. (2018)	Chinese version MMSE	14.6 (1.90)	Aroma-message with acupressure + exercise group (20)	Moderate
		13.85 (1.93)	Aroma-message with acupressure + cognitive training group (20)	
● Jia et al. (2017)	ADAS-Cog	29.38 (9.43)	Acupuncture group (43)	Moderate
□ Kwan et al. (2016)	MMSE	6.61 (6.32)	Total study sample, excluding 1 participant who declined (23)	Severe
□ Kwan et al. (2017)	MMSE	7.4 (5.8)	Acupuncture group (39)	Severe
● Kwok et al. (2013)	Chinese version ADAS-Cog	27.28 (10.93)	Total study sample (19)	Moderate
□ Lin et al. (2009)	MMSE	6.9 (6.1)	Sequence 1 Acupressure-Presence-Montessori (42)	Severe
		7.1 (6.5)	Sequence 2 Montessori-Acupressure-Presence (39)	
		8.0 (6.1)	Sequence 3 Presence-Montessori-Acupressure (52)	
● Lombardo et al. (2001)	MMSE	21.9 (5.9)	Total study sample (11)	Mild
□ Rodríguez-Mansilla et al. (2015)	MMSE	Mean scores not reported	Ear acupressure group (40)	50% of participants in acupressure group had moderate dementia, 50% had severe dementia
● Shi et al. (2012)	MMSE	18.24 (0.91)	Total study sample (16)	Moderate
● Shi et al. (2015)	MMSE	18.27 (4.08)	Randomized group (22) Non-randomized group (19)	Moderate
		17.74 (3.33)	Non-randomized group (19)	
□ Simoncini et al. (2015)	MMSE	18.0 (4.6)	Total study sample (129)	Moderate
● Wang et al. (2014)	MMSE	18.4 (2.9)	Combined group (27)	Moderate

Note. CF cognitive function, ADAS-Cog Alzheimer's Disease Assessment Scale-Cognitive subscale, MMSE Mini-Mental Status Exam

●Acupuncture studies

□Acupressure studies

Locations, Settings and Designs

Most of the studies were conducted in China (*n* = 11). (Fung & Tsang, 2018; Jia et al., 2017; Kwan et al., 2016, 2017; Kwok et al., 2013; Lin et al., 2009; Shi et al., 2015; Shi et al., 2012; Wang et al., 2014; Yang et al., 2015; Yang et al., 2007). Approximately 83% of acupuncture and 67% of acupressure studies took place in China. One acupressure study was conducted in Spain (Rodríguez-Mansilla et al., 2015). Only one acupuncture study was conducted in the United States, and it was of small sample size with only 11 participants (Lombardo et al., 2001). Two studies did not specify the geographic location (Simoncini et al., 2015; Sutherland et al., 1999).

The majority of the studies took place in settings such as nursing homes, specialized dementia and residential care homes, and long-term care facilities (*n*=10) (Fung & Tsang, 2018; Kwan et al., 2016, 2017; Kwok et al., 2013; Lin et al., 2009; Rodríguez-Mansilla et al., 2015; Simoncini et al., 2015; Sutherland et al., 1999; Yang et al., 2015; Yang et al., 2007). Two acupuncture studies took place in a hospital setting (Shi et al., 2015; Shi et al., 2012). One acupuncture study was conducted in the home (Jia et al., 2017), and one included participants from an inpatient and outpatient neurology department (Wang et al., 2014). One acupuncture study did not specify the setting where the study was conducted (Lombardo et al., 2001). The majority (~89%) of acupressure studies took place in long-term care settings (Table 2.3).

Most of the studies used a randomized controlled trial design with 2 or 3 arms (*n*=8) (Fung & Tsang, 2018; Jia et al., 2017; Kwan et al., 2017; Lin et al., 2009; Rodríguez-Mansilla et al., 2015; Shi et al., 2015; Wang et al., 2014; Yang et al., 2015). Four of these studies were double-blinded (Kwan et al., 2017; Rodríguez-Mansilla et al., 2015; Wang et al., 2014; Yang et al., 2015). Six studies used single group designs such as repeated measures and longitudinal prospective designs (Kwan et al., 2016; Kwok et al., 2013; Lombardo et al., 2001; Shi et al., 2012; Simoncini et al., 2015; Yang et al., 2007). One study used a quasi-experimental design with purposive sampling and random assignment of participants to the experimental and control groups (Sutherland et al., 1999). Half of the acupuncture studies were RCTs, while the other half were single group designs with repeated measures (Table 2.2). Over 55% (5 of 9) of the acupressure studies were RCTs (Table 2.3).

Delivery of Acutherapy Interventions

Acupuncture Interventions

Intervention delivery procedures varied widely across the 15 studies (Table 2.2 and 2.3). Of the 6 acupuncture studies, 2 studies combined acupuncture therapy with medication (donepezil) for improving memory in dementia (Jia et al., 2017; Wang et al., 2014). Intervention period durations ranged from 3 weeks to 12 weeks, with acupuncture treatment session frequencies ranging from 2 to 3 times per week. Duration of treatments sessions was approximately 30 minutes for all studies, except one which did not report the average session duration (Jia et al., 2017).

Acupoints used across studies varied, with one study not reporting specific acupoints (Wang et al., 2014). The only common acupoint targeted across the 5 studies was ST36, which is located below the knee cap and is commonly used to treat gastrointestinal discomfort, nausea, vomiting, stress and fatigue (Chao et al., 2013). Three studies reported using auxiliary points, which could be added to the treatment based on the individual’s condition at the acupuncturist’s discretion. These intervention sessions were individualized for each person for each session (Jia et al., 2017; Shi et al., 2015; Shi et al., 2012). All treatments were delivered by professional acupuncturists (Jia et al., 2017; Kwok et al., 2013; Lombardo et al., 2001; Rodríguez-Mansilla et al., 2015; Shi et al., 2015; Shi et al., 2012).

Acupressure Interventions

Of the 9 acupressure studies, 3 studies used multi- modal treatments that involved acupressure therapy in combination with another alternative treatment, such as massage, Montessori-based activities, and aromatherapy. (Fung & Tsang, 2018; Lin et al., 2009; Yang et al., 2015). Durations of the acupressure intervention periods ranged from 1 week to 3 months, with treatment session frequencies ranging from 2 times per week to 2 times per day. Two studies used acupressure ear seeds to apply continuous pressure to acupoints for 2 (Simoncini et al., 2015), and 3 months (Rodríguez-Mansilla et al., 2015). Only 1 study examined optimal dosage of acupressure for BPSD by evaluating what dosage and frequency yielded the most significant effect on agitation in PLWD. The optimal dosage of acupressure therapy for treating agitation was determined to be twice a day for 2 weeks (Kwan et al., 2016). The findings of this pilot study were then used in a larger RCT testing a twice daily, 2 week acupressure intervention in individuals with ADRD living in residential care homes (Kwan et al., 2017).

Acupoints stimulated across acupressure intervention treatments varied, while one study did not report the specific acupoints used (Sutherland et al., 1999). Common acupoints stimulated across the studies were HT7 and GB 20 (Fung & Tsang, 2018; R. Kwan et al., 2016; Kwan et al., 2017; Lin et al., 2009; Yang et al., 2015; Yang et al., 2007). Four of the studies included acupressure interventions delivered by non-professional and non-healthcare individuals trained in acupressure (Fung & Tsang, 2018; Kwan et al., 2016; Kwan et al., 2017; Lin et al., 2009). One study evaluated nurse delivered acupressure therapy (Simoncini et al., 2015).

Effects of Acutherapy Interventions on BPSD and Measurement Tools Used

Table 2.5 summarizes the BPSD outcomes evaluated in the 15 studies and indicates those for which there was significant treatment effect. Agitation and activities of daily living (ADL) function were the most commonly measured outcomes across acutherapy studies. ADL function was an outcome of interest in this review, as BPSD are often marked by increased ADL dependence and poor hygiene (Kar, 2009). Four studies included multiple BPSD outcome measures (Fung & Tsang, 2018; Jia et al., 2017; Lombardo et al., 2001; Simoncini et al., 2015).

Eight studies included ADL function as an outcome variable (*n*=4 acupuncture studies, *n*=4 acupressure studies) (Fung & Tsang, 2018; Jia et al., 2017; Lin et al., 2009; Shi et al., 2015; Shi et al., 2012; Simoncini et al., 2015; Wang et al., 2014; Yang et al., 2007). Six of these studies (*n*=2 acupuncture, *n*=4 acupressure) showed statistically significant improvement in ADL function scores post-intervention (Fung & Tsang, 2018; Lin et al., 2009; Shi et al., 2015; Simoncini et al., 2015; Wang et al., 2014; Yang et al., 2007). The ADCS-ADL and Barthel Index were used to measure ADLs, both instruments have been validated and demonstrated good reliability in older adults with dementia (Galasko et al., 1997; Sheehan, 2012).

Table 2.5
Behavioral and Psychological Symptoms of Dementia Evaluated Across Acupuncture and Acupressure Studies and Those that Demonstrated Significant Treatment Effects

BPSD Outcomes	Number of Studies that Evaluated Outcome (*N*=15)	Number of Studies with Statistically Significant Improvement in Outcomes (%)
ADL function	8	6 (75%)
Agitation	6	6 (100%)
Anxiety	3	2 (67%)
Depression	2	2 (100%)
Mood	1	1 (100%)
Neuropsychiatric symptoms	3	2 (67%)
Sleep disturbances	2	2 (100%)
Total	25	21 (84%)

Note. ADL activities of daily living, BPSD behavioral and psychological symptoms of dementia

Six acupressure studies included agitation as an outcome measure and all demonstrated significant improvements in agitation scores after delivery of the acupressure therapies (Fung & Tsang, 2018; Kwan et al., 2016, 2017; Lin et al., 2009; Yang et al., 2015; Yang et al., 2007). The Cohen-Mansfield Agitation Inventory was most commonly used to measure agitation across studies, which has demonstrated high reliability in people with ADRD (Cohen-Mansfield, 1986).

Three studies evaluated anxiety as an outcome (*n*=1 acupuncture, *n*=2 acupressure) (Lombardo et al., 2001; Rodríguez-Mansilla et al., 2015; Simoncini et al., 2015) The acupressure study by Simoncini et al. (2015) was the only one that did not demonstrate improvement in anxiety, which was attributed to many participants having low anxiety at baseline (Simoncini et al., 2015). The Spielberger State-Trait Anxiety Inventory was used in two studies; it is known to have a demonstrated bias of increased anxiety for geriatric adults, which may be confounded by a decreased well-being in this population (Kvaal et al., 2001). The Campbell scale was used in one study (Rodríguez-Mansilla et al., 2015); the validity and reliability of this measure in the geriatric or dementia population is unknown.

The outcome of depression was measured in two studies (*n*=1 acupuncture, *n*=1 acupressure) (Lombardo et al., 2001; Rodríguez-Mansilla et al., 2015), both demonstrated significant improvement in depression scores after the acupuncture or acupressure intervention. The Cornell Scale for Depression in Dementia was used to measure depression – a tool that is commonly used in people with ADRD with good reliability and validity for this population (Alexopoulos et al., 1988).

Mood was an uncommon outcome measure and was only examined in one acupuncture study, which demonstrated significant improvement following the intervention period. Mood was measured using the Profile of Mood States (POMS) instrument (Lombardo et al., 2001). The validity and reliability of this tool has been established in an older adult sample; however, this sample did not include people with cognitive impairment (Kaye et al., 1988).

The broad cluster of neuropsychiatric symptoms was examined in three studies (*n*=1 acupuncture, *n*=2 acupressure) (Fung & Tsang, 2018; Jia et al., 2017; Simoncini et al., 2015). The acupuncture study by Jia et al. was the only study to not demonstrate significant improvement in this outcome; however, it did demonstrate significant improvement in cognitive function after the intervention (2017). The Neuropsychiatric Inventory was used to measure neuropsychiatric symptoms in all three studies (Cummings et al., 1994).

Finally, sleep disturbance was included as an outcome in two studies (*n*=1 acupuncture, *n*=1 acupressure) (Kwok et al., 2013; Simoncini et al., 2015). Both studies demonstrated improvement in sleep at post-intervention. Wrist actigraphy was used in one study (Kwok et al., 2013), while the Pittsburgh Sleep Quality Index (PSQI) was used in the other (Simoncini et al., 2015). The PSQI has been used in a nursing home population and showed to have good reliability scores; however, the sample included only residents with normal cognition (Gentili, Werner, Kuchibhatla, & Edinger, 1995). No information was found on the reliability and validity of the PSQI in people with ADRD.

Six studies included physiologic outcome measures, 2 were acupuncture intervention studies (Kwok et al., 2013; Shi et al., 2012), and four were acupressure (Kwan et al., 2016, 2017; Rodríguez-Mansilla et al., 2015; Sutherland et al., 1999). Kwok et al. included wrist actigraphy to measure sleep and rest cycles (2013), the acupressure study by Rodríguez-Mansilla et al. (2015) included pain as an outcome, while the acupressure study by Sutherland et al. (1999) included pulse and respirations.

The 2012 study by Shi et al. included urine samples to detect an oxidative marker indicative of DNA damage, which significantly decreased immediately after participants received the acupuncture treatments. Kwan et al. (2016, 2017) used salivary cortisol samples to evaluate stress. The results of both studies by Kwan et al. indicated the acupressure treatment groups had significant reductions in salivary cortisol levels, suggesting a reduction in stress. Together, these three studies support the relationship between acutherapy, and the stress process outlined in the conceptual framework guiding this research (Chapter 1, Figure 1.1, p. 6).

Across all acutherapy studies focused on BPSD outcomes, acutherapy interventions were most effective for reducing agitation and depression among individuals with ADRD. Needle acupuncture demonstrated significant treatment effects on ADL function, as well as other non-BPSD related outcomes such as cognitive function and quality of life (Table 2.2). Acupressure interventions demonstrated significant improvements in agitation scores in all 6 studies that included agitation as an outcome, and in both studies that examined the broad cluster of neuropsychiatric symptoms as an outcome (Table 2.3).

Evaluations of Intervention Acceptability

Four studies reported findings relating to intervention acceptability, 2 of which were acupuncture studies (Kwok et al., 2013; Lombardo et al., 2001), and 2 tested acupressure therapy (Kwan et al., 2016, 2017). Two acupressure studies and one acupuncture study evaluated completion rates, which ranged from 79%-91% (Kwan et al., 2016, 2017; Kwok et al., 2013). The acupuncture study by Kwok et al. (2013) also tracked refusal to participate rates, of which there were no reported refusals, although this study did use a convenience sampling approach. The acupuncture study by Lombardo et al. (2001) used a participant satisfaction questionnaire and reported that 82% of participants reported being satisfied with the acupuncture treatments; however, this study did not describe the specific questions in the questionnaire, the data collection methods, or how data was analyzed. This study was also a small sample, with only 11 participants.

Safety

No adverse effects were reported across the 15 studies. One acupuncture study reported that 10.8% of participants experienced punctate hemorrhage when acupuncture needles were withdrawn (bleeding stopped within 5-10 seconds of holding dry, sterile cotton to the sites) (Jia et al., 2017). Another acupuncture study stated that 25% of participants reported mild discomfort at the acupoint sites during treatments and 20% experienced mild bruising (Shi et al., 2015). These side effects were reported as non-significant in both studies.

Discussion

Summary of Findings

The results of this review suggest acupuncture and acupressure therapy have the potential to improve BPSD. All 15 of the studies reported high degrees of safety and overall satisfaction of the acutherapy intervention treatments in individuals with ADRD. Thirteen of the studies demonstrated statistically significant ($p<0.05$) improvements in at least one BPSD outcome. Two acupuncture studies did not demonstrate a treatment effect for BPSD measures but did demonstrate significant improvements in other important outcomes, including cognitive function and quality of life (Jia et al., 2017; Shi et al., 2012). There is an ongoing need for safe and effective non-pharmacologic treatment options for BPSD for individuals in all stages of the disease. Findings relating to cognitive impairment severity across studies suggest that these therapies are feasible and safe for individuals with mild, moderate, and severe cognitive impairment. The significant findings suggest that acutherapy may be a reasonable option for BPSD management, but additional research is needed to support its efficacy. Acupuncture and acupressure offer an area for future research for treating BPSD.

Limitations

Findings of this scoping review should be interpreted in light of some limitations. First, studies were excluded that were not in English, as reviewers were only proficient in English. This may have led to the exclusion of potentially relevant studies as acutherapy is rooted in Traditional Chinese Medicine; however, no studies that were reviewed by full text were excluded for this reason, and many abstracts that were originally published in another language were translated to English. Despite this, it is possible that relevant studies were missed due to this criterion. Second, this review did not exclude studies based on quality, as it was unclear what the state of the science would be prior to the review. Given this limitation, many studies included were found to be methodologically flawed and findings related to efficacy for BPSD should be interpreted with caution. Finally, for feasibility this review excluded gray literature including dissertations/theses, conference proceedings, and white papers, which may have excluded new research focused on this topic; however, the original database search was conducted in 2018 and again in 2020 and no new studies were found. As research on acutherapy for BPSD continues to emerge, it will be important to cumulatively review the quality of studies and their effects on BPSD.

Gaps Identified and Recommendations

Despite these limitations the findings of this review are encouraging, but due to variations in study designs and measures, as well as incomplete explanations of intervention procedures (such as use of specific acupoints, acutherapy dose, and who carried out the interventions) it is difficult to determine exact conclusions about the efficacy of these therapies. Given the methodological flaws in these studies including the limited theoretical basis for the interventions and symptoms, differences in measures, variations in study designs and intervention dosage, and overall limitations in internal and external validity, there remains a gap in the knowledge and quality of evidence needed to use acupuncture and acupressure for BPSD.

There is a need for additional research to evaluate the use of acupuncture and acupressure, specifically in countries with a Westernized approach to medical care where acutherapy is not as widely used. The majority of the studies were conducted in China, as acutherapy is rooted in Traditional Chinese Medicine; however, acupuncture and acupressure have the potential to expand treatment for many diagnoses and symptoms in Western society. Therefore, additional studies conducted in Western healthcare systems are needed to support the generalizability of acupuncture and acupressure treatments for BPSD.

Despite the significant impact that BPSD have on home-dwelling individuals with dementia and their family caregivers, most of the studies (*n*=10/15) were conducted in long-term care facilities. Additional research is needed to evaluate the feasibility of applying these interventions in the home. To promote the uptake of acutherapies in real world settings, future research should evaluate intervention acceptability in addition to testing the effectiveness of the intervention. By evaluating acceptability, researchers will better understand how the targeted population perceive it and respond to it, which may help promote broader implementation and sustained use. As family caregivers play a pivotal role in directing care for their relatives with ADRD, it is important for future research to evaluate the acceptability of acutherapy from their perspectives and explore their perceptions regarding the use of acutherapy as a potential care strategy for BPSD.

Acupuncture is often performed by licensed acupuncturists and state level regulations may require acupuncturists to work under the supervision of a medical doctor, which can be a limitation for applying this intervention in the home. Alternatively, this review supports that acupressure can feasibly be performed by a non-professional given adequate training. Acupressure presents as an opportunity to support informal caregivers (such as family members and friends) in having complementary treatment options for better managing BPSD.

Another option to promote delivery and uptake may be the use of a new, less invasive, virtually pain-free acutherapy technique called laser acutherapy which does not require interventionists to work under the supervision of licensed physicians. Only one study led by Dr. Laura Struble PhD, GNP-BC at the University of Michigan School of Nursing is focused on laser acutherapy use in PLWD. This pilot study was being conducted in assisted living and memory care settings to examine the effects of a 6-week laser acutherapy protocol on BPSD (agitation specifically), cognitive function and activities of daily living in individuals with ADRD. The study was paused due to the COVID-19 pandemic in March 2020. Further examination of laser acutherapy and its effects on BPSD will be needed when in-person intervention research with vulnerable older adults continues, as they are likely in even greater need of effective symptom management strategies as a result of the pandemic (Keng et al., 2020).

Many national and state level entities exist to educate healthcare professionals, family members, friends and those diagnosed with dementia regarding BPSD management techniques. These organizations can empower healthcare professionals and families with knowledge regarding non-pharmacologic care strategies in times when other, more traditional approaches, such as psychotropic medications fail, or when they cause more harm than healing. Organizations such as the Alzheimer's Association and the Alzheimer's Foundation of America present significant opportunities to promote education for informal and formal caregivers alike regarding alternative and complementary approaches to dementia symptom management.

The policy implications of this work are based on the fact that national programs, such as Medicare, currently cover pharmacologic interventions for ADRD care; however, there is limited or conditional coverage for non-pharmacologic therapies. As the research in support of non-pharmacologic treatments continues to grow and as the research builds relating to their efficacy in reducing BPSD, there will be a need for policy makers to advocate for coverage for non-pharmacologic treatments and incentives for community support services and clinicians to provide them.

Conclusion

BPSD ultimately threaten a person's ability to remain in the home, resulting in negative effects on society due to increased healthcare utilization and cost. Due to the increased susceptibility to adverse effects of pharmacologic treatments in this population, there is an ever-increasing need to prioritize non-pharmacologic care strategies in the management of BPSD. This review evaluated the current research relevant to acupuncture and acupressure treatments for BPSD. Fifteen studies were included in the final review and findings tended to be in support of acupuncture and acupressure for symptoms such as agitation, anxiety, ADL function, sleep, mood, depression, and neuropsychological disturbances. Limitations in study designs, intervention procedures and outcome measures limit the interpretations regarding efficacy of acupuncture and acupressure for BPSD. Additionally, concerns relating to generalizability limit the ability to make broad statements in support of the use of acutherapy in practice. As BPSD continue to have devastating effects on PLWD, their families, and society, there is an overwhelming need to examine the efficacy of non-pharmacologic interventions that demonstrate potential such as acutherapy.

CHAPTER III

Perceptions of Family Caregivers of Older Adults Living with Dementia Regarding Behavioral and Psychological Symptoms of Dementia and the Impact of the COVID-19 Pandemic

Background and Significance

More than 16 million Americans provide over 18 billion hours of informal, unpaid care to older adults living with Alzheimer's disease or related dementias (ADRD); the majority of care being for a family member living in the community (AARP and National Alliance for Caregiving, 2020). ADRD are chronically debilitating, progressive diseases that affect not only cognitive function, but also physical, psychological, behavioral, and social function (National Institute on Aging, 2019). Care demands are high for those with ADRD given the many effects on health (McLaughlin et al., 2010), which present substantial physical and emotional health risks for family caregivers (Schulz & Martire, 2004; Stall et al., 2019).

Older adults with ADRD often experience, interpret, and respond to situations and the environment differently from people without cognitive impairment (Hall & Buckwalter, 1987). This change in perception can increase the person's susceptibility to an array of behavioral and psychological symptoms, such as anxiety, frustration, anger, depression, delusions, paranoia, hallucinations, apathy, irritability, and mood lability. These symptoms can manifest as a spectrum of behaviors such as restlessness, agitation, aggression, resistance to care, tearfulness, paranoid behaviors, suspiciousness, inappropriate or irrational behaviors, sleep disturbances, isolation, repetitive actions, and mood changes (Kales et al., 2015; McShane, 2000). Clinicians and researchers term these symptoms and behaviors as behavioral and psychological symptoms of dementia (BPSD), which affect 98% of people living with ADRD (Cerejeira et al., 2012; Steinberg et al., 2008).

The occurrence of BPSD cannot be explained by cognitive impairment alone but is theorized to be multifactorial and dependent on dynamic interactions between many behavioral, biological, pathological, environmental, and individual level factors (Eriksson, 2000; Garand, Buckwalter, & Hall, 2000; Hall & Buckwalter, 1987; Kales, Gitlin, & Lyketsos, 2015; Smith et al., 2004). BPSD are prevalent throughout the disease process and are a significant predictor of increasing caregiver burden and distress (Allen et al., 2017; Ornstein & Gaugler, 2012). More severe BPSD leading to increased caregiver distress are also associated with earlier rates of institutionalization (or placement in long term care settings), increased risk of elder abuse, and increased healthcare utilization and costs (Stall et al., 2019).

Family caregivers of those with ADRD often have an increased amount, intensity, and complexity of caregiving demands, even when compared to caregivers of people with other chronic conditions (AARP and National Alliance for Caregiving, 2020; Kasper et al., 2015). The experiences of ADRD family caregivers are highly variable across different types and severities of ADRD (Liu et al., 2017; Mioshi et al., 2013). These findings suggest that ADRD family caregivers are experiencing unique challenges when it comes to providing care and coping with a loved ones' progressive health decline. Despite their distinct caregiving experiences, prior research has demonstrated that the insights, perceptions, and unique needs of ADRD family caregivers are often not prioritized when it comes to ADRD symptom management research (Feast et al., 2016).

Similarly, in clinical practice, care planning for those with ADRD often fails to encompass the unique needs of family caregivers, even though they are primarily responsible for the daily care of people living with ADRD in the community (Prorok et al., 2013). While the experiences of clinicians and formal caregivers have been explored, there is a need to better understand the broader experiences of family caregivers with symptoms experienced by their relatives with ADRD and their experiences with managing these symptoms in the home (Appleton & Pereira, 2017; Cohen-Mansfield et al., 2012).

The COVID-19 pandemic that began in the Spring of 2020 has increased the stress experienced by many family caregivers (Cohen et al., 2020). Due to restrictions and modifications to standard care practices and support programs during the pandemic, family caregivers may be experiencing increasing challenges to managing symptoms experienced by their loved ones with ADRD. These already vulnerable older adults with ADRD and their family caregivers have limited access to resources that they previously relied on to manage challenging symptoms at home (e.g., in-person consultations with clinicians, adult daycare programs, social support programs) (Brown et al., 2020; Greenberg et al., 2020). Public health restrictions may directly affect how their loved one manages the ADRD (e.g., physical activity, social activities) and their own ability to act as caregivers (e.g., limited support from other informal caregivers, limited experience in accessing home-based services). Families may also face new challenges related to the disease process of COVID-19, as those who experienced severe BPSD prior to the pandemic are likely to be at an increased risk of contracting the coronavirus and of experiencing more severe symptoms (Keng et al., 2020). Qualitative exploration during this time is key to understanding the impact of this global crisis on the health and wellness of vulnerable populations, such as those with ADRD and their families (Leach et al., 2020; Teti et al., 2020).

The aims of this exploratory study were driven by the need for additional research to better understand the broader experiences of family caregivers and BPSD as experienced and managed by people with ADRD and their caregivers. It also addresses how their experiences have changed as a result of the COVID-19 pandemic.

Specific Aims and Research Questions

This study was guided by 2 specific aims with 6 corresponding research questions which were:

Specific Aim 1

To explore the perspectives and experiences of family caregivers of community dwelling older adults with ADRD regarding BPSD and use of non-pharmacologic interventions for BPSD management.

Research Question 1

How do family caregivers living with older adult family members with ADRD describe their experience as caregivers?

Research Question 2

What is the nature and extent of the impact of BPSD on family caregivers of community dwelling older adults with ADRD living in the community?

Research Question 3

How do family caregivers manage (or attempt to manage) these symptoms and behaviors in the home setting and to what extent have the strategies used been helpful?

Specific Aim 2

To explore the perspectives and experiences of family caregivers of community dwelling older adult family members with ADRD regarding changes in their caregiving experiences, BPSD displayed by their family member with ADRD, and BPSD management strategies used during the COVID-19 pandemic.

Research Question 4

How do family caregivers living with people with ADRD describe their experience as caregivers during this time of COVID-19?

Research Question 5

What is the extent and nature of the impact of the COVID 19 pandemic on BPSD of community dwelling older adults with ADRD and how has this impacted family caregivers?

Research Question 6

To what extent have strategies used to manage BPSD in the home been affected during this time of COVID-19?

An additional research question for Aim 1 of this study was, “Following a brief description and visual presentation of weighted blankets, what are the perceptions of family caregivers regarding the use of weighted blankets to help manage BPSD of community dwelling older adults with ADRD?”. The findings relevant to this question are presented in Paper 3 of this dissertation.

Methods

Study Design

A qualitative, exploratory approach was used for this study. Semi-structured interviews using Zoom virtual conferencing system were conducted with family caregivers of older adults with ADRD living at home. Semi-structured interviews were designed to elicit family caregivers’ perceptions and experiences regarding behavioral and psychological symptoms exhibited by their family member with ADRD, non-pharmacological strategies they used to address these symptoms and how helpful these strategies were to better manage challenging symptoms. Furthermore, interviews explored how the COVID-19 pandemic affected caregivers' experiences in caring for their family member with ADRD, the BPSD experienced by their family member, and strategies they used to manage BPSD.

Semi-structured interviews were selected because they allow for open-ended responses and in-depth exploration of topics that may be too sensitive to discuss in a group setting (Newcomer et al., 2015). Virtual, video conference-based interviews were used as they are a feasible, acceptable, and increasingly used technique for collecting qualitative data (Archibald et al., 2019; Nehls et al., 2015). Given COVID-19 related research restrictions, this approach protected both the participants and the interviewer by limiting exposure through direct, in-person contact, which is required for traditional face-to-face interviews.

Study Sample

Family caregivers living at home with an individual with ADRD were invited to participate in virtual semi-structured interviews. The total sample size included 21 family caregivers of 20 older adults with ADRD. Two caregivers participated in the interview together as a couple, for a total of 20 interviews.

Family caregivers were selected as the population of interest, as over 70% of individuals with ADRD reside in the community setting and receive most of their care from informal caregivers, such as family members and friends (Lepore et al., 2017; Spillman et al., 2014). Across studies, a wide range of definitions have been used to define informal and family caregivers for eligibility to participate in community-based studies involving caregivers of individuals with ADRD. There is no consistent definition. This study aimed to gain insight into the perceptions and experiences of family caregivers who act as the primary or key member of the diagnosed individual's care network. Thus, this study defined family caregivers as any relative, partner or other family member who provides a broad range of assistance for an older adult with ADRD and lived in the same household (Family Caregiver Alliance, 2014).

Eligibility Criteria. The following criteria were used to identify eligible caregivers.

Inclusion criteria:

1) 21 years of age or older and identify themselves as a primary caregiver of an older adult (60 years of age or older) with ADRD who lives in the same household

2) has access and ability to use a telephone, smart phone, tablet (with internet access), or computer (with internet access and a microphone)

Exclusion criteria:

1) less than 21 years of age

2) unable to read or speak English

3) has a hearing or visual impairment that limits their ability to participate in the study

Having a family member with a specific type of ADRD (e.g., Alzheimer's disease, vascular dementia) was not a criterion for inclusion for caregiver participants. This was decided for several reasons. First, distinguishing between types of dementia can be difficult and requires advanced testing (e.g., PET imaging, CSF biomarker analysis) that individuals in earlier stages of disease living in the community may not have received. Second, diagnoses made without advanced testing may not always be accurate. Third, people with ADRD do not always receive a specific type of diagnosis from physicians (Alzheimer's Association, 2021). Not specifying an ADRD type for inclusion allowed for a broader, more inclusive eligibility criteria by not excluding individuals who may not have access to advanced diagnostic testing. Individuals were not excluded based on their relationship to the person with dementia, which means that spousal, sibling, child, and other family members were invited to participate, if they lived with a person diagnosed with ADRD and identified themselves as being a primary, nonpaid caregiver.

Recruitment

Family caregivers were recruited through two entities, the Alzheimer's Association of Michigan and the Michigan Alzheimer's Disease Research Center (MADRC). Study information and flyers were shared with potential participants at virtual support groups, educational events, organizational newsletters, websites, and by word of mouth. Interested individuals contacted the PI (Harris) directly, at which time the PI used an eligibility determination form that included the criteria listed above to confirm eligibility. Of the 25 caregivers that were screened, 21 were eligible for participation and enrolled. Of the 21 participants, 13 were referred to the study through the Alzheimer's

Association, and 8 were through the MADRC. The 4 individuals that were excluded did not live in the same household as their family member with ADRD. Recruitment began in mid-October and concluded in mid-November 2020.

Consent

Prior to scheduled interviews, all participants were provided with the study consent form electronically and reviewed the form with the PI by phone or Zoom. Participants signed the form electronically using secure, HIPAA compliant SignNow software (SignNow, 2021).

Instrumentation

A semi-structured interview guide was used to elicit information from family caregivers about:

- their experiences with behavioral and psychological symptoms experienced by their family members
- how distressing these symptoms were to them
- how they managed these symptoms
- their opinions about approaches they had tried for symptom management and
- how their experiences were affected by the COVID-19 pandemic.

The initial guide was presented individually to 3 people who identified as current or past family caregivers of individuals with ADRD to gain their feedback regarding the content, flow, cohesion of the guide and recommendations for modifications. In general, the 3 individuals found all the questions to be distinct, important, and well-stated, but they made suggestions on the order of the questions. Edits were made to the guide based on this feedback. In response to the progression of the global pandemic and resultant public health response, additional items related to the pandemic were added to finalize the guide (Appendix A).

Data Collection Procedures

Prior to beginning the recorded interview, participants were asked to answer questions relating to their demographics and caregiving status: age, race, ethnicity, gender, education level, marital status, duration of being a caregiver and their relationship to the family member with ADRD. This information was entered and stored in REDCap (Research Electronic Data Capture), a secure web database electronic data capture platform hosted by the University of Michigan (Harris et al., 2009).

Semi-structured interviews were digitally recorded using the audio recording function on Zoom. Interviews were stored in a secure Shared Account folder using a designated institutional Box.com account. Interviews lasted from 35 to 90 minutes with an average of 60 minutes. The PI led the interviews, using the semi-structured guide (Appendix A). Participants were recruited and interviewed until data saturation was reached.

Data Analysis

Descriptive statistics (frequencies, percentiles, means, standard deviations (SDs)) were used to analyze demographic data of the 21 caregivers.

To analyze interview data, audio recordings were transcribed verbatim using a transcription service. Two individuals checked transcriptions for accuracy. One interview included two primary family caregivers that participated together as a couple, in this case the unit of analysis was the transcript as a whole. All transcripts were analyzed inductively and iteratively using content analysis and constant comparative methods by a 3-member coding team (Glaser & Strauss, 1967; Strauss & Corbin, 1990). Three coders read the first 5 transcripts independently and identified minor themes that emerged from each of the transcripts. The minor themes were compared among the 3 and discussed until consensus was reached about the minor themes. Two coders then independently identified minor themes that emerged from the next 5 transcripts and discussed until consensus was reached about the minor themes from the first 10 transcripts. One coder (Harris) reviewed the final 10 transcripts and identified minor themes, which were discussed with the analytic team to finalize the minor themes across all transcripts.

Considering the minor themes within and across the interviews, 2 coders then independently grouped the minor themes that conceptually clustered together into major themes. Analysists met over a series of meetings to compare and reach consensus regarding minor theme clusters and names of major themes. Discrepancies were resolved through consensus. Steps were taken to maintain rigor and reduce bias in the analysis by cross-checking transcripts with recordings, verifying emerging themes with review of transcripts by a 3-member coding team, maintaining records of the iterations of the coding process, and by using direct quotes from participants to describe and define themes (Mays & Pope, 1995).

Findings

Participant Characteristics

Of the 21 participants, the majority were female (n=17; 81%) and non-Hispanic white (n=20; 95%). The average age was 66.2 years (SD=8.7). Nineteen participants reported education levels of some college or above. Most of the participants were caring for a spouse (n=17), while 4 were caring for a parent with ADRD.

On average, participants reported being the primary caregiver for approximately 3 years and reported providing 84 hours (SD=55.9) of care a week to their relative with ADRD. Relatives were diagnosed with Alzheimer's disease (n=9), vascular dementia (n=1), mixed-type dementia (n=2), frontotemporal dementia (n=1), Lewy body dementia (n=7), posterior cortical atrophy (n=1).

Minor and Major Themes

Minor themes that emerged from the data clustered into 10 major themes including: 1) Emotional and psychological experiences of the caregiver, 2) Emotional and psychological experiences and responses of the person with ADRD, 3) Cognition of the person with ADRD, 4) Loss, 5) Anticipation, 6) Reliance, 7) Learning to caregive, 8) Rewarding, 9) Caregiver perspectives, 10) Care strategies (Table 3.1).

Major and minor themes are presented in Table 3.1 and in the narrative below, along with illustrative examples from the data. Major themes are indicated as bolded, italicized headings and minor themes are underlined in the narrative. Minor themes highlighted in dark gray in Table 3.1 relate to the pandemic specifically and address Specific Aim 2 of this study.

Table 3.1

Themes and Quotations from Family Caregivers of Those with ADRD Living at Home

Major Theme: Emotional and Psychological Experiences of Caregiver	
Minor Themes*	Example Quotations
Loneliness related to dementia	It's just challenging the whole day especially when you're stuck in a house, it's raining, no support anywhere in sight for the next 24 hours.
Frustration	Sometimes it can be a frustrating day. She can be accusatory so I would try to retaliate "Damn it. I didn't say that. That's not what I said".
Stress	Juggling six balls in the air with details. This for me right now is the stress of the constant unending flow of details to attend to be it car insurance, be it healthcare changing over, be it a credit card getting hacked, be it whatever comes up which there are many, many things and, uh, I keep getting them.
Fatigue	I'm also more willing to order food in than I ever used to. I just have so much more on my plate and I just get exhausted. I'll say "Let's go get some food from somewhere and bring it home".
Feelings of being judged	I'm not going to, you know, deal with someone's opinion negatively about my wife, so I'm not going to take her anywhere and put her on display, you know. I don't know how she's going to be.
Reflection on early stages of dementia	Well, I didn't see any of these things as Alzheimer's. I mean I had worked in the aging field all my life and I didn't see any of the signs of Alzheimer's, you know, cutting the wrong piece of wood, not getting along with your coworkers. I totally missed it.
Feelings of isolation related to pandemic	We just can't engage in life anymore. We're just huddled hiding in our house from this disease, trying to survive it as best we can."
Neutral feelings about pandemic	Yeah, so COVID-19… so one thing I'm saying and before that… a lot of people have found this profound change in their lives because of COVID, but we have been living that life for the last almost three or four years since the diagnosis.
Major Theme: Emotional and Psychological Experiences and Responses of Person with ADRD	
Minor Themes*	Example Quotations
Loneliness related to dementia	People with dementia are still socially isolated, COVID aside. You know, they're still going to be home wishing there were people they could interact with.
Frustration	He is not angry like he used to be. He's rarely bubbling. He stays in the low frustration. I mean he doesn't stay there all the time but when he goes up, it's mild frustration. It doesn't go to the boiling point, and it doesn't go over.
Anger/agitation	He was so angry and having these terrible fits of anger, and um, was pushing me. He was throwing things and storm out of the house. Um, it was very difficult especially at night he would do these things. I understand he would wake up not knowing where he is and be scared and it would go into anger. But it was very hard for me and I would get mad back at him. "Don't you push me" and all this kind of stuff, which I think I have a right to say but also didn't have, you know. He's so focused. He has to be angry, angry, angry and work it out and then it's done. Like he can't stop midway. And so, I'm not sure he can stop midway.
Anxiety	Anxiety has been part of his life for his whole life. He's learned ways of dealing with it. He was more effective at it before he started getting dementia.
Delusions	He'll recreate whatever story he needs to help him understand it. So if I'm telling him he can't do something, uh, he'll say "Well, when you go home and my wife comes here to take care of me, I'll see if I can get her to do it." Um, so he simply creates a second one of me that's kinder and gentler to him.
Hallucinations	One of the hallucinations he had was probably a few years ago now was he saw a gorilla in our den, and I kid him and always say "I hope it was a hallucination or we have a much bigger problem."

	He'll say "Where did he go?" (giggle). And I'd say "Who?" He'd say "You know, the guy that was across the table from us." Um, and sometimes he won't tell me but it's clear that he's thought someone was there.
Paranoia	Back in November was the first time I was aware of how paranoid he was and how he was able to recreate a reality that had nothing to do with my reality
Depression	She's very emotional, depressed. I think she has a realization that the prognosis is not good.
Lack of interest	There's a number of things we used to do that we don't do anymore because she just doesn't seem to have an interest in them.
Lack of filter (acting in a way that is socially inappropriate in certain situations)	Sometimes when we go out though she says things that are just really inappropriate in kind of a loud voice like if someone's really tall or if someone's kind of heavy or if someone has a lot of tattoos, you know, she'll just make a comment and it's not quiet and it's really embarrassing. And I don't know if people hear it or if they just ignore it or what, and I'm never sure what to do, um, except that I whisper to her, you know, like "please, let's not talk about that right now.
Repetitive behaviors	Like when he washes his hands, it's just like… Well, you know, probably with the COVID thing, you're supposed to wash your hands for 20 seconds and that feels like forever counting to 20. Now, stand there and watch him do it for three minutes
Hiding things	I can't leave papers around, bills because they'll disappear, he will grab them and hide them, so as soon as I see anything, I snatch it up. He likes to hide stuff and tuck things away. So, he tends to lose things and can't remember where he put it. He's always been like that like hiding his money. But now he can't figure out what he did with it.
Sleep disturbances	He's been dozing off at the table at meals for quite a long time which I just attributed to he's not sleeping well. I'm beginning to recognize it's really a common symptom of Lewy body. He gets tired very easily now. He can sleep 11 hours at night and still take a 2 hour nap in the afternoon
Feelings of isolation related to pandemic	He always wanted a crowd of people around. But, of course, I learned to enjoy that and now it's very hard because he still wants to invite everybody over and I have to keep explaining to him because he doesn't remember what the COVID thing is.
Major Theme: Cognition of Person with ADRD	
Minor Themes*	Example Quotations
Decreased awareness in general	He doesn't recognize his house anymore where he lived for over 20 years. He doesn't know he's in (stated city name). He's lived in my house for a year. Every day he asks me where's the bathroom still.
Impaired decision making	He was driving during a whiteout and he started driving on the wrong side of the road. I think he had his brights on, which is not a problem for you. It's a problem for the other drivers. And he said "Well, it doesn't matter. It doesn't matter that it's bothering them but I've got to be able to see.' That was not characteristic of him. I mean the whiteout yes but ordinarily, he would stop and say 'I can't see anything and this is really dangerous driving. I'm going to have to pull over or something.' instead of saying 'Well, it doesn't matter if this bothers anybody else' and just want to keep going.
Impaired comprehension	About nine years ago we were at my son's who lives in California and we have some other friends out there, and I wasn't there so I heard about this, but they apparently… somebody took out a new game, like some kind of card game, and wanted to play. And he could not get the rules and instead he just made fun of it. He made it into a big joke. And it was significant enough that people told me about it when I got back that evening.
Pandemic impact on dementia progression	His cognitive decline was he was hanging in there and since we started quarantining, he has just plummeted in many ways, physically and cognitively.
Impaired awareness of pandemic	I don't really think he understands what's going on. He just understands that it's affecting him by him not being able to do the things that he likes to do.
Major Theme: Loss	
Minor Themes*	Example Quotations

Loss of independence (caregiver)	Well, I would say that it limits my ability to do things for myself and that, uh, you know, I just can't run up to the store and leave him home. I can't. I'm afraid he'll wander if I do that. So, it just really limits your personal freedom to care for an Alzheimer patient.
Loss of independence (relative with ADRD)	You know, it just changes everything and we're really not equals in our marriage anymore. He's not capable of being independent.
Loss of socialization (caregiver)	And friends, um, having someone with dementia is very socially isolating so we had a pretty good circle of friends or several circles of friends, and for the most part, they've dropped away except there's really one family and maybe my own family.
Loss of socialization (relative with ADRD)	I am a little PO'd that nobody reaches out to him, you know. That makes me sad. So then what does that do in terms of the impact of his day? He waits. He waits for me. He waits, he waits, he waits because people living with dementia frequently have a hard time initiating new things, activities. And so, if I'm busy working, he sits. It's not like she has a cold. You're not going to get it. I know we're concerned about the COVID thing but, you know, prior to COVID you could hug her. You're not going to get Alzheimer's. I don't know why certain people aren't around.
Loss of sense of self in relative with ADRD	He redesigned the Hubble telescope for NASA. I mean he is a smart, smart, smart, smart man and was well received in doing what he did in his life. And to then be reduced and I used that word… I wouldn't use it if he was here, but it's very frustrating for him, and it's frustrating for me too.
Loss of pre-dementia relationship dynamics	As the child, it's not always easy to say, you know, "You shouldn't be buying that" or "You shouldn't be acting like that" or "You shouldn't"… so taking more of like a parent/guardian role and speaking up is hard. Because in a relationship it's 50/50. Yeah, I'll cut the grass. You cook the dinner. I'll wash the car. You go shopping, or vice versa, but you can't delegate nothing no more. You are it, and you get bitter sometimes because you're tired.
Loss of pre-dementia relationship roles	And he was very good about noticing what needed to be done and making sure it was repaired. It was kind of his territory so I didn't… I could kind of ignore a lot of stuff because he would take care of it, and I can't ignore anything now. We used to be two chiefs in this family. We both wanted to do things our own way and so we would, um, you know squabble about a lot of things about who's deciding and who's going to do it their way. So, I'm the only one making the decisions now.
Loss of socialization due to pandemic (caregiver)	I miss going out with my friends. I miss my, you know… not that I went out that much but I just hold back now because I cannot afford to bring that back into the home, you know.
Loss of socialization due to pandemic (person with ADRD)	So, she doesn't really remember that kind of stuff, but I know that she realizes that she's had fewer visitors than she did before COVID.
Loss of activities and outings due to pandemic	Pumping gas, ordering food at a restaurant, you know, being in a used clothing store, you know, looking for fun T-shirts, you know, returning things, picking up prescriptions. I just tried to keep him engaged in actual life in addition to his groups. Well, I can't keep him engaged in life anymore. He just watches TV. I think it has bothered him the fact that we have not been able to attend church services. I think that has really bothered him a great deal, but I refuse and he refuses to go and did during that time and even continuing not going because we both are fearful of getting it and we both know one or the other cannot get it because that would be a nightmare.
Loss of dementia related support programs due to pandemic	I was setting him up for an adult daycare program just as this thing started and they all closed. It would have been great for me and for him to have that, you know, and who knows if we'll ever be able to do it because it seems to me… I'm not too knowledgeable about these things, but he seems to be progressing pretty quickly so he may not be able to use one of these programs by the time they open.

	What minimal support we had, you know, we can’t go to Alzheimer’s meetings, right. We can Zoom but she can’t Zoom because why? Because she can’t see, she can’t hear. It leads to frustration for her so I don’t participate in that. So, there’s whatever little support is nil.
Loss of access to resources due to pandemic	I go to Costco and try and buy Depends. In the beginning, I wanted to buy a whole bunch of boxes so I don’t have to go out a lot. They limit you to two, which it’s just stressful to be out there worrying about catching it, bringing it home, dying from it
Major Theme: Anticipation	
Minor Themes*	Example Quotations
Of disease progression	So, what I’m seeing now is a little anger, a little depression. It’s a little. It’s not a lot and it’s not out of control by any means, but um, you know, that just causes concern. Where are we going here, you know? Is this it or is this going to get worse? Knowing that it’s going to get continually worse is the hardest part for me.
Long term care planning	He’s on the waiting list for the Veteran’s Home so if it happens one year from now or five years from now, I know he’s going to have a place to go.”
End of life planning	I’m going to love him to death both in terms of loving him beyond belief and then loving him until he dies, and I want him to die here at home. Our legal affairs and our financial affairs are all in order but uh. So, we’re always looking forward to make the care easier at the end.
Of unexpected changes	It has slowly but surely taken over our lives. We were at a point where we were really starting to talk about, you know, what life would be like when we retire and we have grown children so we’re super proud of them and visit them whenever we can and they come home whenever they can. It really stopped that momentum kind of forever, um, because we don’t really know what the future holds. I mean I can sort of predict and it’s not pretty so it stopped… it really stopped our lives in a slow progression. It’s like not just advanced care planning. It’s about how to live your life the fullest today. Today’s today but what’s going to happen tomorrow because you know there’s going to be changes. So, how will we talk about that change before it actually happens.
Of pandemic effects on dementia progression	But even now, I wonder what it’s going to be like when COVID goes away and he hasn’t drove as much and he hasn’t been as social at church, and he hasn’t done his choir. And like for right now he’s bored and he’s not very motivated but what’s going to happen… I don’t think that’s going to go away. I just think it’s going to get worse.
Of caregiver or relative with ADRD getting COVID-19	If one of us got COVID, we would never survive that. So, I’ve made a decision that if I get COVID, it’s in my daughters’ hands and that I will model for them how I want him cared for and, hopefully, they can do that because no one is going to take better care of him than me. I have to tell him, we cannot do any of these things because that’s the quickest way to attract and bring that home with us and we cannot do it because we would not have a caregiver. If I come down with it, who would care for you?
Pandemic effects on care planning	First of all, you can’t plan anything. There’s nothing you can plan under COVID. There’s nothing. You can’t plan for the future. You can’t even usually plan for the day. That whole plan I had of caring for him so that he didn’t have to go into memory care I could handle it, you know with help, has all changed.
Major Theme: Reliance	
Minor Themes*	Example Quotations

Of relative with ADRD on caregiver to address physical needs	He’ll have a bite of something and then he won’t have any more and I will sit there and start feeding him bites. I mean even six months ago he would have… the fact that I’m feeding him, he would never do that before.
Of relative with ADRD on caregiver to manage new responsibilities	He’s a runner. He used to be on the city track club board. He was a major player in organizing like community events and those were his friends and now I do the communication with those friends if they want to get together to run, and he’s off all those responsibilities. When he was in a major role, um, I became his advocate to help explain the things that he could do still. So, I would say he’s still involved in service projects and I might be his interpret… I call it his cognitive interpreter. So, I will kind of say he’s really good at this or, um, I may reword something because I know he may not have understood what they’re asking him to do but it might be a two-step and I may break it down to a one-step.
Of relative with ADRD on caregiver to maintain safety	I can leave him alone yet for periods of time, but I certainly wouldn’t go away for the whole day. If I were gone away most of the day, he might venture into trying things or doing things that aren’t the best choices for him and there would be more of a chance he’d get hurt. Well, I’ve got to be very vigilant because no matter what I do she will fall somewhere along the line so I don’t want that to happen. You cannot take your eyes off her. So, a fall I think is inevitable as hard as I work to prevent that. Then it’s the beginning of the end, right? So, you fall, god forbid you break a bone, you’re admitted, you know a urinary tract infection, you know, pneumonia, bedsores, sepsis, septic shock, you know, so. I can’t leave him with the grandchildren if we’re in a babysitting situation or even if we’re there visiting if he wants to go outside with the children, I’ve got to be aware of what’s going on. So, him not being able to be responsible for children is a challenge too.
Of others on caregiver (multiple caregiving demands)	We had a neighbor die this summer and his birthday is today. He would have been 71 and his wife is at the same kind of stage that my husband. She couldn’t take him to the hospital so I had to and I became her cognitive interpreter talking through palliative care and when to take him off the vent and everything and involving the family. So, that’s kind of where I learned and I said “I’m her cognitive interpreter and I’m a nurse” so I could help explain, breakdown what was going on with him, so. That was another caring role I took on this year.
Of relative with ADRD on caregiver to maintain COVID-19 precautions	Caregiving during the pandemic… well, one of the things to be more watchful about are these changes in routines about things to do safely like wear a mask, wash your hands, etc., maintain social distance. I had to be constantly vigilant with him about doing that and actually we had one experience where he didn’t which caused me to pretty much have a total meltdown because I hadn’t realized his forgetfulness about wearing a mask or maintaining social distance. Of course, I knew that put him at risk and if he’s at risk, I’m at risk because we live together. Um, but that was a real game changer for me in that I didn’t… hadn’t appreciated the additional risk we were at. I don’t think that event changed our level of risk it just changed my appreciation for the risk that his condition would cause to us.
Major Theme: Learning to Caregive	
Minor Themes*	Example Quotations
Experiential learning	Well, for me, it’s learning by fire and I guess at first it’s kind of uncomfortable talking about the disease. So, I’ve learned to be more open with him and talking about you know you’ve got Lewy body and that this is happening or that’s happening. I don’t know if he understands it all the time, but at least more openly talking about you have something that’s causing you to do that. I’m not just, you know, being mean. I’m doing this to try to help you.
Learning from others	I worked with a lot of families through my job who had somebody with dementia. I wish they were around now because they loved me and they thought I was so great and did all this stuff for them, but little do they know, I learned from them for what we are going through now.

Learning to be flexible	When I know that I’m rested and taken care of I can be very affirming and positive and know not to ask certain questions that can’t be answered because being able to keep on my toes and one step ahead is kind of the name of the game.
Learning to be patient	It’s a loved one and, unfortunately, she has no control. And you have to be understanding but you have to be beyond your wildest imagination patient.
Major Theme: Rewarding	
Minor Themes*	Example Quotations
Increased togetherness due to dementia diagnosis	He’s probably heading towards the end of his life so the up side is we’re getting to spend some quality time with him that you wouldn’t normally get.
New opportunities	It did great things for him, and um, then it also opened up this social opportunity because we had never been to a dog show and we put her in dog obedience and, you know, won of course. So, our dog trainer, she loves it because now she does our dementia stuff. Whenever we do a dementia training, she does our dementia stuff. And she’s like “I opened the dog world up to you and you opened up the dementia world to me. I keep thinking of taking a picture of him and sending it to the fellow that heads up the brain bank and telling him he’s keeping it warm now because you’re going to keep it on ice for a very long time (laughing). We try to have a little humor about all of this, but uh, he feels… He’s going to be able to literally keep doing something after he dies. How many people can say that? That he may literally do the most important thing he’s done in his entire life after he dies, you know, I mean it’s a pretty amazing things.
Greater appreciation for the little things	The other day we were out on the patio and she was just spontaneously starts dancing. We were playing the 60s and Motown music and it was cute. I took a couple of videos and sent it to people. She did it for 20 to 30 minutes and so that was nice.
Opportunity to care for loved one	Just being there for him. I think in some ways just helping him, um, helping him with things and making him feel good about himself, you know, especially when he’s kind of down or something to just be there for him. I guess rewarding or fulfilling for me is that when I am able to help him and he recognizes that that help is valuable and really appreciates it. He’s becoming as I see it more dependent on me and, um, he knows it. Again, he knows it and appreciates it, so The best is that I’m still able to take care of him at home, uh, you know, other than the five hours that I’m really doing some very direct caregiving, uh, we’re living in the same house that we’ve lived in for over 20 years and it’s familiar and there’s still a lot about him that’s familiar from time to time less, but generally more. Uh, and we’ve had a really nice life together.
Increased togetherness due to pandemic	The pandemic has given us an opportunity to be really close with one another and have more conversations.
Simplification of caregiving process due to pandemic	Of course, doctors’ appointments are great now that everybody is doing teledoc appointments. It’s almost easier for him because he would get very nervous because it’s something new. He would get very agitated when we’re going out or doing something that he’s not sure of what we’re doing. So, it makes it easy now. We’re sitting on the couch. The doctor chats with (stated first name) for a minute or two and then we can talk away so that’s been really helpful. Ironically, in some ways it makes it easier because before the quarantine went into place, he would want to go to the bookstore or the grocery store or the mall to do stuff and, frankly, his executive ability was so impaired that it was a matter of, um, just being indecisive. He’d get to the bookstore and he’d look at books for two or three hours until I would finally say “We need to go home and make dinner.” Um, and now, I can say “Barnes and Nobles is closed. Sorry.”
Major Theme: Caregiver Perspectives	
Minor Themes*	Example Quotations

Views on caregiving	Being a nurse helps. Over the years, I saw people who were navigating changes in their life and I think in my 20s as a nurse with spinal cord injuries, burns, multiple trauma, I learned that, hey, life is fragile and we don’t get to pick what gets thrown our way, and so um, I think that has helped me because even being a psych nurse helped me realize that navigating change is critical. Um, I used to love the saying normal is just a setting on your dryer.
Views on long term care	I started thinking I am never going to put him in a memory care facility, ever, which is why I bought this small condo retro kind of fitted for a wheelchair person that was there before because I was going to go home and have my family members help me because I decided that I was never putting him in memory care.
Views on person with ADRD’s pre-dementia characteristics	Uh, in his own personality he is a person that within our marriage faces outward instead of inward, and he’s been that way with the family and, you know, so that has really exacerbated with the disease because it’s my understanding that they turn in on themselves even more. Now, that may seem weird but he has core goodness about him. And, for example, he won’t have a penny on him. Before COVID, we would be out. His wallet just had his ID and his emergency card for EMS people, and he would see a homeless person and he would like immediately grab for his wallet.
Views on virtual resources during pandemic	It strips away everything from you but just trying to do Zoom, and I don’t think he comprehends Zoom and who’s on the other end. I just don’t think it’s an interface he really connects to, the computer anymore.
Views on social distancing during pandemic	Well, being in the quarantine for 90 days was difficult but, in all honesty, I’ve lightened things up a little bit. Have I become foolish? Am I going to large gatherings?” No, but we walk on Wednesdays with a small group of people.
Views on pre-pandemic degree of socialization	A lot of people have found this profound change in their lives because of COVID, but we have been living that life for the last almost three or four years. In the initial three years of her disease, you know, we were able to travel and visit friends, family and everything but since 2015 we are mostly homebound.
Major Theme: Care Strategies *General Management Strategies*	
Minor Themes*	Example Quotations
Self-care for caregiver	I tell myself every day this; I just need to unplug and I do that. He goes to bed every night at nine faithfully, and I just stop everything and I sit down and I read a novel.
Self-care for person with ADRD	My husband has taken it upon himself to write a blog, and um, it’s based, um… It’s loosely based on his faith, Christian faith, and it’s interesting. It’s his thoughts with dementia and in one of his blogs I have an expiration date or I know my expiration date which is interesting. So, he at least has somewhat of a healthy attitude. Um, he has told me he’s reading up a lot lately on caregiving and how hard caregiving is and maybe that’s helped him too.
Reorient person with ADRD	The other thing that I started months ago that is clearly useful is, uh, we have a big whiteboard in the library and every evening I go in and write down what tomorrow’s activities will be including what’s for breakfast and what’s for dinner. Those are the things he can respond to and appreciate
Incontinence care	There were two different kinds of Depends. Some that are better for the short term and some that are called Nighttime Depends. And I just stopped ordering the daytime ones so he just wears the nighttime ones and changes them whenever he needs to, wants to, thinks it’s a good idea, and again, we have the financial resources that, you know, I can do that.
Maintain routine	I’m kind of a schedule oriented person and a routine oriented person so coming up with one that fit us both was something I did from the very beginning and I think it’s very helpful.
Humor	So, um, he sometimes sees two of me and I tell him that’s my evil twin. We kid about my evil twin. Sometimes he says “You know, your evil twin is kind of cute.” I said, “Well, she’s my twin, you know.” So, we kind of kid about it. It helps, you know, it puts it into perspective.

	I use a lot of humor repetitively as a measuring tool to see where he is, and um, that’s just like an example of the humor I use. I use a lot, a whole lot of sexual humor because, uh, I think men respond to sexual stimuli even an Alzheimer man.
Support from healthcare providers	I would advocate for training in medical schools for doctors because I have not had positive experiences with the doctors, um, and they don’t seem to know how to handle a person with dementia, or how to care for them.
Respite care	I tried taking him to an adult daycare, and I could see he was quickly spinning out of control. I didn’t realize how he just hated that place so anytime we go anywhere near that place, he starts getting so agitated now. He remembers that experience and he doesn’t like it.
Virtual activities and social support programs	We watched a concert. We have a band we like called the We Banjo 3, and they had a virtual concert last week or was it the week before? So, we watched that from here. So, that’s something that she can enjoy. It doesn’t require a lot of deep mental comprehension.
Influence of pandemic on care strategies	It made it all harder probably because he can’t go do the things he enjoyed doing, and I feel like that helped his OCD (obsessive compulsive disorder). You know, it made him more tired so he slept better at night. It just brought him joy.
Care Strategies Related to the Emotional and Psychological Experiences of the Person with ADRD	
Minor Themes*	Example Quotations
Change caregiving perspective	I talk in terms of Lewy being this third character that lives in our house. In fact, I actually use the words “There are three of us that live in this house now. You, me and Lewy, and the two of us have to work together to deal with Lewy. As opposed to saying to him “You’re not doing this. You can’t do this.” It’s like “Lewy is getting in the way of you doing this.” It puts a totally different spin on it from saying you can’t do it.
Change caregiving behavior	So managing it means managing me and managing sort of the environment or whatever it is that led up to it. When I talk to you about behavioral symptoms and signs of dementia, I see that fog and I can adjust myself accordingly so that he doesn’t have what people would say “those behavioral signs and symptoms” of dementia because I can adjust my approach to him. Now, if I’m not in tuned to it, we both pay the price, you know.
Withdrawing from challenging situations	I have little things… when I get sad or upset I, you know, I stay away from him for a few minutes and then I calm myself down and then I go back because he picks up my mood. I have to walk off. I have to because if I think continuing on with it is the answer to the problem, it is not. I say rule number one is give him space and walk off.
Care strategies for anger/agitation	Before COVID we started CBD (cannabidiol oil) and we had a night and day difference. I mean he has the frustration… but he doesn’t have the fearful, I’m so afraid of him anger. I think the most helpful thing is just waiting until he’s calm to go back and try to talk and, fortunately, he’s still okay enough to say “I didn’t realize I did that” or “I didn’t know I did it.” And “Is that really what happened?” And he trusts us.
Care strategies for anxiety	Our service dog Sophie is a huge… just the purpose of getting up, letting her go potty, training her. Yeah, and the sense of having her there he says it’s huge with his anxiety. He does not feel like he’s alone… He loves music. That’s been a really great thing. If I’m in my office doing work and he’s really restless, he’ll walk in my office to try to sort of see what I’m doing and, um, my son gave me some cordless… a cordless headset for my birthday and I love it because I can block him out. But he really likes wearing them so I find his favorite 80s music which brings back memories from college and he’ll sit down and he’ll listen to music.

	Yeah, one thing when she is really upset or something, we keep grapes handy, you know, and put grapes in her mouth or something. And what happens is that I think just the chewing, you know, the process takes her mind off whatever she may be, you know, so that helps. My wife loves to sit in the van. We have a Chrysler Pacifica. We always had minivan and somehow she loves to, you know, sit in the car so in a 24 hour day maybe she would sit in the car for one or two hours and that's her time. She has her own time.
Care strategies for paranoia	"I've tried to be truthful. I'll say, "I love you. I'm here for the journey." "I'm not going anywhere." "You leaving?" "No, I'm not leaving." She'll cry "They said you're going." "No." And then if that doesn't work being truthful, I'll just go to the change the subject. You can't explain and rationalize with them, correct? So, you just try to change the subject.
Care strategies for sleep	He takes a nap early, he's often strikingly better for most of the afternoon and evening.
Medications	When he went on Seroquel, his hallucinations and his wanderings both subsided. I'm not going to drug her like...she's her on Lexapro for anti-anxiety. And does it work? Who in the hell knows. Personally, I don't.

Note. ADRD Alzheimer's disease or related dementias
*Minor themes related to the COVID-19 pandemic specifically are highlighted in dark gray with white text.

Emotional and Psychological Experiences of Caregiver

Caregivers described their own emotional and psychological experiences through stories and detailed narratives. This major theme is comprised of 8 minor themes experienced pre-pandemic: feelings of loneliness, frustration, stress, fatigue, feelings of being judged by others, and reflections on early stages of their relative's ADRD (Table 3.1).

Caregivers described feelings of loneliness related to their relative's ADRD diagnosis (Table 3.1).

> *"I feel loneliness because of the dementia. I mean it changes everything. You know, it just changes everything and we're really not equals in our marriage anymore."*

Caregivers also provided examples of their feelings of frustration which linked to feelings of loneliness (Table 3.1).

> *"The hardest part is probably my own impatience and my need to remind myself that this is the disease talking and not him talking. Sometimes he even reminds me of that when he's got some insight, but otherwise I just get so frustrated that he's not able to do the things he used to be able to do. Um, and at those points I feel somewhat alone."*

They described how changes in their relative's abilities often led to new responsibilities, which increased their feelings of stress and fatigue (Table 3.1).

> *"I'm also more willing to order food in than I ever used to. I just have so much more on my plate and I just get exhausted. I'll say "Let's go get some food from somewhere and bring it home."*

Some participants described situations where they felt judged by others (Table 3.1), which prompted efforts to protect themselves and their relatives from embarrassment when in public

> *"I try to protect him a lot. I try to protect him from embarrassment and of being judged, and perhaps that's selfish; perhaps I'm protecting me from embarrassment too."*

Caregivers reflected on how they responded emotionally to the early stages of their relative's dementia (Table 3.1).

> *"So, all those emotions happen, you know, some before… before, early on in the process is denial. Some people are in denial throughout the journey even after the person is no longer there."*

They described many ways in which their experiences as caregivers were influenced by the COVID-19 pandemic. One caregiver said:

> *"The COVID, um, concerns or the condition of having COVID in our lives is another layer of, um, things to cope with or manage or see your way through. Kind of every decision has a COVID overlay…"*

Most caregivers experienced feelings of isolation during the pandemic (Table 3.1).

> *"Then with the COVID thing, it just kind of compounds it, compounds the isolation even more because we've been self-isolated for over three months."*

Other caregivers described more neutral feelings towards they pandemic as the isolation they felt during the pandemic was less severe because they were already experiencing similar isolation due to the ADRD diagnosis.

> *"I would wholeheartedly agree with that maybe because I've been prepped for it as this began and, therefore, the lifestyle had changed already when his dementia began. You know, my lifestyle changed back then already so it… the pandemic just didn't do that much to change my life that drastically to be quite honest with you."*

Emotional and Psychological Experiences and Responses of the Person with ADRD

Caregivers described the experiences and responses of the person with ADRD without using the words symptoms or behaviors. Instead, caregivers described emotional and psychological experiences of their relatives, which in some cases were linked to certain responses that clinicians and investigators would consider BPSD. The stories and examples told by caregivers were often dynamic and reflected their relative's thoughts, feelings, responses, and reactions to the disease, as well as to other aspects of daily life. In attempt to remain as true to the stories of participants, this analysis and the following narrative uses the terms “experiences” and “responses” instead of the clinical terms of “symptoms” and “behaviors”. This major theme is comprised of 14 minor themes: feelings of loneliness related to the ADRD, frustration, anger/agitation, anxiety, delusions, hallucinations, paranoia, depression, a lack of interest, a lack of filter (or acting in a way that is socially inappropriate), repetitive behaviors, hiding things, and sleep disturbances (Table 3.1). Caregivers also described their relative’s feelings of isolation related to the pandemic (Table 3.1).

In addition to their own feelings, caregivers also described loneliness and frustration felt by their relatives with ADRD (Table 3.1).

> *“I’m reading this diagnostic information and he and I are sitting together, not side by side, but where our knees were touching, and um, I read it and it was vascular dementia and a couple other things there. I was thinking we are physically touching but that we must be probably as far apart as any two people could be because it is happening to his body. How alone he must have felt.”*

Another said:

> *“I say he’s more frequently frustrated because he is now in a way, he has a level of awareness about the changes that are happening to him and not liking them.”*

Caregivers gave many examples of anxiety experienced by their relatives, such as separation anxiety, restlessness, pacing, panic attacks, loss of emotional control, worry, and physical complaints (Table 3.1). One caregiver described the following:

> *“He gets anxious and panicky. He paces. He has a couple phrases he always says that don’t make any sense. He repeats them over and over and over, and he walks around the house. He goes outside. He’s just beside himself, um, and it is hard to deal with.”*

One caregiver described a distinction between a caregiver’s interpretation of anger in their relative, versus what the relative described as anxiety.

> *“When I talked with the wives’ of these people living with dementia, and um, husbands or significant others, that’s when I discovered that the person living with dementia described it as anxiety. The care partner described it as anger. So, their anxiety comes out as anger apparently.”*

Anger and agitation were described as the most challenging responses for caregivers (Table 3.1), which often began with anxiety or frustration.

> *"With his anger, there's low level, there's bubbling and then there's overflow. We are always trying to prevent the overflow."*

Another said:

> *"I can help somebody eat. I can wipe a butt. I can do all that, but the anger and the insult is the hardest thing."*

Caregivers described psychologic manifestations experienced by their relatives such as hallucinations, delusions, and paranoia (Table 3.1). Some caregivers described a disconnect with their relative that they felt due to paranoid delusions.

> *"Back in November was the first time I was aware of how paranoid he was and how he was able to recreate a reality that had nothing to do with my reality"*

Many caregivers described how their relatives experienced depression and a lack of interest since the ADRD diagnosis (Table 3.1). Some caregivers attributed these feelings directly to the ADRD diagnosis.

> *"The depression and the sadness, it came from the Alzheimer's, being told he had Alzheimer's. He was quite depressed about that and was worried."*
>
> *"There's a number of things we used to do that we don't do anymore because she just doesn't seem to have an interest in them."*

Caregivers provided examples of when their relatives had a lack of filter or acted in a way that was socially inappropriate for the situation (Table 3.1). Some of these moments led to caregivers having feelings of embarrassment, or feelings of being judged by others.

> *"Sometimes when we go out though she says things that are just really inappropriate in kind of a loud voice like if someone's really tall or if someone's kind of heavy or if someone has a lot of tattoos, you know, she'll just make a comment and it's not quiet and it's really embarrassing. And I don't know if people hear it or if they just ignore it or what, and I'm never sure what to do, um, except that I whisper to her, you know, like "please, let's not talk about that right now"."*

Caregivers described specific habits that their relatives had that were once challenging for them (e.g., hiding things, repetitive actions) (Table 3.1), of which they learned to tolerate as they continued in their caregiving journey.

> *"So, he had another habit of hiding… taking my things and hide them all around the house. Um, and it would just drive me crazy. And then, I just said, well, what the heck. He's going to do it anyway."*

Sleep disturbances experienced by relatives were described by most caregivers and included examples such as difficulty falling asleep, difficulty staying asleep, daytime sleepiness and fatigue, and restless sleep (Table 3.1). Some caregivers described how these sleep disturbances affected their own ability to sleep as they felt obligated to monitor their relative overnight to maintain safety.

> *"He would wake up every two hours like clockwork and wake me up and want to get up and do something or just be angry for no reason or what was no apparent reason, so I wasn't getting any sleep."*

Related to the pandemic, caregivers that described their relative as someone who experienced challenging symptoms pre-pandemic often described how their symptoms had progressed more quickly during the pandemic:

> *"It's accelerated them you know, from COVID, that otherwise I don't think he would have been experiencing them so quickly."*

Meanwhile, caregivers that described their relative as someone who did not experience many symptoms before the pandemic described that the pandemic had not significantly affected their relative's experiences during the pandemic:

> *"I don't think it's affected him so much because, we just didn't have any really challenging symptoms before."*

Caregivers often attributed more pronounced symptoms and behaviors, as well as accelerated disease progression during the pandemic to the loss of socialization and activity for their relative due to pandemic related public health responses. One caregiver described the following when talking about her relative's anxiety:

> *"I think if we were able to get out more, I think that he wouldn't… it wouldn't weigh so heavy on his mind. He'd have other things to think about besides worrying about his ailments."*

Cognition of Person with ADRD

In addition to emotional and psychological experiences and responses, caregivers also described their relative's cognition through descriptions of their decreased awareness, impaired decision making, and impaired comprehension (Table 3.1). One caregiver described:

> *"The Alzheimer's affected her ability to not be able to remember things but also not to comprehend what's going on in her life and other people's life."*

The decrease in awareness sometimes influenced their relative's emotional experience.

> *"A lot of the times she'll just sit on the couch and watch TV and kind of not be mindful of what else is going on and then it's like she'll have a little awakening and realize that she's got a memory issue or an awareness issue and kind of talk about being frustrated by it and kind of get irritated by that fact."*

Caregivers also described their relative's lack of awareness of the pandemic specifically (Table 3.1), which impacted their ability to adhere to public health guidelines:

> *"He doesn't comprehend washing his hands, wiping his hands. He doesn't comprehend the safety, the staying six feet from people."*

They also noted the impact the pandemic had on their relative's disease progression more generally (Table 3.1):

> *"His cognitive decline was he was hanging in there and since we started quarantining, he has just plummeted in many ways, physically and cognitively."*

Loss

Descriptions of loss relating to the ADRD were very prevalent. Minor themes included loss of independence (for caregiver and for the relative with ADRD), loss of socialization (for caregiver and for the relative with ADRD), loss of sense of self in the relative with ADRD, and loss of pre-dementia relationship dynamics and roles (Table 3.11).

Caregivers described loss of their own independence, as well as the loss of their relative's independence since diagnosis:

> "It's pretty profound because not only does she lose her independence, you lose your independence because she needs 24/7 care."

Another caregiver said:

> *"It limits my ability to do things for myself and that, you know, I just can't run up to the store and leave him home. I can't. I'm afraid he'll wander if I do that. So, it just really limits your personal freedom to care for an Alzheimer patient."*

The also described a loss of socialization, for both themselves and for their relatives (Table 3.1).

> *"This is a very strange thing, you know, the people you know, the people you thought who very close. Somehow they're not in your life anymore..."*

Caregivers gave examples of how their relatives experienced a loss of their sense of self since diagnosis (Table 3.1).

> *"So, it's unfortunate because she's always considered her mind to be her greatest asset and that's gone."*

As reported by another caregiver:

> *"He's just pulling inward more which is… he's not that kind of person. He's more out… he's an outgoing person."*

Others described a loss of a previously known relationship roles and relationship dynamics since their relative's diagnosis, which posed many challenges as caregivers often had to take on new responsibilities (e.g., paying bills, managing all the household chores, home repairs) (Table 3.1).

> *"Um, well, I mean it's not easy, it's making that shift of me as a partner, a partnership, to me as caregiver for somebody who's not offering much back."*

Another (adult child of the person with dementia) said:

> *"As the child, it's not always easy to say, you know, "You shouldn't be buying that" or "You shouldn't be acting like that" or "You shouldn't"… so taking more of like a parent/guardian role and speaking up is hard."*

Caregivers described a loss of socialization related to the pandemic (Table 3.1). Many said that the pandemic related restrictions exacerbated the loss of socialization that they already felt due to their relative's ADRD. Descriptions of loss of activities and outings were common, such as loss of social activities, travel, religious services, and family gatherings (Table 3.1). Caregivers described loss of physical activities and exercise, which impacted their own and their relative's overall health and well-being (Table 3.1).

> *"He can't go do the things he enjoyed doing like walking and going to the gym, and I feel like that helped his OCD. You know, it made him more tired so he slept better at night. It just brought him joy."*

The most often mentioned lost outing was the opportunity to go out to eat at restaurants, which was a significant social activity for many caregivers and their relatives with ADRD.

> *"One thing we used to go out to eat a lot and that was socialization for me, you know, just talking to the wait person a little bit or being just out. And he enjoyed it. It was an outing, you know, and we can't do that anymore."*

Many described loss of access to dementia related support programs, such as adult day programs, support groups, and caregiver wellness programs, in addition to a general loss of access to resources (Table 3.1). These losses compounded challenges dyads were experiencing prior to the pandemic and presented new challenges to in-home care during the pandemic.

Anticipation

Caregivers gave many examples of anticipation of their relative's disease progression and of unexpected changes, as well as descriptions of long-term care and end-of-life planning (Table 3.1). Anticipation of disease progression and of unexpected changes was a concern for many caregivers:

> *"Uncertainty as to how this disease will progress over time is a great source of concern for me, worry I guess."*

Another said:

> *"It has slowly but surely taken over our lives. We were at a point where we were really starting to talk about, you know, what life would be like when we retire and we have grown children so we're super proud of them and visit them whenever we can and they come home whenever they can. It really stopped that momentum kind of forever, um, because we don't really know what the future holds. I mean I can sort of predict and it's not pretty so it stopped… it really stopped our lives in a slow progression."*

These concerns about the future prompted the need for long-term-care and end-of-life planning (Table 3.1).

> *"In preparation, we did visit some senior communities. So, we did that together because I said I could be the one that has the stroke and you could need someone to cook for you, you know, because I take on most of the cooking. So, we had done some planning and we both decided that as long as we're physically able we love staying in this house."*

Caregivers anticipated the pandemic's effects on their relative's disease progression, as well as what would happen if they or their relative contracted the coronavirus (Table 3.1).

> *"I think, that it's going to shorten my husband's life significantly. I don't think that the world, or political powers are looking at the half-life of this stuff and the fallout and how long it's going to last."*

In general, caregivers described that the pandemic greatly inhibited their ability to plan for future care of their relative:

> *"First of all, you can't plan anything. There's nothing you can plan under COVID. There's nothing. You can't plan for the future. You can't even usually plan for the day.".*

Reliance

Caregivers described many ways in which their relatives with ADRD were reliant on them as caregivers. Their relatives were reliant on them to address their physical needs, to manage new responsibilities, and to maintain safety before and during the COVID-19 pandemic (Table 3.1). This reliance often inhibited caregivers' degree of independence.

> *"You know, I have to get dressed. She has to get dressed. I have to wash. I have to wash her. I have to feed her. She can't be a participant in a collaborative effort.".*

> *"From time to time, I just have to quit work during the day and do something because he needs something or wants something or he just needs some attention."*

Reliance on the caregiver to maintain safety was prevalent across interviews, which increased the caregiver's level of responsibility.

> *"I can leave him alone yet for periods of time, but I certainly wouldn't go away for the whole day. If I were gone away most of the day, he might venture into trying things or doing things that aren't the best choices for him and there would be more of a chance he'd get hurt."*

Caregivers also described the challenges of having multiple caregiving demands:

> *"I also watch my two grandkids all summer a couple days a week so it was bringing them up here and having the kids here and my dad here and trying to have all that activity and stuff. The kids would go one way. He would go another way. That was challenging."*

The pandemic posed new challenges to care outside the home, as relatives with ADRD were often reliant on their caregivers to maintain COVID-19 specific safety precautions (Table 3.1).

> *"Making sure the mask was with us when we went places; making sure we don't separate from each other just because social distancing isn't comprehended very well and to go places I have to be a supervisor of that."*

Learning to Caregive

Many caregivers described the process of learning to caregive as an experiential learning process, as well as learning from others (Table 3.1).

> *"It's like having a kid. It's like having… even though I don't have children, you know, no one ever gives you the manual of how to do all these things, and you just kind of learn on the fly."*

> *"I've learned the most is by talking with our group of eight people who have dementia and hear from them specifically what it's like to have dementia."*

Flexibility and patience were identified as important aspects to learn to be a caregiver for a relative with ADRD (Table 3.1).

> *"You know, the hardest part is, uh, you know, as she's changing, you know, I have to keep changing myself. So, I can't be fixed in my thoughts, my strategy or anything so every strategy has to evolve."*

Rewarding

All caregivers identified rewarding aspects of caregiving including increased togetherness due to the relative's ADRD, new opportunities, and a greater appreciation for the little things in life (Table 3.1). Feelings of love and increased togetherness as a couple were prevalent.

> *"I love our life and we have a great life. I'm happy. I think my husband's happy most of the time too."*

Examples of rewarding new opportunities since the relative's diagnosis, such as personal growth, and opportunities to contribute to society were also described.

> *"So, the disease has taught me that, you know, to come to some level of emotional acceptance and another thing I would say; just taking care of her it requires a lot of love and care and compassion so I believe I have become a little bit more compassionate."*

Another said:

> *"But our mission really is to do as much education as we can, be as transparent as we can. You know, I don't want people to have to go to the point that we did before you get a diagnosis. I don't want people to think that life can't be good after a diagnosis. And so, we're just very much just seeking opportunities so I very much appreciate it."*

Caregivers described a deeper appreciation for the little things since the relative's diagnosis.

> *"The other day we were out on the patio and she was just spontaneously starts dancing. We were playing the 60s and Motown music and it was cute. I took a couple of videos and sent it to people. She did it for 20 to 30 minutes and that was so nice."*

Many caregivers described the opportunity to care for a loved one as the most rewarding aspect of the caregiving experience.

> *"Just being there for him. I think in some ways just helping him, um, helping him with things and making him feel good about himself, you know, especially when he's kind of down or something to just be there for him."*

Some caregivers also identified rewarding aspects of the pandemic, such as increased togetherness and simplification of the caring process (Table 3.1). One caregiver said:

> *"I would say the pandemic made it easier because we don't have other challenges to our simple routine."*

Meanwhile others maintained that the pandemic was not rewarding to them, but it represented a major threat to the health of their relative with ADRD.

> *"I think he's declined, but I totally think it's the lack of socialization and engaging in life that has exponentially caused his decline. It's COVID in my opinion, totally COVID."*

Caregiver Perspectives

Caregivers held many views and perspectives that shaped their experiences and their caring process. They described views on caregiving in general, on long-term-care, and on their relative's pre-dementia characteristics (Table 3.1). In terms of views on caregiving, one participant said:

> *"Words mean different things to different people. So, my very first time that somebody called me a caregiver I felt like they called me a babysitter. I'm like "Caregiver? He's my husband." You can call me care partner because we care*

> *about each other. We've been partners for a lifetime. We are partners. It's not a one way giver."*

This view was prevalent in many caregivers as they described the caring process as a partnership experience.

Caregivers described their perspectives regarding long-term care (Table 3.1).

> *"I am enabling her life to be better as compared to let's say she was in an assisted living space. I think I can provide her a better level of care and love that she wouldn't get there. Um, you know, and we've been married 49 years so, you know, after all that time you develop, obviously a closeness for the person you're caring for as opposed to being somebody that you're not related to."*

They also gave many examples of their perspectives on how characteristics that their relatives had before the dementia diagnosis influenced their experiences with the disease (Table 3.1).

> *"He's a little farm boy from way back and so he never spent much time in the house in his younger years. He would be out in the woods on his ten acres picking up branches, building a fire to burn the branches, trimming things that don't need trimming, you know, so it's very difficult for him to just sit. He doesn't want to watch TV. He doesn't want to play cards. He doesn't want to read a book. Today he said, "Well, if we could just get an old tractor, we could go out and rebuild it out in the garage." You know, so that's the kind of activity he wants to do. It can't be done now, I guess."*

Caregivers also held views related to the pandemic, including views on virtual resources, social distancing, and how their pre-pandemic degree of socialization influenced their experiences during the pandemic (Table 3.1).

Views on virtual resources during the pandemic were mixed (Table 3.1). Some caregivers held negative views and described how they were not useful to their relatives or their caregiving experience.

> *"What minimal support we had, you know, we can't go to Alzheimer's meetings, right. We can Zoom but she can't Zoom because why? Because she can't see, she can't hear. It leads to frustration for her so I don't participate in that. So, there's whatever little support is nil."*

Others said that virtual approach was not preferred, but they appreciated having the option given the circumstances of the pandemic.

> *"My husband belongs to a discussion group that he used to go to every Thursday. Well, that's still going but on Zoom now, you know. So, he still does that. Our synagogue has a lot of stuff on Zoom, so um. Yeah, we listened to a speaker last night on Zoom. Uh, so it's really helped. It helps. Is it ideal? No, it's not."*

Caregivers held views on social distancing during the pandemic (Table 3.1), most described relatively strict adherence to social distancing guidelines.

> *"So, with COVID in our house, um, we are almost like when we were in total shutdown like when you were supposed to stay home. We're almost like that but, like I said, we don't have our housekeepers come in anymore. Um, we don't go anywhere. I've gone to the grocery store a couple of times but mostly I do the… order my food and they put it in my trunk kind of thing."*

Many caregivers also described how their pre-pandemic degree of socialization influenced the impact that the loss of socialization had on them during the pandemic (Table 3.1).

> *"Yeah, so COVID-19… a lot of people have found this profound change in their lives because of COVID, but we have been living that life for the last almost three or four years. In the initial three years of her disease, you know, we were able to travel and visit friends, family and everything but since 2015 we are mostly homebound."*

> *"We were already isolating because of the dementia, then with the COVID thing, it just kind of compounds it or, yeah, compounds it even more because we've been self-isolated for over what over three months."*

Others described how they were very social before the pandemic, which came at a significant loss to them during the pandemic.

> *"We used to be very social. We had friends. We went out. We went to events. We're very political. We went to a political event. Um, and uh, that has basically not totally but basically stopped which has been one of the really hard things for him because he's a very social person and he wants to be around a crowd."*

Care Strategies

Caregivers gave many examples of care strategies they used in the home to promote their own and their relative's well-being. This theme relates to two major areas including *general management strategies* and *care strategies related to the emotional and psychological experiences of the person with ADRD***.**

General Management Strategies. Caregivers described general management strategies, such as self-care strategies (for themselves and for their relatives with ADRD), strategies to reorient their relatives, and for incontinence care (Table 1). They detailed the importance of using humor and maintaining a daily routine when caring for their relatives with ADRD. Some described their experiences in using respite care and support from healthcare providers (Table 3.1)

Self-care strategies used by caregivers (e.g., yoga, tai chi, support groups, diaries), as well as those used by relatives with ADRD (e.g., blogging, "alone time", music) were described as important to both caregivers and their relatives

> *"For me, one of the things I find helpful is just to walk out of the room, leave him to his own devices for a little while, um. I used to go for a short walk. I'm a little less eager to do that now so I do go outside. We have a tree swing that I sit down on and swing for 10 or 15 minutes. Uh, I take a couple of Zoom yoga classes during the week and I'm able to say "Okay, this is my time. I'm going off to the family room to do some yoga"."*

> *"So, he's writing a book. He's going to put it together and give it to the grandchildren but it's very cute. It's from the dog's perspective about dementia. It is good for him to get out how he feels you know, even if doesn't really finish it."*

Other important general management strategies included maintenance of a daily routine and the use of humor (Table 3.1). Humor specifically was described as a strategy that was beneficial for the person with ADRD and the caregiver.

> *"We have a lot of humor and like even when I'm cutting his hair… I do his haircuts and we just make events out of simple everyday things. Like we may have a beer and a wine while we're doing a haircut. We have happy hour every day and happy hour is kind of for me because he might want to keep working into the evening if it was daylight and I'll say "No, we're quitting. We're having music. We're having happy hour.*

Many strategies designed to reorient the person with ADRD to place, time, and situation (e.g., the use of white boards with the date and reminders of the daily schedule, repetitive songs as reminders) were proposed by caregivers.

> *"He can still read. And so, we put as much things in writing as we can. We have big posters on the wall with people's pictures and their relationship. So, we're using that tool to kind of keep him informed of things."*

Incontinence was a challenging aspect of ADRD for many caregivers. They had identified very few effective management options for incontinence.

> *"I've tried a gazillion ways to try to figure out how to keep him from wetting all over himself. I can't seem to figure out how to keep him dry at night. I bought these rubber pants from the internet that said they're guaranteed, well not guaranteed but, you know, every review said that it stopped that. I bought those, $25 for one pair of rubber pants, right? Did nothing."*

Some caregivers described their experiences with trying to receive <u>support from healthcare providers</u>, the majority of whom described that these supports were less helpful than they had expected them to be.

> *"And the regular doctors, the primary care, or at least the ones I've seen didn't really know how to handle the situation. They just shooed me off into that department to deal with it."*

Another caregiver suggested the following:

> *"I think all the doctors… they have a lot of elderly patients. They must have a lot of people with dementia so they need better training in my opinion. So, I think it would be great if someone with some knowledge on the topic did some training in medical schools. I don't know if they do."*

<u>Respite care</u> was described as a strategy employed by a few caregivers, but their relative's emotional response to respite care environments limited the helpfulness of this resource.

> *"I tried taking him to an adult daycare, and I could see he was quickly spinning out of control. I didn't realize how he just hated that place so anytime we go anywhere near that place, he starts getting so agitated now. He remembers that experience and he doesn't like it."*

Relating to the pandemic, caregivers described their <u>use of virtual activities</u> and <u>social support programs</u> and the overall <u>influence the pandemic had on their in-home</u>

care strategies (Table 3.1). Most caregivers described that the specific in-home care strategies they used to help their loved one manage the disease remained unchanged during the pandemic, but that caring for their relative in general became more difficult.

> *"It's definitely more challenging. More challenging just to manage wellbeing and happiness, let alone address any behavioral manifestations or communications."*

Caregivers described how specific in-home care strategies that were effective pre-pandemic became increasingly important during the pandemic.

> *"Okay, so he started the CBD before the pandemic. If he wasn't on the CBD and all these restrictions and having to stay home, I can almost predict what it would be like for him. Um, because he really misses… I suspect without the CBD I think we would have had a stronger impact to the relationship too, um, behaviors that were manifested because of his lack of social interaction and just frustration level."*

The loss of dementia related support programs because of the pandemic played a significant role in the impact the pandemic had on the caregiving process and disease management more generally. Caregivers described how some programs were cancelled, while others were modified in some way in response to the pandemic. These modifications were typically transferring of educational programs, support groups, group activities, and day programs to a virtual platform.

> *"I am so grateful Zoom and all the other technologies. Had it been ten years ago, I don't know that it would have been… I think I'd be pulling my hair out by now, but we're involved in a lot."*

Care Strategies Related to the Emotional and Psychological Experiences of the Person with ADRD. Participants described care strategies they used to support their relative's emotional and psychological experiences. They identified the importance of changing their own caregiving perspective and behaviors, as well as withdrawing from challenging situations (Table 3.1). One caregiver said,

> *"Really it's like a two-way management; managing my own emotions as a response to it and then helping manage, you know, look at what set that off, you know, and trying to figure out… backing it all up, right? What got us to that angry point? "*

Another caregiver described:

> *"If my wife is doing something, you know, it's not her but it is her disease, you know. So, I am able to separate when she's angry, you know, I know it's her disease. It's not her."*

One caregiver described an innovative approach for helping both the person with ADRD and the caregiver to cope by essentially "naming" the disease and attributing the changes in thoughts and behaviors to the personified disease, and not the person specifically.

> *"I talk in terms of Lewy being this third character that lives in our house (giggle). In fact, I actually use the words "There are three of us that live in this house now. You, me and Lewy, and the two of us have to work together to deal with Lewy"."*

<u>Withdrawing from particularly challenging situations</u> was described as a short-term approach to help the caregiver and the person with ADRD to manage at home.

> *"You know, there's some reason for it, and um, if I feel like things are getting out of control, I back off and I might go to the bedroom and lock the door. And by next morning things are in much better shape but I know that it's not a good idea to keep arguing at night."*

Changing caregiving behavior, perspective, and withdrawing all involved caregivers taking the burden of symptom management on themselves, which was described as an experiential learning process.

> *"Don't be reactionary. That don't work. So, again, it's just not her fault and you have to learn that, and that's tough…"*

Anger was described as the most difficult emotion to manage by all caregivers that reported that their relative experienced anger or displayed agitation. A few helpful <u>anger management strategies</u> were described, many of which were reliant on the caregiver changing their own behavior (e.g., not raising their voice, avoiding ultimatums) and monitoring their relative's behavior overtime to prevent anxiety from turning into angry outbursts.

Caregivers described that once agitation was present, there was not much to be done that helped reduce it. One caregiver detailed the importance of waiting for their relative to calm down then later approaching them to discuss the outburst and ways to prevent them in the future.

> *"I think the most helpful thing is just waiting until he's calm to go back and try to talk and, fortunately, he's still okay enough to say "I didn't realize I did that" or "I didn't know I did it." And "Is that really what happened?" And he trust us."*

Helpful strategies for anxiety included the use of music, audio books, car rides, words of affirmation, and snacks as a form of distraction (Table 3.1). Pet dogs generally and dementia service dogs more specifically, were commonly described as anxiety reducing and provided the person with dementia with a renewed sense of purpose.

> *"Our service dog Sophie is a huge… just the purpose of getting up, letting her go potty, training her. Yeah, and the sense of having her there he says it's huge with his anxiety. He does not feel like he's alone…"*

One caregiver described the use of cannabidiol oil (CBD) for anxiety and anger management as an important approach for their relative. CBD is an active ingredient in cannabis, which is derived from hemp.

> *"Before COVID we started CBD and, um, we had a night and day difference. I mean does he have the frustration… but he doesn't have the fearful, I'm so afraid of him anger."*

Despite the many strategies described, most caregivers still highlighted anxiety, anger, and agitation as being difficult to manage at home.

Helpful strategies for paranoia included words of affirmation and reassurance, while rationalization and reorientation were described as less helpful (Table 3.1). Most sleep specific strategies were described as less helpful (e.g., medications, blue light glasses), but one strategy that was helpful for many caregivers were planned daily naps for their relatives (Table 3.1).

Caregivers described the use of medications by their relatives, including antidepressants, anti-anxiety medications, and anti-psychotics (Table 3.1). Comments were overall equivocal, as some caregivers described improvements in select symptoms, while others described medications as not at all helpful to their relative with ADRD.

> *"He's on two medications, He's on rivastigmine and on Lexapro. The Lexapro has really made a huge difference in his anxiety. Um, it's almost a wonder drug"*

Another caregiver said:

> *"I'm not going to drug her...she's on Lexapro for anti-anxiety. And does it work? Who in the hell knows. Personally, I don't."*

Discussion

This study described multiple life changes and challenges to caregiving in the home for a loved one with ADRD, many of which were exacerbated by the pandemic. Caregivers' experiences were dynamically related to those of their relatives with ADRD and the caring process was described as a partnership. Caregivers identified a need for in-home care strategies to promote their own and their relative's well-being even before the pandemic began. The pandemic compounded many of those needs due to the loss of activities, access to resources, and ADRD related support services.

Similar to previous studies focused on ADRD caregivers (Wang et al., 2019), findings demonstrated varying experiences across participants, as well as within participants over time. Experiences differed in terms of how changes in the relative with ADRD impacted the caregiver, how caregivers responded, and how they perceived their caregiving experience. Reflections on earlier stages of the relative's disease demonstrate that the caregiving experience changed over time. Given that ADRD are known to have variable effects on those diagnosed with dynamic changes occurring throughout the disease process (Wu et al., 2018), it is reasonable to find variation within and across caregiver experiences.

Caregivers and their relatives with ADRD experienced substantial changes in their lives because of the ADRD diagnosis. Changes described by caregivers spanned across many aspects of life, including social function, physical ability, cognitive ability, and emotional and psychological experiences. Descriptions of decline in the health of the relative with ADRD were often followed by examples of increased reliance that they had on their caregivers. Although caregivers gave examples specific to their own experiences and their relative’s experiences, most of their narratives intertwined both perspectives together in a manner that were dynamically related. These findings are consistent with theories of interdependence which posit that the health, wellness, and behaviors of one member in a close partnership is dependent and interactive with the other member (Kershaw et al., 2015; Streck et al., 2020).

The caring partnership described by participants is evident in research and practice as caregiving is now recognized as a primary component of the ADRD experience (National Academies of Sciences & Medicine, 2021). Some participants asked to be referred to as *care partners* to accurately reflect how they viewed themselves, and the caring partnership they had with their relative living with ADRD. Care partners often described caring as a process of co-managing their own emotions, responses, and reactions and those of their relative with ADRD. Care partnering was described as distinct from caregiving as it is not a one way, give-take relationship, but instead was described as a joint ongoing interaction with the relative with ADRD acting as an active participant in the caring process. The significance of the care partner further expounds upon the need for healthcare providers to address the multidimensional needs of the dyad (Miller et al., 2019). Dyadic care planning programs that connect people with early stage ADRD, their care partners, other relatives/friends, and service providers show promise for initiating early care discussions and promoting family-centered care planning (Orsulic-Jeras et al., 2019). Additional research is needed to examine effectiveness of these interventions to promote broader implementation and support for a wider range of families (Orsulic-Jeras et al., 2019, 2020).

Findings showed that participants did not use the terms “behaviors” or “symptoms” for many of the examples that would be described as BPSD by clinicians and researchers. Instead, caregivers connected their relative’s experiences with the disease and their responses to different situations and circumstances, many of which related to their own experiences as caregivers. In some instances, these experiences and responses were directly related to the ADRD, while others were not related to the disease specifically. These findings suggest a need for clinicians and researchers to expand their views on how to define, assess, measure, and communicate about the concept traditionally termed BPSD. Clinicians and researchers often focus on treating challenging symptoms of ADRD, as opposed to understanding the lived experience of those with ADRD and their families. By asking patients and families about broader factors related to BPSD (e.g., unmet needs, personality traits, communication, home environment, daily routines) clinicians may be able to assess for BPSD more comprehensively, as opposed to asking about symptoms and behaviors specifically (Kales, Gitlin, & Lyketsos, 2015).

Findings from this study and prior research demonstrate substantial losses in terms of social support among families affected by ADRD, many of which were prevalent prior to the pandemic and were intensified by it (Gielbel et al., 2020). Cumulatively these findings support that in addition to modified social support programs, care strategies that can be used in the home without reliance on in-person interaction are needed. As nearly 1/3 of Medicare beneficiaries reported a lack of digital access at home (Reyes et al., 2020), support strategies that do not rely on internet access must also be prioritized.

Caregivers described many home-based strategies to support their relatives that did not require internet or in-person access. Examples included pets and dementia support dogs, CBD oil for anxiety and agitation, mindfulness activities and meditation, reorientation tools (e.g., white boards, visual reminders), exercise (e.g., tai chi, yoga, walking), and journaling. Research is needed to explore how acceptable these interventions are to individuals and families affected by ADRD and to determine their efficacy for improving important outcomes such as BPSD, well-being, and quality of life.

Dementia service dogs were described by many participants and represent an innovative in-home care strategy for families affected by ADRD. Dementia service dogs are specially trained to address needs unique to individuals with ADRD. They can be trained in tracking to locate and redirect people home or closer to their caregiver, to distract and engage potentially anxious or agitated people, and can provide physical support with activities of daily living (e.g., fetching medication and clothing items) (Markss & McVilly, 2020). As many participants in this study described, they can also provide companionship, emotional support, and a sense of purpose for people with ADRD. Despite the potential value of dementia service dogs, there has been limited use of these animals in the U.S. This may be largely due to cost, as training and placing a dementia service dog can cost anywhere between $15,000-$50,000 (“4 Paws for Ability”, n.d.). Insurance companies do not cover any costs related to service animals and much of the cost burden is placed on families. Additional research is needed to examine the effects of dementia service dogs on a variety of outcomes of interest to individuals and families affected by ADRD, as well as the cost benefit of ADRD service dogs (Markss & McVilly, 2020). Furthermore, efforts are needed to educate ADRD community support organizations and providers on their availability, but more importantly policy updates are needed to provide coverage for families interested in having dementia service dogs.

Limitations

Limitations of this study relate to the lack of variability of the sample. Participants were recruited through ADRD organizations that serve regions of a state comprised primarily of non-Hispanic White families, limiting diversity of the sample in terms of race and ethnicity. Additionally, most caring dyads were related by marriage, which is not congruent with the broader population, as most primary caregivers of people with ADRD are children caring for parents (Alzheimer’s Association, 2021). As the perceived value of different care strategies varies based on individual circumstances, situations, and contexts (National Academies of Sciences & Medicine, 2021), the lack of diversity of this study sample limits the understanding of the in-home care needs of families affected by ADRD from diverse sociodemographic backgrounds. The pandemic related experiences of caregivers may also vary substantially across groups given variations in virtual resource accessibility specifically and healthcare access more generally. Alternative recruitment strategies (e.g., through providers and programs that support families in disadvantaged communities, spiritual communities that offer services to older adults, rural outreach programs) will need to be used in future research to engage caregivers from a broader range of backgrounds and to enhance generalizability of the findings.

Conclusion

Findings from this exploratory study show that family caregivers and their relatives living with ADRD experienced challenges to in-home care prior to the COVID-19 pandemic, many of which were compounded by it. There are key areas that hold promise for future research to better understand the experiences of a broader range of caregivers and to bridge gaps between researchers, clinicians, community support providers, people living with ADRD, and their families. As community dwelling dyads living with ADRD continue to experience challenges to care, there is a critical need to examine strategies that can feasibly be delivered in the home to promote the well-being of families, particularly during the pandemic.

CHAPTER IV

Examining the Feasibility and Acceptability of a Virtually Delivered In-Home Weighted Blanket Intervention for Older Adults Living with Dementia and their Family Caregivers

Background and Significance

Up to 98% of individuals with Alzheimer's disease and related dementias (ADRD) living in the community experience behavioral and psychological symptoms of dementia (BPSD) (Banerjee et al., 2006; Cerejeira et al., 2012). These behaviors and symptoms can have detrimental effects on the health and quality of life of not only those diagnosed, but also on family caregivers (Fonareva & Oken, 2014; Majer et al., 2019). Although psychotropic medications are commonly prescribed to treat BPSD, they have minimal effectiveness and are associated with several life-threatening risks including, falls, fractures, injuries and in worst cases, death in older adults with ADRD (Defrancesco et al., 2015; Jeste et al., 2008; Seyfried et al., 2011; Van Strien et al., 2013).

Due to these dangers, practice guidelines emphasize non-pharmacologic interventions as the primary treatment of BPSD among people living with dementia (PLWD) (Austrom et al., 2018; Reus et al., 2016). Non-pharmacologic interventions are those that do not rely solely on medication to treat or mitigate a specific disease, condition, or symptom. Findings from caregiver interviews revealed several non-pharmacologic care strategies used by family caregivers (See Chapter 3). Most caregivers, however, noted that the availability and effectiveness of such interventions were limited before, as well as throughout the COVID-19 pandemic.

Many non-pharmacologic interventions have demonstrated improvements in BPSD outcomes in community dwelling PLWD (Trivedi et al., 2018). These interventions, however, have had limited uptake in real world community settings (Gitlin et al., 2015). To be implemented and sustained in practice, interventions must be accepted by those who use them (Carter & Wheeler, 2019).

Previously investigated non-pharmacologic interventions may have limited use in the community setting due to the complexity of the interventions (e.g., multiple components and steps of the intervention, need for frequent interactions with trained or licensed professionals, costly resources not covered by current insurance structures), which can inhibit their acceptability and applicability. Crucial steps in developing acceptable and applicable interventions are to first explore the feasibility of delivering the intervention in a real world setting and second, to evaluate the acceptability of the intervention by the population of interest during the early stages of development (Baier et al., 2019). Evaluating acceptability before (prospectively) and after (retrospectively) delivery of an intervention provides insight into the opinions and needs of the target population throughout the intervention development and delivery process (Sekhon et al., 2017). Prospective evaluations of intervention acceptability provide valuable information regarding the preconceived notions of the target population towards the intervention, level of burden required for participation, the ethicality of the intervention, and/or the extent to which potential subjects understand the intervention. Retrospective evaluations examine the benefit of the intervention and satisfaction with the intervention by those who received it, barriers of the intervention, confidence in being able to participate in the intervention, and costs vs. benefit of participating in the intervention (Sekhon et al., 2017).

Interventions that are likely to be successful are those that are feasible for the setting of interest and are acceptable to multiple stakeholders including those who deliver and receive them (Gadke et al., 2021). Thus, evaluating intervention feasibility and acceptability early in the intervention development process is paramount to future intervention testing and implementation.

Sensory Stimulation Therapies for PLWD

Sensory stimulation is one category of non-pharmacological interventions that has been tested among community dwelling PLWD (Trivedi et al., 2018). Sensory stimulation therapies are those that use everyday objects and tools to arouse at least one of the five senses (i.e., hearing, sight, smell, taste, touch) with the intent of promoting positive feelings and increased well-being (Strøm et al., 2016). Examples of sensory stimulation therapies include art therapy, music therapy and multi-sensory stimulation involving two or more stimulation therapies in a single program, such as combined auditory and tactile stimulation (also referred to as Snoezelen therapy) (Trivedi et al., 2018; Ueda et al., 2013).

There has been limited research conducted on sensory stimulation for treating BPSD in community dwelling people with dementia (Trivedi et al., 2018). However, research supports that sensory stimulation therapies can reduce challenging behaviors and improve emotional well-being, as well as other important outcomes such as quality of life and functional ability in PLWD residing in long term care settings (Haigh & Mytton, 2015; Strøm et al., 2016). Systematic reviews have recommended additional research focused on sensory stimulation therapies in PLWD residing in the community with broader outcomes examined, such as BPSD and quality of life (Haigh & Mytton, 2015; Strøm et al., 2016; Trivedi et al., 2018).

Weighted Blankets as a Deep Pressure Tactile Stimulation Therapy

Weighted blankets are a form of deep pressure tactile or touch stimulation that have shown to be safe for older adults (Parker, 2016). Research demonstrates that deep pressure tactile stimulation may increase the arousal of the parasympathetic nervous system, while also reducing sympathetic arousal (Chen et al., 2016; Reynolds, Lane, & Mullen, 2015). The increase in parasympathetic arousal is hypothesized to have a calming effect, while the decrease in sympathetic arousal is associated with changes in emotional and cognitive processes (Chen et al., 2016; Mullen et al., 2008; Reynolds et al., 2015).

Regular nightly use of weighted blankets has demonstrated improvements in overall sleep maintenance, daytime fatigue, depression, and anxiety in non-cognitively impaired adults with a variety of psychiatric conditions (e.g., insomnia, major depressive, generalized anxiety, attention deficit hyperactivity, and bipolar disorders) (Ekholm et al., 2020). Research on daily use of weighted blankets has also shown reductions in anxiety and stress related physiologic factors among non-cognitively impaired older adults with mental health conditions (Champagne et al., 2015; Mullen et al., 2008). Despite research in support of weighted blankets to improve stress and psychologic outcomes in other populations, no studies have tested the effects of weighted blankets on BPSD experienced by PLWD, including those living in the community (Eron et al., 2020). In fact, most studies testing weighted blankets exclude people with cognitive impairment without justification (Becklund et al., 2021; Ekholm et al., 2020). Furthermore, the acceptability of weighted blankets as perceived by older adults with ADRD and their family caregivers has not been explored.

COVID-19 Pandemic and the Impact on Community Dwelling Dyads Affected by ADRD

Findings presented in Chapter 3 demonstrated that the COVID-19 pandemic posed unique challenges that impacted the lives of PLWD and their family caregivers. Mandated stay-at-home orders and social distancing recommendations across the nation affected the day-to-day function of programs, businesses, primary care practices and healthcare systems that typically provide face-to-face support to dyads affected by ADRD (Brown et al., 2020). Restrictions in access to standard care and support programs impacted family caregivers’ ability to effectively manage challenging situations, experiences, responses, and reactions in relatives with ADRD in the home setting.

Given the limited availability and effectiveness of non-pharmacologic interventions for PLWD in the community, in addition to the COVID-19 related restrictions, older adults with ADRD and their family caregivers have experienced an increased need for care strategies that can be easily implemented in the home setting (Alves et al., 2020). Weighted blankets are a potential non-pharmacologic care strategy that may feasibly be delivered by family caregivers in the home, even during this time of social distancing and limited access to typical ADRD related care programs and resources.

Since no research has examined the use of weighted blanket by PLWD, this study will provide novel information regarding the feasibility and acceptability of weighted blankets as an in-home care strategy for home dwelling PLWD during this global pandemic. Findings will inform future research focused on weighted blankets for reducing BPSD among community dwelling older adults living with ADRD.

Specific Aims

The aims of this feasibility and acceptability study were to:

Specific Aim 1

Explore the initial perceptions of family caregivers regarding weighted blankets as an in-home care strategy for community dwelling older adults with ADRD following a brief description and visual presentation of weighted blankets.

Specific Aim 2

Examine the feasibility and acceptability of a virtually delivered, in-home weighted blanket intervention for older adults with ADRD living in the community as perceived by the family caregiver and the person with ADRD.

Specific Aim 3

Examine the feasibility of collecting outcome measures of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health status of family caregivers.

Methods

Study Design

Two study designs were used to address these aims which are described below.

Aim 1

An exploratory qualitative design was used for Aim 1. Participants were those enrolled in the *Perceptions of Family Caregivers of Older Adults Living with Dementia Regarding Behavioral and Psychological Symptoms of Dementia and the Impact of the COVID-19 Pandemic* study (See Chapter 3, Methods-Study design, p. 52). Participants were provided with a brief description and virtual demonstration of the weighted blanket followed by semi-structured interviews using the following questions:

1. What do you think about use of the weighted blanket for your loved one?
2. Can you give any examples as to why the weighted blanket might work or not work for them?
3. Do you have any questions, worries, or concerns about using a weighted blanket?

Aims 2 and 3

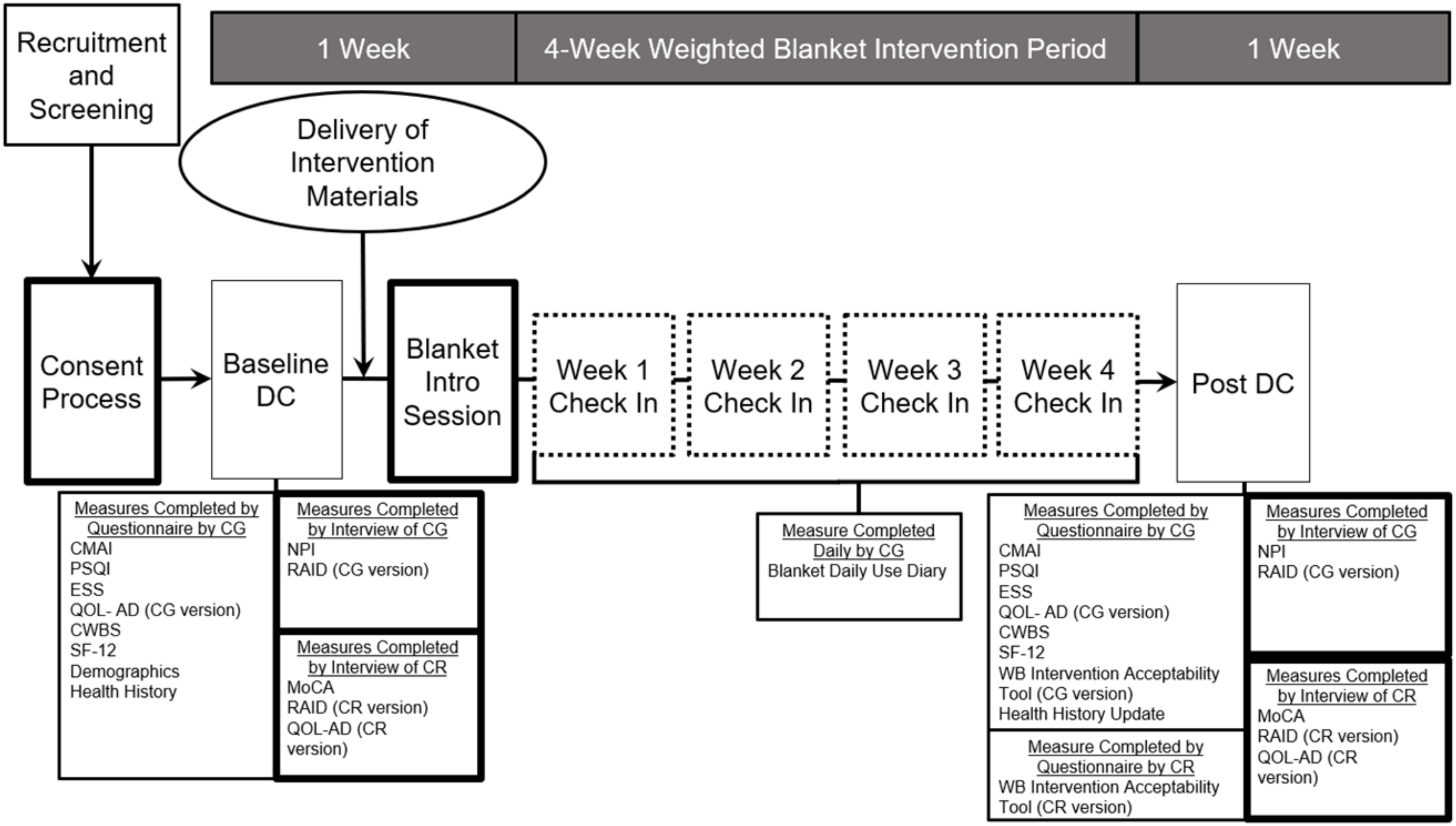
A feasibility and acceptability study using a prospective, within subjects, pre-post design was used for Aims 2 and 3 (See Figure 4.1). The weighted blanket intervention period was 4 weeks. Measures were collected at baseline (within 1 week prior to the start of the intervention period) and at post-intervention (within 1 week of completing the intervention period). The consenting process, data collection sessions, and the intervention introduction session were all conducted over Zoom virtual conferencing system, or by telephone. Weekly intervention check-in sessions were conducted by telephone.

Study Sample

The sample was 21 community-dwelling older adults with ADRD and their family caregivers (21 dyads). The projected sample size was 20, which was selected based on prior dyadic, non-pharmacologic intervention community-based feasibility studies, which have ranged from 5-22 dyads (Hamel et al., 2016; Moyle et al., 2014; Sprange et al., 2015).

A wide range of definitions are used to define family caregivers for eligibility to participate in ADRD research (Novelli et al., 2018; Robinson et al., 2018). Family caregivers were defined for this study as any relative, partner or other family member who provides a broad range of assistance for an older adult with dementia and lives in the same household (Family Caregiver Alliance, 2014). The following criteria were used to identify eligible dyads (including both family caregivers and people with ADRD).

Figure 4.1
Overview of Weighted Blanket Study Design



Eligibility Criteria

<u>Inclusion criteria for participants with ADRD</u> (Aim 2 and 3):

1) Aged 60 and over with a diagnosis of ADRD as reported by the family caregiver
2) Lived in the home with a family caregiver
3) Demonstrated at least 2 behavioral or psychological symptoms listed on the Neuropsychiatric Inventory (NPI) within the most recent 4 weeks as reported by the family caregiver (Novelli et al., 2018), with symptoms or behaviors occurring at least once a week. The NPI is described in the Data Collection section.
4) Weight of 100 pounds or more, as reported by the family caregiver
5) Was able to lift at least 10 pounds, as reported by the family caregiver

<u>Exclusion criteria for participants with ADRD</u>:

1) Lived in assisted living or long-term care setting
2) Had a diagnosis of asthma, sleep apnea, or other respiratory disorder that inhibits respiratory function
3) Had paralysis or limited mobility of the upper or lower limb(s)
4) Had a history of claustrophobia, or fear of confined and/or enclosed spaces
5) Had open wounds or rashes on the skin
6) Had diabetes
7) Had used a weighted blanket within the most recent month
8) Had a current diagnosis of an acute or chronic unstable medical condition anticipated to limit the individual’s ability to participate in the study as reported by the family caregiver

<u>Inclusion criteria for family caregivers (Aims 2 and 3)</u>:

1) 21 years of age or older
2) Identified as a primary caregiver of an older adult (60 years of age or older) with ADRD
3) Lived in the same household as the family member with ADRD who met the above inclusion criteria
4) Had lived with the care recipient for at least one month
5) Had access and ability to use a telephone, smart phone (with internet access), tablet (with internet access), or computer (with internet access) to access the virtual Zoom sessions

<u>Exclusion criteria for family caregivers</u>:

1) Less than 21 years of age
2) Was unable to read or speak English
3) Had a hearing or visual impairment that limits the ability to complete the screening or consenting process

Although Alzheimer’s disease and vascular dementia were anticipated to be the most common type of dementia among participants with ADRD, having a specific type of ADRD (e.g., Alzheimer's disease, vascular dementia) was not a criterion for inclusion for several reasons, 1) distinguishing between types of dementia can be difficult and requires advanced testing (e.g., PET imaging, CSF biomarker analysis) that individuals in earlier stages of disease living in the community may not have received; 2) diagnoses made without advanced testing may not always be accurate; and 3) people with ADRD do not always receive a specific type of diagnosis from physicians (Alzheimer's Association, 2021).

Recruitment

Dyads were recruited through the Alzheimer's Association of Greater Michigan Chapter, the Michigan Alzheimer's Disease Research Center, and the Family Caregiver Alliance National Center on Caregiving.

Alzheimer's Association of Greater Michigan Chapter. The Alzheimer's Association Greater Michigan Chapter serves over 60 counties in Michigan and provides support to individuals and families affected by ADRD through a variety of services. This study was promoted by word of mouth and electronic flyers displayed at support groups, care consultations, helpline packets, education programs, conferences, and other virtual events. Interested caregivers contacted the PI (Ms. Harris) directly using the contact information provided on the study flyer (Appendix B-1). Six dyads were recruited through the Alzheimer's Association.

Michigan Alzheimer's Disease Research Center. The Michigan Alzheimer's Disease Research Center (MADRC) is based in the Department of Neurology in Michigan Medicine and is directed by Henry Paulson, MD, PhD; Associate Director is Bruno Giordani, PhD (dissertation committee member). This was an MADRC supported study which permitted sharing of study information with MADRC clients (including diagnosed individuals and their care partners) interested in research opportunities. Study information was shared on the MADRC's Currently Enrolling Studies webpage, through e-newsletters, online support groups and outreach programs. The MADRC also provided contact information (names, addresses, telephone numbers) of potential research participants from the MADRC MiNDSet Research Registry, which lists individuals with ADRD and their caregivers who are interested in participating in research. The MADRC provided an introduction letter, which was mailed out to potential participants along with the study flyer. Interested individuals contacted the PI directly using the provided contact information. Ten dyads were recruited through the MADRC.

Family Caregiver Alliance National Center on Caregiving. The Family Caregiver Alliance (FCA) is a national organization that offers services, education programs, and resources designed for caregivers. They provide support, tailored information, and tools to manage the complex demands of caregiving. This study was listed on the graduate student research registry via the FCA website, as well as through monthly FCA e-newsletters distributed to caregivers nationwide. Postings included Ms. Harris' contact information. Interested individuals contacted her directly by phone or email. Five dyads were recruited through the FCA.

Eligibility Screening

When potential participants expressed interest in the study, they received a study overview booklet either by e-mail, or by U.S. mail (Appendix B-2). The PI further described the purpose of the study, the eligibility criteria, and the web-based format through a telephone conversation. The PI completed an eligibility determination form (Appendix B-3) directly in REDCap (See Data Security and Management section below of more information) for each dyad. Family caregivers provided responses relating to their own eligibility, as well as the eligibility of their relative with ADRD.

Setting

The consenting process, all data collection sessions and the intervention introduction session were conducted through Zoom conferencing system, which was accessed virtually, or by telephone. The weekly intervention check-in sessions were conducted by telephone.

The use of the weighted blankets occurred in the homes of participant dyads. Dyads received education about use of the weighted blanket during the Weighted Blanket Introduction Session (See Weighted Blanket Intervention section below).

Consent

Interested and eligible dyads received a study consent form, which was delivered electronically by e-mail, or through U.S. Mail based on participant preference. Dyads reviewed the form with the PI by telephone, or by Zoom. Both care recipients and caregivers signed consents for participation in the study. If care recipients with ADRD were unable to sign for themselves, their caregiver signed on their behalf as a proxy. Participants signed consent forms via SignNow software, which is a secure, HIPAA compliant electronic signature service (SignNow, 2021). Three dyads did not have reliable internet access and instead received a consent form via U.S. Mail, they signed the hardcopy consent form and returned it using a stamped, preaddressed envelope.

Weighted Blanket Intervention

Participant dyads received a weighted blanket and a Weighted Blanket Use Guide along with other intervention materials after completion of the virtual baseline data collection session (See Data Collection Procedures section below). After receipt of the intervention materials, each dyad participated in an introduction session with the PI via Zoom. The use of the weighted blanket by the care recipient with ADRD was individualized based on the needs and preferences of the dyad. All dyads were encouraged to have the care recipient use the blanket daily for at least 5 minutes at a time for a total of at least 20 minutes throughout each day (day referring to each 24-hour period, meaning the blanket could be used during the daytime or overnight). They could use the blanket for a total of 20 minutes at one time, or they could use the blanket multiple times for shorter periods throughout the day. Although this was the minimum recommended time, dyads were encouraged to have the participant with ADRD use the blanket as often as they liked. Caregivers played a significant role in initiating and encouraging daily use of the blanket. The intervention is described in the following sections and includes a description of the weighted blankets, safety information, the Weighted Blanket Use Guide, the delivery of the intervention materials, the weighted blanket introduction session, and the weekly intervention check-in sessions.

Weighted Blankets

A weighted blanket is similar to a traditional comforter, except it is filled with non-toxic, hypoallergenic plastic pellets to add weight to the blanket. Blankets in this study were supplied by Magic Weighted Blanket ©. (https://magicweightedblanket.com/), which is a family created business that invented the first weighted blanket in 1997. Participants were provided a blanket by the study. As compensation for participation, participants kept the weighted blanket at the end of the study period.

No definitive weight recommendations have been established across studies for weighted blanket use by older adults (Eron et al. 2020); however, the suggested weight across practical reports and by weighted blanket manufacturers is 10% of the individual's body weight (Parker, 2016). In consideration of this recommendation, two different blanket weights were used. Dyads received a 10-pound blanket if the care recipient with ADRD weighed under 120 pounds, or a 12-pound blanket if they weighed 120 pounds or more. All blankets were navy blue or gray and made of cotton material. They were 42 inches wide by 72 inches long.

Safety Considerations. There are no adverse effects associated with weighted blanket use across prior research (Champagne et al., 2015; Eron et al., 2020; Mullen et al., 2008). There are two anecdotal reports that misuse of weighted blankets resulted in the death of a 9-year-old child, and a 7-month-old baby. In these cases, the blankets used were well over the 10% body weight recommendation (e.g., a 39-pound blanket was used for the 9-year-old child) and the blankets were applied over the children's faces (Parker, 2016). There are no reports of adverse effects regarding the use of weighted blankets by adults.

There are no standardized safety guidelines for the use of weighted blankets by older adults. The guidelines below were developed for this study based on prior research (Champagne et al., 2015; Eron et al., 2020; Mullen et al., 2008), and experiences in use of weighted blankets among individuals across age groups (Parker, 2016).

- Weighted blankets should never be used as a restraint.
- The individual using the weighted blanket should be able to remove the blanket on his/her own.
- A person should not be rolled up in the blanket.
- The blanket should not be used when the person is standing or walking.
- The blanket should not cover a person's face or head.
- There is a minor risk for infection if the blanket is used by multiple people and not washed between uses.
- Weighted blankets should be used with caution by people with claustrophobia, or fear of confined and/or enclosed spaces.
- Weighted blankets should be used with caution in people with asthma, sleep apnea, or other disorders that inhibit respiratory function.
- Providers should consider the mobility of individuals interested in using a weighted blanket (e.g., paralysis, bone fractures).

- Weighted blankets should be used with caution in people with open wounds, fragile skin, rashes, or those with diabetes who may be prone to diabetic ulcers.
- Although unanticipated, if plastic pellets come out of the blanket, the blanket should not be used.
- Plastic pellets should not be ingested or swallowed. If swallowed, the individual should seek medical attention.
- The blanket should not be put in the microwave, as this can melt the plastic pellets.

These safety guidelines were addressed in this study in the eligibility criteria for study inclusion and in the Weighted Blanket Use Guide, which was provided and reviewed with all participant dyads (described below).

Weighted Blanket Use Guide

A Weighted Blanket Use Guide was developed for this study based on prior research and experiential reports (See Appendix C-1). The guide was reviewed by 3 older adults who identified as family caregivers of people with ADRD. These individuals assessed the guide for readability, clarity, and cohesion. Based on their feedback, edits were made, and the guide was finalized.

The PI reviewed the guide with each dyad during the Weighted Blanket Introduction Session (See Weighted Blanket Introduction Session section below). Dyads were encouraged to refer to the guide together throughout the study period. After completion of the baseline data collection session, one guide was provided for both the caregiver and the care recipient to use, which included the following:

- Description and purpose of the weighted blanket
- Suggestions of when to use the weighted blanket
- Directions for applying the blanket
- Recommended duration of use
- Safety recommendations
- Blanket cleaning recommendations

Delivery of Weighted Blanket and Weighted Blanket Use Guide to Dyads

Study materials were delivered to participants using UPS shipping services. Packages included the weighted blanket (either 10, or 12 pounds depending on the participant with ADRD's body weight), the Weighted Blanket Use Guide, and the Weighted Blanket Daily Use Diary (See Data Collection Procedures for more information). Each package also included a note instructing participants not to start using the blanket, or open the Weighted Blanket Use Guide, or Daily Diary until after the Weighted Blanket Introduction Session (described below). On average, shipping of study materials took 3 days to reach participants.

Weighted Blanket Introduction Session

Upon delivery of the study materials, participant dyads participated in an introduction session with the PI using Zoom, which was accessed by participants virtually or by telephone. During this session, the PI reviewed with both the caregiver and the care recipient the Weighted Blanket Use Guide and provided directions on how to complete the Weighted Blanket Daily Use Diary (See Data Collection Procedures for more information). For introduction sessions over Zoom, the PI demonstrated how to apply the weighted blanket. If participants were using the video function, the PI then asked them to return demonstrate use of the blanket. Both members of the dyad were encouraged to participate in this session, but if the participant with ADRD was unable to participate in the full session, the family caregiver participated independently. These sessions lasted 20-30 minutes on average.

Completion of the Weighted Blanket Introduction Session marked the beginning of the 4-week intervention period. Each week, family caregivers and care recipients participated in a telephone check-in conversation with the PI. If care recipients were unable to fully participate, caregivers participated in the calls independently. The purpose of these check-in calls was to 1) answer questions or address concerns of the participants throughout the intervention period, 2) explore the recommended duration and frequency of use of the weighted blankets by participants with ADRD, and 3) help participants identify strategies to improve the use of the blanket if applicable. A Weekly Intervention Telephone Check-In Form (Appendix C-2) was used by the PI to guide the phone conversations and to document participant responses. These calls lasted approximately 10 minutes.

Outcome Measures and Instruments

The following sections describe the outcomes and corresponding instruments for Aims 2 and 3.

Outcomes Aim 2

Outcomes for Aim 2 were measures of feasibility and acceptability of a virtually delivered, in-home weighted blanket intervention for older adults with ADRD living in the home with family caregivers, as perceived by the family caregiver and the person with ADRD.

Feasibility of Intervention. Feasibility was conceptually defined as the extent to which the intervention was appropriate for further testing with emphasis on whether the intervention was carried out as intended in the setting and with the population of interest (i.e., community setting, older adults with ADRD living with family caregivers) (Bowen et al., 2009).

Feasibility was operationalized as the:

- Enrollment rate (calculated by the number of people who were enrolled divided by the number of people who were screened)
- Length of time (in days) to recruit the desired number of participants
- Average number of days the weighted blanket was used for the recommended duration (at least 20 minutes) across participants (Items 1-3 of the Weighted Blanket Daily Use Diary, described below, was used to capture the number of days care recipients used the blanket for at least 20 minutes each day over the 4-week intervention period)
- Withdrawal rate and reasons for withdrawal (participants were asked, but not required to report their reasons for withdrawal, which were tracked using the Study Completion Form (Appendix D-1)
- Injuries and adverse events (any adverse events, or injuries were to be tracked using an Adverse Event Form (Appendix D-2) and then reported to the IRB)

There are no established criteria to determine non-pharmacologic intervention feasibility in research focused on this population. Benchmarks set a priori for this study were selected based on findings from prior non-pharmacological intervention studies that were considered feasible. Benchmarks were modified from studies that were similar in terms of population, projected sample sizes, and study durations (Farina et al., 2019; Tamplin et al., 2018). This intervention would be considered feasible if the following were achieved: 1) no adverse events or injuries, 2) recruitment of the target sample size within five months, 3) use of the blanket for the recommended duration, on average, at least 21 of the 28 intervention days across participants who completed the intervention period, and 4) withdrawal of less than 25% of the participant dyads that were enrolled in the study. Most non-pharmacologic intervention ADRD studies have not reported enrollment rates, but prior reviews suggest that enrollment rates in ADRD community-based research is highly variable and can range between 1%-80%, with no standard across studies (Bartlett et al., 2018; Cooper et al., 2014). The enrollment rate for this study was predetermined to be feasible if at least 50% of individuals screened were enrolled.

Measure of Use of the Weighted Blanket. A Weighted Blanket Daily Use Diary completed by family caregivers captured the number of days that the weighted blanket was used for the recommended duration by the care recipient (See Appendix D-3). Semi-structured daily diaries have been used as a tool to collect both qualitative and quantitative data relating to individualized use of non-pharmacologic interventions (Logsdon et al., 2005; Lowery et al., 2014; Mausbach et al., 2011; McCurry et al., 1998).

The daily diary was developed by using items generated based on prior research focused on weighted blankets and prior studies testing other interventions that have used a daily diary tool (Champagne et al., 2007; Logsdon et al., 2005; Lowery et al., 2014; Mausbach et al., 2011; McCurry et al., 1998). The family caregiver completed one diary entry at the end of each day to document the use of the weighted blanket by the person with ADRD. As no prior studies have used daily diaries to explore the use of weighted blankets by research participants, the percentage of completion of daily diaries was used to ascertain the feasibility of using this tool as a measure of daily use of the weighted blanket.

Acceptability of the Weighted Blanket Intervention. Intervention acceptability was conceptually defined as a multi-faceted concept that reflects the extent to which the people receiving the intervention tolerate it, consider it to be beneficial, and their satisfaction with the intervention (Sekhon et al., 2017). Intervention acceptability in this study was operationally defined as 1) the extent to which the weighted blanket intervention was tolerated by care recipients with ADRD, 2) the degree of satisfaction with the intervention, and 3) benefit as reported by the care recipient with ADRD and the family caregiver**.**

Tolerability. Tolerability was quantitatively measured using a single item on the Weekly Intervention Telephone Check-In Form that was assessed during each of the four phone sessions (Appendix C-2). Family caregivers were asked to rate on a scale from 0 (did not tolerate the blanket at all) to 10 (tolerated the blanket all of the time), the care recipients' degree of tolerability of the weighted blanket over the past week. Information regarding barriers to use of the weighted blanket that may have reduced a person's tolerability was captured through item 6 of the Weighted Blanket Daily Use Diary, which provides qualitative data pertaining to what made the use of the weighted blanket a challenge on days where caregivers indicated the blanket was not used at all by the care recipient.

Satisfaction. Satisfaction with the weighted blanket as perceived by caregivers and care recipients with ADRD was measured using the Weighted Blanket Satisfaction Scale - Caregiver and Care recipient versions. There are no prior tools used to measure satisfaction with weighted blankets, so items were generated from a review of research on intervention acceptability of non-pharmacologic, community-based intervention studies focused on individuals with ADRD (Harris & Titler, 2020; Qiu et al., 2019; Robinson et al., 2007).

The caregiver and care recipient versions of the Weighted Blanket Satisfaction Scales were constructed for this study using items and response scales modified from a tool used to measure satisfaction of a psychoeducational intervention called FOCUS delivered to dyads affected by cancer, of which content validity and reliability (Cronbach's **α**=0.89 for care recipients with cancer, Cronbach's **α** =0.93 for family caregivers) have been established (Northouse et al., 2002; Titler et al., 2020).

Items and response scales were also modified from tools used in the multicomponent non-pharmacologic intervention studies focused on community dwelling PLWD and their caregivers by Gitlin et al. (2010a, 2010b) (Table 4.1). Psychometric properties were not reported for the tools used in these studies; however, both studies demonstrated statistically significant differences in satisfaction scores among caregivers who received the non-pharmacologic intervention, compared to those in the active control groups. These between-group differences provide some evidence regarding content validity of the satisfaction tool by their ability to demonstrate differences between those who received the intervention and those who did not.

Table 4.1
Items of Satisfaction with Weighted Blanket Intervention - Caregiver and Care Recipients Versions

Concept	Items	Response Scale
Satisfaction – Caregiver version	How satisfied were you with having the weighted blanket to be used by your relative in the home?	1 = not satisfied to 5 = very satisfied

	How satisfied were you with having the intervention materials delivered to your home?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with how the weighted blanket was explained to you during the Weighted Blanket Introduction session?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with using a web-based platform to learn how to use the weighted blanket?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with participating in weekly check-in telephone call with the research team?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with the Weighted Blanket Use Guide that came with the blanket?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with the way your questions were answered throughout the study period?	1 = not satisfied to 5 = very satisfied
	How satisfied were you with how you were involved in the process of encouraging your relative to use the weighted blanket?	1 = not satisfied to 5 = very satisfied
	How heavy was the blanket that your relative used?	10 pounds 12 pounds I don't know
	What did you think about the weight of the blanket for your relative?	1 = The weight was about right for my relative. 2 = I would have liked it to be heavier. 3 = I would have liked it to be lighter.
	What is your opinion about the recommendation that the weighted blanket be used daily by your relative?	1 = The recommended every day use of the weighted blanket was about right for us. 2 = I would have liked less recommended blanket use time. 3 = I would have liked more recommended blanket use time.
	What is your opinion about the recommended amount of time the weighted blanket was to be used by your relative each day? (Reminder: the weighted blanket was recommended to be used for at least 5 minutes at a time for a total of at least 20 minutes throughout each day)	1 = The recommended amount of time was about right for us. 2 = I would have liked less time recommended. 3 = I would have liked more time recommended.
	What did you think about completing a Weighted Blanket Daily Use Diary?	1 = Completing a diary entry every day was about right for me. 2 = I would have liked to complete fewer diary entries. 3 = I would have liked to complete more diary entries.
	Overall, would you recommend the use of a weighted blanket to other individuals caring for someone with dementia?	Yes, No
	Will you continue to encourage your relative to use the weighted blanket?	Yes, No
Satisfaction - Care recipient version	How did you like using the weighted blanket?	1 = Not at all 2 = Some 3 = A great deal
	How did you like being able to choose when you used the weighted blanket?	1 = Not at all 2 = Some 3 = A great deal
	How did you like being able to choose how often you used the weighted blanket?	1 = Not at all 2 = Some 3 = A great deal

	How comfortable did you feel when using the weighted blanket?	1 = Not at all 2 = Somewhat comfortable 3 = Very comfortable
	How did you like the feeling of the fabric of the blanket that you used?	1 = Not at all 2 = Some 3 = A great deal
	How did you like the warmth of the blanket that you used?	1 = Not at all 2 = Some 3 = A great deal
	How did the weight of the blanket feel to you?	1 = The weight was about right for me. 2 = I would have liked it to be heavier. 3 = I would have liked it to be lighter.
	Will you continue to use the weighted blanket?	Yes, No
	Overall, would you recommend using a weighted blanket to other individuals with dementia?	Yes, No
	What did you like most about using the weighted blanket?	Free-text response
	What did you like least about using the weighted blanket?	Free-text response

Benefit. Table 4.2 outlines items of the Weighted Blanket Benefit Scale - Caregivers and Care recipient versions. Items and response scales were modified from the studies by Titler et al. (2020), Gitlin et al. (2010a, 2010b), and from the program evaluation tool used in the dyadic skills training intervention by Judge et al. (2010). No psychometric properties were reported for the intervention evaluation tool used by Judge et al. (2010), but approximately 81% of the care recipients that received the intervention completed the program evaluation tool, which supports that they were able to answer the items with the provided responses, despite having cognitive impairment.

Table 4.2

Items of Benefit of the Weighted Blanket Intervention - Caregiver and Care Recipients Versions

Concept	Items	Response Scale
Benefit - Caregiver version	How much did the use of the weighted blanket help in decreasing challenging symptoms displayed by your family member with dementia? (such as anxiety, agitation, restlessness, difficulty sleeping)	1 = Not at all 2 = Some 3 = A great deal
	How beneficial was the study information booklet in explaining the study process?	1 = Not at all 2 = Some 3 = A great deal
	How beneficial was the Weighted Blanket Use Guide in explaining the use of the weighted blanket?	1 = Not at all 2 = Some 3 = A great deal
	How beneficial were the four weekly telephone calls?	1 = Not at all 2 = Some 3 = A great deal
	When was using the weighted blanket most helpful for your relative?	Free-text response
	When was using the weighted blanket the least helpful for your relative?	Free-text response

	Overall, how much did the use of the weighted blanket by your relative benefit you as the caregiver of someone with dementia?	1 = Not at all 2 = Some 3 = A great deal
	Overall, how much did the use of the weighted blanket benefit your family member with dementia	1 = Not at all 2 = Some 3 = A great deal
	Do you have any comments or suggestions about the study materials (such as the study booklet, the Weighted Blanket Use Guide, or the Weighted Blanket Daily Use Diary)?	Yes, No If yes, please described: (Free-text response)
	Do you have any comments or suggestions about the weighted blankets specifically?	Yes, No If yes, please described: (Free-text response)
	Would you recommend or suggest any changes for using the weighted blanket?	Yes, No If yes, please described: (Free-text response)
Benefit - Care recipient version	How relaxed did you feel when using the weighted blanket?	1 = Not at all 2 = Some 3 = A great deal
	How else did you feel when using the weighted blanket?	Free-text response
	Would you recommend or suggest any changes for using the weighted blanket?	Yes, No If yes, please described: (Free-text response)

Weighted Blanket Intervention Acceptability Tools. The satisfaction scales and benefit scales formulated the Weighted Blanket Intervention Acceptability Tools (WBIAT) – Caregiver version (Appendix D-4) and Care recipient version (Appendix D-5). The caregiver version evaluated acceptability from the perspective of the family caregiver at the post-intervention data collection period. The WBIAT – Caregiver version included items scored on 1 to 5 rating scales, 3 choice option items, and open-ended questions. The care recipient version evaluated acceptability from the perspective of the care recipients with 1 to 3-point Likert scaled items and simpler (yes-no) responses and open-ended questions (See Tables 4.1 & 4.2). Care recipients could receive some assistance from caregivers in completing the WBIAT – Care recipient version if needed, but caregivers were instructed not to complete it by proxy without input from the care recipient.

Outcomes Aim 3

Aim 3 examined the feasibility of collecting outcome measures for care recipients and family caregivers before and after receipt of the weighted blanket intervention. The following concepts derived from the conceptual framework (See Figure 1.1, Chapter 1, p. 6) were examined: cognitive function, behavioral and psychological symptoms of dementia, and well-being of the person with ADRD; and caregiver well-being. The specific outcomes collected relevant to the care recipient were cognitive function, BPSD, and quality of life. Caregiver specific outcomes were caregiver well-being and self-reported health status. Table 4.3 outlines the concepts, conceptual definitions, operationalized definitions, measures, and psychometric properties of the instruments. Instruments are included in Appendix E, along with information on completing and scoring each instrument.

Care Recipient Cognitive Function. Cognitive function refers to multiple mental abilities, including attention, memory, language, perception, decision making and problem solving. In this study cognitive function was specified as the severity of cognitive function impairment, or premature decline in cognitive function that is attributed to the limitations caused by neuropathological changes in the brain caused by ADRD (Cheung et al., 2011; Rabinovich et al., 2008).

The Montreal Cognitive Assessment Test (MoCA) was used to measure cognitive function (Appendix E-1) (Nasreddine et al., 2005). The MoCA assesses short-term memory; visuospatial abilities; executive functions; attention, concentration and working memory; language; and orientation to time and place. The maximum number of possible points on the MoCA is 30, with a score higher than 26 considered normal cognitive function. Scores less than 26 are indicative of some form of cognitive impairment. It takes approximately 10 minutes to complete and is completed by interview.

The MoCA has demonstrated high internal consistency (Cronbach's **α**- 0.83), and test-retest reliability (*r*=0.92). The MoCA has demonstrated a 100% sensitivity to detecting Alzheimer's disease, and 90% for detecting mild cognitive impairment (Nasreddine et al., 2005). Construct validity of this instrument has been established through confirmatory factor analysis (Freitas et al., 2012). The full MoCA can be delivered remotely using audio-visual conference (Lindauer et al., 2017). The MoCA-Telephone format is identical to the full MoCA, except it does not include the trail making, cube, or clock drawing items. The MoCA-Telephone is scored the same but has a possible 22 points instead of 30. The MoCA-Telephone score is converted back to 30. Example: a participant score of 19/22 converts back to 30 by performing the following equation: ((19/30) ÷ 22) (Chapman et al., 2019; DeYoung & Shenal, 2018; Wittich et al., 2010).

Table 4.3

Concepts, Conceptual Definitions, Operationalized Definitions, Measures and Psychometric Properties of Selected Instruments

Concepts	Conceptual Definition	Operationalized Definition	Measures	Psychometric Properties of Selected Instruments
Care Recipient Cognitive Function	A mental action or process of acquiring knowledge and understanding through thought, experience, and the senses, which includes interrelated functions including attention, memory, language, perception, decision making and problem solving (Glisky, 2007).	Severity of cognitive function impairment, which in dementia is defined as a premature decline in cognitive function that is attributed to the limitations caused by neuropathological changes in the brain caused by ADRD (Cheung, Chien, & Lai, 2011; Rabinovich, Huerta, Varona, & Afraimovich, 2008).	Montreal Cognitive Assessment (MoCA)	Cronbach's α range: 0.83 Test-retest reliability: *r* = 0.92 Concurrent validity with the MMSE: *r* = 0.87 Sensitivity: 76%. Specificity: 88-100% Construct validity of this instrument has been established through confirmatory factor analysis (Frietas et al., 2012; Nasreddine et al., 2019; Wittich et al., 2010)
Care Recipient BPSD	Disruptions in perception, thought content, mood, emotions, and/or behavior resulting from the decreased ability to manage and respond to stress (Cerejeira, Lagarto, & Mukaetova-Ladinska, 2012; Steinberg et al., 2008)	Individual and collective disturbance or change across behavioral and psychiatric domains including delusions, hallucinations, agitation and aggression, depression and dysphoria, anxiety, euphoria, apathy, disinhibition, irritability and lability, aberrant motor behaviors, sleep disturbance and nighttime behavior, and eating and appetite behavior (Cummings et al., 1994).	Global BPSD Neuropsychiatric Inventory-12 item (Cummings et al., 1994)	Cronbach's α range: 0.71-0.88 Percentage agreement between raters: 93.6%-100% Test-retest reliability range (*r*): 0.79-0.86 (Jackson et al., 2014; Lai, 2014)
			Agitation Specific Cohen-Mansfield Agitation Inventory (CMAI)	Cronbach's α range: 0.86-0.91 Inter-rater reliability: 0.41 (Cohen-Mansfield et al., 1989; Finkel et al., 1992) Construct validity has been established through confirmatory factor analysis (Rabinowitz et al., 2005)
			Anxiety Specific Rating Anxiety in Dementia Scale (RAID)	Cronbach's α: 0.83 Inter-rater reliability k range: 0.51-1 Test-retest reliability k range: 0.53-1 Content validity established through expert consultation, concurrent validity established with other anxiety scales including the Clinical Anxiety Scale and the Anxiety Sensitivity Index, construct validity established through factor analysis (Shankar et al., 1999)
			Sleep Disturbance Specific Neuropsychiatric Inventory-sleep disturbance item	NPI Cronbach's α range: 0.71-0.88 Percentage agreement between raters: 93.6%-100%

			Pittsburgh Sleep Quality Index (PSQI) Epworth Sleepiness Scale	Test-retest reliability range (*r*): 0.79-0.86 (Jackson et al., 2014; Lai, 2014) PSQI Cronbach's α: 0.85 Test-retest reliability: r = 0.87 Sensitivity: 98.7% Specificity: 84.4% (Backhaus et al., 2002) ESS Cronbach's α: 0.73-0.86 Convergent validity established by comparing ESS with PSQI scores (Kendzerska et al., 2014; Spira et al., 2011)
Care Recipient Well-Being	Multifaceted concept reflective of the quality of life of the care recipient, which is composed of interpersonal, environmental, function, physical and psychological domains (Lawton, 1997).	Care recipient and caregiver appraisal of the care recipient's physical condition, mood, interpersonal relationships, ability to participate in meaningful activities, financial situation and overall assessment of self as a whole, and life quality as a whole (Logsdon, Gibbons, McCurry, & Teri, 1999).	Quality of Life in Alzheimer's Disease Scale (QOL-AD) (Logsdon et al., 1999)	CR Report Cronbach's α: 0.83 CG Proxy Report Cronbach's α: 0.90 ICC between CR and proxy CG proxy report: r = 0.14-0.39 Inter-rater reliability: ICC ≥0.75 (p<0.001) (Logsdon et al., 2002) Criterion concurrent validity established with four other quality of life indices in dementia. Construct validity established through factor analysis (Thorgrimsen et al., 2003)
Caregiver Well-Being	Multicomponent concept comprised of caregiver health status, assets and resources from a strength-based perspective. Health status encompasses physical and mental well-being, while assets and resources include a basic needs	Caregiver perception of their overall health status (physical and mental well-being) and the extent to which their basic human needs (emotional needs, physical needs, self-security) are met and degree to which they are able to attend to their activities of daily living (i.e. self-care, connectedness,	Caregiver Well-Being Scale (CWBS) (short form, 16 items about basic needs and activities of daily living) (Tebb et al., 2013)	Content validity established using experts and use of items from the long form (Tebb et al., 2013) Construct validity through confirmatory factor analysis (Tebb et al., 2013) Overall Cronbach's α: 0.83 Basic Needs Subscale Cronbach's α: 0.73

	dimension and an activities of daily living dimension. (George & Gwyther, 1986; Tebb et al., 1995).	time for self) (Rubio et al., 1999; Tebb et al., 2013)		Activities of Daily Living Subscale Cronbach's α: 0.74 (Rubio et al., 1999; Tebb et al., 2013)
			Optum SF-12v.2 Health Survey (Ware et al., 1996)	Physical Composite Scale Cronbach's α: 0.85 Test-retest reliability: 0.89 Mental Composite Scale Cronbach's α: 0.76 Test-retest reliability: 0.76 (Jakobsson, 2007; Jenkinson et al., 1997) Construct validity established through confirmatory factor analysis (Okonkwo et al., 2010)

Note. ADRD Alzheimer’s disease and related dementias

Care Recipient BPSD. BPSD was defined for this study as individual and collective disturbance or change across behavioral and psychiatric domains including delusions, hallucinations, agitation and aggression, depression and dysphoria, anxiety, euphoria, apathy, disinhibition, irritability and lability, aberrant motor behaviors, sleep disturbance and nighttime behavior, and eating and appetite behavior (Cummings et al., 1994). To inform measurement selection for a future pilot study, this study explored the feasibility of collecting multiple measures of BPSD which are described below.

Global BPSD. The Neuropsychiatric Inventory (NPI) was used to measure the global cluster of BPSD (Appendix E-2) (Cummings et al., 1994). The NPI assesses 12 symptoms and behavioral domains commonly manifested by individuals with ADRD: hallucinations, delusions, agitation and aggression, dysphoria and depression, anxiety, irritability, disinhibition, euphoria, apathy, aberrant motor behavior, appetite and eating disorders, and sleep and nighttime behavior disorders. Each behavioral domain is rated based on frequency (1=rarely, 2=sometimes, 3=often, 4=very often), severity (1=mild, 2=moderate, 3=severe) and level of caregiver distress (0=not at all, 1=minimal, 2=mild, 3=moderate, 4=severe, 5=very severe). Ratings are reported by caregivers based on behaviors and symptoms experienced by care recipients within the most recent 4 weeks. Frequency and severity scales for each domain are multiplied together to yield domain scores, domain scores are then summed to yield a total NPI score (Cummings et al., 1994). Total NPI scores range from 0-144 with higher scores indicative of greater frequency and severity of neuropsychiatric symptoms. Caregiver distress scores for each domain are added together to yield a caregiver distress subscale total score (range 0-60) with higher scores indicative of greater caregiver distress.

The NPI does not have any cut points indicative of “abnormal” results, as some symptoms are always considered abnormal (e.g., hallucinations and delusions), while others may be expected in dementia, as well as other psychiatric conditions (e.g., depression and anxiety). Typically, a decrease in 4 points, or a 30% reduction in baseline score is regarded as a clinically meaningful change in symptoms and behaviors, but a smaller change in certain symptoms and behaviors may be meaningful to caregivers, thus changes should be interpreted on an individual study basis (Cummings et al., 1994). Psychometric testing of the NPI has been performed in persons with ADRD. Internal consistency reliability has ranged from 0.71-0.88, the interrater reliability ranged from 0.936-1.0 (Jackson et al., 2014; Lai, 2014). Test-retest reliability was 0.79 for frequency scores and 0.86 for severity scores (Cummings et al., 1994; Jackson et al., 2014; Lai, 2014).

Agitation was measured using the Cohen-Mansfield Agitation Inventory (CMAI) – Relatives Version (Appendix E-3) (Cohen-Mansfield, Marx, & Rosenthal, 1989). This inventory is completed by relatives of community-dwelling older adults. The CMAI assesses the frequency with which subjects demonstrate up to 34 agitated behaviors from four different domains: verbal aggressive behaviors, verbal non-aggressive behaviors, physical aggressive behaviors, and physical non-aggressive behaviors. Each behavior is rated on a 7-point scale (1=never, 7=several times an hour) to indicate the frequency that a behavior is demonstrated in the most recent 2 weeks. Total scores range from 34-238, with higher scores indicative of greater agitation severity.

Internal consistency (Cronbach's α range: 0.86-0.91) and interrater reliability (k=0.41) of the CMAI have been demonstrated in older adults with ADRD (Cohen-Mansfield, Marx, & Rosenthal, 1989; Finkel, Lyons, & Anderson, 1992). Construct validity has been established by confirmatory factor analysis (Rabinowitz et al., 2005).

Specific BPSD of Anxiety. Anxiety was measured using the Rating Anxiety in Dementia (RAID) scale (Appendix E-4) (Shankar et al., 1999), which measures five anxiety-related domains: worry, apprehension, vigilance, motor tension, autonomic hyperactivity. It includes 18 items, that are scored from 0 to 3 (0=symptom is absent; 1= symptom is mild or intermittent; 2=symptom is moderate; 3=symptom is severe). This measure takes about 15 minutes to complete and requires interviewing both members of the dyad separately (the caregiver first, then the care recipient). The same items and response options are used for the care recipient self-report and the caregiver proxy report. Scores for each of the 18 items are summed for the caregiver to yield a caregiver score, then the care recipient to yield a care recipient score, then averaged to yield a total RAID score. Scores ≥11 suggests significant clinical anxiety.

Internal consistency (Cronbach's α: 0.83), interrater reliability (k range: 0.5-1.0) and test-retest reliability (k range: 0.5-1.0) of the RAID scale have been demonstrated (Shankar et al., 1999). Concurrent validity has been established using other anxiety scales including the Clinical Anxiety Scale and the Anxiety Sensitivity Index, while construct validity has been established through factor analysis (Shankar et al., 1999).

Specific BPSD of Sleep Disturbances. Sleep disturbances were measured using three instruments: the Neuropsychiatric Inventory-Sleep item (NPI-Sleep) (Appendix E-2, item 11) (Cummings et al. 1994), the Pittsburgh Sleep Quality Index (PSQI) (Appendix E-5) (Buysse et al., 1989), and the Epworth Sleepiness Scale (ESS) (Appendix E-6) (Johns, M., 1991).

The NPI-Sleep item was used to assess sleep disordered behaviors, which was obtained through the NPI (See Global BPSD section above for more information). Sleep and nighttime behaviors of PLWD are rated based on frequency (1=rarely, 2=sometimes, 3=often, 4=very often), severity (1=mild, 2=moderate, 3=severe) and level of caregiver distress (0=not at all, 1=minimal, 2=mild, 3=moderate, 4=severe, 5=very severe).

The PSQI evaluates overall sleep quality and includes 9 items pertaining to one of 7 subcategories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication and daytime dysfunction (Appendix E-5). In ADRD research, the PSQI is completed by caregivers to indicate care recipients’ sleep habits over the most recent month. Items are combined to yield subscale component scores. Each of the component scores range from 0-3 with higher scores indicative of worse sleep quality (Component 1), longer sleep latency (Component 2), shorter sleep duration (Component 3), lower sleep habitual sleep efficiency (Component 4), more severe sleep disturbances (Component 5), more sleep medication use (Component 6), and more severe daytime dysfunction due to sleep disturbances (Component 7). Subscale component scores are added together to yield a global score that ranges from 0-21, with higher scores indicative of overall worse sleep quality.

The PSQI has been widely used among older adults. Internal consistency (Cronbach's α=0.85), and test-retest reliability (*r*=0.87) of the PSQI have been demonstrated (Backhaus et al., 2002). The PSQI has been used in many studies focused on older adults with ADRD and completed by caregivers (Boddy et al., 2007;

Kinnunen et al., 2017; Kwok et al., 2013; Simoncini et al., 2015), but has not been validated among older adults with cognitive impairment specifically.

The ESS assesses daytime sleepiness through 8-items rated on a 4-point scale (0-would never doze, 3=high chance of dozing), to indicate an individual’s chances of dozing off or falling asleep while engaged in eight different activities. In ADRD research, the ESS is completed by caregivers based on care recipients’ recent daytime behaviors. Higher scores indicate more severe daytime sleepiness.

Internal consistency (Cronbach's α: 0.73-0.86) of the ESS has been demonstrated and convergent validity established by comparing ESS with PSQI scores (Kendzerska et al., 2014; Spira et al., 2011). The ESS has been used in studies of older adults and completed by caregivers but has not been validated among older adults with cognitive impairment specifically.

Care Recipient Well-Being. The concept of care recipient well-being was measured using the Quality of Life in Alzheimer’s Disease Scale (QOL-AD) (Appendix E-7) (Logsdon et al., 1999). The QOL-AD is a brief, 13-item measure designed to obtain a rating of the quality of life for a person with ADRD, from both the perspective of the care recipient and the caregiver as a proxy reporter. The measure uses simple and straightforward language to assess the care recipient’s relationships with friends and family, concerns about finances, physical condition, mood, and an overall assessment of life quality.

Each of the13-items are rated on a 4-point Likert scales (1=poor to 4=excellent). Scoring of the scale is the sum of all items, with total scores ranging from 13-52. Higher scores are reflective of higher quality of life. The same items and response options are used for the care recipient self-report and for caregiver proxy. Caregiver and care recipient item scores are summed separately to yield a caregiver and a care recipient specific score. These scores are then averaged to yield a total QOL score. This tool has been psychometrically tested in samples of community-dwelling individuals with ADRD and their informal caregivers. Internal consistency (Cronbach’s α: 0.83 for care recipient report, and 0.90 for caregiver report) and inter-rater reliability (ICC ≥ 0.75, $p<0.001$) have been demonstrated (Logsdon et al., 2002). Concurrent validity has been established with four other quality of life indices in dementia, while construct validity was established through factor analysis (Thorgrimsen et al., 2003).

Caregiver Well-Being. Caregiver well-being was defined as caregivers' perception of their overall health status (physical and mental well-being), the extent to which their basic human needs (emotional needs, physical needs, self-security) are met, and the degree to which they are able to attend to their activities of daily living (i.e., self-care, connectedness, time for self) (Rubio et al., 1995; Tebb et al., 2013). Caregiver well-being was measured with the Caregiver Well-Being Scale-short form (CWBS) (Appendix E-8) (Rubio et al., 1995; Tebb et al., 2013), and the Optum SF-12v.2 Health Survey (Appendix E-9) (Ware et al., 1996).

The CWBS includes 16-items composed of two subscales with a basic needs domain (factors associated with meeting the biopsychosocial needs to sustain life) and an activities of daily living domain (implementation of the biopsychosocial needs) (Rubio et al., 1995; Tebb et al., 2013). Eight items are asked in each domain. Respondents rate each item on a 5-point Likert scale (1=rarely, 2=occasionally, 3=sometimes, 4=frequently, 5=usually). Scores are summed across items within each subscale then divided by 8 to yield a basic needs score and an activities of daily living (ADL) score. A combine scale total score is calculated by summing all items and dividing by 16. Higher needs and activities of daily living domain scores indicate that the needs and activities are being met.

Internal consistency reliability for the basic needs subscale (Cronbach's α=0.73), the ADL subscale (Cronbach's α=0.74), and overall total scale (Cronbach's α=0.83) have been demonstrated (Rubio et al., 1995; Tebb et al., 2013). Construct validity was established through confirmatory factor analysis (Table 4.3) (Tebb et al., 2013).

The Optum SF-12v.2 Health Survey is a commonly used 12-item self-report survey composed of a mental and physical health components, and 8 domains: physical functioning, role functioning physical, role functioning emotional, bodily pain, general health, vitality, social functioning, and mental health (Appendix E-9) (Ware et al., 1996). The physical health component and the mental health component subscales both have a range from 0-100, which are averaged to yield an overall SF-12 score. Higher scores on the subscales are reflective of better physical and mental self-reported health functioning, while higher overall SF-12 scores are indicative of better overall self-reported health (Ware et al., 1996).

This measure has been psychometrically tested across many populations, but not specifically caregivers of individuals with ADRD. Among a sample of community dwelling older adults, internal consistency (Cronbach's α: 0.85 for the physical composite scale and 0.76 for the mental composite scale) and test-retest reliability (0.89 for the physical composite scale and 0.76 for the mental composite scale) have been demonstrated. Construct validity has been established through confirmatory factor analysis (Okonkwo et al., 2010).

Demographic and Health History Data. A Demographics Form from Dr. Laura Struble's (dissertation committee member) pilot study, *Using Laser Acupuncture to Decrease Behavioral and Psychological Symptoms of Dementia in Assisted Living Facilities,* was adapted to the community setting to collect demographic information relating to the caregivers and the care recipients. The form included items related to age, gender, race, education level and marital status of both members of the dyad (Appendix E-10). It also included caregiving specific related items, including the relationship of the caregiver to the participant with ADRD, when the family caregiver began acting as primary caregiver, how many hours of caregiving he/she provided on average per week, and when the dyad began living together. A Health History Form was used to collect information regarding the dementia type, date of dementia diagnosis, co-morbidities, and medications of the person with ADRD (Appendix E-11). A Health Status Update Form completed at post-intervention collected information on changes in medications and health status of the care recipient with ADRD that occurred throughout the study period (Appendix E-12).

Measures Completed by Interview at Baseline and at Post-Intervention

Some instruments were completed by interviewing the caregiver (i.e., NPI, RAID – CG), others were completed by interviewing the care recipient (i.e., MoCA, RAID – CR, QOL-AD – CR). Interviews with the caregiver occurred first, followed by the interview with the care recipient. Table 4.4 outlines the average time taken to complete each of interview sessions, the data source (who completed the interview), the instruments that were completed, and the order they were completed at each data collection timepoint.

Table 4.4

Instruments Completed by Interview at Baseline and at Post-Intervention

Data Collection Timepoint	Average Time to Complete	Source of Completion	Instruments and Order of Completion
Baseline	22 minutes	Caregiver	NPI RAID – CG*
	28 minutes	Care recipient	MoCA RAID – CR* QOL-AD – CR*
Post-intervention	22 minutes	Caregiver	NPI RAID-CG*
	28 minutes	Care recipient	MoCA RAID – CR* QOL-AD – CR*

Note. CG caregiver, CR care recipient, MoCA Montreal Cognitive Assessment Test, NPI Neuropsychiatric Inventory, QOL-AD Quality of Life in Alzheimer's Disease Scale, RAID Rating Anxiety in Dementia Scale

*The RAID and QOL-AD were completed by self-report by the care recipient with ADRD and by proxy report by the caregiver

Data Collected by Questionnaires at Baseline and at Post-Intervention

The Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2) were developed incorporating each of the scales (Table 4.5) with directions for each section. Table 4.5 summarizes the average time participants took to complete each questionnaire, the source of completion (who completed the questionnaire), the instruments included in each questionnaire, and the order in which they appeared in the questionnaire at each data collection timepoint.

Table 4.5

Instruments Completed by Questionnaire at Baseline and at Post-Intervention

Data Collection Timepoint	Average Time to Complete	Questionnaire	Source of Completion	Instruments and Order
Baseline	40 minutes	Baseline Caregiver Questionnaire	Caregiver	CMAI PSQI ESS QOL-AD – CG* CWBS SF-12 Demographics form Health History
Post-intervention	40 minutes	Follow-Up Caregiver Questionnaire	Caregiver	CMAI PSQI ESS QOL-AD – CG* CWBS SF-12 WBIAT – CG version Health History Update
	10 minutes	WBIAT – CR version	Care recipient	WBIAT – CR version

Note. CG caregiver, CMAI Cohen-Mansfield Agitation Inventory, CR Care recipient, CWBS Caregiver Well-Being Scale Short Form, ESS Epworth Sleepiness Scale, PSQI Pittsburgh Sleep Quality Index, QOL-AD Quality of Life in Alzheimer's Disease Scale, WBIAT Weighted Blanket Intervention Acceptability Tool

*The QOL-AD was completed by self-report by the care recipient with ADRD and by proxy report by the caregiver

Data Collection Procedures

Aim 1 Data Collection

The same data collection procedures used in the *Perceptions of Family Caregivers of Older Adults Living with Dementia Regarding Behavioral and Psychological Symptoms of Dementia and the Impact of the COVID-19 Pandemic* study were used in this study (See Chapter 3, Methods, p. 51). The PI provided a brief description of weighted blankets using the prompt below:

“Weighted blankets feel like regular blankets or comforters; however, they are filled with materials to add weight to the blanket and can range from 10 to 12 pounds. The feeling of weighted blankets is said to have a grounding effect that increases a person’s level of relaxation. People have compared it to a feeling of being swaddled, while others describe it as a feeling like a long-term gentle hug. They are commonly used for people with ADRD in hospital settings and are typically used multiple times throughout the day for 15-25 minutes at a time when individuals are anxious, restless, or agitated. There is not enough research to say definitively that weighted blankets help with challenging dementia symptoms. The goal of the next stage of my dissertation work is to explore the potential use of weighted blankets as a treatment option for individuals with ADRD who live at home to help with symptoms such as anxiety, agitation and restlessness.” (If the participant was able to view the PI’s video, she shared her screen to show a picture of weighted blankets as an example). Following this description, participants responded to three questions (see page 97) included in the semi-structured interview guide (Appendix A) about weighted blankets over a Zoom interview that was recorded using the audio recording function.

Aim 2 Data Collection

Feasibility Data Collection. The PI tracked the number of individuals screened, enrolled and those that completed the study using a tracking sheet. This tracking sheet included the date participants began and ended the study, as well as reasons for ending the study. The PI completed a Study Completion Form (Appendix D-1) for every participant when they reached the end of the study. Participants that withdrew from the study were asked by phone but were not required to report their reason for withdrawal, which was entered in the Study Completion Form.

Items 1-3 of the Weighted Blanket Daily Use Diary (Appendix D-3) were completed every day by caregiver participants. Responses were used to summarize the number of days care recipients used the blanket for the recommended duration over the 4-week intervention period. All caregiver participants were provided with a hardcopy Weighted Blanket Use Diary with the delivery of the weighted blanket and the Weighted Blanket Use Guide. At home, caregivers completed one entry at the end of each day throughout the 4-week intervention period. Directions for completing the diary entries were reviewed with the caregiver by the PI during the Weighted Blanket Introduction Session and reiterated throughout the weekly check-in telephone calls. Completed diaries were returned to the PI by U.S. Mail at the end of the 4-week intervention period using a stamped, pre-addressed envelope.

Acceptability Data Collection.

Tolerability Data. Tolerability data were collected during the Weekly Intervention Telephone Check-In sessions. Near the end of the calls, caregivers were asked to rate on a scale from 0-10, with 0 being the care recipient did not tolerate the blanket at all, 10 being the care recipient tolerated the blanket all of the time, the number that best described the care recipient's degree of tolerability of the weighted blanket over the past week. This was asked for each of the 4 weeks, yielding a total of 4 tolerability scores. Semi-structured Weighted Blanket Intervention Telephone Check-In Forms were completed by the PI electronically in REDCap during the calls (Appendix C-2). Open ended responses pertaining to challenges to use were collected through item #6 of the Weighted Blanket Daily Use Diary on days caregivers reported the care recipient did not use the blanket at all.

Weighted Blanket Intervention Acceptability Tool Satisfaction and Benefit Data. The Weighted Blanket Intervention Acceptability Tool (WBIAT) – Caregiver (Appendix D-4) and Care recipient versions (Appendix D-5) - was composed of the weighted blanket satisfaction scale and the weighted blanket benefit scale. The WBIAT – Caregiver version was completed by caregivers through the Follow-Up Caregiver Questionnaire at the end of the intervention period. Care recipients completed the WBIAT – Care recipient version by hardcopy questionnaires, which were mailed to participants via U.S Mail during the third week of the intervention. Care recipients were prompted to complete the WBIAT independently but could receive assistance from their family caregivers if unable to do so. Completed WBIAT – Care recipient versions were returned by U.S. using preaddressed and stamped envelopes.

Aim 3 Data Collection of Care Recipient and Caregiver Specific Measures

Baseline data collection occurred within a week prior to the start of the 4-week weighted blanket intervention period and consisted of interviews (See Table 4.4) and questionnaires (See Table 4.5). Post-intervention data collection occurred within 1 week after completion of the weighted blanket intervention period and also consisted of questionnaires and interviews (See Tables 4.4 and 4.5).

Collection of Measures by Interview. Measures completed by interview (See Table 4.4) were conducted over Zoom virtual conferencing system accessible by internet or by telephone. Data were entered directly by the PI in REDCap secure data management system (See Data Security and Management section for more information about REDCap) as the interview was being conducted. The PI checked all data entry after completion of each interview to ensure data entry was accurate and complete.

Collection of Baseline and Follow-up Questionnaires. Caregivers were encouraged to complete the Baseline (Appendix F-1) and the Follow-Up Caregiver Questionnaires (Appendix F-2) electronically by completing REDCap surveys e-mailed to them by the PI. Four caregivers chose to complete hardcopy versions, which they received through U.S. Mail. Instructions for completing the questionnaires were embedded in the hardcopy forms, and the REDCap electronic surveys.

Electronic Baseline Caregiver Questionnaires were sent to participants after completion of the Baseline Interview Data Collection Zoom sessions. The electronic Follow-Up Caregiver Questionnaires were sent after completion of the Post-Intervention Interview Data Collection Zoom session. For participants that preferred to complete questionnaires electronically through the REDCap's survey function, an email was generated by the PI through the REDCap system with a secure link to complete the questionnaires at the designated time (at baseline, or post-intervention). Once surveys were completed, the results were auto populated into the REDcap secure data management system. (See Data Security and Management section for more information about REDCap)

For the four caregivers that preferred hardcopy versions of questionnaires, the Baseline Caregiver Questionnaires were mailed to caregivers after informed consent was obtained. Follow-Up Caregiver Questionnaires were mailed during the third week of the intervention period. Dyads were provided with pre-addressed stamped envelopes to return the completed questionnaires to the PI.

Data Security and Management

All electronically signed consent forms were stored directly in the PI's SignNow account, accessible only to her. SignNow is a HIPAA compliant E-Signature service (SignNow, 2021). Hardcopy forms were scanned upon receipt and saved into SignNow, then immediately shredded. All outcome measures, demographics, and health history data collected electronically was stored in REDCap, which is a secure, HIPAA compliant, web-based application designed to support electronic data capture for research projects (Harris et al., 2009). All hardcopy completed questionnaires were entered into REDCap upon receipt then shredded. All hardcopy diary entries were immediately scanned and saved to a Shared Account folder within Box.com, U-M 's secure cloud storage and collaboration service. The PI was the only one with access to these secure records in SignNow, REDCap, and the Shared Account folder.

All data collection forms were coded using unique ID numbers for each participant individually (caregivers and care recipients), and for the dyad. An electronic list of the IDs and participant names was kept in a separate Shared Account folder in Box.com, accessible only to the PI to protect the participants' confidentiality.

Data Analysis

Qualitative Data Analysis (Aim 1)

The same analysis outlined in Chapter 3 was carried out to address Specific Aim 1 of this study (See Chapter 3, Data Analysis, p. 55). In brief, descriptive statistics [frequencies, percentiles, means, standard deviations (SDs)] were used to describe the demographics of the 21 family caregivers. Audio recordings were transcribed. Transcripts were analyzed inductively and iteratively using content analysis and constant comparative methods (Glaser & Strauss, 1967). Three analysts independently coded and identified minor themes that emerged from the data. Minor themes were clustered into major themes. Analysts met over a series of meetings to compare and reach consensus regarding minor theme clusters and names of major themes. Discrepancies were resolved through consensus.

Demographic, Caregiving and Health History Data Analysis (Aims 2 and 3)

To describe the characteristics of the dyads, descriptive statistics [frequencies, percentiles, means, standard deviations (SDs)] were performed to analyze demographic data of both care recipients and caregivers, the caregiving information data, and the health history data specific to the care recipients.

Feasibility Data Analysis (Aim 2)

Enrollment rate was calculated by the number of people enrolled divided by the number of people screened, which was reported as a percentage by multiplying by 100. The length of time to recruit the desired number of participants (20 dyads) was reported in days and the timeline began the day the IRB application was approved (October 26, 2020). Withdrawal rate was calculated by the number of people that withdrew from the study, divided by the total number of people that enrolled, which was multiplied by 100 to report as a percentage.

Items 1-3 of the Weighted Blanket Daily Use Diary captured the number of days care recipients used the blanket for the recommended duration over the 4-week intervention period. The number of days the weighted blanket was used for the recommended duration was calculated for each care recipient participant by adding the number of days that the 20 minutes was completed across the 4-week intervention period. A group mean (SD) of days that the weighted blanket was used for the recommended duration was calculated for the sample by adding the total number of days for each participant and dividing by the total number of participants.

The analysis plan for adverse event or injuries was to group events into similar clusters and reporting them as frequencies reported by the number of individuals that experienced a similar adverse event or injury.

Acceptability Data Analysis (Aim 2)

Findings related to acceptability of the weighted blanket intervention are presented below and includes findings related to tolerability, satisfaction, and benefit.

Tolerability. To analyze the measure of tolerability of the weighted blanket, descriptive statistics (means and standard deviations) were used to compare the weekly tolerability scores (ranged 0 to 10) on the single item from the semi-structured Weekly Intervention Telephone Check-In forms (See Appendix C-2). At the subject level, each participant received 4 tolerability scores, which were added and divided by 4 to determine an overall individual tolerability score for each participant. The mean (SD) was then calculated for the group by adding all participants individual tolerability scores and dividing by the total number of participants with data collected during the intervention period.

Qualitative data relating to tolerability of the weighted blanket from item #6 of the Weighted Blanket Daily Use Diary (See Appendix D-3) were analyzed using content analysis and grouping responses that clustered together into categories. Frequencies were calculated for each of the categories.

Weighted Blanket Intervention Acceptability. Descriptive statistics were used to analyze satisfaction and benefit of the weighted blanket. An overall caregiver satisfaction score was calculated for each participant by adding the responses (1=not satisfied to 5=very satisfied) for items #1-8 of the Weighted Blanket Satisfaction Scale included in the Weighted Blanket Intervention Acceptability Tool (WBIAT) - Caregiver version (See Appendix D-4) and dividing by 8. A group mean (SD) of caregiver satisfaction was then calculated by adding the individual caregiver satisfaction scores and dividing by the total number of caregivers that completed the WBIAT - Caregiver version (See Appendix D-4). Satisfaction items with categorical responses (#9 through #13) and dichotomous yes-no responses (#20 and #21) (See Appendix D-4) were analyzed using frequencies and percentages.

An overall care recipient satisfaction score was calculated for each participant by adding the responses (1, 2, 3) for items #1-6 (See Appendix D-5) and dividing by 6. A group mean (SD) for care recipient satisfaction was calculated by adding the individual care recipient satisfaction scores and dividing by the total number of care recipients that completed the Weighted Blanket Intervention Acceptability Tool (WBIAT) - Care recipient version. Satisfaction items with categorical responses (#7) and dichotomous yes-no responses (#10 and 11) (See Appendix D-5) were analyzed using frequencies and percentages. Open ended items (#12, #13) were analyzed using content analysis by grouping responses that clustered together into categories. Frequencies were calculated for each category.

An overall caregiver benefit score was calculated for each participant by adding the responses (1=not at all, 2=some, 3=a great deal) of items #14-19 (See Appendix D-4) and dividing by 6. A group mean (SD) was calculated by adding the individual caregiver benefit scores and dividing by the total number of caregivers that completed the Weighted Blanket Intervention Acceptability Tool-Caregiver version. Open ended items (#22-26) relating to caregiver benefit (See Appendix D-4) were analyzed using content analysis, grouping responses that clustered together into categories, and calculating frequencies for each category.

The care recipient benefit item was scored for each participant (1 = Not at all, 2 = Some, 3 = A great deal) (See Appendix D-5). A group mean (SD) for this item was calculated by adding each individual care recipient's score and dividing by the total number of care recipients that completed the Weighted Blanket Intervention Acceptability Tool (WBIAT)-Care recipient version. The open-ended items (#9, #14) on the care recipient WBIAT related to benefit (See Appendix D-5) were analyzed using content analysis by grouping responses that clustered together into categories, which are reported as frequencies.

Feasibility of Collecting Outcomes Measures Data Analysis (Aim 3)

Participant and overall sample level analysis for Aim 3 are summarized in Table 4.6. Each measure completed at each data collection timepoint for each participant was scored as "Complete" or "Not Complete". A measure was considered complete if there were no missing item responses. A group percentage of participant completion for each measure was calculated by summing the number of participants that fully completed the specific measure at the specific time point divided by the total number of participants with data collected at the specific data collection timepoint then multiplying by 100 to arrive at a percentage.

Table 4.6
Aim 3 Instrument Completion Outcomes, Measures, Individual Calculations and Group Analysis Plans

Outcome	Measure	Subject Level Calculation	Analysis Across Subjects

Participant completion of measures (analyzed at baseline and at post-intervention)	Percentage of completion by participants of each individual measure at each timepoint	Each measure at each timepoint was scored using a dichotomous response of “Complete” or “Not Complete”. A measure was considered complete if there were no missing item responses	Group percentage of participant completion = total # of subjects that fully complete the specific measure at the specific timepoint / total # of subjects
Missing data (analyzed at baseline and at post-intervention)	Percentage of missing data of each individual measure at each timepoint	N/A	Percentage of missing data = (total # of missing items across subjects for each measure at each timepoint / (total # of items in the measure x total # of subjects)) multiplied by 100

Note. CG Caregiver, CR Care recipient with ADRD

The percentage of missing data for each measure at each timepoint was calculated by adding the number of items missed across participants for each measure at each timepoint, divided by the number of items in the specific scale multiplied by the total number of participants who completed the scale, then multiplying by 100. For example, there are 34 items in the Cohen-Mansfield Agitation Inventory (CMAI). If three caregivers had data collected using the CMAI at baseline and one caregiver missed 2 items, the second caregiver missed 5, and the third caregiver missed 0, the percentage of missing data for the group would be calculated as ((2+5+0)/(34x3)) x 100 = 6.9%

Each of the outcome measurement tools were scored for each subject at baseline and at post-intervention. A mean (SD) for all scales and subscales were calculated across participants at baseline and at post-intervention by adding individual subject scores and dividing by the total number of subjects (See Table 4.7).

The QOL-AD and RAID scales were completed by proxy report by caregivers and by self-report by care recipients which were scored separately to yield caregiver and care recipient overall scores. According to the scoring guidelines and recommendations of the instrument developers, individual caregiver and care recipient scores are averaged to yield a total score for each instrument for each participant dyad (Logsdon et al., 1999; Shankar et al., 1999). The group mean (SD) of caregiver scores, care recipient scores, and the total scale scores are reported.

Table 4.7
Scoring and Analysis of Instrument Scores at Baseline and at Post-intervention

Instrument	Overall Scale Score Range	Subscale Score Range	Analysis Across Subjects
CMAI	34-238	N/A	Mean (SD) for baseline and post-intervention overall scale scores
PSQI	0-21	Component 1: 0-3 Component 2: 0-3 Component 3: 0-3 Component 4: 0-3 Component 5: 0-3 Component 6: 0-3 Component 7: 0-3	Mean (SD) for baseline and post-intervention overall scale and subscale scores
ESS	0-24	N/A	Mean (SD) for baseline and post-intervention overall scale scores
NPI-Sleep Item	0-12	Frequency: 1-4 Severity: 1-3 CG distress 0-5	Mean (SD) for baseline and post-intervention overall scale and subscale scores
QOL-AD – CG	13-52	N/A	Mean (SD) for baseline and post-intervention CG scale scores
QOL-AD – CR			Mean (SD) for baseline and post-intervention CR scale scores
QOL-AD Overall Score			Caregiver and care recipient scores were averaged for each participant to yield an overall QOL-AD score. Group mean (SD) of overall scores were calculated at baseline and post-intervention
CWBS	1-5	Basic Needs Subscale: 1-5 ADL subscale: 1-5	Mean (SD) for baseline and post-intervention overall and subscale scores
SF-12	0-100	Physical health subscale: 0-100 Mental health subscale: 0-100	Mean (SD) for baseline and post-intervention overall and subscale scores
MoCA	0-30	N/A	Mean (SD) for baseline and post-intervention overall scale scores
NPI	0-144	CG distress subscale: 0-60	Mean (SD) for baseline and post-intervention overall and CG distress subscale scores
RAID – CG	0-54	N/A	Mean (SD) for baseline and post-intervention CG scale scores
RAID – CR	0-54	N/A	Mean (SD) for baseline and post-intervention CR scale scores
RAID Overall Score	0-54	N/A	Caregiver and care recipient RAID scores were averaged for each participant to yield an overall RAID score. Group mean (SD) of overall RAID scores were calculated at baseline and post-intervention

Note. ADL Activities of daily living, CG caregiver, CMAI Cohen-Mansfield Agitation Inventory, CR care recipient, CWBS Caregiver Well-Being Scale Short Form, ESS Epworth Sleepiness Scale, MoCA Montreal Cognitive Assessment Test, NPI Neuropsychiatric Inventory, PSQI Pittsburgh Sleep Quality Index, QOL-AD Quality of Life in Alzheimer's Disease Scale, RAID Rating Anxiety in Dementia Scale
*The RAID and QOL-AD were completed by self-report by the care recipient with ADRD and by proxy report by the caregiver.

Results

Aim 1 Participant Characteristics

Of the 21 caregivers, the majority were female (*n*=17; 81%) and non-Hispanic white (*n*=20; 95%). The average age was 66.2 years (SD=8.7). Nineteen participants reported education levels of some college or above. Most of the participants were caring for a spouse (*n*=17), while 4 were caring for a parent with ADRD.

Participants reported having acted as the primary caregiver for an average of 40.0 months (SD=36.0), or approximately 3.33 years. The mean number of hours of caregiving per week was 84 (SD=55.9). Based on participants' self-report, nine cared for a relative with Alzheimer's disease, 1 with vascular dementia, 1 with a mixed dementia diagnosis, 1 with frontotemporal dementia, 7 with Lewy Body dementia, 1 with posterior cortical atrophy, and 1 with an unspecified dementia diagnosis.

Family Caregivers' Initial Perceptions of Weighted Blankets (Aim 1)

Caregiver perceptions' about the use of weighted blankets consisted of three minor themes (underlined below) that clustered into one major theme, "Caregiver perspectives on weighted blankets" (See Table 4.8).

Caregivers made suggestions relating to weighted blankets after hearing the brief description and seeing a visual presentation of the blankets (See Table 4.8).

> *"I would definitely need to be able to wash it. My husband is incontinent, I wash his bedding every day. If it isn't washable, I can't use it."*

Some caregivers mentioned potential concerns. One caregiver mentioned cost being a concern.

> *"I don't know if I'd want to spend that kind of money on something without having tried it out first to see if it would be of benefit."*

One caregiver described how her loved one had tried a weighted blanket before, but his experience was a concern for her.

> *"He was using a really heavy blanket. He was saying he couldn't stand it because he couldn't move. And so, it wasn't, you know, normally that weight is supposed to feel good even with your autism. He doesn't like that. It's almost like it's the opposite effect for him.*

Others expressed positive initial perceptions towards the weighted blanket.

> *"She got a blanket for her birthday from (stated name), and we have some blankets here and a couple from Costco that we've had a long time. They are all on the heavier side. I think it's secondary to the warmth but who wouldn't like it? You know, I'm big into hugs so who wouldn't like a hug?"*

Table 4.8
Major and Minor Themes Relating to Family Caregivers' Initial Perceptions of Weighted Blankets

Major Theme	Minor Theme	Examples
Caregiver perspectives on weighted blankets	Suggestions	*I know for him, he would want something bright. He loves bright colors, blues, yellows, reds. The primary colors. If it was bright yellow, oh he would be surely be more likely to use it.* *How soft is it? You have two different kinds in that picture, a softer looking one and one that looks like cotton. I think my husband would like the softer one, but wouldn't have much interest in the cotton one. Would he have a choice in the type of fabric?*
	Concerns	*I'm looking at the pictures of blankets. The other thing is, um, especially since I bought such a heavy one is could a weighted blanket ever turn into a form of restraint?* *I don't know if I'd want to spend that kind of money on something without having tried it out first to see if it would be of benefit.*
	Positive perceptions	*I had heard of the heavy blanket but when I heard of it in terms of Alzheimer's patients, I thought boy that's interesting if that blanket on him, the weight of it would bring comfort somehow and maybe settle him down more.* *When I take her into the bedroom I put this weighted blanket, I mean she has a sigh of relief that, okay, it's something I know and within three, four, five minutes she's sleeping.*

Participant Characteristics of Study Sample for Aims 2 and 3

Of the 21 participant dyads that were enrolled, 20 completed the study. The sociodemographic characteristics, along with characteristics relating to the dementia diagnoses and caregiving patterns of the 20 dyads that completed the weighted blanket intervention period are in Table 4.9. Overall, the sample was mostly non-Hispanic White and well-educated. Most dyads were married or partnered. Most care recipients had Alzheimer's disease and on average caregivers reported providing 19 hours of care a day to their relatives with ADRD (Table 4.9). Characteristics of the dyad that withdrew were similar to the sample that was retained (e.g., female caregiver, caregiver and care recipient were both 82 years old, both were non-Hispanic white, and both had at least some college education).

Table 4.9
Sociodemographic, Dementia Diagnosis, and Caregiving Characteristics of Study Sample

	Care Recipients (*n*=20)	Caregivers (*n*=20)
Female (%)	35	80
Mean age (SD)	77.7 (10.2)	66.4 (11.2)
Race/ethnicity (%)		
Non-Hispanic White	95	95

Non-Hispanic Black	5	5
Education (%)		
< High school	10	0
High school	15	20
Some college	20	10
College and above	55	70
Relationship between members of dyad % (n)		
Married or partnered	80 (16)	
Child caring for parent	20 (4)	
Mean duration of ADRD diagnosis in months (SD)	45.7 (28.1)	
Number of care recipients with type of ADRD		
Alzheimer’s dementia	13	
Vascular dementia	1	
Mixed type dementia	1	
Lewy Body dementia	1	
Posterior cortical atrophy	1	
Not specified or unknown	3	
Mean number of years having lived together (SD)	35.6 (19.7)	
Mean number of hours of care provided by caregiver each day (SD)	19.0 (32.3)	

Table 4.10 outlines health conditions of care recipients and describes the psychotropic, sleep, and memory related medications care recipients were taking at baseline. No new conditions were reported at follow up. One care recipient had started taking Rivastigmine and one had stopped taking Ativan during the 4-week study period.

Table 4.10

Health Conditions and Select Medications of Care Recipient Participants as Reported by Caregivers at Baseline

Conditions	*n*		Medication	Indication	*n*
Hypertension	3		Donepezil	Enhance cognition	11
Other heart conditions	4		Namenda	Enhance cognition	7
High cholesterol	3		Zoloft	Treat depression and/or obsessive-compulsive behaviors	5
Cancer	2		Lexapro	Treat depression and/or anxiety	4
Congestive heart failure	2		Celexa	Treat depression	3
Anxiety	2		Trazodone	Promote sleep	2
Hearing impairment	2		Bupropion	Treat depression	1
Urological conditions	2		Rivastigmine	Enhance cognition	1
Arthritis	1		Xanax	Treat anxiety	1
Chronic traumatic encephalopathy	1		Ativan	Treat anxiety	1
Cerebrovascular accident	1		Clonazepam	Treat anxiety	1
Depression	1		Melatonin	Promote sleep	1
Enlarged prostate	1		Seroquel	Treat psychosis	1
Gastroesophageal reflux	1		Cymbalta	Treat depression and/or anxiety	1

Glaucoma	1	
Hypothyroidism	1	
Macular degeneration	1	
Obsessive compulsive disorder	1	

Feasibility Results (Aim 2)

Feasibility results and the a priori feasibility benchmarks are in Table 4.11. The enrollment rate was higher than anticipated and the withdrawal rate was low. Eleven dyads did not enroll which was due to: care recipients with ADRD had sleep apnea (n=6), care recipients had COPD (n=2), the perceived time commitment to participate was too much (n=2), and the care recipient had a shoulder injury (n=1). One dyad withdrew due to caregiver sickness before the intervention period began.

Table 4.11
Results of Feasibility Measures Compared to Predefined Benchmarks of Feasibility

Measures of Feasibility	Predefined Benchmarks of Feasibility	Results of This Study
Enrollment percentage	≥ 50%	64%
Length of time to recruit desired sample	≤ 5 months	3.9 months
Average number of days weighted blanket was used for the recommended duration (SD)	≥ 21	23.8 days (SD=6.4)
Withdrawal percentage	< 25%	5%
Injuries and adverse events	None	None

On average, participants used the weighted blanket for 3.7 (SD=3.9) hours a day, which was more than the minimum recommended 20 minutes a day. Information about the use of weighted blankets by care recipients throughout the 28-day intervention period is in Table 4.12. Over half of the participants did not use the blanket at all at least one of the days throughout the intervention period, and three did not use it for the recommended 20 minutes for 10 or more days (Table 4.12).

Table 4.12
Patterns of Use of Weighted Blankets by Participants with Dementia Throughout the 28-Day Intervention Period

Use of the Weighted Blanket	Care Recipients (*n*=20)
Mean number of hours of WB use per day (SD)	3.7 (3.9)
Number (%) of CRs that did not use the WB at all at least 1 day*	12 (60)
Number (%) of CRs that did not use the WB for the recommended 20 minutes or more for:	
1 day*	3 (15)
2 to 3 days*	3 (15)
4 to 5 days*	3 (15)
10 or more days*	3 (15)

Note. CR care recipient, WB Weighted blanket
*Throughout the 28-day intervention period, as reported by caregivers.

Acceptability Results: Tolerability, Satisfaction and Benefit (Aim 2)

Results pertaining to acceptability of the intervention consists of measures of tolerability, satisfaction, and benefit. The descriptive statistics for each of the quantitative measures are in Table 4.13.

Table 4.13
Results of Measures of Acceptability: Tolerability, Satisfaction and Benefit

Measure	*n*	Mean (SD)	Median	Range of Sample Scores	Scale Range
Tolerability*	20 CRs	8.9 (2.1)	10	1-10	0 did not tolerate the blanket at all to 10 tolerated the blanket all of the time
Caregiver Satisfaction	20 CGs	4.7 (0.4)	4.9	3.6 to 5	1 = Not satisfied to 5 = Very satisfied
Care Recipient Satisfaction	13 CRs	2.8 (0.2)	2.8	2.5-3.0	1 = Not satisfied to 5 = Very satisfied
Caregiver Benefit	20 CGs	2.5 (0.4)	2.7	1.7 – 3.0	1 = Not at all to 3 = A great deal
Care Recipient Benefit	13 CRs	2.8 (0.4)	3	2-3	1 = Not at all to 3 = A great deal

Note. CG caregivers, CR care recipients, SD standard deviation
*Care recipient tolerability of the weighted blanket as reported by caregivers

The results of other informational items in the satisfaction scales from the caregivers and care recipients are in tables 4.14 and 4.15 respectively.

Table 4.14
Information about the Weighted Blanket in the Caregiver Satisfaction Scale (N=20)

Item	Response Options	Frequency (%)
How heavy was the blanket that your relative used	10 pounds	1 (5)
	12 pounds	15 (75)
	I don't know	4 (20)
What did you think about the weight of the blanket for your relative	The weight was about right for my relative	16 (80)
	I would have liked it to be lighter	4 (20)
	I would have liked it to be heavier	0 (0)
What is your opinion about the recommendation that the weighted blanket be used daily by your relative?	The recommended everyday use of the weighted blanket was about right for us.	17 (85)
	I would have liked the recommended use of the weighted blanket be less than every day.	2 (10)
	I would have liked the recommended use of the weighted blanket be multiple times a day.	1 (5)
What is your opinion about the recommended amount of time the weighted blanket was to be used by your relative each day?	The recommended amount of time was about right for us.	11 (57.9)
	I would have liked less recommended blanket use time.	1 (5.3)
	I would have liked more recommended blanket use time.	7 (36.8)
What did you think about completing a Weighted Blanket Daily Use Diary?	Completing a diary entry every day was about right for me.	16 (80)
	I would have liked to complete fewer diary entries.	4 (20)
	I would have liked to complete more diary entries.	0 (0)
Overall, would you recommend the use of a weighted blanket to other	Yes	19 (95)
	No	1 (5)

individuals caring for someone with dementia?		
Will you continue to encourage your relative to use the weighted blanket?	Yes	19 (95)
	No	1 (5)

Table 4.15
Information about the Weighted Blanket in the Care Recipient Satisfaction Scale (N=13)

Item	Response Options	Frequency (%)
How did the weight of the blanket feel to you?	The weight was about right for me.	12 (92.3)
	I would have liked it to be heavier.	0 (0)
	I would have liked it to be lighter.	1 (7.7)
Will you continue to use the weighted blanket?	Yes	12 (92.3)
	No	1 (7.7)
Overall, would you recommend using a weighted blanket to other individuals with dementia?	Yes	13 (100)
	No	0 (0)

Qualitative Findings Related to Tolerability

Twelve caregivers recorded days that the blanket was not used at all by their relatives with ADRD and described situations or circumstances that made using blanket a challenge which clustered into 4 categories: dyads were too busy, care recipients did not want to use the blanket (reason not specified), contextual circumstances (e.g., holiday celebrations, warm climates), the blanket was too heavy (Table 4.16).

As these data were collected using the Weighted Blanket Daily Diary (See Appendix D-3), many provided more than one example for each category because the diary was completed daily. The number of instances for which an example was provided for the category and the total number of participants that gave examples is noted in Table 4.16.

Table 4.16
Reasons Using the Weighted Blanket was a Challenge as Reported by Caregivers (n=12)

Category	Examples	Number of Instances per Category (Number of Participants that Gave Examples)
Dyads were too busy	*We were busy and hardly sat down at all today, so she didn't use the blanket.*	23 (6)
Contextual circumstances	*We were busy with the holiday celebrations, we had family over today. With all the excitement, he just did not use the blanket.* *It was very warm out today, so he did not want to use the blanket.*	9 (4)
Care recipients did not want to use the blanket (reason not specified)	*I tried to encourage him to use it multiple times, but he just didn't want to.*	7 (4)
Blanket was too heavy	*I asked her to use it, but she said, "too heavy, too heavy" so I didn't put it on her today.*	13 (2)

	She asked to use her lighter, softer blanket today instead of the weighted blanket.	

Qualitative Findings Related to Satisfaction

When care recipients were asked, using the Satisfaction Scale in the Weighted Blanket Intervention Acceptability Tool, what they liked most and least about using the weighted blanket, the responses clustered into three (See Table 4.17) and four categories (See Table 4.18), respectively.

Table 4.17
What Care Recipients Liked Most About Using the Weighted Blanket (n=12)

Category	Examples	Number of Participants that Gave Examples
It provided comfort	*It was cozy and comfy and blue is my favorite color* *It was very comfortable, relaxing, and made me feel safe.*	*6*
It improved sleep	*I liked how much better I slept at night.*	*4*
It provided warmth	*It was so warm and cuddly.*	2

Table 4.18
What Care Recipients Liked Least About Using the Weighted Blanket (n=9)

Category	Examples	Number of Participants that Gave Examples
It was too heavy (at times)	*It got heavy after a while and I needed to move my legs.*	*3*
The weighted beads clumped together	*The small balls that cluster together. I have to break them apart with my hands or my feet.*	*2*
It was too hot (at times)	*At times it was too hot in the Florida climate*	2
It could be softer	*I prefer a regular, softer blanket.*	2

Qualitative Findings Related to Benefit

When caregivers were asked about when the weighted blanket was most helpful and least helpful for their relatives using the weighted blanket benefit scale, responses clustered into 3 categories (See Table 4.19) and 2 categories respectively (See Table 4.20).

Table 4.19
When Using the Weighted Blanket was Most Helpful as Reported by Caregivers (n=16)

Category	Examples	Number of Participants that Gave Examples
Overnight	*It was most helpful overnight, his sleep improved noticeably.*	6
Afternoon naptime	*It helped her get into relax mode during her afternoon naps.*	6
After dinner/evening time	*I noticed much less confusion at sundowning time in the evenings after dinner.*	4

Table 4.20
When Using the Weighted Blanket was Least Helpful to Care Recipients as Reported by Caregivers (n=7)

Category	Examples	Number of Participants that Gave Examples
Overnight	*From what I observed, at bedtime/overnight. I believe that the weight was too much to be comfortable and get a good night's rest for him.*	5
When relative was restless or agitated	*When he was already agitated, he would pull it off.*	2

Two caregivers provided suggestions regarding the weighted blankets.

> *"Not sure how the weight by body weight was determined but I wonder if my Dad would fare better with a lighter weight blanket especially come summer heat and humidity. Because of our success with the weighted blanket through this study, it is my intention to purchase a lighter weight version to use as our weather changes."*
>
> *"Maybe a soft cover that's removable"*

Care recipients provided responses on the Benefit Scale regarding how they felt when using the weighted blanket, which clustered into 3 categories (See Table 4.21).

Table 4.21
How Care Recipients Felt While Using the Weighted Blanket (n=13)

Category	Examples	Number of Participants that Gave Examples
Comfortable	*It felt comfortable, great and warm.*	*8*
Warm	*It made me feel warm, safe and secure.*	*7*
Sleepy	*Made me fall right to sleep.*	2

Three care recipients provided recommendations and changes for the weighted blanket. One recommended that couples use the blanket together. The other 2 care recipients suggested the blanket be made of a softer material, such as fleece instead of cotton. One also suggested making a grid in the fabric, so the weighted beads stayed more evenly disbursed throughout the blanket.

Feasibility of Collecting Outcomes Measures (Aim 3)

The feasibility of collecting care recipient outcome measures (i.e., BPSD, cognitive function, quality of life) and caregiver measures (well-being, self-reported health) is reported here. Specifically, information on the completion of measures and missing data is reported first, followed by the scored results of each measure.

Participant Completion of Measures and Missing Data Results

Overall participant completion percentages and percentages of missing data of all measures are in Table 4.22. Completion rates of caregiver measures (i.e., CMAI, PSQI, ESS, QOL-AD – CG, CWBS, SF-12, NPI, RAID – CG) ranged from 80-100% across timepoints. The completion rate for the MoCA for those with ADRD was 100%. The RAID – CR and the QOL – CR completed by interview of those with ADRD had over 50% missing data and low completion rates.

Table 4.22
Participant Completion Rates and Missing Data for Each Outcome Measure

Measure	Source of Completion	Baseline (*n*=21)		Post-Intervention (*n*=20)	
		% of Participant Completion [A*]	% of Missing Data [B*]	% of Participant Completion [A*]	% of Missing Data [B*]
CMAI	CG questionnaire	100.0	0	90.0	0.3
PSQI	CG questionnaire	95.0	0.5	100.0	0
ESS	CG questionnaire	100.0	0	100.0	0
QOL-AD – CG	CG questionnaire	81.0	1.5	80.0	1.5
CWBS	CG questionnaire	100.0	0	100.0	0
SF-12	CG questionnaire	100.0	0	100.0	0
NPI	CG interview	100.0	0	100.0	0
RAID – CG	CG interview	100.0	0	100.0	0
RAID – CR	CR interview	47.6	52.3	40.0	50.0
QOL-AD – CR	CR interview	38.1	61.1	35.0	50.8
MoCA	CR interview	100.0	0	100.0	0

Note. CG caregiver, CR care recipient, CMAI Cohen-Mansfield Agitation Inventory, CWBS Caregiver Well-Being Scale Short Form, DC data collection, ESS Epworth Sleepiness Scale, MoCA Montreal Cognitive Assessment Test, NPI Neuropsychiatric inventory, PSQI Pittsburgh Sleep Quality Index, QOL-AD Quality of Life in Alzheimer's Disease Scale, RAID Rating Anxiety in Dementia Scale

[A] % of Participant Completion = total # of subjects that fully complete the specific measure at the specific timepoint / total number of participants (n=21 at baseline, n=20 at post-intervention).

[B] % of missing data = total # of items missed across participants for each measure at each timepoint, divided by the number of items in the specific scale multiplied by the total number of participants, then multiplying by 100

*Columns A and B will not necessarily add up to 100, as the unit of analysis for A was each measure as a whole, and for B was items within each measure.

The only item that was missed more than once across participants was from the QOL-AD, item #7 which asked caregivers and care recipients to rate the care recipient's quality of life in terms of their marriage. This item was missed by 4 caregiver and 2 care recipient participants at baseline and at post-intervention. For these participants, the care recipients were widowed, so this item was skipped, thus missing. Other items were missed only once and appeared to be missing at random.

Results of Outcome Measures

The mean (SD) for overall scale and subscale scores for each instrument at each data collection time point for the 20 dyads that completed the intervention are in Table 4.23. The cognitive impairment severity of the sample varied but was overall moderate with a mean MoCA of 9.2 (SD=8.0) at baseline (Saczynski et al., 2015). Given the large amount of missing data on the RAID and QOL-AD measures completed by care recipients, a RAID Total and QOL-AD Total score were not calculated, which are typically calculated by averaging care recipient and caregiver scores.

Overall, 4 of 6 measures of BPSD showed improvements from baseline to post-intervention (NPI-Total and caregiver distress scores, CMAI, RAID – CG, ESS; See Table 4.23), but efficacy testing was not performed, and these improvements are not indicative of clinical significance. Total NPI scores were similar to prior community-based samples of PLWD (Charlesworth et al., 2016; Maidment et al., 2020), while the caregiver distress scores were higher (Huang et al., 2015). The CMAI scores were overall higher than other community-based samples of PLWD, while the RAID scores were lower (Figueiro et al., 2019; Livingston et al., 2017; Stanley et al., 2013). The RAID scores of the 10 care recipients able to complete this measure tended to be lower than those reported by their caregivers (Table 4.23). RAID scores suggest that overall, the anxiety level of the sample was not clinically significant (Shankar et al.,1999).

Table 4.23

Results of Scored Outcome Measures Collected at Baseline and at Post-Intervention

Concept	Measures and Subscales	Scale Ranges ^{A}	Baseline (*n*=20)*	Post-Intervention (*n*=20)*
			Mean (SD)	Mean (SD)
CR Cognitive Function	MoCA	0-30	9.2 (8.0)	9.1 (8.2)
CR BPSD (Global BPSD)	NPI Total	0-144	25.0 (16.0)	22.8 (20.1)
	CG Distress Subscale	0-60	13.2 (7.6)	11.3 (9.8)
CR BPSD (Agitation Specific)	CMAI	34-238	59.1 (13.4)	55.8 (14.4)
CR BPSD (Anxiety Specific)	RAID			
	RAID – CG	0-54	9.7 (6.0)	7.7 (5.0)
	RAID – CR **(n=10)**	0-54	5.7 (5.8)	5.4 (4.8)
CR BPSD (Sleep Disturbance Specific)	NPI-Sleep Domain Total	0-12	3.9 (2.9)	4.3 (3.7)
	Frequency	0-4	1.9 (1.0)	2.0 (1.1)
	Severity	0-3	1.8 (0.7)	1.9 (0.8)
	CG Distress	0-5	2.8 (1.4)	2.8 (1.4)
	PSQI Total	0-21	6.3 (3.1)	6.3 (3.5)
	C1 Subscale	0-3	0.9 (0.7)	1.0 (0.8)
	C2 Subscale	0-3	0.8 (0.8)	1.0 (0.8)
	C3 Subscale	0-3	0.3 (0.6)	0.3 (0.6)
	C4 Subscale	0-3	0.7 (0.8)	0.7 (1.0)
	C5 Subscale	0-3	1.4 (0.5)	1.2 (0.5)
	C6 Subscale	0-3	1.0 (1.3)	0.9 (1.3)
	C7 Subscale	0-3	1.3 (0.9)	1.4 (1.0)
	ESS	0-24	9.9 (5.7)	9.3 (6.3)
CR Well-Being	QOL-AD			
	QOL-AD – CG	13-52	33.3 (5.7)	33.7 (5.3)
	QOL-AD – CR **(*n*=10)**	13-52	41.3 (5.1)	42.4 (3.0)
CG Well-Being	CWBS Overall	1-5	3.9 (0.6)	4.0 (0.6)
	Basic Needs Subscale	1-5	4.2 (0.7)	4.2 (0.6)
	ADL Subscale	1-5	3.8 (0.7)	3.8 (0.7)
	SF-12 Total	0-100	50.2 (5.5)	48.3 (6.1)
	PCS	0-100	56.9 (6.7)	52.8 (9.2)
	MCS	0-100	43.1 (12.6)	43.9 (11.1)

Note. ADL Activities of daily living, BPSD behavioral and psychological symptoms of dementia, C* Composite* (*=1,2,3,4,5,6, or 7) subscale, CG caregiver, CR care recipient, CMAI Cohen-Mansfield Agitation Inventory, CWBS Caregiver Well-Being Scale Short Form, DC data collection, ESS Epworth Sleepiness Scale, MCS Mental Composite Scale, MoCA Montreal Cognitive Assessment Test, NPI Neuropsychiatric inventory, PCS Physical Composite Scale, PSQI Pittsburgh Sleep Quality Index, QOL-AD Quality of Life in Alzheimer's Disease Scale, RAID Rating Anxiety in Dementia Scale

*All measures scored using data from the 20 dyads that completed the intervention period. The QOL-AD and the RAID by care recipient report were only completed by 10 care recipients, thus the *n* for these scored measures is 10 instead of 20.

[A] <u>Information on Scale and Subscale Ranges</u>

-MoCA: Higher scores indicate better cognitive function. ≤9 indicative of moderate dementia, ≤17 indicative of mild dementia, ≤23 indicative of mild cognitive impairment, ≤30 normal cognitive function

-NPI: Higher scores indicative of greater frequency and severity of neuropsychiatric symptoms. Higher caregiver distress scores indicate of greater caregiver distress related to neuropsychiatric symptoms.

-CMAI: Higher scores indicative of greater agitation severity.

-RAID: Higher scores indicative of greater anxiety, a score of 11 or more suggests significant clinical anxiety.

-PSQI: Higher total scores indicative of overall worse sleep quality. Component 1: higher scores indicate worse sleep quality. Component 2: higher scores indicate longer sleep latency. Component 3: higher scores indicate shorter sleep duration. Component 4: higher scores indicate lower sleep habitual efficiency. Component 5: higher scores indicate more severe sleep disturbances. Component 6: higher scores indicate more sleep medication use. Component 7: higher scores indicate more severe daytime dysfunction due to sleep disturbances.

-ESS: Higher scores indicate more severe daytime sleepiness.

-QOL-AD: Higher scores are reflective of higher reported quality of life.

-CWBS: Higher total scores indicate greater reported well-being. Higher needs and activities of daily living domain scores indicate that the needs and activities are being met.

-SF-12: Higher scores on subscale scores are reflective of better physical and mental self-reported health functioning, while higher overall SF-12 scores are indicative of better overall self-reported health.

The Pittsburgh Sleep Quality Index and Epworth Sleepiness Scale scores were similar from baseline to post-intervention and were comparable to another sample of older adults with ADRD (Figueiro et al., 2019). PSQI scores of ≥ 5 are typically indicative of moderate or severe sleep difficulties (Buysse et al., 1989), which suggests that overall, participants did experience sleep difficulties. The highest component scores were component 5, which measures sleep disturbances and component 7, which measures daytime dysfunction. NPI-Sleep item scores increased from baseline to post-intervention (See Table 4.23), but this increase was not clinically significant (Aarsland et al., 2007).

Regarding measures of care recipient quality of life, the QOL-AD scores were similar from baseline to post-intervention (See Table 4.23). The scores of the 10 care recipients that reported on the QOL-AD tended to be higher than those reported by their caregivers (Table 4.23). Similar differences in self-reported quality of life by PLWD and their caregivers have been shown in prior research (Moyle et al., 2014).

Measures of caregiver well-being demonstrated that CWBS scores remained the same from baseline to post-intervention, while scores on the total SF-12 Health Survey decreased reflecting a decrease in overall self-reported health (Table 4.23). The Mental Health Component scores (MCS) stayed relatively the same, while the Physical Health Component scores (PCS) decreased reflecting a decrease in self-reported physical health (Table 4.23). Compared to a similar community-based sample, the PCS scores were higher in this study and MCS scores were lower (Farina et al., 2017).

Discussion

Findings support that weighted blankets are a feasible and acceptable non-pharmacologic in-home care strategy as perceived by older adults with ADRD and their family caregivers. Collecting outcomes of care recipient BPSD and quality of life, as well as caregiver well-being and self-reported health by caregiver completed measures was feasible. It was feasible to collect the outcome of cognitive function by interview of participants with ADRD but collecting measures of BPSD and quality of life by care recipient self-report was not. Findings provide information to further refine the development and testing of the virtually delivered weighted blanket intervention for PLWD residing in the community.

Significance of Findings

This study provides preliminary support for 4 key areas that are essential to the development of successful community-based interventions for families affected by ADRD including safety, acceptability, feasibility of the virtual delivery, and feasibility of collecting multiple types of caregiver and care recipient specific outcomes.

Safety

No side effects were reported with the use of the weighted blanket. This is the first study to indicate safety with use of weighted blankets by older adults with ADRD who have historically been excluded from weighted blanket intervention studies (Eron et al., 2020). Safety is an essential component of successful, widely adopted community-based interventions (Gadke et al., 2021), yet safety has proven to be difficult to maintain when managing BPSD, particularly with the use of pharmacologic approaches (Seitz et al., 2013). Alternatively, non-pharmacologic interventions have consistently demonstrated high degrees of safety (Trivedi et al., 2018), which is consistent with the findings of this study. Given the critical need for home-based non-pharmacologic interventions to treat BPSD and the essential role of safety in promoting broader use of these interventions in the community, findings of this study are a promising indication of the potential of weighted blankets for community dwelling PLWD.

High Degree of Intervention Acceptability

Overall high scores of tolerability, participant satisfaction, and benefit with the intervention in this study are meaningful indicators of intervention acceptability. As acceptability is often an underexamined, but key factor in promoting widespread, sustained use of interventions in the community (Gadke et al., 2021; Harris & Titler, 2020), this study’s findings related to acceptability are significant. By involving participants with ADRD and their family caregivers as key stakeholders and by determining acceptability in the preliminary stages of development, this intervention has an increased likelihood of successful implementation and greater capacity to make a meaningful impact in the future in the lives of families affected by ADRD (Gitlin et al., 2020; Qiu et al., 2019). These findings are a steppingstone in the development of an intervention that has the potential to be well tolerated, satisfying, and beneficial to families affected by ADRD living in the community.

Feasibility of Virtual Delivery of the Intervention

Feasibility of the virtual delivery of the weighted blanket intervention was demonstrated by high degrees of satisfaction with the web-based delivery and the intervention overall. These findings are significant as there is a critical need for virtually delivered home-based interventions even before the COVID-19 pandemic began (Hopwood et al., 2018), but in many ways pandemic related public health restrictions heightened this need (Aledeh & Adam, 2020).

Key barriers to use of virtual interventions by this population include increased complexity in accessing virtual study resources and lack of tailoring interventions to the unique needs of participants (Hopwood et al., 2018). This study addressed these barriers by using a widely adopted, user friendly virtual conferencing system (Zoom) to interact with study participants. For those that did not have reliable internet access, all virtual components (e.g., consent, data collection, review of study materials) could be completed by accessing Zoom by telephone. Having the option to participate using the internet or by telephone is significant when considering more widespread intervention adoption, as nearly 1/3 of Medicare beneficiaries report not having reliable digital access at home (Reyes et al., 2020). Tailoring the intervention to the needs of participants was prioritized in this study by offering multiple avenues to interact and participate in the study, by providing blankets of different weights based on participant body weight, and by encouraging personalized daily use of the blanket based on individual preferences and circumstances. The design of this intervention and study components addressed primary barriers to online-intervention success (Hopwood et al., 2018), which likely bolstered the feasibility of the virtual delivery.

Feasibility of Collecting Multiple Outcomes

To promote broader use by individuals, families, and clinicians, it will be necessary to determine the effects of weighted blankets on outcomes of importance to families affected by ADRD, such as BPSD. Although this study did not examine efficacy, it does provide valuable information that can be used to inform measurement selection in future weighted blanket intervention randomized clinical trials. Despite limitations in collecting outcomes by care recipient self-report, findings of this study demonstrate that multiple types of outcomes can be collected with minimal missing data, including care recipient and caregiver specific outcomes. These outcomes can be included in future community based, non-pharmacologic intervention ADRD research to measure key concepts of cognitive impairment, BPSD, and well-being of PLWD and their caregivers.

Limitations

There are 4 major limitations of this study. First, the sample lacked diversity in race and ethnicity, socioeconomic status, and educational level thereby limiting the generalizability regarding feasibility and acceptability of the weighted blanket in more diverse populations. Recruitment strategies relied on organizations that offer support to families affected by ADRD, which likely excluded those who have limited access, knowledge, or do not regularly use these services. People from disadvantaged socioeconomic backgrounds have historically had limited access to and knowledge of support services, which could have resulted in the lack of variation in sociodemographic characteristics of this study's sample (Cooper et al., 2010). There is a need to examine the feasibility of use of weighted blankets in more diverse populations in terms of socioeconomic and demographic contexts. Alternative recruitment strategies to target those with limited access to support services will need to be prioritized, such as through programs offered in disadvantaged communities, spiritual communities that offer services for older adults, and rural outreach programs.

Second, outcomes completed by self-report of the care recipient had significant amounts of incomplete data. Although the high degree of missing data limits the interpretation of the scored measures, this limitation does highlight an important area for future research in terms of developing and refining measurement tools that can be completed by people with varying degrees of cognitive impairment (further described below, see Implications for Future Research).

Third, self-reported measures inherently have a risk of response bias and satisfaction surveys have demonstrated a risk of participants being more inclined to provide socially acceptability answers (Mazor et al., 2002). In attempt to mitigate this risk, clear directions were embedded in the Weighted Blanket Intervention Acceptability Tools advising participants to provide honest answers, but it is possible that participants provided more positive ratings than what they actually perceived.

Fourth, the Weighted Blanket Daily Use Diary was developed to collect information regarding daily use of the blankets by participants with ADRD based on caregivers' observations. These diaries may not be an accurate indicator of actual blanket use, especially for dyads that were not bed partners, or for those that did not spend as much time in the same physical space throughout the day. In these cases, PLWD could have used the blanket more or less than their caregivers observed.

Implications for Future Research

Findings of this study carry implications for future research focused on weighted blankets for PLWD, as well as other populations. Areas that hold promise for future research include studies focused on: safety of use of weighted blankets by people with respiratory conditions and those living in warm climates; refining of measurement tools completed by self-report by PLWD; pilot testing this study's intervention to inform a larger randomized controlled trial (RCT) to determine efficacy; cost benefit of weighted blankets; use of other types of deep pressure stimulation tools such as compression garments and deep pressure massage tools by PLWD; the use of weighted blankets by people with other stress related conditions.

Safety Considerations for Future Research

Although safety was demonstrated in this study, there are other important areas regarding safety to consider in future research focused on this population. These considerations include the use of weighted blankets by individuals with respiratory conditions and by those that live in warmer climates. As little is known about the safety of weighted blankets for people with respiratory conditions (Parker, 2016), the exclusion criteria for this study were comorbidities like sleep apnea, asthma, and COPD. Sleep apnea was the primary reason participants were excluded from participation. To promote broader use of weighted blankets by PLWD, additional research is needed to better understand the relationship between use of weighted blankets and respiratory function to determine if this exclusion criteria is necessary. This is critical, as PLWD with sleep apnea often experience more severe sleep disturbances and likely have an even greater need for simple care strategies to improve sleep at home (Benca & Teodorescu, 2019)

In terms of climate, a few participants that lived in warmer climates expressed that excessive warmth was a barrier to use of the weighted blanket. Older adults with ADRD are typically less able to adapt to temperature changes and maintain body temperature, particularly when living in environments with high degrees of temperature variability (Wei et al., 2019). The weighted blanket may potentiate difficulties in maintaining body temperature for those living in warmer climates, which poses a potential safety concern. Additional research is needed to examine differences in feasibility and acceptability based on climate and to determine the safety of weighted blankets by PLWD in very warm climates

Refining of Measurement Tools Completed by Self-Report by PLWD

Given the limited feasibility of collecting measures completed by self-report by PLWD, research is needed that addresses development of new and/or refining current measures. Modifications may include limiting the number of items, modifying response options to simpler dichotomous responses, and field testing to ensure items and responses are appropriate for a broad range of people with cognitive impairment (Clarke et al., 2020). Measures of "in the moment" feelings may be needed as PLWD are often less able to reflect on past experiences (Clarke et al., 2020). For this intervention specifically, the Weighted Blanket Daily Use Diary presents an option to capture "in the moment" experiences with the weighted blanket, as it is completed each day rather than at the end of the study period. As an example, an item could be added that asks caregivers to ask their relative with ADRD how they are feeling while they are using the blanket. Responses to this item would provide some indication of their relative's feelings towards the blanket throughout the study period. Modifications are also needed for the care recipient version of the Weighted Blanket Intervention Acceptability Tool to improve completion rates, which may include limiting the number of items and modifying response items that have 3 response choices to simpler dichotomous responses.

Pilot Study

Study findings will be used to further refine the development of the virtually delivered weighted blanket intervention and to inform a future pilot study. A critical next step is to calculate an effect size, which will be used to determine the sample size needed for a

RCT to determine the efficacy of the weighted blanket intervention on BPSD outcomes. (Bothwell et al., 2018). The future pilot study will be designed to determine an effect size by having an intervention and a control group to compare the mean differences in BPSD from pre to post intervention. The effect size will then be used in a power analysis to determine the number of participants needed in the RCT.

An important outcome that was not included in this study was stress. A future pilot study will need to include an outcome of stress to provide information to further inform measurement selection for the RCT. As collection of measures completed by self-report by PLWD is less feasible, a biomarker to measure stress is preferred. Collection of blood and salivary cortisol (a biomarker of stress) has demonstrated to be feasible in PLWD living in the community and present as potential measures of stress for the pilot study (Ng et al., 2020). By collecting a measure of stress, the pilot study and following RCT will be able to explore the relationships between weighted blankets, stress, and BPSD.

As no prior research has examined the optimal amount of use of weighted blankets needed to yield therapeutic effects (Eron et al., 2020), another important next step for this research is to determine the optimal dose, or amount of weighted blanket use needed to demonstrate an effect on BPSD. An adaptive study design would be useful in determining optimal dose, which allows for the comparison of intervention components through adaptation of those components throughout the intervention period (Bothwell et al., 2018). In this case, the component being modified could be the dose. Another potentially modifiable component of the intervention could be daytime vs. nighttime use. By comparing intervention components, the dose finding study will be able to determine the minimum amount of use of the weighted blanket and optimal time of day to demonstrate meaningful effects on BPSD.

Cost Benefit of Weighted Blankets

Cost is another important area for future research, as weighted blankets range in price from $50-$150. This may be a barrier to use for some families, which caregivers identified as a potential concern in this study. Weighted blankets are covered as a medical device by some private insurance for some populations, but currently they are not covered for PLWD. There is a need to explore the cost-benefit of weighted blankets for PLWD in future research and efficacy will need to be determined to convince insurers that these are cost efficient tools that effectively improve health outcomes.

Other Types of Deep Pressure Stimulation Tools

Other types of deep pressure stimulation tools include weighted and compression garments, weighted lap pads, deep pressure massage tools, and therapy dogs trained to provide deep pressure stimulation (Davis et al., 2013; Duvall et al., 2016; Lloyd et al., 2019). Very little is known about the use of these tools by older adults with ADRD. Although this study demonstrated the feasibility of daily use of weighted blankets, weighted and compression garments may be preferred as they can be worn throughout the day even during times of physical activity. While additional research is warranted that focuses on use of weighted blankets in this population, studies focused on other types of deep pressure stimulation are also promising areas to explore to identify the most feasible option for delivering deep pressure stimulation therapy in the home setting.

Weighted Blanket Research Focused on Other Populations

This study can inform weighted blanket research focused on other populations (Eron et al., 2020). Prior weighted blanket research has focused primarily on physiologic safety outcomes and therapeutic effects (Becklund et al., 2021; Ekholm et al., 2020). To increase the likelihood of implementing weighted blankets in other populations, it is critical to examine outcomes beyond effectiveness such as feasibility and acceptability. This study provides specific tools to examine acceptability of weighted blankets that can be modified and used to inform weighted blanket studies focused on other populations. Populations that may benefit most are those with other stress-related conditions, such as individuals with post-traumatic stress disorder, anxiety, and insomnia (Crowley & Kirschner, 2015).

Implications for Practice

Weighted blankets are a care strategy already being used in some clinical settings, yet there is limited research to support them. This has likely been a factor leading to the lack of standardization for use of weighted blankets in practice. Safety standards are important to clinical practice, yet no formal technical standards have been published regarding use of weighted blankets among PLWD. The safety recommendations used in this study are based on available research and experiential reports. They may be helpful in guiding policies focused on use of weighted blankets in settings that already use them; however, determinations of efficacy are needed prior to making recommendations for widespread use in practice for PLWD.

Implications for Families Affected by ADRD

For those living with ADRD and their caregivers, findings from this small study suggest that weighted blankets can be a satisfying and beneficial tool to use in the home. They are feasible, well tolerated, and they can be used daily even during times of disruption and challenging circumstances. Participants with ADRD described feelings of comfort and warmth, while caregivers described how it helped their relatives with relaxation and sleep. Although additional research is needed to determine the effects of weighted blankets on BPSD, this study supports that weighted blankets at the very least are a promising “tool for the toolkit” of comfort and relaxation promotion. During stress-inducing times such as the pandemic, having in-home care strategies to promote comfort is necessary, especially for older adults with ADRD and their caregivers who needed such strategies even before the pandemic began.

Conclusion

This study found use of weighted blankets to be a feasible and acceptable in-home, non-pharmacologic care strategy for PLWD residing with their family caregivers. The virtual delivery of the intervention was feasible, as well as the collection of care recipient and caregiver specific outcome measures completed by caregivers; however, collection of measures completed by care recipient self-report was not. Key findings will inform future research focused on use of weighted blankets for managing BPSD experienced by PLWD living in the community with family caregivers. As PLWD and their families are in desperate need of simple, in-home care strategies, weighted blankets are a potential intervention to promote comfort in their daily lives.

CHAPTER V

Synthesis and Conclusions

The purpose of this three-paper dissertation was to explore the use of non-pharmacologic care strategies, specifically acutherapy and use of weighted blankets as potential interventions for treating behavioral and psychological symptoms of dementia (BPSD) experienced by people living with dementia (PLWD). This research informs future research about non-pharmacological interventions to address BPSD for those with Alzheimer's disease or related dementias (ADRD) and to improve care for those living with ADRD and their families residing in the community.

This research was carried out in three phases. The first phase (Chapter 2) identified, examined, and synthesized the state of the science relating to acutherapy and its effects on BPSD using a scoping review methodology.

The second phase (Chapter 3) explored the perspectives of family caregivers (n=21) living with older adults with ADRD regarding their experiences as caregivers, BPSD experienced by their relatives with ADRD, and their experiences with non-pharmacologic interventions for BPSD management (Aim 2). Changes in family caregivers' experiences, BPSD, and BPSD management during the COVID-19 pandemic were also explored (Aim 3).

The third phase comprised three components (Chapter 4). First, family caregivers' initial perceptions regarding use of weighted blankets as an in-home care strategy for PLWD were explored (Aim 4).

A prospective study was then conducted to examine the feasibility and acceptability of a virtually delivered in-home weighted blanket intervention for older adults with ADRD living in the community (n=20) (Aim 5). This study also examined the feasibility of collecting outcome measures of BPSD, cognitive function, and quality of life of care recipients with ADRD, and well-being and self-reported health of family caregivers (Aim 6).

The purpose of this chapter is to summarize and synthesize major findings across all 3 papers of this dissertation. Findings across papers are synthesized and integrated with the *Conceptual Framework of Sensory Stimulation Therapies for Reducing Behavioral and Psychological Symptoms of Dementia* presented in Chapter 1 (See Figure 1.1, p. 6). Significance of the findings is described followed by the strengths and limitations of the dissertation studies. Directions for future research are then presented.

Summary of Major Research Findings

This dissertation research has six key findings: 1) Acutherapy is a safe non-pharmacologic care strategy for PLWD and a potential treatment option for BPSD, but additional research is needed to determine efficacy; 2) The caregiving experience of family caregivers of community dwelling PLWD is perceived as an interdependent partnership between the caregiver and the relative with ADRD; 3) Family caregivers and PLWD experience challenges to in-home care prior to the COVID-19 pandemic, many of which were compounded by it; 4) The virtually delivered in-home weighted blanket intervention for community dwelling PLWD is feasible and acceptable to care recipients with ADRD and their family caregivers; 5) Collecting outcome measures of care recipient cognitive function, as well as caregiver well-being and self-reported health is feasible; 6) Collecting outcomes measures of care recipient BPSD and quality of life is feasible through measures completed by caregivers, but not by care recipient self-report.

In many ways these key findings are congruent with prior research, including findings relating to interdependence (Kershaw et al., 2015; Streck et al., 2020), the safety of non-pharmacologic interventions (Kales et al., 2015), the challenges to in-home care for families affected by ADRD (Lee et al., 2019), the feasibility of collecting several care recipient and caregiver specific outcome measures (Ayton et al., 2020), and the limitations of collecting measures by self-report by PLWD (Perfect et al., 2021). Findings expand the state of the science in this area by deepening the understanding of the experiences of family caregivers during the COVID-19 pandemic, by highlighting 2 interventions that have been underexamined in past research focused on this population (acutherapy and weighted blankets), and by identifying multiple areas that show promise for future research on improving symptom management for families affected by ADRD living in the community. Overall, findings add considerably to the conceptual framework guiding this research by further substantiating some concepts and relationships in the model, while also indicating major gaps in this area of science.

Integration of Findings Through Conceptual Framework

Multiple concepts and relationships proposed in the conceptual framework were explored in this dissertation. Findings related to key concepts and relationships are integrated below followed by modifications made to the framework based on the findings. Modifications are illustrated in Figure 5.1 and described in Table 5.1 at the end of the narrative.

Concept of Non-Pharmacologic Interventions

Each phase of this dissertation research detailed non-pharmacologic care strategies that may benefit PLWD. Acupressure and acupuncture are feasible therapies for PLWD with varying degrees of cognitive impairment and have had positive effects on BPSD but their efficacy for reducing BPSD is not confirmed. Additionally, findings do not fully support the feasibility of acutherapy delivered in the community, or home delivered acutherapy.

Caregivers of those with dementia identified a number of in-home care strategies beneficial for the dyad (e.g., the use of humor, caregivers managing the environment and their own behaviors and reactions, pets and dementia service dogs, maintaining a daily routine), the caregiver (e.g., meditation, tai chi, yoga, mindfulness, reading, journaling), and the PLWD (e.g., CBD oil, reading, blogging, music, designated alone times). Of these interventions, only 2 are substantiated by prior research to effectively reduce BPSD experienced by community dwelling PLWD. Music has demonstrated a moderate effect on BPSD of PLWD in the community (Ueda et al., 2013). Interventions designed to improve caregivers' ability to manage the environment and their own behaviors and responses have demonstrated significant effects on BPSD and caregiver distress (Brodaty & Arasaratnam, 2012).

Feasibility of some of the other care strategies described by caregivers (e.g., animal assisted therapies, CBD oil, tai chi, mindfulness, meditation) have been explored in prior research. Overall, the quality of the evidence is low and there are not enough high-quality studies to determine efficacy of nonpharmacological interventions for reducing BPSD (Park et al., 2020; Tampi et al., 2018; Trivedi et al., 2018).

The findings of the weighted blanket study support the potential of weighted blankets as an in-home care strategy for community dwelling PLWD by demonstrating feasibility and acceptability. This study did not examine efficacy for reducing BPSD or improving any other outcomes, but 4 of 6 measures of BPSD did show improvements from baseline to post-intervention which are promising results.

Together, findings across this dissertation research demonstrate potential benefits that non-pharmacologic interventions can have for PLWD and their family caregivers, while some interventions have also shown promising effects on BPSD specifically. But overall, there is limited knowledge pertaining to their efficacy for reducing BPSD, as well as the feasibility of their use among PLWD in the community.

Concept of BPSD

This research has important findings relating to the concept of BPSD. Cumulatively the findings show that BPSD are highly prevalent, but severity varies among those with ADRD living in the community. Findings collectively demonstrate that although caregivers describe many of the same symptoms and behaviors that researchers and clinicians would term BPSD, they do not use the terms “behaviors” or “symptoms”. Instead, family caregivers described their relatives’ experiences in terms of their emotions, feelings, and psychological responses. They also described other prominent feelings their relatives experienced that are not included in the cluster of BPSD including feelings of isolation, loneliness, and a sense of purpose. Experiences and responses of PLWD were intertwined with the experiences of their caregivers, in this way their “symptom management” strategies were dependent on both members of the dyad, or the partnership. The findings support that many of the emotional and psychological experiences and responses of PLWD can be challenging and strategies currently used in the home do not adequately address the needs of PLWD and their families.

Relationships Between Sensory Stimulation Therapies, Stress, and BPSD

Although stress reduction is a hypothesized mechanism of action for non-pharmacologic interventions and sensory stimulation therapies more specifically for influencing BPSD (Chen et al., 2016; Mullen et al., 2008; Reynolds et al., 2015), there is limited exploration of the relationships between these interventions, stress, and BPSD. Although stress is an important concept in theoretical and conceptual frameworks relating to BPSD, it has been under examined as an outcome measure in community based ADRD intervention research.

Concepts of Caregiver Well-Being, Care Recipient Well-Being, and the Relationship Between Them

Findings support that family caregivers play a pivotal role in providing care for PLWD (Brodaty & Donkin, 2009; Huang et al., 2015). In this study, however, caregivers describe the caring process as a partnership involving interactions between the experiences and responses of both members of the dyad. Their experiences as caregivers were deeply rooted in those of their relatives with ADRD. These findings are congruent with theories of interdependence commonly used in caregiving research (Bom et al., 2018; Graham & Bassett, 2006; Kershaw et al., 2015; Norton et al., 2009). Interdependence supports that a dynamic, interactive relationship exists between caregivers and PLWD and that the health and well-being of one member of the dyad influences the other (Harris, Titler, & Hoffman, 2020; Stall et al., 2019).

The dyadic, partnership experience was prevalent throughout caregivers’ stories in how they managed the disease at home. It was also evident in the weighted blanket study by collaborative efforts of caregivers with the care recipient throughout the intervention period to use the blanket and to engage in the study. Their engagement exemplified the dyadic process of caring that occurs between caregivers and PLWD.

Concept of Internal Factors

Given the lack of variation in sociodemographic characteristics of study samples, this dissertation does not provide insight into the experiences of the broader population of PLWD and their caregivers. For these reasons, findings do not clarify how varying internal factors such as demographic characteristics (e.g., race, ethnicity, marital status, education level) relate to other concepts in the framework. The lack of understanding of how these internal factors influence outcomes is congruent with prior community based ADRD research, which has historically underrepresented those from diverse racial and ethnic backgrounds and those who have been stigmatized due to disease (Babulal et al., 2019; Brewster et al., 2019).

Concept of External Factors

Similar to restrictions in findings related to internal factors, the lack of variation in the study samples limit the findings related to external factors. Specifically related to the scoping review of acutherapy, the homogeneity of the study characteristics (i.e., most studies were conducted in China and most in long-term care settings) limits the understanding of how contextual circumstances such as setting and location may influence the delivery of acutherapy to PLWD and their response to it. Most caregivers in the studies presented in paper 2 (Chapter 3) and paper 3 (Chapter 4) were related to their relatives with ADRD by marriage, which is not representative of the broader population of community dwelling PLWD and their family caregivers (Alzheimer's Association, 2021). This limits the understanding of how the external factor of social relationships may differentially impact the experiences of PLWD and their family caregivers. Caregiver participants in these studies (papers 2 and 3) were also restricted to those that were family members living with their relatives with ADRD, which limits the understanding of how care provided by caregivers outside the home influences BPSD.

Contextual Circumstance of the COVID-19 Pandemic as an External Factor

The COVID-19 pandemic presents as a unique, historical global contextual circumstance that represents an external factor influencing multiple aspects of life of PLWD and their family caregivers. Findings of this dissertation show that the COVID-19 pandemic that began in the Spring of 2020 has compounded feelings of loss and decreased socialization of family caregivers, which has intensified in-home care challenges for PLWD and their families. Cumulatively, findings suggest that PLWD and their family caregivers living in the community desperately needed in-home care strategies to manage BPSD and promote well-being prior to the pandemic, but the pandemic exaggerated those needs and created new barriers to in-home care. Findings provide a preliminary understanding of the contextual circumstance of the COVID-19 pandemic and its influence on the lives of PLWD and their families.

Relationships Between Internal and External Factors and Other Concepts in the Framework

Findings support that the internal and external factors of PLWD likely influence other concepts in the model besides just the stress process. Some examples identified through this research are listed below:

- Caregivers described how their relatives' cognition varied from day to day and was often dependent on their physical health (an external factor)
- Caregivers identified contextual circumstances (external factors such as busy schedules, holiday celebrations, pandemic restrictions) that made using non-pharmacologic care strategies challenging and sometimes inhibited their use.
- Internal factors also influenced use of the weighted blanket specifically, such as temperature regulation and fabric preference
- The COVID-19 pandemic (a contextual, external factor) influenced many aspects of life of PLWD and their families (e.g., physical health, social well-being, functional abilities)

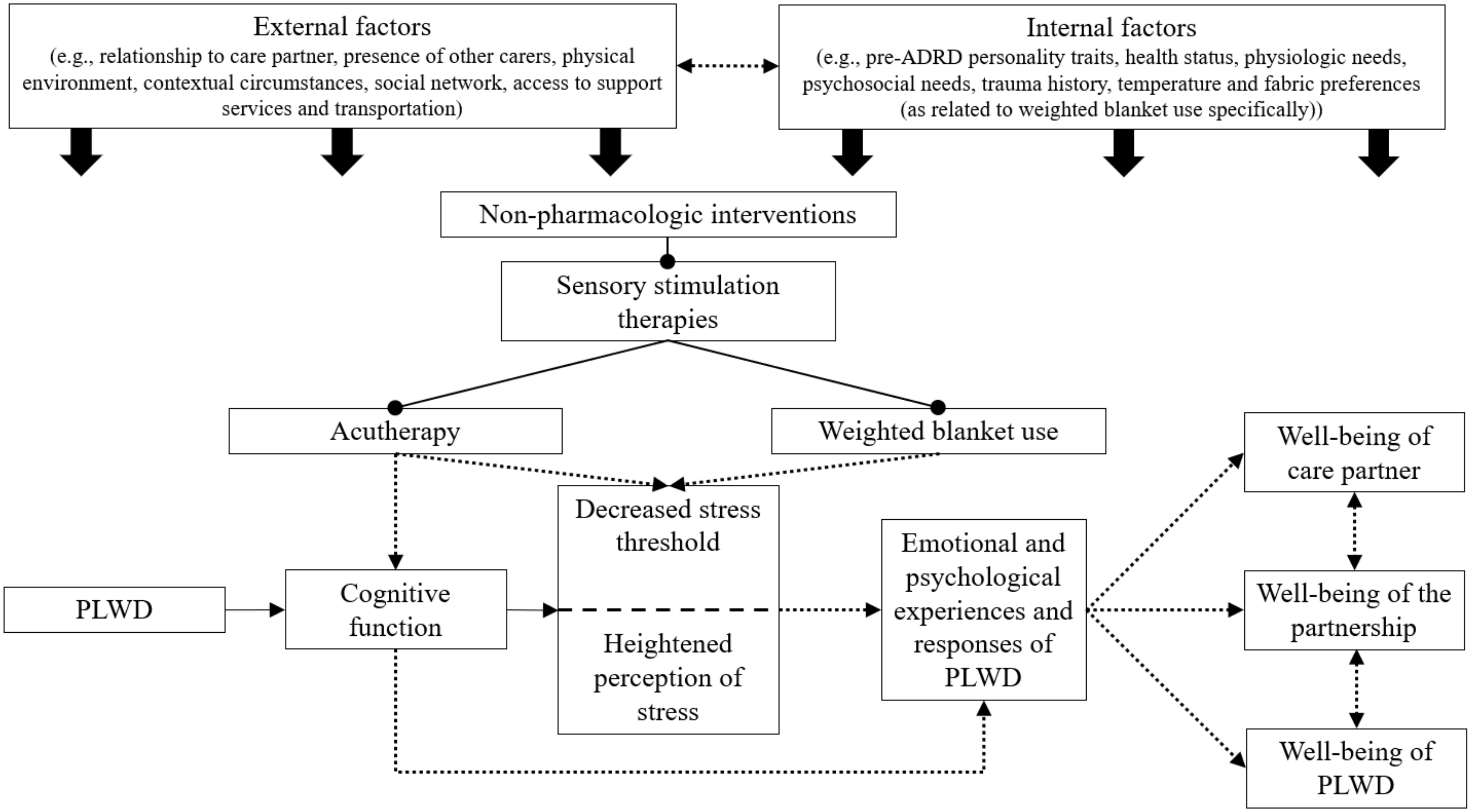
These examples suggest that internal and external factors are not only related to the stress process of PLWD as depicted in the original framework in Chapter 1 (See Figure 1.1, p. 6), but more broadly influence many if not all the concepts in the framework. The concepts of internal and external factors in the original framework were modified from the need-driven dementia-compromised behavior model, which is linear in nature (Algase et al., 1996). The stress process model by Judge, Menne, and Whitlatch (2009) relates internal and external factors to the stress process, as well as to other concepts including outcomes of well-being of PLWD, which is more aligned with findings of this research.

Modifications Made to Framework Based on Findings

Based on the findings, modifications and additions were made to the conceptual framework as illustrated in the updated framework in Figure 5.1. Relationships between concepts shown with dotted lines represent hypothesized relationships between concepts that may be areas to explicate through future research. Table 5.1 includes modifications made and the rationale for making each change.

Figure 5.1

Conceptual Framework of Sensory Stimulation Therapies for Improving Emotional and Psychological Experiences and Responses of People Living with Dementia



Model Key

———●	Non-pharmacologic interventions for PLWD specified to acutherapy and weighted blanket use
··········▶	Hypothesized mechanism of action of how sensory stimulation therapies (e.g., acutherapy, weighted blanket use) may improve EPER of PLWD
———▶	Process of how ADRD may affect EPER of PLWD
– – – – – – –	Dynamic, progressive interaction between the decreased stress threshold and heightened perception of stress in PLWD which decreases the person's ability to cope with stress

Note. ADRD Alzheimer's disease and other related dementias, EPER Emotional and psychological experiences and responses, PLWD person living with dementia

Table 5.1
Modifications Made to Conceptual Framework Based on Dissertation Research Findings

Addition or Modification	Rationale
Concept of **BPSD** changed to **Emotional and Psychological Experiences and Responses of PLWD (EPER)**	To more accurately depict the broad experiences of PLWD described by family caregivers. BPSD is still encompassed in this concept, but EPER can also include other emotions felt by PLWD such as feelings of isolation, loneliness, and a sense of purpose, which were described by caregivers in this research and prior research (Balouch et al., 2019).
Concept of **Caregiver well-being** changed to **Well-being of care partner**	For multiple caregivers, the term "caregiver" did not reflect their experience in caring, as it did not capture the significance of the partnership. The term "care partner" is being increasingly used in research and practice to more accurately depict the partnership experience described by those caring for people with ADRD (Zhou et al., 2020).
Concept of **Care recipient well-being** changed to **Well-being of PLWD**	To capture the significance of the partnership and depict the active role PLWD play in the caring process, as described by their care partners in this research. This terminology also takes a strengths-based approach by recognizing the abilities of PLWD, not just their disabilities or impairments and highlights the importance of living well even with ADRD (McGovern, 2015).
Added concept of **Well-being of partnership**	The prior model did include a bidirectional arrow between care recipient well-being and caregiver well-being with a note regarding the interactive, dynamic relationship between them. But care partners in this research highlighted the importance of the partnership and the well-being of the dyad as a whole and brought the well-being of the partnership to the forefront. For this reason, the bidirectional arrows are still in the framework to connect well-being of PLWD and care partners, but the well-being of the partnership is emphasized as a unique concept.
Internal and **External factors** moved, and arrows added to hypothesize relationships to other concepts in the framework	These modifications were made based on the stress model by Judge et al. (2009), and the many examples described by care partners in this research relating to how internal and external factors influenced other concepts in the model including cognitive function, non-pharmacologic intervention use, EPER, and well-being. Internal and external factors were moved to the top and a bidirectional arrow was added to represent that it is hypothesized that these factors interact with one another, while the bold black arrows represent that these factors are hypothesized to influence other concepts in the framework. Examples of potentially relevant factors are included in the framework.
Concept of **Decreased ability to cope with stress** removed	This concept is redundant to the concept before that includes the decreased stress threshold, heightened perception of stress, and the dashed line. The dashed line, as indicated in the model key, illustrates the dynamic, progressive interaction between the decreased stress threshold and heightened perception of stress in PLWD that decreases the person's overall ability to cope with stress. For the sake of parsimony, this concept was removed.
Title changed to *Conceptual Framework of Sensory Stimulation Therapies for Improving Emotional and Psychological Experiences and Responses of People Living with Dementia*	As BPSD was changed to EPER the title was changed to include the broader concept. Using terms "improving" instead of "reducing" takes a strengths-based approach that prioritizes the potential for living well even with ADRD (McGovern, 2015).

Gaps Identified Through this Research

Through the findings of this dissertation and integration with the conceptual framework, key gaps in research have been identified. These gaps are listed below:

- There are discrepancies in how researchers, clinicians, PLWD and their families communicate about emotional and psychological experiences of PLWD and their responses. This gap in common terminology was also identified as a major gap in community based ADRD research through a systematic review by Trivedi et al, (2018).

- Few high-quality studies have examined efficacy of non-pharmacologic interventions for improving emotional and psychological experiences and responses (EPER) of PLWD residing in the community, including limited studies focused on sensory stimulation therapies and care strategies that families report already using in the home (e.g., service dogs and animal assisted therapies, CBD oil, tai chi, mindfulness, meditation).
- Very few studies have examined stress related outcomes in sensory stimulation intervention studies focused on PLWD, thus limiting support for the hypothesized relationships between these interventions, stress, and EPER in the conceptual framework.
- There are limitations in measurement of BPSD and well-being by care recipient self-report that decreases the feasibility of available measures.
- How varying internal (e.g., sociodemographic characteristics, pre-ADRD personality traits, personal care preferences) and external factors (e.g., the pandemic restrictions, access to services, social network, relationship to caregivers) influence concepts such as EPER and non-pharmacologic intervention use among PLWD residing in the home is not fully understood.
- There is limited understanding of the pandemic’s effects on PLWD and their families from diverse sociodemographic backgrounds.

In addition to gaps in this area of research, a couple of key gaps in care for community dwelling PLWD and their families were also identified. First, care partners described challenges to in-home care prior to the pandemic, many of which were compounded by it due to the limited availability of helpful in-home care strategies during the pandemic. Their experiences with and feelings towards virtual resources during the pandemic were mixed. Not all families transitioned well to virtual support groups, educational programs, and activities. Second, many care partners described challenges they and their relatives with ADRD faced in obtaining ADRD diagnoses from providers, as well as accessing support services after diagnosis. These findings further substantiate significant gaps in coordination of care for older adults with cognitive decline and their families, which have been identified as critical areas that need to be addressed to tackle the challenges of caring for PLWD (National Academies of Sciences, Engineering and Medicine, 2021).

Significance

The findings of this dissertation add to the knowledge base pertaining to non-pharmacologic interventions and their use by PLWD residing in the community in several ways. This research was among the first to explore family caregivers' experiences with symptom management for PLWD and in-home care strategies used during the COVID-19 pandemic. Findings relating to their in-home care needs are highly relevant as the pandemic is likely to remain a contextual factor influencing the lives of PLWD and their families for the foreseeable future. In addition, the pandemic is anticipated to have long-term effects on those with neurological conditions (Aggarwal et al., 2020).

There has historically been limited use of conceptual and theoretical frameworks to guide the development of non-pharmacologic interventions for PLWD residing in the community, which could be a factor in their limited efficacy in improving BPSD outcomes (Kolanowsk et al., 2005). This dissertation was guided by a conceptual framework developed from prior research and theoretical models, and was subsequently modified based on findings from the three unique studies. Although research is needed to further substantiate concepts and relationships, future intervention studies can maximize their potential to demonstrate meaningful effects on outcomes of importance to PLWD and their families (e.g., EPER, well-being) by using this framework as a guide. This is significant as care partners identified an overwhelming need for feasible and effective in-home care strategies even before the pandemic began.

This research also provides preliminary support for 2 sensory stimulation therapies for PLWD, including acutherapy and weighted blankets. The high degree of safety demonstrated across acutherapy studies and the variations in cognitive impairment severity across samples demonstrates that these are safe and feasible therapy options for PLWD with potential to decrease BPSD. This dissertation was the first to explore the feasibility and acceptability of weighted blankets by PLWD, who have historically been excluded from weighted blanket intervention studies (Eron et al., 2020). Although this study did not examine the efficacy of weighted blankets for BPSD, it does provide preliminary data regarding feasibility and acceptability of a virtually delivered weighted blanket intervention, and the feasibility of collecting caregiver and care recipient specific outcomes. This information can inform futures efficacy studies focused on weighted blankets and emotional and psychological experiences and responses (EPER) of

PLWD. Overall, findings demonstrate sensory stimulation therapies, including acutherapy and weighted blankets are promising options for PLWD and offer multiple directions for future research.

Strengths and Limitations

This research aimed to address key gaps in this area of research including the lack of review and synthesis of acutherapy studies on BPSD outcomes; the limited research on family caregiver experiences with BPSD and BPSD management, particularly during the COVID-19 pandemic; and the paucity of studies exploring intervention acceptability in non-pharmacologic interventions focused on PLWD in the community. The strengths of phase 1 of this research (Chapter 2) included the use of a systematized database search of 5 databases, and the use of a search strategy that included multiple keywords, controlled vocabulary and MeSH terms that was developed with support from library informationalists focused on healthcare research.

The strengths of phase 2 (Chapter 3) included multiple steps to maintain rigor of the qualitative analysis, most significant being the use of a 3-member coding team. This study also used a semi-structured interview guide that was fielded to 3 caregivers of PLWD and edited based on their recommendations prior to being finalized. This ensured that each question was relevant, clear, and distinct; that the guide flowed well and was cohesive; and that areas of importance to caregivers were addressed throughout the interview.

The strengths of phase 3 (Chapter 4) included the use of multiple outcome measures that have been validated and determined to be reliable for use in community dwelling PLWD or caregivers. This study also used the Weighted Blanket Intervention Acceptability Tool to examine intervention satisfaction and benefit, which was modified from a tool with established validity and reliability (Northouse et al., 2002; Titler et al., 2020). This study also followed a standardized intervention protocol; used recruitment and intervention materials that were vetted by family caregivers; provided the weighted blankets for all participants in the study; set benchmarks a priori to determine feasibility.

The results of this dissertation should be considered within the context of several limitations. First, the database search conducted in phase 1 (Chapter 2) only included studies published in English. Relevant applicable studies may not have been identified given these exclusions, since the majority of included studies were conducted in China (n=11/15) and acutherapy is based in Traditional Chinese Medicine.

A potential shortfall in the design of the phase 2 (Chapter 3) was the eligibility criteria that required family caregivers to live with their relative with ADRD. This criterion may have disproportionately excluded children caring for parents with ADRD as suggested by the majority of caregivers in this study being related to their relatives with ADRD by marriage (n=17). This is not congruent with the broad population of family caregivers of PLWD in the U.S., as over half are children caring for parents (Alzheimer's Association, 2021). Second, the recruitment strategies relied on reaching potential participants through organizations that provide ADRD support services. This likely limited the reach to families that do not have access to, or knowledge of services, or who do not regularly use them. This may have led to the underrepresentation of individuals from diverse socioeconomic backgrounds who historically have had limited access to and use of ADRD support services (Cooper et al., 2010). These limitations in eligibility criteria and recruitment were also relevant to phase 3 (Chapter 4). Together, these limitations raise questions regarding external validity of the studies and limit the generalizability of findings.

Other limitations of the weighted blanket study relate to the high degree of missing data on self-reported measures by PLWD, the risk of response bias on self-reported measures of satisfaction and benefit, and the potential of the Weighted Blanket Use Diary not being a completely accurate indicator of actual blanket use. Although these limitations are relevant to this study, they are promising potential areas for future research in terms of measurement development.

Directions for Future Research

Findings of this research and the gaps identified through the integration of findings lead to several directions for future research that are described below.

Explore the Concept of Well-Being of the Partnership and Examine its Relationship to the Well-Being of PLWD and Their Care Partners

Research supports an interdependent relationship exists between the well-being of care partners and PLWD (Harris, Titler, & Hoffman, 2020; Bom et al., 2019; Kershaw et al., 2019; Graham & Bassett, 2006; Norton et al., 2009; Stall et al., 2019). There is less research focused on the well-being of the partnership as a holistic unit, which is a distinct concept identified through this research. It is possible that the well-being of the partnership is significant to spousal dyads but less relevant to dyads that are not partnered or married. A recent cross-sectional study of a large, more diverse sample (N=1283) of ADRD caring dyads demonstrated the quality of the relationship influences the well-being of both members (Rippon et al., 2020), which suggests that the well-being of the partnership is applicable to a broad range of dyads. However, findings of the study by Rippon et al., (2020) and this dissertation research support that additional research is needed to explore the experiences of other familial dyads to further substantiate the well-being of the partnership as a distinct concept.

Prior research supports that among caring dyads there are important factors that influence the well-being of both members of the dyad individually, and the dyad as a unit (Miller et al., 2019). Some of these factors include relationship closeness, degree of conflict or strain, and relationship quality (Quinn et al., 2009), yet few studies have included these measures in prior community based ADRD research. Examination of these factors is needed to better understand the concept of well-being of the partnership and the influence on other outcomes including well-being of PLWD and their care partners. Outcome measures specific to the well-being of the partnership need to be included in future non-pharmacologic intervention research to further substantiate hypothesized relationships in the conceptual framework.

Examine Other Outcomes to Operationalize the Concept of EPER

To substantiate the concept of emotional and psychological experiences and responses (EPER) of PLWD, other outcomes besides BPSD need to be examined in future non-pharmacologic intervention research. Outcomes may include feelings of connectedness, engagement, and sense of purpose of PLWD. Valid and reliable measures exist for these outcomes, which have been developed for this population of PLWD specifically or have been psychometrically tested among PLWD (Cohen-Mansfield et al., 2017; Lara et al., 2019; Poey et al., 2017). The selection of outcomes will be dependent on the mechanism by which the intervention is hypothesized to influence EPER. For example, if an intervention is focused on improving relationship quality, connectedness may be a more appropriate outcome to operationalize EPER. If the intervention is designed to improve sleep, a measure of BPSD is likely more appropriate. For these reasons, conceptual frameworks must be used to guide intervention development and study design. This dissertation research provides a framework for sensory stimulation therapies for EPER that can guide outcome selection for studies focused on these interventions.

Develop New and Modify Existing Tools to Measure Well-Being and BPSD That Can Feasibly Be Completed by PLWD

Although the completion percentages were low for measures of well-being and BPSD completed by self-report by PLWD, the scores of these measures that were completed by PLWD varied from scores of their care partners in the weighted blanket study. These results are congruent with prior research, which suggests that reports by PLWD of their own experiences do not always align with those reported by care partners (Moyle et al., 2012). How PLWD view their own health and symptoms can influence their overall well-being (Orgeta et al., 2015), thus their self-report is important to capture when possible.

Findings from this study, along with prior research, highlight a need for measures for PLWD who have varying degrees of cognitive impairment that they can feasibly complete. (Clarke et al., 2020). Important considerations for measurement development is to ensure the number of items and response formats are suitable for a full range of PLWD with varying degrees of cognitive impairment. As measures that require reflection on past experiences may be more difficult for people with cognitive impairment to complete, measures that capture in the moment well-being and emotions are needed (Clarke et al., 2020). Use of psychometrically sound measures of well-being and EPER completed by PLWD will improve the internal validity of non-pharmacologic intervention studies.

Explore the Experiences of a Broader Range of PLWD and their Families During the COVID-19 Pandemic

Given the lack of variation in the sociodemographic characteristics of the study samples in this research, additional studies are needed to explore the experiences and needs of families affected by ADRD from a broader range of backgrounds and contexts, more diverse racial and ethnical backgrounds, from different geographic locations, and with varying degrees of community service use. Future research must explore how the pandemic (an external factor) influences internal factors such as physical health of PLWD, and how the interplay of internal and external factors influences other key concepts such as use of non-pharmacologic interventions, EPER, and well-being. Exploration of the experiences of families affected by ADRD during the pandemic is critical to identifying needs and potential solutions that are feasible for the home setting, even during times of social isolation and limited access to in-person services.

Explore the Feasibility and Acceptability of Acutherapy for PLWD Residing in the Community

This dissertation supports that acupressure is a promising therapy for PLWD that is safe and can be feasibly delivered by non-licensed, non-healthcare trained individuals. Laser acutherapy is a relatively new and innovative acutherapy technique that is a promising treatment option for people with ADRD as it is easy to deliver, is non-invasive, safe, and virtually pain free (Whittaker, 2004). Despite their high degrees of safety and ease of delivery, no studies have explored the use of acupressure or laser acutherapy among PLWD in the community. Future research is need to explore the feasibility and acceptability of acutherapies delivered to PLWD by their care partners living at home or delivered through community services that already offer programs to support PLWD (e.g., adult day programs, support groups, memory cafes).

By exploring feasibility and acceptability, future research will be able to inform important components of intervention development for this population. Some of these components include acutherapy intervention content and modes of delivery, available resources, and time restraints relevant to community dwelling PLWD and their caregivers, and recruitment capacity. Feasibility and acceptability studies of these interventions are necessary to develop an acutherapy intervention that can undergo testing for efficacy with subsequent scale-up for community settings.

Future research focused on acutherapy for PLWD will need to prioritize intervention fidelity by clearly defining and measuring intervention components and procedures including specific acupoints, dose, and delivery to promote consistency of delivery across participants and enhance the internal validity of studies. The *Conceptual Framework of Sensory Stimulation Therapies for Improving Emotional and*

Psychological Experiences and Responses of People Living with Dementia may be used to guide the development of acutherapy interventions for PLWD as it hypothesizes mechanisms by which acutherapy may improve EPER. Outcomes of stress will need to be examined in future research to substantiate the relationship between acutherapy, the stress process, and EPER.

Examine the Efficacy of Non-Pharmacologic Interventions for Improving EPER Among PLWD Living in the Community

Care partners described several non-pharmacologic interventions that they use in the home that were beneficial to them, their relatives with ADRD, or both as a partnership (e.g., the use of humor, caregivers managing the environment and their own behaviors and reactions, pets and dementia service dogs, CBD oil, maintaining a daily routine, meditation, tai chi, yoga, mindfulness, reading, journaling, blogging, music, designated alone times for PLWD). Yet only 2 of these interventions have consistently demonstrated efficacy in reducing BPSD among community dwelling PLWD in prior research (i.e., music and interventions focused on caregivers' managing their own behaviors and the environment). There is dire need for high quality studies to examine efficacy of care strategies that care partners already use in the home.

Large and clinically meaningful effects of non-pharmacologic interventions on EPER may be more likely by combining strategies to form multicomponent interventions. Multicomponent interventions that combine more than one non-pharmacologic intervention have demonstrated significant reductions in BPSD in community dwelling PLWD (Özbe et al., 2019). The major drawback of multicomponent interventions is their complexity, and when not theoretically based, these interventions are often limited in terms of understanding active components that are necessary to demonstrate effects on outcomes (Özbe et al., 2019). This limits the ability to apply active ingredients of these interventions to other research. Additionally, as demonstrated through this research, using non-pharmacologic care strategies in the home often adds responsibility to care partners. Unnecessarily combining interventions may add burden to care partners who are likely already burdened, which can limit the broader implementation and sustained use of these interventions in the community.

For these reasons, examinations of efficacy of non-pharmacologic interventions focused on improving EPER must prioritize examination of active ingredients, or components of the intervention that are necessary to influence outcomes. Adaptive study designs can be used to examine active ingredients of multicomponent interventions (Biron et al., 2016). These designs evaluate interventions by observing participant outcomes on a predetermined schedule and modifying parameters of the interventions based on the observations. Modification of parameters may include dosage changes, adding or dropping components of the interventions, or combining interventions. The study protocol predetermines the adaptation schedule and processes that occur throughout the study (Bothwell et al., 2018; Kairalla et al., 2012). Adaptive study designs can be used to screen out ineffective interventions and save resources for more promising ones (Shan et al., 2018). These designs have been used in ADRD clinical trials examining effects of medications, but have been underutilized in community-based, non-pharmacologic intervention studies (Cummings et al., 2012). Future research focused on community dwelling PLWD may benefit from adaptive designs to examine multiple interventions and to determine active components necessary to result in effects on outcomes of EPER.

Results demonstrating efficacy for improving EPER of PLWD are needed to persuade policymakers and insurers to incentivize use of non-pharmacologic care strategies for PLWD residing in the community. Financial incentives and alternate payment models can encourage clinicians and ADRD community service providers to adopt, prioritize, and educate on feasible and effective interventions to better address the needs of individuals and families affected by ADRD (Boustani et al., 2019).

Develop and Test Interventions for PLWD and Their Care Partners Residing in the Community During the Pandemic

Care partners described a need for in-home care strategies that can be used during the pandemic. As Medicare expanded coverage for telehealth services due to the pandemic, ADRD telehealth care is being increasingly used and interventions will need to be tested for wider implementation to reach a broader range of families affected by ADRD (Kruse et al., 2020). Many care partners described virtual concerts as enjoyable to them and as easy activities for their relatives with ADRD to engage in during the pandemic. As music has demonstrated to be an effective intervention to reduce BPSD (Ueda et al., 2013), virtual concerts during this time of the pandemic represent a potential direction for virtual intervention development.

To address the loss of socialization due to the pandemic but given the mixed feelings towards virtual resources described by care partners, future research will also need to focus on promoting socialization and engagement through alternative mechanisms. As described by care partners in this research, dementia service dogs and pets offer the opportunity to promote engagement and a sense of purpose among PLWD. Other socially engaging activities described included socially distanced walking, yoga, and tai chi. Additional research is needed to determine the broader acceptability of these interventions, as well as their efficacy in promoting engagement, and reducing feelings of isolation among PLWD and their care partners.

Determine Effect Size for Future Efficacy Testing of Weighted Blankets

The weighted blanket feasibility and acceptability study provides information that can be used to inform a future pilot study. The pilot study will be conducted to calculate an effect size, which will be used to determine the sample size needed for an RCT to determine efficacy of weighted blankets on BPSD. This dissertation's feasibility and acceptability study provides information to inform measurement selection and recruitment capacity for the pilot study.

This study demonstrated the feasibility of collecting several outcome measures relevant to the conceptual framework that can be included in the pilot study. These outcomes are included in Table 5.2. Those highlighted in gray have demonstrated feasibility through this dissertation research, those in white are new measures being proposed for the pilot study.

Table 5.2
Concepts and Measures for Future Pilot Study

Concept	Measure
EPER	NPI (Global measure of BPSD)
	CMAI (Agitation specific)
	PSQI (Sleep specific)
	ESS (Sleep specific)
Cognitive function	MoCA
Well-being of PLWD	QOL-AD CP Report
Well-being of care partner	CWBS
	Optum SF-12
Stress	Biomarker of physiologic stress (e.g., cortisol level collected through hair, urine, salivary, or blood sample)

Well-being of the partnership	Dyadic Relationship Scale (Sebern & Whitlatch, 2007)

Note. CP care partner, CMAI Cohen-Mansfield Agitation Inventory, CWBS Caregiver Well-Being Scale, ESS Epworth Sleepiness Scale, MoCA Montreal Cognitive Assessment Test, NPI Neuropsychiatric Test, PSQI Pittsburgh Sleep Quality Index, QOL-AD Quality of Life in Alzheimer's Disease

Conclusion

Due to the high prevalence and societal costs associated with ADRD and the limitations in treating BPSD among those living in the community, this dissertation was conducted to explore the potential use of non-pharmacologic care strategies, specifically acutherapy and weighted blankets as in-home care strategies for treating BPSD experienced by PLWD. Engagement of family caregivers of PLWD has been underutilized in prior research, possibly leading to limited uptake and sustained use of these interventions in the community. This research involved family caregivers at the onset of development of the weighted blanket intervention. Although findings of this research highlight the potential of these interventions for PLWD, research supporting their efficacy is desperately needed. As the burden of ADRD and associated BPSD is overwhelming for PLWD, their families, and the health system, we are in dire need of evidence-based non-pharmacological interventions to reduce the burden of these cureless conditions and improve the quality of life of individuals affected by ADRD and their families.

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APPENDICES

Appendix A

Semi-Structured Interview Guide Used for Caregiver Interviews

Semi-Structured Interview Guide

The participant was welcomed and answered 9 demographic related questions prior to beginning the interview. The PI answered any questions that the participant had before beginning the interview.

Introduction
Hello (name of participant), I'd like to welcome you and say thank you for your time in logging in today. We truly value your time; I recognize that we both have busy schedules and we are hoping to get as much as possible from this interview. I anticipate that this interview will last about an hour.

The purpose of this meeting is to get a better understanding of your experiences as a family caregiver of an older adult with dementia. Today I am interested in hearing your experiences and thoughts about some of the challenging behaviors and symptoms displayed by your loved one. I am also interested in your experiences in handling these challenging symptoms in the home setting and in how your experiences as a caregiver has been affected by the COVID-19 pandemic. Near the end of this session, I will describe a therapy option for such symptoms that we are working on and I will ask you about your initial thoughts on this treatment option. I plan to use your input and input from other family caregivers to develop a therapy that can be used in the home to better manage challenging symptoms and behaviors of dementia.

This interview will be recorded and then transcribed for analysis. There will be no names attached to the transcripts so your words will remain confidential. I have a series of questions that I would like to ask to prompt your responses, examples and stories about your caregiving experience and dementia symptoms; there are no right or wrong answers here, just your own thoughts and insights. I will mute my audio when I am not asking questions to help improve the quality of your audio. Again, thank you so much for your participation, if you are ready, I will begin with the first question. [Zoom recording turned on]

Interview Questions
<u>Opening questions relating to the caregiver experience</u>

1. Share your name and who it is that you provide care for.
2. Describe what is the best part of caring for your loved one
3. What is the hardest part of caring for them?
4. How does caring for someone with dementia impact your ability to manage your daily life?
   Potential probe question: Compared to a time before your loved one had dementia, how has your life changed?
5. In general, how has your life changed or been affected during this time of COVID-19?
6. How has your experience as a caregiver been affected during this time of COVID-19?

<u>Key questions related to dementia symptoms</u>

7. Describe an example where it was particularly challenging for you to care for your loved one
   Potential probe question: Please explain further why that situation was so challenging compared to other days/situations?
8. Please describe specific behaviors or things your loved one does that is particularly challenging for you as a caregiver.
9. How has your loved one's behaviors been affected, if at all, during this time of COVID-19?
   Potential probe question: Can you describe a specific situation where his/her behavior has changed during this pandemic?

<u>Questions related to treatment strategies</u>

10. What are some of the approaches you have used to help your loved one when they are agitated, anxious, upset, withdrawn, restless or angry?
11. We discussed challenging behaviors already. What strategies have you tried to manage these behaviors?
12. Please give a detailed example of a time when a strategy worked well for managing a challenging behavior.
    Potential probe question: Please provide your insights about why you think this strategy worked?

13. Please describe an example of when a particular strategy did not work well?
    Potential probe question: Please provide your insights about why you think this strategy did not work well?
14. How have your approaches to managing your loved one's challenging symptoms and behaviors been affected during this time of COVID-19?
15. Please describe any resources or strategies that you used before to help manage your loved one's symptoms that were affected in some way by the pandemic.
16. In general, has the COVID-19 pandemic made it more or less challenging to manage your love one's symptoms and behaviors?
    Potential probe question: If so, in what ways is it more (or less) challenging?

(PI then provided a brief description of weighted blankets and shared a visual presentation of weighted blankets using the Zoom share screen function)

"Weighted blankets feel like a regular blanket or comforter; however they are filled with materials to add weight to the blanket and can range from 10 to 12.5 pounds. The feeling of weighted blankets is said to have a grounding effect that increases a person's level of relaxation. People have compared it to a feeling of being swaddled, while others describe it as a feeling like a long-term gentle hug. They are commonly used for people with dementia in hospital settings and are typically used multiple times throughout the day for 15-25 minutes at a time when individuals are anxious, restless, or agitated. There is not enough research to say definitively that weighted blankets help with challenging dementia symptoms. The goal of the next stage of my dissertation work is to explore the potential use of weighted blankets as a treatment option for individuals with dementia who live at home to help with symptoms such as anxiety, agitation and restlessness. (if participant is able to view my video, I will share my screen and show a picture of a weighted blanket as an example as I describe it)

Questions related to weighted blankets
17. What do you think about use of the weighted blanket for your loved one?
18. Can you give any examples as to why the weighted blanket might work or not work for them?
19. Do you have any questions, worries, or concerns about using a weighted blanket?

(PI provided a brief (less than 2 minute) oral summary of key points of the interview)

Final question
20. Are there any corrections, additions or other comments that you would like to share?

Conclusion
Thank you for participating today. I truly appreciate your time and unique insights; your contributions today have been truly valuable. Is there anything else that you would like to share?

If not, again thank you for joining today and sharing. [recording turned off]

Appendix B

Recruitment and Enrollment Materials Used for Weighted Blanket Intervention Feasibility and Acceptability Study

Appendix B-1: Study Flyer

ATTENTION Caregiver

ARE YOU AND YOUR LOVED ONE
WITH DEMENTIA INTERESTED IN:

U-M IRBMED ID: HUM00186832

Treatment options for reducing symptoms of dementia that can be used in the home?

Participating in research?

Learning how the use of weighted blankets may improve challenging symptoms of dementia?

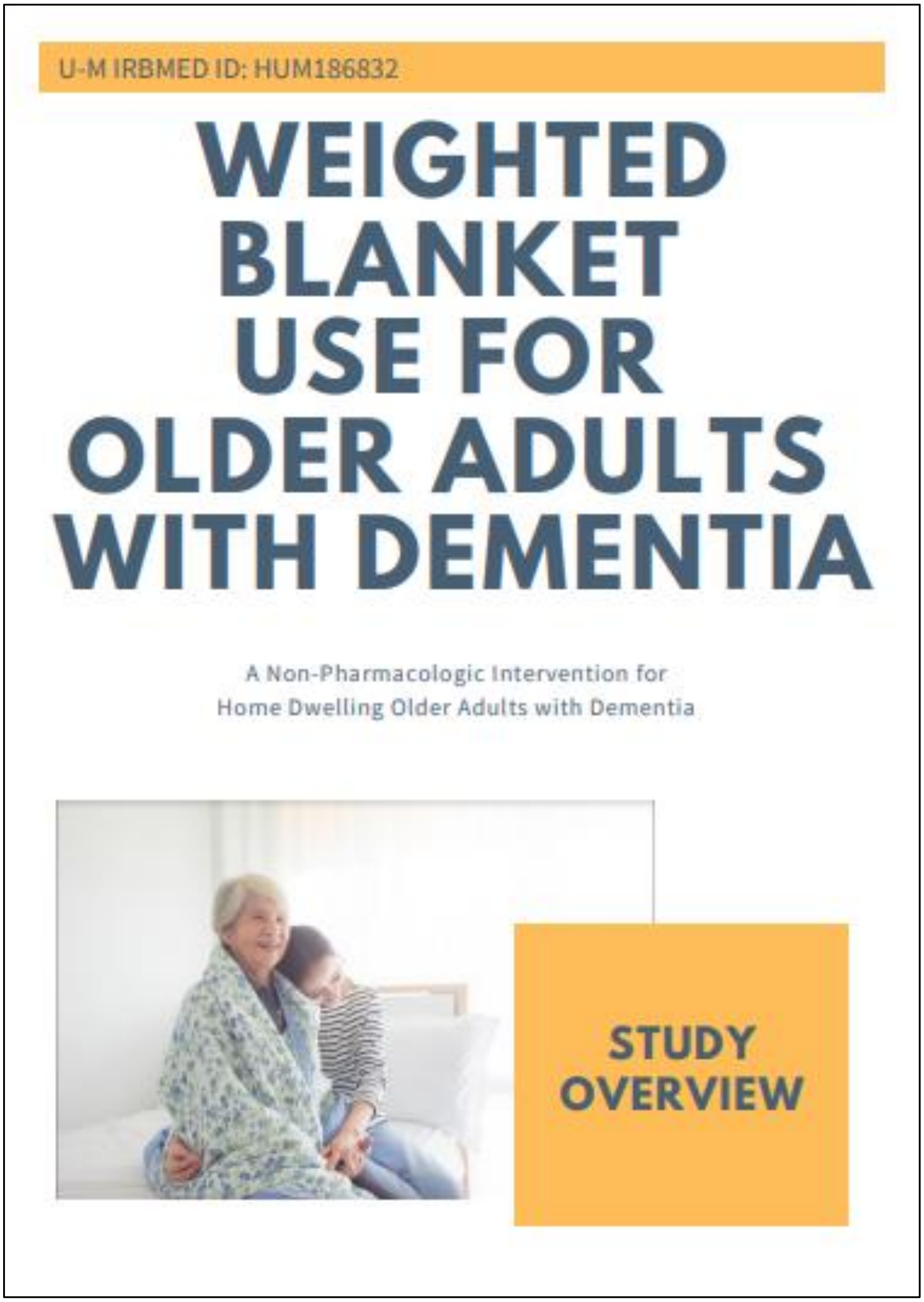
Melissa Harris is PhD student at the University of Michigan School of Nursing. She is seeking people with dementia living with family caregivers in the community.

Together, eligible people with dementia and their family caregivers will be invited to participate in a 4 week study to explore the potential of weighted blankets as an in-home treatment option for challenging symptoms of dementia.

This study requires no in person contact with the research team, but instead will involve ongoing interaction through virtual conferencing and telephone conversations.

If interested in receiving further information about this study, please contact Melissa Harris directly at 405-513-1271 or by email at mharrisl@umich.edu.

Appendix B-2: Study Overview Booklet



U-M IRBMED ID: HUM186832

WEIGHTED BLANKET USE FOR OLDER ADULTS WITH DEMENTIA

A Non-Pharmacologic Intervention for
Home Dwelling Older Adults with Dementia

STUDY OVERVIEW

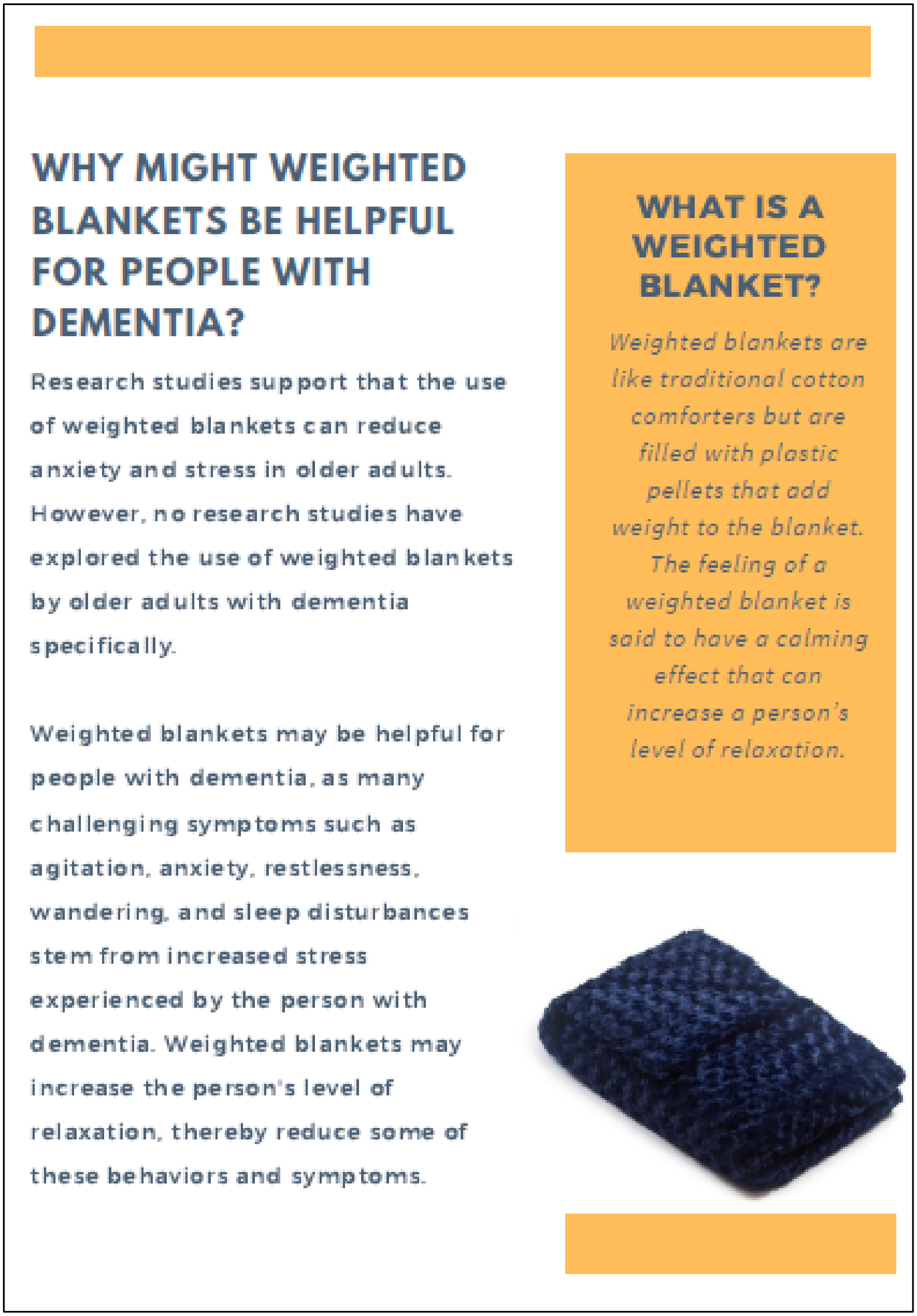
THANK YOU FOR YOUR INTEREST IN PARTICIPATING IN OUR STUDY.

This study will explore the use of weighted blankets as an in-home treatment option for older adults with dementia living with family caregivers.

Please feel free to contact us at any time with questions, comments, or concerns.

Principal Investigator
Melissa Harris
Phone: 405-513-1271
E-mail: mharrisl@med.umich.edu

Supervising Faculty Advisor
Dr. Marita Titler
E-mail: mtitler@med.umich.edu



WHY MIGHT WEIGHTED BLANKETS BE HELPFUL FOR PEOPLE WITH DEMENTIA?

Research studies support that the use of weighted blankets can reduce anxiety and stress in older adults. However, no research studies have explored the use of weighted blankets by older adults with dementia specifically.

Weighted blankets may be helpful for people with dementia, as many challenging symptoms such as agitation, anxiety, restlessness, wandering, and sleep disturbances stem from increased stress experienced by the person with dementia. Weighted blankets may increase the person's level of relaxation, thereby reduce some of these behaviors and symptoms.

WHAT IS A WEIGHTED BLANKET?

Weighted blankets are like traditional cotton comforters but are filled with plastic pellets that add weight to the blanket. The feeling of a weighted blanket is said to have a calming effect that can increase a person's level of relaxation.

STUDY TIMELINE

Throughout this 6-week study, you will move through several steps guided by the research team. The following provides information on each step, how this step will be carried out, and the anticipated duration of each step.

STEP 1 | DETERMINE ELIGIBILITY

There are certain reasons why people may or may not participate in this study.

- The study's Principal Investigator (PI), Melissa Harris will review these requirements with you to determine if you and your loved one may move forward in participating in this study.
- This will be carried out through a virtual conferencing session over Zoom. Melissa will provide step-by-step instructions on how to use Zoom.
- Anticipated length: 20 minutes

STEP 2 | REVIEW OF INFORMED CONSENT FORM

Participants will need to sign an informed consent form to participate in this study. If needed, the caregiver can also provide consent on behalf of the person with dementia. The research team will provide you with an electronic, or hardcopy of the consent form to review.

- Form will be provided to you by email or sent by U.S Mail depending on your preference
- E-mailed consent forms will be sent immediately after completion of Step 1.
- Hardcopy consent forms sent by U.S. mail may take 3-7 days to arrive.

STUDY TIMELINE

STEP 3 | CONSENT PROCESS SESSION

- Upon receipt of the Informed Consent Form, you will be scheduled for a Zoom session to review the consent form and ask any questions that you have about participation in this study with Ms. Harris.
- Melissa will walk you through how to sign and return the consent form. This may be done electronically, or by U.S. Mail depending on your preference.
- Anticipated length: About 30 minutes

STEP 4 | BASELINE DATA COLLECTION

- After completion of Step 3, you will be scheduled to complete baseline data collection measures to explore different aspects of health, behaviors, and well-being of the person with dementia and the caregiver.
- Some measures will be completed by interview of the person with dementia, and the caregiver separately. Other measures will be completed by the caregiver using a questionnaire composed of several parts, which can be completed by paper and pen, or electronically based on your preference.
- Interviews will be carried out through a virtual conferencing session over Zoom.
- Anticipated length: about 45 minutes for the Zoom session and about an hour to complete questionnaires

STEP 5 | RECEIVE STUDY MATERIALS

- Based on your location, Melissa will either personally deliver, or ship a weighted blanket, a Weighted Blanket Use Guide, and a Weighted Blanket Daily Use Diary to your home.
- The delivery of the study materials will require no face-to-face contact between you and the research team.
- Anticipated length: Less than 10 minutes

STUDY TIMELINE

STEP 6 | INTRODUCTION TO THE WEIGHTED BLANKET

- Melissa will review the study materials with you and demonstrate how to use the weighted blanket. She will answer any questions that you have during this time.
- This information session will take place though a virtual conferencing session via Zoom.
- Anticipated length: 30-45 minutes.

STEP 7A | PERSON WITH DEMENTIA STARTS USING THE WEIGHTED BLANKET DAILY

- After Step 6, the care person with dementia will begin the using the weighted blanket every day at home with assistance of their caregiver for 4 weeks.
- The weighted blanket will be used daily by the person with dementia for <u>at least</u> 5 minutes at a time for a total of at least 20 minutes throughout each day. The blanket may be used more if you choose.
- Exactly when and how often the blanket is used will be based on the needs and preferences of the person with dementia and their caregiver.

STEP 7B | CAREGIVER COMPLETES WEIGHTED BLANKET DAILY USE DIARY

- After Step 6, family caregivers will complete a Weighted Blanket Daily Use Diary at the end of each day to describe when and how often the weighted blanket was used by the person with dementia.
- To be completed in the home at the convenience of the caregiver
- Anticipated Length: 10 minutes

STUDY TIMELINE

STEP 8 | WEEKLY TELEPHONE CHECK-INS

- Near the end of each of the 4 weeks, you will participate in a telephone check-in session with Melissa. During this time she will address any questions you have had over the past week regarding the use of the weighted blanket. She will ask you about how often and when the blanket was used, and help address any issues that you have had in using the blanket over the past week.
- These will be telephone calls with Melissa.
- Anticipated length: 25 minutes each

STEP 9 | END OF STUDY DATA COLLECTION

- Within a week of completing the 4 weeks of using the weighted blanket, the caregiver and the person with dementia will complete the follow up data collection measures, many of which are the same as the baseline measures (Step 4). Both the person with dementia and the caregiver will also complete a questionnaire relating to how satisfied and how much benefit you received from using the weighted blanket.
- Interviews will be carried out through a virtual conferencing session over Zoom.
- Anticipated length: About 45 minutes for the Zoom interview session and 1 hour to complete questionnaires

WHAT IS ZOOM?

Zoom is a virtual conferencing system that allows for audio and video communication between parties. You can use a telephone, smart phone, tablet (with internet access), or computer (with internet access) to access the Zoom sessions. The research team will provide you with detailed instructions on how to login to the Zoom sessions.

WHAT HAPPENS AT THE END OF THE STUDY?

The research team will combine your results with the other participants, your individual data will not be identifiable, published or presented. Results will be shared with you by e-mail after the final data is analyzed. Findings will also be shared with the research community through publications and presentations. At the end of the study you will keep the weighted blanket as a token of appreciation for your participation in this study.

Appendix B-3: Eligibility Determination Form

Date and time:
Reviewer’s initials:
Caregiver and care recipient initials:

Caregiver Eligibility Questions	**Yes (✓)**	**No (✓)**
Is the individual 21 years of age or older?		
Does the individual live with a family member with Alzheimer’s disease or related dementia?		
Has the individual lived with the family member with dementia for at least one month?		
Does the individual identify as a primary caregiver of the diagnosed family member?		
Can the individual read and speak English?		
Does the individual have any hearing or visual impairment that may limit their ability to participate in the screening process or read and sign a consent form?		
Does the individual have access and ability to use a telephone, smart phone (with internet access), tablet (with internet access), or computer (with internet access) to access the virtual Zoom sessions?		
Care Recipient Eligibility Questions	**Yes (✓)**	**No (✓)**
Is this individual 60 years of age or older?		
Does this individual have Alzheimer’s disease or related dementia		
Does this individual live in an assisted living, or long-term care setting?		
Does the individual weigh 100 pounds, or more?		
Is the individual able to lift at least 10 pounds? (this is about the weight of a cat, a small dog, or a gallon paint can)		

Has the individual demonstrated any of the following behaviors or symptoms during the last two weeks? (Need to report *yes* to at least 2 to be eligible)	**Yes (✓)**	**Occur At Least Once a Week? (✓)**	**No (✓)**
Delusions			
Hallucinations			
Agitation or aggression			
Depression or dysphoria			
Anxiety			
Elation or euphoria			
Apathy or indifference			
Disinhibition			
Irritability or lability			
Motor disturbance			
Nighttime behaviors			
Appetite or eating changes			

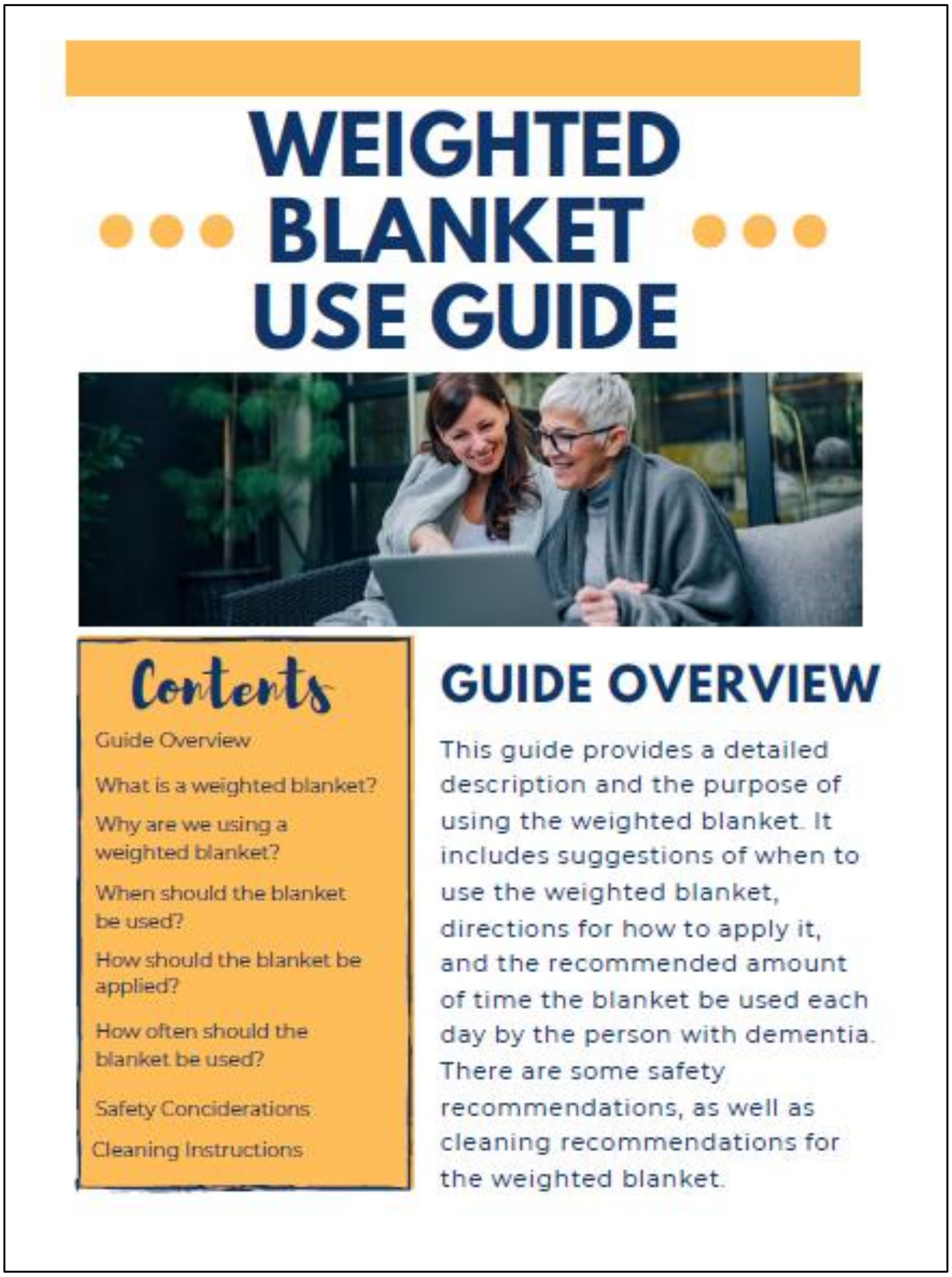
	Yes (✓)	**No (✓)**
Does this individual have asthma, sleep apnea, or other respiratory disorders that inhibit respiratory function?		

Does the individual have paralysis or limited mobility of the upper or lower limbs?		
Does the individual have a history of claustrophobia, or fear of confined and/or enclosed spaces?		
Does the individual have diabetes?		
Does the individual have open wounds or rashes on the skin?		
If yes, please describe:		
Has the individual used a weighted blanket within the past month?		
Does this individual have an acute or chronic unstable medical condition that may limit their ability to participate in the study?		
Is this caregiver eligible to participate in the study?		
Is this care recipient eligible to participate in the study?		
Is this dyad eligible to participate in the study?		
Assigned caregiver participant ID for eligible individuals:		
Assigned care recipient participant ID for eligible individuals:		
Assigned dyadic participant ID for eligible individuals:		

Appendix C

Weighted Blanket Intervention Materials

Appendix C-1: Weighted Blanket Use Guide



WEIGHTED BLANKET USE GUIDE

Contents

GUIDE OVERVIEW

This guide provides a detailed description and the purpose of using the weighted blanket. It includes suggestions of when to use the weighted blanket, directions for how to apply it, and the recommended amount of time the blanket be used each day by the person with dementia. There are some safety recommendations, as well as cleaning recommendations for the weighted blanket.

WHAT IS A WEIGHTED BLANKET?

A weighted blanket is like a traditional cotton comforter, except it is filled with non-toxic, hypoallergenic plastic pellets that add weight to the blanket. Based on the participant with dementia's body weight, you will receive either a 10 or 12-pound weighted blanket to use throughout the study period. The blanket is made of cool cotton fabric that is like a bed sheet fabric.

The blanket you will receive in this study is supplied by Magic Weighted Blanket©, which is a family created business that invented the first weighted blanket in 1997. They have over 21 years of experience in manufacturing and selling weighted blankets to individuals across all ages. Blankets purchased from Magic Weighted Blanket© come with a lifetime warranty. More information on weighted blankets can be found at their website at https://magicweightedblanket.com/.

WHY ARE WE USING A WEIGHTED BLANKET?

The feeling of a weighted blanket is said to have a calming effect that can increase a person's level of relaxation. People have compared it to a feeling of being swaddled, while others describe it as a feeling like a long-term gentle hug. Research supports that weighted blankets can reduce anxiety and stress in older adults. Although weighted blankets are already commonly used in long-term care facilities, no prior research studies have explored the use of weighted blankets among older adults with dementia specifically.

Weighted blankets may be helpful for people with dementia, as many challenging symptoms such as agitation, anxiety, restlessness, wandering, and sleep disturbances stem from increased stress experienced by the person with dementia. The calming effect of the weighted blanket may help reduce some of this stress and improve these often-distressing behaviors and symptoms.

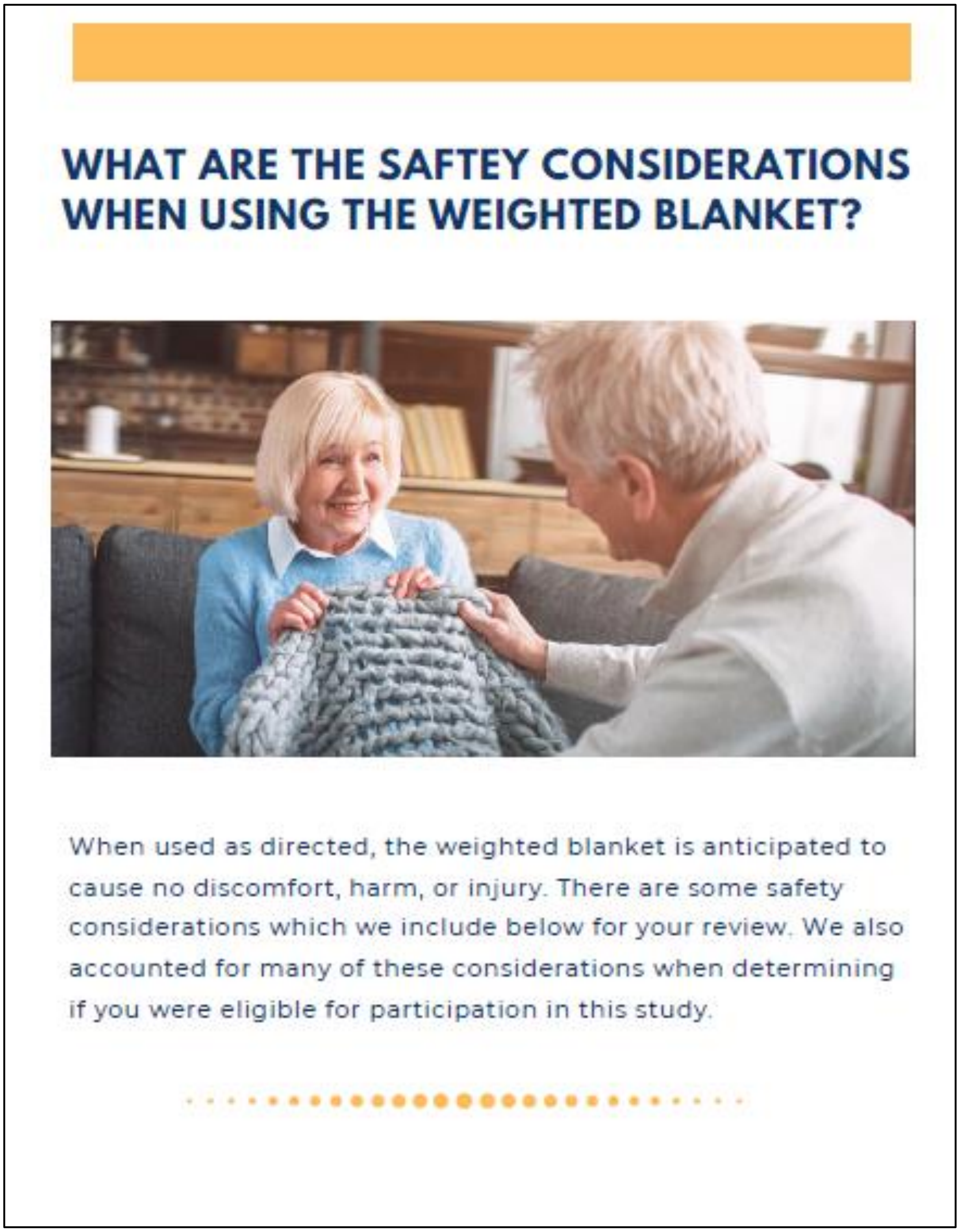
WHEN SHOULD THE BLANKET BE USED?

The weighted blanket is applied like a traditional blanket, or comforter. It can be draped over the person, or around their shoulders while in a sitting position. It can be placed on top of their body while in a lying down position. The blanket should never be placed over the person's head or face, and it should not be used while the person is walking or standing.

HOW OFTEN SHOULD THE BLANKET BE USED?

We recommend the person with dementia use the weighted blanket daily for at least 5 minutes at a time, for a total of at least 20 minutes throughout each day.

This is the minimum amount of time we recommend, but we hope that you use it as often as you feel is necessary and appropriate. You have full control of how often and when to use the weighted blanket.



WHAT ARE THE SAFTEY CONSIDERATIONS WHEN USING THE WEIGHTED BLANKET?

When used as directed, the weighted blanket is anticipated to cause no discomfort, harm, or injury. There are some safety considerations which we include below for your review. We also accounted for many of these considerations when determining if you were eligible for participation in this study.

SAFTEY CONSIDERATIONS

- Weighted blankets should never be used as a restraint.
- The individual should be able to remove the blanket on his/her own.
- A person should not be rolled up in the blanket.
- The blanket should not be used when the person is standing or walking.
- The blanket should not cover a person's face or head.
- There is a minor risk for infection if the blanket is used by multiple people and not washed between uses.
- Weighted blankets should be used with caution by people with claustrophobia, or fear of confined and/or enclosed spaces.
- Weighted blankets should be used with caution in people with asthma, sleep apnea, or other disorders that inhibit respiratory function.
- A person using the blanket should have full mobility of their upper and lower limbs.
- Weighted blankets should be used with caution in people with open wounds, fragile skin, rashes, or those with diabetes who may be prone to diabetic ulcers.
- Although unanticipated, if plastic pellets come out of the blanket, the blanket should not be used. Please immediately stop using the blanket and contact the study's Principal Investigator (contact information at the end of this guide) to provide you with a replacement blanket.
- Plastic pellets should not be ingested or swallowed. If swallowed, the individual should seek medical attention.
- The blanket should not be put in the microwave, as this can melt the plastic pellets.

HOW TO CLEAN THE WEIGHTED BLANKET

The weighted blanket can be machine washed with cold water on the regular cycle and dried on low to medium heat in the dryer.

- It is NOT recommended to use fabric softener when washing the blanket.
- We encourage the blanket to only be used by the participant with dementia throughout the study period. The blanket should be washed between uses by different people and when it is visibly soiled.

WHO DO WE CONTACT FOR QUESTIONS OR CONCERNS?

You can contact the study's Principal Investigator, Melissa Harris at anytime for any reason by telephone at 405-513-1271. She can also be reached by e-mail at mharrisl@umich.edu.
Ms. Harris' supervising faculty advisor, Dr. Marita Titler can also be contacted by e-mail at mtitler@umich.edu.

Appendix C-2: Weekly Intervention Telephone Check-In Form

Weekly Intervention Telephone Check in Form

Date:
Participant dyad ID:
Week of Check-In (circle): Week 1 Week 2 Week 3 Week 4

Directions for completion of form:
Use this form to direct the conversation with the family caregiver and keep brief notes electronically as the person responds to each question. This form is only meant to guide the conversation, the focus can change based on the needs of the caregiver and not all questions need detailed responses. Immediately after completion of the call, review the form again and add in details that you remember from the conversation as appropriate.

Introduction:
(Start by greeting the family caregiver and asking how they are doing today)

"I've been looking forward to the chance to check in with you today to discuss how the use of the weighted blanket by your loved one has been this week, as well as to address any questions or concerns you have about the blanket. I anticipate this conversation will last about 25 minutes. I encourage you to refer to your Weighted Blanket Daily Use Diary throughout our conversation as a reference.

I do have some specific questions to guide our conversation today, but first can you give me a brief one to two-minute summary of how this week has gone in terms of your loved one using the weighted blanket? "

Questions relating to <u>frequency</u> and <u>duration</u> of blanket use:
1) About how many days this week did your loved one use the weighted blanket?

___________ days

2) About how many times did your loved one use the weighted blanket each day?

___________ times

3) For about how long did your loved one use the blanket at a time?

___________ minutes

4) What time of day did your loved one use the weighted blanket the most over the past week?
☐ Morning ☐ Evening ☐ Afternoon

☐ At bedtime ☐ Overnight

Questions relating to how the person with dementia <u>responded and tolerated</u> use of blanket:

5) How did your loved one respond to use of the blanket over the past week?

6) On a scale of 0 to 10, with 0 being did not tolerate the blanket at all and 10 being tolerated the blanket all of the time, what number best describes how your loved one tolerated the weighted blanket over the past week (Circle)?

Did not tolerate the blanket at all									**Tolerated the blanket all of the time**
1	2	3	4	5	6	7	8	9	10

7. Can you describe a specific situation when your loved one did not tolerate the blanket?

If the person with dementia used the blanket less than every day this week:
8) If your loved one did not use the blanket every day this week, can you describe why and include any situations or circumstance that made using the blanket a challenge:

> **Help the caregiver identify strategies to increase use of the blanket as necessary (some examples below):**
> -Encourage use of the blanket during passive activity times that the person enjoys (e.g. watching television, reading, while doing puzzles).
> -Encourage the person with dementia to use the blanket by using a blanket yourself, suggest that it is “blanket time” and that everyone is using a blanket to relax.
> -Ask the person with dementia why they like, or do not like using the blanket.
> -Set aside 5-minute increments throughout the day to encourage use of the blanket that fits into your usual routine (e.g. during meal preparation times, during times you as the caregiver are working on other tasks or chores).
> -Encourage use of the blanket while you are filling out the Weighted Blanket Daily Use Diary at the end of each day.

9) Do you have any concerns, comments or questions relating to the use of the weighted blanket by your loved one?

Questions relating to the study materials:

10) Did you use or refer to the Weighted Blanket Use Guide at all this week?
-If so, was it helpful?

11) Do you have any concerns, comments or questions relating to the Weighted Blanket Use Guide?

> **Encourage continued use of the Weighted Blanket Use Guide throughout the upcoming week.**

12) How did filling out the daily diary entries at the end of each day go this week?

> **Help address difficulties and identify strategies for increasing completion of the diary entries as needed.**

13) Do you have any concerns, comments or questions relating to completion of the daily diary entries?

Encourage continued completion of the Weighted Blanket Daily Use Diary throughout the upcoming week.

14) Any final comments or questions before we end the conversation?

Conclusion:
Thank you so much for taking the time to talk with me today. Please do not hesitate to call me throughout the upcoming week if you have any comments, questions or concerns. Just to confirm, we will have another check in next week at (time of next schedule check-in session).

Appendix D

Weighted Blanket Intervention Feasibility and Acceptability Study Aim 2 Data Collection Forms

Appendix D-1: Study Completion Form

Participant ID:
Date and time of form completion:
Initials of individual completing form:

Date of study completion: ______________________

Primary reason for termination of participation in the study (✓ appropriate box):

☐ Completed study
☐ Participant(s) was determined after enrollment to be ineligible (provide description in comments section)
☐Participant(s) withdrew consent to participate (please ask participant(s) for their reason for withdrawing, but know that they are <u>not</u> required to provide this information)
☐ In the principal investigator's opinion, it was not in the participant's best interest to continue (provide additional comments as appropriate)
☐ Adverse event (adverse event form must also be completed)
☐ Death
☐ Hospitalization
☐ Lost to follow up
☐ Other (please specify)
☐ Unknown or not reported

Additional comments:
____
____
____
____
____
____
____
____
____

Appendix D-2: Adverse Event Form

Adverse Event Form

Please fill out a new form for each adverse event.

1. Description of adverse event and/or injury

____

____

____

____

2. Start date of adverse event

____

3. Stop date of AE

____

4. Severity of adverse event (check box)

☐ Mild

☐ Moderate

☐ Severe

☐ Life threatening

5. Relationship to the study intervention (check box)

☐ Not related

☐ Unlikely related

☐ Possibly related

☐ Probably related

☐ Definitely related

6. Action taken for AE (check box)

☐ None

☐ Dose or protocol modification

☐ Medical intervention

☐ Hospitalization

☐ Intervention discontinued

☐ Other

Please describe if other:

7. Outcome of AE (check box)

☐ Resolved

☐ Recovered with minor sequelae

☐ Recovered with major sequelae

☐ Ongoing/continuing treatment

☐ Condition worsening

☐ Death

☐ Unknown

8. Was this AE expected? (check box)

☐ Yes

☐ No

9. Was this a serious adverse event? (If yes, please describe below)

☐ Yes

☐ No

Additional comments

____

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Appendix D-3: Weighted Blanket Daily Use Diary

Blanket Daily Use Diary

University of Michigan School of Nursing Research Study

Exploring the Use of Weighted Blankets as a Non-Pharmacologic Intervention for Home Dwelling Older Adults with Dementia

U-M IRBMED ID: HUM00186832

Principal Investigator: Melissa Harris, BSN, RN, PhD Student
Supervising Faculty Advisor: Marita Titler, PhD

Introduction

This daily diary is designed for you to write down information each day about use of the weighted blanket by your family member with dementia. We are asking you as the family caregiver to complete the diary at the end of each day throughout the 4-week period.

Date: ___/___/___ Time: ______ AM / PM (*circle*)

Weighted Blanket Use Day 1 (Actual diary included 28 daily entries in total)

If your loved one did not use the blanket at all today, please skip questions 2-5 and only answer questions 1 and 6. If your loved one used the blanket at least once today, please answer questions 1-5, skip question 6. Space for additional comments is at the end of today's entry.

1. About how many times did your loved one with dementia use the weighted blanket today (*Check best response*)?

☐ Not at all

☐ Once

☐ 2 to 4 times

☐ 5 or more times

2. On average, how long did your loved one use the blanket each time they used it today?

______________________ minutes / hours (*Circle*)

3. About how long was the blanket used **in total** for today?

______________________ minutes / hours (*Circle*)

4. What time of day did your loved one use the blanket today (*Check all that apply*)?

☐ Morning

☐ Afternoon

☐ Evening

☐ At bedtime

☐ Overnight

5. How did your loved one appear while using the weighted blanket today (*Check all that apply*)?

☐ Aggressive ☐ Agitated ☐ Angry ☐ Anxious ☐ Calm

☐ Comfortable ☐ Distracted ☐ Fell asleep ☐ Irritated ☐ Relaxed

☐ Restless ☐ Showed no change in behavior ☐ Stressed ☐ Tired

☐ Other

If checked *Other*, please described:

____

6. If your loved one did not use the blanket at all today, please describe why and include any situations or circumstances that made using the blanket a challenge:

If you have any other comments for today regarding the weighted blanket use by your loved one, please include them below:

Appendix D-4: Weighted Blanket Intervention Acceptability Tools – Caregiver version

Instrument Completion Information: The Weighted Blanket Intervention Acceptability Tool Caregiver Version was completed by the caregiver by questionnaire at post-intervention. Instructions for completing the tool are listed below and were included in the Follow-Up Caregiver Questionnaire (Appendix F-2).

Now that you and your relative with dementia have completed all 4 weeks of using the weighted blanket, we would like to know how satisfied you as the caregiver was with the weighted blanket and how beneficial the weighted blanket was for both of you.

Directions:
Please answer these questions from your perspective as the caregiver of a family member with dementia. We encourage you to provide honest answers relating to the use of weighted blanket by your family member.

Indicate with a ✓ your response.

		Not satisfied				Very satisfied
In general, how satisfied were you with:		1	2	3	4	5
1.	Having the weighted blanket to be used by your relative in the home?					
2.	Having the intervention materials delivered to your home?					
3.	How the weighted blanket was explained to you during the Weighted Blanket Introduction session?					
4.	Using a web-based platform to learn how to use the weighted blanket?					
5.	Participating in weekly check-in telephone call with the research team?					
6.	With the Weighted Blanket Use Guide that came with the blanket?					
7.	With the way your questions were answered throughout the study period?					
8.	You with how you were involved in the process of encouraging your relative to use the weighted blanket?					

9. How heavy was the blanket that your relative used?

☐ 10 pounds

☐ 12 pounds ☐ I don't know

10. What did you think about the weight of the blanket for your relative?

☐ The weight was about right for my relative

☐ I would have liked it to be heavier.

☐ I would have liked it to be lighter.

11. What is your opinion about the recommendation that the weighted blanket be used daily by your relative?

☐ The recommended everyday use of the weighted blanket was about right for us.

☐ I would have liked the recommended use of the weighted blanket be less than every day.

☐ I would have liked the recommended use of the weighted blanket be multiple times a day.

12. What is your opinion about the recommended amount of time the weighted blanket was to be used by your relative each day? (Reminder: the weighted blanket was recommended to be used for at least 5 minutes at a time for a total of at least 20 minutes throughout each day)

☐ The recommended amount of time was about right for us.

☐ I would have liked less recommended blanket use time.

☐ I would have liked more recommended blanket use time.

13. What did you think about completing a Weighted Blanket Daily Use Diary?

☐ Completing a diary entry every day was about right for me.

☐ I would have liked to complete fewer diary entries.

☐ I would have liked to complete more diary entries.

Overall:		Not at all	Some	A great deal
		1	2	3
14.	How much did the use of the weighted blanket help in decreasing challenging symptoms displayed by your relative with dementia? (such as anxiety, agitation, restlessness, difficulty sleeping)			
15.	How beneficial was the study information booklet in explaining the study process?			
16.	How beneficial was the Weighted Blanket Use Guide in explaining the use of the weighted blanket?			
17.	How beneficial were the weekly telephone check ins throughout the 4-week intervention period?			
18.	How much did the use of the weighted blanket by your relative benefit you as the caregiver of someone with dementia?			
19.	How much did the use of the weighted blanket benefit your family member with dementia?			

20. Overall, would you recommend the use of a weighted blanket to other individuals caring for someone with dementia?

☐ Yes ☐ No

21. Will you continue to encourage your relative to use the weighted blanket?

☐ Yes ☐ No

22. When was using the weighted blanket most helpful for your relative?

23. When was using the weighted blanket the least helpful for your relative?

24. Do you have any comments or suggestions about the study materials (such as the study information booklet, the Weighted Blanket Use Guide, or the Blanket Daily Use Diary)?

☐ Yes ☐ No

If yes, please describe.

25. Do you have any comments or suggestions about the weighted blankets specifically?

☐ Yes ☐ No

If yes, please describe.

____

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26. Would you recommend or suggest any other changes for the weighted blanket study?

☐ Yes ☐ No

If yes, please describe.

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Appendix D-5: Weighted Blanket Intervention Acceptability Tools – Care recipient version

Instrument Completion Information: The Weighted Blanket Intervention Acceptability Tool Care Recipient Version was completed by the care recipient with dementia by questionnaire at post-intervention. Care recipients were prompted to complete the care recipient specific questions independently but could receive assistance from their family caregivers if unable to do so. Instructions for completing the tool are listed below.

Participant ID: _________________

Date: _________________

Now that you have completed all 4 weeks of using the weighted blanket, we would like to know how satisfied you were with the weighted blanket and how beneficial the weighted blanket was for both of you.

Directions:
Please answer these questions the best you can, you can ask for help from your family caregiver as needed. Please circle one answer for each question.

---

1. How did you like using the weighted blanket in the home?

Not at all   Some   A great deal

2. How did you like being able to choose when you used the weighted blanket?

Not at all   Some   A great deal

3. How did you like being able to choose how often you used the weighted blanket?

Not at all   Some   A great deal

4. How comfortable did you feel when using the weighted blanket?

Not at all   Somewhat   Very

comfortable	comfortable	comfortable

5. How did you like the feeling of the <u>fabric</u> of the blanket that you used?

Not at all	Some	A great deal

6. How did you like the <u>warmth</u> of the blanket that you used?

Not at all	Some	A great deal

7. How did the <u>weight</u> of the blanket feel to you?

The weight was about right for me.	I would have liked It to be heavier.	I would have liked It to be lighter.

8. How relaxed did you feel when using the weighted blanket?

Not at all	Some	A great deal

9. How else did you feel when using the weighted blanket?

____

____

____

____

____

____

10. Will you continue to use the weighted blanket?

Yes No

11. Overall, would you recommend using a weighted blanket to other individuals with dementia?

Yes No

12. What did you like most about using the weighted blanket?

13. What did you like least about using the weighted blanket?

14. Would you recommend or suggest any changes for using the weighted blanket?

Yes No

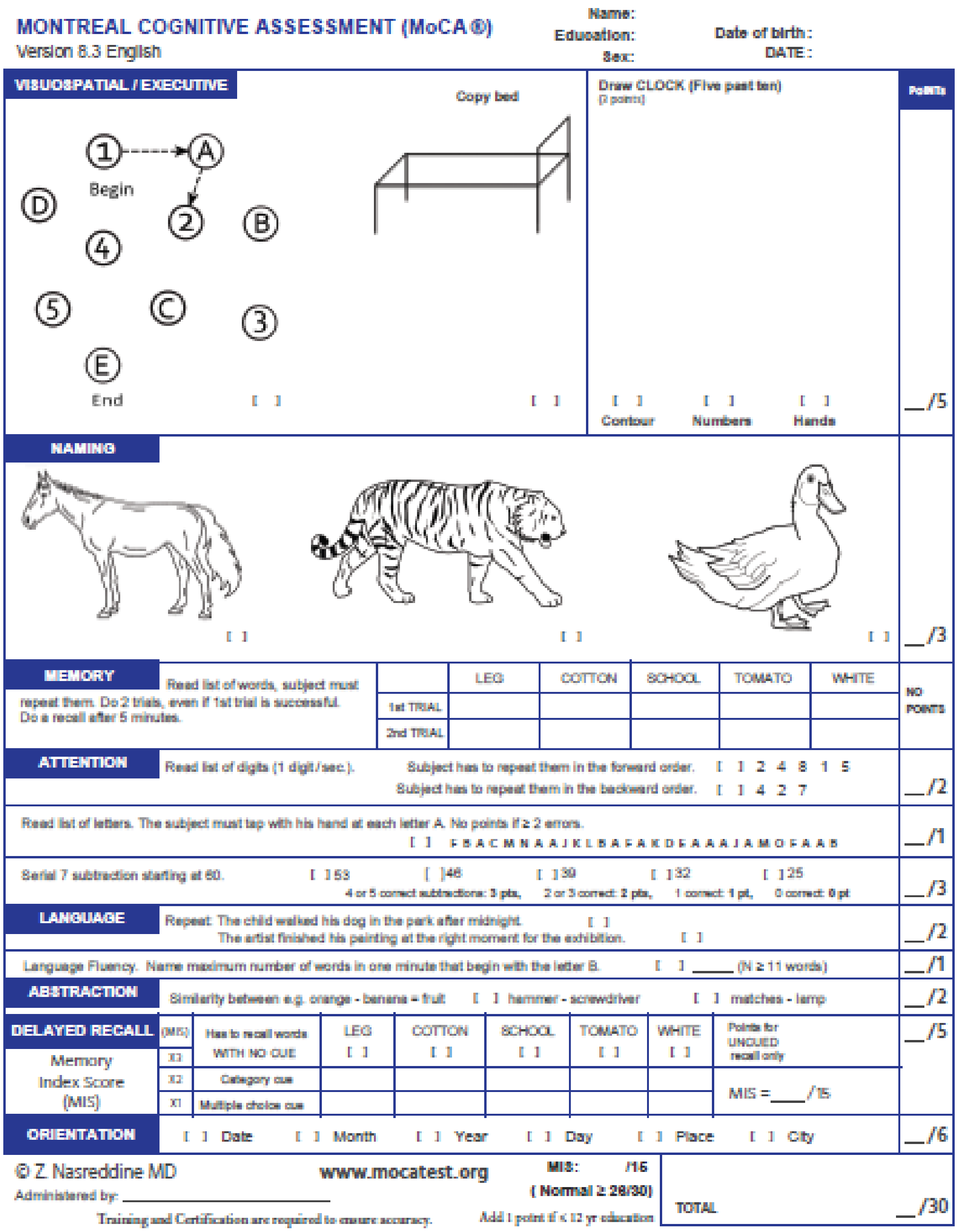
If yes, please describe**:**

Appendix E

Weighted Blanket Intervention Feasibility and Acceptability Study Aim 3 Data Collection Forms

Appendix E-1: Montreal Cognitive Assessment Test

Instrument Completion Information: The MoCA was completed by interview of the care recipient with dementia using audio-visual conferencing at baseline and at post-intervention. Instructions for completing the MoCA via audio-visual conferencing were followed and are available at https://www.mocatest.org/training-certification/



MONTREAL COGNITIVE ASSESSMENT (MoCA®)
Version 8.3 English

Name:
Education:
Sex:
Date of birth :
DATE :

VISUOSPATIAL / EXECUTIVE

Copy bed [ ] [ ]

Draw CLOCK (Five past ten) (3 points)
[ ] Contour [ ] Numbers [ ] Hands

POINTS __/5

NAMING
[ ] [ ] [ ] __/3

MEMORY Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	LEG	COTTON	SCHOOL	TOMATO	WHITE	
1st TRIAL						NO POINTS
2nd TRIAL						

ATTENTION Read list of digits (1 digit/sec.).
Subject has to repeat them in the forward order. [ ] 2 4 8 1 5
Subject has to repeat them in the backward order. [ ] 4 2 7 __/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors.
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B __/1

Serial 7 subtraction starting at 60. [ ] 53 [ ] 46 [ ] 39 [ ] 32 [ ] 25
4 or 5 correct subtractions: 3 pts, 2 or 3 correct: 2 pts, 1 correct: 1 pt, 0 correct: 0 pt __/3

LANGUAGE Repeat: The child walked his dog in the park after midnight. [ ]
The artist finished his painting at the right moment for the exhibition. [ ] __/2

Language Fluency. Name maximum number of words in one minute that begin with the letter B. [ ] ____ (N ≥ 11 words) __/1

ABSTRACTION Similarity between e.g. orange - banana = fruit [ ] hammer - screwdriver [ ] matches - lamp __/2

DELAYED RECALL	(MIS)	Has to recall words WITH NO CUE	LEG [ ]	COTTON [ ]	SCHOOL [ ]	TOMATO [ ]	WHITE [ ]	Points for UNCUED recall only	__/5
Memory Index Score (MIS)	X3								
	X2	Category cue						MIS = ___/15	
	X1	Multiple choice cue							

ORIENTATION [ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City __/6

© Z. Nasreddine MD
www.mocatest.org
MIS: /15
(Normal ≥ 26/30)
Add 1 point if ≤ 12 yr education
TOTAL __/30
Administered by: ____________________
Training and Certification are required to ensure accuracy.

Scoring Instructions:

All subscale scores listed on the right-hand side are summed. One point is added for subject who has 12 years or fewer of formal education, for a possible maximum of 30 points. A final total score of 26 and above is considered normal cognition.

Appendix E-2: Neuropsychiatric Inventory

Instrument Completion Information: The NPI was completed by interview of the family caregiver at baseline and at post-intervention. Caregivers were asked to reflect on the care recipient with dementia's behaviors and symptoms displayed over the most recent 4 weeks. The family caregiver was interviewed over Zoom, or by telephone. Instructions for administering the NPI were followed and are available at https://eprovide.mapi-trust.org/instruments/neuropsychiatric-inventory-questionnaire

Domain	N/A	Absent	Frequency	Severity	Domain Scores (Frequency X Severity)	Caregiver Distress
		0	1 2 3 4	1 2 3		0 1 2 3 4 5
1. Delusions	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
2. Hallucinations	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
3. Agitation/ Aggression	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
4. Depression/ Dysphoria	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
5. Anxiety	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
6. Elation/ Euphoria	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
7. Apathy/Indifference	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
8. Disinhibition	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
9. Irritability/ Lability	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
10. Aberrant Motor Behavior	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
11. Sleep and Nighttime Behavior Disorders	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
12. Appetite/ Eating Changes	☐	☐	☐☐☐☐	☐☐☐		☐☐☐☐☐☐
TOTAL SCORE (add all domain scores)						
TOTAL DISTRESS SCORE (add all distress scores)						

Scoring Instructions: Each domain subscale receives a frequency score (1-4), a severity score (1-3), and a caregiver distress score (0-5). A domain score is calculated for each subscale by multiplying the frequency score and severity score. A total NPI score is calculated by adding the scores of the 12 domain scores together. Each of the caregiver distress scores for each domain are added together to yield a total distress score.

Appendix E-3: Cohen-Mansfield Agitation Inventory-Relatives

Instrument Completion Information: The CMAI-Relatives version was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the CMAI are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The section below asks about specific behaviors displayed by your relative with dementia. We have listed behaviors that are sometimes associated with older adults; they are arranged from physical to verbal, and from benign to aggressive. We do not expect that all these behaviors will apply to your relative.

Directions:
Read each of the behaviors, and circle how often (from 1-7) each applied to your relative over the last 2 weeks.

Frequency ratings:
1 = Never
2 = Less than once a week
3 = Once or twice a week
4 = Several times a week
5 = Once or twice a day
6 = Several times a day
7 = Several times an hour

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
1. General restlessness, fidgeting, always moving around	1	2	3	4	5	6	7
2. Performing repetitious mannerisms (tapping, rocking, rubbing)	1	2	3	4	5	6	7
3. Pacing, aimless wandering, constantly walking back and forth (including wandering while in wheelchair)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
4. Trying to get to a different place (sneaking out of the room, out of the house, off the property)	1	2	3	4	5	6	7
5. Handling things inappropriately (rummaging through drawers, moving furniture)	1	2	3	4	5	6	7
6. Hiding or hoarding things	1	2	3	4	5	6	7
7. Grabbing things from others (food from other's plate)	1	2	3	4	5	6	7
8. Tearing things or destroying property	1	2	3	4	5	6	7
9. Inappropriate dressing or underdressing (put clothes on in a strange way or take them off in public)	1	2	3	4	5	6	7
10. Spitting, including at mealtimes	1	2	3	4	5	6	7
11. Eating or drinking inappropriate substances	1	2	3	4	5	6	7
12. Grabbing onto people	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
13. Hitting (self or others)	1	2	3	4	5	6	7
14. Kicking	1	2	3	4	5	6	7
15. Pushing, shoving	1	2	3	4	5	6	7
16. Throwing things, hurling, flinging	1	2	3	4	5	6	7
17. Biting people or things	1	2	3	4	5	6	7
18. Scratching people or self	1	2	3	4	5	6	7
19. Intentional falling (including from wheelchair or bed)	1	2	3	4	5	6	7
20. Hurting self (burns, cuts, etc.)	1	2	3	4	5	6	7
21. Hurting others (burns, cuts, etc.)	1	2	3	4	5	6	7
22. Making physical sexual advances, exposing self	1	2	3	4	5	6	7
23. Relevant verbal interruptions (i.e. cut others short who are speaking to relative; being rude, even if does not seem to be intentional)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
24. Unrelated verbal interruptions (i.e. having nothing to do with ongoing conversations or activity)	1	2	3	4	5	6	7
25. Repetitive questions or sentences (do not include complaining)	1	2	3	4	5	6	7
26. Constant requests for help or attention (nagging, pleading, calling out)	1	2	3	4	5	6	7
27. Verbal bossiness or pushiness	1	2	3	4	5	6	7
28. Complaining, whining	1	2	3	4	5	6	7
29. Negativism, bad attitude, doesn't like anything, nothing is right (uncooperative, refusing)	1	2	3	4	5	6	7
30. Cursing or verbal aggression, threatening, insulting	1	2	3	4	5	6	7
31. Temper outburst (verbal or non-verbal expression of anger)	1	2	3	4	5	6	7
32. Strange noises (weird laughter, crying, moaning)	1	2	3	4	5	6	7
33. Screaming, shouting, howling	1	2	3	4	5	6	7
34. Making verbal sexual advances	1	2	3	4	5	6	7

Scoring instructions: Each behavior is rated on a 1-7-point scale, 1=never, 7=several times an hour that a behavior is demonstrated in the last 2 weeks. Individual behavior scores are added together to yield a total agitation score.

Appendix E-4: Rating Anxiety in Dementia Scale

Instrument Completion Information: The RAID scale was completed by first interviewing the family caregiver, and then the care recipient with dementia separately over Zoom or by phone. The caregiver and care recipient were asked to answer based on the care recipient's behaviors over the most recent 2 weeks. The RAID scale was completed at baseline and at post-intervention. Instructions for completing the RAID scale were followed and are available at https://discovery.ucl.ac.uk/id/eprint/136552/1/13607869956424.pdf.

			Score (✓)
Worry	1.	Worry about physical health.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	2.	Worry about cognitive performance (failing memory, getting lost when goes out, not able to follow conversations)	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	3.	Worry over finances, family problems, physical health of relatives.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	4.	Worry associated with false beliefs and/or perception	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	5.	Worry over trifles (repeatedly calling for attention over trivial matters).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
Apprehension and vigilance	6.	Frightened and anxious (keyed up and on edge).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	7.	Sensitivity to noise (exaggerated startle response).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	8.	Sleep disturbance (trouble falling or staying asleep).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	9.	Irritability (more easily annoyed than usual, short tempered, and angry outbursts).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe

Motor tension	10.	Trembling.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	11.	Motor tension (complain of headache, other body aches, and pains).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	12.	Restlessness (fidgeting, cannot sit still, pacing, wringing hands, picking clothes).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	13.	Fatigability, excessive tiredness.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
Autonomic hypersensitivity	14.	Palpitations (complains of heart racing or thumping).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	15.	Dry mouth (not due to medication), sinking feeling in the stomach.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	16.	Hyperventilating, shortness of breath (even when not exerting)	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	17.	Dizziness or light-headedness (complains as if going to faint).	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe
	18.	Sweating, flushes or chills, tingling or numbness of fingers and toes.	☐ U. Unable to evaluate ☐ 0. Absent ☐ 1. Mild or intermittent ☐ 2. Moderate ☐ 3. Severe

Scoring Instructions: Rating options include: U. Unable to evaluate, 0. Absent, 1. Mild or intermittent, 2. Moderate, 3. Severe. No score should be given if symptoms result from physical disability or illness. Scores of items 1 to 18 are summed for the caregiver and the care recipient to yield a caregiver score and a care recipient score. These two scores are then averaged to yield a total RAID score, a score of 11 or more suggests significant clinical anxiety.

Appendix E-5: Pittsburgh Sleep Quality Index

Instrument Completion Information: The PSQI was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the PSQI are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The section below asks about your relative with dementia's sleep quality over the past month. We have included questions relating to your relative's sleep quality, sleep duration and onset, use of medicine to help with sleep, daytime function, and sleep disturbances. We do not expect all the sleep disturbances to apply to your relative.

Directions:

The following questions relate to your relative's usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

---

1. During the past month, what time has your relative usually gone to bed at night?

BED TIME ___________________

2. During the past month, how long (in minutes) has it usually taken for your relative to fall asleep each night?

NUMBER OF MINUTES___________________

3. During the past month, what time has your relative usually gotten up in the morning?

GETTING UP TIME ___________________

4. During the past month, how many hours of actual sleep did your relative get at night? (This may be different than the number of hours he/she spent in bed)

HOURS OF SLEEP PER NIGHT ___________________

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often has your relative had trouble sleeping because he/she . . .	**Not during the past month**	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
a) Could not get to sleep within 30 minutes				
b) Woke up in the middle of the night or early morning				
c) Had to get up to use the bathroom				
d) Could not breathe comfortably				
e) Coughed or snored loudly				
f) Felt too cold				
g) Felt too hot				

h) Had bad dreams				
i) Had pain				
j) Other reason(s) please describe:				
6. During the past month, how often has your relative taken medicine to help with sleep (prescribed or "over the counter")?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	**Only a very slight problem**	**Somewhat of a problem**	**A very big problem**
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	**Fairly good**	**Fairly bad**	**Very bad**
9. During the past month, how would you rate your sleep quality overall?				

Scoring Instructions: Each of the component scores range from 0-3 with higher scores indicative of worse sleep quality (Component 1), longer sleep latency (Component 2), shorter sleep duration (Component 3), lower sleep habitual sleep efficiency (Component 4), more severe sleep disturbances, more sleep medication use (Component 4), and more severe daytime dysfunction due to sleep disturbances (Component 7). Subscale component scores are added together to yield a global score that ranges from 0-21, with higher scores indicative of overall worse sleep quality.

Appendix E-6: Epworth Sleepiness Scale

Instrument Completion Information: The ESS was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the ESS are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The section below asks about daytime sleepiness that your relative with dementia may or may not experience. How likely is your relative to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your relative's usual way of life recently.

Directions:
*Use the following scale to choose the **most appropriate number** for each situation:*

*0 = **no chance** of dozing*
*1 = **slight chance** of dozing*
*2 = **moderate chance** of dozing*
*3 = **high chance** of dozing*

It is important that you answer each item as best as you can.

	Situation	**Chance of Dozing (0-3)**
1.	Sitting and reading ________________________________	___
2.	Watching TV ____________________________________	___
3.	Sitting inactive in a public place (e.g., a theater or a meeting)	___
4.	As a passenger in a car for an hour without a break _______	___
5.	Lying down to rest in the afternoon when circumstances permit ____	___
6.	Sitting and talking to someone _______________________	___
7.	Sitting quietly after a lunch without alcohol ______________	___
8.	In a car or bus, while stopped for a few minutes in traffic ___	___

Scoring instructions: Items are rated, on a 4-point scale (0- would never dose, 3=high chance of dozing), to indicate an individual's chances of dozing off or falling asleep while engaged in eight different activities. Item scores are summed to yield a total daytime sleepiness score.

Appendix E-7: Quality of Life in Alzheimer's Disease Scale-Care Recipient Version

Instrument Completion Information: The care recipient version of the QOL-AD scale was completed by interview of the care recipient with dementia. The interviews occurred over Zoom or by phone. Instructions for completed the QOL-AD care recipient version were followed and are available at https://eprovide.mapi-trust.org/instruments/quality-of-life-in-alzheimer-s-disease.

1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

Comments:____

____

____

____

____

____

Quality of Life in Alzheimer's Disease Scale-Caregiver Version

Instrument Completion Information: The QOL-AD Caregiver version was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the QOL-AD Caregiver Version are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The following questions are about your relative's quality of life. When you think about your relative's life, there are different aspects, some of which are listed below.

Directions:
Please think about each item and rate your relative's current quality of life in each area using one of four words: poor, fair, good, or excellent. Please rate these items based on your relative's life at the present time. Circle your responses.

1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

Comments:____

____

____

Scoring Instructions: Caregiver and care recipient item scores are summed to yield a caregiver and a care recipient specific score. These scores are then averaged to yield a total QOL score.

Appendix E-8: Caregiver Well-Being Scale-short form

Instrument Completion Information: The CWBS-short form was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the CWBS are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The following section relates to <u>your</u> well-being as the caregiver of a relative with dementia.

Directions:
Listed below are a number of activities that each of us do or someone does for us. Thinking over the past month, indicate to what extent you think each activity has been met by circling the appropriate number on the scale provided. You do not have to be the one doing the activity. You are being asked to rate the extent to which each activity has been taken care of in a timely way.

Activities

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Buying food	1	2	3	4	5
2. Taking care of personal daily activities (meals, hygiene, laundry)	1	2	3	4	5
3. Attending to medical needs	1	2	3	4	5
4. Keeping up with home maintenance activities (lawn, cleaning, house repairs etc.)	1	2	3	4	5
5. Participating in events at church and/or in the community	1	2	3	4	5
6. Taking time to have fun with friends and/or family	1	2	3	4	5
7. Treating or rewarding yourself	1	2	3	4	5
8. Making plans for your financial future	1	2	3	4	5

Directions:
Below are listed a number of needs we all have. For each need listed, think about your life over the past three months. During this period of time, indicate to what extent you think each need has been met by circling the appropriate number on the scale provided below.

Needs

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Eating a well-balanced diet	1	2	3	4	5
2. Getting enough sleep	1	2	3	4	5
3. Receiving appropriate health care	1	2	3	4	5
4. Having adequate shelter	1	2	3	4	5
5. Feeling good about yourself	1	2	3	4	5
6. Feeling secure about your financial future	1	2	3	4	5

Scoring Instructions: Scores are summed across items within each subscale then divided by 8 to yield a basic needs score and an activities of daily living (ADL) score. All item scores are added and divided by 16 to yield a total score.

Appendix E-9: Optum SF-12v.2 Health Survey

Instrument Completion Information: The Optum SF-12v.2 was completed by the family caregiver by questionnaire at baseline and at post-intervention. Instructions for completing the Optum SF-12v.2 are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1) and the Follow-Up Caregiver Questionnaire (Appendix F-2).

The following section asks for your views about <u>your own</u> health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Directions:
Answer each question by choosing just one answer. If you are unsure how to answer a question, please give the best answer you can. Please indicate your answer with a check (✓)

1. In general would you say your health is:

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	☐	☐	☐
3. Climbing several flights of stairs?	☐	☐	☐

During <u>the past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health?</u>

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the kind of work or other activities	☐	☐

During <u>the past 4 weeks</u>, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐

7. Didn’t do work or other activities as carefully as usually	☐	☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ A little bit ☐Moderately ☐Quite a bit ☐ Extremely

These questions are about how you feel and how things have been with you during <u>the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During <u>the past 4 weeks</u>, how much of the time has your <u>physical health or emotional health</u> problems interfered with your social activities (like visiting with friends, relatives etc.)?

☐ Not at all ☐ Most of the time ☐ Some of the time ☐ A little of the time ☐ None of the time

Scoring Instructions: Item responses are standardized into both physical and mental standardized values using the table available here: https://medicine.umich.edu/sites/default/files/content/downloads/Scoring%20Instructions%20for%20the%20EPIC%2026.pdf. The physical standardized values from step 2 are summed across all 12 idems and added to 56.57706 to create the SF-12 physical health component score (PCS). The mental standardized values are summed and added to 60.75781 to create the SF-12 mental component score (MCS).

Appendix E-10: Care Recipient and Caregiver Demographics Form

Instrument Completion Information: The Demographic Form was completed by the caregiver by questionnaire at baseline. Instructions for completing the Demographics Form are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1).

The following section asks questions relating to the demographics of your relative with dementia and yourself. The first 6 questions pertain to your relative, while questions 7-15 relate to you as the caregiver. The last 3 questions relate to the caregiving you provide to your relative.

Care Recipient Demographics

Directions:
Please answer the following questions (1-6) as they relate to *<u>your relative with dementia.</u>*

---

1. What is your age (in years)

____

2. Race (Indicate with a ✓ for those with which you identify)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or Pacific Islander

☐ White or Caucasian

☐ More than one race

☐ Unknown or do not wish to report

3. Ethnicity (Indicate with a ✓ for the choice you most closely identify)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or do not wish to report

4. Gender (Indicate with a ✓ for the choice you most closely identify)

☐ Male

☐ Female

☐ Other

5. Education (Select highest education you have received)

☐ Less than high school

☐ High school graduate or GED

☐ Some college

☐ College and above

6. What is your marital status?

☐ Single / never married

☐ Married / domestic partnership

☐ Divorced

☐ Widowed

☐ Separated

Caregiver Demographics

Directions:
Please answer the following questions (7-12) as they relate to you, the caregiver of the person with dementia.

---

7. What is your age (in years)

____

8. Race (Indicate with a ✓ for those with which you identify)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or Pacific Islander

☐ White or Caucasian

☐ More than one race

☐ Unknown or do not wish to report

9. Ethnicity (Indicate with a ✓ for the choice you most closely identify)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or do not wish to report

10. Gender (Indicate with a ✓ for the choice you most closely identify)

☐ Male

☐ Female

☐ Other

11. Education (Select highest education you have received)

☐ Less than high school

☐ High school graduate or GED

☐ Some college

☐ College and above

6. What is your marital status?

☐ Single / never married

☐ Married / domestic partnership

☐ Divorced or separated

☐ Widowed

12. How are you related to your family member with dementia?

☐ Spouse

☐ Child

☐ Sibling

☐ Other

Please specify if other:

____

Caregiving Information

Directions:
Please answer the following questions (13-18) as they relate to the caregiving you provide to your relative with dementia.

---

13. How long have you been a primary caregiver for your family member with dementia?

_________________ month(s) / year(s) (Circle)

14. How long have you been living with your family member with dementia?

_________________ month(s) / year(s) (Circle)

15. On average, how many hours of caregiving do <u>you</u> provide on a weekly basis to your family member with dementia?

_______________ hour(s)

Appendix E-11: Health History Form

Instrument Completion Information: The Health History Form was completed by the caregiver by questionnaire at baseline. The Health History Form relates to the health history of the care recipient with dementia. Instructions for completing the Health History Form are listed below and were included in the Baseline Caregiver Questionnaire (Appendix F-1).

Health History of the Care Recipient with Dementia

The following section relates to your relative with dementia's health history and medication information.

Directions:
Please answer all the following questions as they relate to your relative with dementia.

---

1. What type of dementia or memory-related disease does he/she have?

☐ Alzheimer's disease
☐ Vascular dementia
☐ Mixed type dementia
☐ Frontotemporal dementia
☐ Dementia with Lewy bodies
☐ Parkinson's disease dementia
☐ Posterior cortical atrophy
☐ Other
☐ Not specified
☐ Unknown

2. Approximately when did he/she receive the dementia diagnosis?

____

3. Please list any other physical or mental health conditions, or diagnoses that your relative has:

____

____

____

____

Please list any medications he/she is currently taking, include the dosage (how much), frequency (how often he/she takes it) and reason for taking it:

Medication	Dosage	Frequency	Reason

Appendix E-12: Health Status Update Form

Instrument Completion Information: The Health Status Update Form was completed by the caregiver by questionnaire at post-intervention. The Health History Form Update relates to changes in the health status of the care recipient with dementia. Instructions for completing the Health History Form are listed below and were included in the Follow-Up Caregiver Questionnaire (Appendix F-2).

Health Status Update

The following section relates to your relative with dementia's health status over the past 4 weeks.

Directions:
Please answer all the following questions as they relate to your relative with dementia.

---

1. Please list any physical or mental health conditions, or diagnoses that your relative received within the past 4 weeks:

____

____

____

____

____

____

____

____

____

____

____

____

3. Has he/she had a fall over the past 4 weeks?

Yes No

4. Has he/she sustained any injuries over the past 4 weeks?

Yes No

If *yes*, please specify type <u>and</u> how severe the injury was:

____

____

____

5. Has he/she been hospitalized <u>over the past 4 weeks</u>?

Yes No

If *yes*, please specify reason for hospitalization <u>and</u> how long he/she was hospitalized:

____

____

____

Please list any <u>new</u> medications he/she is taking, include the dosage (how much), frequency (how often he/she takes it) and reason for taking it:

Medication	Dosage	Frequency	Reason

Appendix F

Caregiver Questionnaires Used in Weighted Blanket Intervention Feasibility and Acceptability Study

Appendix F-1: Baseline Caregiver Questionnaire

Baseline Caregiver Questionnaire

You are receiving this questionnaire because you identified as a primary caregiver living with a family member with dementia. This questionnaire is designed to gather information relating to the health and well-being of you as the caregiver, and of your relative with dementia. It is composed of several parts. At the beginning of each section are directions on how to answer the questions that follow.

This questionnaire is expected to take about an hour to complete and we ask that you complete it within the next 5 to 7 days. You do not have to complete the entire questionnaire at one time. You are welcome to take a break and return later to complete the remaining sections.

The University of Michigan IRB reviewed and approved this study. All your responses are confidential and only reported in aggregate.

Please contact Melissa if you have any questions about completing this questionnaire at 405-513-1271.

University of Michigan School of Nursing Research Study

Exploring the Use of Weighted Blankets as a Non-Pharmacologic Intervention for Home Dwelling Older Adults with Dementia

Principal Investigator: Melissa Harris, BSN, RN, PhD Student
Supervising Faculty Advisor: Marita Titler, PhD, RN, FAAN

SECTION ONE

The first section of this questionnaire relates to behaviors and symptoms displayed by your relative with dementia in recent weeks. We hope to learn about some of the more challenging behaviors and symptoms experienced by your relative, such as agitation, anxiety, restlessness, and sleep disturbances.

Section 1 - Part 1: Agitation Inventory

The section below asks about specific behaviors displayed by your relative with dementia. We have listed behaviors that are sometimes associated with older adults; they are arranged from physical to verbal, and from benign to aggressive. We do not expect that all these behaviors will apply to your relative.

Directions:
Read each of the behaviors, and circle how often (from 1-7) each applied to your relative over the last 2 weeks.

Frequency ratings:

1 = Never
2 = Less than once a week
3 = Once or twice a week
4 = Several times a week
5 = Once or twice a day
6 = Several times a day
7 = Several times an hour

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
1. General restlessness, fidgeting, always moving around	1	2	3	4	5	6	7
2. Performing repetitious mannerisms (tapping, rocking, rubbing)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
3. Pacing, aimless wandering, constantly walking back and forth (including wandering while in wheelchair)	1	2	3	4	5	6	7
4. Trying to get to a different place (sneaking out of the room, out of the house, off the property)	1	2	3	4	5	6	7
5. Handling things inappropriately (rummaging through drawers, moving furniture)	1	2	3	4	5	6	7
6. Hiding or hoarding things	1	2	3	4	5	6	7
7. Grabbing things from others (food from other’s plate)	1	2	3	4	5	6	7
8. Tearing things or destroying property	1	2	3	4	5	6	7
9. Inappropriate dressing or underdressing (put clothes on in a strange way or take them off in public)	1	2	3	4	5	6	7
10. Spitting, including at mealtimes	1	2	3	4	5	6	7
11. Eating or drinking inappropriate substances	1	2	3	4	5	6	7
12. Grabbing onto people	1	2	3	4	5	6	7
13. Hitting (self or others)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
14. Kicking	1	2	3	4	5	6	7
15. Pushing, shoving	1	2	3	4	5	6	7
16. Throwing things, hurling, flinging	1	2	3	4	5	6	7
17. Biting people or things	1	2	3	4	5	6	7
18. Scratching people or self	1	2	3	4	5	6	7
19. Intentional falling (including from wheelchair or bed)	1	2	3	4	5	6	7
20. Hurting self (burns, cuts, etc.)	1	2	3	4	5	6	7
21. Hurting others (burns, cuts, etc.)	1	2	3	4	5	6	7
22. Making physical sexual advances, exposing self	1	2	3	4	5	6	7
23. Relevant verbal interruptions (i.e. cut others short who are speaking to relative; being rude, even if does not seem to be intentional)	1	2	3	4	5	6	7
24. Unrelated verbal interruptions (i.e. having nothing to do with ongoing conversations or activity)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
25. Repetitive questions or sentences (do not include complaining)	1	2	3	4	5	6	7
26. Constant requests for help or attention (nagging, pleading, calling out)	1	2	3	4	5	6	7
27. Verbal bossiness or pushiness	1	2	3	4	5	6	7
28. Complaining, whining	1	2	3	4	5	6	7
29. Negativism, bad attitude, doesn't like anything, nothing is right (uncooperative, refusing)	1	2	3	4	5	6	7
30. Cursing or verbal aggression, threatening, insulting	1	2	3	4	5	6	7
31. Temper outburst (verbal or non-verbal expression of anger)	1	2	3	4	5	6	7
32. Strange noises (weird laughter, crying, moaning)	1	2	3	4	5	6	7
33. Screaming, shouting, howling	1	2	3	4	5	6	7
34. Making verbal sexual advances	1	2	3	4	5	6	7

Section 1 - Part 2: Sleep Quality Index

The section below asks about your relative with dementia's sleep quality over the past month. We have included questions relating to your relative's sleep quality, sleep duration and onset, use of medicine to help with sleep, daytime function, and sleep disturbances. We do not expect all the sleep disturbances to apply to your relative.

Directions:
The following questions relate to your relative's usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

---

1. During the past month, what time has your relative usually gone to bed at night?

BED TIME ___________________

2. During the past month, how long (in minutes) has it usually taken for your relative to fall asleep each night?

NUMBER OF MINUTES___________________

3. During the past month, what time has your relative usually gotten up in the morning?

GETTING UP TIME ___________________

4. During the past month, how many hours of actual sleep did your relative get at night? (This may be different than the number of hours he/she spent in bed)

HOURS OF SLEEP PER NIGHT ___________________

For each of the remaining questions, check the <u>one best response</u> for all questions.

5. During the past month, how often has your relative had trouble sleeping because he/she . . .	**Not during the past month**	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
a) Could not get to sleep within 30 minutes				
b) Woke up in the middle of the night or early morning				
c) Had to get up to use the bathroom				
d) Could not breathe comfortably				
e) Coughed or snored loudly				
f) Felt too cold				
g) Felt too hot				
h) Had bad dreams				
i) Had pain				
j) Other reason(s) please describe:				
6. During the past month, how often has your relative taken medicine to help with sleep (prescribed or "over the counter")?				
7. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	**Only a very slight problem**	**Somewhat of a problem**	**A very big problem**
8. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?				
	Very good	**Fairly good**	**Fairly bad**	**Very bad**
9. During the past month, how would you rate your sleep quality overall?				

Section 1 - Part 3: Daytime Sleepiness Scale

The section below asks about daytime sleepiness that your relative with dementia may or may not experience. How likely is your relative to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your relative's usual way of life recently.

Directions:
Please indicate with a check (✓) the response that is most appropriate for your relative for each situation. It is important that you answer each item as best as you can.

	Situation	***No chance of dozing***	***Slight chance of dozing***	***Moderate chance of dozing***	***High chance of dozing***
1.	Sitting and reading				
2.	Watching TV				
3.	Sitting inactive in a public place (e.g., a theater or a meeting)				
4.	As a passenger in a car for an hour without a break				
5.	Lying down to rest in the afternoon when circumstances permit				
6.	Sitting and talking to someone				
7.	Sitting quietly after a lunch without alcohol				
8.	In a car or bus, while stopped for a few minutes in traffic				

SECTION TWO

Section two of this questionnaire relates to the quality of life and well-being of your relative with dementia.

Section 2 - Part 1: Care Recipient with Dementia Quality of Life Scale

The following questions are about your relative's quality of life. When you think about your relative's life, there are different aspects, some of which are listed below.

Directions:
Please think about each item and rate your relative's current quality of life in each area using one of four words: poor, fair, good, or excellent. Please rate these items based on your relative's life at the present time. Circle your responses.

---

1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

Comments:____

____

____

____

SECTION THREE

Section three of this questionnaire relates to your own well-being and health as the caregiver of a relative with dementia.

Section 3 - Part 1: Caregiver Well-Being Scale

The following section relates to your well-being as the caregiver of a relative with dementia.

Directions:
Listed below are a number of activities that each of us do or someone does for us. Thinking over the past month, indicate to what extent you think each activity has been met by circling the appropriate number on the scale provided. You do not have to be the one doing the activity. You are being asked to rate the extent to which each activity has been taken care of in a timely way.

Activities

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Buying food	1	2	3	4	5
2. Taking care of personal daily activities (meals, hygiene, laundry)	1	2	3	4	5
3. Attending to medical needs	1	2	3	4	5
4. Keeping up with home maintenance activities (lawn, cleaning, house repairs etc.)	1	2	3	4	5
5. Participating in events at church and/or in the community	1	2	3	4	5
6. Taking time to have fun with friends and/or family	1	2	3	4	5
7. Treating or rewarding yourself	1	2	3	4	5
8. Making plans for your financial future	1	2	3	4	5

Directions:
Below are listed a number of needs we all have. For each need listed, think about your life over the past three months. During this period of time, indicate to what extent you think each need has been met by circling the appropriate number on the scale provided below.

Needs

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Eating a well-balanced diet	1	2	3	4	5
2. Getting enough sleep	1	2	3	4	5
3. Receiving appropriate health care	1	2	3	4	5
4. Having adequate shelter	1	2	3	4	5
5. Feeling good about yourself	1	2	3	4	5
6. Feeling secure about your financial future	1	2	3	4	5

Section 3 - Part 2: Caregiver Health Survey

The following section asks for your views about your own health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Directions:
Answer each question by choosing just one answer. If you are unsure how to answer a question, please give the best answer you can. Please indicate your answer with a check (✓)

---

1. In general would you say your health is:

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	☐	☐	☐
3. Climbing several flights of stairs?	☐	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the kind of work or other activities	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐
7. Didn’t do work or other activities as carefully as usually	☐	☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ A little bit ☐Moderately ☐Quite a bit ☐ Extremely

These questions are about how you feel and how things have been with you during <u>the past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During <u>the past 4 weeks</u>, how much of the time has your <u>physical health or emotional health</u> problems interfered with your social activities (like visiting with friends, relatives etc.)?

☐ Not at all
☐ Most of the time
☐ Some of the time
☐ A little of the time
☐ None of the time

SECTION FOUR

Section four of this questionnaire relates to you and your relative's demographic information, and information relating to the caregiving you provide to your relative. The last part of this section includes questions pertaining to the health history of your relative with dementia.

Section 4 - Part 1: Demographics and Caregiving Information

The following section asks questions relating to the demographics of your relative with dementia and yourself. The first 6 questions pertain to your relative, while questions 7-15 relate to you as the caregiver. The last 3 questions relate to the caregiving you provide to your relative.

Care Recipient Demographics

Directions:
Please answer the following questions (1-6) as they relate to your relative with dementia.

---

1. What is his/her age (in years)

____

2. Race (Indicate with a ✓ for the choice he/she most closely identifies)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or Pacific Islander

☐ White or Caucasian

☐ More than one race

☐ Unknown or do not wish to report

3. Ethnicity (Indicate with a ✓ for the choice he/she most closely identifies)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or do not wish to report

4. Gender (Indicate with a ✓ for the choice he/she most closely identifies)

☐ Male

☐ Female

☐ Other

5. Education (Select highest education he/she has received)

- ☐ Less than high school
- ☐ High school graduate or GED
- ☐ Some college
- ☐ College and above

6. What is his/her marital status?

- ☐ Single / never married
- ☐ Married / domestic partnership
- ☐ Divorced
- ☐ Widowed
- ☐ Separated

Caregiver Demographics

Directions:
Please answer the following questions (7-12) as they relate to you, the caregiver of the person with dementia.

---

7. What is your age (in years)

____

8. Race (Indicate with a ✓ for those with which you identify)

☐ American Indian or Alaska Native

☐ Asian

☐ Black or African American

☐ Native Hawaiian or Pacific Islander

☐ White or Caucasian

☐ More than one race

☐ Unknown or do not wish to report

9. Ethnicity (Indicate with a ✓ for the choice you most closely identify)

☐ Hispanic or Latino

☐ Not Hispanic or Latino

☐ Unknown or do not wish to report

10. Gender (Indicate with a ✓ for the choice you most closely identify)

☐ Male

☐ Female

☐ Other

11. Education (Select highest education you have received)

☐ Less than high school

☐ High school graduate or GED

☐ Some college

☐ College and above

6. What is your marital status?

☐ Single / never married

☐ Married / domestic partnership

☐ Divorced or separated

☐ Widowed

12. How are you related to your family member with dementia?

☐ Spouse

☐ Child

☐ Sibling

☐ Other

Please specify if other:

____

Caregiving Information

Directions:
Please answer the following questions (13-18) as they relate to the caregiving you provide to your relative with dementia.

---

13. How long have you been a primary caregiver for your family member with dementia?

_________________ month(s) / year(s) (Circle)

14. How long have you been living with your family member with dementia?

_________________ month(s) / year(s) (Circle)

15. On average, how many hours of caregiving do <u>you</u> provide on a daily basis to your family member with dementia?

_______________ hour(s)

Section 4 - Part 2: Care Recipient with Dementia Health History

The following section relates to your relative with dementia's health history and medication information.

Directions:
Please answer all the following questions as they relate to your *<u>relative with dementia.</u>*

---

1. What type of dementia or memory-related disease does he/she have?

☐ Alzheimer's disease

☐ Vascular dementia

☐ Mixed type dementia

☐ Frontotemporal dementia

☐ Dementia with Lewy bodies

☐ Parkinson's disease dementia

☐ Not specified

☐ Unknown

2. Approximately when did he/she receive the dementia diagnosis?

____

3. Please list any other physical or mental health conditions, or diagnoses that your relative has:

____

____

____

____

____

____

____

____

Please list any medications he/she is currently taking, include the dosage (how much), frequency (how often he/she takes it) and reason for taking it:

Medication	Dosage	Frequency	Reason

Thank you for completing this Baseline Questionnaire, please indicate below how long it took you to complete.

________________________________ minutes

Please indicate with a check (✓) the option below that most closely matches your opinion about the length of this questionnaire:

☐ The length of this questionnaire was about right for me.

☐ I would have liked the questionnaire to be shorter.

☐ I would have been okay with completing a longer questionnaire.

.

End of Questionnaire

Appendix F-2: Follow-Up Caregiver Questionnaire

Follow-Up Caregiver Questionnaire

You are receiving this questionnaire as you and your relative have completed the 4 weeks of using the weighted blanket in the home. This questionnaire is designed to gather information relating to the health and well-being of you as the caregiver, and of your relative with dementia. In addition, the last section addresses your overall satisfaction and perceived benefits of the weighted blanket use by your relative with dementia over the past 4 weeks.

This questionnaire is composed of several parts. At the beginning of each section are directions on how to answer the questions that follow.

This questionnaire is expected to take about an hour to complete and we ask that you complete it within the next 5 to 7 days. You do not have to complete the entire questionnaire at one time. You are welcome to take a break and return later to complete the remaining sections.

The University of Michigan IRB reviewed and approved this study. All your responses are confidential and only reported in aggregate.

Please contact Melissa if you have any questions about completing this questionnaire at 405-513-1271.

University of Michigan School of Nursing Research Study

Exploring the Use of Weighted Blankets as a Non-Pharmacologic Intervention for Home Dwelling Older Adults with Dementia

Principal Investigator: Melissa Harris, BSN, RN, PhD Student
Supervising Faculty Advisor: Marita Titler, PhD, RN, FAAN

SECTION ONE

The first section of this questionnaire relates to behaviors and symptoms displayed by your relative with dementia in recent weeks. We hope to learn about some of the more challenging behaviors and symptoms experienced by your relative, such as agitation, anxiety, restlessness, and sleep disturbances.

Section 1 - Part 1: Agitation Inventory

The section below asks about specific behaviors displayed by your relative with dementia. We have listed behaviors that are sometimes associated with older adults; they are arranged from physical to verbal, and from benign to aggressive. We do not expect that all these behaviors will apply to your relative.

Directions:
Read each of the behaviors, and circle how often (from 1-7) each applied to your relative over the last 2 weeks.

Frequency ratings:

1 = Never
2 = Less than once a week
3 = Once or twice a week
4 = Several times a week

4 = Several times a week
5 = Once or twice a day
6 = Several times a day
7 = Several times an hour

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
1. General restlessness, fidgeting, always moving around	1	2	3	4	5	6	7
2. Performing repetitious mannerisms (tapping, rocking, rubbing)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
3. Pacing, aimless wandering, constantly walking back and forth (including wandering while in wheelchair)	1	2	3	4	5	6	7
4. Trying to get to a different place (sneaking out of the room, out of the house, off the property)	1	2	3	4	5	6	7
5. Handling things inappropriately (rummaging through drawers, moving furniture)	1	2	3	4	5	6	7
6. Hiding or hoarding things	1	2	3	4	5	6	7
7. Grabbing things from others (food from other's plate)	1	2	3	4	5	6	7
8. Tearing things or destroying property	1	2	3	4	5	6	7
9. Inappropriate dressing or underdressing (put clothes on in a strange way or take them off in public)	1	2	3	4	5	6	7
10. Spitting, including at mealtimes	1	2	3	4	5	6	7
11. Eating or drinking inappropriate substances	1	2	3	4	5	6	7
12. Grabbing onto people	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
13. Hitting (self or others)	1	2	3	4	5	6	7
14. Kicking	1	2	3	4	5	6	7
15. Pushing, shoving	1	2	3	4	5	6	7
16. Throwing things, hurling, flinging	1	2	3	4	5	6	7
17. Biting people or things	1	2	3	4	5	6	7
18. Scratching people or self	1	2	3	4	5	6	7
19. Intentional falling (including from wheelchair or bed)	1	2	3	4	5	6	7
20. Hurting self (burns, cuts, etc.)	1	2	3	4	5	6	7
21. Hurting others (burns, cuts, etc.)	1	2	3	4	5	6	7
22. Making physical sexual advances, exposing self	1	2	3	4	5	6	7
23. Relevant verbal interruptions (i.e. cut others short who are speaking to relative; being rude, even if does not seem to be intentional)	1	2	3	4	5	6	7
24. Unrelated verbal interruptions (i.e. having nothing to do with ongoing conversations or activity)	1	2	3	4	5	6	7

	Never	Less than once a week	Once or twice a week	Several times a week	Once or twice a day	Several times a day	Several times an hour
25. Repetitive questions or sentences (do not include complaining)	1	2	3	4	5	6	7
26. Constant requests for help or attention (nagging, pleading, calling out)	1	2	3	4	5	6	7
27. Verbal bossiness or pushiness	1	2	3	4	5	6	7
28. Complaining, whining	1	2	3	4	5	6	7
29. Negativism, bad attitude, doesn't like anything, nothing is right (uncooperative, refusing)	1	2	3	4	5	6	7
30. Cursing or verbal aggression, threatening, insulting	1	2	3	4	5	6	7
31. Temper outburst (verbal or non-verbal expression of anger)	1	2	3	4	5	6	7
32. Strange noises (weird laughter, crying, moaning)	1	2	3	4	5	6	7
33. Screaming, shouting, howling	1	2	3	4	5	6	7
34. Making verbal sexual advances	1	2	3	4	5	6	7

Section 1 - Part 2: Sleep Quality Index

The section below asks about your relative with dementia's sleep quality over the past month. We have included questions relating to your relative's sleep quality, sleep duration and onset, use of medicine to help with sleep, daytime function, and sleep disturbances. We do not expect all the sleep disturbances to apply to your relative.

Directions:
The following questions relate to your relative's usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month.

---

1. During the past month, what time has your relative usually gone to bed at night?

BED TIME ___________________

2. During the past month, how long (in minutes) has it usually taken for your relative to fall asleep each night?

NUMBER OF MINUTES___________________

3. During the past month, what time has your relative usually gotten up in the morning?

GETTING UP TIME ___________________

4. During the past month, how many hours of actual sleep did your relative get at night? (This may be different than the number of hours he/she spent in bed)

HOURS OF SLEEP PER NIGHT ___________________

For each of the remaining questions, check the <u>one best response</u> for all questions.

5. During the past month, how often has your relative had trouble sleeping because he/she . . .	**Not during the past month**	**Less than once a week**	**Once or twice a week**	**Three or more times a week**
a) Could not get to sleep within 30 minutes				
b) Woke up in the middle of the night or early morning				
c) Had to get up to use the bathroom				
d) Could not breathe comfortably				
e) Coughed or snored loudly				
f) Felt too cold				
g) Felt too hot				
h) Had bad dreams				
i) Had pain				
j) Other reason(s) please describe:				
6. During the past month, how often has your relative taken medicine to help with sleep (prescribed or "over the counter")?				
7. During the past month, how often has your relative had trouble staying awake while driving, eating meals, or engaging in social activity?				
	No problem at all	**Only a very slight problem**	**Somewhat of a problem**	**A very big problem**
8. During the past month, how much of a problem has it been for you relative to keep up enough enthusiasm to get things done?				
	Very good	**Fairly good**	**Fairly bad**	**Very bad**
9. During the past month, how would you rate your relative's sleep quality overall?				

Section 1 - Part 3: Daytime Sleepiness Scale

The section below asks about daytime sleepiness that your relative with dementia may or may not experience. How likely is your relative to doze off or fall asleep in the following situations, in contrast to just feeling tired? This refers to your relative's usual way of life recently.

Directions:
Please indicate with a check (✓) the response that is most appropriate for your relative for each situation.

It is important that you answer each item as best as you can.

	Situation	***No chance of dozing***	***Slight chance of dozing***	***Moderate chance of dozing***	***High chance of dozing***
1.	Sitting and reading				
2.	Watching TV				
3.	Sitting inactive in a public place (e.g., a theater or a meeting)				
4.	As a passenger in a car for an hour without a break				
5.	Lying down to rest in the afternoon when circumstances permit				
6.	Sitting and talking to someone				
7.	Sitting quietly after a lunch without alcohol				
8.	In a car or bus, while stopped for a few minutes in traffic				

SECTION TWO

Section two of this questionnaire relates to the quality of life and well-being of your relative with dementia.

Section 2 - Part 1: Care Recipient with Dementia Quality of Life Scale

The following questions are about your relative's quality of life. When you think about your relative's life, there are different aspects, some of which are listed below.

Directions:
Please think about each item and rate your relative's current quality of life in each area using one of four words: poor, fair, good, or excellent. Please rate these items based on your relative's life at the present time. Circle your responses.

1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

Comments:____

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SECTION THREE

Section three of this questionnaire relates to your own well-being and health as the caregiver of a relative with dementia.

Section 3 - Part 1: Caregiver Well-Being Scale

The following section relates to your well-being as the caregiver of a relative with dementia.

Directions:
Listed below are a number of activities that each of us do or someone does for us. Thinking over the past month, indicate to what extent you think each activity has been met by circling the appropriate number on the scale provided. You do not have to be the one doing the activity. You are being asked to rate the extent to which each activity has been taken care of in a timely way.

Activities

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Buying food	1	2	3	4	5
2. Taking care of personal daily activities (meals, hygiene, laundry)	1	2	3	4	5
3. Attending to medical needs	1	2	3	4	5
4. Keeping up with home maintenance activities (lawn, cleaning, house repairs etc.)	1	2	3	4	5
5. Participating in events at church and/or in the community	1	2	3	4	5
6. Taking time to have fun with friends and/or family	1	2	3	4	5
7. Treating or rewarding yourself	1	2	3	4	5
8. Making plans for your financial future	1	2	3	4	5

Directions:
Below are listed a number of needs we all have. For each need listed, think about your life over the past three months. During this period of time, indicate to what extent you think each need has been met by circling the appropriate number on the scale provided below.

Needs

1. Rarely 2. Occasionally 3. Sometimes 4. Frequently 5. Usually

1. Eating a well-balanced diet	1	2	3	4	5
2. Getting enough sleep	1	2	3	4	5
3. Receiving appropriate health care	1	2	3	4	5
4. Having adequate shelter	1	2	3	4	5
5. Feeling good about yourself	1	2	3	4	5
6. Feeling secure about your financial future	1	2	3	4	5

Section 3 - Part 2: Caregiver Health Survey

The following section asks for your views about your own health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Directions:
Answer each question by choosing just one answer. If you are unsure how to answer a question, please give the best answer you can. Please indicate your answer with a check (✓)

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1. In general would you say your health is:

☐ Excellent ☐ Very good ☐ Good ☐ Fair ☐ Poor

The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities such as moving a table, pushing a vacuum cleaner, bowling, or playing golf?	☐	☐	☐
3. Climbing several flights of stairs?	☐	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐	☐
5. Were limited in the kind of work or other activities	☐	☐

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐	☐
7. Didn’t do work or other activities as carefully as usually	☐	☐

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

☐ Not at all ☐ A little bit ☐Moderately ☐Quite a bit ☐ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the past 4 weeks, how much of the time has your physical health or emotional health problems interfered with your social activities (like visiting with friends, relatives etc.)?

☐ Not at all
☐ Most of the time
☐ Some of the time
☐ A little of the time
☐ None of the time

SECTION FIVE

Section five of this questionnaire relates to your overall satisfaction with the weighted blanket use by your relative with dementia and how beneficial the weighted blanket was for you and your relative.

Section 5 – Part 1: Now that you and your relative with dementia have completed all 4 weeks of using the weighted blanket, we would like to know how satisfied you as the caregiver were with the weighted blanket and how beneficial the weighted blanket was for both of you.

Directions:

Please answer these questions from your perspective as the caregiver of a family member with dementia. We encourage you to provide honest answers relating to the use of weighted blanket by your family member. Indicate with a ✓ your response for each question.

		Not satisfied				Very satisfied
In general, how satisfied were you with:		1	2	3	4	5
1.	Having the weighted blanket to be used by your relative in the home?					
2.	Having the intervention materials delivered to your home?					
3.	How the weighted blanket was explained to you during the Weighted Blanket Introduction session?					
4.	Using a web-based platform to learn how to use the weighted blanket?					
5.	Participating in weekly check-in telephone call with the research team?					
6.	How satisfied were you with the Weighted Blanket Use Guide that came with the blanket?					
7.	How satisfied were you with the way your questions were answered throughout the study period?					
8.	How satisfied were you with how you were involved in the process of encouraging your relative to use the weighted blanket?					

9. How heavy was the blanket that your relative used?

☐ 10 pounds

☐ 12 pounds ☐ I don’t know

10. What did you think about the weight of the blanket for your relative?

☐ The weight was about right for my relative

☐ I would have liked it to be heavier.

☐ I would have liked it to be lighter.

11. What is your opinion about the recommendation that the weighted blanket be used daily by your relative?

☐ The recommended everyday use of the weighted blanket was about right for us.

☐ I would have liked the recommended use of the weighted blanket be less than every day.

☐ I would have liked the recommended use of the weighted blanket be multiple times a day.

12. What is your opinion about the recommended amount of time the weighted blanket was to be used by your relative each day? (Reminder: the weighted blanket was recommended to be used for <u>at least</u> 5 minutes at a time for a total of <u>at least</u> 20 minutes throughout each day)

☐ The recommended amount of time was about right for us.

☐ I would have liked less recommended blanket use time.

☐ I would have liked more recommended blanket use time.

13. What did you think about completing a Weighted Blanket Daily Use Diary?

☐ Completing a diary entry every day was about right for me.

☐ I would have liked to complete fewer diary entries.

☐ I would have liked to complete more diary entries.

Overall:		Not at all	Some	A great deal
14.	How much did the use of the weighted blanket help in decreasing challenging symptoms displayed by your relative with dementia? (such as anxiety, agitation, restlessness, difficulty sleeping)			
15.	How beneficial was the study information booklet in explaining the study process?			
16.	How beneficial was the Weighted Blanket Use Guide in explaining the use of the weighted blanket?			
17.	How beneficial were the weekly telephone check ins throughout the 4-week intervention period?			
18.	How much did the use of the weighted blanket by your relative benefit you as the caregiver of someone with dementia?			
19.	How much did the use of the weighted blanket benefit your family member with dementia?			

20. Overall, would you recommend the use of a weighted blanket to other individuals caring for someone with dementia?

☐ Yes ☐ No

21. Will you continue to encourage your relative to use the weighted blanket?

☐ Yes ☐ No

22. When was using the weighted blanket most helpful for your relative?

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23. When was using the weighted blanket the least helpful for your relative?

24. Do you have any comments or suggestions about the study materials (such as the study information booklet, the Weighted Blanket Use Guide, or the Blanket Daily Use Diary)?

☐ Yes ☐ No

If yes, please describe.

25. Do you have any comments or suggestions about the weighted blankets specifically?

☐ Yes ☐ No

If yes, please describe.

26. Would you recommend or suggest any other changes for the weighted blanket study?

☐ Yes ☐ No

If yes, please describe.

SECTION SIX

Section six of this questionnaire relates to your relative with dementia's health status over the past four weeks. This section is meant to provide an update to the health history information you provided at the beginning of this study.

Section 4 - Part 1: The following section relates to your relative with dementia's health status over the past 4 weeks.

Directions:
Please answer all the following questions as they relate to your *<u>relative with dementia.</u>*

1. Please list any physical or mental health conditions, or diagnoses that your relative received <u>within the past 4 weeks</u>:

3. Has he/she had a fall <u>over the past 4 weeks</u>?

Yes No

4. Has he/she sustained any injuries <u>over the past 4 weeks</u>?

Yes No

If *yes*, please specify type and how severe the injury was:

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5. Has he/she been hospitalized over the past 4 weeks?

Yes No

If *yes*, please specify reason for hospitalization and how long he/she was hospitalized:

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Please list any new medications he/she is taking, include the dosage (how much), frequency (how often he/she takes it) and reason for taking it:

Medication	Dosage	Frequency	Reason

Thank you for completing this Follow-Up Questionnaire, please indicate below how long it took you to complete.

________________________________ minutes

Please indicate with a check (✓) the option below that most closely aligns with your opinion about the length of this questionnaire:

☐ The length of this questionnaire was about right for me.

☐ I would have liked the questionnaire to be shorter.

☐ I would have been okay with completing a longer questionnaire.

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End of Questionnaire